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

Jeanne E. Poole, MD; Michael R. Gold, MD, PhD

The evolution of implantable cardioverter defibrillator (ICD) technology for the past 3 decades has been nothing short of explosive, incorporating progressively transvenous leads, multizone programming, dual chamber antibradycardia pacing, antitachycardia pacing (ATP), sophisticated single- and dual-chamber discrimination algorithms, cardiac resynchronization therapy (CRT), and programmable options numbering into the thousands. As a consequence, ICDs have been used to treat patients with a variety of clinical needs, including those with a known history of ventricular tachycardia (VT), survivors of out of hospital cardiac arrest, patients with requirements for pacing or resynchronization with concomitant indications for an ICD, and patients who do not fit within these categories but are at risk for sudden cardiac death (SCD).

Response by Rav Acha and Milan on p 1244

Typically, the efficacy of most cardiac therapies is assessed initially on the sickest patients or those at highest risk. Such was the case for the ICD that was initially approved only for patients who had survived cardiac arrest. These early systems had epicardial leads and no pacing capabilities. Subsequently, transvenous lead systems and other advances were made in ICD technology, as noted above. However, these devices were approved and used based on the demonstration of the ability to detect and to terminate VT and ventricular fibrillation (VF). In fact, more complex therapies are not always better for patient outcomes. The Dual Chamber and VVI Implantable Defibrillator (DAVID) trial showed that indiscriminate right ventricular pacing is associated with increased risk of heart failure hospitalization and death, and more recent analyses continue to question the overuse of dual chamber devices.1,2 Similarly, CRT may be associated with more heart failure hospitalization among patients without QRS prolongation.3 The landmark prospective randomized trials showed a mortality benefit of ICDs for both primary and secondary prevention of SCD. The early secondary prevention trials, such as Antiarrhythmics versus Implantable Defibrillator (AVID) and Canadian Implantable Defibrillator Study (CIDS), used both epicardial and transvenous lead systems, with devices capable of limited programming with little or no pacing.4,5 Transvenous leads were subsequently developed to simplify the implant procedure and to reduce the morbidity of thoracotomy for implantation.6 The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) used single-lead ICDs, whereas the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) allowed the use of dual-chamber ICDs.7,8 Although the ICD achieved the intended goal to prevent death from life-threatening arrhythmias, transvenous leads have their own risks, such as pneumothorax, cardiac tamponade, upper extremity DVT, and pulmonary embolus. As survival improves...
in the ICD population, the long-term risks of lead malfunction and infection become greater concerns. Studies have shown that >20% of patients will have a lead failure by 10 years, and this observation does not include recalled leads, such as Fidelis and Riata, that have shown much higher failure rates.9–11

Given the short- and long-term risks of ICDs, it is important to select the right device carefully for each patient. Indiscriminate use of CRT, dual-chamber ICDs, suboptimal programming, or poorly designed transvenous leads undermines the role of these devices to prevent SCD. It is in this context that the subcutaneous (S)-ICD should be considered for patients without pacing needs undergoing ICD implantation.

### S-ICD Efficacy

One concern with any new technology is to confirm that it performs the function for which it is designed. As already discussed, the primary purpose of an ICD is to detect and to terminate life-threatening ventricular arrhythmias. Early studies with the S-ICD confirmed the ability to detect and defibrillate.12

