IMPLANTABLE DEFIBRILLATION THERAPY

COMPLEX CASE STUDY

Inappropriate Shocks within 24 hours after Implantation of a Subcutaneous Defibrillator with a Two-incision Technique

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ABSTRACT. The subcutaneous implantable cardioverter-defibrillator (S-ICD) has traditionally been implanted using three incisions, but a two-incision technique has emerged involving a subaxillary and single parasternal incision. We present two cases of early inappropriate discharge after S-ICD implant with the two-incision technique. Two patients underwent S-ICD implantation using the two-incision technique. Patient 1 is a 56-year-old male with prior coronary artery bypass graft who underwent transvenous ICD extraction for pocket infection, and was later reimplanted with an S-ICD. Patient 2 is a 73-year-old male with prior mitral valve repair and severe left ventricular dysfunction. In both cases chest X-ray confirmed good lead position without evidence of subcutaneous air, and the patients were discharged the day of implant. Several hours after discharge, both patients experienced a sudden shock, and device interrogation demonstrated a decrease in signal amplitude and abrupt baseline shift, followed by an inappropriate 80-J discharge. The artifact was not reproducible on device testing the next day. No subsequent inappropriate therapy was observed on follow-up. Inappropriate S-ICD shocks are rare in the early post-implant period using traditional implant techniques. The two-incision technique is a simplified implant method, but may predispose to oversensing and inappropriate therapy in the early post-implant period, possibly due to introduction of air along the sternal track as the lead is inserted and sheath is removed.

KEYWORDS. Inappropriate shock, subcutaneous air, subcutaneous defibrillator, subcutaneous ICD, two-incision technique.

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Introduction

The subcutaneous implantable cardioverter-defibrillator (S-ICD; Boston Scientific, Marlborough, MA) is an important tool in the armamentarium for patients at risk of sudden cardiac death. This device avoids transvenous lead placement, and has demonstrated a success rate of

over 98% for electrical conversion. However, pooled results from worldwide registries¹ have noted an incidence of inappropriate therapy of 13.1% over 3 years, most commonly related to cardiac signal oversensing (typically T-wave or low-amplitude sensing). Based on these reports, the incidence of inappropriate therapy appears low in the early post-implant period, and increases over time.¹ In the original descriptions² and in most patients included in the post-market registries, the S-ICD was implanted through a three-incision technique, including a mid-axillary incision where the device is implanted at the level of the cardiac apex, an inferior parasternal incision at the level of the xiphoid process, and a superior parasternal incision adjacent to the sternomanubrial junction. More recently, a two-incision technique has emerged eliminating the need

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for the superior parasternal incision by using a sheath and tunneling tool to track the distal portion of the lead superiorly.³ Although this technique provides a simplified approach for device implantation with a better cosmetic result, the unique risks and outcomes associated with this approach are unknown. Herein we report two cases of inappropriate shocks within 24 hours after S-ICD implantation utilizing the two-incision technique.

Case reports

Case 1

A 56-year-old male with a past medical history of ischemic cardiomyopathy and coronary artery bypass surgery presented to our hospital with fevers and drainage from his transvenous ICD incision site. He underwent extraction of his dual-chamber ICD system, and returned for S-ICD implantation after a period of 4 weeks of antibiotics. The implant procedure was uncomplicated, and utilized the two-incision technique. Empiric defibrillation threshold testing was not performed. The automatic programming algorithm selected the alternate vector for sensing, which involves the proximal and the distal sensing electrodes (**Figure 1**, S-ICD sensing vectors). The device was programmed with a conditional shock zone of 190 bpm and a shock zone of 230 bpm. Post-procedure chest radiography (**Figure 1**) showed appropriate device placement without physical interaction between the high-voltage lead and sternal wires, with no evidence of subcutaneous air. The postoperative course was uneventful and the patient was discharged home the same day. Several hours after discharge the patient experienced a sudden shock. Device interrogation revealed an abrupt baseline shift with a decrease in signal amplitude followed by an inappropriate 80-J discharge (**Figure 2a**). The signal aberration at the time of shock was not reproducible the following morning. Testing confirmed optimal sensing parameters using the alternate vector, and the sensing

configuration was not changed. Electrogram analysis performed by the device manufacturer suggested air in the vicinity of the sensing electrodes as the most likely etiology of the findings. No device or lead revision was performed, and no further sensing abnormalities have been observed on follow-up.

Case 2

A 73-year-old male with valvular cardiomyopathy developed ventricular tachycardia storm and cardiogenic shock after mitral valve repair. After >3 months of optimal medical therapy during which he wore a temporary defibrillator (LifeVest, ZOLL, Pittsburgh, PA), he continued to have severe left ventricular dysfunction. Owing to concern for his risk of infectious complications, he was referred for S-ICD implantation. The implant procedure was uncomplicated, and the automatic set-up algorithm selected the secondary vector (distal tip electrode to device generator, **Figure 1**). Defibrillation threshold testing was not performed, and the device was programmed for a conditional shock zone at 200 bpm and a shock zone of 250 bpm. Chest x-ray revealed appropriate placement of the device and high-voltage lead without evidence of subcutaneous air, but with anterior angulation of the distal lead tip (**Figure 3**). The patient was discharged home the same day, and that evening experienced a sudden shock without prodrome. Device interrogation showed an abrupt baseline shift with a decrease in signal amplitude followed by an inappropriate 80-J shock (**Figure 2b**). The signal aberration at the time of shock was not reproducible the following morning. Owing to concern that the anterior deflection seen on lateral radiography may have indicated air entrapment or lead migration around the distal electrode, the sensing algorithm was reprogrammed to the primary vector (proximal electrode to device generator). No further sensing abnormalities have been observed on follow-up. Electrogram analysis by the manufacturer again suggested subcutaneous air as the etiology of the oversensing episode.

