

Lead or be led: an update on leadless cardiac devices for general physicians

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ABSTRACT

Implantable cardiac devices have an increasingly important role. Pacemakers remain the only effective treatment for symptomatic bradycardia; cardiac resynchronisation therapy is a proven treatment for heart failure; and implantable cardioverter defibrillators (ICD) are superior to medical therapy in prevention of sudden cardiac death. Our ageing population has led to a rising number of device implants. Physicians in all specialties increasingly encounter patients with cardiac devices and require an understanding of their capabilities and functions. The rising prevalence of implantable devices has been matched by a parallel expanse in device technology. Leadless devices have become a reality and represent the future of device therapy. The absence of a transvenous lead offers a significant clinical advantage because of many well established issues related to lead complications. The leadless pacemaker and subcutaneous ICD are significant new products that are currently not well recognised or understood by general physicians.

KEYWORDS: Defibrillator, ICD, leadless, pacemaker, subcutaneous

Introduction

Implantable cardiac devices have an important and expanding role in the management of cardiovascular disease. The cardiac pacemaker is the only effective treatment for symptomatic bradycardia and remains the most prevalent cardiac device.^{1,2} First implanted in 1958, pacemaker technology has evolved significantly.³ From single chamber systems delivering fixed rate ventricular pacing, to physiological and multi-chamber pacing with integrated defibrillator technology, complex cardiac devices are now commonplace.

Cardiac resynchronisation therapy (CRT) is a well established treatment for patients with left ventricular systolic dysfunction and asynchronous left ventricular contraction, improving quality of life and reducing heart failure-related hospitalisations

and mortality.⁴ Implantable cardioverter defibrillators (ICDs) are an important treatment for ventricular arrhythmias and have been consistently superior to medical therapy for both primary and secondary prevention of sudden cardiac death (SCD) in large studies.^{5,6}

Technological advances and improved recognition of patients at risk of sudden cardiac death have broadened the clinical indications for device therapy.¹ Implant rates are subsequently steadily increasing across Europe.² Implant incidence is also strongly correlated with advancing age. In developed economies, device prevalence has doubled over the last 15 years.⁷ Until our ageing population reaches an equilibrium, this demand will continue to grow.⁷

All physicians increasingly encounter patients with implanted cardiac devices, such that an understanding of their functions and capabilities is warranted. Challengingly, the cardiac device landscape develops quickly. Since 2012, two new cardiac devices have come to market: the subcutaneous ICD (S-ICD) and the leadless pacemaker. Neither device has a transvenous component, representing a new approach in device therapy. Understandably, these devices are not well recognised or understood by many clinicians, including some cardiologists.