The IDE (Investigational Device Exemption) study, which was designed and performed to provide data for Food and Drug Administration approval of this system, allowed for a more rigorous evaluation of the performance of this device prospectively.13 The 180-day freedom from the primary safety end point was 99% and was 92% from any complication related to the device or implant. This was well above the minimum level established as a coprimary end point on the basis of similarly conducted trials of transvenous systems. The primary efficacy end point was the acute conversion of induced VF (2 consecutive successes of 4 trials). Of the 321 patients undergoing device implantation, testing was not performed on 1 subject, and another 16 (5%) did not complete the protocol. The defibrillation efficacy end point was achieved in all 304 subjects (100%) who completed the protocol. Sensitivity testing showed that even in a worst case scenario, this conversion performance was also well above the prospectively defined end point criterion. The detection of VF without significant delay was >99%, and all spontaneous VT/VF episodes were terminated by S-ICD shocks or spontaneously terminated. For spontaneous VT/VF episodes, first shock efficacy was 92.1%, which was similar or better than published reports using transvenous systems.14,15 Moreover, all episodes spontaneously terminated or were terminated with an S-ICD shock with no external defibrillation or arrhythmic death in this trial. Overall, this study clearly demonstrated the safety and efficacy of the S-ICD.

### Who Are the Right Patients for an S-ICD?

There are certain groups of patients who many consider to be excellent candidates for the S-ICD. These include niche indications, such as subjects with no or limited vascular access including patients with congenital heart abnormalities. Other excellent potential patients include those with channelopathies at risk of sudden death but not of monomorphic VT, such as long-QT syndrome, Brugada syndrome, and hypertrophic cardiomyopathy. Cohorts that are disproportionately enriched with an S-ICD use in the S-ICD clinical trials and other registries include those with previous transvenous ICD infection and lead malfunction, cardiac arrest survivors with preserved ejection fractions, and hemodialysis patients.16 However, the more recent experience in Europe suggests that the S-ICD is increasingly used in the more commonly indicated primary prevention patients with cardiomyopathy and secondary indicated patients who have VT or VT.17

Notwithstanding the appeal of an ICD with no transvenous leads for these unique populations, the most common indication for ICD use currently is for primary prevention among dilated and ischemic cardiomyopathy cohorts. Should these patients also be considered for an S-ICD, and would this device provide a better option for many?

This question is particularly pertinent given increasing concerns raised on the relative risks and benefits of primary prevention ICD therapy. These concerns include the relatively low ICD use rates observed in clinical trials, the safety of ICD shocks, inappropriate ICD therapy rates, and complications, both surgical and medical associated with implantation of these devices. These issues will be discussed, focusing on how the S-ICD is well positioned to address them.

The MADIT II and SCD-HeFT randomized clinical trials established the ICD as superior therapy to medical therapy alone to prevent death from life-threatening ventricular tachyarrhythmias using primarily single-lead devices.2,3 Nonetheless, ICD use rates in these trials have often been criticized as too low to justify the use of an expensive technology that carries procedural risk to the broad population of patients targeted by these studies. Counterpoint to the perception of low ICD use rates is the fact that between one fifth and one quarter of patients received appropriate ICD therapy over the course of the studies’ respective follow-ups (21 months and 45.5 months), many of whom would have otherwise succumbed to SCD.18,19 These are not trivial rates, especially when one considers the progressive nature of heart failure and the associated persistent risk of SCD.20 However, it remains true that a majority of patients will not use their device in the first years after implant, and many will never experience VT or VF before dying from end-stage heart failure. During these years, the patient is exposed to the adverse risks of transvenous ICD leads.

Efforts to improve risk stratification of patients considered for ICD therapy have been undertaken by numerous investigators, including the use of multiple clinical variables, myocardial scar burden, and perturbations of electrocardiographic features, such as T-wave alternans, signal-averaged ECG, and heart rate variability.21–31 These strategies are generally associated with moderate to high predictive capacity for VT/VF events or all-cause mortality, but no one tool has demonstrated adequate specificity and sensitivity specifically for reducing mortality because of SCD.

One of the reasons for this discrepancy is that ICD treatment for VT/VF is not the same as prevention of SCD. Consistently, appropriate ICD use rates are approximately double the rescue from SCD in the same trials.1,18,19,21,32,33 This observation, in part,
reflects earlier programming strategies that tended to emphasize rapid detection of a tachyarrhythmia. However, the singular benefit of ICD therapy is to prevent death after the spontaneous initiation of high-rate ventricular arrhythmias that are not in the setting of otherwise terminal disease. Therefore, to enhance the specificity of ICD therapy, clinical risk models must be able to discriminate between modes of death (progressive heart failure or SCD) and not just appropriate ICD therapy for VT or VF. Ventricular arrhythmias may be epiphenomenon to death caused by end-stage disease, be it heart failure or otherwise. The ICD will be credited with appropriate therapy; however, these situations are not the same as a save from SCD.

