Europace (2014) **16**, 246–251
doi:10.1093/europace/eut301

Battery longevity in cardiac resynchronization therapy implantable cardioverter defibrillators

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Received 26 June 2013; accepted after revision 4 September 2013; online publish-ahead-of-print 6 October 2013

Aims Cardiac resynchronization therapy (CRT) implantable cardioverter defibrillators (ICDs) deliver high burden ventricular pacing to heart failure patients, which has a significant effect on battery longevity. The aim of this study was to investigate whether battery longevity is comparable for CRT-ICDs from different manufacturers in a contemporary cohort of patients.

Methods and results All the CRT-ICDs implanted at our institution from 1 January 2008 to 31 December 2010 were included in this analysis. Baseline demographic and clinical data were collected on all patients using the electronic medical record. Detailed device information was collected on all patients from scanned device printouts obtained during routine follow-up. The primary endpoint was device replacement for battery reaching the elective replacement indicator (ERI). A total of 646 patients (age 69 $\pm$ 13 years), implanted with CRT-ICDs (Boston Scientific 173, Medtronic 416, and St Jude Medical 57) were included in this analysis. During 2.7 $\pm$ 1.5 years follow-up, 113 (17%) devices had reached ERI (Boston scientific 4%, Medtronic 25%, and St Jude Medical 7%, $P < 0.001$). The 4-year survival rate of device battery was significantly worse for Medtronic devices compared with devices from other manufacturers (94% for Boston scientific, 67% for Medtronic, and 92% for St Jude Medical, $P < 0.001$). The difference in battery longevity by manufacturer was independent of pacing burden, lead parameters, and burden of ICD therapy.

Conclusion There are significant discrepancies in CRT-ICD battery longevity by manufacturer. These data have important implications on clinical practice and patient outcomes.

Keywords Cardiac resynchronization therapy • Defibrillator • Battery longevity • Manufacturer

Introduction

Cardiac resynchronization therapy (CRT) implantable cardioverter defibrillators (ICDs) are indicated for the management of heart failure patients with severe left ventricular (LV) systolic dysfunction and a wide QRS complex.[1–3] The benefit of CRT-ICDs depends upon achieving a high burden of ventricular pacing in both the right and left ventricles, with greater benefit seen at or near 100% biventricular pacing.[4,5] The need for nearly 100% biventricular pacing comprises of a significant battery drain and is usually the major determinant of battery longevity and thus of the time from device implant to the elective replacement indicator (ERI).

Cardiac resynchronization therapy-ICD pulse generator replacement is an invasive procedure with the potential risks of infection, bleeding, and damage to the implanted leads.[6–9] It is an expensive procedure, which along with the cost of a new device, contributes to rising healthcare costs. Minimizing the frequency of CRT-ICD replacement for battery depletion is therefore desirable for both patients and the healthcare system as a whole. Device manufacturers have claims of superior battery longevity for their CRT-ICD compared with the equivalent products from their competitors. Products performance reports are published regularly by each manufacturer for their own products, but comparisons across manufacturers are difficult because of different pacing parameters and definitions of ERI. Independent head-to-head comparisons for battery longevity for CRT-ICDs from various manufacturers are lacking.

We therefore investigated the battery performance of CRT-ICDs from three major device manufacturers implanted in a contemporary cohort of patients at our institution.

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What's new?

- This is the first study comparing the battery longevity of cardiac resynchronization therapy defibrillator (CRT-D) devices across three major manufacturers.
- The present study focuses on a contemporary cohort of patients with current models of CRT-D defibrillators still implanted today across the world.
- The findings of this study have direct and immediate implications on patient outcomes and may therefore impact clinical practice in CRT-D therapy.

Methods

Patient population

The present study was a retrospective, observational analysis of battery longevity of CRT-ICDs. All chart reviews were performed in March 2013. Research activities for this study were approved by the University of Pittsburgh Investigational Review Board. All the patients implanted with CRT-ICDs from 1 January 2008 to 31 December 2010 at the hospitals of the University of Pittsburgh Medical Center were included in this analysis. Patients' demographic and clinical information were extracted from the electronic medical record. Detailed device information was extracted from scanned device printouts for each CRT-ICD manufacturer from regular device clinic follow-up visits. These data included, for each lead, the pacing burden, the programmed voltage and pulse width outputs, and the pacing lead impedance. The proportion of patients receiving ICD therapy (shocks or anti-tachycardia pacing) was also recorded. Parameters of event storage for each device model were not changed from the out-of-the-box settings. Frequency of routine remote device transmissions was similar for all manufacturers as per the standards used in our outpatient device clinic (once every 3 months). Last access to patients' medical records was on 15 April 2013.

