Clinical aspects and socio-economic implications of implantable cardioverter defibrillator treatment

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Chapter 7

Implantable Cardioverter-Defibrillator Longevity under Clinical Circumstances: an Analysis According to Device Type, Generation, and Manufacturer

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ABSTRACT

Background

One of the major drawbacks of implantable cardioverter defibrillator (ICD) treatment is the limited device service life. Thus far, data concerning ICD longevity under clinical circumstances are scarce. In this study, the ICD service life was assessed in a large cohort of ICD recipients.

Methods

All patients receiving an ICD in the Leiden University Medical Center were included in the analysis. During prospectively recorded follow-up visits, reasons for ICD replacement were assessed and categorized as battery depletion and non-battery depletion. Device longevity and battery longevity were calculated. The impact of device type, generation, manufacturer, percentage of pacing, pacing output, and the number of shocks on the battery longevity was assessed.

Results

Since 1996, 4,673 ICDs were implanted of which 1,479 ICDs (33%) were replaced. Mean device longevity was 5.0±0.1 years. A total of 1,072 (72%) ICDs were replaced because of battery depletion. Mean battery longevity of an ICD was 5.5±0.1 years. When divided into different types, mean battery longevity was 5.5±0.2 years for single-chamber ICDs, 5.8±0.1 for dual-chamber ICDs and 4.7±0.1 years for cardiac resynchronization therapy-defibrillators (CRT-Ds) ($p<0.001$). Devices implanted after 2002 had a significantly better battery longevity as compared to devices implanted before 2002 (5.6±0.1 vs. 4.9±0.2 years, $p<0.001$). In addition, large differences in battery longevity between manufacturers were noted (overall log rank test $p<0.001$).

Conclusion

The majority of ICDs were replaced because of battery depletion. Large differences in longevity exist between different ICD types and manufacturers. Modern ICD generations demonstrated improved longevity.

INTRODUCTION

Large randomized trials have shown a beneficial effect of implantable cardioverter-defibrillator (ICD) treatment on mortality in selected groups of patients at risk for a life-threatening ventricular arrhythmia.[1-9] With the rapid expansion of indications for ICD therapy, worldwide implantation rates increased greatly in the last decade.[10-12] However, despite the improved survival in selected patients with an ICD, some limitations of ICD therapy should not be overseen. One of these limitations is the finite lifespan of ICD devices and, consequently, 70% of all ICD recipients will need an ICD replacement because of battery depletion at a certain point in time.[10] Since ICD replacement is associated with major drawbacks, such as infectious and non-infectious complications, reduced patient comfort, and reduced cost-effectiveness, assessment of improvement and potential differences in battery longevity is essential for the evaluation of ICD performance.[13-15]

However, most data considering device longevity are provided by manufacturers and are based on intensive testing under standardized and conditioned laboratory measurements. Although this manufacturer provided data might be different from device longevity in clinical practice, data concerning ICD longevity under clinical circumstances are scarce.

The aim of the current study was to assess the longevity of ICDs in routine clinical practice in a large cohort of patients. This assessment was performed over a 15-year period in a large university hospital in the Netherlands. Additionally, the current dataset provides an opportunity to assess potential differences in longevity between different types of ICDs, manufacturers and to evaluate improvements throughout time.

METHODS

Patients

Since 1996, all consecutive patients who received an ICD system in the Leiden University Medical Center were collected in the departmental Cardiology Information System (EPD-Vision®, Leiden University Medical Center). Baseline characteristics of the patient, data of the implant procedure, and all follow-up visits (until April 2011) were recorded prospectively. Collected data of follow-up visits included the pacing percentage, the pacing threshold, the pacing output, and the number of delivered shocks (appropriate and inappropriate) delivered by each single ICD. Data regarding the implanted defibrillator as manufacturer, device model, and the type of ICD (single-chamber, dual-chamber or cardiac resynchronization therapy-defibrillator (CRT-D)) were noted.