The patients most likely to benefit from ICD therapy are those whose highest proportional mode of death is SCD, patients with less severe heart failure. This concept was well described in trials of heart failure medical therapy. For instance, in the Metoprolol CR/XL Randomised Intervention Trial in Congestive Heart Failure (MERIT-HF) study, patients were identified on a continuum of higher overall mortality according to New York Heart Association (NYHA) class IV heart failure compared with less ill NYHA class I/II heart failure coincident with an increase in the absolute number of patients dying of SCD. However, as a proportion of total deaths, the percentage of SCD decreases as the patient progresses from mild to severe heart failure. That is, those patients most likely to benefit from an ICD are the same patients least likely to die overall (lower total mortality event rates). However, NYHA alone is inadequate to identify these patients. Risk models using commonly collected clinical factors were studied in both MADIT II and SCD-HeFT and support this premise. Both of these analyses demonstrated that the lowest risk patients (for all-cause mortality) were benefited most from the ICD, whereas the highest risk patients did not benefit from the ICD. Estimation of life-years saved using the Seattle Heart Failure Model applied to the SCD-HeFT ICD and placebo patients showed that a single-lead ICD can extend a low-risk patient’s life by 5 to 10 years (Figure 1). However, the paradox persists that among those most likely to benefit, many will not experience VT or VF. Thus, the S-ICD is a reasonable first line of therapy especially for the less ill patients who have a clinical episode of VT. However, to understand whether ATP should be a mandatory option for primary prevention indicated patients, the likelihood of developing first time monomorphic VT needs to be understood.

When considering primary prevention patients, many physicians think that a device which does not provide ATP to be inferior therapy. ATP was introduced early in the development of the ICD to avoid shocks for patients with monomorphic VT. This makes sense for secondary prevention indicated patients who have a clinical episode of VT. However, to understand whether ATP should be a mandatory option for primary prevention indicated patients, the likelihood of developing first time monomorphic VT needs to be understood. Data from SCD-HeFT are helpful in this regard. SCD-HeFT enrolled 2521 patients with NYHA class II or III ischemic and nonischemic heart failure to receive an ICD, amiodarone, or placebo drug therapy. The single-lead ICD used in the trial was protocol proscribed for shock-only treatment and for arrhythmias ≥188 beats per minute to unify therapy type for study analysis and because patients enrolled into the trial had no previous history of sustained ventricular arrhythmias.

Of the 811 SCD-HeFT ICD patients, 182 (22%) received at least 1 ICD shock for VT or VF. Fifty percent of these 182 patients (12% of the 811) had at least 1 episode of de novo VF not preceded by any VT, while two-thirds of the 182 patients (15% of 811) had one or more episodes of monomorphic VT (≥188 bpm). Therefore, it could be estimated that ≥15% of patients with moderate heart failure may experience high rate monomorphic VT during the first few years following ICD placement. SCD-HeFT data again can be examined to understand the likelihood of having more than a single episode of high rate monomorphic VT. Over the course of the 45.5 months of follow up, only 1/3 of the patients with VT had more than a single episode, representing only 7% of the 811 ICD patients in the trial, or a 1.8% per year risk. This is lower than the risk of transvenous lead failure in many registries and trials, as noted previously.

