NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Leadless cardiac pacemaker implantation for bradyarrhythmias

Information for the public

Bradyarrhythmias are when the heart beats abnormally slowly. 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. This is used to put the leadless cardiac pacemaker into the heart chamber. The aim is to stimulate the heart when needed 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 the safety and efficacy of these procedures. 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. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

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 efficacy and safety 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.

Key dates:

Closing date for comments: 11 November 2025

Third committee meeting: 11 December 2025

1 Recommendations

Right ventricular pacing

1.1 Leadless cardiac pacemaker implantation can be used as an option for right ventricular pacing for bradyarrhythmias.

Dual-chamber pacing when transvenous pacing is not an option

1.2 When transvenous pacing is not an option, leadless cardiac pacemaker implantation can be used during the evidence generation period for dual-chamber pacing for bradyarrhythmias. There must be enhanced informed consent and auditing of outcomes.

Dual-chamber pacing when transvenous pacing is an option

1.3 When transvenous pacing is an option, more research is needed on leadless cardiac pacemaker implantation for dual-chamber pacing for bradyarrhythmias.

1.4 This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

Atrial pacing

1.5 More research is needed on leadless cardiac pacemaker implantation for atrial pacing for bradyarrhythmias before it can be used in the NHS.

1.6 This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

What this means in practice

Right ventricular pacing

There is enough evidence on the safety and efficacy of this procedure for right ventricular pacing for healthcare professionals to consider it as an option for bradyarrhythmias.

Healthcare professionals should always discuss the available options with the person with a bradyarrhythmia 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 when transvenous pacing is not an option

There are uncertainties around the safety and efficacy of this procedure for dual-chamber pacing. When transvenous pacing is not an option for bradyarrhythmias, dual-chamber pacing can be used if needed while more evidence is generated.

After this, the evidence base will be reviewed by NICE periodically and the guidance will only be reconsidered by the committee if there is reason to do so.

Healthcare professionals do not have to offer leadless cardiac pacemaker implantation for dual-chamber pacing when transvenous pacing is not an option for bradyarrhythmias. They should always discuss the available options with the person with a bradyarrhythmia 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.

Enhanced informed consent

Because there are uncertainties about whether this procedure is safe and effective for dual-chamber pacing when transvenous pacing is not an option, there must be an emphasis on informed consent. Healthcare professionals must make sure that people (and their families and carers as appropriate) understand the uncertainty and lack of evidence around a procedure's safety and efficacy using NICE's advice on shared decision making and NICE's information for the public. Healthcare professionals must also inform the clinical governance leads in their organisation if they want to do the procedure.

Dual-chamber pacing when transvenous pacing is an option and atrial pacing

There are uncertainties around the safety and efficacy of this procedure for dual-chamber pacing when transvenous pacing is an option. There is not enough evidence on the safety and efficacy of this procedure for atrial pacing for bradyarrhythmias. For both of these scenarios it should only be done as part of formal research.

For everyone having the procedure

Auditing of outcomes

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

Who should be involved in the procedure

This procedure should only be done in specialist centres by healthcare professionals with specific training on inserting the devices.

What evidence generation and research is needed

Healthcare professionals must collect data specifically around the safety and efficacy of dual-chamber pacing when transvenous pacing is not an option. More evidence generation and research, in the form of observational studies or registry data, is needed for dual-chamber and atrial pacing on:

- 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.

Why the committee made these recommendations

For right ventricular pacing, the evidence includes large observational studies comparing right ventricular leadless cardiac pacemakers with conventional transvenous cardiac pacemakers. It shows that leadless cardiac pacemaker implantation for right ventricular pacing 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 cardiac pacemaker implantation than after conventional transvenous cardiac pacemaker implantation. So, it can be used.

For dual-chamber pacing, the available evidence is limited in quality and quantity and is mainly from observational studies with short term follow-up (12 months or less). So, it is unclear how well the procedure works in the long term, and high-quality evidence on efficacy and safety outcomes is needed.

There are some people who cannot have transvenous dual-chamber pacing and have no other options. For these people, the procedure can be used in the NHS while further evidence is generated. When transvenous pacing is a suitable option, leadless cardiac pacemaker implantation for dual-chamber pacing should only be used in research.

For atrial 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 cardiac pacemaker is to detect cardiac bradyarrhythmias and deliver electric pulses to help regulate the heartbeat. Most leadless cardiac pacemakers deliver single-chamber right ventricular pacing (with or without atrial sensing), but dual-chamber systems that deliver atrial or atrioventricular pacing using 2 devices are also available. Right atrial leadless cardiac pacemakers are a recent advancement and are suitable for people needing right atrial pacing only.

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 right ventricular leadless cardiac pacemakers, the proximal end of the leadless cardiac pacemaker is attached to a deflectable delivery catheter system. It 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 near the apex or lower septum. An atrial device does not cross the tricuspid valve into the right ventricle. Once in place, the leadless cardiac pacemaker is securely implanted into the endocardial wall using a fixation mechanism. Electrical measurements are taken and, if satisfactory, the leadless

cardiac pacemaker is released from the catheter and the catheter is removed. If the position is suboptimal, the leadless cardiac pacemaker can be detached from the endocardium and repositioned before the catheter is released.

2.3 The cardiac 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 cardiac pacemaker when needed.

2.4 A dual-chamber leadless cardiac pacemaker system consists of 2 devices implanted percutaneously, either in a single procedure or over multiple procedures, 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 associated with 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 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.

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's technology appraisal guidance on dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block
- NICE's technology appraisal guidance on dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block

3.3 Dual-chamber pacing is used for symptomatic bradycardia caused by sick sinus syndrome, atrioventricular block, or both. Single-chamber ventricular pacemakers may be used for atrioventricular block alone or with sick sinus syndrome for people with continuous atrial fibrillation. It may also be used for 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

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

The evidence

3.5 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 20 sources, which was discussed by the committee. The evidence included a randomised controlled trial, 4 systematic reviews with meta-analyses, 5 registry studies, 8 prospective studies and

2 retrospective studies. Of these, 15 studies focused on right ventricular pacing, 3 on dual-chamber pacing and 2 on atrial pacing. 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.

3.6 Several different devices were used in the studies informing this guidance.

3.7 The professional experts and the committee considered the key efficacy outcomes to be:

- adequate pacing performance
- quality of life.

3.8 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
- duration of device function.

3.9 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

3.10 The committee noted that leadless cardiac pacemakers may be particularly beneficial for people who have a higher risk of complications with a conventional transvenous cardiac pacemaker

or when a transvenous cardiac pacemaker 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
- have dementia (because transvenous pacemakers can be associated with a risk of deliberate or unintentional twisting of the pulse generator in the device pocket, resulting in lead dislodgement)
- have congenital heart disease so access to their heart chambers may be difficult because of abnormal anatomy or previous surgery.

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

3.12 Leadless cardiac pacemaker technology is evolving. There are several devices available, not all offer dual-chamber leadless pacing.

3.13 The dual-chamber pacing system with atrial sensing has been associated with slightly reduced battery life compared with single chamber pacing.

Equality considerations

3.14 The incidence of bradyarrhythmias increases with age because of more frequent underlying causes.

3.15 People with bradyarrhythmias may be covered by the Equality Act (2010) if the condition has a long-term impact on their daily life.

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.

Sm Hasan ul Bari, Lakshmi Mandava
Technical leads

Helen Gallo, Evan Campbell
Technical advisers

Anthony Akobeng
Consultant clinical adviser

Corrina Purdue
Project manager

Emily EatonTurner
Associate director

ISBN: [to be added at publication]