Device Longevity in a Contemporary Cohort of ICD/CRT-D Patients Undergoing Device Replacement

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Longevity of Replaced ICD/CRT-D. ***Introduction:*** **The longevity of defibrillators (ICD) is extremely important from both a clinical and economic perspective. We studied the reasons for device replacement, the longevity of removed ICD, and the existence of possible factors associated with shorter service life.**

Methods and Results: **Consecutive patients who underwent ICD replacement from March 2013 to May 2015 in 36 Italian centers were included in this analysis. Data on replaced devices were collected. A total of 953 patients were included in this analysis. In 813 (85%) patients the reason for replacement was battery depletion, while 88 (9%) devices were removed for clinical reasons and the remaining 52 because of system failure (i.e., lead or ICD generator failure or a safety advisory indication). The median service life was 5.9 years (25th–75th percentile, 4.9–6.9) for single- and dual-chamber ICD and 4.9 years (25th–75th percentile, 4.0–5.7) for CRT-D. On multivariate analysis, the factors CRT-D device, SC/DC ICD generator from Biotronik, percentage of ventricular pacing, and the occurrence of a system failure were positively associated with a replacement procedure. By contrast, the device from Boston Scientific was an independent protective factor against replacement. Considerable differences were seen in battery duration in both ICD and CRT-D. Specifically, Biotronik devices showed the shortest longevity among ICD and Boston Scientific showed the longest longevity among CRT-D (log-rank test, $P < 0.001$ for pairwise comparisons).**

Conclusion: **Several factors were associated with shorter service life of ICD devices: CRT-D, occurrence of system failure and percentage of ventricular pacing. Our results confirmed significant differences among manufacturers.** *(J Cardiovasc Electrophysiol, Vol. 27, pp. 840-845, July 2016)*

Battery, CRT, implantable defibrillator, longevity

Introduction

Implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) are a standard treatment for the prevention of sudden cardiac death and the management of selected heart failure patients.[1] Nonetheless, despite advances in technology, the majority of ICD or CRT-D recipients outlive their device and have to undergo 1 or more pulse generator replacement.[2] Since device replacement involves a considerable risk of complications[3] and engenders costs for healthcare systems, device lifespan is a crucial determinant of the cost-effectiveness of therapy. Few studies have analyzed ICD longevity and these have generally been performed on single-center series.[4-7] The Detect Long-term Complications After ICD Replacement (DECODE) study is a prospective, single-arm, multicenter cohort study designed to estimate long-term complication rates in patients undergoing ICD generator replacement.[8]

The aims of the present analysis were to identify the reason for replacement and to measure the longevity of removed ICD and CRT-D in the DECODE study population. Moreover, we investigated the existence of possible factors associated with shorter service life.

Disclosures: None.

Clinical Trial Registration: URL: http://clinicaltrials.gov/ Identifier: NCT02076789.

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Methods

Patient Population and Study Design

All consecutive patients who underwent replacement or upgrade of a previously implanted ICD or CRT-D at the 36 participating centers were enrolled in the DECODE study. The design of the study has been published previously.[8] The institutional review board of each participating center approved the protocol, and each patient provided written informed consent before enrollment.

In the present analysis, we analyzed data collected at the time of device replacement in order to identify the reason for replacement and to measure the longevity of removed ICD and CRT-D. Moreover, in order to identify possible factors associated with shorter service life, we analyzed device-stored data: pacing output and percentage at the time of replacement and number of shocks delivered.

The endpoint of this analysis was the time to replacement for any reason. The service life of the device was defined as the time from implantation to surgical replacement. We also analyzed the time to replacement for battery depletion. In this latter analysis, removals for other reasons were not counted as events, and patients were censored at the time of their occurrence.

