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Fifteen years of subcutaneous implantable cardioverter-defibrillator therapy: Where do we stand, and what will the future hold?

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ABSTRACT

The subcutaneous implantable cardioverter-defibrillator (S-ICD) has emerged as a feasible alternative to the transvenous ICD in the treatment of ventricular tachyarrhythmias in patients without indications for pacing or cardiac resynchronization therapy. Since its introduction, numerous innovations have been made and clinical experience has been gained, leading to its adoption in current practice and preference in certain populations. Moreover, emerging technologies like the extravascular ICD and the combination of the S-ICD with the leadless pacemaker offer new possibilities for the future. These advancements underscore the evolving role of the S-ICD in management of ventricular tachyarrhythmias. This review outlines implantation considerations, patient selection, and troubleshooting advancements in the last 15 years and provides insights into future perspectives.

KEYWORDS Subcutaneous ICD; Implantable cardioverter-defibrillator; Sudden cardiac death; Ventricular tachycardia; Inappropriate shocks

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History and development

Since its introduction in 1980, the transvenous implantable cardioverter-defibrillator (TV-ICD) has evolved into an essential therapy in current clinical practice to prevent sudden cardiac death. However, despite decades of innovation, implantation-related complications, such as pneumothorax, cardiac tamponade, and thrombotic events, are inherent in the intravascular design of the TV-ICD.[1] Moreover, intravascular leads endure mechanical stress, with 8% of patients experiencing lead failure within 5 years and up to 25% within 10 years of ICD therapy.[1] Intravascular leads are also susceptible to infection, which has a 1-year mortality of 20%.[2]

To overcome these complications, a completely extrathoracic device was developed, the subcutaneous ICD (S-ICD), which was permanently implanted for the first time in 2008.[3] The S-ICD consists of a subcutaneous pulse generator in the midaxillary position on the left side of the thoracic wall and a parasternal subcutaneous lead with an 8-cm coil (Figure 1). Early short-term studies demonstrated that the average defibrillation threshold was approximately 35 J in this position.[3] Incorporating a higher safety margin compared to TV-ICDs, the output of the S-ICD was set at 80 J, resulting in a generator twice the size of the TV-ICD.[3,4]

After the initial introduction, the second-generation device exhibited several enhancements in 2015. The device underwent a 20% reduction in size combined with a 40% increase in battery longevity. Furthermore, remote home monitoring became an option. The current third-generation device, released in 2016, is magnetic resonance imaging compatible, features an atrial fibrillation monitor, and incorporates a novel algorithm aimed at minimizing inappropriate therapy (Figure 2). A fourth-generation device is currently under development.

This review outlines implantation considerations, patient selection, and troubleshooting advancements based on the available evidence of the last 15 years and provides insights into future perspectives.

S-ICD implantation

The S-ICD can be implanted by use of anatomic landmarks without fluoroscopy. However, fluoroscopy before

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implantation to determine optimal positioning of the generator and lead might help in specific patients, such as very tall patients or patients with anatomic deformation of the chest. At its introduction, the implantation required 3 incisions: 1 at the left lateral side of the chest along the inframammary crease for the creation of the pulse generator pocket and 2 inferior and superior parasternal incisions for lead placement. However, in 2013, a 2-incision technique was developed wherein the superior parasternal incision is omitted and the lead is tunneled over the sternum with a standard 11F peel-away sheath through the lower parasternal incision.[5] This approach reduces both procedure time and the risk for infection and has favorable cosmetic outcomes. No significant difference in terms of appropriate or inappropriate shocks, infections, or lead dislodgment is found between the techniques; therefore, the 2-incision technique has been increasingly used over time.[6] Both techniques can be performed before or after sternotomy without compromising the integrity of the S-ICD lead.[7]

The pulse generator can be implanted subcutaneously, intermuscularly between the serratus anterior and latissimus dorsi,[8] submuscularly below the fascia of the serratus anterior,[9] or under the serratus anterior.[10] The intermuscular and submuscular approaches improve device efficacy and reduce pocket complications, such as erosion and discomfort, while improving cosmetics in slim individuals and preventing device migration in obese patients.[8,11] The intermuscular technique has been widely adopted by clinicians in past years; data concerning submuscular techniques are limited. Moreover, the submuscular approach is more complex and requires special attention for the prevention of damage to the long thoracic nerves and sufficient pain management.[9]

Defibrillation threshold testing

After implantation, a defibrillation test is recommended to confirm S-ICD functioning. Suboptimal S-ICD implantation elevates the defibrillation threshold and risk for conversion failure of ventricular tachyarrhythmias (VTs).[12] Computer modeling and clinical experience found that the amount of tissue between the coil and sternum, the amount of tissue between the pulse generator and thoracic wall, the anterior-posterior position of the pulse generator on the thoracic wall, and the body mass index influence the defibrillation threshold the most.[13] These determinants are incorporated in the PRAETORIAN score, which is calculated on postimplantation chest radiographs to identify patients with suboptimal implant position and subsequent high risk for conversion failure.[13,14] The PRAETORIAN score has proved to be a reliable tool for predicting successful defibrillation threshold testing (DFT), with a score below 90 showing a 99% negative predictive value for successful DFT.[15,16] Moreover, the PRAETORIAN score can be used to provide feedback on the individual implant.[17] The currently ongoing PRAETORIAN-DFT trial will determine whether the PRAETORIAN score can be used to safely omit the DFT.

Abbreviations

ARVC: arrhythmogenic right ventricular cardiomyopathy

ATP: antitachycardia pacing

DFT: defibrillation threshold testing

EV-ICD: extravascular ICD

ICD: implantable cardioverter-defibrillator

S-ICD: subcutaneous ICD

TV-ICD: transvenous ICD

VT: ventricular tachyarrhythmia

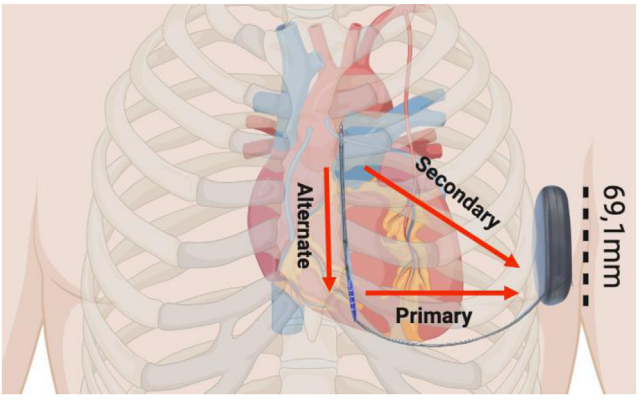


Figure 1
Illustrated configuration of the subcutaneous implantable cardioverter-defibrillator with the 3 possible sensing vectors. Created with BioRender.com.

