

Longevity of implantable cardioverter-defibrillators: implications for clinical practice and health care systems

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Aims Comparative studies on the longevity of implantable cardioverter-defibrillators (ICDs) among different manufacturers have never been reported. Longevity of ICD devices implanted from 1 January 2000 to 31 December 2002 was prospectively investigated according to their type and manufacturer.

Methods and results Longevity of single-chamber (SC), double-chamber (DC), and biventricular (CRT-D) ICDs from Medtronic (MDT), Guidant (GDT), and St Jude Medical (SJM) was measured in all the patients who required device replacement. The observation follow-up ended on 31 December 2007; patients who died prematurely or were transplanted before battery exhaustion were excluded from the analysis. Factors associated with longevity (number of delivered shocks, pacing activity) were researched. One hundred and fifty-three patients received an ICD in the abovementioned period. Six underwent heart transplantation, and 23 died before device replacement; 80 had an SC device, 59 had DC device, and 14 had CRT-D device. Longevity of MDT was superior to GDT and SJM, replacement rates being, respectively, 42%, 95.3%, and 97.2%. Only MDT manufacturers and SC type were associated with greater ICD longevity. Longevity had an impact on the cost/month of treatment of replaced ICDs.

Conclusion Battery longevity is significantly different among manufacturers. ICD cost is strictly dependent on device longevity, whereas device up-front cost is of limited clinical meaning. Appropriate assessment of cost-effectiveness should be based on ICD longevity in the real-life scenario.

Introduction

Implantable cardioverter-defibrillators (ICD) are an effective treatment to prevent sudden death in selected patients.^{1–5} ICD longevity is a very important aspect for clinical practice as far as patients' comfort and safety are concerned, as device replacement carries a substantial risk of serious complications,^{6,7} and for health-care systems, when cost-effectiveness of ICD therapy is being evaluated. Formerly published observations on ICD longevity suffered some limitations, as they did not allow comparisons based on device activity as obtained by a similar programming strategy, or based on the different manufacturers' technology.^{8–10}

We observed the longevity of ICDs from three different manufacturers used in our centre, to understand whether a significant difference exists among technologies.

Methods

All the patients implanted with an ICD from 1 January 2000 up to 31 December 2002 were followed-up to 31 December 2007. Patients who underwent heart transplantation or died before battery replacement were excluded from the analysis. Longevity was calculated up to the day of ICD replacement. To achieve comparisons, all capacitor charges were counted for each device, whether appropriate (ventricular arrhythmias), inappropriate (supraventricular arrhythmias), or diverted (self-terminated arrhythmias, with charge delivered into the internal load of the device). Periodic capacitor reform was left unchanged according to the manufacturer's recommendations: these charges were not counted for longevity evaluation. Device programming followed the strategy of shock therapy minimization: ventricular fibrillation (VF) detection was always set faster than 220 bpm, ventricular tachycardia (VT) detection was also programmed in each patient. At least two attempts to terminate VT by anti-tachycardia therapy (ATP) were programmed. Inappropriate capacitor charge owing to non-sustained VT was avoided by programming an appropriate detection. Sinus tachycardia discriminators were programmed in all devices; AF and 1:1 supraventricular arrhythmias discriminators were programmed when clinically indicated. Intracardiac electrogram (EGM) collection at arrhythmia onset was minimized whenever possible.

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Cardiac stimulation also affects device longevity, hence the amount of pacing was retrieved from the devices at each follow-up, and the pacing output was reported. In patients without pacing indications, devices were programmed at the lowest programmable rate and with the longest attainable atrioventricular delay [double-chamber (DC) ICDs only] in order to minimize the delivery of stimulation. The lower rate of biventricular ICDs was programmed at 40 bpm to minimize atrial pacing, unless atrial stimulation was indicated.

Statistical analysis

Continuous variables were expressed as mean \pm standard deviation (median and range if not normally distributed), while categorical data were expressed as absolute and relative frequency.

