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CASE REPORT

INTERMEDIATE

CLINICAL CASE

Appropriate Implantable Cardioverter-Defibrillator Therapies Delivered 5 Years After End of Service

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ABSTRACT

We present the case of a 57-year-old man with a primary prevention internal cardioverter-defibrillator for severe non-ischemic cardiomyopathy. At the time of elective replacement indicator, systolic function had fully recovered, and his generator was not changed. Nearly 5 years post-elective replacement indicator he received appropriate internal cardioverter-defibrillator therapies during a myocardial infarction. (**Level of Difficulty: Intermediate.**) (J Am Coll Cardiol Case Rep 2020;2:796-801) © 2020 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

The implantable cardioverter-defibrillator (ICD) is a key strategy for primary and secondary prevention of sudden death in patients with severe cardiomyopathy and in patients with previous sustained ventricular tachyarrhythmias without a reversible cause. Normalization of left ventricular systolic function after implantation of an ICD for primary prevention in the absence of any documented tachyarrhythmias or pacing indication raises uncertainty at the time of pulse generator elective replacement indicator (ERI), given that the original indication for device implantation is no longer present (1-4). On the basis of the manufacturer's recommendation, standard practice is to perform pulse generator change for ICDs and pacemakers within 3 months of

LEARNING OBJECTIVES

- To review the uncertainty surrounding optimal management of patients with a primary prevention implantable cardioverter-defibrillator without documented tachyarrhythmias or pacing and full recovery of left ventricular systolic function at the time of pulse generator elective replacement indicator.
- To understand factors that affect current drain and battery depletion in implantable cardioverter-defibrillators.
- To recognize the potential transitioning of ventricular arrhythmia substrate from non-ischemic to ischemic.

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reaching ERI, also known as the recommended replacement time (RRT) or elective replacement time (ERT). This replacement should be done before the device reaches its end of life (EOL), also termed end of service (EOS), to prevent inadequate and erratic therapies or lack of therapies resulting from battery depletion (5,6). The determination of ERI is device specific, largely recommended by manufacturers in the absence of definitive publications or industry standards. Understandably, studies reporting on device performance beyond the 3 months after ERI while these devices remain in situ are lacking. In this case report, we discuss delivery of appropriate ICD therapy nearly 5 years after ERI.

HISTORY OF PRESENTATION

A 57-year-old man presented to the emergency department in 2017 with acute chest pain episodes occurring at rest followed by a syncopal episode at home. He had a dual-chamber ICD device in situ for primary prevention of sudden cardiac death in the setting of nonischemic cardiomyopathy, and he presented 4.5 years after his ICD had reached ERI. His admission vital signs and hemodynamics were stable, and physical examination was unremarkable.

PAST MEDICAL HISTORY

The patient was initially found to have heart failure when he presented with congestive symptoms in 2005 on a background of hypertension, hyperlipidemia, and type 2 diabetes mellitus. A transthoracic echocardiogram showed a severely reduced left ventricular ejection fraction (LVEF) of 20% (improving to 25%) with a dilated left ventricle and global hypokinesis. Cardiac catheterization showed nonobstructive coronary disease, and cardiac output was 2 l/min with a cardiac index of 0.8 l/min/m^2 (by thermodilution). Endomyocardial biopsy revealed nonspecific findings. While in the hospital, he was observed to have intermittent Mobitz type II second degree atrioventricular (AV) block on telemetry. The nonischemic cardiomyopathy was managed according to guideline-directed medical therapy. Given the occurrence of intermittent Mobitz II AV block, a dual-chamber Medtronic ICD (Medtronic, Minneapolis, Minnesota) for primary prevention against sudden cardiac death was implanted without waiting for at least 3 months of guideline-directed medical therapy during his hospitalization; the device was programmed to minimize right ventricular pacing.

LVEF subsequently improved to 50% to 55% in 2010 and to 65% in 2012 when his ICD generator reached ERI, in keeping with the expected longevity. A decision was therefore made not to replace the ICD generator, primarily driven by the patient's own reluctance to have the generator change. He had never had any therapies from his device since implantation to 2012, was paced in the right ventricle <1% of the time, and had atrial pacing of 7.8% at the time of the ERI. The lack of any significant ventricular pacing suggested that his previous intermittent AV conduction disease may have been part of his acute cardiomyopathy, which subsequently resolved. He did not come for any cardiology follow-up visits between 2012 and 2017.

