The Subcutaneous Implantable Defibrillator
A New Technology That Raises an Existential Question for the Implantable Cardioverter-Defibrillator

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This is the fourth decade that the implantable cardioverter-defibrillator (ICD) has been in clinical use for the prevention of sudden cardiac death in high-risk patients. As initially envisioned, the purpose of the ICD was to prevent death by delivering a direct current shock to the heart within seconds after onset of a sustained ventricular tachycardia or ventricular fibrillation (VT/VF) event. Continuous hardware and software innovations have transformed the identity, meaning, purpose and value of the device. 

In its first decade of clinical life, the ICD was a minimally featured and, by current standards, bulky device, used exclusively in patients that survived VT/VF, and ~40,000 devices were implanted yearly in the United States. Clinical trials of transvenous ICD systems that provided the evidence base to justify the widespread use of the ICD for primary prevention of sudden death in heart failure patients on optimal background neurohormonal blocking drug therapies used devices that had 20 and 30 years of advances. The ICDs used in the primary prevention trials were able to sense and terminate VT/VF within seconds, defibrillate VF with <10 J in the majority of subjects, and provided 20% to 30% relative risk reductions in mortality. The addition of a left ventricular transvenous epicardial lead to achieve biventricular pacing for patients with heart failure and left bundle-branch block provided an additional mortality benefit and indications for the ICD by improving heart failure status and mortality. Currently, primary prevention indications are the reason for ICD placement in >70% of ICD recipients. Expanded ICD indications and global reimbursement for the device resulted in exponential increases in ICD use, exceeding 350,000 yearly devices implanted in 2008 and >12,000 yearly implants monthly in the United States. This growth resulted in evidence-based recommendations for optimal device programming and provided data on long-term patient outcomes after implantation. The maturity of additional capabilities such as device-based heart failure status diagnostics have defined and added purpose and value to the third and fourth decades of the clinical life of the ICD, and cost analyses of the device are well within acceptable standards. 

In this issue of Circulation, Weiss et al expand on the clinical experience with the entirely subcutaneous ICD that was evaluated in a multicenter clinical trial and has recently gained Food and Drug Administration approval, but is not yet widely distributed for implantation. This ICD poses a significant existential crisis for the now middle-aged standard, transvenous, and fully featured ICD. By design, the subcutaneous ICD is not dependent on a transvenous lead for defibrillation and is associated with a largely defeatured ICD pulse generator that is larger and heavier than a transvenous ICD. The subcutaneous ICD, like its early predecessor, is pared down to a minimal need of the patient with heart failure. Device size and design improvements and the use of dual-chamber ICDs to enhance arrhythmia discrimination, to provide atrioventricular synchrony for biventricular pacing, and to provide atrial rate support became commonplace. Other software features were quickly cadenced into devices to discriminate supraventricular tachycardia from VT, to treat VT with pacing rather than with shock therapies, and to delay the time to shock to allow for spontaneous arrhythmia termination. Finally, remote monitoring capability was added to ICDs and provided the ability to continuously monitor patients and ICD system status daily or, if a symptom arose, to allow the patient to initiate a remote transmission from home. Remotely collected data in hundreds of thousands of patients receiving implants in the United States and Europe have resulted in an enhanced ability to make observations on the use and utility of the fully featured device in the general population of patients implanted with ICDs. One ICD manufacturer’s remote system, in existence since 2006, has >12 million ICD remotely collected transmissions. 

This has resulted in evidence-based recommendations for optimal device programming and provided data on long-term patient outcomes after implantation. The maturity of additional capabilities such as device-based heart failure status diagnostics have defined and added purpose and value to the third and fourth decades of the clinical life of the ICD, and cost analyses of the device are well within acceptable standards. This has occurred to such an extent, that for many ICD recipients, defibrillation has become an almost lesser-order feature, in comparison with the benefits of having the completely featured, Internet-connected system implanted.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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complications involving the transvenous lead placement, and Food and Drug Administration defibrillating lead safety advisories that have impacted >500,000 patients, as well.\textsuperscript{18,19} Extracting transvenous lead systems for lead malfunctions or to make room for other vascular leads requires a unique set of skills, is associated with the need for additional supporting technology, and carries procedural risks.\textsuperscript{5}

The subcutaneous ICD study, performed in >300 patients with an ICD indication and followed for 11 months, demonstrates that the system is safe to implant and effective at acutely terminating VT/VF. Acute defibrillation testing (DFT) with a subcutaneous ICD evokes the experience with earlier generation ICDs that required longer VF sensing and charge times, higher shock energies, and multiple VF inductions. Those issues were overcome with newer-generation transvenous devices to such an extent that there is now debate about the need to perform DFT testing at all.\textsuperscript{4} The need for DFT testing with the subcutaneous ICD may be associated with patient instability and postoperative complications.\textsuperscript{5} It is unclear whether this issue was adequately answered in this study, because 16 patients were excluded from acute DFT testing, mostly because of implanting physician concerns regarding the risk of rendering the patient clinically unstable. In those patients tested, there were no adverse patient outcomes associated with DFT testing, and 2 consecutive defibrillations at 65 J were achieved successfully in every patient. However, a subset of patients (17\%) required shocking wave polarity reversal to achieve 2 successful conversions of induced VF, increasing the number of VF inductions required during implant.