Comparisons between continuous variables were made by *t*-test or non-parametric test, for independent or paired samples. Categorical data were compared using χ^2 or Fisher's exact test, as appropriate.

Owing to non-normality of distribution, ICD longevity and costs were expressed as median and range.

Comparisons between groups were made by Kruskal-Wallis test.

ICD type and manufacturer were analysed by the Kaplan-Meier method and differences between groups were analysed with the log-rank test.

Independent predictors were detected using Cox proportional hazards regression model.

Variables included in the model were type of ICD, manufacturer, maximum device output (\leq or >31 J), arrhythmia storm (yes/no), amount of paced activity (\leq or $>50\%$), number of delivered shocks per year divided into four subgroups (0, 1–2, 3–5, ≥ 6), coronary artery disease.

The proportional hazard assumption was assessed by Schoenfeld residuals. A *P*-value <0.05 was considered statistically significant. All analyses were performed with Stata for Windows 10 statistical software (StataCorp, TX, USA).

Results

In this 3-year period, 153 patients received an ICD. Eighty (52%) had coronary artery disease, whereas 73 (48%) had several different arrhythmogenic diseases; 38 (24.8%) had idiopathic dilated cardiomyopathy (IDCM), 15 (9.8%) had hypertrophic cardiomyopathy, 10 (6.5%) had right ventricular arrhythmogenic cardiomyopathy, 7 (4.5%) had valvular heart disease, 2 (1.3%) with idiopathic VF, and 1 (0.6%) with Brugada's syndrome. The mean age was 64 ± 12 years, the male:female ratio was 125:28, LV ejection fraction (EF) was 39.7 ± 16.5 (range 17–88). Twenty-eight patients had an LVEF $>60\%$ (hypertrophic cardiomyopathy, ARVD, idiopathic VF, Brugada syndrome), and some valvular and IDCM patients had an EF $>35\%$. Primary prevention of sudden death was the indication for 105 (68%) patients, whereas secondary prevention accounted for 48 (32%) ICD implants. The indication to ICD implantation because of primary prevention of sudden death was: sustained VT inducibility according to the MADIT and MUSTT criteria for patients with previous myocardial infarction; bridge to heart transplantation in patients with severe heart failure and syncopal or recurrent symptomatic NSVT; unexplained syncope and inducible VT/VF, or recurrent near syncopal

NSVT and inducible sustained VT/VF in those with IDCM or moderate heart failure; syncope and family history of sudden death and/or symptomatic NSVT in patients with hypertrophic cardiomyopathy; syncope and inducible monomorphic VT/VF or documented symptomatic NSVT and inducible VT/VF in ARVD patients.

Six patients underwent heart transplantation (1 MDT, 2 GDT, 3 SJM), and 23 died before ICD replacement (6 MDT, 5 GDT, 12 SJM), hence are excluded from analysis; 124 completed the follow-up period. None of the devices were subjected to alerts or corrective actions that could cause a more frequent automatic capacitor reforming or premature device replacement.

Table 1 reports the devices implanted in the study period according to type (single chamber, dual chamber, biventricular), model, and manufacturer. The average service life of replaced ICDs within each model subgroup, the devices still in service, and the number of paced patients is also reported in Table 1. No ICD/lead failure occurred during the follow-up period. Devices were replaced within 30 days after the elective replacement interval had been reached, depending on the recent arrhythmia history and the clinical setting.

Cardiac stimulation was minimized ($<1\%$) by ICD programming, except in patients with pacing indications: three with a SC device, six with a DC device, and all 10 CRT-D patients (Table 1).

All the patients with CRT-Ds devices were $>99\%$ paced in both ventricles; atrial pacing was $<1\%$ in all the patients. Six patients had devices with a common ventricular output (MDT), so that both ventricles were paced by the same strength, whereas four patients had devices capable of independent programmability of the LV output (2 GDT, 2 SJM).

