NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal

Dual-chamber pacemakers for treating symptomatic bradycardia due to sick sinus syndrome or atrioventricular block, part review of Technology Appraisal 88

Draft scope

Appraisal objective

To appraise the clinical and cost effectiveness of dual-chamber pacemakers for treating symptomatic bradycardia in people with sick sinus syndrome in whom there is no evidence of impaired atrioventricular conduction and in people with atrioventricular block and continuous atrial fibrillation and to update the recommendations of Technology Appraisal 88 in relation to these indications.[1,2]

Background

Cardiac arrhythmias are abnormal heart rhythms which may be fast (tachycardia), slow (bradycardia), or irregular and are caused by disturbances in the intrinsic heart rate or the electrical pathway of the heart.

The most common causes of abnormal heart rhythms are ischaemic heart disease, heart valve disorders and heart failure. If untreated, abnormal heart rhythms may lead to fainting, palpitations, dizziness, congestive heart failure and an increased risk of mortality.

Pacemakers are used in the treatment of bradycardia to control or replace the heart's intrinsic electrical activity and restore a normal heart rate.

In 2010 in England, more than 40,000 people had a pacemaker fitted. Hospital Episode Statistics (HES) show that the total number of dual chamber cardiac pacemaker procedures performed in the NHS to treat bradycardia increased between 2006 and 2011 with a higher rate of uptake for the treatment of atrioventricular block compared with sick sinus syndrome. In 2010/11 there were 1,201 dual chamber pacemaker procedures for bradycardia due to sick sinus syndrome, and 5,273 due to atrioventricular

[1] The original Department of Health remit to NICE was "To appraise the clinical and cost effectiveness of dual chamber (atrial and ventricular) pacemakers relative to single chamber ventricular pacemakers, and to advise on the patients for whom the former would be particularly appropriate."

[2] This appraisal will only consider the indications for which dual chamber pacing is not recommended in TA88. The recommendation for dual chamber pacing in people with sick sinus syndrome, atrioventricular block or both in populations other than those specified under 'Appraisal Objective' will remain extant.

block. A national survey conducted by the Network Devices Survey Group that analysed adherence to TA88 in England and Wales in 2008 reported a national average of 77% single chamber atrial-based pacing in sick sinus syndrome with the rate in individual pacing centres varying between 0% to 100%.

The prevalence of sick sinus syndrome is thought to be about 0.03% of the whole population, and increases with age. Estimates of the prevalence of atrioventricular block (based on clinical studies) range from 0.015% to 0.1%, although it is common for people to have coexisting abnormalities of both the sinus node and the atrioventricular node.

NICE technology appraisal 88 recommends dual-chamber pacing for the management of symptomatic bradycardia due to sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and atrioventricular block. This population, for whom dual chamber pacing is currently recommended, will not be included in this review. NICE TA88 did not recommend dual-chamber pacing for the management of sick sinus syndrome in patients whom, after full evaluation, there was no evidence of impaired atrioventricular conduction. It also did not recommend dual-chamber pacing for the management of atrioventricular block in patients with continuous atrial fibrillation. The review date of the original guidance was deferred until the DANPACE study(which compared dual-chamber with single-chamber atrial pacing in people with sick sinus syndrome without atrioventricular block) had been published. The purpose of this part-review is to review the evidence for dual chamber pacing in the indications for which is it not recommended in TA88.

The technology

Pacemakers are indicated for use in the treatment of symptomatic bradycardia, and they control or replace the heart's intrinsic electrical activity. Some patients require intermittent pacing, whereas patients whose intrinsic heart rate is slow for most of the time require a pacemaker to pace most of their heartbeats.

Pacing systems are electrical devices that consist of a small battery-powered generator and one or more pacing leads that are in contact with the inner wall of the right atrium and/or the right ventricle. The pacemaker senses whether an intrinsic depolarisation has occurred. When this has not occurred, the pacemaker generates an electrical impulse, which is delivered to the heart muscle via the pacemaker leads to initiate contraction.

Pacemakers may be broadly classified as single or dual-chamber devices, depending on whether leads are applied to one or two heart chambers. A range of additional features is also available, such as rate modulation (which allows the pacing rate to increase in response to physical activity or metabolic demand).

Intervention(s)	Permanent implantable dual-chamber pacemakers
Population(s)	People with symptomatic bradyarrythmias due to: • sick sinus syndrome without atrioventricular block • atrioventricular block in people with continuous atrial fibrillation.
Comparators	For people with sick sinus syndrome without atrioventricular block • single-chamber atrial pacemakers. For people with atrioventricular block and continuous atrial fibrillation • single-chamber ventricular pacemakers
Outcomes	• mortality • morbidity (including incidence of heart failure) • exercise assessment • cognitive function • adverse effects of treatment (including pacemaker syndrome, paroxysmal atrial fibrillation and device replacement) • health related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the CE marking.

Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 120, May 2007, 'Cardiac resynchronisation therapy for the treatment of heart failure'. A combined review of TA95 and TA120 is in progress, date of publication to be confirmed. Technology Appraisal No. 95, January 2006, 'Implantable cardioverter defibrillators for arrhythmias'. A combined review of TA95 and TA120 is in progress, date of publication to be confirmed. Related guidelines Clinical guideline No. 108, August 2010, 'Chronic heart failure'. Review decision date August 2013. Clinical guideline No. 36, June 2006, 'Atrial fibrillation: risk assessment, diagnosis, treatment and review'. Review in progress, expected publication June 2014. Related Quality Standards Quality Standard No. 9, June 2011, 'Chronic heart failure'. http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp Related NICE Pathways NICE Pathway: Chronic Heart Failure, May 2011. http://pathways.nice.org.uk/
Related NHS England policy	None

Questions for consultation

Are there any additional health outcomes which could be included?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which single chamber pacemakers are indicated;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

Where do you consider single chamber pacing will fit into the existing NICE Chronic Heart Failure pathway?