Subcutaneous Implantable Cardioverter-Defibrillator Technology

Anurag Gupta, MD, Amin Al-Ahmad, MD*,
Paul J. Wang, MD

KEYWORDS

• Subcutaneous ICD • Implantable cardioverter-defibrillator
• Defibrillation • Sudden death • Tachyarrhythmias

The first human implant of the implantable cardioverter-defibrillator (ICD) in 1980 ushered in an era of improved recognition and therapy for sudden cardiac death (SCD).[1] Initial epicardial ICD lead systems required a thoracotomy for placement of epicardial defibrillation patches and epicardial rate-sensing leads. Advances in ICD technology over the last 3 decades have led to decreased device size and the design of effective transvenous defibrillation leads. In addition, there have been significant improvements in ICD detection and discrimination algorithms and improved shock waveforms. This had led to the current paradigm of endocardial ICD lead systems in which endocardial leads (including pace-sense components and shocking coils) are placed transvenously, thus obviating the need for thoracotomy.

Indications for ICD therapy have also changed over the years based upon the results of well-conducted large-scale clinical trials. Whereas, initially, the ICD was only indicated after aborted SCD, current ICD indications have expanded to include prophylactic implantation in individuals who have a high risk of SCD, greatly increasing the pool of potentially eligible candidates.[2–5]

Despite these advancements, there continues to be significant barriers in offering this therapy to appropriately indicated patients. ICD delivery can be technically challenging and expensive. Furthermore, current ICD systems have associated risk, including but not limited to procedural risks, inappropriate device therapy, and long-term device-related complications that prominently include lead failure.

Recently, subcutaneous or so-called leadless ICD systems have been developed that offer a potential new paradigm for facilitating ICD implantation. Though heterogeneous in design, these systems typically share a common theme of using electrodes that are placed subcutaneously without requirement for leads in or on the heart. Although not clinically approved, this article will examine studies investigating the subcutaneous ICD and discuss its possible advantages and disadvantages as compared with current transvenous ICD systems.

EXPERIMENTAL EVIDENCE FOR THE SUBCUTANEOUS ICD

Initial Studies

Defibrillation with implantable devices using noncardiac electrodes is not a new concept. In 1970, Schuder and colleagues[6] demonstrated the efficacy of a completely automatic implantable defibrillator that weighed approximately 1037 g and that used extrathoracic electrodes in three canines. Energy delivery across the chest wall ranged between approximately 23 to 37 J, and the time between induction of ventricular

This article originally appeared in *Cardiac Electrophysiology Clinics*, volume 1, number 1.
Division of Cardiovascular Medicine, Department of Internal Medicine, Cardiac Arrhythmia Service, Stanford University School of Medicine, 300 Pasteur Drive, Room H2146, Stanford, CA 94305-5233, USA
* Corresponding author.
E-mail address: aalahmad@cvmed.stanford.edu

Heart Failure Clin 7 (2011) 287–294
doi:10.1016/j.hfc.2011.01.005
1551-7136/11/$ – see front matter

fibrillation to shock delivery ranged between 14 seconds to 40 seconds with later inductions. The first shock was successful in terminating ventricular fibrillation in 67 of 73 induced episodes, and no animal required external defibrillation.

Subcutaneous Defibrillation in Children

Subcutaneous defibrillation has only been more recently reported in humans. Clinicians wishing to avoid or unable to place fully transvenous or epicardial ICD systems in pediatric patients with complex cardiac disease have reported cases of effective defibrillation using a subcutaneous array as the high-voltage lead.[7–12] For example, Gradaus and colleagues[7] reported successful subcutaneous defibrillation in two patients aged 12- and 14-years-old with a single-chamber ICD with a transvenous and epicardial bipolar pace-sense lead, respectively. Using an active abdominal can and a single subcutaneous array placed dorsolaterally in the left thorax, they reported successful conversion of ventricular fibrillation with defibrillation threshold (DFT) less than or equal to 20 J. Likewise, Berul and colleagues[8] reported successful defibrillation with threshold less than or equal to 14 J using an active abdominal can and a single subcutaneous array in a 2-year-old girl with a single chamber ICD using an epicardial bipolar rate-sensing lead.

Stephenson and colleagues[13] reported a larger, multicenter retrospective review of subcutaneous defibrillation (that is, not using transvenous high-voltage coils or epicardial patches) in children with mean age of 8.9 years and complex cardiac disease. Of 22 patients examined, 14 had a subcutaneous coil system while the remaining 8 had the coil placed on the epicardium; all patients had an epicardial or transvenous bipolar ventricular pace-sense lead and used an active can configuration. While a true DFT was not obtained in all patients, subcutaneous lead placement was associated with a higher DFT than the epicardial system (19 ± 7 vs 13 ± 4 J, $P = .03$). Though 7 of the 22 patients required system revisions, this study again demonstrated the feasibility of subcutaneous defibrillation in children.

Experimental Models of Subcutaneous Defibrillation in Adults

There have also been studies examining a subcutaneous lead system in adults indicated for and receiving transvenous ICDs. Grace and colleagues[14] examined the DFT for subcutaneous ICD systems using various dual electrode configurations between the ICD can and subcutaneous electrode. In one study, 41 patients were enrolled in a multicenter, prospective study comparing DFT between a standard transvenous ICD system and a subcutaneous system. For the subcutaneous system, the active can was placed in the anterolateral axillary line at the sixth intercostal space and the subcutaneous electrode was placed 3 cm left of the sternum with the coil centered at the fifth intercostal space. The DFT for the subcutaneous system was 39 J. As expected, this was higher than the 12 J DFT of the transvenous system but still within a technically feasible range.

Optimal electrode configurations were further examined by Grace and colleagues[15] in a study of 10 patients undergoing standard transvenous ICD implantation. Four electrode configurations were tested: (1) 60 cc lateral can and 8 cm parasternal coil, (2) 60 cc lateral can with a 5 cm squared parasternal disk electrode, (3) 60 cc pectoral can with a 4 cm paraxiphoid coil, and (4) 60 cc pectoral can with a 8 cm inframammary coil electrode. In this study, though the optimal configuration appeared to require a lateral can position, all groups were thought to be in a technically feasible range of defibrillation with mean DFT for the four groups ranging between 27 to 39 J.

Similarly, Lieberman and colleagues[16] examined the efficacy of a nontransvenous defibrillation, this time using an anteroposterior shock pathway. Specifically, 33 patients undergoing standard transvenous ICD implantation had an anterior low pectorally-placed active can emulator and a 25 cm coil tunneled subcutaneously around the back of the left thorax between the 6th and 10th intercostal space. A standard electrophysiology catheter was placed for sensing and for ventricular fibrillation induction. Biphasic shocks with a 50%-50% tilt and total waveform time of 16 ms were delivered and defibrillation testing was performed using a stepwise protocol. Eighty one percent of patients had successful defibrillation using less than or equal to 35 J.

Likewise, Burke and colleagues[17] estimated the subcutaneous defibrillation energy requirement in 20 adults indicated for an ICD, this time using anterior-anterior vector. In their experimental model, a cutaneous electrode patch, acting as a surrogate for a subcutaneous electrode, was first placed at the inferior border and apex of the left heart. Next, a standard transvenous ICD was implanted and DFT testing was performed. The DFT using the standard transvenous system was 10.4 ± 6.5 J. The device was then removed (replaced at the end of study) and an emulator was placed in the device position. Defibrillation was retested for the investigational, nontransvenous configuration using an external defibrillator that delivered a shock between the pectoral