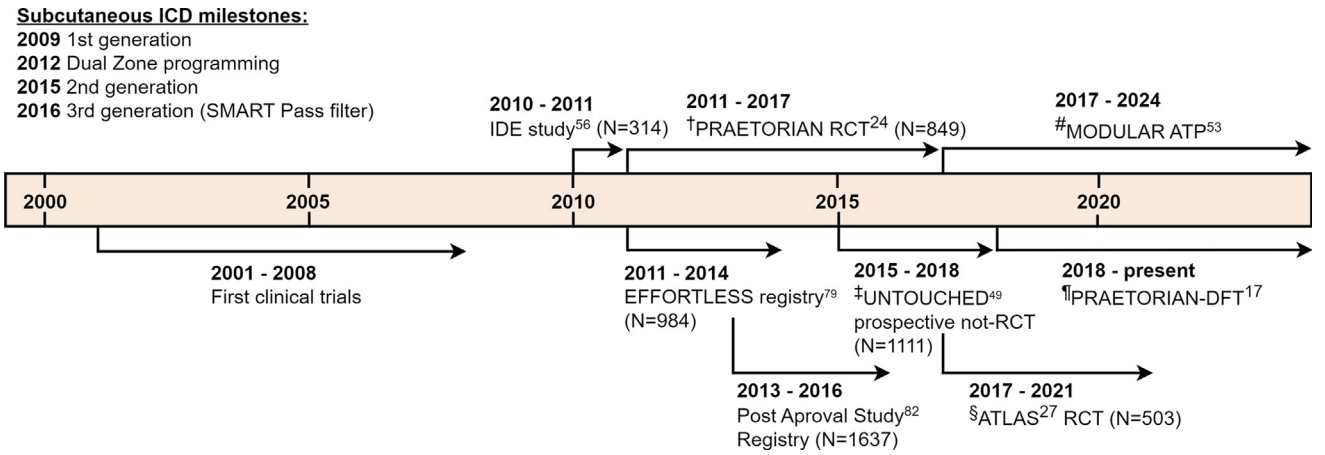
Because the PRAETORIAN score is calculated after implantation, periprocedural strategies to avoid defibrillation testing have been suggested and include the use of high-voltage QRS-synchronized 10 J shock impedance and low-voltage shock impedance measurements.[18] However, caution is warranted in relying on impedance measurements only as too anterior positioning of the generator with insufficient cardiac mass between the components may result in unsuccessful defibrillation despite low impedance. Also, a rise in shock impedance during generator replacement was not associated with DFT failure.[19] Therefore, impedance measurements should always be combined with ensuring adequate positioning. Supine fluoroscopy differs from standing chest radiography, and device shifting during differences in position should be considered.[19]

Anesthesia

Because of a larger tissue dissection area compared with TV-ICD implantation and tunneling on the sternal periosteum, a higher level of sedation and analgesia is necessary during S-ICD implantation. Traditionally, because of the need for DFT, general anesthesia combined with local analgesia has been preferred, but alternative anesthesia strategies, such as monitored anesthesia care and regional nerve blocks, are feasible as well.[20,21]

Patient selection and workup before implantation

The S-ICD can be considered when bradycardia pacing, cardiac resynchronization, or antitachycardia pacing (ATP) is not needed because the extravascular lead withholds pacing options.[22,23] In the PRAETORIAN trial, 849 patients with an ICD indication were randomized to an S-ICD or TV-



Period mentioned refers to inclusion period. RCT = randomized control trial.
† PRAETORIAN: prospective RCT that demonstrated non-inferiority compared to the transvenous-ICD in combined end-point (device-related complications and inappropriate shocks).
‡ UNTOUCHED: non-randomized trial that enrolled only primary prevention patients with a left ventricular ejection fraction <35%.
§ ATLAS: prospective RCT that demonstrated that younger patients or those prone to lead-infection benefit from the S-ICD.
¶ MODULAR ATP: prospective trial designed to investigate effectiveness S-ICD in combination with leadless pacemaker.
# PRAETORIAN DFT: prospective RCT designed to investigate utility of defibrillation threshold test.

Figure 2
Timeline of trials and registries of the subcutaneous implantable cardioverter-defibrillator (ICD). IDE = investigational device exemption.

ICD. During a median follow-up of 49 months, noninferiority was shown for the primary end point of device-related complications and inappropriate shocks. Patients with a pacing indication were excluded in this trial, and during follow-up, crossover to TV-ICDs was necessary in only 1.2% for bradycardia pacing and 1.4% for resynchronization pacing.[24] Moreover, earlier studies of TV-ICD implantation for primary prevention showed that 2%–3% of patients required pacing per year.[25] Therefore, patients without preexisting impulse or conduction abnormalities can be safely implanted with an S-ICD with a relatively low risk for future pacing therapy.

In younger patients with an active lifestyle, S-ICDs could be favored.[26,27] The ATLAS study randomized 544 patients younger than 60 years with a conventional ICD indication to an S-ICD or TV-ICD and demonstrated that in 6 months after implantation, lead-related complications were fewer in the S-ICD arm (Figure 2).[27] The S-ICD may also be preferred in patients with limited vascular access[23,28]; those with previous device infections[28,29]; and those with additional factors for a high infection risk, such as dialysis, immunodeficiency states, and prosthetic heart valves.[30,31] The S-ICD may also be preferred in patients with congenital cardiac anomalies, especially in case of vascular access difficulties. Even right-sided S-ICD implantation is feasible in some patients.[32]

The S-ICD is also a viable alternative in patients with inherited arrhythmia syndromes,[33] such as hypertrophic cardiomyopathy,[34,35] arrhythmogenic right ventricular cardiomyopathy (ARVC),[36] and Brugada syndrome.[37]