These latter four devices paced at the same output (RV = 2 V at 0.5 ms, LV = 3 V at 0.5 ms), and had the same longevity (Table 1). The four MDT devices pacing below battery voltage (2 V at 0.8 ms) are still in service (Table 1), whereas those pacing at high output (3 V at 1.0 ms and 6 V at 1.0 ms) because of a high LV pacing threshold (2 V at 0.8 ms and 4.2 V at 1.0 ms) were replaced after 63 and 35 months, respectively. Lead repositioning to achieve a lower pacing threshold was not feasible in these two patients (lack of another suitable coronary vein in the former, unwillingness to undergo tunnelling from the right side or thoracotomy because of left subclavian thrombosis in the latter).

Shock delivery for VF or VT refractory to ATP occurred in 55 of 124 patients (44%). Overall, therapy for VT/VF (ATP and shock) was delivered to 88 of 124 patients (70%). Eleven arrhythmia storms (>3 shocks in the same day) occurred in 4 of 124 patients (3.2%). No capacitor charge owing to non-sustained VT was observed. Inappropriate shocks were delivered to 14 of 124 patients (11%); these were also counted as charges into the Cox regression model.

Implantable cardioverter-defibrillator longevity

At the end of the follow-up period, replacement rates were: 56 of 57 (97.2%) for SJM, 41 of 43 (95.3%) for GDT, and 10 of 24 (42%) for MDT ($P = 0.0001$ (Figure 1A). Among these 124 patients, 17 still had the device in service: 11 SC (8 MDT, 2 GDT, 1 SJM), 2 DC (MDT), 4 CRT-D (MDT).

Table 1 Devices employed during the study period

Device model (Manufacturer)	Patients; Battery model	Average longevity (months)	Pacing activity: pt, % pacing, Volts at milliseconds
MICROJEWEL (MDT) SC	1; CHI 2326-10	85.3	
GEM (MDT) SC	3; Rho 2230-13	81.1 (2 still in service after 93.3 ± 5.1)	
GEM II VR (MDT) SC	8; CHI 3625-7	7/8 still in service after 65.2 ± 4.5	
VENTAK MINI III (GDT) SC	5; WG 9623	67.3 ± 9.2	
VENTAK MINI IV (GDT) SC	5; WG 9716	49.4 ± 7	1 pt, 100%Vp, 3 V at 0.4 ms
PRIZM VR (GDT) SC	5; WG 9913	51.1 ± 10 (1 still in service after 67)	1 pt, 100%Vp, 3 V at 0.4 ms
PRIZM VR HE (GDT) SC	7; WG 9901	49.1 ± 4.1	
VITALITY (GDT) SC	1; WG 9999	62.6 in service	
CONTOUR MD (SJM) SC	27; WG 9443	53.5 ± 9.2	1 pt, 50%Vp, 3 V at 0.4 ms
ATLAS VR (SJM) SC	4; WG 2150	55.5 ± 5.6 (1 still in service after 62.5)	
GEM DR (MDT) DC	4; CHI 2826i	87 ± 0.5 (1 still in service after 67.7)	1 pt, 100%Vp, 3 V at 0.4 ms; 1pt, 50% Ap, 3 V at 0.4 ms
GEM III DR (MDT) DC	2; CHI 3635-7	50.7 (1 in service after 67.4)	1 pt, 60% Ap and Vp 3 V at 0.4 ms
VENTAK MINI III AVT (GDT) DC	1; WG 9623	43	
PRIZM DR (GDT) DC	3; WG 9913	50.7 ± 7.1	1 pt, 100% Ap 2.6 V at 0.4 ms
PRIZM DR HE (GDT) DC	2; WG 9901	40.1 ± 1.8	
PRIZM AVT(GDT) DC	12; WG 9913	50.6 ± 6.4	2 pts, 100%Vp, 2.6 V at 0.4 ms
PHOTON DR (SJM) DC	22; WG 9610 (20); WG 2150 (2)	44.6 ± 10; 43 ± 11; 59 ± 2	
ATLAS DR (SJM) DC	2; WG 2150	50 ± 6	
INSYNC ICD (MDT) CRT-D	6; CHI 2826i	49.6 ± 19 (4 still in service after 75.4 ± 8.3)	>99% Vp, LV = RV, 1 pt, 6 V at 1 ms; 1 pt, 3 V at 1 ms; 4 pts, 2 V at 0.8 ms
CONTAK RENEWAL (GDT) CRT-D	2; WG 9913	44.7 ± 2.8	2 pts, >99% Vp; LV 3 V at 0.5 ms; RV 2 V at 0.5 ms
EPIC HF (SJM) CRT-D	2; WG 2150	44.6 ± 2.4	2 pts, >99% Vp; LV 3 V at 0.5 ms; RV 2 V at 0.5 ms

