HANDS ON

Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator

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BACKGROUND Three incisions in the chest are necessary for implantation of the entirely subcutaneous implantable cardioverter-defibrillator (S-ICD). The superior parasternal incision is a possible risk for infection and a potential source of discomfort. A less invasive alternative technique of implanting the S-ICD electrode—the two-incision technique—avoids the superior parasternal incision.

OBJECTIVE The purpose of this prospective cohort study was to evaluate the safety and efficacy of the two-incision technique for implantation of the S-ICD.

METHODS Consecutive patients who received an S-ICD between October 2010 and December 2011 were implanted using the two-incision technique, which positions the parasternal part of the S-ICD electrode using a standard 11Fr peel-away sheath. All patients were routinely evaluated for at least 1 year for complications and device interrogation at the outpatient clinic.

RESULTS Thirty-nine patients (46% male, mean age 44 ± 15 years) were implanted with a S-ICD using the two-incision technique. During mean follow-up of 18 months (range 14–27 months) no dislocations were observed, and there was no need for repositioning of either the ICD or the electrode. No serious infections occurred during follow-up except for 2 superficial wound infections of the pocket incision site. Device function was normal in all patients, and no inappropriate sensing occurred related to the implantation technique.

CONCLUSION The two-incision technique is a safe and efficacious alternative for S-ICD implantations and may help to reduce complications. The two-incision technique offers physicians a less invasive and simplified implantation procedure of the S-ICD.

KEYWORDS Implantable cardioverter-defibrillator; Implantation technique; Subcutaneous implantable cardioverter-defibrillator

ABBREVIATIONS **DFT** = defibrillation threshold; **EIT** = electrode insertion tool; **ICD** = implantable cardioverter-defibrillator; **S-ICD** = subcutaneous implantable cardioverter-defibrillator; **VF** = ventricular fibrillation

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Introduction

Prevention of sudden cardiac death with an implantable cardioverter-defibrillator (ICD) has become one of the most important treatment modalities for life-threatening cardiac arrhythmias. Several trials have demonstrated significant survival benefit in both primary and secondary prevention of sudden cardiac death.[1] However, this benefit comes at the cost of ICD-related complications, among which are inappropriate shocks and implantation-related complications, such as pneumothorax, perforation, and lead dislocation.[2] Also, late complications such as lead fractures and infections account for significant morbidity and even mortality in ICD patients.[3]

In search of a solution for some of these ICD-related complications, a new entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) was introduced in 2010.[4] The S-ICD does not require leads in or on the heart. This allows for a more robust lead design. Potentially, the implantation technique and new lead design might result in increased lead longevity and fewer implantation-related complications, but this has yet to be confirmed. To date, there are only reports on the feasibility and safety of the S-ICD.[4,5]

The conventional S-ICD implantation technique consists of electrode and device implantation by making 3 incisions: 1 lateral pocket incision and 2 parasternal incisions. The electrode is then tunneled from the lateral pocket through the parasternal incisions to its final position, and sutures are applied at all incision sites. Particularly, the superior parasternal incision, located on the sternomanubrial junction, may be a risk for infection,[5] a potential source of discomfort, and cosmetically less appealing. On the other hand, adequate electrode positioning is important for appropriate sensing. and inappropriate shocks have been reported due to lead migrations.[5] We present here an alternative technique for implanting the electrode that avoids the superior parasternal

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incision and suture, and we report on the efficacy and safety of this new implantation technique.

Methods

Patients

Consecutive patients who received an S-ICD between October 2010 and December 2011 were included in the study. The inclusion period was chosen to study patients with at least 12 months of follow-up. All patients were aware of the innovative aspects, limitations, and potential advantages and disadvantages of the device. Our institutional review board waived the requirement for informed consent.

Two-incision S-ICD implant technique

Procedures were performed in a catheterization laboratory or operation room under standard sterile conditions. Implantation was performed under guidance of anatomic landmarks, and no fluoroscopy was used. The current implantation technique suggested by the manufacturer is described in the S-ICD User's Manual.[6] The two-incision technique abandons the superior parasternal incision; rather, it positions the lead using a standard 11Fr peel-away sheath of 14 cm length, commonly used in transvenous lead placement (Greatbatch Inc, Clarence, NY).

