Analysis of Implantable Defibrillator Longevity Under Clinical Circumstances: Implications for Device Selection

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Introduction: *Information about implantable cardioverter-defibrillator (ICD) longevity is mostly calculated from measurements under ideal laboratory conditions. However, little information about longevity under clinical circumstances is available. This survey gives an overview on ICD service times and generator replacements in a cohort of consecutive ICD patients.*

Methods: *Indications for replacement were classified as a normal end-of-service (EOS), premature EOS, system malfunction, infection and device advisory, or recall actions. From the premature and normal EOS group, longevity from single-chamber (SC), dual-chamber (DC), and cardiac resynchronization therapy defibrillator (CRT-D), rate-responsive (RR) settings, high output (HO) stimulation, and indication for ICD therapy was compared. Differences between brands were compared as well.*

Results: *In a total of 854 patients, 203 ICD replacements (165 patients) were recorded. Premature and normal EOS replacements consisted of 32 SC, 98 DC and 24 CRT-D systems. Longevity was significantly longer in SC systems compared to DC and CRT-D systems (54 ± 19 vs. 40 ± 17 and 42 ± 15 months; $P = 0.008$). Longevity between non-RR ($n = 143$) and RR ($n = 11$) settings was not significantly different (43 ± 18 vs. 45 ± 13 months) as it also was not for HO* versus *non-HO stimulation (43 ± 19 vs. 46 ± 17 months). Longevity of ICDs was not significantly different between primary and secondary prevention (42 ± 19 vs. 44 ± 18 months). The average longevity on account of a device-based EOS message was 43 ± 18 months. Average longevity for Biotronik (BIO, $n = 72$) was 33 ± 10 months, for ELA Medical (ELA, $n = 12$) 44 ± 17 months, for Guidant (GDT, $n = 36$) 49 ± 12 months, for Medtronic (MDT, $n = 29$) 62 ± 22 months, and for St. Jude Medical (SJM, $n = 5$) 31 ± 9 months ($P < 0.001$).*

Conclusion: *SC ICD generators had a longer service time compared to DC and CRT-D systems. No influence of indication for ICD therapy and HO stimulation on generator longevity was observed in this study. MDT ICDs had the longest service time. (PACE 2009; 32:1276–1285)*

implantable cardioverter defibrillator, replacement, longevity, device selection

Introduction

Large randomized clinical trials have demonstrated that implantable cardioverter-defibrillator (ICD) therapy improves survival in patients at risk for life-threatening ventricular arrhythmias.[1–10] Due to the expanded indications for ICD therapy, the number of implantations on account of a primary prevention indication has increased.[11–14,19–21] It is expected that primary prevention patients will survive their ICD service time, and so will need one or more replacements. For several reasons, as patients' comfort, risk and cost control, there is no doubt to strive for keeping the number of replacements as low as possible. Therefore, device longevity is an important parameter in the choice of a specific device or device system for each individual case. In the last decade, ICD technology has advanced into complex arrhythmia management systems, with comprehensive diagnostic tools. In parallel, battery and lead technology have also improved. Device longevity as provided by the manufacturers is usually based on intensive testing under ideal standardized and conditioned laboratory measurements. In contrast, one may assume that device longevity could be different in clinical situations. About ICD longevity under clinical circumstances, there is little information available. Therefore, the purpose of the study was to investigate ICD service time under clinical circumstances, and whether a relation could be found with some theoretical longevity-influencing parameters.

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Methods

Study Population

The study population consisted of 854 consecutive patients who received a first ICD implantation between October 1998 and December 2006 at Erasmus Medical Center, Rotterdam, the Netherlands. Baseline characteristics of the study

population and characteristics of the implanted ICD system were collected. The baseline characteristics consisted of demographic data, indication for ICD therapy, cardiac function and functional class, underlying cardiac disease, and pharmacological therapy. Regarding the implanted system, data were collected on the manufacturer, device model, and the type of the ICD; whether it was a single-chamber (SC), dual-chamber (DC) or a defibrillator incorporated with cardiac resynchronization therapy (CRT-D).

Indications for Replacement

All replacement procedures within the study population were analyzed with respect to the indication for device replacement. Indications for device replacement were divided into a normal end of service (EOS) premature EOS, infection, device advisory or recall, and system malfunction. Device advisory or recall was defined as a manufacturer initiated recommendation for ICD replacement. Premature EOS was defined as an EOS within 36 months after implantation, which is based on the common value given in the warranties provided by the diverse manufacturers. All other replacements after more than 36 months service time were defined as normal EOS. A system malfunction included a malfunction of the pulse-generator, the header, or at least one of the implanted leads. In addition, insufficient energy capacity for successful defibrillation threshold (DFT) testing was defined as a system malfunction.

ICD Bradycardia and Tachycardia Settings

Cardiac stimulation parameters, in general, were set to low-rate backup pacing modes in SC ICDs, except in patients with an indication for stimulation or rate regulation. In general, DC ICDs were programmed in a nontracking backup mode DDI, to avoid unnecessary right ventricular (RV) pacing, except for those patients, where stimulation was indicated. All CRT-D ICDs were programmed to achieve maximal biventricular (BiV) stimulation. The lower rate was programmed in favor of the patients' natural sinus rhythm, to minimize atrial stimulation. The majority of devices were programmed in a dual-zone configuration for arrhythmia detection (74%). The programmed rate cut-offs of the fibrillation and tachycardia zones were 289 $\pm$ 15 ms and 370 $\pm$ 43 ms, respectively. Available discriminators were immediately activated after ICD implantation to avoid inappropriate ICD therapy for atrial tachyarrhythmias.

