Longevity of implantable cardioverter-defibrillators, influencing factors, and comparison to industry-projected longevity

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BACKGROUND Because the best possible device longevity is crucial (i.e., risk of infection with premature device exchange, current cost-effectiveness calculations depending on reasonable longevity, patient comfort), industry-independent real-life data are fundamental. However, only limited independent data on the longevity of implantable cardioverter-defibrillators (ICDs) are available.

OBJECTIVE The purpose of this study was to determine ICD device longevity and influencing factors.

METHODS From a prospective database, we studied overall device longevity and identified those devices with replacement for battery depletion or prolonged charge time. For every device, we determined factors that included averaged shocks, pacing percentage, pacing mode, device size, and time of implant. Survival probabilities at different time intervals were calculated, and Kaplan-Meier and Cox regression analyses were used. Observed longevity was compared to industry-projected longevity obtained from product performance reports.

RESULTS A total of 644 ICDs (Medtronic 317, Guidant 189, St. Jude 118, Intermedics 20) were implanted in 499 patients. During follow-up, 163 (25.3%) ICDs were replaced. Manufacturer, time of implant, pacing mode, pacing percentage, and capacitor reformation interval influenced longevity, whereas device size and number of shocks did not. Median longevity was 7.6 years for Medtronic devices, 5.0 years for Guidant devices, and 3.8 years for St. Jude devices. After 5 years, only 70% of ICDs were still in service compared to the 80% projected by industry.

CONCLUSION Marked differences in device longevity among manufacturers cannot be explained by pacing mode, number of shocks, or pacing percentage only. Overall, device performance requires further improvement for the sake of patient health and cost.

KEYWORDS Battery performance; Implantable cardioverter-defibrillator; Longevity

ABBREVIATIONS **CRT** = cardiac resynchronization therapy; **ERI** = elective replacement indication; **ICD** = implantable cardioverter defibrillator

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Introduction

Implantable cardioverter-defibrillators (ICDs) have become standard treatment for primary and secondary prevention of sudden cardiac death in selected patients.[1–6] The ICD reduces mortality by effectively terminating ventricular tachycardia and ventricular fibrillation. The ICD also offers reasonable cost-effectiveness, particularly in secondary prevention.[7–9] Undesired aspects of ICD therapy include complications during implantation,[10] inappropriate shocks,[11] changes in quality of life,[12] lead failure,[13] and recalls. Moreover, patients must undergo repeated ICD replacements due to battery depletion. In addition to possible damage to implanted leads, the infection rate with any reoperation is considerably higher than the rate with the first implantation. The majority of device and lead infections occur after elective replacements.[14] Cost-effectiveness calculations usually are based on an ICD lifespan of 7 years, a goal that is hardly achieved in daily practice.[15]

Product performance reports provided by the industry are the main source of information about ICD longevity. The reports estimate device longevity according to charging frequency (automatic capacitor reformation). However, this estimation is based on less than 5% of returned devices of any particular model and barely accounts for pacing need and delivered shock. Industry-independent data on longevity are scarce. To date, only eight studies have been published,[16–23] only one of which included more than 150

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ICDs.[19] These studies are limited in that they included only replaced ICDs and not those still in service. Disregarding information on devices that still are in service might lead to biased estimates of true device longevity, particularly because long-lasting devices are disregarded. Recently, an editorial stated "device longevity is a poorly documented topic in medical literature. . . . it may encourage clinical scientists to gather these data."[24]

Based on our prospective ICD registry, the aim of this study was to analyze device longevity using the Kaplan-Meier method, to identify factors associated with device longevity, and to compare observed longevity to industry-projected longevity based on product performance reports.

Methods

A prospective registry of ICD patients was started in July 1999. For the time period from 1994 to 1999, we retrospectively collected and included information on all patients who had undergone device implantation at our institution and were still alive in July 1999. From July 1999 onward, we consecutively included and prospectively followed all patients who underwent ICD placement at our institution.