Statistical Analysis

Descriptive statistics are reported as means ± SD for normally distributed continuous variables, or medians with 25th to 75th percentiles in the case of skewed distribution. Categorical variables are reported as percentages. Differences in proportions were compared by applying chi-square analysis or Fisher's exact test, as appropriate. Device longevity according to device type was analyzed by the Kaplan–Meier method and differences between groups were analyzed with the log-rank test (level of significance adjusted for multiple testing by Bonferroni correction). Kaplan–Meier analysis was performed considering the manufacturer as grouping factor. Hazard ratios (HRs) and their 95% confidence intervals (CIs) were computed by means of Cox regression models, in which device data were considered as fixed covariates and pulse generator replacements were considered as time-dependent covariates. The proportional hazard assumption was assessed by Schoenfeld residuals. After checking for collinearity, we included in the multivariate Cox models any variable with a P value <0.05 on univariate analysis. A P value <0.05 was considered significant for all tests. All statistical analyses were performed by means of STATISTICA software, version 7.1 (StatSoft, Inc., Tulsa, OK, USA).

Results

Study Population

From March 2013 to May 2015, a total of 1,012 consecutive patients underwent replacement or upgrade of a previously implanted ICD or CRT-D at the 36 study centers. The present analysis was carried out on 953 patients with complete data. Demographics and clinical parameters of the study population at the time of device replacement are summarized in Table 1. The procedure involved simple ICD generator replacement in 771 (81%) patients and device replacement with the addition of transvenous leads in the remaining 182 (19%) patients. The removed devices were 508 (53%) single- or dual-chamber ICD and 445 (47%) CRT-D, and had been implanted from 2002 and 2014. The ICD generators were from 5 manufacturers: 69 (7%) from Biotronik, 306 (32%) from Boston Scientific, 336 (35%) from Medtronic, 38 (4%) from Sorin and 204 (21%) from St. Jude Medical. They belonged to device families released onto the market after 2000, in the case of single- and dual-chamber ICD, and after 2002 in that of CRT-D. Details of the devices in analysis are summarized in Table 2. The stimulation output in all pacing channels was comparable among manufacturers.

TABLE 1

Demographics and Clinical Parameters of the Study Population at the Time of Device Replacement

Parameter	n = 953
Male gender, n (%)	725 (76)
Age, years	71 (63–77)
LV ejection fraction, %	35 (30–45)
Coronary artery disease, n (%)	522 (55)
Primary prevention (at the time of first implantation), n(%)	723 (76)
History of atrial fibrillation, n (%)	371 (39)
Native QRS duration > 120 milliseconds, n(%)	523 (55)
Hypertension, n (%)	590 (62)
Diabetes, n (%)	270 (28)
Chronic kidney disease, n (%)	239 (25)
Chronic obstructive pulmonary disease, n (%)	180 (19)

LV = Left ventricular.

Eighty-eight (9%) devices were removed for clinical reasons: 5 device-related infections, 7 pocket erosions, addition of a left ventricular lead for CRT upgrade in 68 patients, and an atrial lead in 8 patients. Moreover, 39 devices were replaced at the time of lead failure or for elective replacement of a non-malfunctioning lead following a safety advisory, and 13 devices were removed because of a malfunction or an advisory indication of the ICD generator. In the remaining 813 (85%) patients, the reason for replacement was battery depletion and it was significantly different between device types: 411 (92%) of 445 CRT-D and 402 (79%) of 508 single- and dual-chamber devices ($P < 0.0001$).

Overall, the median service life was 5.9 years (25th–75th percentile, 4.9–6.9) in single- and dual-chamber ICD and 4.9 years (25th–75th percentile, 4.0–5.7) in CRT-D.

Predictors of Device Replacement

Multivariate analysis confirmed CRT-D, ICD generator from Biotronik, and the percentage of ventricular pacing as independent factors positively associated with a replacement procedure, together with the occurrence of a system failure (i.e., lead or ICD generator failure or a safety advisory indication) (Table 3). By contrast, the device from Boston Scientific was an independent protective factor against replacement. In addition, among CRT-D devices, left ventricular lead output showed a significant association with early replacement.