Longevity relates to replaced ICDs; ICDs in service are reported together with their own service life. Medtronic (MDT) has 24 patients; Guidant (GDT) has 43 patients; St Jude Medical (SJM) has 57 patients. CRT-D, biventricular ICD; DC, dual chamber; SC, single chamber; pt, patient(s); CHI, Rho, MDT proprietary battery; WG, Wilson Greatbatch battery.

When the duration of replaced devices is analysed, SC ICDs are superior to DC and CRT-D, although this is mainly due to SJM devices (Figure 1B, Table 2). Moreover, four biventricular MDT devices are still in service >6 years after implantation (Table 1). The replacement rate per implantation year is consistent with the Kaplan-Meier curve and the longevity analysis (Table 3).

As reported in Table 1, different longevity among models by the same manufacturer was observed, mainly among GDT who had an intense model turnover in those years. Twenty Photon DR by SJM had the same battery model (9610) as

the Angstrom series,⁸ whereas two Photon DR and two Atlas DR had a different battery (2150). Median longevity of these latter four ICDs was 54 months, although the longest lasting SJM ICDs (64, 62, and 60 months, respectively) were powered by the 9610 battery model.

The median number of device charges is reported in Figure 2: it was slightly (not significantly) higher in MDT DC devices.

SC devices and MDT manufacturer were associated with a superior longevity at Cox regression analysis, whereas the number of capacitor charges had no effect (Table 4). Devices delivering pacing therapy to two cardiac chambers (a single DC and six CRT-D) at a high stimulation strength had a shorter longevity (35–63 months).

Implantable cardioverter-defibrillator cost

Owing to the observed difference in ICD longevity (Table 2), the cost/service life of replaced ICDs was different among manufacturers, longer-lasting devices being on average 38% less expensive than the others.

Discussion

Implantable cardioverter-defibrillator longevity

Our observation is a comparative report on ICD longevity among manufacturers in clinical practice, aside from the area of device recall/malfunction: all the ICDs in our observation were normally performing. In the literature, data on ICD longevity were often triggered by unexpected technical failures,⁸ whereas insight on the longevity of ICDs exhibiting ‘regular’ performance in the ‘true’ clinical scenario may be gained by registries.^{9,10} Hauser report⁹ from a large US registry shows that 5 years after implantation, only 26% of normally performing devices are in service: differently from our study, no analysis based on device activity or on manufacturer has ever been reported.

Longevity of an implanted device is pivotal in the evaluation of its cost, on which studies of cost-effectiveness should be based.^{10–13} In our study we observed important differences among manufacturers in terms of device longevity, unrelated to the amount of delivered high-voltage therapy (Table 4). Although a straight comparison cannot be made as in randomized controlled trials, because of unique characteristics of the individual patients and of their clinical course, substantial differences among technologies seem to exist. Five years ago, Ellinor *et al.*⁸ reported a shorter than expected life of service in Angstrom and Profile devices by SJM, largely because of a poor interaction of a downsized battery and a dedicated safety circuit.

