

What is New in Electrophysiology Technologies and devices?

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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 percent of the ICD market today is composed of cardiac resynchronization therapy (CRT) systems with pacing. Of the remaining 60 percent, Boersma said between 30-50 percent 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.

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 late-breaking HRS trial highlighted a first-in-human study for the Biosense Webster RF balloon catheter in treating patients with AF. The 39-patient RADIANCE study showed it could uniformly 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 tailored to prevent damage to neighboring nerves or the esophagus (8).

Increasing Safety in Lead Extractions

One of the biggest safety concerns in removing old device leads is the possibility of tearing the superior vena cava (SVC). This requires immediate emergency surgical repair to stop the bleeding and the complication currently has a 50 percent mortality rate. However, Spectranetics Bridge Occlusion Balloon, introduced in 2016, offers a new safety net during procedures, allowing rapid inflation of an intravascular balloon to seal the tear and allow the surgical team time to prep and perform a repair without fear of the patient bleeding out. The device is credited with saving about 20 lives in the past year since gaining market clearance. (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 wire 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 are 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 percent 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. As compared with that of conditions with high success rates with catheter ablation, such as atrioventricular nodal reentrant tachycardia, our understanding of the mechanism underlying persistent AF is incomplete and continues to evolve (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, unlike angiography, it can image soft tissue and visualize the tissue response to ablations and when a scar forms, allowing EPs to see the pattern and effectiveness of their ablation points and patterns (12). The merge between MRI and Carto is a new

achievement in pulmonary vein ablation.

Advances in monitoring:

The ECG app can record your 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).

Abbreviations: AF: atrial fibrillation; CCM: Cardiac contractility modulation; CRT: Cardiac Resynchronization Therapy; ICD: Implantable Cardioverter Defibrillator; ICMs: implantable cardiac monitors; PVI: pulmonary vein isolation

References

- 1- Heart Rhythm: Volume 14, Issue 2, February 2017, Pages 294-299
- 2- Niraj Varma, Nassir F. Marrouche, Luis Aguinaga, Christine M. Albert, Elena Arbelo, et al. HRS/EHRA/APHRS/LAQRS/ACC/AHA Worldwide Practice Update for Telehealth and Arrhythmia Monitoring During and After a Pandemic. *Circulation: Arrhythmia and Electrophysiology*. 2020;13:e009007
- 3- Lukas Bereuter, Mirco Gysin, Thomas Kueffer, Martin Kucera, Thomas Niederhauser, Jürg Fuhrer, Paul Heinisch, et al. Leadless Dual-Chamber Pacing A Novel Communication Method for Wireless Pacemaker Synchronization. *JACC: BASIC TO TRANSLATIONAL SCIENCE* VOL. 3, NO. 6, 2018
- 4- DAVE FORNELL. What is New in Electrophysiology Technologies. Diagnostic and interventional cardiology. 2017:JUNE 22,
- 5- Vivek Y Reddy, Marc A Miller, Petr Neuzil, Peter Søgaard, Christian Butter, Martin Seifert, et al. Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing: The SELECT-LV Study. *J Am Coll Cardiol*. 2017 May 2;69(17):2119-2129.
- 6- von Alvensleben JC, Dechert B, Bradley DJ, et al. Subcutaneous Implantable Cardioverter-Defibrillators in Pediatrics and Congenital Heart Disease: A Pediatric and Congenital Electrophysiology Society Multicenter Review. *JACC Clin Electrophysiol* 2020;6:1752-1761.
- 7- Benjamin J Sieniewicz, Timothy R Betts, Simon James, Andrew Turley, Christian Butter, Martin Seifert, et al. Real-world experience of leadless left ventricular endocardial cardiac resynchronization therapy: A multicenter international registry of the WiSE-CRT pacing system. *Heart Rhythm*. 2020 Aug;17(8):1291-1297.
- 8- Skeete, J.R.; Du-Fay-de-Lavallaz, J.M.; Kenigsberg, D.; Macias, C.; Winterfield, J.R.; Sharma, P.S.; Trohman, R.G.; Huang, H.D. Clinical Applications of Laser Technology: Laser Balloon Ablation in the Management of Atrial Fibrillation. *Micromachines* 2021, 12, 188
- 9- Adryan A Perez, Frank W Woo, Darren C Tsang, and Roger G Carrillo. Transvenous Lead Extractions: Current Approaches and Future Trends. *Arrhythm Electrophysiol Rev*. 2018 Aug; 7(3): 210–217.
- 10- Arvind Singhal, Martin R. Cowie. The Role of Wearables in Heart Failure. *Current Heart Failure Reports* 2020; volume 17, pages 125–132
- 11- Vaidya et al. *J Innov Cardiac Rhythm Manage*. 2017;8(12):2943–2955
- 12- Wenker S, van Lieshout C, Frederix G, et al. MRI-guided pulmonary vein isolation for atrial fibrillation: what is good enough? An early health technology assessment. *Open Heart* 2019;6: e001014.
- 13- Tzeis S, Asvestas D, Moraitis N, P Vardas, Mililis P. Et al. Safety of smartwatches and their chargers in patients with cardiac implantable electronic devices. *EP Europace*, Volume 23, Issue 1, January 2021, Pages 99–
- 14- Ajijola O, Gaurav A. Upadhyay, Macias C, Shivkumar K, Tung R. Permanent His-bundle pacing for cardiac resynchronization therapy: Initial feasibility study in lieu of left ventricular lead. *Clinical Devices* 14, 9, P1353-1361, 01, 2017
- 15- Nadine Ali, Daniel Keene, Ahran Arnold, Matthew Shun-Shin, Zachary I Whinnett, His Bundle Pacing: A New Frontier in the

Treatment of Heart Failure. Arrhythm
Electrophysiol Rev. 2018 Jun; 7(2): 103–110.

15- Tint D, Florea F, and Micu S.. New Generation
Cardiac Contractility Modulation Device—

Filling the Gap in Heart Failure Treatment. J Clin
Med. 2019 May; 8(5): 588.

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