We defined device longevity as the time (in months) from implantation to surgical replacement and thus not necessarily to the day of detection of "elective replacement indication" (ERI). Reasons for replacement were ERI, excessive charge time, true device malfunction, device recall, upgrade, or infection. End of follow-up with administrative censoring of longevity of devices still in service was July 2007. Data on baseline characteristics of patients, manufacturers, device models, indication for implantation, pacing mode, and arrhythmic events were collected prospectively since 1999. For every patient, the numbers of shocks for fast ventricular tachycardia and/or true ventricular fibrillation were added up consecutively. For patients in whom more than one device was implanted, the number of shocks was divided by the number of devices, as no specific allocation of the number of shocks per device was possible. These numbers were then divided by the years of follow-up for every patient. We disregarded shocks after ineffective antitachycardia pacing, due to acceleration of a ventricular tachycardia by antitachycardia pacing and charging episodes for aborted ventricular fibrillation, because they were not collected in the database. Shocks delivered for device testing during implantation (usually two), at the discharge test (usually one), and at the 3-month follow-up visit (usually one) also were not registered. Pacing thresholds were determined during every visit, and output was programmed to a value that was twice as high as the pacing threshold (e.g., threshold 1 V/0.5 ms, output 2 V/0.5 ms). The pacing percentage recorded in device memory at the last visit was used for analysis. For DDD ICDs, the percentage of atrial and ventricular pacing was added and divided by two. For cardiac resynchronization therapy (CRT) ICDs, the percentage of atrial and right and left ventricular pacing was added and divided by two. Capacitor reformation interval was programmed according to the manufacturer's recommendations, with the interval at the last visit used as the relevant value for the study.

Several device characteristics that might have an impact on longevity were studied, including manufacturer, pacing percentage, pacing mode, capacitor reformation interval, calendar year of device implantation ("old" and "new" devices), device size, and battery capacity. Information on the last two parameters was provided by the manufacturers. Device characteristics were categorized as follows:

Pacing percentage: $<33\%$, $33\%–65\%$, $\geq 66\%$
Pacing mode: VVI, DDD, CRT
Capacitor reformation interval: ≤ 3 months, 4–6 months
Calendar year of implantation: <2002, ≥ 2002
Device size: ≤ 35 cm^3, 36–40 cm^3, >40 cm^3
Battery capacity (ampere hours): <1, 1.0–1.45, >1.45

Statistical analysis

Kaplan-Meier analysis was used to estimate (latent) device longevity, stratified by manufacturer and device characteristics. Univariate and multivariate Cox regression was used to test the null hypothesis of no difference in longevity among manufacturers. Subjects who reached the end of follow-up without ERI were censored for administrative reasons. Subjects who died prior to ERI were treated as censored observations. Assuming that censoring due to death is noninformative, the Kaplan-Meier approach provides unbiased estimates of latent device survival.[25] Because censoring of dead subjects might depend on covariates, we also used inverse probability of censoring weighting as described by Robins and Finkelstein,[26] in which censoring was allowed to depend on the covariates age, ejection fraction, and primary versus secondary prevention.

Univariate and multivariate Cox regression models were used to compare the hazard of ERI among manufacturers. In multivariable analysis, the effect of manufacturer was adjusted for the patient characteristics of age, ejection fraction, secondary prevention, and underlying heart disease and for the device characteristics (Table 2). Underlying heart disease was not entered as a covariate but as a stratification variable with the levels of dilated cardiomyopathy, coronary artery disease, and other heart diseases to allow for separate baseline hazards in these strata. In addition, sensitivity analyses were performed in population subsets, excluding CRT devices and devices implanted before year 2002. For all Cox models, robust standard errors were used to adjust for multiple device implantations to the same patient.

We also aimed to compare industry data to real-life data obtained in our ICD cohort. For this comparison, 123 devices had to be excluded because no product performance reports were available that provided longevity probability estimates at different follow-up times (Intermedics: all 20 ICDs; St. Jude: all 16 Profile ICDs; Medtronic: 11 Jewel

ICDs; Guidant: 15 and 37 ICDs from the Vitality and Contak Renewal CRT families, and those 24 ICDs exchanged for reasons other than ERI respectively). For the remaining 521 devices in our registry with recent product performance reports,[27–29] we extracted model-specific device survival probabilities from product performance reports at yearly follow-up increments. The average of these product performance reports survival probabilities over all 521 devices at each time point provides an overall manufacturers' predicted survival probability in our population. This prediction was compared with observed population survival probabilities as determined by Kaplan-Meier estimates and corresponding pointwise 95% confidence intervals.

All of the presented data on Intermedics devices are more of historical than clinical interest given the length of time Intermedics has been out of the market. However, for comparison to devices from the three other manufacturers, Intermedics devices are included in the tables and figures but are not discussed in the text in order to facilitate reading.

Analyses were performed using the StatView program version 5.0 (SAS Institute, Cary, NC, USA) and R version 2.6.2.[28] Tests are two sided, with $P < .05$ considered significant. All confidence intervals are reported at the 95% confidence level.

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agreed to the manuscript.