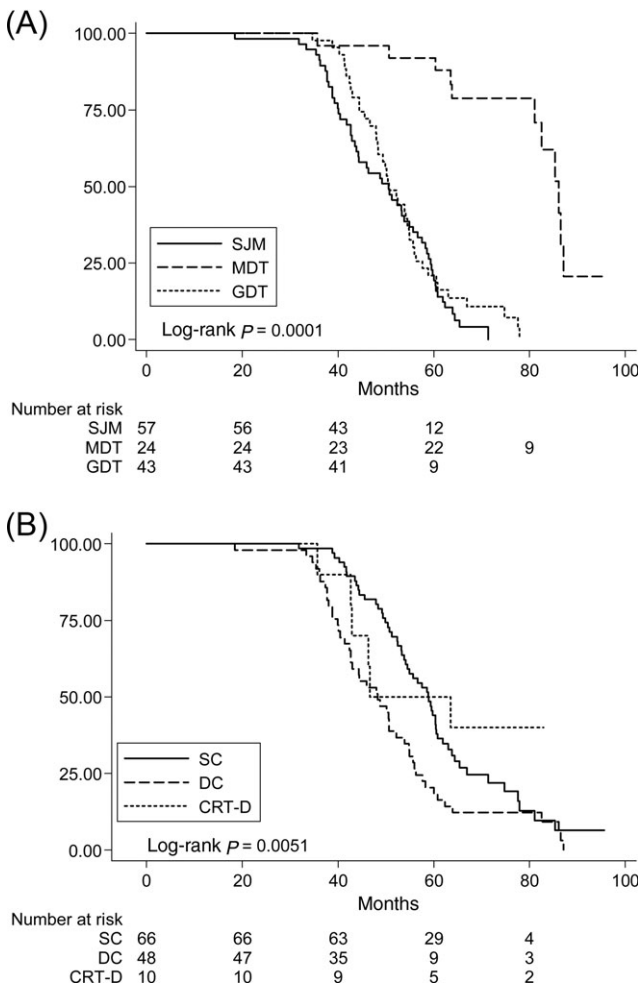


Figure 1 Implantable cardioverter-defibrillator (ICD) replacement according to manufacturer (A) and ICD type (B). GDT, Guidant; MDT, Medtronic; SJM, St Jude Medical; SC, single chamber; DC, double chamber; CRT-D, biventricular.

Table 2 Longevity of 107 implantable cardioverter-defibrillators (ICDs) replaced in the follow-up period

ICD longevity (months)	Single chamber	Double chamber	CRT-D	P
Medtronic	72 (60–85)	84 (50–87)	49 (36–63)	0.150*
Guidant	52 (31–71)	50 (35–58)	45 (43–47)	0.183*
St Jude Medical	55 (40–78)	40 (33–64)	45 (43–46)	0.005*
P	0.028*	0.001*	0.100*	

CRT-D, biventricular ICD.
*Kruskal Wallis.

Table 3 Rate of implantable cardioverter-defibrillator (ICD) replacement per implantation year

Year of implantation	ICD replaced/ICD implanted		
	Medtronic	Guidant	St Jude Medical
2000	6/8	9/9	18/18
2001	2/6	15/15	18/18
2002	2/10	17/19	20/21

The ratio represents the number of devices being implanted in a specific year that were replaced within 31 December 2007.

