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Characterization and financial impact of implantable cardioverter-defibrillator patients without interventions 5 years after implantation

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Summary

Background: Implantable cardioverter defibrillators (ICD's) are increasingly used for primary and secondary prevention of sudden cardiac death. However, data on how many ICD patients indeed receive appropriate ICD therapy during long-term follow-up is scarce.
Aim: The aim of our study was to determine the number of patients without appropriate ICD therapy 5 years after ICD implantation, to identify predicting factors, to assess the occurrence of late first ICD therapy and to quantify the financial impact of ICD therapy in a real-world setting.
Design: Prospective observational study.
Methods: We prospectively enrolled 322 consecutive ICD patients. Baseline data were collected at implantation and patients were followed for a median of 7.3 years (IQR 5.8–9.2 years). Time to first appropriate ICD therapy (either antitachycardia pacing or cardioversion) was documented.
Results: Five years after implantation, 139 patients (43%) had not received appropriate ICD therapy. In multivariable analysis, a primary prevention indication and negative electrophysiological studies prior to ICD implantation were independent predictors of freedom from ICD therapy. Of the patients without ICD therapy, 5 years after implantation, 25% had experienced inappropriate ICD shocks. Two hundred and seven devices (1.5 devices per patient) were needed for the 139 patients without ICD intervention within 5 years, accounting for €31 784 per patient. During an additional follow-up of 3 years, 12% of the patients with unused ICD received a late first appropriate ICD therapy.
Conclusions: About half of the ICD patients receive appropriate ICD therapy within 5 years after implantation. Furthermore, there is a significant proportion of patients receiving late first shocks after five initially uneventful years.

Introduction

The benefits of implantable cardioverter defibrillators (ICD's) in the primary and secondary prevention of sudden cardiac death (SCD) have been established in several studies.[1–4] Based on these studies, clinical indications for implantation of an ICD have been expanded.[5] In parallel, utilization of ICD has steadily increased and is expected to do so over the next years.[6,7]

Given the substantial costs of ICD therapy, serious concerns have been raised regarding the effectiveness and financial implications of this strategy.[7,8] Of note, a substantial proportion of ICD patients will never receive appropriate ICD therapy, reaching 70–80% after 2 years in randomized controlled trials.[9] These patients nevertheless are at risk for ICD complications such as inappropriate shocks, infections and lead malfunction.[10,11] Furthermore,

device replacement is needed periodically due to battery depletion roughly every 5 years.[12–14] There is a feeling 'once ICD, always ICD', indicating that usually the device is replaced without repeated risk assessment at the time of battery depletion.

Patients enrolled in randomized controlled trials often differ significantly from real-world patients and previous studies are limited because of their short follow-up.[15–17] The aim of our study was to determine the number of patients without appropriate ICD therapy at the time point of 5 years after implantation, to identify predicting factors of an unused ICD, to assess the occurrence of late first ICD therapy and to quantify the financial impact of ICD therapy in a real-world setting of consecutive ICD patients.

Methods

Study population

From March 1994 to October 2004, a total of 359 consecutive patients undergoing ICD implantation for primary or secondary prevention were prospectively enrolled to the ICD registry of the Department of Cardiology, University Hospital Basel, Switzerland. Time of last follow-up data acquisition was end of November 2009. Thirty-seven patients were excluded from current analysis because of censored data earlier than 5 years of follow-up without appropriate ICD therapy before. The reasons for premature data censoring in these patients were death [$n=31$; specific causes of death were heart failure ($n=11$), SCD ($n=1$), other cardiovascular death ($n=6$), noncardiac death ($n=9$) and unknown cause of death ($n=4$)], heart transplantation ($n=2$), device explantation ($n=2$) or refusal to replace the device despite reaching end of life replacement indication criteria ($n=2$). This left 322 patients with complete follow-up information of a minimum of 5 years (empirical time point of first-generator replacement[13,14]) for analysis with a median follow-up duration of 7.3 years [interquartile range (IQR) 5.8–9.2 years].

Indications for ICD implantation were based on current guidelines.[18–20] The secondary prevention group consisted of patients with aborted SCD, sustained or clinically critical ventricular tachycardia (VT) or syncope with inducible VT. The implantation policy of ICD primary prevention evolved over time, similar to that for the patient populations enrolled in recent trials.[1–4] All devices used were endocardial, transvenous ICDs implanted according to standard practice.