Results

Overall, 679 devices were implanted in 532 patients. Data on 644 devices in 499 patients are presented. All 33 implanted devices from Biotronik were excluded because none of them has yet been replaced due to a follow-up period of maximum 32 months, making longevity analysis pointless, and 2 devices (1 Medtronic, 1 St. Jude) were excluded due to incomplete data; 24 devices were exchanged for other reasons than ERI (12 recalls, 6 infections, 3 upgrades, 3 device failures due to lead failure and shock into low impedance). The number of patients who died prior to device failure ranged between 6% (St. Jude) and 13% (Guidant) and was similar across devices ($P = .3$).

Baseline characteristics of the 499 patients are given in Table 1. Among the patients, 428 (86%) were male, and 63% had coronary artery disease. Secondary prevention was the indication for ICD placement in 312 (63%) patients. Coronary artery disease was equally distributed among different manufacturers (all 63%). The 644 devices were made by four manufacturers (Medtronic 317, Guidant 189, St. Jude 118, Intermedics 20), and the majority were VVI devices (66%; Table 1)1. Median follow-up duration was 3.2 years (maximum 12.9 years), during which 139 devices (22.4%) were replaced. Data on average shocks per year of patient follow-up and pacing percentage for all devices and after exclusion of CRT devices are given in Table 2.

Table 1 Baseline characteristics of patients and implanted devices

Baseline Characteristics of the 499 Patients	
Gender (male)	428 (86%)
Age (years) [mean (SD)]	59.7 (13.2)
Secondary prevention	312 (63%)
Ventricular fibrillation	86 (17%)
Ventricular tachycardia	156 (31%)
Syncope/inducible ventricular tachycardia	70 (14%)
Cardiopathy	
Ischemic heart disease	317 (63%)
Dilated cardiomyopathy	98 (20%)
Other	84 (17%)
Baseline Characteristics of the 644 Devices	
Manufacturer	
Medtronic	317 (49.2%)
Replaced	63 (19.9%)
Implanted ≥2002	190 (60.0%)
Jewel family	30
GEM I family	61
GEM II family	6
GEM III family	74
Marquis	59
Intrinsic/Entrust/Virtuoso	50
InSync/Concerto (CRT)	37
Guidant	189 (29.3%)
Replaced	41 (21.7%)
Implanted ≥2002	147 (77.7%)
Ventak Prizm	93
Vitality	34
Contak Renewal (CRT)	62
St. Jude	118 (18.3%)
Replaced	41 (34.7%)
Implanted ≥2002	89 (75.4%)
Profile	19
Photon	18
Atlas family	81
Intermedics	20 (3.2%)
Replaced	17 (85.0%)
Implanted ≥2002	NA
Pacing mode	
VVI	426 (66.1%)
DDD	119 (18.5%)
CRT	99 (15.4%)

CRT = cardiac resynchronization therapy.

Manufacturer comparison

Kaplan-Meier curves of device survival split by manufacturer show considerable longevity differences among manufacturers (overall log rank test $P < .001$; Figure 1). Median longevity was 7.6 years for Medtronic, 5.0 years for Guidant, and 3.8 years for St. Jude devices. A separate analysis after exclusion of all CRT devices, which have a disproportionate distribution across manufacturers, displayed similar results as the ones shown. The hazard for ERI was on average approximately three to six times higher for Guidant or St. Jude compared to Medtronic devices. Multivariate adjustments generally led to more extreme discrepancies among manufacturers, and results from all sensitivity analyses were consistent (i.e., after exclusion of CRT devices, restriction to recently implanted devices, or both; Table 3). Because some St. Jude devices (Photon and Profile

Table 2 Mean number of shocks, percentage of pacing, and pacing product according to different manufacturers for all devices and for CRT devices excluded

	All devices	Medtronic	St. Jude	Guidant	Intermedics
Devices overall	644	317	118	189	20
Shock rates					
Devices without shocks	470 (73%)	203 (64%)	94 (80%)	163 (86%)	9 (45%)
Median number of shocks in devices with ≥1 shock per person-year of follow-up	0.35 (0.18/0.64)	0.41 (0.20/0.77)	0.14 (0.1/0.43)	0.36 (0.2/0.61)	0.18 (0.15/0.4)
Pacing percentage					
Devices with <1% pacing	412 (64%)	206 (65%)	104 (88%)	89 (47%)	13 (65%)
Median percentage of pacing	55% (20%/66%)	52% (32%/100%)	15% (2%/52%)	100% (47%/100%)	25% (2%/50%)
Devices, CRT devices excluded	545	281	118	126	20
Pacing percentage					
Devices with <1% pacing	409 (75%)	205 (73%)	104 (88%)	87 (68%)	13 (65%)
Median percentage of pacing	29% (2%/50%)	36% (3%/50%)	15% (2%/52%)	25% (2%/50%)	25% (2%/50%)

CRT = cardiac resynchronization therapy.

families) are suspected of exhibiting poor performance, we compared these devices to the more recent Atlas family. Device survival at 4 years was 64% for Atlas and 33% for Photon and Profile.

