RESEARCH ARTICLE

IMPLANTABLE DEFIBRILLATION THERAPY

Premature Battery Depletion in St. Jude Fortify® and Unify® Cardiac Implanted Electronic Devices

TRAVIS D. RICHARDSON, MD^{1,2}, BABAR PARVEZ, MD¹, SHARON SHEN, MD¹,
CHRISTOPHER R. ELLIS, MD¹ and JEFFREY N. ROTTMAN, MD^{1,2,3}

¹Vanderbilt Heart and Vascular Institute, Division of Cardiac Electrophysiology, Nashville, TN

²Nashville VA Medical Center, Division of Cardiac Electrophysiology, Nashville, TN

³Department of Medicine, University of Maryland School of Medicine, Baltimore, MD

ABSTRACT. The predictability of battery performance in pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs) is necessary for safe clinical management. Unpredictable performance can have life-threatening implications. The aim was to describe the behavior of devices in the St. Jude Fortify® and Unify® device (St. Jude Medical, Minnetonka, MN) families exhibiting premature battery depletion. Five cases of very rapid battery depletion were identified. All available device data from 1 year prior to generator change were reviewed for trend in battery capacity, percent pacing, tachycardia therapies, and remote transmissions. All cases demonstrated rapid and unpredictable depletion of battery capacity and the presence of lithium clusters on device analysis. In the 12 months prior to generator change there were no significant changes in pacing burden or transmissions. None of the patients received either anti-tachycardia pacing or shocks in the 12 months prior to generator change. In two of the five cases the device reached the elective replacement indicator and end of service within 24 hours. In two cases emergent generator change was necessary due to PM dependence. Devices in the St. Jude Fortify® and Unify® families may exhibit precipitous battery depletion. Lithium cluster formation leading to battery depletion has been previously described. These data suggest this may be more common than previously thought. Owing to the unpredictable nature of battery performance in these devices, careful monitoring and potentially generator change for any abnormal battery behavior is indicated.

KEYWORDS. Battery, cardiac implantable electronic devices.

ISSN 2156-3977 (print)
ISSN 2156-3993 (online)

© 2016 Innovations in Cardiac
Rhythm Management

Introduction

As the rate of implantation of cardiac rhythm management devices steadily increases, improvement in battery longevity is of critical importance to clinicians and patients. Shorter battery life leads to more frequent

generator replacement, exposing patients to increased risk for lead damage, hematoma formation, infection, and even death.^{1–3} Also of importance is the predictability of battery performance, allowing clinicians to anticipate the need for generator replacement prior to the onset of unreliable device function, which can expose patients with pacemaker dependence or those with implantable cardioverter-defibrillators (ICDs) with high risk of ventricular arrhythmias to life-threatening consequences. Many mechanisms for battery depletion have been described previously, and these may occur sporadically. However, it is especially important for clinicians to be observant when they see unusual battery behavior as premature battery depletion in certain device families has previously been reported.⁴

Christopher R. Ellis reports research funding from Medtronic, Atracure, Abbott, and Boston Scientific; Advisory board, consulting from Medtronic, Sentre Heart, Spectranetics, Biosense Webster, Boston Scientific, and Atracure. All other authors report no conflicts of interest for the published content.

Manuscript received December 13, 2016, Final version accepted December 22, 2016.

Address correspondence to: Travis D. Richardson, MD, Vanderbilt University Medical Center, 2220 Pierce Ave., 383 Preston Research Building, Nashville, TN 37232-6300.

E-mail: travis.d.richardson@vanderbilt.edu

Table 1: Baseline patient and device characteristics

Case no.	Age (years)	Condition	Device model	Year of implant	Longevity (months)	Mode	Pacing in the last 12 months (%)		Tachycardia therapies in the last 12 months		Remote transmissions in the last 12 months
							Atrial	Ventricular	ATP	Shocks	
1	70	ICM, secondary prevention	Fortify [®] Dual-chamber ICD	2011	51	DDDR 60	86	1.20	0	0	6
2	72	ICM, secondary prevention	Fortify [®] Dual-chamber ICD	2010	50	DDDR 50	2.90	<1	0	0	5
3	60	ICM, PM dependent	Fortify [®] Dual-chamber ICD	2012	34	DDDR 70	97	12	0	0	3
4	67	NICM	Unify [®] Biventricular ICD	2011	47	DDDR 60	67	97	0	0	4
5	69	ICM, PM dependent	Unify [®] Biventricular ICD	2011	50	DDDR 60	19	94	0	0	4

Abbreviations: ATP = anti-tachycardia pacing; ICD = implantable cardioverter-defibrillator; ICM = ischemic cardiomyopathy; NICM = non-ischemic cardiomyopathy; PM = Pacemaker.