Eligibility screening

Because of the far-field sensing, patients with an insufficient R/T ratio are at risk for inappropriate therapy. Therefore, electrocardiographic screening is required to ensure proper sensing in at least 1 sensing vector in standing and supine position. There is an 85%–93% eligibility rate in patients without a pacing indication, whereas hypertrophic cardiomyopathy, obesity, prolonged QRS duration, and R/T ratio <3 are associated with ineligibility.[38–40] In congenital heart patients, eligibility rate is reported to be between 60% and 83%.[41–43]

In patients with Brugada syndrome, ineligibility varies between 13% and 24%. Additional assessments should be done during or after an exercise test and after a drug provocation challenge test to account for dynamic electrocardiographic changes.[37,44,45] Patients with hypertrophic cardiomyopathy commonly express high and inverted T waves, resulting in a heightened S-ICD screening ineligibility rate, ranging from approximately 7% to 16%, that is observed across various studies.[46,47] For patients with hypertrophic cardiomyopathy or Brugada syndrome, right parasternal

electrode placement is recommended during the screening process to improve eligibility rate.[37]

Hypertrophic cardiomyopathy and ARVC are progressive diseases in which the R/T ratio can change over time, affecting the risk of inappropriate therapy after S-ICD implantation. Conversely, ARVC patients with a TV-ICD may have significantly more lead failures, supposedly from the development of myocardial fibrosis.[36,48]

Device efficacy, appropriate shocks, and lack of ATP

Successful conversion of ventricular arrhythmias by the S-ICD was reported to be >96% for induced ventricular arrhythmias and 95%–100% in spontaneous events.[24,27,29,49] Supplemental Table 1 shows shock efficacy for spontaneous events in the major clinical trials. Termination of arrhythmias by the S-ICD is achieved by shock therapy only as the device lacks the ability to give ATP. Indeed, a subanalysis of the PRAETORIAN trial in conventional primary and secondary prevention ICD patients showed that patients with an S-ICD were more likely to receive an appropriate shock compared with TV-ICD patients with a hazard ratio of 1.52, probably because of the lack of ATP.[50] However, the total number of appropriate shocks was not significantly different and an increase of storm episodes was shown, possibly due to ATP acceleration, increasing the number of shocks per patient. Defibrillator shocks, both appropriate and inappropriate, may lead to myocardial damage, and shocks have been linked to higher mortality rates.[51,52] Therefore, the benefits and risks of ATP should be carefully considered per patient.

Selection before implantation of patients who will likely benefit from ATP is difficult but can be done on the basis of the presence of therapy-refractory ventricular arrhythmias. The selection of patients without an ATP indication may become less burdensome with the recent introduction of the EMPOWER™ (Boston Scientific, Marlborough, MA) Modular Pacing System (Figure 3), whereby a leadless pacemaker can provide ATP therapy on receiving a wireless signal by the S-ICD.[53] Simultaneous implantation may be considered for selected patients with a bradycardia or tachycardia pacing indication, particularly those deemed at elevated risk for transvenous lead complications or with limited venous access. However, given the infrequent need for pacing therapy in S-ICD patients[24] alongside cost considerations, a single S-ICD implantation with an upgrade with a leadless pacemaker in patients in whom a pacing indication develops can be a viable strategy. The first clinical trial enrolling up to 293 patients at increased risk for monomorphic VTs showed that 97.5% of patients were free from leadless pacemaker–related major complications, and 61.3% of spontaneous arrhythmias were successfully terminated by ATP at 6 months.[53]

Inappropriate shocks

Because of the subcutaneous position of the device, the sensing signal is morphologically rich and resembles the surface electrocardiogram more closely compared with the TV-ICD. As a result of the morphology-based sensing algorithm, the underlying cause of inappropriate shocks in S-ICD patients differs from that in TV-ICD patients. Inappropriate shocks due to T-wave oversensing and low-amplitude signal oversensing are more frequently observed in S-ICD patients, whereas inappropriate shocks due to supraventricular arrhythmias occur more frequently in TV-ICD patients.[54,55] Moreover, double counting of ventricular tachycardia by the S-ICD may result in shocks on VTs with a rate below the programmed therapy zone. Although these shocks are on ventricular tachycardia, it may be debated whether these shocks should be considered inappropriate or appropriate. However, most of the time, these shocks are unnecessary. Whereas early studies reported inappropriate shock rates for the S-ICD up to 13% at 1 year after implantation,[51,56] in the latest studies using most of these software technologies, the rates are as low as with transvenous devices, with an incidence of approximately 4%–5% at 1-year follow-up (Figure 4; Tables 1 and 2). This reduction is in part due to software updates, such as the introduction of SMART Pass (Boston Scientific), a high-pass filter that reduces the amplitude of lower frequency (slower moving) signals, such as T waves. This enhances the R/T ratio and thus the sensing process, thereby particularly reducing

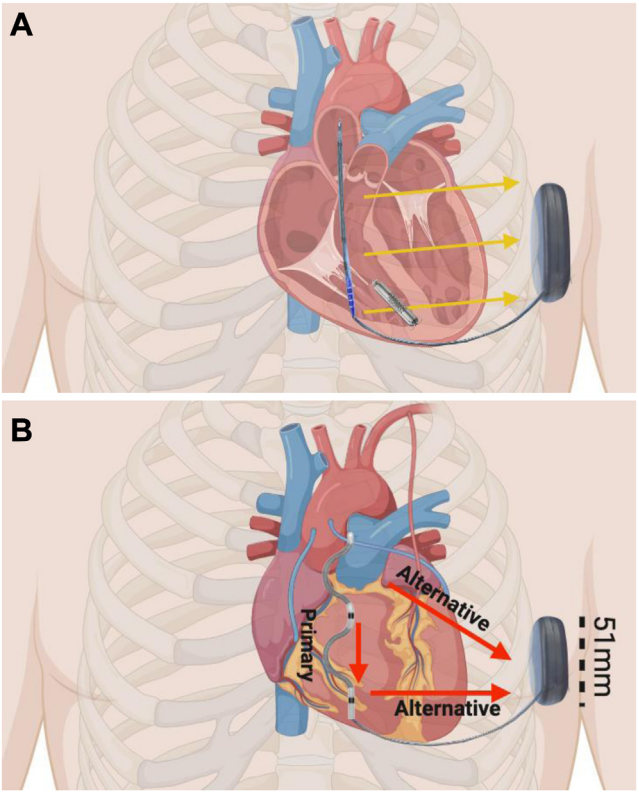


Figure 3
Extravascular alternatives to the subcutaneous implantable cardioverter-defibrillator. **A:** Illustrated configuration of the modular pacing-defibrillator system with the unidirectional communication to the leadless pacemaker using 25 Hz pulses. **B:** Illustrated configuration of the extravascular implantable cardioverter-defibrillator with the 3 possible sensing vectors. Created with BioRender.com.

