Subcutaneous implantable cardioverter-defibrillator (S-ICD)

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Abstract

Current state-of-the-art implantable cardioverter-defibrillator (ICD) systems have been proven to be safe and effective in treating ventricular arrhythmias leading to cardiac death. ICDs require placement of at least one lead in, or on, the heart. Surgical placement under fluoroscopy and the ongoing presence of the transvenous leads within the patient’s heart are associated with a significant proportion of the complications related to this well-established and highly effective therapy. A new ICD has been developed that is implanted entirely subcutaneously (S-ICD), thus eliminating the need for lead placement in or on the heart and simplifying surgery by eliminating the need for imaging equipment. Recent clinical studies suggest that the S-ICD system provides a viable alternative to conventional transvenous devices that may reduce barriers to treatment and lead to the wider adoption of this life-saving therapy. (Cardiol J 2011; 18, 3: 326–331)

Key words: implantable cardioverter-defibrillator, subcutaneous implantation ventricular arrhythmias, subcutaneous lead electrode

Introduction

The development of an implantable cardiac defibrillator was pioneered at Sinai Hospital in Baltimore by a team including Michel Mirowski, Morton Mower, and William Staewen [1]. Parallel developmental work was carried out almost simultaneously by Schuder et al. [2, 3] at the University of Missouri. Implantable cardioverter-defibrillators (ICDs) have proven themselves over the years as an effective treatment of ventricular arrhythmias leading to cardiac death [4–6]. However, conventional ICDs have several disadvantages limiting their wider use:

1. Conventional ICDs must be implanted using somewhat complex and expensive surgical procedures that are performed by specially trained physicians. Moreover, lead placement procedures require a special room equipped for fluoroscopy. These rooms are limited in number, so limiting the number of lead placement procedures, and ultimately the number of ICDs, that can be implanted on any given day.

2. Conventional ICDs rely on transvenous leads for the placement of at least one electrode within the cardiac chambers. It has been found that over a period of time, transvenous lead electrodes may get dislodged from the cardiac tissues. Additionally, complications such as broken leads and undesirable tissue deposits on the electrodes are not uncommon. These problems are especially acute when devices require two or more electrodes. Moreover, infection is a concern when implanting leads within a patient’s vasculature.

3. Removing these transvenous ICD leads and replacing them, if necessary, also requires complicated surgical procedures that can be more life-threatening than the initial implantation.

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Overview of subcutaneous ICD technology

Non-transvenously implanted defibrillators offer potential advantages over conventional ICDs (Fig. 1):

1. Obviation of the need for intravascular sensing and therapy electrodes, and elimination of the risks associated with lead placement within or on the heart.
2. Lowering incidence of inappropriate device therapy.
3. May reduce the surgical complication rate and/or make some complications e.g. infections less serious.
4. Easy to implant and explant the electrodes.

The Cameron Health subcutaneous (S-ICD) system comprises the Q-TRAK implantable lead, SQ-RX implantable pulse generator, Q-GUIDE lead insertion tool and Q-TECH programmer. The latter communicates wirelessly with the SQ-RX pulse generator to enable adjustment of programmable settings and data collection.

Q-TRAK is a 3-mm tripolar parasternal lead electrode (polycarbonate urethane 55D), which is connected to the SQ-RX pulse generator [7].

The lead is positioned parallel to, and 1 to 2 cm to the left of, the sternal midline, and the pulse generator is positioned over the sixth rib between the mid-axillary line and the anterior axillary line (Fig. 2). The lead is equipped with two sensing electrodes (A, B) and an 8-cm long shocking defibrillator coil (C). The distal sensing electrode is positioned adjacent to the manubriosternal junction (A), and the proximal sensing electrode is positioned adjacent to the xiphoid process (B).

During device operation, cardiac rhythm is detected by one of three sensing vectors incorporating either A, B or the ‘can’, as shown in Figure 3. The subcutaneous ICD system automatically selects an appropriate vector for rhythm detection and for avoiding double QRS counting and T-wave oversensing. Once signals have been validated as free of noise as shown in Figure 4 and double detection, feature analysis and rate detection are used to sort rhythm type and determine whether there is a need for shocks.

A conditional discrimination zone incorporating a feature extraction technique can be programmed between rates of 170 and 240 bpm to distinguish supraventricular tachycardia from ventricular tachycardia and avoid inappropriate shocks.

Reconfirmation of ventricular tachyarrhythmia follows capacitor charging to avoid the delivery of shocks for non-sustained ventricular tachyarrhythmias. Testing of the device during implantation is done using 65-J shocks to ensure a margin of safety. However, after the device has been implanted, it delivers only full energy 80-J shocks. It can also reverse shock polarity automatically if the initial shock is unsuccessful. In addition, demand pacing at 50 bpm is available for 30 s after a shock, with the use of a 200-mA biphasic transthoracic pulse. Pacing is activated only after more than 3.5 s of post-shock asystole.

All device settings are automated except for shock therapy (on/off), pacing after a shock (on/off), conditional discrimination of supraventricular tachycardia (on/off), and the upper-rate cutoff for the conditional shock zone (between 170 and 240 bpm). Data storage includes pre-event electrograms and rhythm markers through event termination. Up to 24 treated episodes can be stored, with up to 120 s of data per episode [7].

The S-ICD pulse generator box is about 30% larger than modern ICDs. The larger size is in part to provide a higher-capacity battery, which makes its longevity competitive with standard devices.

S-ICD implantation

Implantation of the S-ICD is a relatively straightforward outpatient procedure. The device’s generator ‘can’ is implanted subcutaneously in the lateral position, while the leads are threaded under the skin in a configuration pre-planned with X-rays and other anatomical markers; the procedure itself is not guided by fluoroscopy or other imaging.