The perceived requirement for ATP championed by many must be considered on balance with the benefit of S-ICD therapy for patients whose risk of any VT, much less recurrent VT, for the first few years after implant is low. ATP is also not without risk. Although acceleration to unstable VT or VF is uncommon, it nevertheless is reported in ≤5% of instances that may place the patient at greater risk because of degeneration of the rhythm to a faster, unstable, and poorly tolerated rhythm. Also, ATP occurs sooner than a shock.
as it is delivered immediately after detection criteria is met, whereas a shock can be delivered only after capacitor charging that generally varies between 4 and 10 s depending on shock strength and battery voltage. It has been shown in multiple studies that patients with ICDs programmed to include ATP when compared with those programmed for shock-only therapy have substantially more appropriate VT events, suggesting that many of those same events would have self-terminated had a longer time to therapy delivery been allowed.38,39

Recent data from the Reduction in Inappropriate Therapy and Mortality through ICD Programming (MADIT-RIT) study supports a strategy of simplified programming.40 This study randomized 1500 patients to 3 treatment strategy arms. The control group was programmed to treat rates >170 beats per minute with a short delay after initial detection and multiple ATP sequences in the lower rate zone. The comparator groups were either a single zone of therapy at 200 beats per minute with conventional detection delay or a 3-zone therapy arm with prolonged delays; both included use of ATP. Both comparator groups programming strategies were associated with a significant reduction in appropriate and inappropriate ICD therapy. In addition to more ICD shocks, there was a significant 3 to 5 times greater use of ATP in the conventional programming arm versus the comparator arms. Importantly, the patients randomized to the programming strategy of single zone, high rate had a significant reduction in all-cause mortality when compared with those of the conventional programming. The simpler S-ICD programming platform dovetails well with these results providing high-rate zones of therapy and prolongation of the time from detection to shock delivery, thereby minimizing unnecessary ICD therapy. In the S-ICD IDE trial, the time to therapy for appropriate shocks was 14.6±2.9 s,13 which is within the range of prolongation of detection shown to be beneficial in MADIT-RIT.

One of the drivers for dependence on ATP therapy is the perception that ICD shock-induced myocardial damage is directly increasing adverse outcomes among ICD recipients. Significant confusion exists around the interpretation of ICD shocks and subsequent mortality. Consistently, patients who experienced ICD shocks for VT or VF in multiple ICD clinical trials were observed to have a 3- to 5-fold greater subsequent mortality than patients who did not experience an ICD shock.18,19,41,42 The 2 possible conclusions are (1) the shocks were directly harmful to patients or (2) the rhythms for which ICD shocks were delivered identified patients more likely to subsequently die. The first conclusion contradicts the results of the randomized clinical ICD trials, which consistently demonstrated reductions in all-cause mortality with ICDs that primarily provided shock therapy. The observation that mortality was also associated with ICD shocks for inappropriate causes continued to foster the debate that ICD shocks were harmful.19,43 However, inappropriate therapies are most often because of atrial fibrillation, a known adverse risk predictor in patients with heart failure.44,45 Other causes of inappropriate therapies include supraventricular tachyarrhythmias, oversensing, or artifact. The relatively small number of patients in the randomized clinical trials experiencing ICD therapies precluded being able to differentiate the association of risk with ICD shocks for abnormal rhythms versus ICD shocks delivered for nonrhythmia triggers. However, recently, a report from the Altitude Study Investigators, using data from the Latitude remote monitoring database, examined the risk of mortality associated with ICD shocks in >3000 patients.46 This study demonstrated that ICD shocks for sinus tachycardia, oversensing, or artifact were not associated with excess mortality, whereas ICD shocks for true arrhythmias (VT/VF and atrial fibrillation) were associated with higher subsequent mortality. These data lend support to the conclusion that abnormal rhythms confer the risk to the patient and not the ICD shock energy per se. Further analysis of this database recently demonstrated reduced patient survival associated with both ATP- and ICD-treated VT.47 Particularly disturbing, the risk of mortality was highest in the 1.6% of patients who experienced acceleration of VT when treated with ATP (hazard ratio, 3.03; 95% confidence interval, 2.65–3.46).