ABBREVIATIONS AND ACRONYMS

AV = atrioventricular

CRT = cardiac resynchronization therapy

EOL = end of life

ERI = elective replacement indicator

ICD = implantable cardioverter-defibrillator

LAD = left anterior descending coronary artery

LVEF = left ventricular ejection fraction

NSVT = nonsustained ventricular tachycardia

VF = ventricular fibrillation

VT = ventricular tachycardia

DIFFERENTIAL DIAGNOSIS

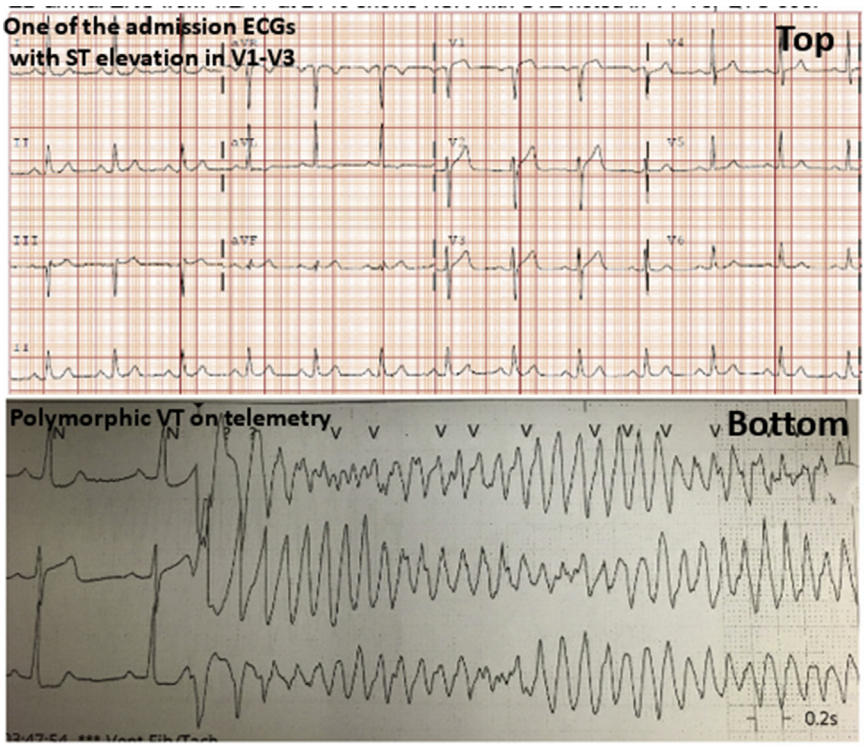
The initial broad differential diagnoses of syncope and chest pain included acute coronary syndrome, cardiac tachyarrhythmias or bradyarrhythmias, and pulmonary embolism.

INVESTIGATIONS

Admission electrocardiograms revealed normal sinus rhythm with dynamic ST-segment elevation in lead V_1 and subtle ST-segment elevation in leads V_2 and V_3, as well as a normal corrected QT interval (**Figure 1**, top panel). Telemetry showed polymorphic nonsustained ventricular tachycardia (NSVT) episodes. There was a minor troponin I elevation that peaked at 0.17 ng/ml (normal: <0.04 ng/ml), but other routine blood tests, including electrolytes and B-type natriuretic peptide, were within normal limits. Given episodes of rest chest pain, anteroseptal wall ST-segment changes, polymorphic NSVT episodes, and minor troponin rise, he was diagnosed with acute coronary syndrome. He underwent coronary angiography, which showed a normal left main stem, severe middle to distal left anterior descending artery (LAD) stenosis (90%), mild left circumflex artery stenosis (10% to 30%), and mild right coronary artery stenosis (10% to 30%) with right dominance (**Figure 2**, Videos 1 and 2). The LAD stenosis was successfully revascularized with 3 drug-eluting stents.