Figure 1: Posterior–anterior and lateral chest radiography in patient 1 post implant. The subcutaneous implantable cardioverter-defibrillator sensing vectors available are shown: primary, proximal ring to device generator; secondary, distal tip electrode to device generator; and alternate, distal tip to proximal ring electrode.

Figure 2: Device interrogation demonstrating recorded subcutaneous implantable cardioverter-defibrillator electrograms before device discharge in patient 1 (a), and patient 2 (b). Normal baseline sensing is followed by abrupt baseline shifts with low signal amplitude and oversensing, then delivery of a 80-J shock.

Discussion

Inappropriate S-ICD shocks have been reported to occur in 13.1% of patients at 3 years.¹ Subcutaneous air in the region of sensing electrodes was not specifically cited as an etiology of inappropriate shocks in the IDE study or post-market S-ICD registries, but “low amplitude signal” was noted as the etiology in 21%.¹ Recently, Zipse et al.⁴ reported a case of oversensing due to artifact from subcutaneous air leading to inappropriate shocks within 48 h of S-ICD implantation; in this report, a traditional three-incision technique was used for device implantation, and subcutaneous emphysema was noted on post-procedure chest X-ray. In addition, device interrogation noted oversensed artifact with abrupt baseline shifts occurring only in the sensing vectors that included the distal sensing electrode, which was found to be insulated by subcutaneous air on chest film. Although this was the first report of subcutaneous air as a cause of oversensing in a S-ICD, this complication had been previously described with unipolar pacemakers, where the device implanted in the subcutaneous pocket was included in the sensing vector.⁵

In a response to the case by Zipse et al., another report was described of two inappropriate shocks occurring 2 h after device implant using a two-incision technique.⁶ On device interrogation, low amplitude signals with artifact on the primary sensing vector was described. Chest radiography showed air entrapped around the proximal electrode, which resolved once the air has been absorbed. In this paper we report two cases at our institution of inappropriate therapy because of non-cardiac signal oversensing within 24 h after S-ICD implant using the two-incision technique. Device recordings at the time of discharge revealed abrupt baseline shifts and loss of amplitude, consistent with the findings in the other cited reports of oversensing artifact related to subcutaneous air.^{4,6} Other causes of non-cardiac oversensing such as myopotentials or interaction with sternal wires were considered unlikely based on the distance between the sternal wires and lead on chest radiography, very low amplitude artifact on device interrogation, and early resolution of the sensing anomaly. Although subcutaneous air was not definitively seen on radiography in our cases, the anterior displacement of the tip electrode seen

Figure 3: Posterior–anterior and lateral chest radiography in patient 2 post implant. The arrow on the lateral image points to the distal tip electrode, which is displaced anteriorly relative to the course of the coil.

on the lateral radiograph in Case 2 (**Figure 3**) raised the suspicion of air entrapment or lead movement in this region; the sensing vector was therefore changed to the primary vector, excluding the distal electrode. As the tip electrode is not secured to the underlying fascia using the two-incision technique, it may be more prone to migration and air entrapment. For cases in which the sensing artifact can be localized, either by provocative device testing or appreciation of air on radiography, the sensing vector can be reprogrammed in the early post-implant period to exclude the affected electrode.

Inappropriate S-ICD shocks within 24–48 h may be more prevalent utilizing the two-incision technique. With this approach, the use of a tear-away sheath to pass the lead up subcutaneous tract in the parasternal space may allow air trapping in a closed space around the lead and sensing electrodes. The risk of this complication resolves within 2 days post implant, as air in the subcutaneous space is absorbed and the electrode tip stabilizes. This event can be identified on device interrogation as abrupt baseline shifts and a decrease in signal amplitude, and may be responsible for many of the cases of inappropriate therapies due to “low-amplitude signal” cited in the post-market registries.¹ As highlighted in this report, subcutaneous air is a relatively common cause of inappropriate shocks in the early post-implant period. Post-procedure chest radiography and device testing should be performed before hospital discharge to detect artifact consistent with subcutaneous air. In addition to reprogramming the sensing vector after air or sensing abnormalities are detected, other operator techniques to prevent inappropriate discharges have been suggested, such as flushing the sternal track with saline, massaging the skin over the lead and incision sites to disperse underlying air, and good suturing technique over the sensing electrodes avoiding dead space within subcutaneous tissue. Extended monitoring post implant may also be useful to detect air-related

sensing abnormalities before discharge. Whether routine defibrillation threshold testing at the time of implant impacts clinical outcomes is unclear.

The traditional three-incision technique may have a lower incidence of early post-implant shocks as the addition of the superior parasternal incision provides two exit points to reduce air entrapment, and prevents migration of the tip electrode. Awareness of this complication, appropriate testing after device implant, and recognition of maneuvers to eliminate subcutaneous air is critical to prevent unnecessary shocks in patients during the vulnerable post-implant period.

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