Device Longevity

To determine the influence of clinical circumstances on ICD longevity, data on bradycardia and tachycardia parameters were collected from saved regular follow-ups and lifetime ICD holters. Bradycardia parameters included the programmed pacing mode, rate cut-off values (at time of implantation), the number and the lifetime percentage of stimulated channels, the presence of high output (HO) stimulation, and the presence of active rate-responsive (RR) settings. HO stimulation was arbitrarily defined as more than 50% stimulation on at least one channel, with at least an output of 3.5 V voltage and 0.4 ms pulse width. For tachycardia therapy history data, the number of delivered HV shocks and the number of automatic capacitor reformations, as far as possible, were collected.

Data Analysis

All patients were followed at 3- to 6-month intervals after the last operation procedure. For the analysis of longevity, only replacements indicated by a device-based EOS message (premature EOS and normal EOS) were used. The exclusion criteria for longevity analysis were replacements indicated by an infection, a device advisory or recall, or a system malfunction, as these events led to prompt corrective and preventive actions. Longevity was calculated as the time span between implantation and replacement (months), and was compared for SC, DC, and CRT-D systems, for systems with HO stimulation versus systems without HO stimulation and for systems with or without active RR settings. Longevity was also compared among different manufacturers. Manufactures, included in the study, were Medtronic (MDT, Medtronic Inc., Minneapolis, MN, USA), Guidant (GDT, Guidant Corp., Indianapolis, IN, USA), St. Jude Medical (SJM, St. Jude Medical, St. Paul, MN, USA), Biotronik (BIO, Biotronik Inc., Berlin, Germany), and ELA Medical (ELA, ELA Medical, Le Plessis-Robinson, France). Continuous data are expressed as mean $\pm$ standard deviations (SD) if normally distributed, otherwise by median, interquartile range 25^{th}–75^{th} percentile. Continuous variables were analyzed with Student's *t*-test and analysis of variance (ANOVA). Categorical data are summarized by percentage. χ^2 test was used for analysis of categorical data. The Kaplan-Meier method was used to calculate actuarial event-free rates from a device replacement, and differences were compared with log-rank testing. A P-value < 0.05 was considered statistically significant.

Results

Study Population

During the 98 months time period between October 1998 and December 2006, a cohort of 854 consecutive patients underwent the first ICD implantation. The baseline demographic and clinical

Table I.

Baseline Demographic and Clinical Data

Characteristics	Total Population (n = 854)
Age (years)	59.0 ± 13.8
Male gender	674 (79)
LVEF (%)	29.9 ± 12.5
NYHA	
– I / II	586 (69)
– III / IV	240 (28)
Underlying disease	
– CAD	533 (62)
– MI	497 (58)
– DCM	178 (21)
– HCM	37 (4)
– CHF	291 (34)
CABG	213 (25)
Pharmacologic therapy	
– Amiodarone	240 (28)
– β-blockers	533 (62)
– Digoxin	164 (19)
– Statins	441 (52)
– ACE-inhibitors	606 (71)
– Diuretics	485 (57)

Categorical data are presented as n, (%).
ACE = angiotensin-converting enzyme; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CHF = congestive heart failure; DCM = dilated cardio-myopathy; HCM = hypertrophic cardio-myopathy; LVEF = left ventricle ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association.

data of these patients are presented in Table I. The majority of the patients were male (78.9%), had documented coronary artery disease (62.4%), and a reduced left ventricular function. Primary prevention indication for ICD therapy was present in 42.8% of the patients. In the same time period, 165 of these patients (19.3%) underwent a total of 203 ICD generator replacements: a total of 127 patients (14.9%) underwent one replacement, 33 patients (3.9%) underwent two replacements, and even three replacement procedures were performed in five patients (0.6%). Primary prevention indication was present in 44 patients (26.7%), who underwent a generator replacement.

The numbers and models of the ICDs, involved in the study, are summarized in Table II, as well as the manufacturers' warranty and the battery specifications.

Indications for a Replacement

Between October 1998 and December 2006, a total of 1,057 implant procedures were performed in our institute. Of these, 854 were first ICD implantations, and 203 were replacements. The indications for a device replacement are presented in Table III. After the first implantation, infection occurred in seven patients (7/854 = 0.8%) of the study population. In addition, three infections were observed after replacement (3/203 = 1.4%). This total of 10 infections resulted in a system replacement and contributed for 4.9% as an indication for a replacement. Device advisory or recall was the indication for a replacement of 30 ICDs (14.8%). From the 203 ICD replacements, nine (4.4%) were due to a system malfunction, including three replacements (1.5%) due to insufficient energy capacity for successful DFT testing. A premature EOS, excluding device advisory or recall, was present in 59 ICDs (29.1%), and a normal EOS was present in 95 ICDs (46.8%).

Distribution of Clinical Variables

The cohort for longevity analysis consisted of replacements on account of a premature and a normal EOS, which represented a total of 154 replacements. Of these, 32 were SC (20.8%), 98 were DC (63.6%), and 24 were CRT-D (15.6%). Table IV summarizes the distribution of pacing percentage, the number and percentage of HO stimulation and active RR settings, and the median number of HV therapies among the replaced devices. The mean percentage of pacing was lower for SC devices (14%) and higher for CRT-D (atrial 21%, ventricular 98%). The percentage of HO stimulation was significantly higher in CRT-D devices compared to SC and DC devices (54% vs. 25% and 38%, respectively; P = 0.02). RR pacing settings were activated only in a minority of the replaced devices. The proportion of active RR pacing settings was higher in SC devices compared to DC and CRT-D devices (13% vs. 5% and 8%, respectively), although statistically this was not significant. There was also no significant difference in the number of HV therapies between SC, DC, and CRT-D devices. In addition, no significant differences in HO stimulation, active RR settings, and median number of HV therapies were found among the different manufacturers between SC, DC, and CRT-D.