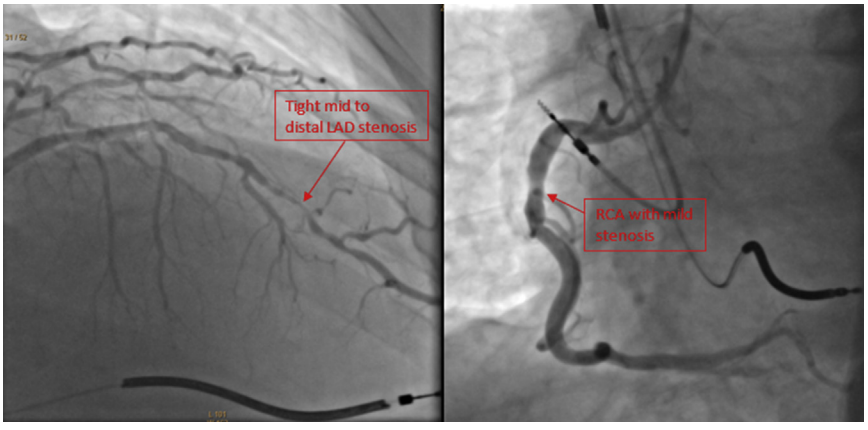
Soon after coronary reperfusion, he developed a ventricular tachyarrhythmia storm. He received multiple shock therapies from the ICD, eventually

FIGURE 1 Admission ECG and Telemetry



(Top) One of the admission electrocardiograms (ECGs) showing ST-segment elevation in lead V_1 and subtle ST-segment elevation in leads V_2 and V_3. **(Bottom)** Telemetry strip showing onset of 1 of the polymorphic ventricular tachycardia (VT) runs during coronary care unit admission.

FIGURE 2 Coronary Angiogram Showing Severe LAD Stenosis as the Culprit of the Acute Coronary Syndrome, and Mild Stenosis in the RCA



LAD = left anterior descending artery; RCA = right coronary artery.

followed by an episode during which the device did not intervene, and external defibrillation was required (see telemetry strip of onset of polymorphic VT at the bottom of Figure 1). ICD interrogation showed battery voltage of 2.58, with ERI reached 4.5 years ago, and revealed that he had ventricular arrhythmia during the syncopal episode at home that led to the hospitalization. The device had registered 13 sustained episodes of ventricular tachycardia (VT) or ventricular fibrillation (VF) after ERI, including 7 within 48 h of the current hospitalization and multiple NSVT episodes, with the ICD shocking him appropriately and successfully terminating the first 6 of the 7 recent VT or VF episodes (Table 1). The seventh episode during hospitalization was treated with external defibrillation (Figure 3). Further interrogation of his device after it failed to deliver therapy revealed abnormally high pacing impedance (>3,000 Ω) and shock impedance (>200 Ω). Of note, the ICD was not interrogated at first opportunity despite his presentation with syncope because it was presumed to be EOL because it had been nearly 5 years since ERI. An echocardiogram revealed normal LVEF of 65% with no significant valvular disease.

TABLE 1 VA Episodes Retrieved From the Implantable Cardioverter-Defibrillator Since it Reached ERI in 2012*

VA Event Number	Date and Time	Type	VA Cycle Length, ms	Last Therapy and Number Delivered	Therapy Success	Duration
13	Jan 03 14:14:35	VF	150s	VF Rx × 1	Yes	1.0 min
12	Jan 03 13:34:22	VF	210	VF Rx × 1	Yes	18 s
11	Jan 03 09:36:15	VF	140	VF Rx × 1	Yes	18 s
10	Jan 03 04:13:39	VF	140	VF Rx × 1	Yes	17 s
9	Jan 03 04:00:57	VF	140	VF Rx × 1	Yes	17 s
8	Jan 02 21:15:04	VF	170	VF Rx × 1	Yes	18 s
7	Jan 02 07:19:05	VF	140	VF Rx × 1	Yes	20 s
6	Nov 03 04:15:30	FVT	390	VF Rx × 1	Yes	55 s
5	May 18 07:51:17	VF	240	No Rx delivered	—	4 s
4	Mar 15 10:57:12	VF	190	No Rx delivered	-—	11 s
3	Jul 01 14:32:38	VF	160	VF Rx × 1	Yes	6 s
2	Jul 01 14:31:50	VF	170	No Rx delivered	—	10 s
1	Jul 01 14:31:03	VF	200	VF Rx × 1	Yes	7 s

*The table depicts VA episodes during the last device interrogation in January 2017. It bears evidence of successful treatment of these VA episodes as shown by "Yes" in column 6.

