Dr Chris Lang for NICE TA88

TA88 Use of Dual Chamber pacemakers in sinus node related bradycardia

Background

Slow heart rhythms (bradycardia) can result in symptoms ranging from fatigue and exertion all breathlessness to sudden loss of consciousness or death. The sinus node is the origin of the normal heartbeat and it's failure can be a possible cause of symptoms. Following sinus node and atrial activation, the ventricles are activated once the electrical impulse has been conducted through the atrio-ventricular (AV) node, which is another potential weakness in the conduction system. Most patients who require pacemakers are elderly but bradycardia can affect patients of all ages. Often, fibrosis of tissues is the cause of damage to the components of the conduction system and can roughly equate to general 'wear and tear' which will be progressive. Certain conditions will predispose to fibrosis and accelerate this ageing process.

Pacemakers are now implanted routinely in patients with symptomatic bradycardia. They can be used to stimulate the atria, ventricles or both depending on the nature of the rhythm disturbance. The choice of type of pacemaker is determined by the known rhythm disturbance and the perceived risk of acquiring further conduction system problems due to the progressive nature of these conditions.

Sinus bradycardia can occur as a consequence of extra-cardiac influences such as increased vagal tone as seen in malignant vaso-vagal syncope or carotid sinus hypersensitivity. In these conditions, the autonomic influence is also known to cause slowing of conduction and lengthened recovery time in the atrio-ventricular node.

Pacemaker implantation requires significant expertise and multi-disciplinary teamwork involving cardiologists, cardiac physiologists, nurses and radiographers. However, the procedure can be performed safely under local anaesthesia in under one hour. There is no major difference in the duration or risk of the procedures when comparing single versus dual chamber pacing (1). There is a small difference in price between single and dual chamber pacemakers of a few hundred pounds. The battery life of both types of device is dependent on the percentage of time pacing but we would expect 8-10 years of life from either type.

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Choice of Pacemaker Type (Single chamber atrial vsDual Chamber) in Patients with Sinus Node Disease: Current Evidence

The DANPACE trial (1) was designed specifically to study the impact of a policy of implanting dual chamber pacemakers in patients felt to have only sinus node disease and therefore, at the time of implantation, would only require atrial pacing. All patients felt to be at risk of requiring ventricular pacing were excluded, as were those with paroxysmal atrial fibrillation and sinus node pauses and any degree of AV block or bundle branch block. During implantation, AV node function was assessed. Any patient where the AV node failed to conduct at 100 beats per minute underwent dual chamber device implantation.

Over the extended follow up period, there was no difference in survival between patients randomised to single or dual chamber pacing. Of note, however, was that re-operation rate was 22% in the AAIR group and only 11% in the DDDR group, the difference mainly being explained by the need change the mode of pacing in the AAIR group. There was also a trend to earlier re operation for battery depletion. There was no difference in acute complication rates at the time of original implant in the two groups. Risk factors for likelihood of re operation include age over 75 and PQ interval on ECG of >180ms.

To summarise, this study shows that although DDDR pacing in people believed to have only sinus node disease does not confer a survival advantage, it reduces the relative risk of re operation by 50%. The number needed to treat (NNT) with DDDR pacing to prevent one re operation is 10.

Risks of re operation:

A previous large multi centre registry (2) collected data on all patients undergoing device replacement related surgery. Patients were divided into two groups according to whether it was simply a generator replacement or a new lead was required eg for upgrading the device. In patients requiring upgrade from single to dual chamber, the major complication rate was 5% with the commonest complication being lead dislodgement requiring re operation.

Advantages of Dual Chamber Pacing vs Single Chamber

Dual chamber device implantation reduces the need for future upgrade of a single chamber device due to the development of symptomatic AV block which, from trial data is likely to occur in approximately 10% of patients during the device lifespan or 1.7% per year. Device

upgrades are associated with a 10% risk of major complications and associated excess costs. If patients have, or develop atrial fibrillation, this may require heart rhythm medication which could precipitate AV node conduction problems. In some patients, symptoms may not be adequately controlled with medication in which case, complete AV node ablation could be performed for symptom relief without the need to upgrade the pacemaker.

Disadvantages of Dual Chamber vs Single Chamber Device implantation

Dual chamber devices are more expensive than single chamber devices. The operation is marginally longer but there is not an increase in the risk of complications. Although not upheld by the DANPACE trial, there is a possibility that unnecessary right ventricular pacing could result in the patient developing cardiac dysfunction and ultimately heart failure. This has previously been shown to result in excess mortality in patients with severe LV dysfunction (3) but as a consequence, practise has changed and devices are programmed in such a way to minimise unnecessary pacing. Furthermore, in response to this data, pacemakers have evolved to actively monitor AV conduction and automatically and dynamically adjust settings to avoid unnecessary ventricular pacing.

Outcomes grouped by NICE Outcome Headings:

- Mortality- no impact
- Morbidity-possible reduction in incidence of atrial fibrillation. No excess of complications
- Exercise capacity- no impact
- Cognitive function-no impact
- requirement for further surgery- reduced by 10%
- adverse effects of treatment (including pacemaker syndrome, atrial fibrillation and device replacement)-no observed negative impact. Reduced re operation rate, increased battery longevity, possibly reduced AF, pacemaker syndrome not likely to happen.
- health-related quality of life- likely to be better if fewer operations
- Cost must always be taken into consideration when creating guidelines- cost calculation must take into account 10% reduction in upgrades, plus 10% risk of major complications from upgrade procedures and the associated costs of complications and surgeries.

Conclusion:

In my opinion, operators should have a low threshold for considering implantation of dual chamber pacemakers over single chamber atrial pacemakers in patients with 'pure' sinus node disease. Assessment of AV node function at the time of implantation of AAIR pacemakers is essential to detect occult AV node dysfunction. The elderly, patients with atrial fibrillation and patients with borderline first degree heart block should be strongly considered for primary dual chamber implantation.

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