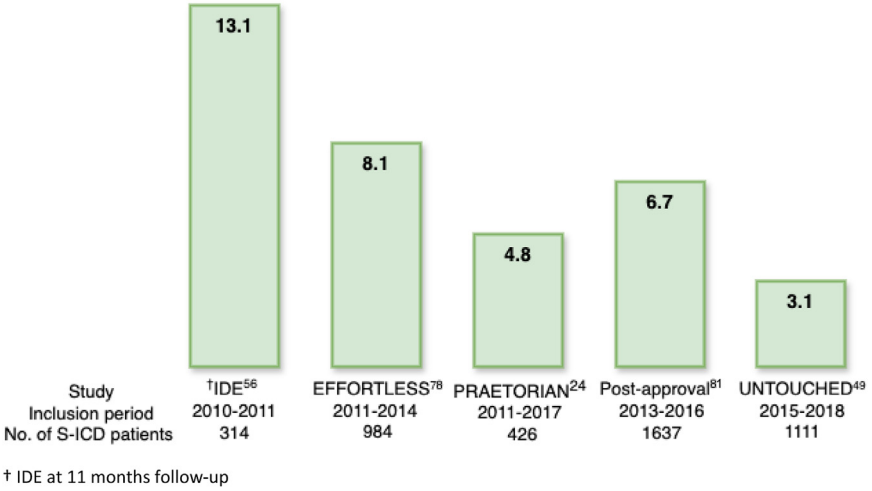


Figure 4
Cumulative incidence of inappropriate shocks at 1-year follow-up based on Kaplan-Meier estimate over time. IDE = investigational device exemption; S-ICD = subcutaneous implantable cardioverter-defibrillator.

shocks due to T-wave oversensing.[57] As SMART Pass automatically deactivates on low-amplitude signals and pauses,[58] SMART Pass status and reason for deactivation should be checked in clinic visits.[58]

To prevent inappropriate shocks, dual zone programming with a conditional and unconditional zone has been demonstrated to be highly effective, especially for supraventricular tachycardias.[29,59] In the conditional zone, a static and dynamic morphology comparison and QRS width comparison is made between the QRS complex of the tachycardia and an earlier made normal sinus rhythm morphology template.[60] Furthermore, optimization of sensing and a reduction of inappropriate shocks can be achieved by performing exercise tests after S-ICD implantation by feeding the device a normal sinus rhythm morphology template during exercise.[61] This is particularly useful in patients with hypertrophic cardiomyopathy who often have dynamic R- and T-wave changes during exercise and in patients with rate-dependent aberrancy.

Complications

Although no significant differences have been observed in the incidence of all device-related complications in the prospective randomized trials comparing the S-ICD with TV-ICDs conducted to date, the nature and severity of these complications differ.[27,62] In the absence of the intravascular lead, lead-related complications such as heart perforation, lead fracture, and lead dislocations are reduced by >90% in S-ICD patients

Table 1 General characteristics of published studies

Studies	Inclusion period	No. of S-ICD patients	Age at implantation (y)	Female (%)	Secondary prevention (%)
Brouwer et al[76]	2009–2015	148	41	41	34
Aydin et al[77]	2010–2011	39	42	29	59
IDE study[56]	2010–2011	314	52	26	21
Honarbakhsh et al[66]	2010–2015	69	35	25	19
EFFORTLESS registry[78]	2011–2014	984	48	28	35
PRAETORIAN[24]	2011–2017	426	63	21	19
Liang et al[79]	2012–2016	86	45	31	21
Sponder et al[80]	2012–2017	236	50	31	42
Postapproval study[81]	2013–2016	1637	53	32	23
Al-Ghamdi et al[82]	2014–2016	30	41	23	17
UNTOUCHED[49]	2015–2018	1111	56	26	0
ELISIR registry[83]	2015–2020	1254	52	22	37
Sasaki et al[84]	2016–2017	60	60	20	60
ATLAS[27]	2017–2021	251	48	24	29

PubMed search on March 18, 2024: "(S-ICD[title]) OR (subcutaneous ICD[title]) OR (subcutaneous AND defibrillator therapy[title]) OR subcutaneous AND cardioverter-defibrillator[title]" with filters: from 2009–2024 yielded 510 results. In Tables 1 and 2, trials and registries written in English with >20 adult patients with S-ICD and >6 months of follow-up are reported. Trials were excluded if serial reporting of a particular patient cohort was present.
IDE = investigational device exemption; S-ICD = subcutaneous implantable cardioverter-defibrillator.

Table 2 Clinical outcomes of published studies

Studies	Median follow-up (y)	Appropriate shocks, No. (%)	Inappropriate shocks, No. (%)	Complications,[a] No. (%)
Brouwer et al[76]	3.0	12 (8.1)	20 (13.5)	14 (9.5)
Aydin et al[77]	0.6	4 (10.2)	2 (5.1)	NR
IDE study[56]	0.9	21 (6.9)	41 (13.1)	NR
Honarbakhsh et al[66]	2.7	3 (4.3)	6 (8.7)	14 (20.3)
EFFORTLESS registry[78]	5.1	157 (16.0)	150 (15.2)	141 (14.3)
PRAETORIAN[24]	4.0	83 (19.5)	41 (9.6)[b]	31 (7.3)
Liang et al[79]	1.9	1 (1.2)	8 (9.3)	NR
Sponder et al[80]	1.7	16 (6.8)	12 (5.1)	9 (3.8)
Postapproval study[81]	4.2	231 (14.1)	218 (13.3)	75 (4.6)
Al-Ghamdi et al[82]	1.9	4 (13.3)	2 (6.7)	NR
UNTOUCHED[49]	1.4	58 (5.2)	45 (4.1)	NR
ELISIR registry[83]	1.9	118 (9.4)	112 (8.9)	117 (9.3)
Sasaki et al[84]	0.75	1 (1.7)	5 (8.3)	NR
ATLAS[27]	2.5	22 (8.8)	16 (6.4)	6 (2.4)

