Updates in ICD and CRT Technology

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Transvenous pacemakers have been in service for about 60 years; however, they have multiple shortcomings such as discomfort, infections associated with the device pocket, mechanical failure, and mobility restrictions, with up to 15% of patients experiencing major complications [Udo EO et al. *Heart Rhythm*. 2012; Ellenbogen KA et al. *Am J Cardiol*. 2003; Connolly SJ et al. *N Engl J Med*. 2000]. The need for more improved pacemaker technology, discussed Petr Neuzil, MD, PhD, Na Homolce Hospital, Prague, Czech Republic, has led to the development of leadless pacemakers.

The transvenous pacemaker requires a surgical pocket and indwelling venous leads. In contrast, the newer pacemaker system requires a less invasive, percutaneous catheter-based procedure without the need for a surgical pocket or retained leads. This results in fewer acute and chronic complications. Communication is achieved by radiofrequency through an antenna or a coil. In addition, the actual procedure time is short, and patients are typically discharged in 1 day. In the LEADLESS trial, implantation of the Nanostim leadless pacemaker was successful in 97% of cases, with a mean introducer in-out time of 28 minutes and catheter in-out time of 16 minutes. Similarly, successful implantation of the Micra leadless pacemaker occurred in 100% of cases with a mean introducer in-out time of 37 minutes [Boersma LVA et al. HRS 2015 (abstr AB06-06)]. In addition, the 6-month major complication–free survival rate was 83% [Ritter P et al. *Europace*. 2015].

Another new pacemaker technology is the subcutaneous implantable cardioverter (S-ICD). Jeanne E. Poole, MD, University of Washington, Seattle, Washington, USA, explained that the S-ICD was developed as a way to avoid the complications associated with transvenous leads, such as endocarditis [Tarakji KG et al. *Europace*. 2014] and injury related to placing and removing a lead in the vascular space.

The S-ICD is placed subcutaneously with 3 incisions: 2 along the left parasternal border, and one in the 5th to 6th intercostal space along the left midaxillary line [Burke M et al. HRS 2012 (session 219)]. A tunneling tool is used to subcutaneously implant the lead, and from there it runs medially from the midaxillary generator pocket and then superiorly along the left parasternal border.

The safety and efficacy of the S-ICD were evaluated in the prospective, nonrandomized, multicenter S-ICD System IDE Clinical Study [NCT01064076], in which the 180-day complication-free rate was 99% and the induced ventricular-fibrillation conversion rate was 100% [Weiss R et al. *Circulation*. 2013]. Infection occurred in 18 patients with 4 patients requiring removal of the device. The infection rate was reduced significantly after adjustments were made in the surgical preparation of the patients. Inappropriate shocks occurred in 13.9% of patients, and inappropriate shocks were reduced to 6.1% using dual-zone programming.

The S-ICD is currently indicated for patients who do not require bradycardia pacing, cardiac resynchronization therapy, or antitachycardia pacing. Indications include primary prevention for heart failure, with particular appeal in patients who are younger, who are at high risk of lead complication or infection, or whose anatomy precludes transvenous lead placement (eg, venous occlusion).

Cardiac resynchronization therapy (CRT) is beneficial in patients with chronic heart failure (CHF); however, coronary sinus lead implantation fails in up to 12% of patients, and as many as 40% do not respond to CRT. Vivek Y. Reddy, MD, Mount Sinai Hospital, New York, New York, USA, discussed alternatives for left ventricular (LV) pacing. One option is endocardial LV pacing instead of epicardial, which is more efficiently implanted, has fewer complications, and improves outcomes [Bordacher P et al. *J Am Coll Cardiol*. 2010].

There are several approaches to endocardial LV pacing: the atrial transseptal approach, the ventricular transseptal approach, pericardial pacing, and leadless LV pacing.

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Leadless LV pacing was evaluated in patients who were eligible for CRT and/or those who failed conventional CRT in the prospective, multicenter SELECT-LV trial [Reddy VY et al. HRS 2015 (abstr PO02-186)]. In the <24-hour perioperative period, 11.4% of patients experienced complications related to the procedure, and 22.9% of patients experienced complications up to 1 month later. With the leadless device, improvements were seen at 6 months compared with baseline in ejection fraction (EF; 33.7% vs 27%), NYHA class (1.8% vs 2.6%), and end systolic and diastolic volumes. Dr Reddy described the technology as promising, and he stated many safety issues have been addressed, but more studies are needed.

The wearable cardioverter defibrillator (WCD), an external defibrillator and monitor unit with electrocardiograph and defibrillation electrodes and response buttons to withhold defibrillation, is worn as a vest; it provides an option to protect the patient considered at risk while risk stratification is performed, until ICD implantation is either indicated or can be deferred. Helmut U. Klein, MD, University of Rochester Medical Center, Rochester, New York, USA, described the WCD as a monitoring tool that is not meant to replace the ICD or automated external defibrillator. Data from the WEARIT-II Registry [Kutyifa V et al. *Circulation*. 2015, now online] demonstrated that 40% of all patients had improvement in LV-EF while awaiting risk stratification and wearing the vest, making ICD implantation unnecessary. The inappropriate shock rate was 0.5%.

The WCD is indicated for patients after acute myocardial infarction with low EF or otherwise high risk, after revascularization but before a traditional ICD can be placed. In addition, the WCD may be indicated after other cardiothoracic interventions in patients with reduced LV function, acute heart failure, or severe comorbidities. For these indications, the typical duration of use is 3 to 4 months. Use of the WCD after revascularization has resulted in improved survival, both within the first 90 days and after 90 days [Zishiri ET et al. *Circ Arrhythm.*].

Other indications include acute heart failure with nonischemic cardiomyopathy such as myocarditis and cardiomyopathy of various etiologies. For these indications, the duration of use is 3 to 6 months. Some patients with syncope of unknown origin, inherited arrhythmia syndromes, and cardiac arrest with reversible causes may also benefit, with a typical duration of use of 1 to 3 months. Furthermore, it can provide temporary protection in patients with planned ICD implantation or after ICD removal, those awaiting a heart transplant, patients with an LV assist device, and those in the initial phase of hemodialysis.

Although current ICD and CRT technology is beneficial for patients, leadless and subcutaneous devices have been developed with the hopes of improving safety by requiring less invasive procedures and decreasing the risk of infection. These devices have been demonstrated to be effective, and their safety is improving. However, more studies are needed.

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The editors would like to thank the many members of the ESC Congress 2015 presenting faculty who generously gave their time to ensure the accuracy and quality of the articles in this publication.