Feasibility and efficacy of extravascular implantable cardioverter-defibrillators in two patients with class III obesity

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Introduction

One of the challenges with the subcutaneous implantable cardioverter-defibrillator (S-ICD) is the amount of subcutaneous fat beneath the lead and generator during implantation, which can affect defibrillation threshold (DFT) testing. The extravascular ICD (EV-ICD), created to address many of the limitations of the S-ICD, carried a similar concern given its external placement. Importantly, in the EV-ICD Pivotal trial there was no statistical difference in implant DFT success by body mass index (BMI), height, or weight. However, most recipients had a lower BMI (28.0 ± 5.6), and there was only a small sample of patients with a BMI in the upper tertile (90 patients with BMI ranging from 29.8 to 45.6 kg/m^2).[1,2] Moreover, the feasibility and safety of using EV-ICD technology in patients with a BMI exceeding this is still uncertain.

In 2023, our institution implanted 2 EV-ICD devices in patients with a BMI greater than 45 kg/m^2; here, we describe our experience.

Case report

Patient A was 67 years old, had a BMI of 45.4 kg/m^2, and was diagnosed with hypertrophic cardiomyopathy with nonsustained ventricular tachycardia. Patient B was 54 years old, had a BMI of 53.4 kg/m^2, and was diagnosed with nonischemic cardiomyopathy with persistent left ventricular dysfunction. Both indications were for primary prevention. The decision to opt for an EV-ICD in patient A was influenced by the presence of atrial fibrillation with slow ventricular rates and patient preference. With the insertion site placed mid-substernally for patient A, and in the upper mid abdomen for patient B, the lead was implanted into the anterior mediastinum using the tunneling tool. For both patients, the device incision was made from the anterior axillary line to mid axillary line, near the 5-6 intercoastal space, and carried down to the prepectoral fascia where the generator was implanted. Figure 1 illustrates the final placement of the generator and lead for patient A and Figure 2 depicts the respective locations for patient B. The total procedure time was 2.27 hours for patient A and 3 hours for patient B, with fluoroscopy times of 3.8 minutes and 7.6 minutes, respectively. Summary of electrical parameters obtained during incision check follow-up are summarized in Table 1. DFT testing was mandatory and served as the primary efficacy endpoint for patient A within the continued access trial, while for patient B it was left to

KEY TEACHING POINTS

- Successful shock efficacy of subcutaneous implantable cardioverter-defibrillator (S-ICD) is reduced in patients with higher body mass index owing to increased adipose tissue affecting high-voltage impedance and defibrillation threshold testing.
- Reducing generator-lead distance by "scraping the sternum" during tunneling and intermuscular placement of the generator can improve successful shock efficacy.
- The PRAETORIAN score, a noninvasive tool that considers the amount of subcoil fat and subgenerator fat, helps identify who is at high risk of first shock failure.
- Additional studies should be pursued to further inform the feasibility and safety of extravascular ICDs (EV-ICD) in patients with class III obesity, given the substernal lead placement minimizes the effect of adipose tissue compared to an S-ICD.

KEYWORDS ICD; Extravascular implantable cardiac defibrillator; Defibrillation testing; Electric impedance; Obesity
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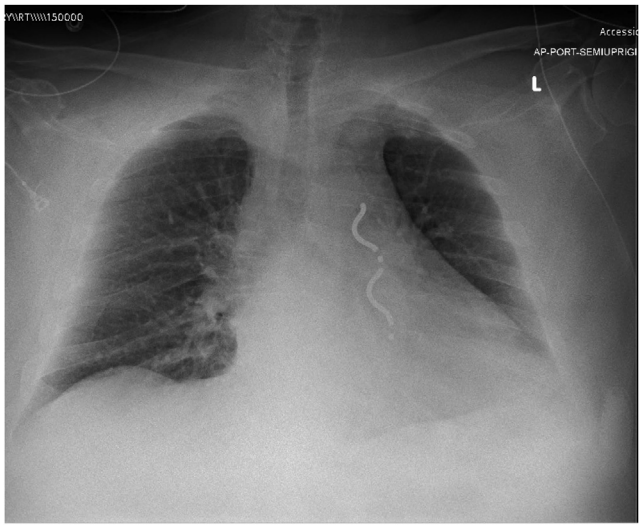

Figure 1 Chest radiography of patient A status post device implant. Epsilon-shaped lead in the anterior mediastinum. Patient was not able raise arm above shoulder height for lateral view.

the provider's discretion. DFT testing for both patients was accomplished with 30 J, and high-voltage (HV) impedance was 93 ohms and 66 ohms. Pacing threshold was 4 V in 4 ms and 5 V in 2 ms.

Discussion

Our main finding is the favorable EV-ICD implant outcome in 2 patients with a BMI exceeding 45 kg/m^2. Despite generator placement in the anterior axilla, both patients had low DFT and HV impedances near the optimal for first shock efficacy and the anticipated successful DFT at 30 J demonstrated in the Pivotal study. This is particularly noteworthy, given the challenges associated with higher BMI commonly observed with S-ICDs.

