

Editorial

The Subcutaneous ICD. Ready to Conquer Everyone's Heart?

El DAI subcutáneo: preparado para conquistar nuestros corazones

Lucas V.A. Boersma^{a,b,*}^a Cardiology Department, St. Antonius Hospital Nieuwegein, The Netherlands^b Cardiology Department, AMC/University of Amsterdam, The Netherlands

Over the last 3 decades, the implantable cardioverter-defibrillator (ICD) has become standard therapy for patients at high risk of sudden arrhythmic cardiac death.¹ Several landmark trials have shown its efficacy both for primary and secondary prevention indications. There are, however, downsides to the therapy, a major proportion of which are related to the introduction of a chronic ICD lead in the cardiovascular space. Implant-related bleeding and pneumothorax, as well as premature dysfunction and infection leading to extraction and added lead implants, result in prolonged hospitalization, higher health care costs, and even mortality. For a long time, the cardiology community was forced to accept these unavoidable downsides of ICD therapy, until the first completely subcutaneous ICD (S-ICD) was introduced a decade ago.² As experience is growing with this therapy, so are decisions on how to optimally use this device, and evaluate patient outcomes compared with the classic transvenous ICD (TV-ICD).

In a recent article published in *Revista Española Cardiología*, Arias et al. describe their single-center experience with the S-ICD from end 2013 to early 2017.³ In this contemporary cohort, lessons from earlier studies about changing the 3-incision to the 2-incision technique, as well as programming of a conditional zone and higher rate cutoff values to avoid unnecessary shocks, were all incorporated into patient management. In addition, the second- and third-generation EMBLEM devices were used in most patients, which include superior T-wave oversensing algorithms, and offer remote care option through the Latitude network. All these novel S-ICD device options demonstrate how the therapy has come of age and is no longer a niche product only for patients with a contraindication to a TV-ICD.

The authors found that both acute as well as long-term device-related complications and inappropriate device therapy were rare, while shock tests were successful in all. They included 50 patients with mixed etiologies including channelopathy (24%) as well as structural heart disease (76%), and both primary (72%) and secondary prevention (28%). The inclusion of primarily primary prevention indications is different from prior large S-ICD registry data, where most patients had a secondary prevention indication.⁴⁻⁷ In a pooled analysis of the EFFORTLES registry and the US IDE study, the S-ICD was found to serve both primary and secondary prevention patients equally well.⁸ Obviously, secondary prevention patients had a greater need for appropriate therapy, but all other outcome parameters were almost identical. Both therapy for

induced ventricular tachycardia/ventricular fibrillation as well as for spontaneous episodes were highly successful. In the present cohort, only 1 patient had a successful appropriate therapy episode during the 18-month follow-up, making it difficult to establish the long-term performance of these later-generation devices. In general, in the light of recent literature such as the DANISH trial,⁹ and improved parallel treatment of heart failure and coronary artery disease, the true benefit of ICD therapy for primary prevention should probably be more carefully weighed against competing risks and comorbidities.

Of interest, the risk for infection of the S-ICD was found to be low. While it was high during the initial learning curve period,¹⁰⁻¹¹ experience with the device,⁴⁻⁷ and adoption of the 2-incision technique¹²⁻¹³ were drivers of very low infection rates, as observed by Arias et al.³ Moreover, to date there have been no reports of lead failure or serious complications of chronic subcutaneous S-ICD lead extractions. Indeed, morbidity and mortality appear to be lower when replacing an infected TV-ICD for an S-ICD than historic data for the TV-ICD.¹⁴

The present data also show that inappropriate shocks (IAS) were rare. This could have been due to chance or the selected population, but may also be related to advanced programming knowledge. The first EFFORTLESS and US IDE study analyses showed how the presently used dual-zone programming reduced the chances for IAS (recurrence).⁴⁻⁵ Although the S-ICD arrhythmia algorithm was very robust to avoid shocks in patients with atrial fibrillation (IAS 1.5%), T-wave oversensing remained an important driver with a total IAS rate of 11.5% during the 3-year follow-up.⁸ The recent changes in T-wave algorithm and filtering (SMART-PASS) have been shown to reduce the potential for IAS by 70%,¹⁵⁻¹⁶ which is in line with the very low rates observed in the present cohort.