Predictors of device longevity

Figure 2 shows longevities according to different device characteristics. Figure 2A shows that more pacing, as obvious in CRT devices, shortens longevity remarkably. Figure 2B shows longevity according to pacing mode. CRT devices, due to their inherent higher percentage of pacing, depleted earlier than VVI or DDD devices. Shorter capacitor reform intervals with more frequent capacitor charges negatively affect device survival (Figure 2C). Interestingly, contemporary devices (i.e. those implanted in 2002 or later) did not exhibit better longevity (Figure 2D). All overall univariate log rank tests shown in Figures 2A to 2D were highly significant ($P < .001$). Battery capacity did not influence longevity, and differences in device size displayed an inconsistent picture without any clear trend (data not shown). Multivariate adjusted analyses revealed a 2.2 times larger hazard of device failure in DDD devices compared with VVI devices and a 9.6 times larger hazard of failure in CRT devices compared with VVI devices.

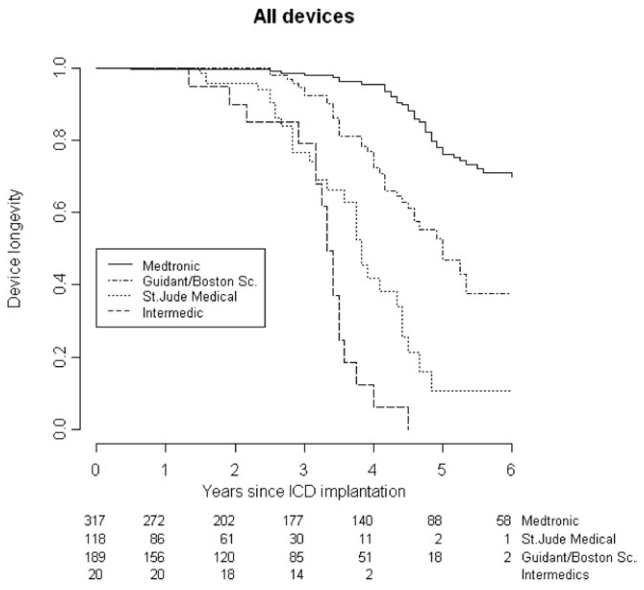

Figure 1 Kaplan-Meier curves of device longevity, stratified by the four manufacturers Medtronic, Guidant, St. Jude, and Intermedics (overall log rank test $P < .001$). ICD = implantable cardioverter-defibrillator.

Industry-projected longevity compared to observed longevity

Comparison of device longevity between our observed data and industry-projected longevity is shown in Figure 3. Overall, industry-projected longevity overestimated observed longevity significantly (estimates outside 95% confidence band of observed longevity). Based on our observed data, 70% of ICDs were still in service after follow-up of 5 years (vs industry-projected longevity 80%) and 62% after 6 years (vs industry-projected longevity 76%). Industry-projected longevity correlated well only up to about 4 years, but only 8% of devices had failed up to that point in time.

Discussion

The main findings of our study are the observed differences in longevity among manufacturers of ICDs, even after exclusion of CRT devices, and the overestimation of true device longevity according to industry-projected data compared to real-life data. Other parameters that showed an influence on device longevity include pacing mode, pacing percentage, capacitor reform interval, and time of implant; device size did not. Our data extend previous findings and allow for more precise determination of true ICD longevity based on the large number of ICDs included in this study, the prolonged follow-up, and the use of Kaplan-Meier analysis. To the best of our knowledge, a comparison to industry-projected longevity has not been previously reported.