Eligibility for ICD implantation was based on international guidelines and included secondary prevention and primary prevention of sudden cardiac death. Due to the evolution of these guidelines, indications have changed over time.[12, 16]

Device implantation and follow-up

All defibrillator systems used were implanted transvenously and without thoracotomy. During the implant procedure, sensing and pacing thresholds were determined. Used systems were manufactured by Biotronik (Berlin, Germany), Boston Scientific [Natick, MA,

USA, formerly CPI, Guidant (St Paul, MN, USA)], Medtronic (Minneapolis, MN, USA), and St Jude Medical/Ventritex (St Paul, MN, USA).

As a training facility, different physicians were involved with ICD implantation throughout the years and to guarantee uniformity, devices were programmed according to a strict protocol. In general, in single-chamber ICD recipients, cardiac stimulation parameters were set to VVI 40. If patients were dependent on stimulation or rate responsive pacing, a pacing mode of VVIR 40-140 was programmed. To avoid unnecessary right ventricular pacing, dual-chamber ICDs were programmed in the nontracking backup mode DDI in the majority of patients with sufficiently long AV delay to secure intrinsic conduction at the lower rate. For those patients with an indication for stimulation or rate responsive pacing, devices were programmed in a mode of DDDR 40-140 with sufficiently long AV delay to secure intrinsic conduction. CRT-D devices were programmed in a biventricular pacing mode, with the lower rate programmed in favor of the patient's natural sinus rhythm resulting in a minimization of atrial stimulation. During follow-up visits, the pacing output was programmed to a value that was twice as high as the recorded pacing threshold with a minimum pacing output of 2.5 V (e.g., threshold 0.5V, output 2.5V; threshold 2.0V, output 4.0V). The average pacing percentage and pacing outputs recorded during subsequent ICD follow-up visits were used for the current analysis. For dual-chamber and CRT-D devices, the percentage of atrial and (bi)ventricular pacing was added resulting in a maximal pacing percentage of 100% for single-chamber ICDs, 200% for dual-chamber ICDs and 300% for CRT-Ds.

The antitachycardia modes in all devices were programmed with three consecutive zones with limits slightly varying per manufacturer: a monitor zone (lower limit between 150-155 bpm; upper limit between 185-190 bpm), an antitachycardia pacing (ATP) shock zone (lower limit between 185-190 bpm; upper limit between 205-210 bpm), and an initial shock zone (≥205-210 bpm). In the monitor zone, no therapy was programmed unless a ventricular arrhythmia was detected during follow-up. In the ATP-shock zone, arrhythmias were initially attempted to be terminated by two bursts of ATP and, if arrhythmia continued, defibrillator shocks were used. In case of a ventricular arrhythmia faster than the ATP shock zone, device shocks were the initial therapy. Furthermore, atrial arrhythmia detection was set to >170 bpm with supraventricular tachycardia discriminators enabled. Therapy settings were adapted, only when clinically indicated.

Device interrogation was scheduled every 3-6 months after implantation. Data of these ICDs were included until the last date of ICD check-up. ICDs of patients referred to another center were tracked (i.e. last date of ICD check-up in referred center) and if device replacement had occurred, its indication was verified.

Indications for replacement

During follow-up, all ICD replacement procedures were assessed and the indication for device replacement was registered. Replacements were categorized as battery depletion (Elective Replacement Indicator [ERI]) and non-battery related causes resulting in device replacement. Non-battery related causes were further categorized as follows: 1) device upgrade, 2) device infection, 3) device advisory or recall, 4) system malfunction, or 5) heart transplantation. Device upgrade was noted when an initial single-chamber was replaced

for a dual-chamber ICD or CRT-D or when a dual-chamber ICD was replaced for a CRT-D without the necessity for replacement because of battery depletion. Device infection was defined as infective symptoms at the generator pocket site with or without verified invasion of pathogenic microorganisms within the ICD pocket.[13] In addition, patients presenting with fever or recurrent bacteremia without an apparent focus, subsequently causing device replacement, were also classified as device infection. Device advisory or recall consisted of a manufacturer initiated advisory to replace an ICD because of technical problems. System malfunction was defined as malfunction of the device, the leads, the header or insufficient energy capacity for successful defibrillation resulting in device replacement.[17] Finally, analyses were performed for all causes of device replacement (i.e. device longevity) and for device replacements because of battery depletion (i.e. battery longevity).