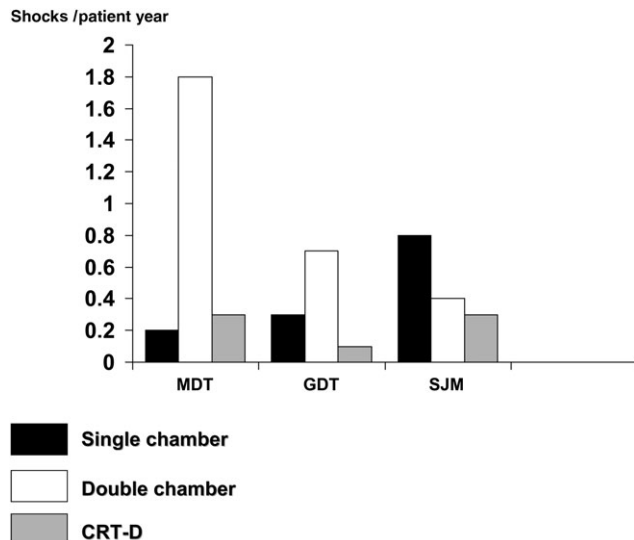


Figure 2 Number of delivered shocks according to device type and manufacturer. GDT, Guidant; MDT, Medtronic; SJM, St Jude Medical; SC, single chamber; DC, double chamber; CRT-D, biventricular; shock/Pat/yr denotes number of shocks/patient/year.

The same battery model in our Photon devices could last as long as 64 months, meaning that an unpredictable behaviour of the battery power source and of circuitry-battery interplay may heavily affect device longevity. In fact, in the Photon series a new platform and the incorporation of ROM and RAM consuming 24% less current allowed an increased device longevity when compared with Angstrom and Profile. Ellinor *et al.*⁸ claimed that attention should be paid to ICD longevity in the future, as the market forces driving towards device downsizing and increased ICD monitoring and diagnostic functions could lead to unpredictable battery behaviour. Our study covers a subset of devices free from recalls and corrective actions in a defined observation period: it thus represents a faithful picture of ICD technology in that time-frame. In our study, MDT devices had a superior longevity. Not surprisingly, similar findings have been recently reported by another European centre:¹⁴ nearly 50% of MDT devices lasted ≥ 7 years, compared with none by all other manufacturers. In the Basel experience, Medtronic technology showed superior longevity over a 12-year period in 679 devices, although a detailed analysis was not reported.¹⁴ According to clinical practice in our centre, we followed the strategy of minimization of shock therapy in favour of painless VT termination, by programming ATP schemes as the first-line therapy. This strategy is actually supported by strong clinical evidence.^{15,16} Accordingly, the shock rate was low, and comparable among the three manufacturers. For this reason, the amount of shock therapy was not predictive of a poorer longevity, as in Hauser's report.¹⁰

It appears from our data that SJM and GDT device longevity (55 months) is quite comparable with the recently reported US registry.¹⁰ As in Hauser's report,¹⁰ SC ICDs had a superior longevity with respect to DC devices, except for the MDT manufacturer, whose SC and DC devices had the same performance. Moreover, the four CRT-Ds with pacing output below battery voltage and less-sophisticated features had a median longevity beyond 6 years.

Table 4 Factors associated with implantable cardioverter-defibrillator (ICD) replacement

	Univariate			Multivariate		
	HR	P	CI	HR	P	CI
SC (n = 66)	1	-	-	1	-	-
DC (n = 48)	1.913	0.001	1.286-2.846	3.084	0.001	1.622-5.865
CRT-D (n = 10)	0.732	0.471	0.314-1.708	3.800	0.063	0.931-15.515
SJM (n = 59)	1	-	-	1	-	-
MDT (n = 24)	0.064	0.000	0.025-0.166	0.058	0.000	0.018-0.181
GDT (n = 41)	0.781	0.242	0.516-1.182	1.004	0.989	0.584-1.725
Maximum output >31 J (n = 43)	0.980	0.920	0.658-1.458	1.622	0.179	0.801-3.286
Arrhythmia storm (n = 5)	0.913	0.845	0.365-2.284	1.558	0.449	0.494-4.916
Paced activity <1% (n = 105)	1	-	-	1	-	-
Paced activity <50% (n = 3)	0.815	0.732	0.252-2.638	1.490	0.636	0.285-7.785
Paced activity $\geq 50\%$ (n = 16)	0.628	0.140	0.339-1.164	0.517	0.406	0.109-2.452
Stimulation output ≥ 3 V at 0.4 ms (n = 11)	1.663	0.131	0.859-3.218	2.302	0.304	0.470-11.270
Delivered shocks = 0 (n = 67)	1	-	-	1	-	-
1-2 shocks/year (n = 26)	1.063	0.804	0.654-1.730	1.363	0.243	0.811-2.292
3-5 shocks/year (n = 11)	0.472	0.061	0.215-1.036	0.614	0.271	0.257-1.464
≥ 6 shocks/year (n = 20)	0.825	0.492	0.475-1.430	0.950	0.874	0.505-1.788
CAD (n = 72)	0.816	0.304	0.554-1.202	0.825	0.394	0.531-1.283

CI, confidence interval; HR, hazard ratio; SC, single chamber; DC, dual chamber.