Only eight reports to date have addressed ICD longevity. According to these studies, longevity increased from a mean

Table 3 Univariate and multivariate adjusted Cox regression analysis of pairwise manufacturer comparisons on time to device failure

	Univariate	*p*-value	Multivariate	
All devices (n = 624*)				
Guidant vs Medtronic	3.1 (1.9, 4.8)	<0.001	2.4 (1.4, 4.0)	<0.001
St. Jude vs Medtronic	9.1 (5.3, 15.7)	<0.001	16.4 (9.1, 29.6)	<0.001
Guidant vs St. Jude	0.3 (0.2, 0.6)	<0.001	0.14 (0.08, 0.26)	<0.001
CRT devices excluded (n = 525)				
Guidant vs Medtronic	2.3 (1.3, 3.8)	0.002	2.4 (1.5, 4.1)	<0.001
St. Jude vs Medtronic	9.9 (5.5, 17.8)	<0.001	15.8 (8.5, 29.4)	<0.001
Guidant vs St. Jude	0.2 (0.1, 0.4)	<0.001	0.15 (0.09, 0.28)	<0.001
Only ICDs implanted in 2002 and later (n = 426)				
Guidant vs Medtronic	4.4 (1.7, 11.4)	0.002	3.2 (1.23, 8.14)	0.02
St. Jude vs Medtronic	4.3 (1.5, 11.9)	0.005	7.15 (2.69, 19.05)	<0.001
Guidant vs St. Jude	1.0 (0.5, 2.2)	0.9	0.44 (0.19, 1.03)	0.06
Only ICDs implanted in 2002 and later, and CRT devices excluded (n = 334)				
Guidant vs Medtronic	3.4 (1.1, 10.6)	0.04	4.1 (1.35, 12.51)	0.01
St. Jude vs Medtronic	5.4 (1.8, 16.1)	0.002	7.9 (2.6, 23.7)	<0.001
Guidant vs St. Jude	0.6 (0.3, 1.5)	0.29	0.52 (0.2, 1.2)	0.13

Multivariable adjustment for age of patient at implantation, prevention mode, ejection fraction, and pacing mode.
CI = confidence interval; CRT = cardiac resynchronization therapy; HR = hazard ratio.
*Intermedics devices excluded from analysis.

19 months in the late 1980[22] to approximately 48 months today.[16–21,23] Three studies that focused on other issues (obstruction of vena cava, overall hospitalization rates) reported mean ICD longevities of 38 ± 9 months (range 15–54 months, n = 29),[17] 45 ± 21 months (n = 30),[20] and 47 ± 12 months (n = 105). However, no differentiation was