Device Longevity

Longevity data are shown in Figure 1. The mean longevity of SC devices was significantly longer compared to DC and CRT-D devices (53.7 ± 19.0 months vs. 40.0 ± 16.9 and 42.2 ± 14.5 months, respectively, P = 0.008). There was no significant difference in longevity between DC and CRT-D devices. The actuarial event-free rates for a replacement of SC, DC, and CRT-D are

Table II.

Numbers and Technical Specifications of ICDs Included for Longevity Analysis

Device Type	Replaced Devices	Manufacturer	ICD Model	Name	Full Warranty Period (Months)	Manufacturer	Battery Model	Type
SC	4	BIO	330444	Belos VR-T	60	LIT	LiS 4082	$LiMnO_2$
	1		347001	Lexos VR-T	30	LIT	LiS 3182E	$LiMnO_2$
	1		356077	Lumos VR-T	30	LIT	LiS 3182E	$LiMnO_2$
	14	GDT	1793	Ventak Mini IV+	48	WGL	WGL 9716	Li/SVO
	3		1852	Ventak Prizm VR HE	36	WGL	WGL 9901	Li/SVO
	7	MDT	7227	Gem VR	36	MECC	Rho 2230-13	Li/SVO
	1		7231	Gem III VR	36	MECC	Chi 3625-7	Li/SVO
	1	SJM	V-199	Atlas VR	36	WGL	WGL 2150	Li/SVO
DC	39	BIO	122382	Phylax AV	60	LIT	LiS 43100+	$LiMnO_2$
	6		122499	Tachos DR	60	LIT	LiS 3482 & LiS 12100	$LiMnO_2$ & LiI
	21		334342	Tachos Atx	48	LIT	LiS 3482 & LiS 12100	$LiMnO_2$ & LiI
	5	ELA	612	Defender IV DR	24	WGL	WGL 9531	Li/SVO
	7		614	Alto DR	24	WGL	WGL 9825	Li/SVO
	2	GDT	1861	Ventak Prizm 2 DR	36	WGL	N/A	Li/SVO
	2		1853	Ventak Prizm DR HE	36	WGL	WGL 9901	Li/SVO
	3		1900	Ventak Prizm AVT	36	WGL	WGL 9913	Li/SVO
	3	MDT	7271	Gem DR	36	MECC	Chi 2826i	Li/SVO
	7		7250	Jewel AF	36	MECC	Chi 2225	Li/SVO
	3	SJM	V-240	Atlas DR	36	WGL	WGL 2150	Li/SVO
CRT-D	2	GDT	1823	Contak CD	36	WGL	N/A	Li/SVO
	5		H135	Contak Renewal	36	WGL	WGL 9913	Li/SVO
	5		H155	Contak Renewal 2	36	WGL	N/A	Li/SVO
	8	MDT	7272	Insync	36	MECC	Chi 2826i	Li/SVO
	3		7279	Insync III Marquis	36	MECC	Chi 4420-L	Li/SVO
	1	SJM	V-341	Atlas+ HF	24	WGL	WGL 2255	Li/SVO

BIO = Biotronik Inc.; CRT-D = cardiac resynchronization therapy—defibrillator; DC = dual chamber; ELA = ELA Medical; GDT = Guidant Corp.; LiI = lithium iodide; $LiMnO_2$ = lithium manganese dioxide; Li/SVO = lithium silver vanadium oxide; LIT = Litronik GmbH; MDT = Medtronic Inc.; MECC = Medtronic Energy and Component Center; N/A = Not Available; SC = single-chamber; SJM = St. Jude Medical; WGL = Wilson Greatbatch Ltd.

Table III.

Replacement Indications

Variables	Number (%)
Total ICD replacements	203 (100.0)
Infection	10 (4.9)
Device advisory or recall	30 (14.8)
System malfunction	9 (4.4)
– Insufficient max. energy at DFT-testing	3 (1.5)
Total device-based EOS indication	154 (75.9)
– Premature EOS indication	59 (29.1)
– Normal EOS indication	95 (46.8)

DFT = defibrillation threshold; EOS = end of service; ICD = implantable cardioverter defibrillator.

presented in Figure 2, which confirmed the previous calculations. No difference in longevity was observed between devices with an active RR setting and devices without an RR setting (44.9 ± 13.4 months vs. 43.1 ± 18.2 months), however an active RR pacing setting was only programmed in 11 of 203 devices (7.1%). A similar result was found for HO stimulation (58 devices or 37.7%), with longevity of 42.6 ± 18.5 months vs. 45.6 ± 16.9 months for non-HO stimulation. No significant difference was observed in ICD longevity with respect to the indication for ICD therapy (primary, 42.4 ± 19.2 months versus secondary prevention, 43.5 ± 17.5 months). The overall longevity of ICDs with a device-based EOS indication was 43.3 ± 17.8 months.

The distribution of device type (SC vs. DC vs. CRT-D) was not equal between the different manufacturers, and longevity turned out to be significantly longer for SC devices compared to DC and CRT-D. In order to analyze the device longevity between the different manufacturers, the Kaplan-Meier survival analysis was corrected for a device type. The mean ICD service time was significantly longer in devices manufactured by Medtronic when compared to other manufactures (62.3 ± 21.7 months vs. 33.3 ± 9.5 months for BIO, 44.2 ± 17.2 months for ELA, 49.3 ± 12.4 months for GDT, 30.7 ± 9.5 months for SJM). Actuarial event-free rates from a device replacement are presented in Figure 3. Devices manufactured by BIO had lower actuarial event-free rates from a device replacement compared with MDT devices

Table IV.