Statistical analysis

Continuous data are expressed as mean and standard deviation (SD) or median with 25th and 75th percentile where appropriate; dichotomous data are presented as numbers and percentages. Mean longevity was defined in years and was calculated as the time from ICD implantation to the time of replacement and expressed with a two-sided 95% confidence interval (95% CI). As described previously, separate analyses were performed for device longevity, taking into account all causes of device replacement and for battery longevity, taking into account only device replacement because of battery depletion. Additional longevity analyses were performed for the type (i.e. single-chamber, dual-chamber, and CRT-D), time of implant (i.e. implanted before or since 2002) and the manufacturer (i.e. Biotronik, Boston Scientific/Guidant, Medtronic and St Jude Medical/Ventritex). Event-free rates from a device replacement were analyzed with the method of Kaplan-Meier and the log-rank test. A p-value < 0.05 was considered statistically significant. Univariate and multivariate Cox proportional-hazards models were constructed to identify independent determinants of battery longevity. Only variables with a p-value<0.25 in univariate analysis were retained in the multivariate model. All statistical analyses were performed with SPSS software (version 18.0, SPSS Inc., Chicago, Illinois).

RESULTS

Patients and ICD Characteristics

Since 1996, 4,673 consecutive ICDs were implanted in 3,194 patients (78% men, mean age 62 [SD 13] years), which were included in the analysis. The majority of these patients had ischaemic heart disease (64%) and a poor LVEF (mean LVEF 34% [SD 15%]) (Table 1). During mean follow-up of 4.1±3.2 years, 708 (22%) patients died and 128 (4%) patients were lost to follow-up.

Of the 4,673 implanted devices, 3,194 (68%) were initial implantations and 1,479 (32%) were replacement ICDs. The types (single-chamber, dual-chamber, and CRT-D) and manufacturers (Biotronik, Guidant, Medtronic and St Jude Medical/Ventritex) included in the analysis are summarized in Table 2.

Table 1. Patient characteristics at initial ICD implantation.

	Patients (n=3194)
Clinical characteristics	
Age, mean (SD), years	62 (13)
Male sex (%)	2507 (78)
Primary prevention indication (%)	1979 (62)
Ejection fraction (%)	34 (15)
QRS, mean (SD), ms	125 (35)
Renal clearance, mean (SD), ml/min	81 (38)
Ischaemic heart disease (%)	2047 (64)
Medication	
Beta-blocker (%)	1760 (55)
Sotalol (%)	437 (14)
ACE inhibitors/AT II antagonist (%)	2411 (75)
Calcium antagonist (%)	284 (9)
Diuretics (%)	1984 (62)
Statins (%)	1846 (58)
Nitrates (%)	572 (18)
Amiodarone (%)	539 (17)
Aspirin (%)	1295 (41)
Oral anticoagulants (%)	1586 (50)

ACE = angiotensin-converting enzyme; AT = angiotensin; SD = standard deviation.

Table 2. ICDs included for longevity analysis

	Single-chamber	Dual-chamber	CRT-D	Total
Biotronik	23 (3%)	323 (16%)	194 (11%)	540 (12%)
Boston Scientific/Guidant	450 (62%)	835 (40%)	1005 (54%)	2290 (49%)
Medtronic	200 (27%)	717 (34%)	634 (34%)	1551 (33%)
St. Jude Medical/Ventritex	57 (8%)	215 (10%)	20 (1%)	292 (6%)
Total	730	2090	1853	4673

CRT-D = cardiac resynchronization therapy-defibrillator.

As is shown in Figure 1, the implanted number of single-chamber devices, dual-chamber devices, and CRT-D devices is unequally distributed over time. In 1996, all defibrillators implanted were single-chamber devices. In 2002 the distribution was as follows: 21% single-chamber devices, 53% dual chamber devices, 26% CRT-D devices. In 2010, of the implanted devices, 6% were single-chambers, 41% were dual-chambers, and 53% were CRT-Ds.

