Pacemaker therapies in cardiology

BACKGROUND
Since the first cardiac pacemaker was inserted in 1958 vast changes have occurred in both the technology of the devices and their indications.

OBJECTIVE
This article discusses the indications for pacemakers, currently available devices, insertion procedure, and patient follow up.

DISCUSSION
Pacemakers have evolved from simple, single chamber devices to multichambered devices capable of treating not only bradycardias but also tachycardias and heart failure. An international classification has been developed regarding arrhythmias and the benefits of pacemakers. In class I conditions, the benefits of pacemakers are well established, decreasing symptoms and improving prognosis. The most common indications are for patients with symptomatic bradycardia associated with sick sinus syndrome and heart block. Patients need to attend for regular device follow up and be aware of precautions relating to electromagnetic radiation, but this usually involves little disruption to their day-to-day life.

Dr Ake Senning implanted the first cardiac pacemaker into Arne Larson in 1958. The device in 1958 only lasted 3 hours and had to be replaced with a second device. Mr Larson subsequently went on to have 26 devices implanted in his lifetime.¹

The initial indication for a pacemaker was for the treatment of bradycardia. Pacemakers are now also used to treat tachycardias, patients at risk of sudden cardiac death (implantable defibrillators), and cardiac failure (cardiac resynchronisation devices). Devices have evolved from single lead systems and fixed rate systems to multichamber, rate responsive systems with increasingly sophisticated software systems.

In Australia in 2001, approximately 500 new pacemakers were inserted per million people per year.²

Pacemaker technology
The pacing system consists of the pacemaker (or pulse generator) and a lead or leads that connect to the pacemaker. This is all located inside the other important part of the pacing system, the patient. There is a desk based programmer to communicate with the device.

Pacemaker (pulse generator)
This is like a mini computer. It contains a tiny 2.5 volt lithium-iodine battery capable of long battery longevity. It also contains the complex circuitry capable of performing functions from delivering the pacing impulse, sensing the intracardiac signal to storing, filtering and analysing intracardiac signals. This is all hermetically sealed in a hard titanium based case. Pulse generators now weigh only about 20 g and are ~20 cc in size (Figure 1, 2).

Pacing leads
These are predominantly transvenous and consist of an insulated wire (silicone or polyurethane covering) that conveys electrical signals between the heart and back to the pacemaker. It connects to the pacemaker by a port and connects to the heart by a fixation mechanism. This is either a tine or screw mechanism (Figure 3).
Programmer
This is a desk based computer system able to interact with the pacemaker by telemetry function. The more recent devices are wireless enabled. This enables the physician to check lead function and battery longevity, make programming changes, and evaluate large amounts of data detected by an in-built holter system in the pacemaker.

Pacing implant
In the early days, pacemakers were inserted by a thoracotomy, however they are now nearly all inserted by the transvenous approach. This is achieved by a small incision under the clavicle to access the cephalic or subclavian vein (Figure 4). The leads are then advanced into the heart and fixed by either small tines (or hooks) or screwed into the myocardium (Figure 5). The leads are then connected to the pacemaker header block and the device implanted in a prepared pocket in the prepectoral region. This procedure typically involves an overnight stay in hospital. Pacemaker generator changes can usually be performed as day procedures. Procedures are available at all major public hospitals, large private hospitals and some regional centres.

As this is a surgical procedure there are both general complications and those specific to the procedure. Specific complications are pneumothorax, wound haematoma, early infection and lead dislodgement.

The average cost of a device is $5000 (AUS) for both the lead(s) and the device.

Indications
The decision to implant a pacemaker in some cases is clear, but in others involves the weighing up of a number of factors including:
• clinical symptoms such as syncope, light headedness, dizziness, confusion, fatigue, reduced exercise tolerance
• drug treatment (where required and produces bradycardia)
• comorbid conditions
• reversibility of the condition
• drug toxicity (ie. digoxin).
Ultimately however, it is the presence of symptoms and associated documented bradycardia that is crucial in the decision to implant a device. To aid in the decision making, guidelines have been issued by the American College of Cardiology, American Heart Association, the Heart Rhythm Society, the European Society of Cardiology, and the European Heart Rhythm Association. These guidelines classify patients into groups and provide evidence based decision making for particular conditions. These are:
• class I: conditions where there is general agreement that a pacemaker should be inserted
• class II: conditions where there is no such agreement. This is divided into those where the weight of evidence supports the implantation (IIA) and those in which its usefulness is less well established (IIB)
• class III: conditions where there is general agreement that a device is not required or may be harmful.