Clinical Data of ICDs Included for Longevity Analysis

Replaced Devices (N)		Percentage Pacing A	Percentage Pacing V	HO Pacing N (%)	RR Pacing N (%)	HV Therapies N (Range)
All						
– SC	(32)	–	14	8 (25)	4 (13)	6.0 (3.0–12.3)
– DC	(98)	32	47	37 (38)	5 (5)	8.0 (4.8–14.0)
– CRT-D	(24)	21	98	13 (54)	2 (8)	6.5 (4.0–12.0)
SC						
– MDT	(8)	–	21	5 (63)	3 (38)	3.0 (2.8–5.0)
– GDT	(17)	–	8	2 (12)	0 (0)	6.0 (5.5–9.5)
– SJM	(1)	–	96	1 (100)	1 (100)	14 (–)
– BIO	(6)	–	6	0 (0)	0 (0)	9.0 (2.0–11.5)
DC						
– MDT	(10)	69	92	3 (30)	0 (0)	9.0 (5.5–9.0)
– GDT	(7)	41	43	2 (29)	2 (29)	7.0 (3.3–13.0)
– SJM	(3)	65	64	2 (67)	1 (33)	6.0 (4.5–36.5)
– BIO	(66)	25	45	20 (30)	1 (2)	8.0 (5.0–13.0)
– ELA	(12)	46	49	10 (83)	1 (8)	9.0 (5.5–23.5)
CRT-D						
– MDT	(11)	27	99	7 (64)	2 (18)	6.5 (4.0–8.3)
– GDT	(12)	11	98	6 (50)	0 (0)	6.5 (4.5–7.8)
– SJM	(1)	83	87	0 (0)	0 (0)	166 (–)

Continuous data are expressed as median (interquartile range 25^{th}–75^{th} percentile).
A = Atrial; BIO = Biotronik Inc.; CRT-D = cardiac resynchronization therapy—defibrillator; DC = dual chamber; ELA = ELA Medical; GDT = Guidant Corp.; HO = high output; HV = high voltage; MDT = Medtronic Inc.; RR = rate response; SC = single chamber; SJM = St. Jude Medical; V = Ventricular.

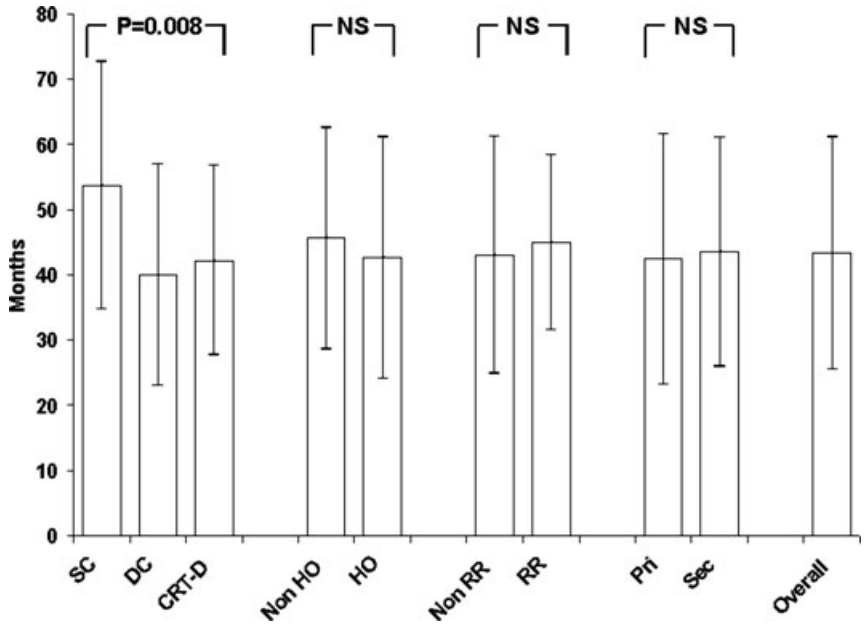

Figure 1. *Longevity data between different groups. SC = single chamber; DC = dual chamber; CRT-D = cardiac resynchronization therapy—defibrillator; HO = high output; RR = rate responsive; Pri = primary prevention; Sec = secondary prevention.*

(99.5%, 90.7%, and 10% vs. 99.5%, 99.5%, and 88.2%, at 1, 2, and 5 years, respectively; $P < 0.001$). ELA, Guidant, and St. Jude had an intermediate position.

Discussion

The major findings of this study were that SC devices have a significantly longer service time, compared to DC or CRT-D devices. In this study,