We present a series of five patients who experienced rapid and unpredictable battery depletion of their St. Jude Medical Fortify[®] and Unify[®] devices.

Methods

Cases of premature battery depletion in St. Jude Fortify[®] and Unify[®] devices were identified from our clinical practice. All available device data including in-office and remote device transmissions occurring within 1 year prior to generator change were reviewed for trend in battery capacity, percent pacing, tachycardia therapies, and remote transmissions. Clinical data were obtained from patient medical records at the Vanderbilt University Medical Center or the Nashville VA Medical Center. Data were obtained as a component of clinical care. The total number of devices followed was obtained as a component of clinical care in responding to the recently described advisory concerning these devices.⁵ Post-explantation analysis results were obtained from correspondence between the device manufacturer and the explanting physician as part of clinical care.

Results

Five cases of rapid and unpredictable battery depletion were identified with implant dates ranging from July 2010 to June 2012. Patient and device characteristics are presented in **Table 1**. The mean age of the patients was 67.6 years. The etiology of cardiomyopathy was ischemic in four of the five patients, and non-ischemic in the fifth. The indication for device implantation was severe left ventricular dysfunction in three cases, history of ventricular tachycardia arrest in one, and inducible ventricular tachycardia on electrophysiology testing in one. All lead impedances were within the normal range and no patient had experienced a change in pacing burden, output, or device transmissions. No patient had received ICD shocks or anti-tachycardia pacing (ATP) within the 12 months prior to generator change. In two of the five cases, the device reached the elective replacement indicator and end of service within 24 hours. In two cases, emergent generator change was necessary because of PM dependence. In one case, wearable cardioverter defibrillator “bridging” was necessary. All patients underwent successful generator replacement after identification of rapid battery depletion. All devices were found to have evidence of lithium clusters within the battery after analysis by the manufacturer.

Case 1

A 70-year-old man with a history of coronary artery disease experienced cardiac arrest because of ventricular tachycardia in April 2011. He underwent percutaneous coronary intervention, was started on amiodarone, and underwent implantation of a dual chamber (St. Jude Fortify[®] DR ICD) at that time. On March 22, 2013, he received two inappropriate shocks for atrial fibrillation with rapid ventricular response. He has not received any further tachycardia therapies from his device.

On July 16 he noted an alarm tone from his ICD, and an unscheduled remote transmission was sent to his cardiologist indicating that his device was at elective replacement indicator (ERI). Review of his remote transmission data revealed that the remaining battery capacity on his device had declined rapidly from 60% on 21 March, 2015, to 18% on 19 May, 2015, and ERI on 15 July, 2015. The patient's underlying rhythm was sinus bradycardia with 86% atrial pacing and 1.2% ventricular pacing. Programmed atrial output was 2 V/0.5 ms and ventricular output was 2.5 V/0.5 ms. Generator change was performed urgently on July 21, 2015.

Case 2

A 72-year-old man with a history of prior myocardial infarction was found to have inducible sustained ventricular tachycardia on an electrophysiology study in May 2008 prompting implantation of a single-chamber ICD. In 2010 he developed atrial fibrillation with rapid ventricular rates leading to inappropriate shocks from his device. This prompted upgrade to a dual-chamber St. Jude Fortify[®] DR ICD on July 12, 2010. He has not received any further tachycardia therapies from his device. On August 13, 2014, he noted vibrations from his device and a remote transmission was sent to his cardiologist indicating that his device was at ERI. Review of his remote transmission data revealed that the remaining battery capacity on his device had declined rapidly from 67% on April 18, 2014, to 58% on July 28, 2014, and ERI on 13 August, 2014. The patient's underlying rhythm was normal sinus with 2.9% atrial pacing and <1% ventricular pacing. Programmed atrial output was 1.5 V/0.5 ms and ventricular output was 2 V/0.5 ms. The patient was asked to urgently come to the clinic where tachycardia therapies on his device were disabled and a wearable defibrillator was placed. Generator change was performed on September 9, 2014.

Case 3

A 60-year-old man with a history of ischemic cardiomyopathy with severely depressed left ventricular function underwent implantation of a dual-chamber St. Jude Fortify[®] DR ICD on June 1, 2012. He has never received tachycardia therapies from his device. On April 19, 2015, a remote transmission was sent to the patient's cardiologist indicating that his device had reached ERI and end of service (EOS) on February 4, 2015. The patient was receiving 97% atrial pacing and 12% ventricular pacing. Programmed atrial output was 1.75 V/0.5 ms and ventricular output was 2.25 V/0.5 ms. He was asked to emergently report to clinic. With pacing inhibited the patient had a 4-s pause followed by junctional bradycardia at 50 BPM, indicating pacemaker dependence. Generator change was performed emergently that night.