The primary endpoints of this analysis were the rate of battery depletion (reaching ERI) as well as the time from device implantation to battery depletion by the device manufacturer. Device replacements for battery depletion were counted as events for the purpose of this study. Patients were censored at the time of death, device replacements for infection, device or lead malfunctions, or removal at the time of heart transplantation as these occurrences did not count as events for the purpose of our present analysis. Patients were followed to the date of event or last outpatient follow-up.

Of the 746 patients implanted with CRT-ICDs at the hospitals of the University of Pittsburgh Medical Center, 94 were excluded from the analysis because they were lost to follow-up within a month after device implantation, because they chose to follow-up in a device clinic closer to their place of residence. Device manufacturers of excluded patients were Boston scientific ($n = 32$), Medtronic ($n = 55$), and St Jude medical ($n = 7$) and were in equivalent proportions to the overall cohort. Six patients implanted with CRT-ICDs from Biotronik were excluded from the analysis because of the small number of devices from this manufacturer that precludes meaningful comparison. The final analysis therefore included the remaining 646 patients who were all followed at the hospitals of the University of Pittsburgh Medical Center. Details of the device models included in this analysis are presented in *Table 1*.

Statistical analyses

All continuous variables are presented as mean ± standard deviation and were compared across device manufacturer using the analysis of variance (ANOVA) test or *t*-test. The median time to follow-up is shown with interquartile intervals between parentheses. All categorical variables are presented as a number and percentage and were compared using

Table 1 Details of models and numbers of devices followed and devices replaced for battery depletion

Manufacturer (*N*)	Device model (*n*)	Devices reaching the ERI (*n*)	Follow-up time (years)
Boston Scientific (173)	H220 LIVIAN (16)		2.5 ± 1.6
	H225 LIVIAN (2)	H225 LIVIAN (1)	
	H227 LIVIAN HE (18)	H227 LIVIAN HE (4)	
	H229 LIVIAN HE (16)		
	N118 COGNIS 100-D (22)		
	N119 COGNIS 100-D (100)	N119 COGNIS 100-D (2)	
	H210 Contak Renewal 3 RF (10)		
	H217 Contak Renewal 3 RF HE (3)		
	H219 Contak Renewal 3 RF HE (1)		
Medtronic (416)	8042 InSync III (6)		2.8 ± 1.5
	C154DWK Concerto (178)	C154DWK Concerto (41)	
	C154VWC Concerto (1)		
	D224TRK Consulta (227)	D224TRK Consulta (60)	
	D274TRK Concerto II (1)		
	D284TRK Maximo II CRT-D (3)	D284TRK Maximo II (1)	
St Jude Medical (57)	3207-30 (3)	3207-30 (1)	2.7 ± 1.5
	3207-36 (37)	3207-36 (3)	
	CD3211-36 (14)		
	CD3215-36Q (1)		
	3211-36 (1)		
	3211-36Q (1)		

the χ^2 test. Kaplan–Meier curves were constructed for the time to battery depletion for all device manufacturers and were compared using the log-rank test. Covariates that can affect the time to battery depletion were included in a multivariate Cox proportional hazard model. A two-sided P value <0.05 was considered statistically significant. All statistical analyses were performed on SPSS (version 10.1).

Results

Baseline characteristics of the study population

The baseline characteristics of patients included in this analysis are shown in *Table 2*. The mean age was 69 ± 13 years. The majority of patients were men (74%) with a history of coronary artery disease (64%). Of the 646 patients included in the final analysis, 173 (27%) had Boston Scientific, 416 (63%) had Medtronic, and 57 (9%) had St Jude Medical CRT-ICDs. Baseline characteristics were comparable between patients with devices from different manufacturers, except for differences consisting of higher rates of coronary artery disease ($P = 0.037$) and higher serum creatinine levels ($P = 0.047$) for patients in the Boston Scientific group ($P = 0.037$), and lower rates of hypertension for patients in the Medtronic group ($P = 0.031$). The mean follow-up of patients was similar in the three study groups (2.5 ± 1.6 years for Boston Scientific, 2.7 ± 1.5 years for Medtronic, and 2.8 ± 1.5 years for St Jude Medical, $P = 0.37$).

