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REVIEW ARTICLE

Innovations in Electrophysiology Technologies and Devices

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Abstract

There are major advances and achievements in devices used in electrophysiology diagnosis and treatment. This short summary is collection of recent publications around this subject.

Keywords

Leadless pacemakers, Subcutaneous ICDs, Ablation, Lead extractions, Implantable cardiac monitors, Mapping, Magnetic resonance imaging, His bundle pacing, Cardiac contractility modulation

Abbreviations

AF: Atrial Fibrillation; CCM: Cardiac Contractility Modulation; CRT: Cardiac Resynchronization Therapy; ICD: Implantable Cardioverter Defibrillator; ICMs: Implantable Cardiac Monitors; PVI: Pulmonary Vein Isolation

Leadless Pacemakers

One of the biggest issues with implantable EP devices is the leads that connect the device to the heart. Leads are frequently cited as the weakest component of pacing, implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT) due to wearing out or complications due to infection [1].

Leadless Dual-Chamber Pacing

A novel communication method for wireless pacemaker synchronization. The presented concept involves 2 leadless pacemakers that communicate wirelessly with each other and thus enable synchronized leadless dual-chamber pacing. A novel technology is presented for pacemaker communication, using the myocardium and blood as the transmission medium. To date, 2 leadless PMs are commercially available: Micra (Medtronic) and Nanostim (St. Jude Medical). However, these devices have the significant limitation of performing single-chamber ventricular pacing only [2].

The presented wireless communication method may in the future also enable leadless cardiac resynchronization therapy. The concept proposed involves multiple implanted leadless PMs that jointly act as a leadless dual-chamber PM system [3,4].

The SELECT-LV study demonstrates the clinical feasibility for the WiSE-CRT system, and provided clinical benefits to a majority of patients within an otherwise "failed" CRT population. Reddy, et al. [5]. The procedure was successful in 97.1% (n = 34) of attempted implants. The most common indications for endocardial LV pacing were difficult CS anatomy (n =12), failure to respond to conventional CRT (n = 10), and a high CS pacing threshold or phrenic nerve capture (n = 5).

Subcutaneous ICDs

Boston Scientific introduced the first subcutaneous implantable cardioverter defibrillator (S-ICD) system in 2009. Since then, there have been many studies published showing the system delivers very effective therapy and reduces the invasiveness of traditional ICD implants by eliminating the leads to the heart. Instead, the system uses a lead placed under the skin of the chest over the heart, eliminating transvenous leads or the need for lead management later on. About 40% of the ICD market today is composed of cardiac resynchronization therapy (CRT) systems with pacing. Of the remaining 60%, Boersma said between 30-50% would benefit from S-ICD therapy if they do not have any need for pacing. It only requires two very small incisions with no need to create a pulse generator pocket.

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EBR Systems is developing the WiSE CRT system, the first endocardial, leadless CRT pacing system. It uses an electrode about the size of a large grain of rice that is implanted inside the wall of the LV using transcatheter delivery. A wireless ultrasound transducer is surgically implanted between the ribs to send ultrasound energy to the electrode, which converts the waves into electrical energy for pacing, eliminating the need for a battery or lead wire, allowing the device to be very small. This works as an adjunct device to work in combination with an existing connected pacemaker, ICD or CRT device. The conventional system senses the RV pacing and can work with the WiSE system to synchronize the LV [6,7].

Improved Ablation Technologies

HeartLight was granted FDA clearance in 2016 for its laser ablation balloon technology indicated for pulmonary vein isolation to treat AF. The system consists of a compliant balloon that seats in the ostia of the pulmonary veins and a laser inside the catheter can be rotated around to ablate the tissue. It also has a camera inside the catheter to offer direct visualization of the ablation and location of the laser, eliminating the need for electro-mapping systems and cutting procedural time. The lesions are created with 20-30 second ablations. About 25 ablations are needed to isolate a pulmonary vein with lesion overlap. The combination of the balloon, camera and variable-energy, steerable ablation is believed to be able to eliminate the interoperator variability in ablation procedures [8].

A recent HRS trial pointed to a first study for the Biosense Webster RF balloon catheter in treating patients with AF. The 39-patient RADIANCE study revealed it could achieve pulmonary vein isolation (PVI) in all patients without the need for “touch-up” with a focal ablation catheter. The system uses a balloon that is lined with several electrodes. The energy level for each electrode can be adjusted to prevent damage to neighboring nerves or the esophagus [8].

