The Totally Subcutaneous Implantable Defibrillator

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KEYWORDS

• Subcutaneous implantable cardioverter-defibrillator • S-ICD • Cardiac arrest • Therapy
• Clinical trial

KEY POINTS

- The subcutaneous implantable cardioverter-defibrillator (S-ICD) system is a new therapeutic option for patients at risk of sudden cardiac arrest.
- The S-ICD is implanted in the lateral thoracic region of the body and uses a tunneled lead to sense and deliver therapy.
- The S-ICD system is entirely outside the vasculature/heart, limiting the risk of systemic infection, vascular/cardiac trauma, and device failure.
- Clinical trials suggest that the S-ICD is effective for the sensing, discrimination, and conversion of spontaneous and induced ventricular tachycardia and ventricular fibrillation.
- The S-ICD may be used for both primary and secondary prevention.

A video of the S-ICD implantation procedure accompanies this article at http://www.cardiology.theclinics.com/

INTRODUCTION

Cardiovascular disease is the most common cause of death in the Western world, and sudden cardiac death (SCD) represents approximately 60% of all cardiovascular mortality.[1] The implanted cardioverter-defibrillator (ICD) was developed to address this issue, and since 1980 has shown significant mortality benefits for both the primary and secondary prevention of SCD.[2,3] The development of well-substantiated indications for primary prevention in particular has resulted in a large expansion of potentially eligible patients with diverse clinical needs and potential procedural and device-related risks.[4–6]

Initial ICDs involved epicardial patch electrodes and epicardial rate-sense leads requiring a thoracotomy for implantation. The current standard ICD uses transvenous leads, which, compared with epicardial patches, are associated with significantly fewer complications.[7,8]

However, the placement of a transvenous ICD system still involves considerable risk, with a major complication rate of approximately 1.5%.[9] These risks include hemorrhage, infection, pneumothorax, cardiac perforation, and death.[10–14] Additional risks present after the time of implantation as well, including inappropriate device therapy, endocarditis, vessel occlusion (of particular concern with patients in need of catheter-mediated dialysis), lead dislodgment, valvular dysfunction, and intrinsic lead defects.[15,16] Lead failure either generates inappropriate shocks or impedes appropriate therapy.[17–19] Over the long term, lead failure

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remains a significant limitation of transvenous ICDs, despite decades of lead research and development.[9,17,18,20–27] One series showed the rate of lead failure of 8-year-old systems to be up to 20%.[28] Furthermore, management of these complications frequently involves significant complexity, morbidity, mortality, and cost.[28–39] Lead failures and infection frequently require extraction and placement of new systems, and inappropriate therapies often result in significant pain and psychological trauma to the patient.

An ICD system that remains outside the heart and vasculature involves significantly less risk of the aforementioned complications, and complications that may ensue would be more easily managed. This improved safety profile and reduction in the complexity of implantation and management may reduce the barrier to the provision of life-saving devices in a rapidly expanding population of eligible patients.

A subcutaneous format may offer physiologic benefits as well. Although subcutaneous systems require larger defibrillation energies than transvenous systems, the energy is distributed more evenly throughout the myocardium.[40] The uneven energy associated with transvenous systems cause electroporation, which leads to transient myocardial stunning.[41,42] Animal models have shown significant troponin release associated with transvenous delivery of 35 J of energy, whereas the subcutaneous delivery of 80 J of energy did not raise troponin. Additional studies in humans have shown a relationship between transvenous ICD shocks and mortality.[43–46] The relationship between subcutaneous ICD shocks and mortality is yet to be determined.

The original ICD concept was developed by Schuder and colleagues[47] in 1970. Two electrodes were implanted between the pectoralis muscle and the rib cage, 2 sensing electrodes in the chest wall musculature, and a pulse generator and capacitor were implanted into the abdomen (**Fig. 1**). The fully implanted, automatic system was successful in the defibrillation of induced ventricular fibrillation (VF) in all 3 animals into which it was implanted, requiring 1 to 3 shocks of 23 to 37 J to terminate the rhythm.

More recently, studies were published exploring the clinical application of a subcutaneous system. Burke and colleagues[48] investigated a pectoral can with a subcutaneous electrode over the cardiac apex. This and other studies produced promising results, showing reliable defibrillation in acute and chronically defibrillated patients. The primary limitations to clinical use were the lack of a dedicated detection algorithm and commercial production, and US Food and Drug Administration (FDA) approval of a subcutaneous ICD system. The first of these limitation was addressed by Burke and colleagues[48] with the suggestion that surface electrocardiogram signals could differentiate VF from sinus rhythm using detection already developed for transvenous ICDs,[19] and was further supported by Gold and colleagues[49] with the Subcutaneous versus Transvenous Arrhythmia Recognition Testing (START) trial, which showed improved specificity of arrhythmia detection and lower rates of inappropriate defibrillation in S-ICDs relative to single-chamber or dual-chamber transvenous devices. Gold and colleagues[49] also showed that subcutaneous electrodes did not differ significantly in sensitivity from relative to transvenous electrodes. The manufacturing and regulatory challenge was addressed by Cameron Health Incorporated (San Clemente, CA) with the development of a commercial platform.

The S-ICD system, comprising the SQ-RX 1010 pulse generator and Q-TRAK 3010 subcutaneous electrode, was first permanently implanted in 2008 into 6 patients. Fifty-five additional patients underwent implantation during the CE (Conformité Européenne) study,[50] and more than 1300 more thereafter.[51] Devices have been implanted for primary and secondary prevention, with a wide range of ages (10–82 years), and challenging substrates including tetralogy of Fallot, hypertrophic cardiomyopathy, sinus inversus, transposition of the great vessels, Brugada syndrome, and long QT syndrome.

After preclinical and clinical studies, the S-ICD was approved for commercial use by the European Union in June of 2009. The device was approved for commercial use by the FDA on September 28, 2012. The recognized indication for an implant is to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have any of the following:

- Symptomatic bradycardia
- Incessant ventricular tachycardia (VT)
- Spontaneous, frequently recurring VT that is reliably terminated with antitachycardia pacing

The FDA also required, in addition to other adverse event reporting, that a postapproval registry be created to track outcomes of patients and devices for at least 60 months after implantation. The primary safety end point of the registry is the complication-free rate at 60 months. The primary effectiveness end point is the overall shock effectiveness in converting spontaneous discrete episodes of VT/VF through 60 months. Results of