NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal

Dual-chamber pacemakers for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block, part review of Technology Appraisal 88

Final 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.[1,2]

Background

Cardiac arrhythmias are abnormal heart rhythms which may be fast (tachycardia), slow (bradycardia), or irregular (most commonly atrial fibrillation) and are caused by abnormalities of impulse formation or electrical conduction in the heart.

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

Pacemakers are used in the treatment of bradycardia to monitor the heart's intrinsic electrical activity and. to prevent bradycardia by stimulating additional heart beats when required.

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 lower rate of uptake for the treatment of sick sinus syndrome compared with atrioventricular block. In 2010/11 there were 1,201 dual chamber pacemaker procedures for bradycardia due to sick sinus syndrome, and 5,273 due to atrioventricular block. A national survey conducted by the Heart Rhythm UK Device Audit

[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 dual-chamber pacemakers for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block. 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.

Group that analysed cardiac device implantation in England and Wales in 2011 reported a national average of 69% atrial-based pacing in sick sinus syndrome. The majority of devices were dual chamber with very few patients receiving single chamber atrial pacemakers.

The prevalence of sick sinus syndrome is thought to be about 0.03% of the whole population, and increases with age.

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 for this indication.

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 heart. 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.
Comparators	Single-chamber atrial pacemakers.
Outcomes	• mortality • morbidity (including incidence of heart failure, atrial fibrillation and stroke) • exercise capacity • cognitive function • requirement for further surgery • adverse effects of treatment (including pacemaker syndrome, 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. If evidence allows the clinical and cost effectiveness of rate responsive pacemakers will be compared with non-responsive pacemakers.

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 NHS England policy	None.