Think S-ICD first: The time has come

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Implantable cardioverter defibrillator (ICD) is an effective therapy in patients with a primary and secondary indication for sudden cardiac arrest (SCA) prevention according to landmark clinical trials [1, 2]. Unfortunately, ICD therapy comes with the risk of device-related complications [3]. At 10 years, the risk of lead failure in patients with transvenous ICD (TV-ICD) can be as high as 25% [4].

The subcutaneous ICD (S-ICD) is a completely extravascular device, designed to avoid intravascular and intracardiac hardware and address the limitations of conventional TV-ICD systems. Actually, the S-ICD has become a safe and viable alternative for TV-ICD therapy [5, 6], and its use has increased significantly [7].

The European and US guidelines recommend the S-ICD (class IIa) as an alternative to TV-ICD in patients who meet the indication for an ICD, and in the absence of bradycardia with a need for pacing, monomorphic ventricular tachycardia presumed to be responsive to anti-tachycardia pacing (ATP), and an indication for cardiac resynchronization therapy (CRT) [8, 9]. The US guidelines also recommend the S-ICD (class I) in patients with inadequate venous access or at high risk of infection [8].

However, despite those recommendations, the early adoption of S-ICD was low, in part due to considering the S-ICD as only a niche device and also due to its cost and delay in economic reimbursement in some countries. However, over the past few years, the use of S-ICDs has increased, for instance, in the US [7] although there has still been hesitancy in its use due to the lack of pacing capabilities.

Therefore, the S-ICD is currently considered mainly in younger patients to avoid long-term transvenous leads and in those who are at higher risk of infection, such as patients with previous ICD infection or undergoing hemodialysis.

An observational study prospectively included consecutive patients who underwent *de novo* ICD implantation in 33 Italian centers for three months in 2015 [10]. A CRT device was implanted in 39% (369/947) of patients. An S-ICD was implanted in 12% of patients with no CRT indication (7% of the total population). S-ICD patients were younger than patients who received TV-ICD, more often had channelopathies, and more frequently received their device for secondary prevention of SCA. More frequently, the clinical reason for preferring a TV-ICD over an S-ICD was the need for pacing (45%), ATP (36%), or the expected future need for CRT (26%).

Some physicians have been concerned that patients will later need bradycardia pacing or CRT although the need for pacing appears to be low if the patient does not require pacing at the time of implantation. In the SCD-HeFT study, the 5-year rate of crossover to ICD or CRT due to pacing need in patients enrolled in the amiodarone arm (845 patients) or in the placebo arm (847 patients) was 11.7% and 10.5%, respectively, nearly 2% per year [11].

In this issue of the journal, Kempa et al. [12] have published an analysis of the data from the Polish S-ICD Registry run by the Polish Cardiac Society between May 2020 and September 2022 to monitor the implementation of S-ICD therapy in Poland. The data include reports on about 440 procedures including 411 *de novo* procedures, representing 75% of the total number of ICD implantations in Poland during that period. The median age of the population was 42 years. Most of the

patients (93.9%) were in sinus rhythm, 89.5% were in New York Heart Association class I–II, and their median left ventricular ejection fraction (LVEF) was 0.33%. Secondary prevention indication was present in one-third of the patients, and ischemic cardiomyopathy was reported in only one-fourth of the patients. Not surprisingly, young age was the main reason for choosing an S-ICD in three-fourths of the patients, while a higher risk of infective complication was present in fewer than one-fifth of the patients.

Those clinical characteristics are representative of a patient population very similar to that designated to utilize S-ICD in the early years after approval of the device by the Food and Drug Administration in the US. In 2012, only 2% of patients having the indications for ICD therapy in the US received an S-ICD [13], which was, therefore, often used as a "niche" device.

However, it should be noted that patients included in the earlier registries conducted in the US and Europe, which have demonstrated the safety and feasibility of the S-ICD system for the prevention of SCA, also included patients with heart failure, low LVEF, and multiple comorbidities [14, 15].

In a pooled analysis of 882 patients with a mean follow-up of 22 months, 42% had congestive heart failure, 35% had previous myocardial infarction, and the S-ICD continued to demonstrate its favorable safety and efficacy [15]. As expected, the study also noted a very low rate of lead issues (<1%) and infection (<2%) in 3-year follow-up.

The UNTOUCHED study included 1111 patients implanted with a S-ICD only for primary prevention, and, for the first time with LVEF ≤35% [6]. Mean LVEF in UNTOUCHED was very similar to that of MADIT-RIT [2], which included only TV-ICDs (27 ± 7% vs. 26 ± 6%, respectively). The S-ICD was proven to be safe and effective, even in older patients (mean age, 55.8 ± 12.4 years) with multiple comorbidities and poorer cardiovascular function [8]. The most important strength of the UNTOUCHED trial was that it enrolled a majority of US participants and those with a high morbidity burden, therefore, its results should be generalizable to many patients seen in real-world practice.

The PRAETORIAN was the first head-to-head trial comparing the S-ICD with the conventional TV-ICD in the general population undergoing ICD implantation, who did not have pacing indications [5]. At a median follow-up of 49.1 months, the S-ICD was deemed non-inferior to the TV-ICD in the primary composite end-point with respect to device-related complications and inappropriate shocks (hazard ratio [HR], 0.99; $P = 0.01$) [5].

Nowadays available evidence strongly supports the use of S-ICD also in the population with heart failure, lower LVEF, and multiple comorbidities; therefore, the S-ICD should not be considered anymore a "niche" device. The previous guidelines had been written before data from more recent trials were available.

We think that the S-ICD can be considered in all primary (and even secondary) prevention patients without any pacing indication (including cardiac pacing, need for ATP, or CRT) regardless of age and underlying heart disease. It is anticipated that the actual level of recommendation will be raised with the next guideline update.

Article information

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