NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Leadless cardiac pacemaker implantation for bradyarrhythmias

Bradyarrhythmias are abnormal heart rhythms that can result in a slow heart rate. They are usually caused by a problem with the heart's electrical system. In this procedure, a cardiac pacemaker that does not have leads (leadless) is implanted directly into the internal wall of the heart. This avoids the need for a pacemaker box under the skin with leads connecting it to the heart. The procedure is done by inserting a tube (catheter) through a large blood vessel (vein) in the leg or neck. The aim is to stimulate the heart to beat at a normal rate and reduce symptoms.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about how safe and effective these procedures are. The guidance supports healthcare professionals and commissioners to ensure that people get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

NICE is producing this guidance on leadless cardiac pacemaker implantation for bradyarrhythmias in the NHS in England. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

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This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again, it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on leadless cardiac pacemaker implantation for bradyarrhythmias. The recommendations in section 1 may change after consultation.

More details are available in NICE's interventional procedures programme manual.

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Key dates:

Closing date for comments: 23 July 2025

Second committee meeting: 11 September 2025

1 Recommendations

Single-chamber pacing

1.1 Leadless cardiac pacemaker implantation can be used as an option for single-chamber pacing in people with bradyarrhythmias.

Dual-chamber pacing

1.2 More research is needed on leadless pacemakers for bradyarrhythmias for people who need dual-chamber pacing before it can be used in the NHS.

1.3 For people who need dual-chamber pacing, this procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

What research is needed

More research, in the form of observational studies or registry data, is needed on dual-chamber pacing:

- patient selection including age, comorbidities and cause of bradyarrhythmias
- implantation site
- clinical outcomes such as adverse events, symptom relief and quality of life, in the short and long term.
- device durability.

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What this means in practice

Single-chamber pacing

There is enough evidence on the safety and efficacy of this procedure for clinicians to consider single-chamber leadless pacemaker implantation as an option for single-chamber pacing.

Clinicians should always discuss the available options with the person with bradyarrhythmias before a joint decision is made (see NICE's page on shared decision making).

Hospital trusts will have their own policies on funding procedures and monitoring results. NHS England may also have policies on funding of procedures.

Dual-chamber pacing

There is not enough evidence to know if this procedure is safe and effective for dual-chamber pacing. Dual-chamber leadless pacemaker implantation should only be done as part of formal research.

For everyone having the procedure

Auditing of outcomes

Clinicians doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having leadless pacemaker implantation for bradyarrhythmias into the National Audit of Cardiac Rhythm Management database, managed by the National Institute for Cardiovascular Outcomes Research (NICOR), and regularly review the data on outcomes and safety.

Who should be involved in the procedure

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The procedure should only be done in specialist centres by clinicians with specific training on inserting the device.

Why the committee made these recommendations

For single-chamber pacing, the evidence includes large observational studies comparing single-chamber leadless pacemakers with conventional transvenous cardiac pacemakers. It shows that leadless pacemaker implantation for bradyarrhythmias is effective at detecting abnormal heart rhythms and restoring normal pacing. The evidence also shows that it improves quality of life. The risk of infection and other complications is lower after leadless pacemaker implantation than after conventional transvenous cardiac pacemaker implantation.

For dual-chamber pacing, there is not enough evidence on the safety and efficacy of the procedure. So, it should only be used in research.

2 Information about the procedure

2.1 The aim of implanting a leadless pacemaker is to detect cardiac bradyarrhythmias and deliver electric pulses to help regulate the heartbeat. Most leadless pacemakers deliver single-chamber right ventricular pacing, but dual-chamber systems that deliver atrial or atrioventricular (AV) pacing are also available.

2.2 The procedure is usually done under local anaesthesia in a cardiac catheterisation laboratory. Fluoroscopic guidance is needed and intracardiac echocardiography or contrast may be needed to guide implantation in the desired location in the heart chamber (right ventricle or atrium). For single-chamber leadless pacemakers, the proximal end of the leadless pacemaker is attached to a deflectable delivery catheter system and is usually inserted percutaneously through the femoral vein or a vein in the neck (jugular access) using an introducer sheath. It is then moved into the right atrium, through the tricuspid valve into the right ventricle, and positioned

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near the apex or lower septum. Once in place, the leadless pacemaker is securely implanted into the endocardial wall using a fixation mechanism. Electrical measurements are taken and, if satisfactory, the leadless pacemaker is released from the catheter and the catheter is removed. If the position is suboptimal, the leadless pacemaker can be detached from the endocardium and repositioned before the catheter is released.

2.3 The pacemaker delivers electrical impulses that pace the heart through an electrode at the distal end of the device. It is adjusted using an external programming system. A catheter retrieval system is used for removal and replacement of the leadless pacemaker when needed.

2.4 A dual-chamber leadless pacemaker system consists of 2 devices implanted percutaneously in a single procedure into the target chambers: one in the right atrium and another in the right ventricle.

2.5 Several different devices are available for leadless cardiac pacemaker implantation for bradyarrhythmias.

3 Committee discussion

The condition

3.1 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 AV block. The most common causes are the natural ageing process, ischaemic heart disease, heart valve disorders and heart failure. If untreated, bradyarrhythmias may lead to fatigue, fainting, palpitations, dizziness, heart failure and an increased risk of death.

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Current practice

3.2 The treatment depends on the underlying cause and the symptoms. If treatment is needed, bradyarrhythmias are usually managed with pacemakers as described in NICE technology appraisal guidance on dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block and dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block. Dual-chamber pacing is recommended for symptomatic bradycardia caused by sick sinus syndrome, AV block, or both. Single-chamber ventricular pacemakers may be used for AV 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.

Unmet need

3.3 Bradyarrhythmias are usually managed with transvenous cardiac pacemaker (TVPs). But these are associated with lead and generator-related complications, including infection and lead failure, which contribute to long-term morbidity. Leadless pacemaker implantation provides an option for people who cannot have conventional TVP implantation. Leadless pacemakers may be particularly beneficial for some people, such as those with previous device infection or endocarditis, immunosuppression, vascular access issues, or high risk of infection.

The evidence

3.4 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 16 sources, which was discussed by the committee. The evidence included a randomised controlled trial, 4 systematic reviews with

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meta-analyses, 5 registry studies, 4 prospective studies and 2 retrospective studies. 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.

3.5 The professional experts and the committee considered the key efficacy outcomes to be: adequate pacing performance and quality of life.

3.6 The professional experts 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.

3.7 Two submissions were received from patient organisations and 1 patient commentary from a person who had this procedure. These were discussed by the committee.

Committee comments

3.8 The committee noted that leadless pacemakers may be particularly beneficial for people who have a higher risk of complications with a conventional TVP or when a TVP is contraindicated. This may include people who:

- are on haemodialysis
- are having radiotherapy
- are at high risk of infection
- are immunocompromised
- have difficult vascular access.

3.9 The committee heard that companies offer comprehensive training programmes on the implantation procedure.

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Equality considerations

3.10 The incidence of bradyarrhythmias increases with age, due to more frequent underlying causes.

3.11 People with bradyarrhythmias may be covered by the Equality Act if the condition has a long-term impact on their daily life. Disability is a protected characteristic under the Equality Act (2010).

4 Committee members and NICE project team

This topic was considered by NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Tom Clutton-Brock

Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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