Briefly, two small incisions are made in the left parasternal area (Fig. 5) to secure the distal (at the level of the second intercostal space) and proximal (at the level of the xiphoid process) sensing electrodes of the lead system that has been tunneled subcutaneously with a non-traumatic tool to position the coil parallel to, and 1–2 cm to the left of, the sternum (Fig. 6).

The pin connector end of the lead is tunneled to the pocket created in the left lateral chest at the level of the sixth rib between the mid axillary line and the anterior axillary line, where the pulse generator will sit as shown in Figures 7 and 8, respectively.

The entire procedure can be performed using anatomic landmarks without the use of fluoroscopy.

S-ICD has been tested in a number of completed and ongoing clinical studies. The Subcutaneous Implantable Defibrillator (S-ICD) System — CE Clinical Investigation trial [7], which enrolled 55 patients, was completed in 2010 [8]. The prima-
Figure 1. Side-by-side comparison of conventional (transvenous) and subcutaneous ICD implantation procedures.

Figure 2. Q-TRAK is a 3-mm tripolar parasternal lead electrode connected to the SQ-RX pulse generator and implanted to the left of the sternal midline. The lead comprises two electrogram sensing electrodes A and B and a defibrillator coil C.

Sensing vectors
1. Primary (xiphoid – CAN)
2. Secondary (sternal-manubrium – CAN)
3. Alternate (sternal-manubrium – xiphoid)

Figure 3. Location of the sensing vectors. These are formed by the sensing electrodes A, B and X, which is the surface of the S-ICD enclosure.

Figure 4. Selection of the appropriate vector for rhythm detection.
The primary objective of this trial was to evaluate the S-ICD system’s ability to identify and terminate induced ventricular fibrillation (VF) in patients during the implant procedure. The safety and performance of the S-ICD system was also assessed throughout the patient follow-up period. In a small 55 patient, non-randomized study, the S-ICD system successfully and consistently detected and converted episodes of VF that were induced during electrophysiologic testing. It also successfully detected and treated all 12 episodes of spontaneous, sustained ventricular tachyarrhythmia [7].

Early clinical experience with S-ICD has been reported by Theuns et al. [9]. The number of subjects enrolled in this study was 26, all males. The implantation was based on anatomical landmarks.
only. There were no short-term procedure-related complications and no lead migration after use of suture sleeves. All VF episodes were accurately detected using SQ-signals. There was no inappropriate therapy caused by supraventricular tachycardia. The study authors concluded that the S-ICD system is a viable alternative to conventional ICD systems for selected patients.

The primary objective of the ongoing S-ICD® System IDE Clinical Study trial [10] is to evaluate the safety and effectiveness of the S-ICD system. This is being conducted under an investigational device exemption (IDE). It is a prospective, multicenter, single-arm design involving up to 330 subjects at up to 35 sites in the U.S., UK, Europe and New Zealand.

In another study, early experience with S-ICD in three Dutch hospitals has been reported [11, 12]. Of the 98 patients in the study, the first 17 were part of the CE trial reported in the *New England Journal of Medicine* in 2010 [7]. The remaining patients were recruited after CE data collection was closed. In this 98-patient experience (78 males, 20 females) from three centers in the Netherlands, reported at the Heart Rhythm Society 2011 Scientific Sessions, the device successfully terminated all 42 episodes of sustained and non-sustained ventricular tachycardia in the cohort over an average of nine months. Thirty-four spontaneous ventricular arrhythmias (sustained and non-sustained) were accurately detected in six patients. A total of 23 arrhythmic episodes were effectively treated in three patients. Inappropriate therapy occurred in eight (early) patients due to oversensing. Of the 98 patients, 62 (63%) received the device for primary prevention; 40 (41%) patients had ischemic cardiomyopathy. Other causes of cardiac disease included non-ischemic dilated cardiomyopathy (14%), Brugada syndrome (7%), and idiopathic VF (28%). Five patients in the series developed cutaneous infections that were apparently device-related. Such infections with transvenous leads can be more serious, as they can include sepsis or endocarditis; but their rate of occurrence is generally lower than 5%. Eight patients experienced 22 inappropriate shocks; in all cases, the problem was resolved by a programming update or by lead repositioning [9]. Lead migration was observed in three early patients, with no recurrence since the use of an additional suture sleeve at the xiphoid incision. The results of this study suggest that subcutaneous defibrillation units are a viable alternative to conventional implantable cardiac defibrillators.

**Limitations of the current S-ICD system**

Although S-ICD systems may mitigate some of the risks associated with conventional ICDs, they provide new shortcomings, such as inability to provide long-term pacing therapy for bradyarrhythmias, or to be able to painlessly terminate monomorphic ventricular arrhythmias using anti-tachycardia pacing. However, the S-ICD can institute ‘backup’ transthoracic pacing for 30 s after a shock. Also, the S-ICD would not be suitable for patients who require cardiac resynchronization therapy.

**Regulatory status**

The S-ICD system received CE approval in 2009 and is commercially available in Europe. In the UK,
eligible patients may receive the S-ICD system as National Health Service treatment. The first U.S. patient was enrolled on March 3, 2010, in Cameron Health’s FDA pivotal trial (IDE number G090013). Enrollment in this study was recently completed.

Conclusions

The S-ICD could be a new alternative therapy for patients at risk of sudden cardiac death. Ongoing clinical evaluation and development are required before the role of S-ICDs as an adjunctive or primary therapy can be fully defined. Further investigation is warranted to allow the more widespread use of ICDs in patients who have indications for primary prevention devices.

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References