IDE = investigational device exemption; NR = not reported.
[a]Device-related complications reported in studies.
[b]Inappropriate shocks were defined as shocks on a rhythm other than ventricular fibrillation or ventricular tachycardia.

compared with conventional TV-ICDs.[27] Systemic infections are significantly lower in S-ICD patients (0% in S-ICD patients vs 1.2% in TV-ICD patients).[62] Also, in patients particularly susceptible to infections, such as patients undergoing long-term kidney dialysis, device-related infections are reported to be low.[30] Conversely, there is a higher prevalence of pocket bleedings after S-ICD implantation, probably because of the larger wound and device pocket besides the less defined perioperative anticoagulant strategies.[63] Moreover, safety notifications have been issued for both the battery and lead of some S-ICD models, although the incidence of premature battery depletion or lead malfunction is reported to be low (3.5% and 0.2%, respectively).[64,65]

Next to the different types of complications, the severity of the device-related complications also differs. Device-related complications in S-ICD patients less often require invasive interventions or hospital admissions compared with TV-ICD complications,[62] which could lead to reduced device costs over time based on long-term follow-up (Figure 5).[66] Over time, implant-related complications decreased by almost half because implanters gained more experience, and this could have had an impact on the early results.[67] Prolonged follow-up will yield further insights into the superiority of the S-ICD over transvenous devices in terms of complications because lead-related complications most often occur years after implantation.

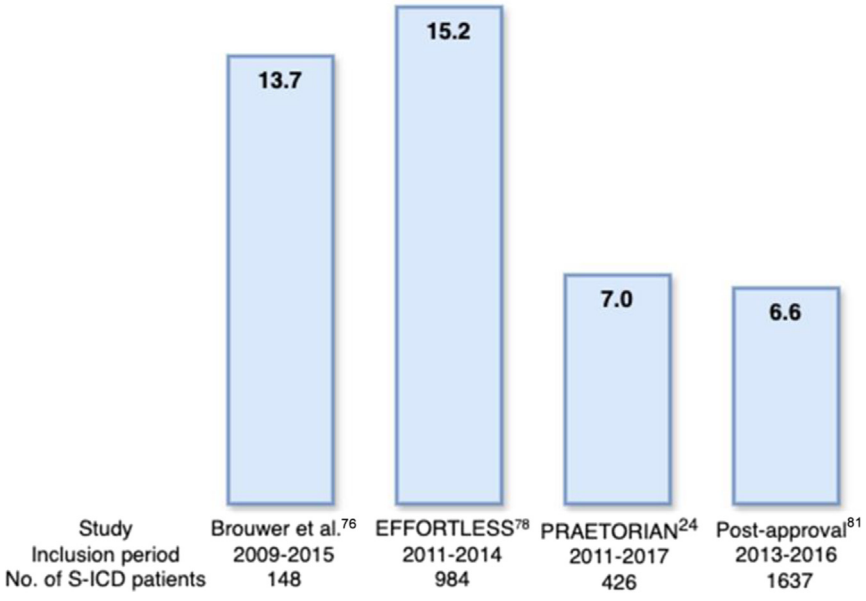


Figure 5
Cumulative incidence of device-related complications at 5-year follow-up based on Kaplan-Meier estimate over time. S-ICD = subcutaneous implantable cardioverter-defibrillator.

Extravascular ICD

In 2023, the extravascular ICD (EV-ICD) was approved by the Food and Drug Administration and received the CE marking. The EV-ICD is positioned subcutaneously on the lateral thoracic wall, with an epsilon-shaped lead that is tunneled under the sternum (Figure 3). This device offers pacing capabilities including pause prevention pacing, ATP, and post-shock pacing. The configuration of the EV-ICD enables achievement of defibrillation thresholds lower than with the S-ICD and comparable to those of the TV-ICD, such that the size of the generator of the EV-ICD is half that of the S-ICD. Given the relatively infrequent use of the substernal space by cardiologists, additional training is required for implanting physicians.

The first-in-human long-term implantation took place in 2019.[68] The first and so far only prospective clinical registry reported a successful conversion of 99% of induced ventricular arrhythmias. The EV-ICD also successfully terminated spontaneous ventricular arrhythmias during 6 months of follow-up. For patients with ATP enabled, successful ATP was provided in 51% of the patients with spontaneous ventricular arrhythmias.[69,70] In 4.9% of patients, the ATP function was disabled because of painful sensation of pacing therapy. One or more inappropriate shocks were reported in 9.7% of patients, predominantly attributed to P-wave oversensing, probably due to proximity of the sensing electrodes to the right atrial appendage. Freedom from major complications was 93%.[69] Given the novelty of this device, long-term follow-up after EV-ICD implantation is not available.

Future

Noninferiority of the S-ICD compared with the TV-ICD in terms of inappropriate shocks and complications has been established alongside a comparable effectiveness in converting ventricular arrhythmias.[24] Both the 2017 American College of Cardiology/American Heart Association/Heart Rhythm Society guideline and the 2022 European Society of Cardiology guideline on management of patients with ventricular arrhythmias state that in patients who meet the indication for an ICD, implantation of an S-ICD is reasonable or should be considered if pacing for bradycardia or VT termination or as part of resynchronization is neither needed nor anticipated.[22,23] Concurrently, advancements in programming have led to a reduction in the occurrence of observed inappropriate shocks over time, and substudies of the large randomized trials report fewer complications requiring invasive intervention.[62,71] These guidelines might therefore be revised with these data. Long-term follow-up studies will further determine whether the S-ICD is a superior alternative to the TV-ICD in patients without the need for pacing and resynchronization therapy.