Battery depletion in follow-up

At a mean follow-up duration of 2.7 ± 1.5 years (median 3.07 years), 113 (17%) devices had reached ERI (7 Boston scientific, 102 Medtronic, and 5 St Jude Medical, *Table 1*). The rates of device replacements for battery depletion were 4, 25, and 7% for Boston Scientific, Medtronic, and St Jude Medical, respectively ($P < 0.001$). The device survival free from battery depletion was significantly shorter for Medtronic devices compared with other manufacturers with a 4-year survival rate of 94% for Boston scientific, 67% for Medtronic, and 92% for St Jude Medical ($P < 0.001$, *Figure 1*). Of the 102 Medtronic devices reaching ERI, 60 were Consulta model D224TRK, 41 were Concerto model C154DWK, and 1 was a Maximo II model D228TRK (*Table 1*).

Lead parameters of impedances, programmed outputs, and pacing burden for each chamber as well as the proportion of patients receiving any device therapy (shock or anti-tachycardia pacing) are shown by manufacturer group in *Table 3*. There were significant differences in lead impedances among the three study groups. Patients implanted with Boston Scientific devices had highest programmed LV outputs and were most likely to receive device therapy (*Table 3*). The difference in battery longevity by manufacturer was independent of pacing burden, lead parameters in each chamber (except for LV lead output), and burden of ICD therapy. After adjusting for these covariates in a multivariate Cox model, Medtronic devices remained more likely to reach ERI compared with devices from other manufacturers (odds ratio = 6.27, $P < 0.001$, *Table 4*).

Patients whose batteries reached ERI had higher LV output (3.1 ± 1.2 vs. 2.7 ± 0.9 V, $P < 0.001$) and higher LV pulse width (0.8 ± 0.4 vs. 0.6 ± 0.3 ms, $P < 0.001$) compared with those who did not reach ERI. No other parameters were different between the devices reaching vs. not reaching ERI. This finding was present across all manufacturer groups.

Discussion

In this study, we examined the device longevity of CRT-ICDs across three major manufacturers. Our data demonstrate a large discrepancy in CRT-ICD battery longevity by device manufacturer in a contemporary cohort of patients with device models that are currently implanted in the USA and all over the world. Information on battery longevity has, thus far, been limited to vendor-specific product performance reports that are updated quarterly. To our knowledge, this is the first head-to-head comparison of CRT-D

Table 2 Baseline characteristics

Variable	Overall cohort	Boston Scientific	Medtronic	St Jude Medical
N	652	173	416	57
Age (years)	69 ± 13	70 ± 12	69 ± 13	70 ± 13
Gender (female)	26%	20%	29%	21%
Coronary artery disease*	64%	70%	62%	61%
Diabetes mellitus	34%	38%	33%	33%
Hypertension*	66%	69%	65%	70%
Left ventricular ejection fraction (%)	29 ± 12	28 ± 12	30 ± 13	29 ± 10
Serum creatinine (mg/dL)*	1.4 ± 2.0	1.7 ± 3.9	1.3 ± 0.5	1.3 ± 0.4
Heart rate (b.p.m.)	74 ± 15	73 ± 16	74 ± 15	75 ± 17
Paced QRS width (ms)	155 ± 29	157 ± 30	154 ± 28	156 ± 30
Follow-up time (years)				
Mean	2.7 ± 1.6	2.5 ± 1.6	2.7 ± 1.5	2.8 ± 1.5
Median (IQR)	3.1 (1.3–3.9)	3.0 (0.9–3.9)	3.1 (1.5–4.0)	3.2 (1.6–4.1)

IQR, interquartile range.
*$P < 0.05$.

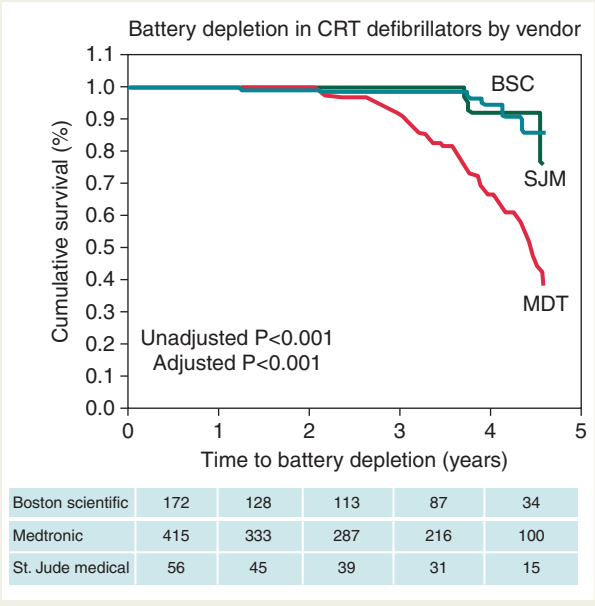

Figure 1 Kaplan–Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer.