Replacement for Battery Depletion

In this latter analysis we considered ICD replacements due to battery depletion only. Among single- and dual-chamber ICD, the median survival from replacement for battery depletion was 5.3 years (95% CI: 5.0–5.5) for Biotronik, 6.3 years (95% CI: 6.2–6.7) for Boston Scientific, 6.4 years (95% CI: 6.2–6.9) for Medtronic, 6.7 years (95% CI: 6.2–

TABLE 2
Details and Numbers of Devices in Analysis

Manufacturer—ICD Family	ICD in Analysis	Replaced for Battery Depletion	Manufacturer—CRT-D Family	CRT-D in Analysis	Replaced for Battery Depletion
Biotronik	*60*	*50*	*Biotronik*	*9*	*7*
Lexos	14		Lumax 300	4	
Lumos	26		Lumax 500	5	
Lumax 300	10				
Lumax 500	7				
Lumax 700	3				
Boston Scientific	*149*	*122*	*Boston Scientific*	*157*	*145*
Ventak Prizm/Prizm 2	34		Contak Renewal 2	2	
Vitality	14		Contak Renewal 4	127	
Vitality 2	79		Livian	8	
Teligen	16		Cognis	18	
Energen/Incepta	6		Energen/Incepta	2	
Medtronic	*141*	*113*	*Medtronic*	*195*	*186*
Gem III	10		InSync III Marquis	31	
Marquis	10		InSync Sentry	4	
Maximo	36		InSync Maximo	17	
Intrinsic	2		Concerto	34	
Onyx	12		Concerto II	9	
Entrust	14		Consulta	60	
Virtuoso	20		Maximo II	18	
Maximo II	11		Protecta	21	
Secura	17		Brava	1	
Protecta	9				
St. Jude Medical	*132*	*98*	*St. Jude Medical*	*72*	*65*
Atlas	50		Atlas	17	
Epic/Epic Plus	41		Epic/Epic Plus	4	
Epic II/Epic II Plus	4		Epic II/Epic II Plus	1	
Atlas II	17		Atlas II	8	
Current	9		Promote	21	
Current Accel	4		Promote Accel	15	
AnalyST Accel	1		Promote Quadra	3	
Fortify	4		Unify	3	
Ellipse	2				
Sorin	*26*	*19*	*Sorin*	*12*	*8*
Ovatio	23		Ovatio	4	
Paradym/Paradym RF	3		Paradym/Paradym RF	8	

6.8) for St. Jude Medical, and 6.4 years (95% CI: 5.8–6.7) for Sorin. Figure 1 shows Kaplan–Meier estimates of time to battery depletion in single- and dual-chamber ICD, stratified by the device manufacturer. This analysis revealed considerable differences in system longevity (overall log-rank test, $P < 0.001$). Specifically, Biotronik ICD displayed the shortest longevity (log-rank test, $P < 0.001$ for pairwise comparisons).

In CRT-D, the median survival from battery depletion was 4.4 years (95% CI: 3.8–5.4) for Biotronik, 5.8 years (95% CI: 5.7–6.1) for Boston Scientific, 4.5 years (95% CI: 4.4–4.6) for Medtronic, 5.0 years (95% CI: 4.7–5.1) for St. Jude Medical, and 5.0 years (95% CI: 4.8–5.6) for Sorin. Kaplan–Meier analysis revealed considerable differences in system longevity (overall log-rank test, $P < 0.001$) (Fig. 2). Specifically, Boston Scientific showed the longest longevity (log-rank test, $P < 0.001$ for pairwise comparisons).

Discussion

Our analysis of ICD replacement procedures showed that the median longevity of the devices removed was about 6 years for single- or dual-chamber ICD and 5 years for CRT-D. The most frequent reason for device replacement was battery depletion, and the main factors associated with replacement were the percentage of ventricular pacing (all devices) and the output of left ventricular pacing (CRT-D). Moreover, differences in longevity emerged among systems from different manufacturers.