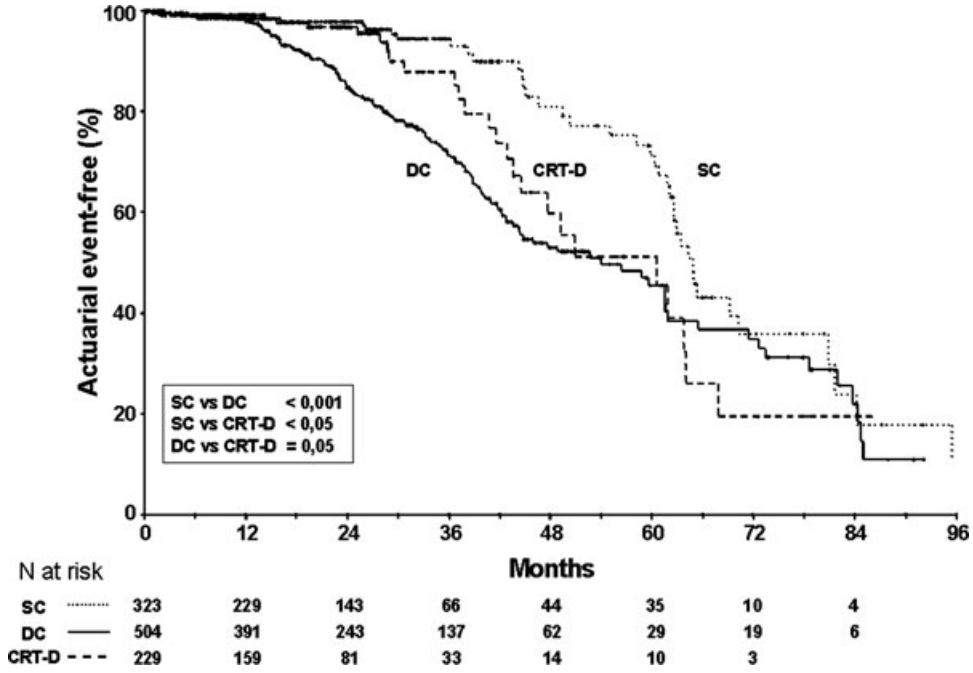

Figure 2. *Event-free survival for single-chamber (SC), dual-chamber (DC), and cardiac resynchronization therapy—defibrillator (CRT-D) devices.*

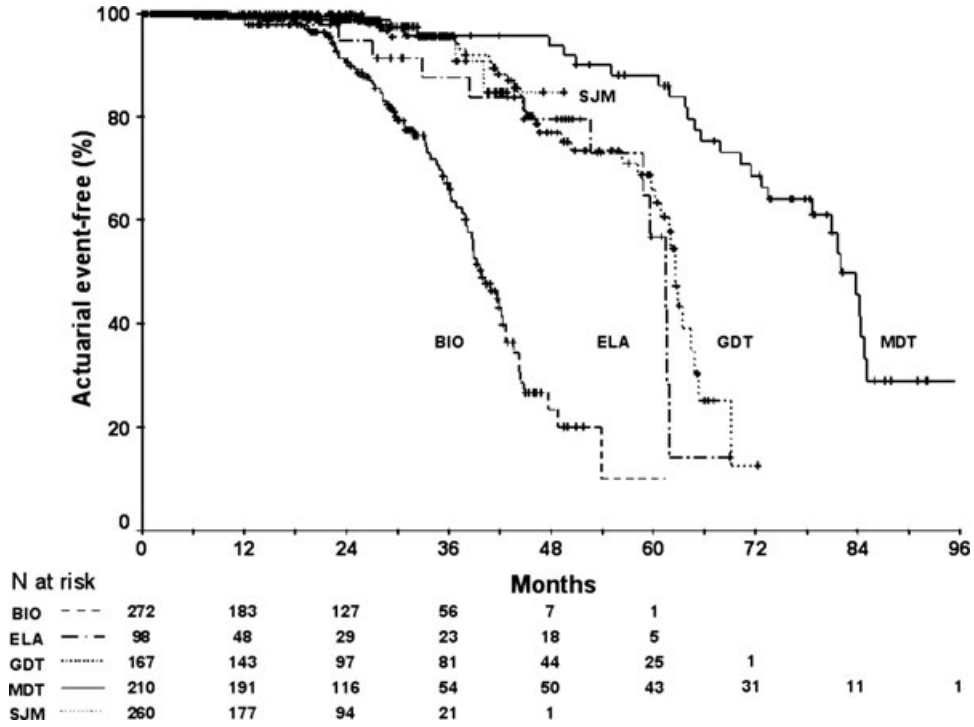

Figure 3. *Event-free survival for different manufacturers. Bio = Biotronik; ELA = ELA Medical; GDT = Guidant; MDT = Medtronic; SJM = St. Jude Medical.*

longevity was not significantly affected by active RR settings and pacing with HO. In addition, no difference was found in longevity between ICDs implanted on indication of a primary or secondary prevention profile. Between manufacturers, the longest service time was provided by ICDs from Medtronic.

Primary Versus Secondary Prevention

In the last decade, several large randomized clinical trials have clarified that prophylactic ICD implantation in patients at risk for life-threatening ventricular tachy-arrhythmias, is more effective in the prevention from sudden cardiac death (SCD) than commonly used pharmacological treatment.[5–10] Due to these trials, the international guidelines for ICD implantation have expanded.[11–13] The guidelines have also included some specific and well-studied structural heart diseases and ion-channel abnormalities.[14–17] Today, the majority of ICDs are implanted on account of a prophylactic indication.[18,19] The majority of these primary prevention patients is expected to survive their first ICD and therefore will need one or more device replacements.[20] Patients themselves, tend to prefer a longer device service time above, for example, device dimensions.[21] Device longevity thus has become an important device characteristic value. We showed in this study that secondary prevention was not associated with shorter device longevity.

Indications for Stimulation

ICD recipients, indicated for prophylactic ICD implantation, commonly do not exhibit any need for (atrioventricular synchronous) cardiac stimulation against bradycardia.[22,23] Even if ICD therapy is combined with drug therapy such as β-blockers, it has been shown that SC (low rate backup stimulation) is preferable over DC stimulation in these patients.[24–26] In the last decade, several authors also showed, that addition of an atrial lead for arrhythmia discrimination is not necessary to avoid an inappropriate therapy,[27–31] and even can have adverse effects.[32–34] So, only in patients, who have significant sinoatrial or atrioventricular rhythm disturbances, the implantation of a DC ICD seems justified. The CRT-D is only indicated for heart failure patients, who meet the criteria for resynchronization therapy and who have an increased risk for arrhythmic death. These patients benefit from bifocal ventricular stimulation, as studies demonstrated.[35–38] Possible reasons for the unequal distribution of the percentage of pacing, HO stimulation, and active RR settings between SC, DC, and CRT-D systems, could be the difference in the implanted system and preferred programming. However, no significantly different distribution of

these variables among manufacturers could be noticed between the SC, DC, and CRT-D groups. We found that DC and CRT-D devices were associated with higher percentages of stimulation (with or without HO) and lower percentage of active RR pacing. In combination, these factors seem to adversely influence longevity. In contrast, an adverse effect of only HO stimulation or RR pacing on device longevity was not found in this study.