Table 3 Device parameters and therapies by device manufacturer

	Boston Scientific	Medtronic	St Jude Medical
RA output (V)	2.6 ± 0.7	2.6 ± 0.9	2.6 ± 0.6
RA pulse width (ms)	0.49 ± 0.04	0.49 ± 0.11	0.50 ± 0.14
RA impedance (Ω)*	493 ± 195	604 ± 596	396 ± 67
RA pacing burden (%)	21 ± 33	25 ± 34	20 ± 29
RV output (V)	2.8 ± 0.7	2.6 ± 0.8	2.8 ± 0.7
RV pulse width (ms)	0.50 ± 0.04	0.52 ± 0.21	0.53 ± 0.12
RV impedance (Ω)*	511 ± 116	503 ± 181	446 ± 93
RV pacing burden (%)	91 ± 17	92 ± 20	94 ± 16
LV output (V)*	2.9 ± 0.9	2.7 ± 1.0	2.7 ± 0.8
LV pulse width (ms)	0.69 ± 0.34	0.65 ± 0.31	0.75 ± 0.38
LV impedance (Ω)*	663 ± 243	587 ± 287	565 ± 190
LV pacing burden (%)	94 ± 12	92 ± 20	94 ± 14
Proportion of patients receiving any shocks including DFT testing (%)*	55	39	5.3
Proportion of patients receiving anti-tachycardia pacing (%)*	30	16	11

RA, right atrial; RV, right ventricular; LV, left ventricular; and DFT, defibrillation threshold.
*$P < 0.05$ for ANOVA comparison of the three manufacturers.

Table 4 Independent predictors of battery depletion

	Odds ratio	95% Confidence interval		*P* value
		Lower	Upper	
Device manufacturer (Medtronic vs. others)	**6.27**	**2.53**	**15.52**	**<0.001**
RA impedance	1.00	1.00	1.00	0.762
RV impedance	1.00	0.99	1.00	0.786
LV output	**1.97**	**1.64**	**2.37**	**<0.001**
LV impedance	1.00	0.99	1.00	0.036
Proportion of patients receiving a shock	1.29	0.85	1.95	0.22

RA, right atrial; RV, right ventricular; and LV, left ventricular.

battery performance, using the hard endpoint of device replacement for battery depletion instead of other surrogate endpoints of estimated longevity. In addition, our present study has controlled for known parameters affecting battery drainage, including lead parameters and burden of pacing and tachyarrhythmia therapy.

Battery longevity has direct implications on patient care and outcomes. Shorter battery life requires more frequent device replacement, which increases healthcare costs. The financial burden of this procedure includes besides the cost of the new device, the cost of performing the surgery and managing the patient peri-operatively with clinic visits, pain medications, and antibiotics. It also includes the potential cost of managing surgical complications which are not uncommon.[6] In addition, the out-of-pocket expenses incurred by patients and their families as well as the time commitment and emotional burden of these procedures are hard to measure.

Complications from device replacements for battery depletion are significant. In the REPLACE database,[6] 7% of patients undergoing CRT-D replacement without addition or replacement of leads had major complications in the 6 months following the procedure. Also, in the aftermath of the Marquis (Medtronic Inc.) defibrillator battery recall, complications of battery replacement were 6%, including two deaths from attempts at lead extraction after pocket infection.[7] It is established in the literature that device replacements are associated with a 1–2% rate of device infections,[8,9] the majority of which require surgical or percutaneous procedures for device explantation and lead extractions, followed at a later stage by new device implantation. For all these reasons, it is desirable to minimize the number of generator changes for battery depletion. This is also important for third-party payers who reimburse hospitals for the cost of devices and procedures. In the era of accountable care, where hospital and physician reimbursements will be exceedingly linked to patient outcomes, longer device battery life is particularly important for hospitals and healthcare professionals.

Manufacturers of devices publish regularly product performance reports that set vendor-specific boundaries for the performance of their devices. Devices that perform outside of these boundaries often prompt the manufacturer to communicate information

to the consumers[10] and may prompt the manufacturer to pay a limited warranty that reimburses the institution for part of the cost of the device depending on how short its performance falls outside of the pre-specified boundaries. Although more often than not devices perform within these preset boundaries, a more important question for the consumers (patients, physicians, hospitals, and third-party payers) is which device actually performs better in comparison with other equivalent, market-released devices, given the huge implications to patient outcomes and cost of care. Clearly, battery longevity is not the only consideration in this realm, but it is one of the important ones to consider when choosing to implant a new device in a patient.