Baseline examinations were carried out at the time of ICD implantation and consisted of patient demographics, comorbidities, New York Heart Association (NYHA) classification, medication use, type of underlying heart disease, index arrhythmia or clinical event leading to device implantation and results of electrophysiological studies (EPS). Left ventricular ejection fraction (LVEF) was determined by echocardiography (biplane, Simpson's method).[21]

Follow-up assessment and event ascertainment

Follow-up visits were performed 1 and 3 months after ICD implantation and every 6 months thereafter. At each patient visit, a standard device interrogation was performed by a cardiologist assisted by a trained nurse.

A trained electrophysiologist (B.S.) classified all stored intracardiac electrograms of ventricular tachyarrhythmias responsible for ICD therapy, together with the event date, and distinguished appropriate from inappropriate ICD shocks. Ambiguous cases were adjudicated in conjunction with at least one further electrophysiologist (M.K., C.S. and S.O.). ICD shocks were considered inappropriate when triggered by supraventricular arrhythmias, sinus tachycardia, noise or T-wave sensing. All visits were registered prospectively and checked regularly for data consistency. Appropriate ICD therapies were classified as follows: VT was terminated by antitachycardia pacing or cardioversion with a detection rate determined at the discretion of the managing cardiologist. In primary prevention, detection rate was usually set to 180 bpm. In secondary prevention, it was programmed 20 beats slower than the documented VT rate. Fast VT (FVT) was defined as a VT with a heart rate >210 bpm and terminated by shocks. Ventricular fibrillation (VF) was characterized by fibrillatory R waves and terminated by defibrillation. Of note, this definition of appropriate ICD therapy involved an electrophysiologist's judgment of every event and hence does not correspond to the clinical device setting, for which the 'VF zone' is usually programmed at detection rates >200–220/min. This modified definition was used in order to be able to take 'VF' as a surrogate marker for SCD.

We recorded date and reason for device exchange if applicable. Patients with device replacements were not removed from the analysis.

Cost calculations

Assumptions for cost calculations were derived from Belgian 2006 Health Care data as a model of a typical Western European country[22,23]. Initial implantation was assumed to cause costs of €23 000, generator replacement of €18 000, lead failure of €6500 and lead infection of €28 000.

Statistical methods

Continuous variables are presented as means (SD) or medians (IQR) and categorical variables as numbers and percentages. Continuous variables were compared with the use of the Mann–Whitney U-test and categorical variables with the use of the Pearson's chi-square test. We used univariate and multivariate binary logistic regression models to compute hazard ratios (HRs) and 95% confidence intervals (95% CIs) of predictors of no ICD therapy after 5 years. All hypothesis testing was two-tailed and $P<0.05$ were considered to indicate statistical significance. All statistical analyses were performed with the use of SPSS for Windows 15.0 (SPSS Inc, Chicago, IL, USA).

Results

Characteristics of the patients

Baseline characteristics of the 322 patients are shown in Table 1. At ICD implantation, patients were 60 (IQR 51–68) years old and predominantly male (90%). The underlying heart disease was coronary artery disease in 66% of patients, dilated cardiomyopathy in 17% and other forms of cardiomyopathy such as hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy or valvular heart disease in the remaining patients (17%). Indication for ICD therapy was secondary prevention in 73% of patients.

Time course of first appropriate ICD therapy within the first 5 years

Five year follow-up information was by study definition available in 100% of patients. Overall, 183 patients (57%) had received appropriate ICD therapy at least once within 5 years whereas 139 patients (43%) were free of appropriate ICD therapy 5 years after implantation (Figure 1). This resulted in a number needed to treat of 1.8 patients to achieve an appropriate ICD therapy within 5 years. The observed rates of appropriate ICD therapy varied in important patient subgroups: there were more appropriate ICD therapies within 5 years in patients with a secondary prevention indication than in those with a primary prevention indication (61 vs. 45%, $p=0.01$), and more in patients with ischemic cardiomyopathy compared to those with nonischemic cardiomyopathy (61 vs. 49%, $P=0.03$). No significant differences in appropriate ICD therapies were observed between different ICD types (single chamber 55%, dual chamber 61%, CRT 62%, $P=0.57$).

Regarding the time course of events, the cumulative percentage of patients with at least one appropriate ICD therapy increased from 26% of patients after 6 months to 44% after 2 years and to 57% after 5 years (Figure 2). The rate of patients receiving first appropriate ICD therapy in a given time period dropped from 26% within the first 6 months down to 2% between months 55 and 60.