ICD Battery Technology and Longevity

ICD battery technology has shown a continuing improvement over time. The results are today's different types of small power sources, of different materials, with different imposing electrical properties and battery capacity. The majority of the power sources for ICDs are composed of a lithium (Li) anode and a cathode of silver vanadium oxide (SVO). The two main differences in cathode technology are the different doses of the individual elements and the different (thermo-chemical) manufacturing process of the SVO compound. Today, this has resulted in a large variety of different SVO cathodes for application in small powerful (ICD) batteries. The latest developments in battery cathode technology are the addition of carbon monofluoride (CFx)/SVO, CFx alone, a metal oxide, for instance manganese dioxide (MnO_2), or combinations of these materials. It is believed, this technology will improve the battery power capability. A large variety of factors have their impact on the discharge characteristics of these batteries. A limitation of manufacturer's predicted ICD longevity is that this value is commonly calculated under generalized laboratory settings with very specific bradycardia settings, without RR or HO stimulation settings and limited and regularly distributed HV discharges. This is not what tends to happen under clinical circumstances. For this reason, a simple comparison between ICD battery type and ICD longevity can not be drawn. For example, each of the following factors are all of importance during battery discharge: current consuming of the ICDs electrical circuit, increased diagnostic functions and remote monitoring tools, capacitor characteristics, lead developments to steroid-eluting leads with different current drawn, IEGM (pre)storage functions, the need of individual device programming for each individual patient, and the battery capacity of the ICD itself. Of course, this summary is not complete. By manufacturers, effective battery capacity is considered to be confidential and is mostly not provided. For ICDs involved in this study, the longest service time was exhibited by MDT devices. Ever since the Marquis platform and in contrast to other manufacturers, MDT has manufactured and has used batteries with a thermally different produced SVO crystal structure. This is the so-called "combination" SVO (CSVO). CSVO makes the batteries more stable.[39] Li/SVO batteries based on CSVO show obvious differences in the crystal morphology and degree of crystallinity, and exhibit a lower rate of time-dependent permanent resistance increase.[40] These factors result in a more stable and better battery performance, which could be translated in a better device performance.[41] For as far as the battery capacity was provided or could be retrieved, MDT ICD batteries showed a greater capacity (>1.1 Ah) when compared to batteries used by other manufacturers. ICDs of BIO in this study, demonstrated the shortest longevity. First of all, also here, it seems that a direct relation with the battery capacity can be noticed. As far as known, involved BIO ICD batteries, showed the smallest capacity (0.6–0.9 Ah). Second, of the investigated ICDs, only BIO batteries are made of $LiMnO_2$ instead of Li/SVO. And finally, some ICD types of BIO are fitted with separated batteries for low-voltage and high-voltage therapy. ELA battery capacity amounted 1.0 Ah and ELA devices showed an intermediate longevity. No battery capacity was provided for GDT and SJM devices. Therefore, their battery capacity could not be compared to other manufacturers.

Limitations

This study had some limitations. First, a complete in-depth analysis on the distribution of the clinical variables in relation to different manufacturers or different device models was not performed. Although a compact overview per manufacturer, per device type is presented in Table IV, the numbers for each particular manufacturer or device model are too low. Clinical variables also can be unequally distributed. For instance, the percent of pacing and the number of HV discharges can be affected by numerous factors, such as different etiology of a cardiac disease, the indication for ICD therapy, presence of electrical storms, selected device type, distribution of different ICD systems between manufacturers, etc. In addition, during service time the interval for battery and capacitor maintenance varied between 3 and 6 months among different manufacturers, and depended on battery voltage as an indicator of battery performance. These charges were not counted within the calculated average number of HV therapies, but have an effect on longevity. Second, the choice for specific manufacturers and device models was not random, but determined by annual agreements between the hospital administration and the different manufacturers. Third, only a minor part of the replaced ICDs was programmed with an active RR sensor setting. No conclusions about the influence of RR settings on longevity could be drawn

from this study data. Another limitation was, that the defined value, whether an output had to be considered as HO stimulation or not, was arbitrarily chosen. Battery drainage is, besides voltage, dependent on multiple other factors, such as lead impedance, current drawn, and stimulation frequency.

During the study, a voluntary recall had a significant impact on the cohort of patients with BIO devices, supplied with the battery type LiS 3482. Due to the formation of a passivation layer at the battery anode, battery impedance increased too fast and extended capacitor charge time.[42] This resulted in an interruption of capacitor charging and a triggering of EOS indication. After intensified testing, the affected ICDs were scheduled for a replacement, and thus excluded from a longevity analysis. The nonaffected ICDs with the same battery type were automatically reprogrammed to an intensive internal battery impedance monitoring protocol by a modified programmer software. In cases the regularly checked battery charge time started to increase too fast, intensified battery charges, to prevent the build-up of a passivation layer, were performed. This intensified battery maintenance may significantly decrease the longevity of these devices. These devices could be followed up until an EOS message from the device occurred. Due to the chosen definitions, these devices were involved in the longevity analysis. Without this extreme capacitor maintenance, it is likely that longevity of these devices, and the average longevity of BIO ICDs would have been higher. On the other hand, we were lucky to have no devices affected from recalls of other manufacturers, which might have influenced the outcome in another direction. Until today, all other ICDs within the study population have not shown abnormal battery behavior, and were not affected by possible malfunctions, as have been described in other advisories. Unfortunately, studies such as these are always outdated: The results of today are based on the technology of past years, and does not predict anything regarding longevity of new ICD releases, with an improved battery technology.