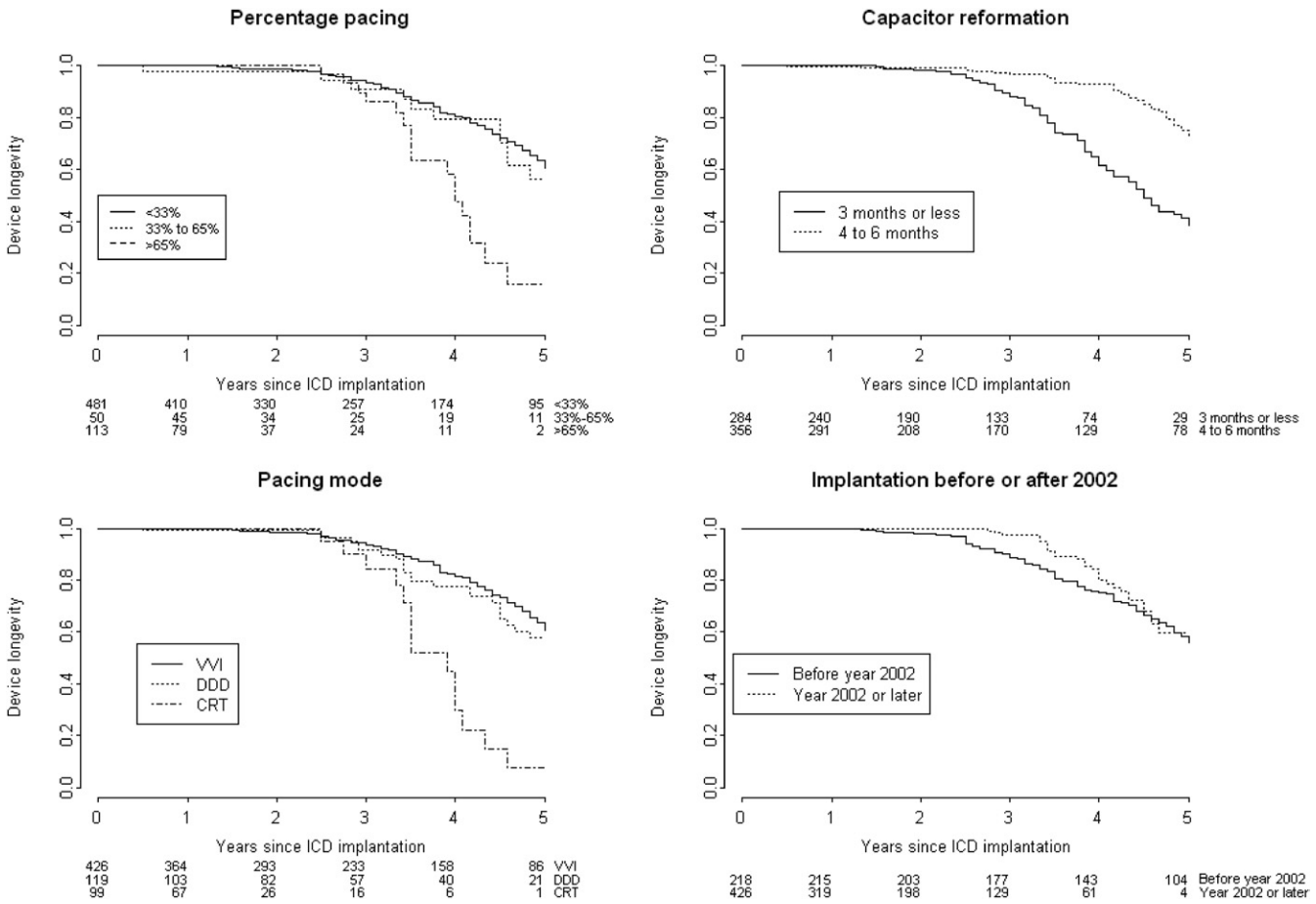

Figure 2 Kaplan-Meier curves of device longevity according to different parameters showing (**A**) pacing percentage (<33%, 33%–65%, >65%), (**B**) capacitor reformation interval (≤3 months, 4–6 months), (**C**) pacing mode (VVI, DDD, CRT), and (**D**) year of implantation (before 2002, 2002 and after). All overall univariate log rank tests were significant ($P < .001$). CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator.

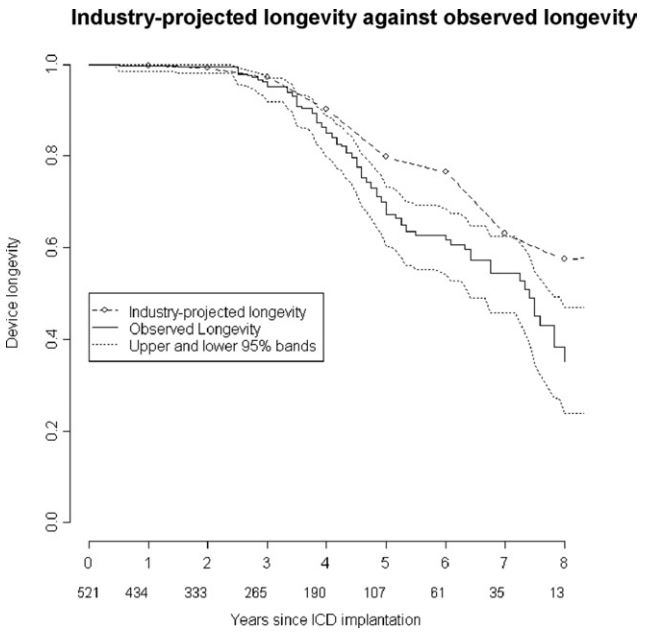

Figure 3 Kaplan-Meier curves of observed device longevity compared to industry-projected longevity, with 95% confidence interval. ICD = implantable cardioverter-defibrillator.

made between single- and dual-chamber ICDs. Another study used Kaplan-Meier analysis to determine device survival[16] and included approximately 700 devices. However, due to a short mean follow-up of just over 600 days, only 50 (7%) of the devices were replaced, compared to more than 22% in our series, and only 16 were replaced due to either battery depletion (n = 4) or prolonged charge time (n = 12). The prolonged charge time was particularly seen in old St. Jude Angstrom devices, a model that was not included in our series. The number of devices studied for more than 3 years dropped dramatically to about 150 patients (21%), compared to almost 50% in our study, indicating insufficient follow-up duration to determine device longevity. The large multicenter registry with 1,200 replaced devices differentiated between single- and dual-chamber devices,[19] but only 4% of the devices were CRT, which accounted for 14% in our study. Mean longevity was approximately 5 years in VVI/DDD devices but dropped to 3.4 years in DDDR, 2.5 years in VVIR, and 1.9 years in CRT devices. Only 26% of the devices were in service for more than 5 years. The fact that virtually no difference was seen between VVI and DDD devices in our study is explained by the low pacing percentage in DDD devices as well (data not shown). An earlier study by the same group[18] of 128 replaced ICDs compared longevity among different manufacturers and found approximately 4.3 years for Medtronic ICDs (n = 40), 4.1 years for St. Jude/Ventritex ICDs (n = 31), and 3.8 years for Guidant ICDs (n = 55). These findings were confirmed by a recent study,[23] which also reported on marked difference between Medtronic and both Guidant and St. Jude devices. Because devices were allocated to patients virtually by chance (apart, of course, from a specific pacing mode chosen for a particular patient), we can be quite sure that our results are not due to a specific bias (e.g., Medtronic devices were not specifically used in younger patients or those with ischemic heart disease) but are due to technical features of the different manufacturers' devices.

