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Multiple Technology Appraisal (MTA)

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

Please sign and return to:

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Personal statement

Dual chamber pacemakers comprise electrical leads connecting the right atrium and ventricle to a small computerised device implanted beneath the skin of the chest. They monitor heart rhythm continuously and deliver electrical stimulation to induce myocardial contraction when the heart falls below a pre-specified rate or ventricular contraction does not follow atrial contraction after a pre-specified interval. In this way, they can prevent bradycardia and restore synchronisation between atrial and ventricular contraction.

Bradycardia commonly results from reduced impulse formation in the sino-atrial node (sinus node disease) or reduced conduction of impulses to the ventricles through the atrioventricular node (atrioventricular heart block). For most people with bradycardia, no single cause is found. If untreated, bradycardia may lead to palpitations, light-headedness, syncope, heart failure and even sudden cardiac death.

International guidelines on device therapy are available from the USA (http://circ.ahajournals.org/content/117/21/e350.full.pdf) and EU (http://eurheartj.oxfordjournals.org/content/34/29/2281.full.pdf). NICE technology appraisal 88 was published in February 2005 and addresses the indications for pacing for in sick sinus syndrome and/or atrioventricular block, but does not cover more complex pacing indications.

Dual-chamber pacing is recommended for the management of symptomatic bradycardia due to sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and atrioventricular block, except:

1) in the management of sick sinus syndrome in patients in whom, after full evaluation, there is no evidence of impaired atrioventricular conduction; in this situation, single-chamber atrial pacing is appropriate

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2) in the management of atrioventricular block in patients with continuous atrial fibrillation; in this situation, single-chamber ventricular pacing is appropriate

3) in the management of atrioventricular block (atrioventricular block alone, or in combination with sick sinus syndrome), when patient-specific factors, such as frailty or the presence of comorbidities, influence the balance of risks and benefits in favour of single-chamber ventricular pacing.

Since the publication of this guidance, further clinical trial data have been published (DANPACE http://eurheartj.oxfordjournals.org/content/32/6/686.full.pdf+html) demonstrating that single chamber atrial (AAI±R) pacing is associated with a higher incidence of paroxysmal atrial fibrillation and a two-fold increased risk of pacemaker reoperation. These findings support the routine use of DDDR pacing in these patients.

As a result, UK practice has moved away from AAI±R pacing except where there are specific patient characteristics making this the most appropriate pacing mode. The most recent national devices report (https://nicor5.nicor.org.uk/ 802571400070B77E.nsf?OpenDatabase) shows that 71% of patients received dual chamber pacemakers, with the remaining 29% receiving VVI± devices. Only 165 patients (0.42%) received single chamber atrial pacemakers.

It is appropriate to revise the guidance and remove the recommendation for the routine use of single-chamber atrial pacing (AAI±R). It would also be appropriate to indicate that pacemakers are indicated for prognostic indications (high degree atrioventricular block) whether symptoms are present or not. Revised guidance should also state that pacemakers able to increase pacing rates in response to patient activity, should be preferred because of superior patient outcomes.

Revised guidance could therefore read:

This guidance refers only to pacing for the primary indications of sick sinus syndrome and/or atrioventricular block, and does not cover more complex indications.

1.1 Dual-chamber rate responsive (DDDR) pacing is recommended for the management of symptomatic sick sinus syndrome, atrioventricular block, or a combination of sick sinus syndrome and atrioventricular block, except:

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- **in the management of atrioventricular block in patients with permanent atrial fibrillation; in this situation, single-chamber rate responsive ventricular pacing (VVIR) is appropriate**

- **in the management of atrioventricular block (atrioventricular block alone, or in combination with sick sinus syndrome), when patient-specific factors, such as frailty or the presence of comorbidities, influence the balance of risks and benefits in favour of single-chamber rate responsive ventricular pacing (VVIR).**

I agree to my submitted personal statement being published on the NICE web site following the first Appraisal Committee meeting.

Signed: [redacted]

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