Events in patients receiving appropriate ICD therapy within 5 years

Patients receiving appropriate ICD therapy at least once experienced a median of 10 episodes (IQR 2–30 episodes) of appropriate ICD therapy within the first 5 years after implantation. Forty-eight patients (15% of all patients) were treated for VF, 57 (18% of all patients) for FVT (but never for VF) and 78 (24% of all patients) for VT (and thus never for VF or FVT). In addition to receiving appropriate ICD therapy, 31% of patients furthermore had experienced inappropriate shocks as well. Five years after implantation, 35 patients (19%) had died having received appropriate ICD therapy before at least once.

Predictors for no ICD therapy after 5 years

Patients without ICD therapy were younger, more often had a primary prevention indication, had higher baseline LVEF, were more often in NYHA classes I and II, more often had negative EPS prior to implantation and were less often on antiarrhythmic drug therapy (Table 1). There were no differences for other medical therapies including β-blockers, angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs).

In multivariate binary logistic regression analysis, primary prevention indication, NYHA class I/II and freedom from antiarrhythmic drug use were independent predictors of an unused ICD (Table 2, Model 1). If results from EPS prior to implantation, which were available in 228 patients were added, only primary prevention indication (HR 1.98, 95% CI 1.06–3.73, $P=0.03$) and negative EPS (HR 2.78, 95% CI 1.37–5.65, $P=0.005$) remained independent predictors of an unused ICD 5 years after implantation (Table 2, Model 2).

Table 1 Baseline characteristics of the patients

	All patients	Appropriate ICD therapy 5 years after Implantation		*P*-value
	(*n* = 322)	No (*n* = 139)	Yes (*n* = 183)	
Age, median (quartiles) (years)	60 (51–68)	57 (45–64)	63 (56–70)	<0.001
Gender: male, *n* (%)	289 (90)	120 (86)	169 (92)	0.08
Cardiomyopathy, *n* (%)				0.06
Coronary artery disease	213 (66)	83 (60)	130 (71)	
Dilated cardiomyopathy	56 (17)	26 (19)	30 (16)	
Other cardiomyopathy	53 (17)	30 (22)	23 (13)	
Indication, *n* (%)				0.01
Primary prevention	86 (27)	47 (34)	39 (21)	
Secondary prevention	236 (73)	92 (66)	144 (79)	
LVEF, median (quartiles) (%)	35 (25–45)	35 (25–53)	32 (25–40)	0.006
NYHA Classification				0.01
NYHA Class I/II	250 (78)	117 (84)	133 (73)	
NYHA Class III/IV	72 (22)	22 (16)	50 (27)	
EPS (available in 228 points)				0.004
Positive	184/228 (81)	74/103 (72)	110/125 (88)	
Negative	44/228 (19)	29/103 (28)	15/125 (12)	
ICD type, *n* (%)				0.57
Single chamber (VVI)	224 (70)	101 (73)	123 (67)	
Dual chamber (DDD or VDD)	69 (21)	27 (19)	42 (23)	
Cardiac resynchronization therapy (CRT)	29 (9)	11 (8)	18 (10)	
History, *n* (%)				
Arterial hypertension	177 (55)	73 (53)	104 (57)	0.44
Diabetes mellitus	50 (16)	19 (14)	31 (17)	0.42
Previous myocardial infarction	211 (66)	83 (60)	128 (70)	0.06
Previous coronary artery bypass surgery	103 (32)	37 (27)	66 (36)	0.07
Previous percutaneous coronary intervention	114 (35)	51 (37)	63 (34)	0.07
Chronic renal failure	44 (14)	14 (10)	30 (16)	0.10
Medical therapy at implantation, *n* (%)				
β-blocker	267 (83)	121 (87)	146 (80)	0.09
ACE inhibitor or ARB	267 (83)	111 (80)	156 (85)	0.20
Diuretic treatment	168 (53)	65 (57)	103 (56)	0.09
Amiodarone	90 (28)	27 (19)	63 (34)	0.003
Digoxin	33 (10)	10 (7)	23 (13)	0.11
Statins	174 (54)	121 (87)	146 (80)	0.09

Inappropriate shocks in patients without appropriate ICD-therapy

Of the patients without appropriate ICD therapy after 5 years, 35 (25%) experienced at least one episode of inappropriate ICD shocks. Among these episodes, 14 (40%) were triggered by sinus tachycardia, 10 (29%) by supraventricular arrhythmias, 6 (17%) by noise and 5 (14%) by T-wave sensing. No significant differences were observed between different ICD types in terms of inappropriate ICD shocks (single-chamber devices 25%, dual-chamber devices 26%, CRT devices 27%, $P = 0.98$).