To date, only one other study has considered the number of shocks and pacing percentage as possible confounders of device survival.[23] In our study, Medtronic ICDs delivered an equivalent amount of shocks as Guidant and even more than St. Jude ICDs. Medtronic devices also exhibited a similar percentage of pacing as Guidant ICDs and a higher percentage than St. Jude ICDs, but longevity in Medtronic ICDs still was prolonged. Thus, in accordance with the study by Biffi et al,[23] we conclude that neither the percentage of pacing nor the number of shocks seems to be responsible for the observed longevity differences. As shown**,** a more relevant factor might be the capacitor reformation interval, which in Guidant ICDs is automatically set to 3 months at the beginning and drops to 1 month toward the end of device life. This is also the case with older St. Jude ICDs but not with Medtronic ICDs.

An often-mentioned argument is that device longevity is not a problem related to the device manufacturer but rather to the battery manufacturer. However, the physician can only choose from among device manufacturers but not battery manufacturers, so for patients this argument is irrelevant. Upcoming improvements in battery technology might lead to extended longevity, but this remains to be proven in real life, and results will not be available for several years.

Newer ICDs (categorized by implant date of 2002 or later) failed to exhibit better longevity in our registry data. This can be explained in part by the fact that more CRT devices are now used with a high amount of pacing. Of note, among the newer ICDs, St. Jude ICDs were no longer inferior to Guidant ICDs. This is explained by the fact that some St. Jude Profile and Photon ICDs had showed a poor performance, but their battery technology now seems to have improved.

Overall, ICD longevity is not quite satisfactory, as even the manufacturer with the best longevity barely reaches a median longevity of 7.5 years. Industry-projected longevity is an overestimation and does not accurately reflect real-world longevity. Device companies and their engineers should concentrate all their efforts to improving battery performance. Based on limited experience with selected models, physicians know that longevity greater than 10 years is technically feasible.[27]

Study limitations

There are several limitations to this study. Because devices from only four manufacturers were studied, the longevity of Biotronik and ELA devices could not be determined. Censoring of dead subjects is potentially informative regarding ERI, so we used inverse probability weighting to adjust survival curves for dependent censoring.[25,26,30] However, adjusted and unadjusted survival curves were very similar, and none of the covariates studied in our dataset were relevant in this regard. This hints that ERI and death are two

independent failure types and that Kaplan-Meier longevity is a useful estimate in a real-life device population. The pacing percentage was considered only at last follow-up and not during the entire functioning period, and shocks after ineffective antitachycardia pacing were not registered. We defined device longevity as the time (in months) from implantation to surgical replacement and thus not to the day of the detection of ERI. We believe that the corresponding overestimation of longevity is small because surgery was performed within 1 to 2 weeks after detection of ERI.

Conclusion

Marked differences in device longevity that exist among manufacturers cannot be explained by pacing mode, number of shocks, or pacing percentage only. Overall, device performance requires further improvement for the sake of patient health and cost.