Collectively, the weight of evidence supports the conclusion that patients with heart failure who experience VT/VF or atrial fibrillation are a high-risk patient group with increased subsequent mortality when compared with patients who do not experience ICD therapy for these rhythms. Shock reduction strategies, including ICD programming incorporating ATP, have not demonstrated a reduction in mortality.48,49 Thus, positing an argument against the S-ICD based solely on a conclusion that ICD shock-related myocardial injury is a risk mitigated by ATP is not supported by recent clinical trial data.

An additional concern that physicians may pose in considering the S-ICD is whether the rates of inappropriate or unnecessary ICD therapy are worse than those reported for transvenous ICD therapy. A comparison of inappropriate shock rates from the S-ICD IDE trial with those reported from several clinical studies shows that the S-ICD performs favorably in this regard (Figure 2).

Figure 2. Comparison of inappropriate ICD therapies reported from six ICD clinical trials and the S-ICD IDE study. Studies differ by inclusion of ICD shocks, ATP or both and trigger of therapy (supraventricular arrhythmias with or without inclusion of oversensing or nonsustained VT). The average follow-up time is noted above each bar. *Data included only from the randomized β-blocker only group. SCD-HeFT is Sudden Cardiac Death in Heart Failure Trial,7 MADIT II is Multicenter Automatic Defibrillator Implantation Trial,7 DEFINITE is Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation,70 PAIN Free II is Optimal Pharmacological Therapy in Cardioverter Defibrillator Patients,71 S-ICD is Subcutaneous ICD IDE study.13 mo indicates months.
Arrhythmia discrimination algorithms are an important component of the strategy to reduce inappropriate therapy. A recent, prospective, randomized study (RIGHT) showed that such algorithms are not generic, with significant differences between manufacturers.49 With regard to the S-ICD, the START (Subcutaneous versus Transvenous Arrhythmia Recognition Testing) study compared the classification of a variety of arrhythmias by the S-ICD and multiple transvenous pulse.50 Identical supraventricular and ventricular arrhythmias were tested with devices programmed to nominal settings. All devices accurately and appropriately detected VF. Notably, the S-ICD showed the best specificity for discriminating supraventricular arrhythmias, including atrial fibrillation. It outperformed the composite results of transvenous systems, which was the primary end point of this study (Table 1) and was statistically superior to 2 of 3 individual systems. Among transvenous systems, a dual-chamber device did not perform better than a single-chamber device. It is noteworthy that nominal settings were used in this trial to avoid bias, and it is likely that better performance can be achieved with programming to non-nominal values, such as longer duration or higher detection rates. It is also possible that newer generation pulse generators may discriminate arrhythmias more accurately.

Although the results of the START study are encouraging, this was not an evaluation of implanted S-ICD systems. In this regard, an analysis of the S-ICD IDE cohort is informative.13 The S-ICD offers 2 zones of therapy, both a high-rate zone and a conditional zone where supraventricular tachyarrhythmias–VT discriminators can be applied. In this study, with blinded adjudication of data, the use of a conditional zone resulted in a 70% reduction of inappropriate shocks for supraventricular arrhythmias.51 Moreover, the rates of inappropriate shocks noted in these early experiences may be an overestimation of rates in clinical practice as a learning curve exists with regard to management of this device resulting in further reductions in shock rates.13

**Complications of Transvenous ICD Therapy**

One of the greatest advantages of the S-ICD is avoidance of transvenous lead complications, which are substantial. These include lead fractures with associated failure to treat life-threatening rhythms, inappropriate ICD therapy, complications of lead extraction, infection, and occlusion of upper extremity veins. Reported complication rates are highly variable and dependent on whether de novo single- or dual-chamber ICDs or CRTs are included, and the follow-up time for which the study was conducted. For instance, significant complications were reported in 14% of patients who received an ICD in SCDF-HeFT for a median follow-up of 45.5 months, but in only 2.5% of patients with ICD in the MADIT II study at an average follow-up of 21 months.7,8 In addition to the difference in follow-up time, the types of complications specified to be collected were vastly different.