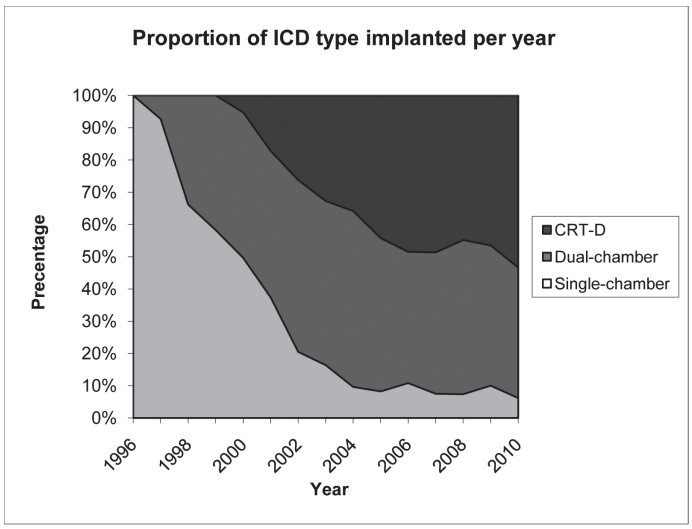


Figure 1. Annual proportion of diverse ICD types out of all implanted ICDs.

Replacement Indications

A total of 1113 (35%) patients experienced device replacement, of whom 229 (21%) patients underwent 2 replacement procedures, 52 (5%) patients underwent 3 replacement procedures and 11 (1%) patients underwent 4 replacement procedures.

The majority of ICD replacements were performed because of an ERI (n = 1072, 72%). Other indications for replacement were device upgrades (n = 145, 10%), device infection (n = 118, 8%), device advisory or recall (n = 49, 3%), system malfunction (n = 83, 6%) and heart transplantation (n = 12, 1%) (Table 3).

Table 3. Indication for replacement

	Total (n=1479)	Single chamber (n=379)	Dual chamber (n=645)	CRT-D (n=455)
End of service, n (%)	1072 (72)	279 (74)	420 (65)	373 (82)
Device upgrade, n (%)	145 (10)	49 (13)	96 (15)	0 (0)
Device infection, n (%)	118 (8)	20 (5)	53 (8)	45 (10)
Device advisory or recall, n (%)	49 (3)	8 (2)	34 (5)	7 (2)
System malfunction, n (%)	83 (6)	23 (6)	38 (6)	22 (5)
Heart transplantation, n (%)	12 (1)	0 (0)	4 (1)	8 (2)

CRT-D = cardiac resynchronization therapy-defibrillator.

Battery and non-battery related longevity

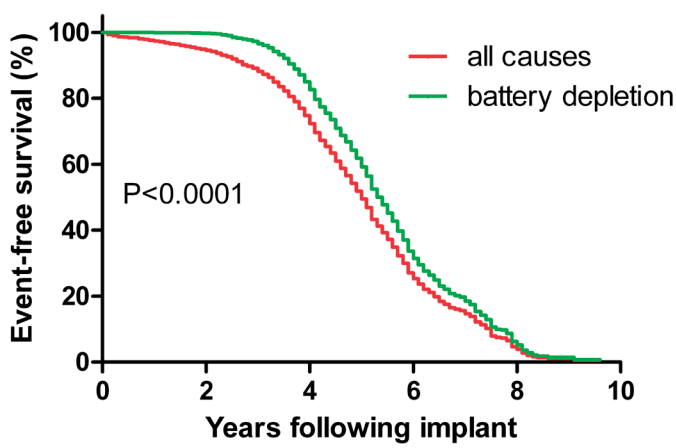
Considering all replacement indications, mean device longevity of ICDs (n=4,673) was 5.0 ± 0.1 years. Event-free rates for a replacement were 94.4% (95% CI 93.6%-95.2%) after 2 years, 73.2% (95% CI 71.4%-75.0%) after 4 years and 25.7 % (95% CI 23.3%-28.1%) after 6 years (Figure 2). Exclusion of the 407 non-battery related replacements, results in a mean battery longevity of 5.5 ± 0.1 years. Event-free rates for replacement because of battery depletion were 99.6 % (95% CI 99.4%-99.8%) after 2 years, 83.7 % (95% CI 81.9%-85.5%) after 4 years and 31.9 % (95% CI 29.2%-34.6%) after 6 years (Figure 2).