First, an incision is made along the inframammary crease such that the device can be placed in the device pocket in the vicinity of the left fifth and sixth intercostal spaces and near the midaxillary line (Figure 1A). Beginning 1 cm left lateral of the xiphoid midline, a small 2-cm horizontal incision (xiphoid incision) is made in the direction of the pocket incision. The distal tip of the electrode insertion tool (EIT), used to create the subcutaneous tunnels in which the electrode is placed, is inserted at the xiphoid incision and tunneled laterally until the distal tip emerges at the device pocket. Conventional suture material is used to tie the anchoring hole of the electrode to the EIT creating a long 15- to 16-cm loop (Figure 1B). With the electrode attached, the EIT is pulled back through the tunnel to the xiphoid incision until the proximal sensing electrode emerges (Figure 1C). A suture sleeve is placed over the electrode shaft 1 cm below the proximal sensing electrode. The preformed grooves are used to bind the suture sleeve to the electrode shaft using nonabsorbable suture material. The suture that connects the tip of the lead to the EIT is cut and removed. The peel-away sheath is placed over the shaft of the EIT (Figure 1D), which is then tunneled approximately 14 cm superior of the xyphoid incision and approximately 1 cm to the left of the sternal midline. The peel-away sheath is advanced over the EIT until it is fully inserted. The EIT is removed, and the peel-away sheath is left in its subcutaneous position. The electrode is inserted into the subcutaneous sheath until the suture sleeve reaches the opening of the sheath (Figure 1E). The lead is now in the desired parasternal position. The sheath is peeled away leaving the electrode in place (Figure 1F). It is possible to confirm manually that the tip of the lead is at the required sternomanubrial location. The suture sleeve is secured to the fascia in a vertical position. The proximal end of the lead is now inserted into the connector port in the device header of the S-ICD and the screw set tightened. The device is inserted into the subcutaneous pocket and sutured to the fascia. After device setup, all incisions are closed using standard suture protocol (Figure 1G).

All implantations were performed by a single experienced operator (REK). Prior to developing this technique, the operator performed 33 implantations with the labeled implantation technique.

Periprocedural defibrillation threshold testing and device programming

At least 1 defibrillation testing was performed with 65 J after ventricular fibrillation (VF) induction with 50-Hz stimulation. Polarity was automatically reversed in case of failure.

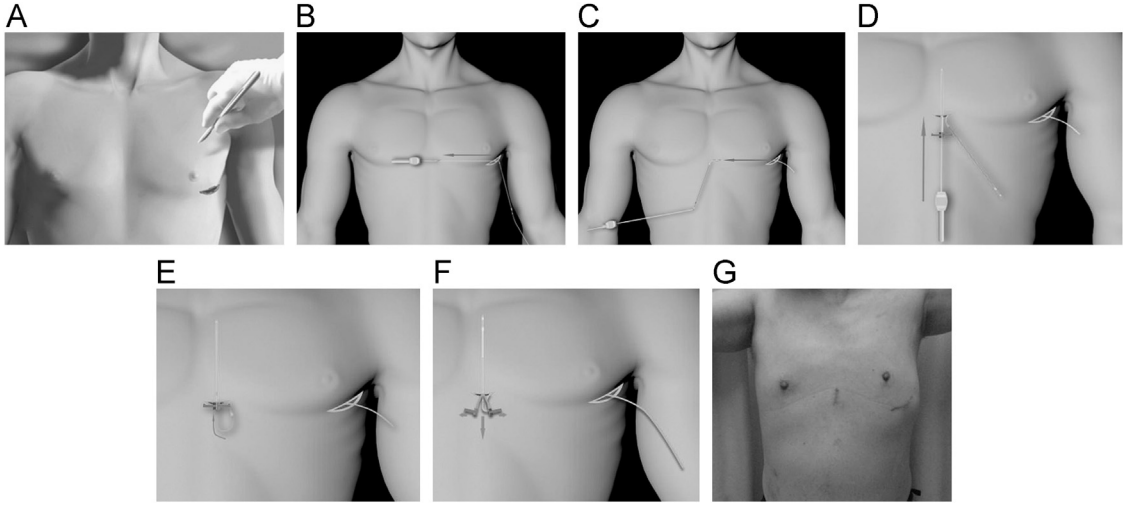

Figure 1 **A:** Creating the device pocket. **B:** Connecting distal end of electrode to the electrode insertion tool (EIT). **C:** Pulling the lead to the inferior parasternal incision. **D:** Tunneling the EIT and peel-away sheath to the superior parasternal position without making a parasternal incision. **E:** After the EIT is removed, the electrode is inserted in the sheath. **F:** Peeling away the sheath, leaving the electrode in the desired subcutaneous position. **G:** Final result after 2 weeks of follow-up.