References

1. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. N Engl J Med 1996;335:1933–1940.
2. Buxton AE, Lee KL, Fisher JD, et al. A randomized study of the prevention of sudden death in patients with coronary artery disease. N Engl J Med 1999;341: 1882–1890.
3. Moss AJ, Zareba W, Hall WJ, et al. Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877–883.
4. Kadish A, Dyer A, Daubert JP, et al. Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) Investigators. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med 2004;350:2151–2158.
5. Bardy GH, Lee KL, Mark DB, et al. Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225–237.
6. Hohnloser SH, Kuck KH, Dorian P, et al. DINAMIT Investigators. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med 2004;351:2481–2488.
7. Larsen G, Hallstrom A, McAnulty J, et al. AVID Investigators Cost-effectiveness of the implantable cardioverter-defibrillator versus antiarrhythmic drugs in survivors of serious ventricular tachyarrhythmias: results of the Antiarrhythmics Versus Implantable Defibrillators (AVID) economic analysis substudy. Circulation 2002;105:2049–2057.
8. Spath MA, O'Brien BJ. Cost effectiveness of implantable cardioverter defibrillator therapy versus drug therapy for patients at high risk of sudden cardiac death. Pharmacoeconomics 2002;20:727–738.
9. Mushlin AI, Hall WJ, Zwanziger J, et al. The cost-effectiveness of automatic implantable cardiac defibrillators: results from MADIT.Circulation 1998;97: 2129–2135.
10. Bracke FA, Meijer A, van Gelder LM. Lead extraction for device related infections: a single-centre experience. Europace 2004;6:243–247.
11. Daubert JP, Zareba W, Cannom DS, et al; for the MADIT II Investigators. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. J Am Coll Cardiol 2008; 51:1357–1365.
12. Kleemann T, Becker T, Doenges K, et al. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. Circulation 2007;115:2474–2480.
13. Pedersen SS, van Domburg RT, Theuns DA, et al. Concerns about the implantable cardioverter defibrillator: a determinant of anxiety and depressive symptoms independent of experienced shocks. Am Heart J 2005;149:664–669.
14. Reynolds MR, Cohen DJ, Kugelmass AD, et al. The frequency and incremental cost of major complications among Medicare beneficiaries receiving implantable cardioverter-defibrillators. J Am Coll Cardiol 2006;47:2493–2497.
15. Hauser RG. The growing mismatch between patient longevity and the service life of implantable cardioverter-defibrillators. J Am Coll Cardiol 2005;45:2022–2025.
16. Ellinor PT, Guy ML, Ruskin JN, et al. Variability in implantable cardioverter defibrillator pulse generator longevity between manufacturers. Pacing Clin Electrophysiol 2003;26:71–75.
17. Korte T, Jung W, Ostermann G, et al. Hospital readmission after transvenous cardioverter/defibrillator implantation: a single centre study. Eur Heart J 2000; 21:1123–1124.
18. Hauser R, Hayes D, Parsonnet V, et al. Feasibility and initial results of an Internet-based pacemaker and ICD pulse generator and lead registry. Pacing Clin Electrophysiol 2001;24:82–87.
19. Hauser RG, Hayes DL, Epstein AE, et al. Multicenter experience with failed and recalled implantable cardioverter-defibrillator pulse generators. Heart Rhythm 2006;3:640–644.
20. Sticherling C, Chough SP, Baker RL, et al. Prevalence of central venous occlusion in patients with chronic defibrillator leads. Am Heart J 2001;141:813–816.
21. Lickfett L, Bitzen A, Arepally A, et al. Incidence of venous obstruction following insertion of an implantable cardioverter defibrillator. A study of systematic contrast venography on patients presenting for their first elective ICD generator replacement. Europace 2004;6:25–31.
22. Aaarons D, Mower M, Veltri E. Use of the elective replacement indicator in predicting time of automatic implantable cardioverter-defibrillator battery depletion. Pacing Clin Electrophysiol 1989;12:1724–1728.
23. Biffi M, Ziacchi M, Bertini M, et al. Longevity of implantable cardioverter-defibrillators: implications for clinical practice and health care systems. Europace 2008;10:1288–1295.
24. Heidbuechel H. The cost of implantable defibrillators: how the perception of reality depends on perspective. Eur Heart J 2007;28:386–387.
25. Grunkemmeier GL, Jin R, Eijkemans MJ, Takkenberg JJ. Actual and actuarial probabilities of competing risks: apples and lemons. Ann Thorac Surg 2007;83: 1586–1592.
26. Robins JM, Finkelstein DM. Correcting for noncompliance and dependent censoring in an AIDS clinical trial with inverse probability of censoring weighted (IPCW) log-rank tests. Biometrics 2000;56:779–788.
27. Medtronic, Inc. Cardiac rhythm disease management product performance report: important patient management information for physicians. 2008 First edition, issue 58. Available at: http://www.medtronic.com/crm/performance/downloads/mdt-prod-performance-2008-1-en.pdf.
28. St. Jude Medical. Product performance report: cardiac rhythm management, April 2009. Available at: http://www.sjm.com/_MediaAssets/documents/ppr.pdf.
29. Boston Scientific. CRM product performance report 2008: Q1 comprehensive edition. Available at: http://www.bostonscientific.com/templatedata/imports/HTML/CRM/Product_Performance_Resource_Center/report_archives/q1_08_ppr.pdf.
30. R Development Core Team. R: a language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing, 2008.