Battery longevity per device type and generation

Battery longevity (i.e. only device replacement because of battery depletion) differed significantly between the 3 different types of ICDs and was the longest in dual-chamber ICDs, followed by single chamber ICDs and thereafter by the CRT-D devices (5.8 ± 0.1 years, 5.5 ± 0.2 years and 4.7 ± 0.1 years, respectively, p<0.001; Figure 3).

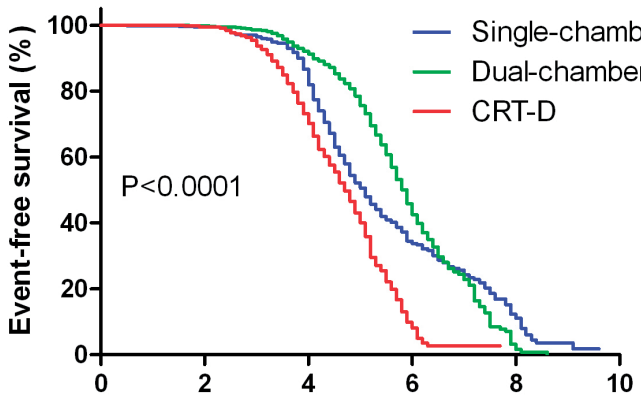
Five hundred and eighty devices (12%) were implanted before 2002 and 4,093 (88%) after 2002.

When analyzed per type of ICD, mean battery longevity (i.e. only device replacement because of battery depletion) was significantly longer in single-chamber ICDs implanted since 2002 as compared with single-chamber ICDs implanted before 2002 (6.7 ± 0.3 vs. 5.0 ± 0.2 years, p<0.001). Similarly, a significantly improved longevity in dual-chamber ICDs (6.0 ± 0.1 vs. 5.0 ± 0.2 years, p<0.001) as well as in CRT-D devices (4.7 ± 0.1 vs. 3.7 ± 0.4 years, p<0.001) was found if devices implanted since 2002 were compared with devices implanted before 2002.



ICDs at risk						
All causes	4673	2925	1371	283	24	0
Battery depletion	4673	2925	1371	283	24	0

Figure 2. Kaplan-Meier curve for event-free rate for a replacement because of all causes (red line) or because of battery depletion alone (green line). Regarding the curve for battery depletion, ICDs were censored in case of ICD explantation for reasons other than battery depletion.



ICDs at risk						
Single-chamber	730	536	333	86	20	0
Dual-chamber	2090	1353	693	180	4	0
CRT-D	1853	1036	345	17	0	0

Figure 3. Kaplan-Meier curve for event-free survival of ICDs, replaced because of battery depletion in single-chamber (blue line), dual-chamber (green line) and CRT-D devices (red line).

Battery longevity per device manufacturer

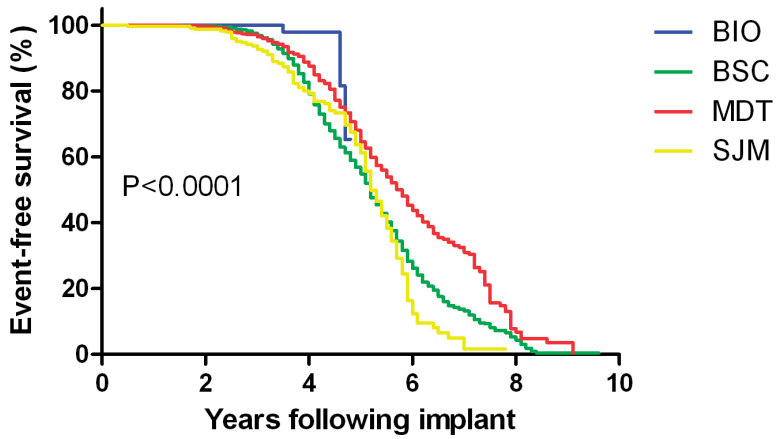
The 4,673 implanted devices in this analysis were produced by four different manufacturers (Table 2). Kaplan-Meier curves for device survival, specifically because of an ERI, demonstrate considerable differences in battery longevity (overall log rank test $p<0.001$; Figure 4). Mean battery longevity was 4.7 ± 0.1 years for Biotronik, 5.3 ± 0.1 years for Boston Scientific, 5.8 ± 0.2 years for Medtronic and 5.0 ± 0.2 years for St Jude Medical devices. All manufacturers demonstrated an improvement in battery longevity since 2002 ($p < 0.05$).