A small battery saving may have been conferred to MDT by minimization of EGM collection before arrhythmia onset and by less frequent capacitor reforming. Indeed, the latter suggests a possible technological advantage in manufacturing, as it implies that less internal dissipation of energy occurs in the battery, and that less reversible degradation of the dielectric layer occurs in the capacitor along time. Indeed, SJM and GDT used Wilson Greatbatch batteries, MDT used proprietary batteries; from GEM II onward, MDT capacitors are also proprietary. The continuous research in battery and capacitor technology has achieved the development of power sources with both a high capacity density and a high power density, suitable for high current drain (capacitor charge for the delivery of high voltage therapy) in a uniformly low charge time throughout the entire service life, as well as for lasting endurance during customary activities.^{17–20} Two major developments in the chemistry of batteries have supported these improvements: the use of 'combination' silver vanadium oxide (CSVO) in the cathode and balancing the cell to an appropriate electron reduction allowed a reduced growth of internal battery impedance over time, which also contributes to the uniformly short capacitor charge time;¹⁸ the development of hybrid cathode batteries (lithium/silver vanadium oxide blended with carbon monofluoride, Li/CFx-SVO) has allowed an increased service life coupled to a short charge time throughout the device service life, with an improved battery predictability.^{19,20} Because of these improvements, Boston Scientific also changed ICDs power supply in Confident/Livian ICDs with Li/CFx-SVO hybrid batteries performing superior to Prizm/Vitality series. Another step towards superior ICD longevity is the recent release of lithium/manganese dioxide (LiMnO₂) powered devices by Boston Scientific. LiMnO₂ batteries have stable voltage for most of the service life with a gradual decay towards replacement, irrespective of the rate of energy usage (high or low), no midlife impedance rise (reforming needed only to measure charge), very high capacity, and stable charge time. This chemistry allows reliable predictability of charge remaining in the battery by the measurement of power consumption (weighing of historical usage and current programming).

Beyond battery technology, the availability of 'improved' stacked-plate electrolytic capacitors has reduced the energy losses related to reforming the dielectric layer while allowing short capacitor charge time.¹⁸ Over years, the increased energy and capacity density in the battery, the shorter charge times, and a better packaging efficiency allowed ICD downsizing at no compromise for longevity when compared with old ICD releases.²¹ In fact, the devices with improved technology employed in our study had a superior longevity compared with older ICD releases²¹ or to bigger abdominal and epicardiac devices, despite an increased amount of EGM collection and additional features.

The improvements in battery and capacitor technology have increased ICD efficiency over time, but some trade-off because of the additional monitoring, diagnostic, and pacing features may occur, as reported in pacemaker technology.²² For instance, the same battery model (WG 2150) powered several SJM devices, from SC to CRT-D (Table 1): longevity decreased, being DC33J > SC35J > DC35J > CRT D30J (Table 1).

The management of the pacing burden also plays a role in technologies. In our CRT-D patients, longevity decreased

when pacing at high outputs was required (Tables 1 and 2). Indeed, very little effort has been made to save battery longevity in the setting of a high pacing threshold, which may occur in DC and CRT-D.²³ As reported by Hauser,⁹ CRT-D and DC replacement rates are, respectively, 87% at 3 years and 67% at 4 years.