Device replacements and costs within the first 5 years

Within 5 years after implantation, a total of 478 devices were needed for the 322 patients (1.5 devices per patient) with equal distribution between patients receiving and not receiving appropriate ICD therapy. Of the 156 device replacements, the reason for change was end of life replacement indications in 125 cases (80%), device recall in 15 cases (10%), device upgrade in 5 cases (3%), lead dysfunction in 6 cases (4%) and infections in 5 cases (3%). Using cost calculations based on Belgian Health Care data,[22,23] this resulted in ICD-related total costs of

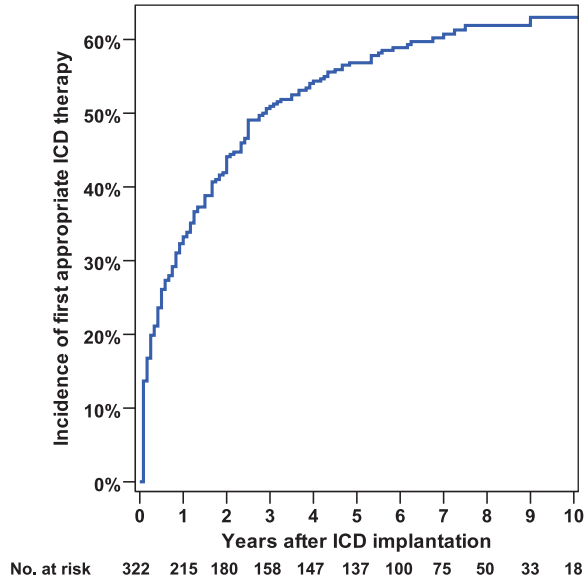

Figure 1. Timing of first appropriate ICD therapies. Kaplan–Meier curve showing the timing of first appropriate ICD therapies in all 322 patients.

€10 195 000 for the 322 patients, corresponding to €31 568 per patient with appropriate ICD therapy within 5 years and to €31 784 per patient without ICD intervention.

Time course and type of late first appropriate ICD therapy beyond the first 5 years

To analyze the likelihood of late first arrhythmia occurrence, the 139 patients free of appropriate ICD therapy after 5 years were followed for an additional median of 1.3 years (IQR 1.0–4.0 years) beyond the 5-year time point. The probability of appropriate ICD therapy was 5% after 1, 9% after 2 and 12% after 3 additional years in these patients (Figure 3). The additional 14 appropriate ICD therapies were delivered for VF in 3, FVT in 4 and VT in 7 patients.

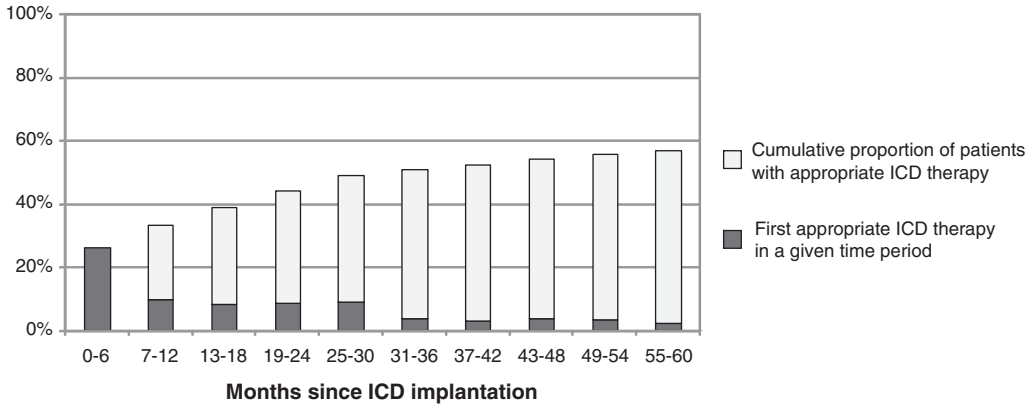

Figure 2. Time course of first appropriate ICD therapy over time. Proportion of patients free of ICD therapy so far with first appropriate ICD therapy in a given time period since ICD Implantation (black). Cumulative proportion of patients in whom at least one appropriate episode of ICD therapy has occurred since ICD implantation (white).