Recommendations

The authors are of opinion that the significantly longer service time of SC ICDs, demonstrated in this study, in combination with previously mentioned results of publications, are strong arguments for the implantation of SC ICDs in primary prevention patients without sinoatrial and atrioventricular conduction disturbances. With the status of current available ICD technology, the implantation of a DC ICD system, with or without CRT seems only justified when atrial or synchronized (bi)ventricular stimulation is needed. The ongoing development of new ICD technology and the implementation of new ICD power sources forces and challenges us to continue the investigation on clinical ICD longevity in today's and future ICDs.

References

1. The Antiarrhythmics Versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. N Engl J Med 1997; 337:1576–1583.
2. Kuck KH, Cappato R, Siebels J, Ruppel R. Randomized comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from cardiac arrest: The cardiac arrest study hamburg (CASH). Circulation 2000; 102:748–754.
3. Connolly SJ, Gent M, Roberts RS, Dorian P, Roy D, Sheldon RS, Mitchell LB, et al. Canadian implantable defibrillator study (CIDS): A randomized trial of the implantable cardioverter defibrillator against amiodarone. Circulation 2000; 101:1297–1302.
4. Lau EW, Griffith MJ, Pathmanathan RK, Ng GA, Clune MM, Cooper J, Marshall HJ, et al. The midlands trial of empirical amiodarone versus electrophysiology-guided interventions and implantable cardioverter-defibrillators (MAVERIC): A multicentre prospective randomized clinical trial on the secondary prevention of sudden cardiac death. Europace 2004; 6:257–266.
5. Moss AJ, Hall WJ, Cannom DS, Daubert JP, Higgins SL, Klein H, Levine JH, et al. Multicenter automatic defibrillator implantation trial (MADIT) investigators. improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. N Engl J Med 1996; 355:1933–1940.
6. Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. Multicenter unsustained tachycardia trial (MUSTT) investigators. a randomized study of the prevention of sudden death in patients with coronary artery disease. N Engl J Med 1999; 341:1882–1890.
7. Hohnloser SH, Kuck KH, Dorian P, Roberts RS, Hampton JR, Hatala R, Fain E, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med 2004; 351:2481–2488.
8. Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, Daubert JP, et al., for the Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infaction and reduced ejection fraction. N Engl J Med 2002; 246:877–883.
9. Kadish A, Dyer A, Daubert JP, Quigg R, Mark Estes NA, Anderson KP, Calkins H, et al., for the 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.
10. Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, Domanski M, et al., for the 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.
11. Gregoratos G, Abrams J, Epstein AE, Freedman RA, Hayes DL, Hlatky MA, Kerber RE, et al. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: Summary article: A report of the American college of cardiology/American heart association task force on practice guidelines (ACC/AHA/NASPE committee to update the 1998 pacemaker guidelines). Circulation 2002; 106:2145–2161.
12. Priori SG, Aliot E, Blomstrom-Lundqvist C, Bossaert L, Breithardt G, Brugada P, Camm JA, et al. Update of the guidelines on sudden cardiac death of the European society of cardiology. Eur Heart J 2003; 24:13–15.
13. Goldberger Z, Lampert R. Implantable cardioverter-defibrillators. Expanding indications and technologies. JAMA 2006; 295:809–818.
14. Zareba W, Moss AJ, Daubert JP, Hall WJ, Robinson JL, Andrews M. Implantable cardioverter defibrillator in high-risk long QT syndrome patients. J Cardiovasc Electrophysiol. 2003; 14:337–341.

