NICE National Institute for Health and Care Excellence

NICE guidance

Leadless cardiac pacemaker implantation for bradyarrhythmias

HealthTech 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.

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This guidance replaces HTG484.

1 Recommendations

Right ventricular pacing alone

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

Dual-chamber pacing or right atrial pacing alone when transvenous pacing is unsuitable

1.2 When transvenous pacing is unsuitable, leadless cardiac pacemaker implantation can be used during the evidence generation period for dual-chamber pacing or right atrial pacing alone for bradyarrhythmias. There must be enhanced informed consent and auditing of outcomes.

Dual-chamber pacing or right atrial pacing alone when transvenous pacing is suitable

1.3 When transvenous pacing is suitable, more research is needed on leadless cardiac pacemaker implantation for dual-chamber pacing or right atrial pacing alone 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.

What this means in practice

Right ventricular pacing alone

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 or right atrial pacing alone when transvenous pacing is unsuitable

There are uncertainties around the safety and efficacy of this procedure for dual-chamber pacing and right atrial pacing alone for bradyarrhythmias. When transvenous pacing is unsuitable for bradyarrhythmias, dual-chamber pacing or right atrial pacing alone 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 or right atrial pacing alone when transvenous pacing is unsuitable 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 or right atrial pacing alone when transvenous pacing is unsuitable, 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 or right atrial pacing alone when transvenous pacing is suitable

There are uncertainties around the safety and efficacy of this procedure for dual-chamber pacing for bradyarrhythmias when transvenous pacing is suitable. There is not enough evidence on the safety and efficacy of this procedure for right atrial pacing alone 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

Evidence generation and research, in the form of observational studies or registry data, is needed for dual-chamber pacing and right atrial pacing alone 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 suitable, leadless cardiac pacemaker implantation for dual-chamber pacing for bradyarrhythmias should only be used in research.

For right atrial pacing, there is not enough evidence on the safety and efficacy of the procedure. There are some people who cannot have transvenous 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 suitable, leadless cardiac pacemaker implantation for right atrial pacing alone for bradyarrhythmias 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 interventional procedures advisory committee considered evidence on leadless cardiac pacemaker implantation for bradyarrhythmias from several sources. This included a review of efficacy and safety evidence, information submitted by 2 companies and responses from stakeholders. Full details are available in the project documents for this guidance.

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 age, 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. Transvenous cardiac pacing may be unsuitable for people with previous device infection or endocarditis, immunosuppression, vascular access issues or other factors placing them at high risk of recurrent device-related infection. Leadless cardiac pacemaker implantation provides an option for people who cannot have conventional transvenous cardiac pacemaker implantation.

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 this type of 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, with transvenous pacemakers, there is 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. Not all offer dual-chamber leadless pacing.

3.13 The dual-chamber pacing system with atrial sensing and pacing has been associated with slightly reduced battery life compared with single-chamber pacing, in line with other pacemakers.

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.

Chairs

Tom Clutton-Brock and Rick Body
Chairs, 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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