In the eyes of many physicians, having all pacing options available both for bradycardia and tachycardia treatment remains a necessary investment in the future in case it becomes useful. The recent Italian S-ICD survey¹⁷ showed how much physicians have come to rely on the TV-ICD as an unavoidable all-or-nothing option therapy. On the other hand, many ICD studies have shown that the need for brady-pacing develops in only 1% annually over a time course of 3 to 5 years.¹⁸⁻¹⁹ In the largest primary prevention ICD study SCD-HeFT,¹⁸ repetitive monomorphic ventricular tachycardia amenable to ATP was seen in only 2% of patients during a mean follow-up of 5 years. If patients with a history of ventricular tachycardia, or with an overt pacing indication are excluded from S-ICD implants, the latest EFFORTLESS data⁹ show that only 1% of patients switched from an S-ICD to a TV-ICD for pacing reasons. By avoiding long PR-intervals and wide QRS in patients with low left ventricular ejection fraction, this should further stratify optimal indication for the S-ICD. And if only a minority of patients in the

SEE RELATED CONTENT:

<https://doi.org/10.1016/j.rec.2017.11.006>

* Cardiology Department, St. Antonius Hospital, PO 2500, 3430 EM, Nieuwegein, The Netherlands.

E-mail address: l.boersma@antoniusziekenhuis.nl

<https://doi.org/10.1016/j.rec.2018.05.018>

1885-5857/© 2018 Sociedad Española de Cardiología. Published by Elsevier España, S.L.U. All rights reserved.

remaining cohort would truly benefit from a TV-ICD, then why should the vast majority of patients be exposed to the potential problems of TV-leads? Now that we have the tools to provide sudden cardiac arrhythmic death prevention both with and without the use of TV-leads, it is time to develop decision trees on how to incorporate these options into our everyday clinical practice.

What does the future of S-ICD therapy hold? One of the remaining shortcomings is that the current platform does not offer pacing options for patients in need of pacemaker therapy, or for patients with recurrent ventricular tachycardia that could benefit from antitachycardia pacing. As battery longevity grows, long-term decisions must be made upfront for a decade of therapy. The fear of withholding pacing options in the future is still a major reason for choosing a TV-ICD instead of an S-ICD, despite the well-known risks of a chronic lead in the cardiovascular space. Several options are currently explored, such as adding an intracardiac leadless pacemaker communicating with the S-ICD to provide ATP.²⁰ In 2019, the results of the randomized controlled PRAETORIAN trial²¹ will become available, comparing safety outcomes of the S-ICD and the TV-ICD. The UNTOUCHED trial²² has finished enrollment and will provide outcome data in primary prevention patients with low left ventricular function. Another issue is that defibrillation testing is still mandated in international guidelines, as physicians have struggled with adhering to optimal implant position of leads and devices.^{2,4-9} As TV-ICD implants are now more and more performed without a shock test after the SIMPLE trial,²³ this hurdle could jeopardize uptake of the S-ICD. Recent data have emphasized the importance of placing the lead under the subcutaneous fat, with a posterior can position lateral to the cardiac silhouette.²⁴ The PRAETORIAN-DFT trial is under design to prospectively validate the optimal anatomical approach to replace the need for postimplant shock testing. Such prospective data will provide more evidence that the S-ICD may provide the platform of the future to save lives without the burden of transvenous lead complications.

CONFLICTS OF INTEREST

L.V.A. Boersma reports consultancy services to Abbott, Boston Scientific Inc, and Medtronic Inc. Fees go to the Cardiology Department.

REFERENCES

1. Priori SG, Blomström-Lundqvist C, Mazzanti A, et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). *Eur Heart J*. 2015;36:2793–2867.
2. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. *N Engl J Med*. 2010;363:36–44.