This study constitutes the largest multicenter analysis of consecutive patients who underwent replacement or upgrade of a previously implanted ICD or CRT-D. The devices in analysis were relatively modern, as all single- and dual-chamber ICD were released onto the market after 2000, and all CRT-D after 2002.

In a previous study,[5] the proportion of devices replaced before battery depletion was approximately 30%. In the current analysis, the proportion was lower, as the reported reason for device removal was battery depletion in 79% of single- and dual-chamber ICD and in 92% of CRT-D. This finding confirms the importance of increasing battery service life in order to reduce the need for replacement procedures, and consequently emphasizes the value of all technical solutions aimed at extending device lifespan (e.g., battery capacity and chemistry, the efficiency of electronic circuitry, the availability of specific algorithms for pacing management and minimization). Among the causes of device replacement, we also reported clinical reasons (e.g., device-related

TABLE 3
Univariate and Multivariate Analysis of Factors Associated With Replacement for Any Reason in the Overall Population

	Univariate Analysis			Multivariate Analysis		
	HR	**95% CI**	**P**	**HR**	**95% CI**	**P**
CRT-D device	2.15	1.88–2.46	<0.001	1.34	1.03–1.76	0.032
Biotronik	2.01	1.57–2.58	<0.001	3.50	2.63–4.66	<0.001
Boston Scientific	0.77	0.67–0.88	<0.001	0.67	0.58–0.79	<0.001
Medtronic	Reference	–	–	Reference	–	–
St. Jude Medical	0.96	0.82–1.12	0.593	–	–	–
Sorin	1.14	0.83–1.58	0.431	–	–	–
Occurrence of system failure	2.46	1.86–3.27	<0.001	3.20	2.33–4.41	<0.001
Shock delivered (yes)	0.87	0.76–0.99	0.046	1.00	0.87–1.16	0.856
Number of shocks delivered	1.00	0.99–1.01	0.586	–	–	–
Percentage of atrial pacing* +	1.02	0.99–1.05	0.123	–	–	–
Percentage of ventricular pacing+	1.10	1.08–1.12	<0.001	1.10	1.07–1.13	< 0.001
Atrial lead output*	1.03	0.91–1.18	0.643	–	–	–
Right ventricular lead output	0.95	0.88–1.03	0.249	–	–	–
Left ventricular lead output*	1.33	1.20–1.48	< 0.001	–	–	–

*Not included in multivariate analysis because related only to specific device types (dual-chamber and CRT-D). +Percentage of pacing considering 10% increment.

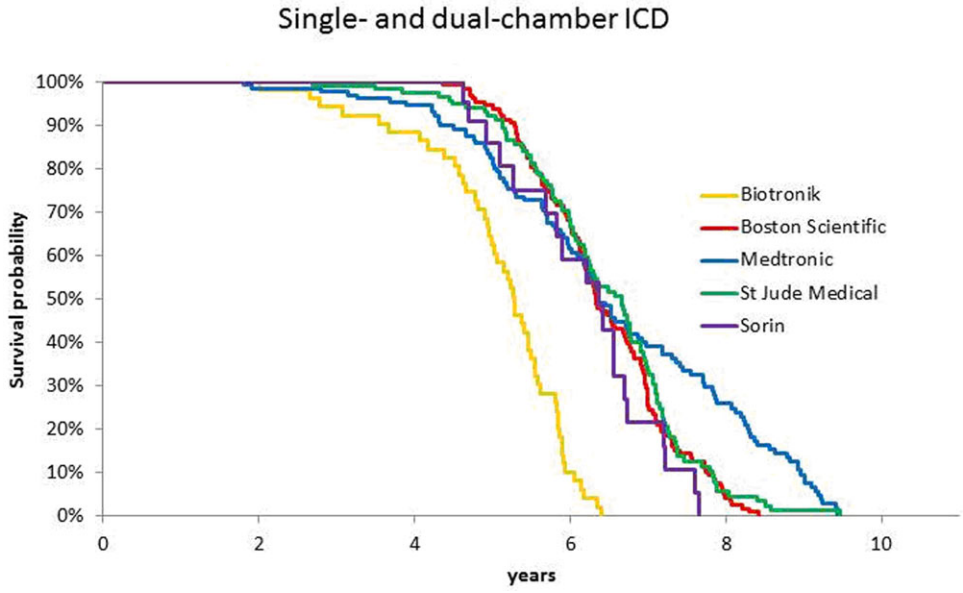

Figure 1. *Kaplan–Meier estimates of survival from device replacement for battery depletion in the single- and dual-chamber ICD groups. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology's website: www.wileyonlinelibrary.com/journal/jce*

