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Innovative pacing: Recent advances, emerging technologies, and future directions in cardiac pacing

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ABSTRACT

The field of cardiovascular medicine is rapidly evolving as advancements in technology and engineering provide clinicians new and exciting ways to care for an aging population. Cardiac pacing, in particular, has seen a series of game-changing technologies emerge in the past several years spurred by low-power electronics, high density batteries, improved catheter delivery systems and innovative software design. We look at several of these emerging pacemaker technologies, discussing the rationale, current state and future directions of these pioneering developments in electrophysiology.

Key words: Pacemaker, Pacing, Leadless, CRT, Biologic, Algorithm, Updates.

Introduction

The field of cardiovascular medicine is rapidly evolving as advancements in technology and engineering provide clinicians new and exciting ways to care for an aging population. Cardiac pacing, in particular, has seen a series of game-changing technologies emerge in the past several years that will be utilized to improve upon and potentially revolutionize the state of implantable pacemakers. These innovations specifically aim to lessen the limitations of the current generation of pacing devices.

Pacemaker implantation is not a benign procedure as one in eight patients has an early complication, most often related to the subcutaneous pocket or pacemaker lead [1]. Late complications include central vein obstruction, or tricuspid valve insufficiency [2,3]. Failure of the pacemaker lead, most commonly from insulation defects, is associated with adverse events and may require lead extraction, a highly complex procedure that has significant potential risks including pericardial tamponade and death [3]. Similarly, the effectiveness of cardiac resynchronization therapy (CRT) has been limited by technological and physiological constraints. Nearly a third of patients are nonresponders to cardiac resynchronization, mostly driven by the anatomic constraints of the coronary sinus and its venous branches limiting ideal placement left ventricular (LV) lead placement subsequently resulting in persistent delay in LV activation and lack of hemodynamic benefit. Ineffective optimization of the CRT device may also limit its clinical usefulness. Finally, despite a high level of research and clinical interest, the identification and treatment of atrial arrhythmias by pacemaker has seen limited success.

Recent innovations in pacemaker technology, spurred by low-power electronics, high-density batteries, improved catheter delivery systems, and innovative software design, have emerged with the hope of obviating these concerns. We will look at several of these emerging pacemaker technologies, discussing the rationale, current state, and future directions of these pioneering developments in electrophysiology.

Recent technological advances in pacemaker design

Since the first cardiac pacemaker was implanted in 1958, improvements in pacing technology have been coupled to

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advances in engineering, material design, and computer sciences. The past decade has been particularly fruitful for these fields and the cardiac pacemaker has reaped the benefits. Most notably, advances in very-large-scale integration (VLSI) circuitry has resulted in highly compact circuit design (<65 nm) with low-power consumption. New techniques in circuit fabrication have lowered semiconductor node sizes to 14 nm and processers using this technology are currently available in today's mobile phones and laptop computers and will likely be an integral part of future pacemaker design. In addition to more efficient hardware, pacing lead construction has also aimed to lessen current drain. High-impedance leads are designed with very a small diameter electrode at the tip of the lead that maximizes current density while keeping pacing thresholds at or below those of a standard lead [4]. Although initial studies of high-impendence leads extended battery life [5–8], the real-life gains of device longevity have been questioned [9]. Lightweight lithium/carbon monofluoride batteries have been used for the past decade and provide higher current densities to support onboard processes as well as pacing without dips in voltage that were seen in lithium/iodine batteries [10]. Finally, MRI-conditional pacemakers have been developed using redesigned components to minimize heating potential, dislodgement, current induction, and electromagnetic interference [11]. Currently, all major manufacturers offer an MRI-conditional device.