Increasing Safety in Lead Extractions

One of the problems in removing old device leads is the possibility of tearing the superior vena cava (SVC). This necessitates emergency surgical repair to stop the bleeding and the complication currently has a 50% mortality rate. However, Spectranetics Bridge Occlusion Balloon, introduced in 2016, offers a reserve safety during procedures, allowing rapid inflation of an intravascular balloon to seal the tear and allow the surgical team time to perform a repair without fear of the patient bleeding out. The device is credited with saving about 20 lives in the past year [9].

The device is one of the most important new developments in lead extraction technology and has become part of Cleveland Clinic’s lead extraction protocol. He said the balloon offers a safety net to minimize the effect of a potentially catastrophic SVC tear.

Replacing Holters with Wearable and Implantable Devices

Small, wearable, stick-on Holter monitoring systems that eliminate the need for a bulky, belt-worn device and the placement of multiple wires leads on the patients. These new devices offer a less expensive, even disposable option to traditional, durable Holter monitoring systems. Some vendors offer the devices themselves; others offer the devices in connection with monitoring services [10].

Another monitoring technology is implantable cardiac monitors (ICMs). Biotronik, Medtronic and St. Jude Medical offer monitors, which are placed subcutaneously in the chest using a simple, fast, in-office procedure. The Medtronic Linq device is of small size which can easily be inserted under the patient’s skin.

REVEAL AF study showed ICMs used for long-term, 24-hour-a-day monitoring, detected a high incidence of AF in patients previously undiagnosed but suspected to be at high-risk for AF and stroke. The study found that at 18 months, continuous monitoring with either the Medtronic Reveal XT or the Reveal Linq resulted in an AF detection rate of 29.3% among previously undiagnosed high-risk patients.

Diagnosing AF with ICMs leads to short- and long-term changes in patient care.

Using insertable cardiac monitors (ICMs) to identify atrial fibrillation (AF) in a population at high risk for stroke guides both immediate and long-term patient management [10].

Improvements in Mapping-Seeing is Believing

Despite exponential improvements in mapping and ablation technology, the success rates of catheter ablation for certain arrhythmias, such as persistent AF, remain suboptimal. Our understanding of the mechanism underlying persistent AF is not complete and is evolving [11].

MRI to Guide Ablation Procedures

Magnetic Resonance Imaging (MRI) offers many advantages over X-ray angiography and traditional mapping systems. It can image without any radiation, eliminating the need to wear heavy protective aprons. Second, MRI can image soft tissue and visualize the tissue response to ablations allowing EPs to see the effectiveness of their ablation points and any scar formation [12]. The merger between MRI and Carto is a new achievement in pulmonary vein ablation.

Advances in Monitoring

The ECG app can record heartbeat and rhythm

using the electrical **heart sensor** on Apple Watch Series 4, Series 5, or Series 6* and then check the recording for **atrial fibrillation** (AFib) [13].

His bundle pacing: A new approach for CRT therapy in patients with failed coronary sinus cannulation [14,15].

Cardiac contractility modulation (CCM) is a modality that delivers a high voltage impulse to the right ventricular septum 30-40 msec after activation of cardiomyocytes during the absolute refractory period. In theory, this improves calcium handling and increases ventricular contractility with resultant improvement in exercise tolerance and functional capacity [16].

Summary: Advances in Devices in Electrophysiology

- New dual chamber leadless pacemaker.
- The Biosense Webster multi-electrode balloon RF ablation catheter, a balloon that is lined with several electrodes.
- Subcutaneous ICDs the first endocardial, leadless CRT pacing system.
- Improved Ablation Technologies.
- Replacing Holters with Wearable and Implantable Devices.
- Medtronic Reveal XT Remote monitoring.
- New Electro-mapping Systems.
- MRI To Guide Ablation Procedures: MRI offers many advantages over X-ray angiography.
- Ultrasound Guidance in the EP Lab.
- Apple Watch Series: Taking an ECG with the ECG app on Apple Watch Series.
- Cardiac Resynchronization Therapy: Pacing from His Bundle.
- Cardiac Contractility Modulation.

Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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