A prior study[11] had undertaken a similar task of comparing battery longevity across device manufacturers. In that study, devices implanted between 1988 and 2009 were included. The main finding of that study was that CRT and high burden of ventricular pacing were the main determinants of earlier battery depletion. Interestingly, Medtronic devices had a better longevity in that study compared with defibrillators from other vendors. It is worth noting that this study by Horlbeck *et al.*[11] was significantly different from our present study in the fact that it included various device models dating back to 1988, most of which consisted of discontinued models at the time of that publication in 2012. Other studies[12–14] have also addressed this same issue of ICD battery longevity across various manufacturers. It is worth noting that, unlike our present analysis, these studies have not been focused on contemporary CRT-ICDs but have included single- and dual-chamber ICDs from various generations. It is also worth noting that two of these studies[13,14] had shown superior battery longevity for the Medtronic devices, which is contrary to our findings. The present study, focused only on contemporary CRT-ICD models still available today for consumers in the USA and the rest of the world. Since battery longevity varies from one device generation to the next based on the battery design itself as well as its interface with the device electronic circuitry, real-time longevity information is very important for guiding consumer selection of devices with the goal of improving patient outcomes.

Improving device longevity across the whole industry should be an important goal. Achieving this goal may be facilitated by creating a system of financial reward for manufacturers, who provide devices with better battery longevity and conversely a system of financial penalty for those with lesser battery performance. Such a system would eliminate any financial incentive for the manufacturer for having shorter device battery life to increase the number of device change-outs. A system where the cost of the device gets annualized, i.e. manufacturers get paid for the device per year of longevity as opposed to upfront, at the time of implantation would probably achieve the goal of aligning the interests of all stakeholders (patients, physicians, third-party payers, and manufacturers).

We acknowledge several limitations to the present study. First, it is a retrospective, single-centre study with results that may not be duplicated at other institutions. Our results are, however, based on a contemporary cohort of a large number of patients with standard management practices in the inpatient and outpatient settings. In addition, the retrospective nature of this study is essential to be able to use the hard endpoint of actual battery depletion as opposed to estimates of battery survival which may often be inaccurate. Secondly, our results are only relevant to CRT-D and may not be applicable to single- or dual-chamber defibrillators or to pacemakers. Thirdly, there are basic differences between vendors in the way the device functions at the level of lead measurements, event storage, and even in the way ERI is defined and declared. Differences in device longevity may therefore not be exclusively a battery issue. Despite this, we have compared, in this study, device longevity across manufacturers based on the specifications adopted by each manufacturer as consumers are most interested in the end result (how long the battery lasts). Also, in this study, no information was available regarding the mean time from device production to implantation for various manufacturers. Finally, although the difference in rates of ERI was statistically different among the manufacturers, the absolute number of ERI events recorded for the St Jude Medical and Boston scientific devices was small. This is due to the relatively short follow-up period of the study, which was mandated by the need to keep the information provided contemporary. With longer follow-up times, the differences in rates of ERI by device manufacturer could possibly be diluted or further accentuated.

In summary, our data demonstrate shorter battery longevity in contemporary Medtronic CRT-D models compared with equivalent devices from other manufacturers. These findings have important implications for patient care. Other large, independent, cohorts of patients at other institutions may be needed to confirm these findings.

Conflict of interest: S.S. has received research support from Medtronic Inc., Boston Scientific Inc., and St Jude Medical Inc.; S.J. received research support from Medtronic Inc.; E.A. received research support from St Jude Medical.

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IMAGES IN ELECTROPHYSIOLOGY

doi:10.1093/europace/eut288
Online publish-ahead-of-print 24 October 2013

Intra-isthmus reentry: diagnosis at-a-glance

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An 80-year-old man was admitted for cardiac failure and recurrence of electrocardiographically typical atrial flutter (figure, upper left panel). Six months earlier he has had cavo-tricuspid isthmus (CTI) ablation with successful block. A new electrophysiological study showed counter-clockwise (CCW) tricuspid annulus activation and proximal-to-distal coronary sinus (CS) activation (upper right panel), compatible with CCW typical flutter recurrence.

Entrainment manoeuvres demonstrated reentry as evidenced by constant fusion and progressive fusion of the intracardiac electrograms during pacing at different cycle length (CL). Based on post-pacing interval (PPI)—CL differences, only the septal CTI and possibly the proximal CS were part of the circuit. The middle pane of the figure depicts the differences between PPI and the flutter CL at all the pacing sites. The maximal duration bipolar electrogram at the septal CTI spanned over 58% of the CL (lower panel). One radiofrequency application at this site terminated the flutter. Pacing manoeuvres (600 ms) in sinus rhythm showed complete bi-directional CTI block.

Conflict of interest: none declared.