The advantages and disadvantages of the various ICD therapies should be carefully discussed with patients for shared decision-making. Not only the reduced risk for serious complications in the S-ICD but also the larger generator size and inability to provide ATP, bradycardia pacing, and resynchronization therapy should be taken into account. Potential ATP benefit should be carefully weighed per patient as recent studies showed that whereas shock rates are lower when ATP is programmed, shock burden remains similar, which may be due to acceleration of arrhythmias after ATP and possible subsequent induction of ventricular storms.[50] Nevertheless, extracardiac ATP technologies are the EV-ICD or the modular pacing-defibrillator system, which includes the addition of a leadless pacemaker to the S-ICD.[53,69] However, short- and long-term clinical experience is limited with these devices. Finally, if impulse or conduction disorders arise over time or cardiac resynchronization is needed, vascular access is preserved in the years with S-ICD therapy, and crossover to transvenous devices with extraction of the S-ICD holds a very low risk.[72]

Another future adjustment that may be feasible is the generator size. Step-down defibrillation threshold studies using the PRAETORIAN score have shown that in patients with optimal S-ICD implantation, the mean defibrillation threshold is approximately 28 J, considerably lower than the 80 J that is currently provided by the S-ICD.[14,73] Furthermore, addition of a second shock lead in the transverse configuration lowered the mean defibrillation threshold by 32%.[74] Barriers to implementation of the S-ICD in clinical practice are the associated costs and reimbursement, as shown in a European survey involving 52 hospitals.[75] Another logistical barrier might be the recommended defibrillation test, which needs anesthetic support. A PRAETORIAN score–based omission of the DFT is currently being studied and will be presented in the coming years.[17]

Conclusion

During the past 15 years, S-ICD therapy has proved to be an effective and safe alternative for patients without pacing indications, demonstrating high efficacy in converting ventricular arrhythmias with a low complication rate. Advances in patient selection, programming, and implantation techniques have led to a reduction in inappropriate shocks and complications associated with S-ICD therapy. In addition, ongoing advancements, including the combination with leadless pacemakers to provide ATP, highlight the evolving role of S-ICD therapy as a valuable option in managing ventricular arrhythmias.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2024.06.028.