The parasternal subcutaneous ICD defibrillating lead does not require fluoroscopy to implant, but proper placement of the parasternal lead and chest wall pulse generator requires new surgical techniques that were associated with acceptable risk in this study. Because the system was designed overcome the complications and failures associated with transvenous implants, it does achieve those goals. Other acute and chronic complications associated with implanted ICD pulse generators and ICD systems, such as infection and the need for wound revision, were not decreased significantly with this system in comparison with the transvenous pulse generators.\textsuperscript{2-5} Additionally, there was 1 safety advisory field action on a pulse generator during the conduct of the trial that required explant of the pulse generator. Therefore, it is unclear, until a greater experience is accumulated, if the ICD system, in its entirety, will be associated with a lower safety advisory rate.

Because the subcutaneous ICD exists and will be identified completely with the ability to deliver shock therapy outside of the hospital, this will be a critical factor in the success and adoption of this device. Over the follow-up interval reported in this study, the subcutaneous ICD terminated spontaneously occurring VT/VF in 6.5\% of the patients implanted (21 patients). There were a total of 22 episodes of spontaneously occurring monomorphic VT and 16 episodes of VF treated. First and second shock success rate was 92\% and 97\%, respectively. Two patients had multiple successful shocks for VT storm. Although these data are reassuring and comparable to transvenous ICD success rates, the overall number of treated episodes is incredibly small in comparison with the data on transvenous defibrillator therapies delivered outside

the hospital, over the life of the device, that are available for analysis in tens of thousands of patients.\textsuperscript{5,11,12,14} Without the ability to remotely collect episodes in all subcutaneous device recipients, it is difficult to know how the learning around spontaneous VT/VF episodes and treatment will occur, other than the old-fashioned way, through case reports and postapproval registries. This is a significant limitation from a clinical learning and safety advisory perspective.

Over the past several years, as data have accumulated with transvenous ICDs to indicate that shocks themselves increase mortality risk, there has been a great deal of effort around the limitation of shock episodes.\textsuperscript{11,14,20} Newer studies have demonstrated that mortality improvements can occur with programming changes to the device.\textsuperscript{11,13,14} It is unknown whether or not the subcutaneous ICD will result in fewer shocks. There were several episodes of nontreated VT that self-terminated before therapy in this study. The rate of inappropriate shocks with subcutaneous ICD is similar to the transvenous device. Inappropriate shocks are more likely to be caused by oversensing versus atrial fibrillation with a rapid ventricular response, with a subcutaneous versus transvenous ICD.\textsuperscript{6,14} Without remote monitoring capability, it will be difficult to track the occurrences of these episodes in the population of patients who receive the subcutaneous ICD. This is concerning, because the population enrolled in the subcutaneous ICD study were 10 to 20 years younger than the standard transvenous ICD recipient.\textsuperscript{5,10} The age of the subcutaneous ICD recipients indicates that they may be a more active and more prone to oversensing owing to subcutaneous sensing challenges or T-wave double counting.

The features and attributes of the subcutaneous versus transvenous ICD that may translate into clinical gains, losses, and equivalences, or are unknown, are summarized in the Table.

The clinical characteristics of patients enrolled in the subcutaneous ICD trial, with the exception of age, are very similar to those enrolled in primary prevention ICD studies, remotely collected ICD data sets, and the National Cardiovascular Data Registry ICD registry.\textsuperscript{5,10} Selecting the appropriate candidate for the subcutaneous rather than transvenous ICD requires an acknowledgment of the strengths and limitation of each device and an educated guess, as well, regarding the clinical course of the patient, over the battery life of the ICD. The expectation of the need (assuming a battery longevity of 5–8 years for the subcutaneous device) for bradycardia pacing, a left ventricular lead for biventricular pacing, or the need for antitachycardia pacing argues for the transvenous device. Patients with advanced symptom class heart failure or very depressed ventricular function may face additional risk at implant because

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<td><strong>Advantages</strong></td>
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<td><strong>No advanced diagnostics</strong></td>
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BiV indicates biventricular; and ICD, implantable cardioverter-defibrillator.
of the need for at least 2 VF inductions and the longer times to defibrillation associated with the subcutaneous device. There remain a significant percentage of patients with clinical profiles favorable for a subcutaneous device. These predominately include those with prohibitive vascular access issues and those at heightened risk for major systemic infection with an indwelling chronic vascular lead.

Although the subcutaneous ICD is defeated and exists only to defibrillate, it does represent a major engineering feat for an entirely subcutaneous system. Yet, the most profound technology advances in the past decades, particularly in the case of devices, allow for an enhancement of capability (and complexity) to the backend architecture and a simplification of design features and user interface. The subcutaneous ICD does not encompass these features nearly as much as the transvenous device.

In the best of all possible worlds, the subcutaneous ICD will grow and evolve into a device whose design supports the growth of features and capabilities that can evolve with the patient’s condition. This includes integrating wirelessly with other hardware- and software-based healthcare solutions that will enhance the device and the device recipient’s overall medical condition. The enhancements will provide multiple reasons for subcutaneous ICD to exist.

Disclosures

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References


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