NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Health Technology Appraisal

Dual chamber pacing

Scope

Objective: To appraise the clinical and cost effectiveness of dual chamber pacemakers compared with single chamber pacemakers, and to provide guidance to the NHS in England and Wales¹.

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 cardiac arrhythmia are heart disease, coronary artery disease, heart valve disorders and heart failure. Arrhythmias may also be caused by congenital anatomical heart defects, thyroid disease and age related changes in the impulse generation and conduction of the heart. If untreated, cardiac arrhythmia may lead to syncope, palpitations, dizziness, congestive heart failure or death.

Pacing systems have been used since the late 1950's in the treatment of cardiac arrhythmias (commonly bradycardia), to control or replace the heart's intrinsic electrical activity and restore a normal physiological heart rate. The majority of pacemakers are implanted for the treatment of sick sinus syndrome and atrioventricular block which accounted for 67% of pacemakers implanted in 2002. Clinical decisions on the choice of pacemaker implanted are based on the symptoms, underlying rhythm abnormality and the general condition of the patient.

In 2002, a total of 25,193 pacemakers were implanted in the United Kingdom and Ireland (which comprised 18,984 new pacemakers and 6,209 replacement devices). This corresponds to an implant rate of approximately 300 per million population. The average age of patients receiving their first pacemaker is 75 years of age.

The technology: Pacing systems are electrical devices, which consist of two implantable cardiac components; the pacemaker and pacing leads, and an external programmer. The pacemaker supplies the electrical energy for pacing which is delivered to the heart by leads, which both sense the intrinsic activity of the heart and deliver electrical pulses to initiate a heart beat. Some "rate responsive" pacemakers monitor an individual's level of physical activity and modulate the heart rate according to metabolic requirements (e.g. increasing the heart rate during exercise). Pacemakers may be classed as

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

dual or single chamber, depending on the number of heart chambers being paced.

Single chamber pacemakers pace either the right atrium or more commonly the right ventricle. Atrial pacing may be required in conditions where the heart's natural pacemaker, the sinoatrial (SA), node is not functioning (sick sinus syndrome). Ventricular pacing is used in the treatment of heart block (disturbances in the conduction of the electrical signal from the atrium to the ventricles) or in patients in sinoatrial node disease to ensure rhythmic contraction of the ventricles.

Dual chamber pacemakers pace both the right atrium and ventricle to maintain physiological atrioventricular (AV) synchrony. Dual chamber pacing (sensing of the intrinsic atrial rate and pacing of the ventricle) may be used in patients with AV block to achieve rate responsive adaptation of atrial and ventricular pacing rate according to changing physiological needs (e.g. during exercise). Dual chamber pacing is thought to reduce the likelihood of "pacemaker syndrome" (symptoms caused by the loss of atrioventricular synchrony) and cardiovascular morbidity, and improve quality of life compared to single chamber ventricular pacing.

Intervention(s)	Permanent implantable dual chamber pacemakers (sensing and pacing of the right atrium and ventricle)
Population(s)	Individuals with symptomatic bradyarrythmias who require a pacemaker for whom single and dual chamber pacing may be appropriate. This includes patients with atrioventricular block, sinus node dysfunction and symptomatic bradycardia from other causes.
Current standard treatments (comparators)	Permanent implantable single chamber pacemakers
Other considerations:	Possible outcomes of interest include: Mortality, morbidity (e.g. incidence of heart failure), exercise assessment, cognitive function, the incidence of adverse events such as pacemaker syndrome and quality of life.
	If the evidence allows the appraisal will evaluate the The effect of pacemaker dependency on effectiveness. The effectiveness of dual chamber pacing for specific patient groups e.g. children and the elderly.
Exclusions	 Pacing for the primary indications of heart failure, atrial fibrillation and neurocardiogenic syncope Bi-ventricular and triple chamber pacing.

APPENDIX A