Case 4

A 67-year-old man with a history of non-ischemic cardiomyopathy with severely depressed left ventricular

function and left bundle branch block underwent implantation of a biventricular St. Jude Unify[®] ICD on September 7, 2011. Since then he has received two inappropriate shocks for atrial fibrillation with rapid ventricular response (RVR), the first in November of 2011 and subsequently in March of 2013. On August 2, 2015, a remote transmission was sent to his cardiologist revealing that his battery capacity was rapidly depleting. Review of remote transmission data indicated that his battery capacity had declined from 56% on August 21, 2014, to 22% on August 2, 2015. He was receiving 67% atrial pacing and 97% biventricular pacing. Programmed atrial output was 1.75 V/0.5 ms, right ventricular output was 2.5 V/0.5 ms, and left ventricular output was 2.5 V/0.5 ms. Out of concern for unreliable battery performance he underwent elective generator replacement on August 12, 2015.

Case 5

A 69-year-old man with coronary artery disease and complete heart block with placement of a dual-chamber permanent pacemaker in April of 2009 underwent upgrade to a St. Jude Unify[®] biventricular ICD on May 12, 2011, because of the development of ischemic cardiomyopathy with severely depressed left ventricular function. Since his ICD was implanted, he has received two shocks for a single episode of ventricular tachycardia on March 13, 2015, one round of appropriate ATP for ventricular tachycardia on July 13, 2014, and one round of inappropriate anti-tachycardia pacing for atrial fibrillation on November 10, 2014. On July 3, 2015, the patient felt his ICD vibrate but was unable to reach his physician because of the Independence Day holiday. He presented to the clinic for routine device follow-up on July 29, 2015, where interrogation revealed that his device reached ERI and EOS on July 3. The patient's underlying rhythm was sinus bradycardia with 19% atrial pacing and 94% ventricular pacing. Programmed atrial output was 2 V/0.5 ms, right ventricular output was 2.5 V/0.5 ms, and left ventricular output was 2 V/0.5 ms. He was admitted to the hospital and generator change was performed emergently because of his history of complete atrioventricular block and prior ventricular tachycardia.

These cases are summarized in **Table 1**. In **Figure 1** we present the estimated generator longevity prior to generator replacement indexed relative to the time of generator replacement. If the prediction of generator depletion were perfect, then these points should fall along a line of unit; that is, the estimated generator longevity at "x" months prior to replacement at ERI should be "x" months. Presenting the data in this way accommodates the more complex relationship between monitored battery voltage and estimated longevity in a way that the manufacturer considers most appropriate. For two devices there was an "inflection" point prior to the final abrupt index change in voltage. In the other generators there was no clear variance from normal behavior prior to the index event.

While we are unable to report the exact number of devices in the St. Jude Medical Fortify[®] and Unify[®]

Figure 1: Plot of expected battery longevity vs. time to either ERI or generator change, whichever was earlier.

families followed at our centers on any given date, there were no more than 600 devices followed at any given time and currently we follow approximately 400 patients with devices in these families.

Discussion

We present five cases of rapid, unpredictable battery depletion in the St. Jude Fortify[®] and Unify[®] device families. The average generator longevity among these cases was 46 months. While this is not particularly short, the finding of great clinical concern was the extremely rapid rate of battery depletion as the device neared EOS. The transition from ERI to EOS occurred rapidly enough to be missed by routine device surveillance or even more aggressive (e.g., monthly) device surveillance in multiple cases. In two of our five cases the device voltage transitioned from "nominal ERI" to "nominal EOS" within 24 h. This occurred in the absence of changes in pacing output or ICD shocks to explain this behavior. No loss of device function was observed.

While there are known to be differences in battery performance among device manufacturers, unusual behavior must be identified and reported, as pre-market surveillance for many technologies can be insufficient.⁶⁻⁸

There are many potential explanations for premature battery depletion. Devices in the St. Jude Fortify[®] and Unify[®] families make use of lithium silver vanadium oxide batteries (Greatbatch Medical, Clarence, NY). In this particular device family, a novel mechanism of battery depletion, lithium cluster formation at the cathode leading to a short circuit to the outer conductive case and overheating of the battery cells, has been reported by Pokorney et al.⁹ In addition, this group reported the prevalence of this mechanism to be 0.004% using data from St. Jude Medical as well as the MAUDE database, although the single center prevalence was 0.6%.