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References

1. Koneru JN, Jones PW, Hammill EF, Wold N, Ellenbogen KA. Risk factors and temporal trends of complications associated with transvenous implantable cardiac defibrillator leads. J Am Heart Assoc 2018;7:e007691.
2. Tarakji KG, Wazni OM, Harb S, Hsu A, Saliba W, Wilkoff BL. Risk factors for 1-year mortality among patients with cardiac implantable electronic device infection undergoing transvenous lead extraction: the impact of the infection type and the presence of vegetation on survival. Europace 2014;16:1490–1495.
3. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med 2010;363:36–44.
4. Gold MR, Higgins S, Klein R, et al. Efficacy and temporal stability of reduced safety margins for ventricular defibrillation: primary results from the Low Energy Safety Study (LESS). Circulation 2002;105:2043–2048.
5. 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.
6. El-Chami M, Weiss R, Burke MC, et al. Outcomes of two versus three incision techniques: results from the subcutaneous ICD post-approval study. J Cardiovasc Electrophysiol 2021;32:792–801.
7. Sugrue A, Ibrahim R, Lu M, et al. Impact of median sternotomy on safety and efficacy of the subcutaneous implantable cardioverter defibrillator. Circ Arrhythm Electrophysiol 2023;16:468–474.
8. Botto GL, Ziacchi M, Nigro G, et al. Intermuscular technique for implantation of the subcutaneous implantable defibrillator: a propensity-matched case-control study. Europace 2023;25:1423–1431.
9. 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.
10. Migliore F, Bottio T, Iliceto S, Bertaglia E. Submuscular approach for subcutaneous implantable cardioverter defibrillator: a potential alternative technique. J Cardiovasc Electrophysiol 2015;26:905.
11. Winter J, Siekiera M, Shin DI, et al. Intermuscular technique for implantation of the subcutaneous implantable cardioverter defibrillator: long-term performance and complications. Europace 2017;19:2036–2041.
12. Amin AK, Gold MR, Burke MC, et al. Factors associated with high-voltage impedance and subcutaneous implantable defibrillator ventricular fibrillation conversion success. Circ Arrhythm Electrophysiol 2019;12:e006665.
13. Quast AB, Baalman SW, Brouwer TF, et al. A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable cardioverter-defibrillator: the PRAETORIAN score. Heart Rhythm 2019;16:403–410.
14. van der Stuijt W, Pepplinkhuizen S, de Veld JA, et al. Defibrillation threshold in elective subcutaneous implantable defibrillator generator replacements: time to reduce the size of the pulse generator? Int J Cardiol 2024;398:131639.
15. Doldi F, Frommeyer G, Löher A, et al. Validation of the PRAETORIAN score in a large subcutaneous implantable cardioverter-defibrillator collective: usefulness in clinical routine. Heart Rhythm Published online February 19, 2024.
16. Knops RE, El-Chami MF, Marquie C, et al. Predictive value of the PRAETORIAN score for defibrillation test success in patients with subcutaneous ICD: a subanalysis of the PRAETORIAN-DFT trial. Heart Rhythm 2024;21:836–844.
17. Quast AB, Baalman SW, Betts TR, et al. Rationale and design of the PRAETORIAN-DFT trial: a prospective randomized comparative trial of subcutaneous implantable cardioverter-defibrillator implantation with and without defibrillation testing. Am Heart J 2019;214:167–174.
18. Schaller RD, Hyman M, Supple GE, et al. Defibrillation testing of the subcutaneous implantable cardioverter-defibrillator at the time of generator replacement. Heart Rhythm 2024;21:117–118.
19. de Veld JA, Pepplinkhuizen S, van der Stuijt W, et al. Successful defibrillation testing in patients undergoing elective subcutaneous implantable cardioverter-defibrillator generator replacement. Europace 2023;25:euad184.
20. Afzal MR, Okabe T, Koppert T, et al. Implantation of subcutaneous defibrillator is feasible and safe with monitored anesthesia care. Pacing Clin Electrophysiol 2019;42:1552–1557.
21. Romero J, Bello J, Díaz JC, et al. Tumescent local anesthesia versus general anesthesia for subcutaneous implantable cardioverter-defibrillator implantation. Heart Rhythm 2021;18:1326–1335.
22. Zeppenfeld K, Tfelt-Hansen J, de Riva M, et al. 2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: developed by 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 the Association for European Paediatric and Congenital Cardiology (AEPC). Eur Heart J 2022;43:3997–4126.
23. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. Circulation 2018;138:e272–e391.
24. Knops RE, Olde Nordkamp LR, Delnoy PH, et al. Subcutaneous or transvenous defibrillator therapy. N Engl J Med 2020;383:526–536.
25. Kutyifa V, Rosero SZ, McNitt S, et al. Need for pacing in patients who qualify for an implantable cardioverter-defibrillator: clinical implications for the subcutaneous ICD. Ann Noninvasive Electrocardiol 2020;25:e12744.
26. Gulletta S, Gasperetti A, Schiavone M, et al. Age-related differences and associated mid-term outcomes of subcutaneous implantable cardioverter-defibrillators: a propensity-matched analysis from a multicenter European registry. Heart Rhythm 2022;19:1109–1115.
27. Healey JS, Krahn AD, Bashir J, et al. Perioperative safety and early patient and device outcomes among subcutaneous versus transvenous implantable cardioverter defibrillator implantations: a randomized, multicenter trial. Ann Intern Med 2022;175:1658–1665.
28. D'Souza BA, Epstein AE, Garcia FC, et al. Outcomes in patients with congenital heart disease receiving the subcutaneous implantable-cardioverter defibrillator: results from a pooled analysis from the IDE study and the EFFORTLESS S-ICD registry. JACC Clin Electrophysiol 2016;2:615–622.
29. 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.
30. El-Chami MF, Levy M, Kelli HM, et al. Outcome of subcutaneous implantable cardioverter defibrillator implantation in patients with end-stage renal disease on dialysis. J Cardiovasc Electrophysiol 2015;26:900–904.
31. Poole JE, Gold MR. Who should receive the subcutaneous implanted defibrillator? The subcutaneous implantable cardioverter defibrillator (ICD) should be considered in all ICD patients who do not require pacing. Circ Arrhythm Electrophysiol 2013;6:1236–1244 [discussion: 1244–1245].
32. Kohli U, von Alvensleben J, Srinivasan C. Subcutaneous implantable cardioverter defibrillators in pediatrics and congenital heart disease. Card Electrophysiol Clin 2023;15:e1–e16.
33. Migliore F, Biffi M, Viani S, et al. Modern subcutaneous implantable defibrillator therapy in patients with cardiomyopathies and channelopathies: data from a large multicentre registry. Europace 2023;25:euad239.
34. Francia P, Ziacchi M, Adduci C, et al. Clinical course of hypertrophic cardiomyopathy patients implanted with a transvenous or subcutaneous defibrillator. Europace 2023;25:euad270.
35. Jankelson L, Garber L, Sherrid M, et al. Subcutaneous versus transvenous implantable defibrillator in patients with hypertrophic cardiomyopathy. Heart Rhythm 2022;19:759–767.
36. Cadrin-Tourigny J, Krahn AD, Saba M. Anti-tachycardia pacing in ARVC: should a transvenous or subcutaneous system be used? Europace 2023;25:euad132.
37. Dendramis G, Brugada P. Lights and shadows of subcutaneous implantable cardioverter-defibrillator in Brugada syndrome. Heart Rhythm 2023;20:274–281.
38. Sakhi R, Yap SC, Michels M, et al. Evaluation of a novel automatic screening tool for determining eligibility for a subcutaneous implantable cardioverter-defibrillator. Int J Cardiol 2018;272:97–101.
39. Olde Nordkamp LR, Warnaars JL, Kooiman KM, et al. Which patients are not suitable for a subcutaneous ICD: incidence and predictors of failed QRS-T-wave morphology screening. J Cardiovasc Electrophysiol 2014;25:494–499.
40. Randles DA, Hawkins NM, Shaw M, Patwala AY, Pettit SJ, Wright DJ. How many patients fulfil the surface electrocardiogram criteria for subcutaneous implantable cardioverter-defibrillator implantation? Europace 2014;16:1015–1021.
41. Waldmann V, Marquié C, Bessière F, et al. Subcutaneous implantable cardioverter-defibrillators in patients with congenital heart disease. J Am Coll Cardiol 2023;82:590–599.
42. Zormpas C, Silber-Peest AS, Eiringhaus J, et al. Eligibility for subcutaneous implantable cardioverter-defibrillator in adults with congenital heart disease. ESC Heart Fail 2021;8:1502–1508.
43. Wang L, Javadekar N, Rajagopalan A, et al. Eligibility for subcutaneous implantable cardioverter-defibrillator in congenital heart disease. Heart Rhythm 2020;17:860–869.
44. Conte G, Kawabata M, de Asmundis C, et al. High rate of subcutaneous implantable cardioverter-defibrillator sensing screening failure in patients with Brugada syndrome: a comparison with other inherited primary arrhythmia syndromes. Europace 2018;20:1188–1193.
45. Tachibana M, Nishii N, Morita H, et al. Exercise stress test reveals ineligibility for subcutaneous implantable cardioverter defibrillator in patients with Brugada syndrome. J Cardiovasc Electrophysiol 2017;28:1454–1459.
46. Guo L, Zhang M, Hu M, et al. Prevalence of subcutaneous implantable cardioverter-defibrillator based on template ECG screening and ineligible surface ECG predicting factors in patients with hypertrophic cardiomyopathy in China. Heart Vessels 2019;34:851–859.
47. Francia P, Adduci C, Palano F, et al. Eligibility for the subcutaneous implantable cardioverter-defibrillator in patients with hypertrophic cardiomyopathy. J Cardiovasc Electrophysiol 2015;26:893–899.
48. Wang W, Gasperetti A, Sears SF, et al. Subcutaneous and transvenous defibrillators in arrhythmogenic right ventricular cardiomyopathy: a comparison of clinical and quality-of-life outcomes. JACC Clin Electrophysiol 2023;9:394–402.
49. Gold MR, Lambiase PD, El-Chami MF, et al. Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) trial. Circulation 2021;143:7–17.

