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EDITORIAL

Noli me tangere: how to defibrillate without touching the heart

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Article Jędrzejczyk-Patej et al., see p. 1507

The implantable cardioverter-defibrillator (ICD) has revolutionised sudden cardiac death prevention in patients at risk for life-threatening ventricular tachyarrhythmias. The progress in ICD technology has made these devices more efficient and safer in terms of their ability to discriminate arrhythmias and deliver appropriate therapies. However, technological advances did not significantly impact transvenous lead-related complications, which are the Achilles' heel of ICD systems, especially in view of the improved survival of ICD recipients.

S-ICD: THE JOURNEY FROM PROOF OF CONCEPT TO A PREFERRED OPTION

Subcutaneous ICD (S-ICD) has been developed to avoid the complications of permanent intracardiac transvenous leads. The pilot trial published in 2010 by Bardy et al. [1] demonstrated short-term safety and efficacy of the S-ICD, and after approval in Europe and the United States, this technology expanded worldwide.

Until now, most of the evidence on S-ICD safety and efficacy has come from observational data from the nonrandomised Investigational Device Exemption (IDE) trial [2] and the Evaluation oF FactORs ImpacTing CLinical Outcome and Cost EffectiveneSS of the S-ICD (EFFORTLESS S-ICD) Registry [3]. A meta-analysis of these two studies demonstrated the high efficacy of S-ICD, with 98.2% of spontaneous ventricular tachyarrhythmia/ventricular fibrillation events treated correctly [4].

A retrospective analysis of S-ICD vs. transvenous ICD (TV-ICD), including 1160 patients from two centres in the Netherlands, revealed similar rates of appropriate and inappropriate therapies, and similar complication rates. S-ICD reduced the incidence of lead-related complications at the cost of those related to detection [5].

PRAETORIAN (ClinicalTrials.gov NCT01296022) and ATLAS S-ICD (ClincialTrials.gov NCT02881255) are ongoing randomised trials designed for a head-to-head comparison of S-ICD vs. TV-ICD.

In the absence of randomised data, all S-ICD recommendations have a C level of evidence. As an alternative to TV-ICD, S-ICD has a class IIa indication when bradycardia pacing, cardiac resynchronisation therapy (CRT), or anti-tachycardia pacing is not needed. Also, there is a class IIb indication for S-ICD when venous access is difficult, in young patients with long-term need for device therapy, and after infection-related TV-ICD extraction [6]. The American Heart Association/American College of Cardiology/Heart Rhythm Society guideline considers S-ICD with a class I recommendation for patients without indication for pacing or anti-tachycardia pacing (ATP), at high risk of infection or without adequate venous access [7].

Apart from guideline indications, there are strong arguments that more patients could benefit from S-ICD implant. The need for ventricular pacing or CRT, especially in patients with a normal atrial-ventricular conduction, was very low (< 2% per year) in the conventional arm of Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II), so S-ICD should be an option in such patients [8]. Similarly, repeated fast monomorphic ventricular tachycardia was infrequent (1.8% per year) in Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), questioning how critical ATP therapy is for avoiding shock therapy by TV-ICD [9]. Programming ATP therapy with longer delays and at higher cut-off rates resulted in a significant reduction of unnecessary ATP with an unchanged delivery of appropriate shocks in the Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy trial (MADIT RIT) [10]. The importance of ATP

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therapy in ICD patients is probably overestimated considering that monomorphic ventricular tachycardia is best treated by medication or ablation.

S-ICD: WHAT WE KNOW AND WHAT WE CAN

Because strong guideline indications to opt for S-ICD or TV-ICD are lacking, the decision is often based on the physician's preference or economic considerations.

In the S-ICD Post-Approval Study, a prospective registry including 1637 patients from 86 American centres, S-ICD was considered the only reasonable device option in 8.8% of patients, either due to cardiac anatomy, lack of venous access, or high risk of infection. When any type of ICD was considered suitable, S-ICD was chosen based on patient preference (52.4%), age (43.7%), and patient activity (12.5%) [11].

The Italian S-ICD survey included consecutive patients from 33 Italian centres. TV-ICD was preferred when there was a current or expected need for pacing (45%), potential need for ATP therapy (36%), and a possible future CRT indication (26%). On the other hand, S-ICD was preferred in young patients with channelopathies, mainly as secondary prevention [12].

Apart from clinical decision criteria, reimbursement policy and accessibility to specialised implant centres may also influence ICD device selection. The European Heart Rhythm Association (EHRA) prospective snapshot survey collected data between April and June 2017, trying to provide a better understanding of S-ICD utilisation across a wide range of European tertiary centres. Even if the 20 centres responding to the survey were located in only six countries, half of them in France and Poland, the results provided an interesting picture of the S-ICD selection strategy. The economic factor significantly favoured the use of TV-ICD (18.5%), while patient preference or aesthetical reasons had negligible impact [13].

In this context, the article published in this issue of *Kardiologia Polska* (*Polish Heart Journal*) by Jedrzejczyk-Patej et al. [14] is of particular interest. In a sub-study of the EHRA prospective survey, the authors analysed the factors influencing the choice between S-ICD and TV-ICD in Poland in comparison with other European countries. The data clearly show the existence of important country-specific differences regarding S-ICD use. For Polish centres the economic factor was significantly more important in the selection of S-ICD compared with other European countries. However, it is interesting to note that the comparison of data from Poland, representing 31.7% of survey participants, was made with countries with very high numbers of implants and high reimbursement for medical devices. However, this survey does not include European countries in which the S-ICD is not reimbursed at all.

In Poland, the economic limitations make S-ICD an alternative to TV-ICD in very selected cases only, such as implant-related infections, electrode-related complications, or lack of venous access. This explains not only the lower proportion of S-ICDs implanted in Poland compared with other European centres (7% vs. 26%), but also the reason why patients implanted with S-ICD in Poland had more advanced heart failure and more comorbidities.

S-ICD VS. TV-ICD: SHOULD WE SHIFT THE PARADIGM?

S-ICD is safe and efficient, as shown by registry data. As a result, S-ICD tends to shift from being a backup alternative in selected cases towards a first-line therapeutic option in specific situations, as when there is no indication for pacing.

There is still excessive caution about S-ICD limitations. In the Italian S-ICD survey, TV-ICD was preferred in 203 patients with current or expected need for pacing, 163 patients with potential need for ATP, and 117 potential future CRT, but only 28 patients actually had a class I indication for permanent pacing, nine had a history of monomorphic ventricular tachycardia with syncope, 25 had a QRS duration > 120 ms, and seven had left bundle branch block [12]. In time, technological progress could change some of the restraints. Thus, by using conductive device-device communication, ATP delivery could be possible on demand with an ATP-enabled leadless pacemaker and an S-ICD [15].

At this moment, economic considerations still play an important role in S-ICD selection, but their importance varies among countries. A propensity-matched case-control study comparing the efficacy, safety, and costs of S-ICD and TV-ICD demonstrated that the higher unit cost of the S-ICD might be compensated in time by lower complication-related costs [16]. Therefore, it is possible that in the coming years the paradigm will shift from deciding which patients could benefit from an S-ICD to which patients should not have an S-ICD.

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