The largest number of patients contributing to contemporary estimates of procedure-related complications comes from the National Cardiovascular Data ICD Registry database.32 Adverse procedure-related events (to hospital discharge) reported in 268701 ICD recipients occurred in 3.2% of patients with new ICD implants between 2006 and 2009. Similarly, the major complication rate reported on 3340 de novo ICD implants from the Ontario ICD database was 3.8% in patients who received an ICD for a primary prevention indication and 4.8% in patients who received an ICD for a secondary prevention indication at 45 days.53 Neither of these registry studies assessed the longer term risk of device therapy, which may not occur for months or years from initial device implantation.

Lead-related complications account for a significant proportion of both early and late reported complications. Lead dislodgements are reported to occur in as many as 6.6% of newly implanted ICD leads and can occur anytime from immediately postprocedure to many months later. The acute lead dislodgement rate reported from the National Cardiovascular ICD Data Registry was 1.2% before hospital discharge for.34 Lead-related major complications comprised 3 of the 5 most frequently observed major complications in the Ontario ICD database, with rates ranging from 0.8% to 2.7%.53 The risk generally increases accordingly with the number of leads implanted.35-57 In a recent analysis of the National Cardiovascular Data ICD Registry, Peterson et al examined complication rates in 32034 patients receiving a de novo single- or dual-chamber ICD. Complications were significantly less for single-chamber ICD recipients when compared with dual-chamber ICD recipients (3.5% versus 4.7%; P<0.001). A further observation that favors the S-ICD is that transvenous lead ICD complications tend to be higher in women.52,58

**Table 1. Primary Results From START Comparing Transvenous and Subcutaneous Discrimination of Induced Supraventricular Arrhythmias**

| Specificity Results for Transvenous* and S-ICD Systems |
|-----------------|----------|----------|
|                 | Single Chamber | Dual Chamber | S-ICD |
| Appropriately withheld therapy | 115 | 100 | 49 |
| Inappropriate shock | 35 | 47 | 1 |
| Specificity, % | 77 | 68 | 98 |

Adapted from Rowley and Gold.72 S-ICD indicates subcutaneous implantable cardioverter defibrillator.

*Pooled results from 3 manufacturers with devices programmed in single- or dual-chamber mode.
Table 2. Characterization of Patient Groups for S-ICD Implantation

<table>
<thead>
<tr>
<th>S-ICD is preferred device</th>
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</thead>
<tbody>
<tr>
<td>No venous access (occluded veins or congenital anomalies)</td>
</tr>
<tr>
<td>High risk of complications for transvenous systems have (dialysis, pediatric, and immunocompromised)</td>
</tr>
<tr>
<td>Channelopathies (long-QT syndrome, Brugada, hypertrophic cardiomyopathy)</td>
</tr>
<tr>
<td>Previous device infections or lead failures</td>
</tr>
<tr>
<td>History of endocarditis</td>
</tr>
<tr>
<td>S-ICD should be strongly considered</td>
</tr>
<tr>
<td>Young patients</td>
</tr>
<tr>
<td>Life expectancy &gt;10 y</td>
</tr>
<tr>
<td>Primary prevention indicated patients with ischemic/nonischemic heart failure</td>
</tr>
<tr>
<td>Prosthetic valves</td>
</tr>
<tr>
<td>Women (preferred generator placement lateral wall)</td>
</tr>
<tr>
<td>Selected secondary prevention indicated patients (survivors of out-of-hospital VF, no evidence of monomorphic VT)</td>
</tr>
<tr>
<td>S-ICD should be avoided</td>
</tr>
<tr>
<td>Systolic heart failure and LBBB who are indicated for CRT</td>
</tr>
<tr>
<td>Symptomatic bradycardia requiring pacemaker</td>
</tr>
<tr>
<td>Recurrent sustained monomorphic VT for whom ATP is deemed appropriate</td>
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ATP indicates antitachycardia pacing; CRT, cardiac resynchronization therapy; LBBB, left bundle branch block; S-ICD, subcutaneous implantable cardioverter defibrillator; and VT, ventricular tachycardia.