Table 1 Patient characteristics and extravascular implantable cardioverter-defibrillator electrical parameters

	Patient A	Patient B
Age	67	54
Weight (kg) and BMI (kg/m^2)	152 (45.4)	174 (53.4)
Diagnosis	HCM with NSVT	NICM with persistent LV dysfunction
Indication	Primary prevention	Primary prevention
Device type	Medtronic EV-ICD	Medtronic EV-ICD
Procedural time (h)	2.27	3
Fluoroscopy time (min)	3.8	7.6
Dose area product (mGy·cm^2)	41.1	15.8
DFT (J)	30	30
Ring 1 to ring 2 impedance (ohms)	418	323
Ring 1 to coil 2 impedance (ohms)	228	190
High-voltage impedance (ohms)	93	66
R wave at ring 1 to ring 2 (mV)	2.6	2.2
R wave at implant (mV)	3.4	3.0
Pacing threshold (V/ms)	4.0/4.0	5.0/2.0

BMI = body mass index; DFT = defibrillation threshold; EV-ICD = extravascular implantable cardioverter-defibrillator; HCM = hypertrophic cardiomyopathy; LV = left ventricular; NICM = nonischemic cardiomyopathy; NSVT = nonsustained ventricular tachycardia.

As aforementioned, given the extrathoracic placement of an S-ICD, the amount of adipose tissue under the lead and the generator can affect performance, requiring a larger generator than the traditional ICD. This is attributed to thick subcutaneous fat causing elevated HV impedance and leading to first shock failure.[3] Amin and colleagues[4] showed that low BMI and low HV impedance were associated with

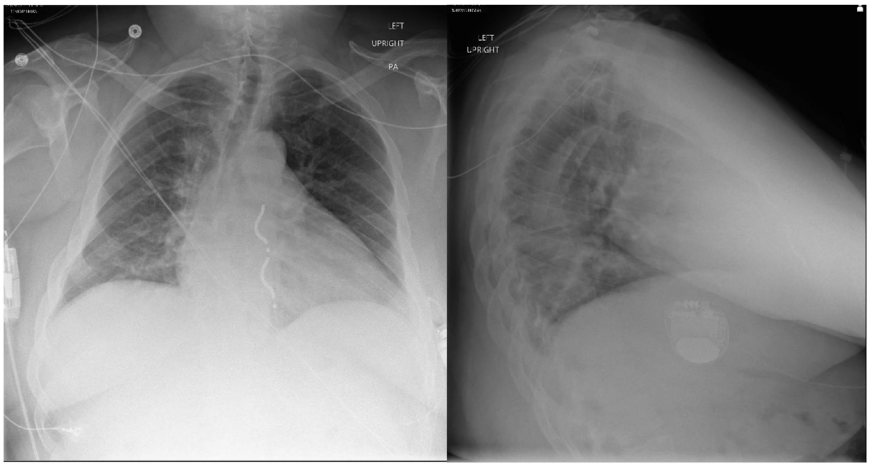

Figure 2 Chest radiography, posteroanterior and lateral view, of patient B status post device implant.

conversion success and first shock efficacy was highest for impedances ≤89 ohms. However, when optimal lead positioning was achieved, high BMI was not associated with conversion failure.[4]

Likewise, Quast and colleagues[5] identified that minimizing the space between the ICD coil and the sternum was essential and built a noninvasive scoring system, which, when low, is associated with successful DFT, regardless of BMI.[5,6] This further emphasizes the (1) importance of optimizing the position and (2) reducing generator-lead distance secondary to excess adipose tissue will lead to increased first shock efficacy.[7–9] Additionally, S-ICD generator placement posterior to the midaxillary line was also associated with increased first shock efficacy.[5] Therefore, the EV-ICD's intrathoracic design, with the lead tunneled underneath the sternum into the anterior mediastinum, has ideal placement. This factor is likely the primary determinant to DFT success with the EV-ICD, especially considering both patients had anterior axillary placement of the generator.

This is not the only advantage the EV-ICD has over the S-ICD, however. It is a smaller device (33 cm^3 compared to ∼60 cm^3), with antitachycardia pacing, postshock pacing, pause prevention pacing, and longer longevity. The most distinctive difference is the epsilon-shaped lead, which allows for these sensing and pacing options. Extraction concerns of the mediastinal lead have also been addressed. In the Pivotal study, all 15 patients who underwent lead explantation did so with manual traction up to 392 days after implant. Although long-term extraction data are underway, studies in sheep show that chronic removal of EV-ICD leads up to 5 years from implant can be performed safely using traction and currently available extraction tools.[10]

Conclusion

These results support further studies on the efficacy and feasibility in patients with class III obesity and make EV-ICDs a promising alternative to an S-ICD in these patients.

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During the preparation of this work the corresponding author used Canva.com to improve language and readability. After using this tool/service, the author(s) reviewed and edited the content as needed and take full responsibility for the content of the publication.

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