Sinus node dysfunction
Sinus node dysfunction (sick sinus syndrome) is a condition characterised by a spectrum of arrhythmias: sinus bradycardia, sinus pauses, atrial fibrillation, atrial flutter and paroxysmal supraventricular tachycardia (Figure 6). Clinical symptoms can result from both the tachycardia and the bradycardia, and it is important to correlate these to the arrhythmias. It is a leading reason for a cardiac pacemaker (in Australia it accounts for...
approximately 46% of devices). It is thought to have a long natural history with early stages having a good prognosis; as it becomes more advanced and symptoms develop the prognosis is reduced. The guidelines for pacemakers in this condition are shown in Table 1. It is believed that atrial based pacing confers an advantage over single chamber ventricular pacing, however the data is limited to a reduction in the occurrence of atrial fibrillation and possibly stroke.6-9

Heart block

A block in the atrioventricular (AV) conduction system is the second common reason for cardiac pacing. Heart block is classified into:

• first degree AV block – typified by prolonged PR interval (0.20 msec)
• second degree AV block (Figure 7) – this is divided into two groups: Mobitz I (Wenchebach block) and Mobitz II. Mobitz I is manifested by progressive prolongation of the PR interval with a dropped QRS (beat). It generally involves block in the AV node and tends not to present with syncope. Mobitz II is typified by a constant PR interval before a dropped QRS (dropped beat). The association of a wide QRS it typically involves block in the infrahsian system. This is a less stable rhythm and therefore more likely to present with symptoms such as syncope
• complete heart block – typified by the absence of all AV conduction or dissociated P waves from the QRS (Figure 8). The patient is generally symptomatic and has either symptoms of reduced cardiac output or syncope. The natural history of asymptomatic type II AV block without a pacemaker is a 5 year survival rate of 61%;10,11 pacing improves this significantly. Type II AV block is therefore a class I indication for an insertion of a pacemaker (Figure 9).

The decision to implant a pacemaker in AV block is strengthened by the presence of symptoms (Table 2). Long term observational studies have shown that pacing improves survival in patients with complete AV block and advanced AV block, especially if they manifest symptoms (syncope) or have associated cardiac disease.12 Original data without pacing in patients with complete heart block (before the availability of permanent pacemakers) showed a 1 year survival of 60% and a 5 year survival of 30%.12 The mode of death was sudden in 30%. This was improved to aged matched controls with pacing, especially 1 year after the implant where survival equalled that of the general population.13 Again it is important to consider reversibility of the condition before a decision to implant is made.
Heart failure and CRT
Up to 50% of patients with significant heart failure have advanced conduction abnormalities. The presence of a left bundle block has been associated as a predictor of increased mortality. A relatively new indication for pacing – cardiac resynchronisation therapy (CRT) – involves the insertion of leads in the standard chambers (right atrium and right ventricle) and the positioning of a lead to pace the lateral wall of the left ventricle via a lateral vein, this is reached via the coronary sinus.14,15 A relatively new indication for pacing – cardiac resynchronisation therapy (CRT) – involves the insertion of leads in the standard chambers (right atrium and right ventricle) and the positioning of a lead to pace the lateral wall of the left ventricle via a lateral vein, this is reached via the coronary sinus.16

Table 1. Pacing for sinus node dysfunction

<table>
<thead>
<tr>
<th>Pacing required (class I)</th>
<th>Documented symptomatic bradycardia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Documented symptomatic bradycardia secondary to medications not able to be modified</td>
</tr>
<tr>
<td>Pacing probably required (class II)</td>
<td>Bradycardia with symptoms but no clear correlation of symptoms to bradycardia</td>
</tr>
<tr>
<td>Pacing not required (class III)</td>
<td>Sinus node disease with no symptoms</td>
</tr>
</tbody>
</table>

Figure 7. ECG showing 2:1 AV block

Figure 8. ECG showing complete heart block

Patients currently selected for a CRT pacemaker implant are medically refractory symptomatic patient with:
- class III/IV symptoms
- a prolonged QRS 0.130 msec
- ejection fraction <35%, and
- an end diastolic volume of 55 mm.

Trials have shown impressive results in the reduction of combined endpoint mortality and morbidity in patients with drug refractory heart failure and dysynchrony; it has also shown to reverse LV remodelling.17,18 The only caveat from these studies were that the majority of patients were in NYHA class III. The data is less convincing for minimally (class II) or highly symptomatic patients (class IV) and patients in atrial fibrillation.