infections, need for CRT upgrade). It is therefore reasonable to suppose that strategies for the minimization of infective risk[9] can also contribute to reducing replacements. Similarly, thorough evaluation of indications at the time of first implantation is crucial, as the early adoption of CRT-D in a patient undergoing ICD implantation could obviate the need for premature device upgrade. Moreover, we noted that about 5% of devices were replaced because of a system failure (lead or ICD generator malfunction or safety advisory/recall). Although this proportion was lower than that reported by Hauser a decade ago,[10] these events were confirmed as independent predictors of early replacement, and therefore had a negative impact on the cost-effectiveness of therapy.

Among device characteristics and working parameters, the percentage of ventricular pacing turned out to be an independent predictor of replacement. This finding is in agreement with previous results regarding earlier ICD systems,[5-7] while it differs from recent results concerning only CRT-D, which generally display a constant pacing burden close to 100%.[11] Left ventricular output was strongly associated with early CRT-D replacement,[5,11,12] owing to the high battery drain required for consistent left ventricle capture and for biventricular stimulation delivery, that dictates the same voltage being used in each channel with devices featuring a common output capacitor. In addition, battery depletion was independent of the burden of defibrillator therapy being delivered, confirming previous findings.[4-6,11,12] Our multivariate analysis also revealed independent associations between replacement and different device manufacturers, in agreement with recent studies. Specifically, Boston Scientific defibrillators were associated with a longer lifespan[1,12] and Biotronik defibrillators with early replacement,[13] compared to Medtronic devices.

Interestingly, in these works[4-7] the authors unanimously reported better longevity for the Medtronic devices