Predictors of battery longevity

Multivariate Cox regression analysis demonstrated that device type, device manufacturer, device generation (i.e. implanted before or since 2002), the percentage of pacing and the pacing output were all highly significant independent predictors of battery longevity (Table 4). Noteworthy, the number of shocks (i.e. appropriate and inappropriate) did not influence the battery longevity.

DISCUSSION

In the present study on the longevity of ICD devices, findings can be summarized as follows: (i) although the majority of devices is replaced because of battery depletion, approximately 30% of devices is explanted because of a non-battery related indication; (ii) CRT-D devices had a significantly shorter battery longevity when compared with single-chamber and dual-chamber devices; (iii) modern ICD generations of all three types of ICDs demonstrated significantly improved mean battery longevity when compared with early generations; (iv) large differences



ICDs at risk						
BIO	540	212	17	0	0	0
BSC	2290	1520	719	131	16	0
MDT	1551	962	507	140	8	0
SJM	292	231	128	12	0	0

Figure 4. Kaplan-Meier curve for event-free survival of ICDs replaced because of battery depletion for the manufacturers (Biotronik (=BIO, blue line), Boston Scientific/Guidant (=BSC, green line), Medtronic (=MDT, red line), St. Jude Medical/Ventritex (=SJM, yellow line).

exist between manufacturers; (v) variables such as device type, device manufacturer, device generation (i.e. implanted before or since 2002), the percentage of pacing and the pacing output were all highly significant independent predictors of battery longevity.

Non-battery related indications for replacement

Approximately 30% of all implanted devices in the current analysis were replaced prior to battery depletion. Due to this considerable part of early replacements, mean device longevity is heavily reduced and many patients are confronted with a premature replacement procedure. Important is that 61% of reasons other than battery depletion consist out of preventable technical issues or device infection resulting in such an early replacement. In addition, other studies demonstrate similar results. For example in a study of Knops et al., 24% of implanted devices had a non-battery related replacement indication. 17 Although there are some remarkable differences between both studies, they clearly demonstrate the necessity of reducing non-battery related indications for replacement in order to improve device longevity. Even if it is not realistic to completely eliminate these causes, major efforts should be made to minimize these occurrences.

Battery related ICD longevity

Another notable outcome from the current analysis is that dual-chamber ICDs have a significantly longer mean battery longevity (i.e. 5.8 ± 0.1 years) as compared to single-

Table 4. Cox proportional hazard ratio model to predict ICD battery depletion

	Univariate			Multivariate		
	HR	95%CI	p-value	HR	95%CI	p-value
Device type						
Single-chamber	Reference		<0.001†	Reference		<0.001
Dual-chamber	0.80	0.69-0.94	0.005†	1.29	1.08-1.54	0.01
CRT-D	2.25	1.91-2.66	<0.001†	2.51	1.94-3.26	<0.001
Manufacturer*						
Medtronic	Reference		<0.001†	Reference		<0.001
Boston Scientific/Guidant	1.52	1.33-1.73	<0.001†	1.35	1.18-1.55	<0.001
St. Jude Medical/Ventritex	1.75	1.42-2.16	<0.001†	3.00	2.41-3.74	<0.001
Device generation <2002 vs. ≥2002	0.59	0.52-0.67	<0.001†	0.34	0.29-0.40	<0.001
Pacing percentage (per 10% increase)	1.16	1.14-1.18	<0.001†	1.14	1.10-1.17	<0.001
Pacing output (per V increase)	1.17	1.09-1.25	<0.001†	1.23	1.14-1.32	<0.001
Number of shocks	1.00	0.98-1.02	0.89			