3. Arias MA, Pachón M, Akerström F, Puchol A, Martín-Sierra C, Rodríguez-Padial L. Acute and Long-term Results After Contemporary Subcutaneous Implantable Cardioverter- defibrillator Implantation: A Single-center Experience. *Rev Esp Cardiol*. 2018;71:894–900.
4. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. *Circulation*. 2013;128:944–953.
5. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S- ICD Registry. *Eur Heart J*. 2014;35:1657–1665.
6. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. *Circulation*. 2013;128:944–953.
7. Burke MC, Gold MR, Knight BP, et al. Safety and Efficacy of the Totally Subcutaneous Implantable Defibrillator: 2-Year Results From a Pooled Analysis of the IDE Study and EFFORTLESS Registry. *J Am Coll Cardiol*. 2015;65:1605–1615.
8. Boersma L, Barr C, Knops R, et al. EFFORTLESS Investigator Group. Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. *J Am Coll Cardiol*. 2017;70:830–841.
9. Boersma LV, Barr CS, Burke MC, et al. Performance of the subcutaneous implantable cardioverter-defibrillator in patients with a primary prevention indication with and without a reduced ejection fraction versus patients with a secondary prevention indication. *Heart Rhythm*. 2017;14:367–375.
10. Køber L, Thune JJ, Nielsen JC, et al. DANISH Investigators. Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure. *N Engl J Med*. 2016;375:1221–1230.
11. Olde Nordkamp LR, Dabiri Abkenari L, Boersma LV, et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort. *J Am Coll Cardiol*. 2012;60:1933–1939.
12. Brouwer TF, Miller MA, Quast AB, et al. Implantation of the subcutaneous implantable cardioverter-defibrillator: an evaluation of 4 implantation techniques. *Circ Arrhythm Electrophysiol*. 2017;10:e004663.
13. Knops RE, Olde Nordkamp LR, De Groot JR, Wilde AA. Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm*. 2013;10:1240–1243.
14. Boersma L, Burke MC, Neuzil P, Lambiase P, et al. EFFORTLESS and IDE Study Investigators. Infection and mortality after implantation of a subcutaneous ICD after transvenous ICD extraction. *Heart Rhythm*. 2016;13:157–164.
15. Theuns DA, Burke M, Allavatam V, Jones P, Gold M. 56-44: Evaluation of a High Pass Filter Designed to Reduce Oversensing in the S-ICD [abstract]. *EP Europace*. 2016;18(Suppl 1):i42.
16. Brisben AJ, Burke MC, Knight BP, et al. A new algorithm to reduce inappropriate therapy in the S-ICD system. *J Cardiovasc Electrophysiol*. 2015;26:417–423.
17. Botto GL, Forleo GB, Capucci A, et al. 'AIAC S-ICD Why Not' Survey Investigators. The Italian subcutaneous implantable cardioverter-defibrillator survey: S-ICD why not? *Europace*. 2017;19:1826–1832.
18. Sweeney MO, Ellenbogen KA, Tang AS, et al. Managed Ventricular Pacing Versus VVI 40 Pacing Trial Investigators. Atrial pacing or ventricular backup-only pacing in implantable cardioverter-defibrillator patients. *Heart Rhythm*. 2010;7:1552–1560.
19. Bardy GH, Lee KL, Mark DB, et al. Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med*. 2005;352:225–237.
20. Tjong FV, Brouwer TF, Smeding L, et al. Combined leadless pacemaker and subcutaneous implantable defibrillator therapy: feasibility, safety, and performance. *Europace*. 2016;18:1740–1747.
21. Olde Nordkamp LR, Knops RE, Bardy GH, et al. Rationale and design of the PRAETORIAN trial: a Prospective, RANdomizEd comparison of subcuTaneous and tRansvenous ImplAntable cardioverter-defibrillator therapy. *Am Heart J*. 2012;163:753–760.
22. Gold MR, Knops R, Burke MC, et al. The Design of the Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low EF Study (UNTOUCHED). *Pacing Clin Electrophysiol*. 2017;40:1–8.
23. Healey JS, Hohnloser SH, Glikson M, et al. Shockless IMPLant Evaluation [SIMPLE] investigators. Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomised controlled trial (SIMPLE). *Lancet*. 2015;385:785–791.
24. Heist EK, Belalcazar A, Stahl W, Brouwer TF, Knops RE. Determinants of subcutaneous implantable cardioverter-defibrillator efficacy. A computer modeling study. *J Am Coll Cardiol EP*. 2017;3:405–414.