15. Sarkozy A, Boussy T, Kourgiannides G, Chierchia GB, Richter S, De Potter T, Geelen P, et al. Long-term follow-up of primary prophylactic implantable cardioverter-defibrillator therapy in Brugada syndrome. Eur Heart J 2007; 28:334–344.
16. Maron BJ, Mark Estes III NA, Maron MS, Almquist AK, Link MS, Udelson JE. Primary prevention of sudden death as a novel treatment strategy in hypertrophic cardiomyopathy. Circulation 2003; 107:2872–2875.
17. Corrado D, Leoni L, Link MS, Della Bella P, Gaita F, Curnis A, Salemo JU, et al. Implantable cardioverter-defibrillator therapy for prevention of sudden death in patients with arrhythmogenic right ventricular cardiomyopathy/dysplasia. Circulation 2003; 108:3084–3091.
18. Bernstein AD, Parsonnet V. Survey of cardiac pacing and implanted defibrillator practice patterns in the united states in 1997. Pacing Clin Electrophysiol 2001; 24:842–855.
19. Ector H, Rickards AF, Kappenberger L, Linde C, Vardas P, Oto A, Santini M, et al., on behalf of the Working Group on Cardiac Pacing. The world survey of cardiac pacing and implantable cardioverter defibrillators: Calendar year 1997—Europe. Pacing Clin Electrophysiol 2001; 24:863–868.
20. Hauser RG. The growing mismatch between patient longevity and the service life of implantable cardioverter-defibrillators. J Am Coll Cardiol 2005; 45:2022–2025.
21. Wild DM, Fisher JD, Kim SG, Ferrick KJ, Gross JN, Palma EC. Pacemakers and implantable cardioverter defibrillators: Device longevity is more important than smaller size: The patient's viewpoint. Pacing Clin Electrophysiol 2004; 27:1526–1529.
22. Proclemer A, Della Bella P, Facchin D, Fattore L, Carbucicchio C, Tondo C, Lunati M, et al. Indications for dual-chamber cardioverter defibrillators at implant and at 1 year follow-up: A retrospective analysis in the single-chamber defibrillator era. Europace 2001; 3:132–135.
23. Kolb C, Deisenhofer I, Schmieder S, Barthel P, Zrenner B, Karch MR, Schmitt C. Long-term follow-up of patients supplied with single-chamber or dual-chamber cardioverter defibrillators. Pacing Clin Electrophysiol 2006; 29:946–952.
24. Wilkoff BL, Cook JR, Epstein AE, Greene L, Hallstrom AP, Hsia H, Kutalek SP, et al., for The DAVID Trial Investigators. Dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator. the dual chamber and VVI implantable defibrillator (DAVID) trial. JAMA 2002; 288:3115–3123.
25. Sweeny MO, Hellkamp AS, Ellenbogen KA, Greenspon AJ, Freedman RA, Lee KL, Lamas GA; for the MOde Selection Trial (MOST) Investigators. Adverse effect of ventricular pacing on heart failure and atrial fibrillation in a clinical trial of pacemaker therapy for sinus node dysfunction. Circulation 2003; 107:2932–2937.
26. Olshansky B, Day JD, Moore S, Gering L, Rosenbaum M, McGuire M, Brown S, et al. Is dual-chamber programming inferior to single-chamber programming in an implantable cardioverter-defibrillator?: Results of the intrinsic RV (inhibition of unnecessary RV pacing with AVSH in ICDs) study. Circulation 2007; 115:9–16.
27. Friedman PA, McClelland RL, Bamlet WR, Acosta H, Kessler D, Munger TM, Kavesh NG, et al. Dual-chamber versus single-chamber detection enhancements for implantable defibrillator rhythm diagnosis: The detect supraventricular tachycardia study. Circulation 2006; 113:2871–2879.
28. Deisenhofer I, Kolb C, Ndrepepa G, Schreieck J, Karch M, Schmieder S, Zrenner B, et al. Do current dual chamber cardioverter defibrillators have advantages over conventional single chamber cardioverter defibrillators in reducing inappropriate therapies? a randomized, prospective study. J Cardiovasc Electrophysiol 2001; 12:134–142.
29. Kouakam C, Kacet S, Hazard JR, Ferraci A, Mansour H, Defaye P, Davy JM, et al., Ventak AV Investigators. Performance of a dual-chamber implantable defibrillator algorithm for discrimination of ventricular from supraventricular tachycardia. Europace 2004; 6:32–42.
30. Theuns DAMJ, Klootwijk APJ, Goedhart DM, Jordaens LJLM. Prevention of inappropriate therapy in implantable cardioverter-defibrillators. Results of a prospective, randomized study of tachyarrhythmia detection algorithms. J Am Coll Cardiol 2004; 44:2362–2367.
31. Theuns DA, Rivero-Ayerza M, Boersma E, Jordaens L. Prevention of inappropriate therapy in implantable defibrillators: A meta-analysis of clinical trials comparing single-chamber and dual-chamber arrhythmia discrimination algorithms. Int J Cardiol. 2008; 125:352–357.
32. Israel CW, Grönefeld G, Iscolo N, Stöppler C, Hohnloser SH. Discrimination between ventricular and supraventricular tachycardia by dual chamber cardioverter defibrillators: Importance of the atrial sensing function. Pacing Clin Electrophysiol 2001; 24:183–190.
33. Gradaus R, Breithardt G, Böcker D. ICD leads: Design and chronic dysfunctions. Pacing Clin Electrophysiol 2003; 26:649–657.
34. Alter P, Waldhans S, Plachta E, Moosdorf R, Grimm W. Complications of implantable cardioverter defibrillator therapy in 440 consecutive patients. Pacing Clin Electrophysiol 2005; 28:926–932.
35. Abraham WT, Fisher WG, Smith AL, Delurgio DB, Leon AR, Loh E, Kocovic DZ, et al., for the MIRACLE Study Group. Cardiac resynchronization in chronic heart failure. N Engl J Med 2002; 346:1845–1853.
36. Linde C, Braunschweig F, Gadler F, Brailleul C, Daubert JC. Long-term improvements in quality of life by biventricular pacing in patients with chronic heart failure: Results from the multisite stimulation in cardiomyopathy study (MUSTIC). Am J Cardiol 2003; 91:1090–1095.
37. Bristow MR, Saxon LA, Boehmer J, Krueger S, Kass DA, De Marco T, Carson P, et al., for the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Investigators. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med 2004; 350:2140–2150.
38. Cleland JG, Daubert JC, Erdmann E, Freemantle N, Gras D, Kappenberger L, Tavazzi L, for the Cardiac Resynchronization – Heart Failure (CARE-HF) Study Investigators. The effect of cardiac resynchronization on morbidity and mortality in heart failure. N Engl J Med 2005; 352:1539–1549.
39. Schmidt CL, Crespi AM, Skarstad PM. Modelling of long-term lithium/silver vanadium oxide battery performance. Abstract 601, Electrochemical Society 1999. Available at: http://www.medtronic.com/physician/tachy/icd/microt.html.
40. Crespi AM, Schmidt CL, Norton J, Chen K, Skarstad PM. Modeling and characterization of the resistance of lithium/SVO batteries for implantable cardioverter defibrillators. J Electrochem Soc 2001; 148:A30–A37.
41. Chen K, Crespi AM, Schmidt CL, Skarstad PM. Influence of cathode synthesis method on the long-term performance of li/silver vanadium oxide batteries. ECS Fall Meeting 1999 Abstract 302.
42. Biotronik. Urgent safety information regarding biotronik ICDs deikos, tachos and tupos. Technical Note. Inappropriate Extended and Short Charge Times in BIOTRONIK Implantable Cardioverter-Defibrillators of the Tachos Family (Tachos DR, Deikos A+, Tupos LV) April 26, 2004.