Despite the improvement in steroid-eluting pacing leads, pacing threshold may unpredictably increase at long-term: in a recent study, right ventricular pacing threshold increased beyond 1.5 V at 0.5 ms in 25% of patients 1 year after implantation.²⁴ Use of voltage multipliers then occurs to ensure a 100% safety margin, possibly wasting device longevity.²⁵ Late variability of pacing threshold was largely ignored until the development of algorithms for stimulation by automatic verification of capture, which provide details of the pacing threshold over time.^{26,27} The automatic adjustment of pacing output according to the measured threshold allows to increase device longevity by avoiding the use of voltage multipliers, the benefit being greater at high pacing thresholds.²⁵ Despite successful feasibility studies,^{27–30} these algorithms have only recently been implemented in CRT-Ds.³¹ A benefit in terms of longevity can be expected by the use of such algorithms in all paced chambers so as to minimize the use of voltage multipliers.

On a different perspective, when ventricular pacing is not needed, an SC or a DC ICD capable of minimizing ventricular stimulation³² should be mandatory to improve longevity. In fact, ICD longevity is the priority with respect to size not only for health systems, but also for the patients themselves. In a recent survey 90% of patients preferred a larger long-lasting device, the result being independent of patient sex, age, body size, and clinical status.³³ Thus, the ideal ICD to cover a hypothetical 10-year life span should be appropriately sized and capable of minimizing battery drain in routine operation.

Implantable cardioverter-defibrillator cost

ICD therapy is considered a cost-effective treatment, and cost-effectiveness estimates are sensitive to variations in device longevity.^{34–37} Indeed, in the analysis reported by Sanders *et al.*³⁴ and by Al-Khatib *et al.*,³⁵ extension of device longevity from 5 to 7 years and up to 10 years yielded a substantial improvement of cost-effectiveness estimates. Moreover, increased device longevity would translate into reduction of ICD replacements. Based on Hauser's report,¹⁰ a 10-year lasting device would save most ICD replacements, as only 40% of ICD carriers with LV dysfunction are likely to survive longer than 10 years. This figure may be somewhat different when patients with primary arrhythmogenic diseases, hypertrophic, or right ventricular arrhythmogenic cardiomyopathy are considered; nonetheless, it reinforces the concept that health system expenditures would be largely reduced by long-lasting ICDs.¹⁰ From the patients' point of view, it would translate into a decreased risk of severe complications related to repeated replacements, which cause costly hospitalizations and interventions. In the large Danish registry⁷ complications were more likely at device replacement (2%) than at implantation (0.75%). In Gould's report⁶ on ICD replacement following advisories, pocket infection requiring lead extraction occurred in 2% of patients, and mortality related to lead extraction was 0.4%.

The implant of a device with extended longevity would also imply the possibility of lengthening the time between follow-up visits, thus obtaining a combined effect on patient comfort and cost-effectiveness improvement.^{34,37}

In our study, longevity impacted the cost per service life of ICDs, meaning that the up-front cost is of limited value. Indeed, this is very important, as Camm *et al.*³⁷ recently highlighted that cost perception and misleading cost-effectiveness studies have negative drawbacks on clinical practice. Fitzpatrick *et al.*³⁸ claimed that, based on an expected service life of 7–11 years and on ICD discounting through suppliers competition, ICD therapy should be made available to all the patients currently being denied this treatment because of misleading cost-effectiveness computations.

Conclusion

Significant differences were observed in the past years among American ICD manufacturers. Extensive technological research is needed to improve ICD longevity, matching clinical requirements. Cost-effectiveness studies should be based on actual ICD longevity.

Study limitations

Our study related to a relatively small number of devices, hence a per-model analysis would have been meaningless. Such an analysis has never been performed in the large report by Hauser.⁹ On the other hand, our single-centre experience allowed comparable ICD programming, so that an analysis based on ICD activity was possible.

In any study of actual device longevity, the devices under investigation are outdated at their replacement owing to the continuing technological improvements and device releases turnover. Our results may not apply to current or future devices, nonetheless our observations may be helpful, where they represent a milestone for comparison with future ICD releases.

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