Leadless Pacemakers
State of the Art and Future Perspectives

Domenico G. Della Rocca, MD[a], Carola Gianni, MD, PhD[a], Luigi Di Biase, MD, PhD[a,b,c,d], Andrea Natale, MD[a,c,e,f,g,h,i], Amin Al-Ahmad, MD[a,*]

KEYWORDS

• Cardiac pacing • Cardiac arrhythmias • Leadless pacemaker • Transvenous pacemaker • Bradyarrhythmias • Transvenous leads • Cardiac resynchronization therapy

KEY POINTS

- Conventional cardiac pacemakers are prone to multiple potential short- and long-term complications owing to the surgical pocket and/or placement of epicardial or transvenous leads.
- Leadless pacemaker therapy is a new technology that aims at avoiding lead- and pocket-related complications of conventional transvenous and epicardial pacing.
- Two self-contained leadless pacemakers for right ventricular pacing are available clinically: the Nanostim Leadless Pacemaker System and the Micra Transcatheter Pacing System.
- A new multicomponent leadless pacemaker for endocardial left ventricular pacing (WiSE-CRT) has been proposed as an alternative for cardiac resynchronization therapy.

INTRODUCTION

Leadless pacemaker (PMK) therapy is a new technology that has been recently introduced into clinical practice. The aim of leadless pacing is to avoid lead- and pocket-related complications. Conventional cardiac PMKs are prone to multiple potential short- and long-term complications as a result of the creation of a surgical pocket and/or the placement of epicardial or transvenous leads. In this article, we sought to describe the state of the art of leadless pacing and compare the currently available devices with traditional transvenous PMKs. This article also addresses the future perspectives of leadless pacing.

Disclosures: Dr L. Di Biase is a consultant for Biosense Webster, Boston Scientific, Stereotaxis, and St. Jude Medical; and has received speaker honoraria from Medtronic, AtriCure, EPiEP, and Biotronik. Dr A. Natale has received speaker honoraria from Boston Scientific, Biosense Webster, St. Jude Medical, Biotronik, and Medtronic, and is a consultant for Biosense Webster, St. Jude Medical, and Janssen. Dr A. Al-Ahmad has received honoraria from Medtronic and St. Jude Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

[a] Texas Cardiac Arrhythmia Institute, St. David's Medical Center, 3000 North IH-35, Suite 720, Austin, TX 78705, USA; [b] Albert Einstein College of Medicine, Montefiore Hospital, Bronx, NY, USA; [c] Department of Biomedical Engineering, Cockrell School of Engineering, University of Texas, Austin, TX, USA; [d] Department of Cardiology, University of Foggia, Foggia, Italy; [e] Department of Internal Medicine, Dell Medical School, University of Texas, Austin, TX, USA; [f] Interventional Electrophysiology, Scripps Clinic, La Jolla, CA, USA; [g] Department of Cardiology, MetroHealth Medical Center, Case Western Reserve University School of Medicine, Cleveland, OH, USA; [h] Division of Cardiology, Stanford University, Stanford, CA, USA; [i] Atrial Fibrillation and Arrhythmia Center, California Pacific Medical Center, San Francisco, CA, USA

* Corresponding author.

E-mail address: aalahmadmd@gmail.com

Card Electrophysiol Clin 10 (2018) 17–29
https://doi.org/10.1016/j.ccep.2017.11.003
1877-9182/18/© 2017 Elsevier Inc. All rights reserved.

PACEMAKER TECHNOLOGY: HISTORICAL CONSIDERATIONS AND STATISTICS

In 1932, Albert S. Hyman reported for the first time the effect of an external cardiac PMK: a bipolar needle electrode introduced via an intercostal space was used to direct electrical impulses into the patient's right atrium at pacing rates of 30, 60, or 120 per minutes. Since the report on the successful implantation of the first epicardial pacing system by Rune Elmquist and Åke Senning and of the first transvenous temporary pacing lead in 1958, technology for conventional cardiac pacing has evolved considerably. Initially, efforts were addressed to size and battery life, in an attempt to downsize the body and prolong longevity.