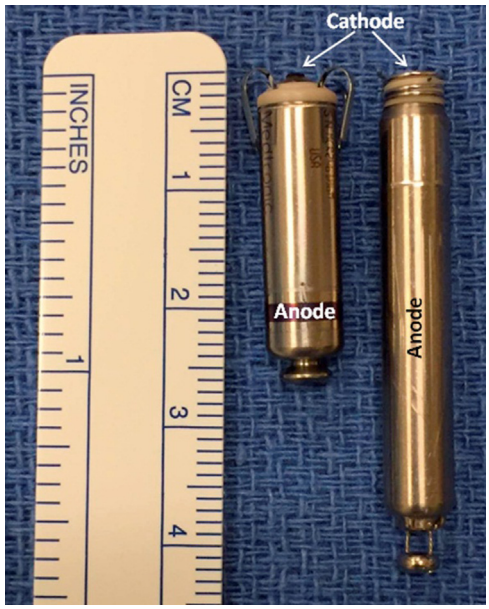

Fig. 1 – Leadless Pacemakers [14]. The Micra Transcatheter Pacing System (left) and Nanostim leadless cardiac pacemaker (right) are shown next to a ruler. The active fixation (cathode) tines can be seen. Both devices are retrievable by catheter attachment at the proximal (anode) end. (Color version of figure is available online.)

Leadless pacemakers

The design of the transvenous permanent pacemaker (PPM) is simple yet reliable, comprised of a pulse generator and one or more transvenous leads. This basic design has seen iterative changes resulting in improved battery life, lead performance, and device programming; however, the general makeup of the PPM is mostly unchanged [12,13]. Despite their dependability, contemporary cardiac pacemakers still have several liabilities such as device infection, lead failure requiring replacement, or extraction and secondary tricuspid regurgitation. Because of these limitations, the leadless cardiac pacemaker (LCP) has long been of interest to cardiologists. Recent technologic advances have made the dream of the leadless cardiac pacemaker a reality [14]. We will describe the two fully contained, single component LCPs currently available for commercial use in Europe and under clinical investigation in the United States as well as a multicomponent leadless left ventricular (LV) endocardial pacing system for delivery of CRT.

Single component leadless pacemakers

The Nanostim LCP (St. Jude Medical, Inc., St. Paul, MN) is currently approved for use in Europe and is under clinical investigation in the United States (Fig. 1). This device features single-chamber VVIR pacing with rate modulation based on monitored blood temperature. Measuring 42 mm × 5.99 mm and weighing 2 g with a volume of 1 cc, this LCP is delivered through an 18 Fr venous catheter system and is fixed to the right ventricular endocardium by a screw in helix mechanism and 3 nitinol tines. This LCP is designed to be fully retrievable via catheter and has been reliably extracted (100%) in sheep 5 months after implantation with average retrieval taking a mere 2 min and 35 s [15]. After demonstrating safe, efficient implantation in the LEADLESS [16] trial, the device was studied prospectively in a nonrandomized cohort of 300 patients followed for 6 months in the LEADLESS II trial [17]. The Nanostim LCP had safety results similar to historical rates reported for traditional single-chamber pacemakers and over 93% of the patients were free from serious adverse device events at 6 months post-implantation. No device events were reported after 30 days post-implantation. Projected longevity of the LCP was 8.3–21.7 years and the device was retrieved successfully in all 7 patients that required retrieval in the cohort.

The Micra Transcatheter Pacing System (TPS) (Medtronic Inc., Minneapolis, MN) is a self-contained leadless pacemaker currently under investigation in Europe and the United States (Fig. 1). Similar to the Nanostim LCP, the Micra TPS is capable of pacing in VVIR mode; however, the rate responsiveness is based on a three-axis accelerometer, allowing rate responsiveness to change in altitude during activities such as climbing stairs. It is shorter and slightly wider than the Nanostim at 25.9 mm × 6.7 mm, and at 2 g and 0.8 cc the overall device mass and volume is comparable [18]. It is delivered through a 23 Fr femoral vein introducer and is affixed to the myocardium through four nitinol tines located at the distal end of the device. This device was studied in a prospective, nonrandomized cohort of 725 patients that underwent implantation attempt [19]. Of those attempted implantations, 719 (99.2%) were successful and followed for a mean of 4 months. Overall, 96% of those patients were free of