British Cardiovascular Society

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BCS Guidelines and Practice Committee Reviews

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BCS Professional organisation submission:

Bradycardia (without atrioventricular block) - dual chamber pacemakers (part review of TA88) [ID697]

Introduction

Sick sinus syndrome is a term used to describe a slow heartbeat (bradycardia) due to disease of the heart's natural pacemaker, the sinus node. The sinus node is a group of cells in one of the top chambers of the heart, the right atrium, which beats in a regular rhythm at a rate proportional to the degree of physical activity. Sick sinus syndrome may manifest itself in two ways: i) a sudden slowing of the sinus node rate, causing a drop in blood pressure, which may result in episodes of dizziness or even loss of consciousness or ii) failure of the heart rate to rise adequately during exercise resulting in reduced exercise capacity as a result of fatigue and/or breathlessness.

The primary aim of permanent pacing is to prevent the heart from beating too slowly. An important secondary aim is to reproduce, as far as possible, the function of the heart's normal electrical conduction system, which coordinates the way the heart muscle contracts. Although a ventricular-based single chamber pacemaker will prevent bradycardia due to sinus node disease, the normal sequence of cardiac contraction is lost and may even be reversed, with the ventricles beating before the atria, which can cause unpleasant symptoms known as pacemaker syndrome, and may increase the risk of atrial fibrillation and stroke. The superiority of atrial based pacing over ventricular based pacing for sick sinus syndrome is well established [1] and reflected by current NICE guidance [2] and international guidelines for permanent pacing [3,4].

Although an atrial-based single-chamber ('AAI') pacemaker should theoretically suffice for the treatment of sick sinus syndrome, sinus node disease is frequently accompanied by disease of the other components of the cardiac conduction system including the atrioventricular node and His-Purkinje system, which may not be evident at the time of presentation with sick sinus syndrome. An important concern is that if a patient with a atrial-based single-chamber pacemaker goes on to develop atrioventricular block as a result of progressive conduction system disease they may then re-present with dizzy spells or loss of consciousness and require upgrade of their pacemaker to a dual chamber system. For this reason many heart rhythm specialists elect to implant a dual chamber system from the

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outset in patients with sick sinus syndrome and no evidence of impaired atrioventricular conduction.

Arguments in favour of implanting a atrial-based single-chamber pacemaker in patients with sick sinus syndrome without evidence of impaired atrioventricular conduction:

i) Patients who do not go on to develop atrioventricular block have been paced appropriately and have not received a more complex system than they needed
ii) In a a study comparing atrial-based single-chamber pacemakers with dual chambers for the treatment of sick sinus syndrome [5], the incidence of atrial fibrillation during a mean follow-up of 2.9 ± 1.1 years was significantly lower in in the single chamber group (7.4%) than in the two dual chamber groups (23.3% and 17.5%, $p = 0.03$)
iii) Single chamber pacing systems are cheaper than dual chamber systems
iv) Procedure duration for a single chamber pacemaker implant is generally shorter than that for a dual chamber pacemaker implant
v) It is possible that certain complications of the pacemaker implant procedure such as cardiac perforation, pneumothorax and infection (related to procedure duration) may occur less frequently with single chamber pacemaker implants than with dual chamber implants.
vi) Even with sophisticated modern algorithms designed to avoid unnecessary ventricular pacing, some right ventricular pacing may be seen in patients with intact atrioventricular conduction, which may have adverse consequences for pacemaker battery longevity and for cardiac function.
vii) Pacemaker follow-up takes less time for single chamber systems than for dual chamber systems.
viii) A single pacemaker lead may be less likely than two leads to cause narrowing or obstruction of the great veins
ix) Extracting one chronically-implanted pacemaker lead is easier than extracting two leads.

Arguments in favour of implanting a dual chamber pacemaker in patients with sick sinus syndrome without evidence of impaired atrioventricular conduction are

i) Patients with dual chamber pacemakers who go on to develop high-grade atrioventricular block will be protected by the presence of a ventricular lead. There is no robust way of identifying which patients will go on to develop atrioventricular block.

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ii) Patients with single-chamber pacemakers who go on to develop atrioventricular block will need a further procedure to upgrade their pacemaker to a dual-chamber system. Consequences of this include:

a) the existing single-chamber pulse generator will be explanted before its battery is depleted
b) the implant and device cost of a new dual chamber pacemaker
c) the additional morbidity from a further pacemaker-related procedure. The risk of a procedural complication is 5-6% and is higher for generator replacement/system revision than for a first time implant
d) Some patients will be found at the time of the upgrade procedure to have an occluded subclavian vein, necessitating an alternative approach including an implant on the contralateral side or lead extraction with their associated cost and morbidity. In addition it is inevitable that some such cases will be referred to a specialist pacing service resulting in yet another admission and procedure.