ERI = elective replacement interval; FVT = fast ventricular tachycardia; Rx = therapy; VA = ventricular arrhythmia; VF = ventricular fibrillation.

MANAGEMENT

Cardiac catheterization in combination with LAD stent placement was undertaken. Given the likelihood that the substrate for arrhythmia risk had changed from initially nonischemic to now ischemic, he underwent an ICD pulse generator change for secondary prevention before discharge. He received a new Medtronic device with satisfactory parameters using the existing leads. The patient had a Medtronic Spring Fidelis ICD lead in situ with potential for recall. However, good lead parameters were observed during generator change (R-wave sensing: 14.8 mV; threshold: 0.7 V; impedance: 471 Ω), and fluoroscopy and cine acquisition revealed no conductor abnormalities or physical damage to the lead, so it was left in place. He also began standard secondary prevention therapy for ischemic heart disease, dual antiplatelet therapy, and sotalol 80 mg twice daily to prevent further arrhythmias, in case the VT or VF episodes were not entirely driven by the acute coronary syndrome.

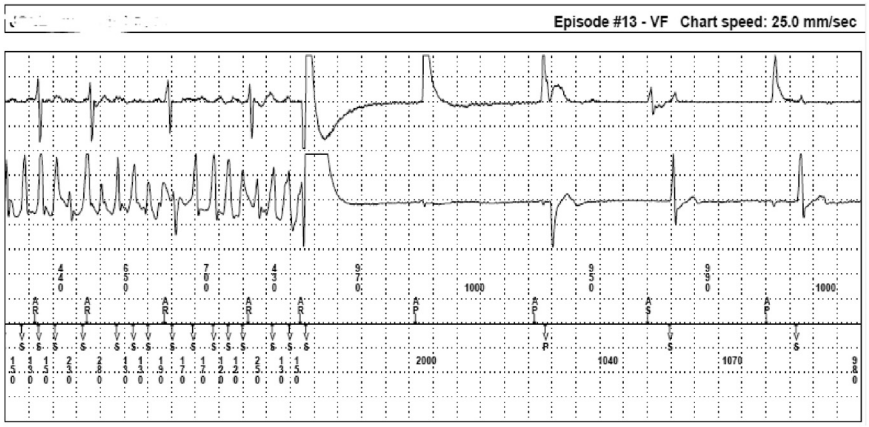
DISCUSSION

Our patient had successful appropriate discharging of ICD therapies nearly 5 years after the device had reached ERI. A publication search did not reveal any prior reports of successful therapies by ICD this long after reaching ERI. It remains unclear why the device still had the electrical capacity to deliver therapies after such a long period.

Factors that affect current drain and battery depletion include pacing percentage, pacing rate, programmed output voltage, pulse width, lead impedance, number of ICD shocks, energy levels of shocks, and capacitor maintenance. The batteries commonly used in contemporary pacemakers and ICD are lithium iodine, lithium silver vanadium oxide, and lithium manganese oxide. Two commonly used battery depletion indicators determining the ERI are battery cell impedance elevation above a given threshold (usually >15,000 to 20,000 Ω) and battery voltage drop below a given threshold, depending on the type of battery and manufacturer (6). Ampere hour also has been shown to be a predictor of ERI (7). Some studies have suggested that these variables may not reliably predict ERI, whereas others have suggested that the 3-month window from ERI to EOL may be too conservative (8). Device interrogation in our patient showed presumably inappropriate pacing and shock impedance elevation despite documented lead integrity at the time of generator change probably as a result of generator battery depletion. Event #13 with VF detected for 1 min had no therapies delivered, presumably because of the inability to charge secondary to battery depletion.

This case report raises some interesting clinical conundrums. There has been much debate about what to do when patients with a primary prevention

FIGURE 3 Last VT or VF Episode Successfully Treated With External Defibrillation After ICD Failed to Deliver Therapy



ICD = implantable cardioverter-defibrillator; VF = ventricular fibrillation; VT = ventricular tachycardia.