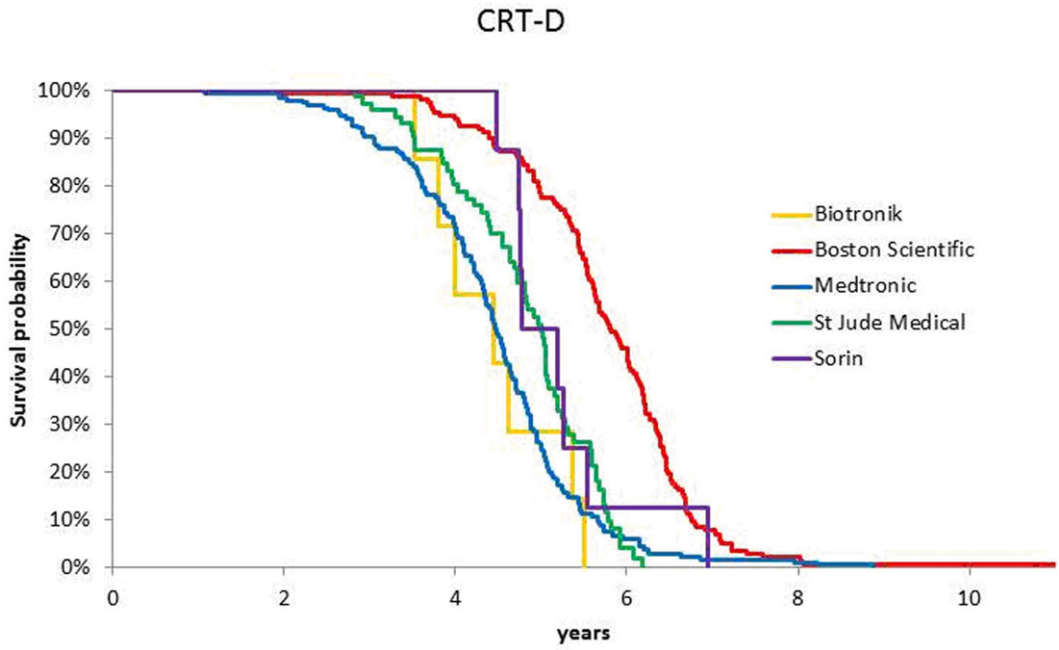

Figure 2. *Kaplan–Meier estimates of survival from device replacement for battery depletion in the CRT-D group. For a high quality, full color version of this figure, please see Journal of Cardiovascular Electrophysiology's website: www.wileyonlinelibrary.com/journal/jce*

included in their analyses and available at that time on the market.[11] In contrast, on including CRT-D devices released onto the market after 2002 and still available today, we observed shorter longevity in Medtronic CRT-Ds, according to Landolina *et al.*[11]

Kaplan–Meier analysis of the time to battery depletion revealed comparable performances among manufacturers in the single- and dual-chamber ICD groups, with the exception of Biotronik ICD, which displayed shorter survival. Among CRT-D, Boston Scientific generators showed the longest longevity on pairwise comparisons. These results can be explained by the battery technology, as the majority of single- and dual-chamber Biotronik ICD in analysis were equipped with low-capacity cells (0.68 Ah), while Boston Scientific CRT-D generators were powered by > 1.8 Ah batteries. Indeed, the type of power cell is known to impact device performance,[14,15] and it has been demonstrated that battery capacity in particular is a determinant of ICD service life.[10] Our findings confirmed a recently published study by Alam *et al.*[12] where Boston Scientific CRTDs showed a superior longevity compared to Medtronic. This could be explained by the downsizing of ICD power supply along years in Medtronic devices. Indeed, the In-Sync ICDs were outlasting 6 years in the study by Biffi *et al.*,[4] while Concerto/MAXIMO/Consulta/Protecta devices showed longevity of about 5 years in the study by Landolina *et al.*[11] In addition, there is a consistent similarity of our findings with previous reports.[4-7] in that single-chamber ICD had a superior longevity compared to CRTDs owing to the different percentage of ventricular pacing, and differences among CRTD manufacturers were related to battery capacity and LV output.

In summary, our results showed that in current clinical practice the service life of ICD systems ranged from 5 to 7 years and that of CRT-D from 4 to 6 years. According to Boriani *et al.*,[16] who recently determined the cost-impact of extending defibrillator longevity in various clinical scenarios, an increase in device longevity of about 2 years would yield a relative saving of about 20% over a 15-year time horizon, owing to the avoidance of ICD generator replacements. Nevertheless, the values reported in the present study are in the range considered acceptable by researchers who have investigated whether the clinical benefits of ICD or CRT-D are economically viable and can be achieved at a reasonable cost.[17]

Limitations

As our analysis was performed at the time of device removal, the most recent ICD currently implanted in clinical practice were not considered. As modern devices are expected to last longer,[11] our results may not apply to newer devices. In addition, data on pacing output and the percentage of ventricular pacing were gathered at the time of device removal and not throughout the entire life of the device. However, these values should constitute reliable surrogates for measurements taken over the lifespan of the device. The devices in analysis differed in terms of battery capacity, chemistry, and features potentially influencing the battery longevity. Moreover, although the overall number of devices in analysis was high, some subgroups were poorly represented (e.g., Biotronik and Sorin CRT-D); thus for them the results could be imprecise.

Conclusion

The median longevity of removed devices was about 6 years for single- or dual-chamber ICD and 5 years for CRT-D. The most frequent reason for replacement was battery depletion, and the main factors associated with replacement were the percentage of ventricular pacing, in the case of all devices, and the output of left ventricular pacing, in

that of CRT-D. Moreover, differences in longevity emerged among systems from different manufacturers.

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Appendix

Steering Committee:

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