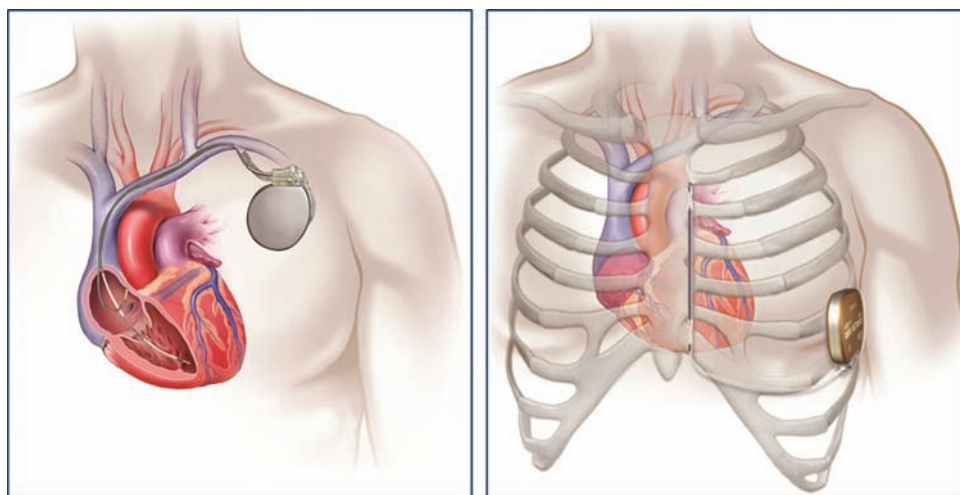
Transvenous leads

Cardiac devices traditionally comprise two components: a pulse generator (can), most commonly implanted in a prepectoral subcutaneous pocket, and a number of transvenous leads. Each lead is attached proximally to the can and fixated distally to the endocardial aspect of the heart (Fig 1). Implantation of the lead requires venous puncture, with the subclavian, axillary and cephalic veins frequently used. Device implantation is associated with infection, haematoma, inadvertent arterial puncture, pneumothorax, haemothorax and cardiac tamponade. Late complications associated with transvenous systems include lead fracture, lead displacement, venous obstruction and infective endocarditis.

Device related complication rates remain high. Registry data from Denmark show that 10% of patients undergoing device implantation experience a complication, with a 6% chance of major complication.⁸ Defibrillator implants are even higher risk, with in-hospital complication rates of 11–16%.⁸ Lead longevity is also a significant issue. The annual rate of ICD lead defects requiring intervention increases with time and reaches 20% in 10-year-old leads.⁹ Estimated defibrillator lead

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Fig 1. Implantable cardioverter defibrillators (ICDs). A – an implanted transvenous defibrillator system comprising a pulse generator and two transvenous leads (right atrial and right ventricular). B – a Boston Scientific subcutaneous implantable cardioverter defibrillator implanted in the left axillary position. The subcutaneous lead can be seen emerging from the inferior aspect of the can, travelling towards the midline (parallel to the rib cage) before turning 90° to run superiorly adjacent to the left sternal edge. Reproduced with permission from Boston Scientific.



survival at 5 and 8 years are just 85% and 60%, respectively.⁹ One third of patients who experience lead failure present with inappropriate shock therapy.⁹

Subcutaneous implantable cardioverter defibrillator

The S-ICD does not enter the heart or vascular system. It comprises a subcutaneous can, implanted in a left axillary position, and a tunnelled subcutaneous lead (Fig 1). The lead is not exposed to the repetitive contractions of the cardiac cycle or the hostile environment of the vasculature.⁹ S-ICD registry data show that in 882 patients with an S-ICD, followed up for an average of 2 years, there were no episodes of endocarditis, cardiac injury or electrode failures. Acute major complication rates for implants were also reduced in comparison to transvenous ICD (TV-ICD) implants (haematoma, lead malposition or displacement and pneumothorax).¹⁰ The S-ICD is particularly useful in patients with no appropriate venous access and in younger patients, although 43% of the registry patients were actually primary prevention patients at risk of sudden cardiac death due to reduced ejection fraction.¹⁰

The S-ICD records electrocardiogram (ECG) signal between any two of its three sensing points: distal lead electrode, proximal lead electrode and can. The signal resembles the surface ECG, allowing improved discrimination of arrhythmias on the basis of morphology. Appropriate ventricular arrhythmia detection is excellent, while supraventricular arrhythmia discrimination specificity is superior to some TV-ICD systems.¹¹

The S-ICD signal is more susceptible to noise, myopotentials and T-wave oversensing than the endocardial signals of the TV-ICD. Around 8% of S-ICD patients receive inappropriate therapy and this is mainly due to oversensing.¹¹ This rate is comparable to present TV-ICD systems and can be substantially and safely reduced with appropriate device programming.¹²

The S-ICD requires greater defibrillation energy (80 Joules) than a TV-ICD (35 Joules). These higher energy requirements result in longer charge times and necessitate a larger and heavier can. The S-ICD in its current form also has extremely limited pacing capabilities. Subcutaneous pacing is similar to

transcutaneous pacing in that it is significantly uncomfortable for the patient and is associated with mechanical capture of skeletal muscle. The S-ICD, therefore, only delivers pacing to treat transient post-shock bradycardia. Consequently, the S-ICD is not suitable for patients with a permanent pacing indication, including those who require resynchronisation pacing for heart failure.