*CI = confidence interval; HR = hazard ratio. *Biotronik was not included in the analyses since limited data (i.e. 3 battery depletions) made outcomes unreliable, †variable was included in multivariate analysis.*

chamber ICDs (5.5 ± 0.2 years). This is in contrast with previous reports of Hauser et al., in which the service life of pulse generators was 4.7 year for single-chamber devices and 4.0 year for dual-chamber devices.[10, 18]

However, this difference can be explained by the fact that the distribution of device types (i.e. single-chamber, dual-chamber and CRT-D) implanted in our center was unequally distributed over time (Figure 1). As a result, a relatively older compilation of single-chamber devices with a less advanced battery technology was compared with a relatively newer compilation of dual-chamber devices. This 'bias' is resolved when longevity of dual-chamber devices is corrected, among others, for device generation: in univariate analysis having a dual-chamber decreases the risk for battery depletion as compared with single-chamber devices while in multivariate analysis this effect is reversed (HR 1.29 (95% CI 1.08-1.54, p<0.001).

Moreover, in CRT-D devices, battery longevity was remarkably shortened as compared with single-chamber and dual-chamber devices. This is most likely due to their inherent higher percentage of pacing, which diminishes battery longevity significantly.[19, 20]

Given the battery longevity among different manufacturers, devices manufactured by Medtronic provided the longest service time. Since devices were implanted in a prespecified sequence per device type and independently of their manufacturer over the cohort of patients, it can be assumed that no specific bias favoring one certain manufacturer exists. Furthermore, these results were similar to other studies, in which it was considered to be the effect of a more stable and better battery performance and minimization of intracardiac electrogram collection in Medtronic devices.[17, 19, 21]

Implications of ICD longevity on health care

Similar to results of the study of Schaer et al., the latest ICD generations (i.e. implanted since 2002) in the current analysis demonstrated improved battery longevity when compared to older generations (i.e. implanted before 2002).[20] However, despite these advances in battery longevity, a substantial part of ICD recipients will still outlive their first device.[10] Hauser et al. already estimated that mean battery longevity of devices should at least exceed 10 years of service, in order to prevent replacement procedures to occur in the majority of ICD recipients. Although technically feasible because of improved battery platforms and advanced battery saving device algorithms, such longevity reports in clinical practice are, to the best of our knowledge, not published so far. Consequently, an enormous number of ICD recipients will be exposed to the additional risk for complications when undergoing a device replacement procedure because of battery depletion.[13, 22, 23] In addition to impending adverse effects for ICD patients, increased device longevity will also result in improved cost-effectiveness of ICDs and reduction in the burden of growing health care cost worldwide.[15] Therefore, all efforts should be made to increase battery longevity of ICDs in the near-term. Since upcoming improvements in battery technology remain to be proven in real life, the most feasible near-term solution appears to be the provision of devices with larger, longer-life batteries. In a study by Wild et al., 90% of the patients preferred a larger device that could reduce the number of potential replacement procedures instead of a smaller device with the same or reduced longevity.[24] However, ICD manufacturers and physicians (i.e. depending on the organization of the national health care system) have little incentive to provide long-lived pulse generators since frequent replacements increase sales and profits.[10] In order to encourage manufacturers to produce longer-life devices, manufacturers should be rewarded on the basis of the amount of functional service years per ICD implanted. This could result in a substantial reduction of replacement surgery, adverse effects for the patient, increased cost-effectiveness and appropriate compensation for ICD manufacturers.

Limitations

There are several limitations to this study. First of all, battery longevity was only studied in four different manufacturers. Furthermore, although the sequence per device type was prespecified (i.e. at random) for the different manufacturers, annual price-volume agreements resulted in an unequal number of ICDs implanted per different manufacturer. In addition, it is important to be aware of the fact that replaced devices in every longevity analysis are outdated and therefore ICD longevity results may not apply to current or future devices.

CONCLUSION

Although the majority of devices are replaced because of battery depletion, approximately 30% of the devices are replaced for other reasons. Furthermore, device type, device manufacturer, device generation (i.e. implanted before or since 2002), the percentage of pacing and the pacing output had significant influence on battery longevity. Multivariate analysis demonstrated improved battery longevity in modern ICD generations and large.

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