Choice of device
The decision over the type of device (dual or single chamber device) rests upon the desire to maintain AV synchrony (and hence normal physiology). Trials have shown the benefit of dual chamber devices to be more pronounced in patients where the indication was sinus node dysfunction; this benefit is largely manifested by a reduction of atrial fibrillation episodes and embolic events.8,9 In patients with AV block there is no clear advantage of dual versus single chamber pacing. More recent data would also suggest that programming the device to reduce the percentage of right ventricular pacing to the lowest amount possible is important in long term survival.19–21 At present, although pacing is very effective at improving symptoms and prognosis, it does not exactly replicate normal electrical physiology and therefore to avoid any potential deleterious effects of pacing it is very important to insert a device only when needed.

Pacing sites
The standard sites for pacing have long been the right atrial appendage and the right ventricular apex. However, there has been increasing concern that right ventricular apical pacing has been associated with deterioration of myocardial function in certain patients.20,21 This has led to the increasing utilisation of alternate sites.21 This involves the positioning of the lead in what is hoped is a more physiological position in the right ventricular outflow tract or the right ventricular septum, with the hope that this will reduce the potential left ventricular function deterioration noted in some patients. These sites of pacing are the subject of a number of ongoing trials, the results of which should be available in the next few years.
Follow up

All patients require regular follow up after the implant. At this time, the device is interrogated utilising a telemetry function to gather important information about lead function (such as threshold and sensing) and battery life. More complicated information can be gleaned from the device’s memory including information about arrhythmias and their frequency, percentage of pacing and a number of automated functions that ultimately provide the patient with a stable, safe pacing system. Follow up also provides an opportunity to tailor any program changes (or pacemaker settings) to a patient’s particular needs and troubleshoot any problems (Figure 11).

Patient information

There are some practical aspects that need to be mentioned about the patient’s long term follow up. All patients will receive an ID card that contains important information about the implant device and the leads – it is important for patients to carry this at all times.

Driving is generally restricted for about 2 weeks (although this is dependent upon wound healing and pacemaker dependence). While patients should be made aware of avoiding strong electromagnetic fields (Table 3) there is usually little that they need to be concerned about in their day-to-day life.22,23 Mobile phones can potentially affect pacemakers, but in practical terms pose limited threat; patients are advised to keep the phone 15 cm from the device (so utilise in the opposite ear and keep out of ipsilateral shirt pocket).24 The usual domestic appliances (ie. microwave ovens) rarely pose any problems and are quite safe.25 Patients are readily able to travel by air but should have their ID card with them to present at security areas. The practical management of patients requiring surgery is beyond the scope of this article.

Conclusion

Since the first pacemaker was inserted in 1958 vast changes have occurred in both the technology of devices and their indications. Devices have evolved from simple single chamber devices to multichambered devices capable of treating not only bradycardias but also tachycardias and heart failure. The decision to insert a pacemaker is usually based on the presence of a documented symptomatic bradycardia. International guidelines are available classifying conditions from class I, in which pacing is clearly beneficial for symptom control and prognosis to class III, in which pacing is not indicated and may potentially be harmful. The most common indications are for sick sinus syndrome and heart block. Patients need to attend regular follow up, and although they need to be aware of precautions relating to electromagnetic fields, they can go about their daily lives with little interference.

<table>
<thead>
<tr>
<th>Table 2. Pacing for AV block</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pacing required (class I)</strong></td>
</tr>
<tr>
<td>Symptomatic complete AV block</td>
</tr>
<tr>
<td>Asymptomatic complete AV block</td>
</tr>
<tr>
<td>Symptomatic second degree AV block regardless of level</td>
</tr>
<tr>
<td>Asymptomatic second degree AV block with wide QRS</td>
</tr>
<tr>
<td><strong>Pacing probably required (class II)</strong></td>
</tr>
<tr>
<td>Asymptomatic type II AV block (with narrow QRS)</td>
</tr>
<tr>
<td>Asymptomatic type I AV block with low escape</td>
</tr>
<tr>
<td><strong>Pacing not required (class III)</strong></td>
</tr>
<tr>
<td>First degree AV block</td>
</tr>
</tbody>
</table>

Figure 9. ECG showing dual chamber pacing

Figure 10. Typical chest X-ray showing CRT defibrillator
Table 3. Advice for patients with pacemakers on electromagnetic fields

- MRI scanners: avoid!
- Arc welding: generally avoid but requires specialist advice
- Mobile phones: keep ~15 cm away from the pacemaker (ie. use opposite ear), but generally safe
- Electronic surveillance scanners: do not stand in these but usually safe to walk quickly through
- Surgical diathermy: requires specialist advice

Resources

- Ellenbogen K, Lau W. Clinical cardiac pacing, defibrillation and resynchronisation therapy. 3rd edn. Saunders, 2006
- Kenny T. The nuts and bolts of cardiac pacing. Blackwell Futura, 2006
- St Jude Medical www.sjm.com
- Boston Scientific www.guidant.com

Conflict of interest: none declared.

References