The S-ICD also cannot deliver anti-tachycardia pacing. This is a painless treatment for monomorphic ventricular tachycardia whereby arrhythmia termination is achieved through the delivery of rapid bursts of right ventricular pacing at a faster rate than the tachycardia. Therefore, an S-ICD is not advised in patients with a history of ventricular tachycardia successfully treated by anti-tachycardia pacing.

Potential S-ICD patients require non-invasive ECG screening prior to implant. This is to ensure that the S-ICD will be able to accurately recognise the patient's ECG and relies upon the patient having suitable QRS and T wave morphology. While this reduces the risk of over sensing and inappropriate therapies, it also reduces the number of patients eligible for the device.

Leadless pacing

Leadless pacing is possible because of the production of self-contained pacemakers, small enough to be implanted into the right ventricle (Fig 2). These encapsulated devices combine surface electrodes capable of endocardial sensing and pacing with a small battery and can be implanted non-surgically via the femoral vein. There is no transvenous lead and no subcutaneous pocket, avoiding the many potential adverse events associated with these components.

Large bore femoral sheaths are required to facilitate delivery of the device and its steerable dedicated delivery system to the ventricle. Deployed on the septal aspect of the right ventricular apex, with active fixation to the endocardial ventricular surface, the device is designed to remain implanted for the patient's lifetime. Battery longevity is predicted to exceed traditional devices. Once battery life has been exhausted, the leadless pacemaker is small enough that the right ventricle can accommodate further implantations without the need for



Fig 2. Medtronic Micra leadless pacemaker. A – compared in size to a one Euro coin; B – implanted. Reproduced with permission from Medtronic.

extraction. Currently, pacing and sensing are limited to the right ventricle, as the device has no atrial or left ventricular component. Preservation of atrioventricular synchrony and cardiac resynchronisation are, therefore, not achievable although rate responsive ventricular pacing is.

Early trials have demonstrated leadless pacing to be both feasible and safe.^{13,14} Implant-related complications include dislodgement requiring percutaneous retrieval, cardiac perforation, device repositioning due to pacing-threshold increase and vascular groin complications.¹³ However, the overall safety profile is similar to that of a transvenous system.¹⁴

Future developments

It is anticipated that over the next decade the use of leadless cardiac devices will increase tremendously, thereby reducing the role of traditional transvenous systems. Device programming will improve and recognition of those patients who will benefit most from leadless systems will be refined.

Progress has also been made toward the production of a wireless communication system that would allow an S-ICD to communicate with an implanted leadless pacemaker. This would generate an entirely leadless system capable of permanent pacing, defibrillation and anti-tachycardia pacing. Early animal trials have demonstrated that this is feasible.¹⁵ Human trials are anticipated within the next few years.

Leadless cardiac resynchronisation therapy may also be achieved in the future. Endovascular left ventricular pacing confers a number of advantages over traditional epicardial pacing via the cardiac venous tributaries and has been demonstrated to be both safe and effective.^{16,17} Leadless endocardial left ventricular pacing is also a reality, as is wireless communication between implanted systems to achieve resynchronisation.¹⁸

Conclusions

Leadless devices are in their infancy and long-term data on their safety and efficacy are awaited. However, they do

offer significant advantages over transvenous systems and are likely to represent the future of cardiac device therapy. Implant numbers are expected to grow and all physicians will increasingly encounter this new wave of device technology. ■

Conflicts of interest

BMW receives a fellowship grant from Boston Scientific. PRR receives consultancy and advisory board payments from both Medtronic and Boston Scientific.

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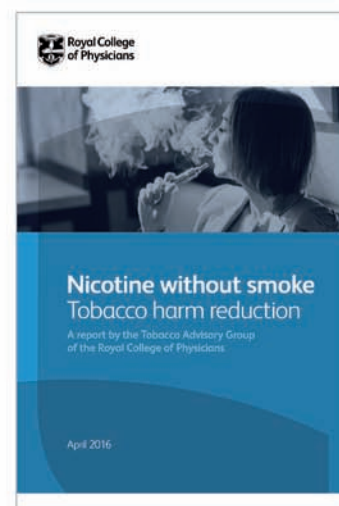
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