ICD for nonischemic cardiomyopathy reach ERI with sustained normalization of ventricular ejection fraction and no significant tachyarrhythmias or bradyarrhythmias requiring therapies. A few studies have suggested that at the time of ERI, patients with partially recovered left ventricular systolic function (LVEF of 36% to 49%) and fully recovered left ventricular systolic function (LVEF ≥50%) after primary prevention ICD implantation have a relatively low risk of ventricular tachyarrhythmias, heart failure admissions, and mortality when compared with patients with LVEF ≤35% (1,4). Although some studies have shown no appropriate ICD therapies or an extremely low risk of ventricular arrhythmias in patients with completely normalized LVEF (≥50%) prospectively during follow-up (1), the majority of studies showed a persistent residual risk of ventricular arrhythmias requiring appropriate ICD therapies in patients with LVEF >35% who no longer met primary prevention ICD indications, albeit at a significantly lower rate compared with LVEF ≤35% (4). However, in this latter group of patents with LVEF >35%, ventricular arrhythmia outcomes in a subset of patients with LVEF ≥50% at time of generator change were not separately reported. Therefore, we currently have no robust data to recommend whether patients with fully recovered LVEF and no previous appropriate tachycardia or bradycardia therapies should or should not undergo ICD generator at time of ERI. The MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial With Cardiac Resynchronization Therapy) substudy suggested that in view of the risk of inappropriate ICD therapies, those patients with normalized ejection fractions could be considered for downgrade from a cardiac resynchronization therapy (CRT) defibrillator to a CRT pacemaker at the time of battery depletion if no ventricular arrhythmia episodes have occurred (1). However, a potential continuous benefit from ICDs in patients with recovered LVEF has been highlighted in primary prevention recipients with improved LVEF without a previous history of appropriate ICD therapy at generator change (3). Comparable risks of all-cause mortality between improved and unimproved left ventricular systolic function have been observed, with benefit from ICD largely preserved (9). In addition, a joint task force report on the appropriate use criteria for ICD and CRT by the American College of Cardiology Foundation, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance suggested that it may be appropriate for patients with primary prevention ICD and no clinically relevant ventricular arrhythmias and normalized LVEF of ≥50% at time of ERI to proceed with the generator replacements (2). Cardiac implantable electronic device generator changes carry periprocedural and short- to medium-term risks (10). The REPLACE registry (Implantable Cardiac

Pulse Generator Replacement Registry) data showed that pacemaker and ICD pulse generator change are not benign procedures, with a risk of complications as high as 4.0% in patients without an upgrade and 15.3% with an upgrade or lead revision and higher for ICDs compared with pacemakers (10).

On the basis of contemporary evidence, risk restratification at the time of generator change in patients with recovered LVEF is likely to be important. The risk of undergoing a potentially risky ICD generator change with possibly no palpable benefit and its potential inappropriate shocks should be weighed against the residual risk of malignant arrhythmias and sudden cardiac death in the context of comorbidities and life expectancy, in a careful, shared decision-making process between the implanting physician and the patient. As demonstrated by our patient, normalization of LVEF with no prior tachycardia therapies did not absolve him from a future risk of ventricular arrhythmias related to a new disorder.

FOLLOW-UP

Periodic device interrogations, with the most recent occurring 19 months after his myocardial infarction, revealed only 1 episode of NSVT, which lasted 11 beats at 187 beats/min without any associated symptoms. He has had no issues identified with the Sprint Fidelis ICD lead, which is being monitored closely with the Lead Integrity Alert algorithm through the currently implanted device. His LVEF remains preserved at 60%.

CONCLUSIONS

We have reported on a case of an ICD delivering appropriate tachycardia therapies nearly 5 years after reaching ERI and no generator change as a result of recovered LVEF in the patient. Given that uncertainty remains about what to do with patients who have ICDs for primary prevention and whose cardiomyopathy resolves by the time of ERI, prospective clinical trials comparing outcomes in patients with full LVEF recovery who did not undergo generator change versus those who did at the time of ERI may help decipher this clinical equipoise.

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KEY WORDS cardiomyopathy, elective replacement indicator, implantable cardioverter-defibrillator, ventricular arrhythmias

APPENDIX For supplemental videos, please see the online version of this paper.