Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter–defibrillator. N Engl J Med 2010;363:36-44. DOI: 10.1056/NEJMoa0909545.

Defibrillation threshold testing protocol.

The defibrillation threshold testing protocol used in the first acute human protocol described in the subcutaneous ICD (S-ICD) development process is described here in detail.

A step-up/step-down testing protocol was used to determine defibrillation thresholds (DFTs) using a 50% tilt biphasic waveform. Test shocks were delivered after 10 seconds of induced ventricular fibrillation (VF). The initial test shock was 40 joules (J). Unsuccessful shocks led to immediate transthoracic defibrillator rescue. Following a minimum 5 minute rest period, VF was re-induced. If the 40 J index test shock was unsuccessful, the next energy tested was incremented by 20 J to 60 J. If this failed, then another induction was done at a maximum energy of 80 J. Success at any energy in the range of 40 J to 80 J was followed by a 10 J energy decrement with another induction to finalize the assigned DFT value. Failure at 80 J was conservatively assigned a DFT value of 100 J. Only one patient had this occurrence with a lead position that was 6cm away from the sternum. Conversely, if the initial 40 J test shock succeeded, a sequential 10 J step-down repetitive induction protocol was undertaken until failure. The minimum energy tested was 10 J. Success at 10 J was conservatively assigned a DFT of 10 J. It should be noted that not all patients had all methods tested, depending on clinical circumstances as judged by the physician responsible for patient safety. Comparisons were made using a one-way analysis of variance (ANOVA).

The DFT protocol for the second acute protocol comparing the S-ICD to a transvenous ICD was identical to that employed for the first acute trial described above except that the starting energy setting for the transvenous system was 20 J with 10 J increments and 5 J decrements.

S-ICD Surgical and Testing Procedures.

Using standard sterile precautions, a 6 cm left lateral incision was made along Langer's lines over the 6th rib for pocket formation in the anterior axillary line. The dissection was carried perpendicular to the incision down to fascia overlying the rib cage and then the pocket was formed over the rib cage and partially beneath the *latissimus dorsi* muscle which was visible at the lateral and cephalad extent of the pocket. Care was taken to visualize blood vessels in the thoracic wall pocket between the latissimus dorsus muscle and the ribs in order to minimize bleeding and to ensure adequate hemostasis.

The parasternal electrode was placed no more than 1-2 cm to the left of the sternal midline. Two horizontal incisions of 2 cm length were carried down to the subcutaneous fascia for electrode placement: the first was made at the xiphoid and the second was made at the sternal-manubrium junction at the second rib. Defibrillation failure was usually associated with malpositioning of the parasternal electrode, which occurred once in the second acute trial and once in the 55 patient clinical trial. Both were corrected with repositioning of the parasternal electrode medially to the proper parasternal location.

To pull the parasternal electrode into position from the generator pocket, a tunneling tool facilitated drawing the electrode from the pocket along the inferior margin of *pectoralis major* to the xiphoid incision and, subsequently, from the xiphoid incision to the sternal-manubrium incision whereupon it was sutured at the distal tip to underlying periostial fascia and fixed at the xiphoid incision with an anchoring sleeve. Using blunt finger dissection the implanter could usually guide and feel the tunneling tool as it passed from the xiphoid to the pocket thereby drawing the electrode medially. When anchoring the tip of the parasternal electrode, the more easily accessible subcutaneous fat was deemed insufficient to secure the lead. Instead, the implanter used the periostial fascia above the sternum and ribs to provide a better suture anchor site. Similar considerations held for the para-xiphoid fixation process, using an anchoring sleeve that became a standard procedural tool when electrode dislodgement was found to occur without it in the early implant experience (See Results Section).

When tunneling, the path chosen for the electrode avoided proximity to the dermis as much as practical. Care was taken to tunnel over the rib and the muscular fascia and not through the subcutaneous fat. This path limited unwanted mobility of the lead post-operatively. This concern of a superficial route for the lead during tunneling was more prominent in obese patients where the implanting physician needed to be careful to use adequate retraction and lighting in deeper pockets to ensure visualization of the fascia overlying the ribs. The tunneling and anchoring process was identical for women as the proper path for tunneling of the lead was inferior to any breast tissue. Similarly, because of the midline location of the parasternal leads, breast tissue in women did not interfere with these incisions anymore than in men.

Once the parasternal electrode was appropriately tunneled and after connecting the proximal pin of the electrode to the generator, a suture was inserted through the connector block suture portal to anchor the S-ICD to the underlying fascia. The suture was placed through the connector block first, followed by suture placement in the pocket fascia overlying the ribs. This suturing sequence was done prior to seating the generator in the pocket and prior to securing the suture knot to the generator in order to facilitate device anchoring to the fascia.

Once the generator was in position, VF was induced (50Hz stimulation between shock coil and pulse generator) to confirm appropriate detection and termination of VF. This testing followed rather than preceded incision closure to avoid pocket air from interfering with defibrillation. In the patients included in the chronic implant studies (6 pilot and 55 regulatory trial patients), two consecutive successful defibrillations at 65J out of four attempts were required to conclude that defibrillation was efficacious. This energy limit also provided a 15J safety margin for this 80J device. A minimum 5 minute rest period was maintained between inductions and 65J test shocks. Chest x-rays and clinical follow-up were performed immediately post-operatively, at one week and one month to detect any system component migration.

There were a few considerations regarding the surgical field that differed slightly from what one might have anticipated in a transvenous ICD procedure. First, the transthoracic rescue pads required a different orientation so as to not interfere with surgical sterility. Placing the right posterior rescue pad in a higher location between the right scapula and the high thoracic spine accommodated a lower left anterior rescue pad located at the left costal margin in the mid-clavicular line. This pad orientation ensured a good cardiac current vector through the thorax while simultaneously being sufficiently inferior to the rib margin to allow sterile surgical draping for pocket formation and tunneling. Finally, we positioned the head and left arm of the patient both to facilitate the surgery and to promote sterility. Because of the pocket location, a slight abduction of the left arm (15°-30°) improved pocket access and ensured that the generator was seated in the appropriate left lateral location described above. The patient’s left arm was secured to and supported on an arm board for patient comfort and to enhance sterile draping. In addition, immobilizing the left arm prevented disruption of the surgical drapes during use of the 50Hz VF induction current which stimulated the striated musculature and caused the left arm to flex. Holding the left arm firmly in place also helped during inductions of VF. Finally, a slight rotation of the patient’s head to the patient’s right aided in sterile draping over the manubrium and sternum and facilitated tunneling of the parasternal electrode into its upper location.

Both the pilot trial of six patients and the larger clinical trial of 55 patients in Europe followed the same surgical implant technique and testing protocol.

Figure

Figure. Electrocardiogram of a spontaneously occurring episode of rapid ventricular tachycardia (270bpm) terminated with a single 80 J shock by the S-ICD. The patient was a 76 year old man with coronary disease and a history of ventricular tachyarrhythmias treated for secondary prevention of sudden cardiac death.