Collectively, the potential for serious adverse effects related to transvenous lead systems is substantial. Given the primary purpose of the ICD to rescue a patient from unanticipated SCD, the S-ICD offers a clear advantage in avoiding transvenous lead-related risks, postponing their use until and only if required for pacing indications.

There are several other aspects of the S-ICD system that may influence the recommendation of whether this is the right device for a patient. By avoiding vascular access, this preserves the venous system for other purposes, such as infusion ports, dialysis catheters, hemodynamic monitoring, autonomic modulation, etc. In addition, the position of the pulse generator inferolateral to the breast has cosmetic advantages for many patients, and particularly women, who prefer this to an anterior, infraclavicular position, despite a larger pulse generator size. Patients that may be considered appropriate candidates for an S-ICD are shown in Table 2.

Finally, the option of an S-ICD may also address concerns raised on underuse of ICD therapy. Patients with well-compensated NYHA class II heart failure may be overlooked for ICD therapy. Although highly symptomatic patients are likely to be under the care of heart failure specialists and thus considered for ICD or CRT therapy, the less ill patient is more likely to be followed by their primary care physician or general cardiologists where the risk of SCD may not be considered a realistic threat, the risks of ICD therapy are considered too high or the medical practice guidelines less familiar. If such patients reside in communities far removed from large tertiary and quaternary referral centers, the problem of underuse may be further exaggerated. The benefits of the S-ICD may allay some of the concerns expressed by referring physicians and provide a renewed opportunity to highlight SCD prevention in this patient population, with appropriate referral to an electrophysiologist for consideration of an ICD.

In summary, the S-ICD is a new technology that is proven to be safe and effective. The earliest implants of this system were in 2008, so these systems have been in place for ≤5 years with no signs of conductor or insulation failures. It has obvious advantages and some disadvantages when compared with transvenous systems, including the need for appropriate training to address the differences in surgical technique required to implant the S-ICD. However, the ability to provide implantable defibrillation therapy to patients without the use of a transvenous lead is an important advance and should help to reduce complications and expand the use of ICD therapy. Of note, this device has been used in much fewer centers than transvenous ICD. The excellent outcomes noted above may reflect the training of physicians and other personnel at these sites, which should be recommended for all new centers adopting this technology. Although we would not advocate that this device or this approach will completely replace transvenous ICDs in its current iteration, there is little doubt that it should be strongly considered in the decision process of selecting devices for many patients, including most primary prevention indicated patients who are early in the course of heart failure. These decisions need to be individualized given the complexity of factors that influence device choices, but the S-ICD is an important addition to our armamentarium for reducing SCD.

Disclosures
Dr Poole has equity interests in Cameron Health and serves on the advisory board for Boston Scientific. She receives honoraria from Biotronik, Boston Scientific, and Medtronic. Her institution receives fellowship educational support from Boston Scientific, Medtronic, and St Jude Medical. Her institution receives research funding from Boston Scientific and St Jude Medical. Dr Gold receives honoraria and research support and serves on the advisory board for Cameron Health, receives honoraria and research support from Boston Scientific, receives honoraria and research support and serves on the advisory board for Medtronic, and receives honoraria and research support from St Jude.

References


References


Key Words: arrhythmias, cardiac implantable defibrillators, implantable

Response to Jeanne E. Poole, MD, and Michael R. Gold, MD, PhD

Moshe Rav Acha, MD, PhD; David Milan, MD

We commend Drs Poole and Gold for a well-written article. Although we agree that a well-functioning subcutaneous implantable cardioverter defibrillator (S-ICD) system that bypasses implantation risks and long-term complications of transvenous leads could advance SCD protection, we still have concerns about the function and long-term performance of the current S-ICD. The device is designed and approved to prevent SCD, but there are still no clinical data that demonstrate it can prevent SCD or prolong life.