Relevant research published since NICE guidance TA88 2005

The DANPACE study [5] has provided useful evidence to help guide the choice between atrial-based single-chamber pacing and dual-chamber pacing in patients with sick sinus syndrome. That study randomly assigned 1415 patients with symptomatic sick sinus syndrome and no evidence at the time of implant of high grade atrioventricular block or other conduction system disease to implantation with either an atrial-based rate-responsive single chamber ('AAIR') pacemaker or a rate-responsive dual-chamber ('DDDR') pacemaker. These patients were followed for a mean of 5.4 years. The results, analysed on an intention-to-treat basis, showed no difference between the treatment groups in terms of all-cause mortality, persistent atrial fibrillation, stroke or heart failure. Paroxysmal atrial fibrillation occurred in 28.4% of the patients assigned to AAIR pacing compared to 23.0% of patients assigned to DDDR pacing (hazard ratio 1.27, 95% CI 1.03 – 1.56, $p = 0.024$). Complications related to the pacemaker itself or to the implant procedure occurred with similar frequency in the two groups. Perhaps most importantly 22.1% of the patients assigned to AAIR pacing required pacemaker reoperation compared to 11.9% in the DDDR group (hazard ratio 2.00, 95% CI 1.53 – 2.591, $p < 0.001$). The excess of pacemaker reoperations in the AAIR group was due to procedures to upgrade AAIR systems to dual-chamber systems due to the development of high-grade atrioventricular block. The rate of reoperation for this indication was 1.7% per year (an earlier study estimated the reoperation rate at 1.9% per year [6]).

The DANPACE study has certain limitations. Most notably patients with first-degree atrioventricular block were eligible for enrolment into the study. No data are given about the baseline prevalence of first-degree atrioventricular block or its relationship with the subsequent need for upgrade to a dual chamber system.

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Furthermore, although the follow-up period was generous at a mean of 5.4 years, it can be anticipated that the rate of pacemaker reoperation for the development of high grade atrioventricular block would increase steadily over time and so the results of this study almost certainly underestimate the reoperation rate during the lifetime of an atrial-based single chamber pacemaker (typically 10-12 years). Finally although the DDDR pacemakers in the DANPACE were programmed in a way intended to reduce unnecessary ventricular pacing, the study was largely conducted before the availability of modern pacemaker algorithms designed to minimize ventricular pacing in patients with intact atrioventricular conduction. Consequently, RV pacing was seen for 65 ± 33% of the time during follow-up, which may conceivably have offset some of the benefit of implanting a dual chamber system.

Other considerations

Avoiding unnecessary right ventricular pacing

Chronic right ventricular apical pacing has an adverse effect on cardiac structure and function including ventricular remodelling, reduced left ventricular ejection fraction, atrial dilatation and, probably as a consequence of the latter, an increased risk of atrial fibrillation. Studies comparing atrial-based single-chamber with dual-chamber pacing for sick sinus syndrome [5,6] give apparently conflicting results about the effect of dual-chamber pacing on the incidence of atrial fibrillation in patients with sick sinus syndrome. It is likely that the adverse cardiac structural and functional changes are proportionate to the degree of right ventricular apical pacing. Dual chamber pacemakers implanted for sick sinus syndrome with apparently intact atrioventricular conduction should use algorithms (‘Managed Ventricular Pacing’) in order to minimize unnecessary ventricular pacing.

Rate-responsive pacing

The heart rate is determined by the rate of firing of the sinus node, under the influence of a variety of nerves and hormones. Sick sinus syndrome may manifest as sinus pauses resulting in a sudden drop in the heart rate and/or a failure of the heart rate to rise adequately during physical exertion. While a non rate-responsive pacemaker will prevent sudden bradycardia due to sinus pauses, only a rate-responsive system will increase the atrial rate in proportion to the degree of physical exertion thus replicating the physiological function of the sinus node. Although it would seem logical that all patients undergoing pacemaker implantation for sick sinus syndrome should receive a rate-responsive pacemaker, evidence for the superiority of rate-responsive dual chamber pacing over non rate-responsive dual chamber pacing is weak [7].

Summary and clinical recommendation

Although there are arguments in favour of both atrial-based single-chamber pacing and dual-chamber pacing in patients with sick sinus syndrome without

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evidence at presentation of impaired atrioventricular conduction, the high rate of progression to advanced atrioventricular block argues strongly in favour of dual-chamber pacing in this group of patients.
Patients undergoing pacemaker implantation for sick sinus syndrome with no evidence at the time of implant of impaired atrioventricular conduction should receive a dual chamber pacemaker employing an algorithm designed to minimize unnecessary right ventricular pacing. A case can be made for the routine use of a rate responsive pacemaker in this group of patients.

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