50. Knops RE, van der Stuijt W, Delnoy P, et al. Efficacy and safety of appropriate shocks and antitachycardia pacing in transvenous and subcutaneous implantable defibrillators: analysis of all appropriate therapy in the PRAETORIAN trial. Circulation 2022;145:321–329.
51. Moss AJ, Schuger C, Beck CA, et al. Reduction in inappropriate therapy and mortality through ICD programming. N Engl J Med 2012;367:2275–2283.
52. Poole JE, Johnson GW, Hellkamp AS, et al. Prognostic importance of defibrillator shocks in patients with heart failure. N Engl J Med 2008;359:1009–1017.
53. Knops RE, Lloyd MS, Roberts PR, et al. A modular communicative leadless pacing-defibrillator system. N Engl J Med Published online May 18, 2024.
54. 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.
55. 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.
56. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation 2013;128:944–953.
57. Brisben A. How the S-ICD (subcutaneous implantable cardiac defibrillator) senses cardiac signals to minimize cardiac over-sensing and maximize rhythm discrimination. J Electrocardiol 2018;51:S38–S43.
58. Monkhouse C, Wharmby A, Carter Z, et al. Exploiting SMART pass filter deactivation detection to minimize inappropriate subcutaneous implantable cardioverter defibrillator therapies: a real-world single-centre experience and management guide. Europace 2023;25:euad040.
59. Rordorf R, Viani S, Biffi M, et al. Reduction in inappropriate therapies through device programming in subcutaneous implantable defibrillator patients: data from clinical practice. Europace 2023;25:euac234.
60. 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.
61. Kooiman KM, Knops RE, Olde Nordkamp L, Wilde AA, de Groot JR. Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: implications for management. Heart Rhythm 2014;11:426–434.
62. Knops RE, Pepplinkhuizen S, Delnoy P, et al. Device-related complications in subcutaneous versus transvenous ICD: a secondary analysis of the PRAETORIAN trial. Eur Heart J 2022;43:4872–4883.
63. Glikson M, Nielsen JC, Kronborg MB, et al. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. Eur Heart J 2021;42:3427–3520.
64. Lüker J, Strik M, Andrade JG, et al. Incidence of premature battery depletion in subcutaneous cardioverter-defibrillator patients: insights from a multicenter registry. J Interv Card Electrophysiol Published online January 18, 2023.
65. Viani S, Migliore F, Ottaviano L, et al. Longevity of model 3501 subcutaneous implantable cardioverter-defibrillator leads in clinical practice. Heart Rhythm 2022;19:1206–1207.
66. Honarbakhsh S, Providencia R, Srinivasan N, et al. A propensity matched case-control study comparing efficacy, safety and costs of the subcutaneous vs. transvenous implantable cardioverter defibrillator. Int J Cardiol 2017;228:280–285.
67. Knops RE, Brouwer TF, Barr CS, et al. The learning curve associated with the introduction of the subcutaneous implantable defibrillator. Europace 2016;18:1010–1015.
68. Crozier I, Haqqani H, Kotschet E, et al. First-in-human chronic implant experience of the substernal extravascular implantable cardioverter-defibrillator. JACC Clin Electrophysiol 2020;6:1525–1536.
69. Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and safety of an extravascular implantable cardioverter-defibrillator. N Engl J Med 2022;387:1292–1302.
70. Crozier I, Haqqani H, Kotschet E, et al. Three-year chronic follow-up from the pilot study of a substernal extravascular implantable cardioverter-defibrillator. Europace 2023;25:euad301.
71. Theuns D, Brouwer TF, Jones PW, et al. Prospective blinded evaluation of a novel sensing methodology designed to reduce inappropriate shocks by the subcutaneous implantable cardioverter-defibrillator. Heart Rhythm 2018;15:1515–1522.
72. Pothineni NV, Cherian T, Patel N, et al. Subcutaneous implantable cardioverter-defibrillator explantation—a single tertiary center experience. J Innov Card Rhythm Manag 2022;13:4947–4953.
73. Quast AB, Baalman SW, van der Stuijt W, Wilde AA, Knops RE. Minimal defibrillation thresholds and the correlation with implant position in subcutaneous implantable-defibrillator patients. J Cardiovasc Electrophysiol 2019;30:2441–2447.
74. Yap SC, Oosterwerff EF, Boersma LV, et al. Acute human defibrillation performance of a subcutaneous implantable cardioverter-defibrillator with an additional coil electrode. Heart Rhythm 2023;20:1649–1656.
75. Boveda S, Lenarczyk R, Haugaa K, et al. Implantation of subcutaneous implantable cardioverter defibrillators in Europe: results of the European Heart Rhythm Association survey. Europace 2016;18:1434–1439.
76. Brouwer TF, Yilmaz D, Lindeboom R, et al. Long-term clinical outcomes of subcutaneous versus transvenous implantable defibrillator therapy. J Am Coll Cardiol 2016;68:2047–2055.
77. Aydin A, Hartel F, Schlüter M, et al. Shock efficacy of subcutaneous implantable cardioverter-defibrillator for prevention of sudden cardiac death: initial multicenter experience. Circ Arrhythm Electrophysiol 2012;5:913–919.
78. Lambiase PD, Theuns DA, Murgatroyd F, et al. Subcutaneous implantable cardioverter-defibrillators: long-term results of the EFFORTLESS study. Eur Heart J 2022;43:2037–2050.
79. Liang JJ, Okamura H, Asirvatham R, et al. Comparative outcomes of subcutaneous and transvenous cardioverter-defibrillators. Chin Med J (Engl) 2019;132:631–637.
80. Sponder M, Khazen C, Dichtl W, et al. Specific indications and clinical outcome in patients with subcutaneous implantable cardioverter-defibrillator (ICD)—a nationwide multicentre registry. Eur J Intern Med 2018;48:64–68.
81. Gold MR, El-Chami MF, Burke MC, et al. Postapproval study of a subcutaneous implantable cardioverter-defibrillator system. J Am Coll Cardiol 2023;82:383–397.
82. Al-Ghamdi B, Shafquat A, Alruwaili N, Emmanual S, Shoukri M, Mallawi Y. Subcutaneous implantable cardioverter defibrillators implantation without defibrillation threshold testing: a single center experience. Cardiol Res 2017;8:319–326.
83. Gasperetti A, Schiavone M, Ziacchi M, et al. Long-term complications in patients implanted with subcutaneous implantable cardioverter-defibrillators: real-world data from the extended ELISIR experience. Heart Rhythm 2021;18:2050–2058.
84. Sasaki S, Tomita H, Tsurugi T, et al. Safety and efficacy of subcutaneous cardioverter defibrillator in patients at high risk of sudden cardiac death—primary Japanese experience. Circ J 2018;82:1546–1551.