In the mid 1980s, rate-responsive PMKs were developed; this feature can adapt the pacing rates according to the patient's physical activity. In the 1990s, microprocessor-driven PMKs were introduced into clinical practice; as a result of the development of several algorithms, devices became automatically capable of adapting their internal parameters to the changing needs of the patient. The idea of biventricular pacing was developed in the late 1980s and early 1990s, after the results of several animal studies that demonstrated a linear decrease in left ventricular pressure as the QRS duration increases.[1] In 1996, Cazeau and colleagues[2] demonstrated that biventricular pacing is associated with an acute and sustained hemodynamic improvement in patients with end-stage heart failure. In patients undergoing cardiac resynchronization therapy (CRT), an additional lead is generally introduced to the epicardial surface of the left ventricle (LV) via the coronary sinus, in the attempt to resynchronize contraction of the LV, thereby improving cardiac function and symptoms.

Despite remarkable advances in cardiac pacing and resynchronization therapy,[3–5] this technology is still prone to several potential acute and chronic complications.

Overall, approximately 1 million pacemakers are implanted worldwide, with 26% of the total being replacement devices.[6] Complications are mainly related to the transvenous leads and the subcutaneous generator pocket. Short-term complications often related to the procedure include pneumothorax, cardiac tamponade, lead dislodgement, and pocket hematoma. Long-term complications include insulation breaches, lead fractures, skin erosions, pocket infections, and septicemia. Transvenous leads can also cause upper extremity deep vein thrombosis, venous obstruction, tricuspid valve insufficiency, and endocarditis. The incidence of postoperative adverse events has been estimated as high as 10%.[7] Transvenous leads are the most vulnerable components of the system: in addition to insulation defects and fractures, which require reintervention, endocarditis can be a life-threatening complication with mortality rates of 12% to 31%.[8,9] Pocket-related complications occur in 0.7% to 2.4% of patients[10,11]: a clinically significant pocket hematoma is an important risk factor of infection, which is associated with a greater than 7-fold increased risk of hospitalization owing to infection within 1 year after device implantation.[11]

Leadless cardiac pacing was proposed in the 1970s[12] as an alternative solution to conventional pacing, with the aim to avoid transvenous leads and the need for a subcutaneous device pocket, thereby eliminating lead- and pocket-related complications. Additionally, a self-contained device, delivered directly to the heart, prevents any cosmetic concern by eliminating the physical signs of the device.

The leadless pacing system proposed in 1970[12] was a prototype capsule, 8 mm in diameter and 18 mm in length, designed to allow transvenous insertion in animal models. The intracardiac system was powered by a mercury battery and had a radially directed spiral barb system that showed stable thresholds. The system was implanted in a dog and showed stable pacing rates even during severe exercise. The further development of these technologies have led to the introduction of 2 different leadless pacing systems.

To date, 2 self-contained leadless pacemakers are clinically available: the Nanostim Leadless Pacemaker System (LPS; St. Jude Medical, Sylmar, CA) and the Micra Transcatheter Pacing System (TPS; Medtronic, Minneapolis, MN).

TECHNOLOGICAL FEATURES OF CURRENTLY AVAILABLE SINGLE-COMPONENT LEADLESS PACEMAKERS

Technological Aspects

The Nanostim LPS (St. Jude Medical) was the world's first commercially available leadless pacing system: it received the CE mark in October 2013, but is still awaiting US Food and Drug Administration approval. The Micra TPS (Medtronic) received the CE mark in April 2015 and US Food and Drug Administration approval in April 2016. A comparison of the characteristics of the 2 pacing systems is reported in **Table 1**. The Nanostim LPS measures 41.4 $\times$ 5.99 mm and has a volume of 1 cm^3. The Micra TPS is a 25.9 $\times$ 6.7-mm device, which displaces a volume of 0.8 cm^3. The 2 currently available leadless pacing systems share a few similarities: (a) they are delivered

Download English Version:

https://daneshyari.com/en/article/8657356

Download Persian Version:

https://daneshyari.com/article/8657356

Daneshyari.com