One of the potential disadvantages of the S-ICD system is arrhythmia detection and time to therapy. The authors cite the START trial as evidence of excellent arrhythmia detection by S-ICD. However, this trial tested S-ICD performance in vitro and included a few dozen induced arrhythmia episodes. Although the results are encouraging, the authors of the START trial (Dr Gold among them) point out that prospective long-term follow-up on S-ICD real-life arrhythmia detection and discrimination are needed.

Significantly longer detection times are also a concerning caveat of this device. The authors claim that the S-ICD mean time to therapy of 14.2 s, as revealed in the IDE (Investigational Device Exemption) trial, is similar to the delayed therapy programming shown to be beneficial in the Reduction in Inappropriate Therapy and Mortality with ICD Programming (MADIT-RIT) trial. However, they did not note that the delayed therapy programming was primarily in the ventricular tachycardia zone, whereas in the fast malignant ventricular fibrillation zone there was no >2.5 s delay in both the high-rate and delayed therapy programming. Moreover, although the S-ICD mean time to therapy was 14.2 s, the time to therapy distribution was not symmetrical with 12% of patients showing time to therapy exceeding 18 s and 5% exceeding 21 s. In addition, these S-ICD times came from the implantation DFT using 65J, but in real-life these devices use 80J, adding even more charge time. There are already published cases where time to therapy has exceeded 24 s and was associated with syncope.

As for defibrillation efficacy, Poole and Gold refer to the IDE study, which is the largest S-ICD study to date, including 321 patients; the first shock efficacy was 92% among those who had successful defibrillation testing. However, for spontaneous events the IDE data is based on only 16 patients highlighting the need for more data to confirm efficacy. Moreover, as the authors themselves note, not all implanted patients could complete defibrillation testing. There were 17 (5.3%) who did not fulfill successful defibrillation testing.

Despite its limitations and caveats, we agree that the S-ICD may be preferred in specific candidates with high infectious risk, limited vascular access, and complex congenital anomalies. However, for the young and active population although we acknowledge their increased lifetime risk of complications, we also think that this young population deserves the most efficacious devices. Furthermore, young active patients likely have a greater risk of shocks from T-wave oversensing during sinus tachycardia and may be at greater risk of complications from prolonged detection intervals during fast malignant arrhythmias while being active. Finally, the anticipated reduced battery life of these devices (5.4 years when compared with 8 years of transvenous devices) will expose these young patients to the risks of multiple generator changes throughout their lives.

In contrast with the authors, we do not think the S-ICD should be used as first-line therapy for primary and secondary prevention until more efficacy data are acquired. Inability to provide antitachycardia pacing (ATP) therapy should make the
S-ICD a second-line device for patients with previous MMVT (monomorphic ventricular tachycardia), especially those successfully treated by ATP. Although results from MADIT-RIT suggest that ATP may not be necessary and could even increase mortality, this study addressed only primary prevention patients and by no means implied the absence of ATP benefit in secondary prevention patients with previously ATP-treated events. Indeed, in the Dutch cohort study, an S-ICD was explanted in a patient because of recurrent MMVT requiring ATP therapy.

Finally, the authors argue that S-ICD can improve the risk benefit balance in low-risk primary prevention patients. There are several implicit assumptions in this argument, including that the subcutaneous system is free of lead-related complications. However, in reality, the S-ICD is not free of such complications, as revealed by 14% complication rate in the large S-ICD registry. The other major assumption is that the S-ICD will have similar real-world efficacy and inappropriate shock rates to the transvenous ICDs, which we feel remains unproven.

On balance, the S-ICD is purported to be a novel protection device for SCD, yet there are no clinical data to demonstrate that it can save lives or prevent SCD. Our role in the coming years will be to examine S-ICD performance in real life, confirm its safety and efficacy, and determine the appropriate candidates who would most benefit from this device.
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