Given that we have observed five cases of unreliable battery performance and lithium cluster formation within a single practice that follows no more than 600 of these devices, we suspect that the prevalence of lithium cluster mediated battery drain is higher than reported. An advisory has recently been issued that includes remote monitoring and setting of ERI alarms because of the potential for depletion in several classes of St. Jude Medical ICD generators including the Fortify[®] and Unify[®] families.⁵ We believe that these cases provide support for those recommendations and provide critical information about the expected time frames for generator depletion in affected devices.

The presence of this number of cases in a modest population of devices suggests a greater incidence than the so-far reported 0.2%. One factor in this may be definitional: if a generator lasts longer than the predicted generator longevity, but voltage declines very rapidly from ERI to EOS, then generator depletion may be “precipitous” but not “premature.” However, defining this behavior is still essential for appropriate clinical care. Certainly, any St. Jude Medical ICD generator within the advisory set found to be at or beyond ERI should be replaced promptly. However, the exact time frame for that remains uncertain. Does it imply the need for admission and telemetry observation until the procedure can be performed? Does it imply the need for a wearable defibrillator (LifeVest[®], ZOLL[®] Medical Corporation, Chelmsford, MA) with an early scheduled outpatient generator replacement? The cases presented refer specifically to this, and reinforce that the transition to “EOS” may occur in hours to days, and may be faster than the typical scheduling of elective generator replacements. The same considerations apply to patients incapable of reliable remote follow-up or response to an alarm, or those with potentially catastrophic consequences to precipitous depletion (such as pacing dependence). In these cases we believe that consideration must be given to generator replacement prior to ERI.

In cases where estimated battery longevity does not follow the expected temporal trend, we also propose that generator replacement be undertaken prior to ERI, as evidenced by the two “inflections” in **Figure 1**.

Study limitations

Owing to the small sample size represented in this study, rigorous attempts at modeling device behavior could not be achieved in this manuscript. Further efforts to characterize battery behavior in these device families should provide further clarity as to the most appropriate care of affected patients.

Conclusions

Devices in the St. Jude Medical Fortify[®] and Unify[®] families are potentially subject to rapid battery depletion because of the development of lithium clusters. We have described five cases exhibiting this behavior. These cases clearly illustrate the precipitous decline in

performance that may occur with several devices reaching ERI and EOS within 24 h. Additionally, the frequency with which we have seen this behavior in our population suggests a higher prevalence than previously described. On the basis of these results we suggest close remote monitoring in all patients and consideration of elective device replacement prior to ERI in those who are either pacemaker dependent or have secondary prevention devices.

References

1. Poole JE, Gleva MJ, Mela T, et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: Results from the REPLACE registry. *Circulation*. 2010; 122(16):1553–1561.
2. Krahn AD, Lee DS, Birnie D, et al. Predictors of short-term complications after implantable cardioverter-defibrillator replacement: Results from the Ontario ICD Database. *Circ Arrhythm Electrophysiol*. 2011;4(2):136–142.
3. Hauser RG, Hayes DL, Epstein AE, et al. Multicenter experience with failed and recalled implantable cardioverter-defibrillator pulse generators. *Heart Rhythm*. 2006; 3(6):640–644.
4. Ozcan C, Rottman JN, Heist K, et al. Unpredictable battery depletion of St. Jude Atlas II and Atlas + II HF implantable cardioverter-defibrillators. *Heart Rhythm*. 2012;9(5):717–720.
5. Food and Drug Administration. *Premature battery depletion of St Jude Medical ICD and CRT-D devices: FDA safety communication*. <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm524666.htm>. Published October 11, 2016. Accessed December 11, 2016.
6. Knops P, Theuns DA, Res JC, Jordaens L. Analysis of implantable defibrillator longevity under clinical circumstances: Implications for device selection. *Pacing Clin Electrophysiol*. 2009;32(10):1276–1285.
7. Schaer BA, Koller MT, Sticherling C, Altmann D, Joerg L, Osswald S. Longevity of implantable cardioverter defibrillators, influencing factors, and comparison to industry-projected longevity. *Heart Rhythm*. 2009;6(12):1737–1743.
8. Ellinor PT, Guy ML, Ruskin JN, McGovern BA. Variability in implantable cardioverter defibrillator pulse generator longevity between manufacturers. *Pacing Clin Electrophysiol*. 2003;26(1 Pt 1):71–75.
9. Pokorney SD, Greenfield RA, Atwater BD, Daubert JP, Piccini JP. Novel mechanism of premature battery failure due to lithium cluster formation in implantable cardioverter-defibrillators. *Heart Rhythm*. 2014;11(12):2190–2195.