Table 2 Predictors for no ICD therapy 5 years after ICD implantation: binary logistic regression analysis

Variable	Univariate Model		Multivariate Model 1[a]		Multivariate Model 2[b]	
	HR (95% CI)	*P*-value	HR (95% CI)	*P*-value	HR (95% CI)	*P*-value
Age <60 years	2.10 (1.34–3.30)	0.001		n.s.		n.s.
Cardiomyopathy other than CAD	1.66 (1.04–2.64)	0.03		n.s.		n.s.
Primary prevention	1.89 (1.15–3.11)	0.01	1.79 (1.04–3.09)	0.04	1.98 (1.06–3.73)	0.03
LVEF >35%	1.57 (1.00–2.45)	0.05		n.s.		n.s.
NYHA Class I/II	2.00 (1.14–3.50)	0.01	2.02 (1.11–3.70)	0.02		n.s.
Freedom of amiodarone therapy	2.18 (1.30–3.66)	0.003	1.83 (1.06–3.15)	0.03		n.s.
Negative results in EPS	2.87 (1.44–5.73)	0.003			2.78 (1.37–5.65)	0.005

[a]The model was adjusted for age, type of cardiomyopathy, type of prevention, LVEF, NYHA class and amiodarone therapy.
[b]The model was adjusted as for Model 1, with additional adjustment for results of EPS. CAD: coronary artery disease. n.s.: not significant.

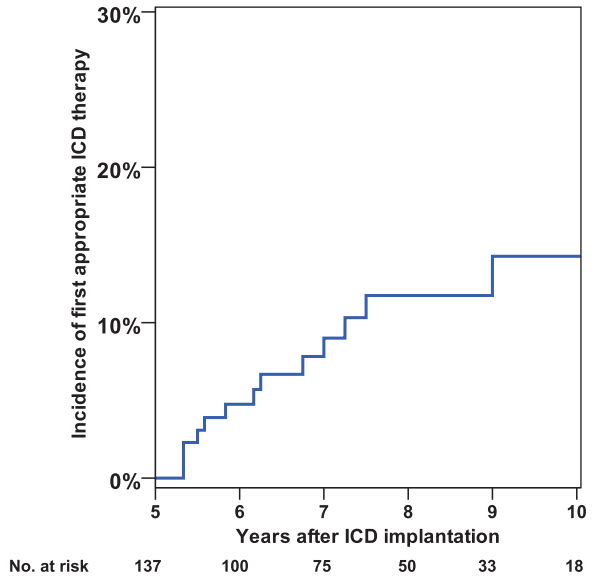

Figure 3. Late first appropriate ICD therapies in patients free of appropriate ICD therapy 5 years after implantation. Kaplan–Meier curve showing the incidence of late first appropriate ICD therapies in the 139 patients that had not received appropriate ICD therapy within the first 5 years after implantation.

Discussion

This prospective observational study involving consecutive patients undergoing ICD implantation for primary and secondary prevention with a median follow-up of 7.3 years examined amount, predictors and financial impact of patients without appropriate ICD therapy at the time point of 5 years after implantation. In contrast to other studies published in the past, complete follow-up information is available for at least 5 years in all patients.

We report four major findings: first, 57% of ICD patients seen in daily practice received appropriate ICD therapy within 5 years after implantation, while 43% of patients were free of appropriate ICD therapy. The majority of ICD therapy was delivered for potentially not life-threatening VTs. A primary prevention indication and negative EPS prior to ICD implantation were independent predictors of freedom from appropriate ICD therapy after 5 years. Second, in patients free of appropriate ICD therapy after 5 years, there is still a small, yet quantifiable risk for late first arrhythmia occurrence requiring appropriate ICD therapy reaching 12% after three additional years. Third, 25% of the patients without appropriate ICD therapy had experienced at least one episode of inappropriate ICD shock. Fourth, 1.5 devices per patient were needed in patients without appropriate ICD therapy within 5 years accounting for cost of €31 784 per patient.

These findings derived from a large cohort of consecutive ICD patients with detailed follow-up and ICD therapy information for a minimum of 5 years in all patients are of great clinical importance for three reasons: knowledge of and decisions related to ICDs are based mainly on randomized controlled trials.[1–4] However, patients seen in the community often differ substantially from patients enrolled in randomized trials (Table 3). Second, most studies examining predictors of occurrence of VT and VF in ICD patients so far were limited by a relatively short follow-up duration. And third, since numbers of ICD implantations have steadily increased in past years and are expected to increase even more, medical and especially economic issues associated with ICDs will become critical in the future. A recent study by Cowie *et al.*[23] using a detailed meta-analysis of recent randomized controlled ICD primary prevention trials demonstrated that prophylactic ICD implantation in patients with reduced LVEF is cost-effective in a European health-care setting. Cost data on ICD therapy from a European real-world setting, however, is rare.

The rate of 57% of patients receiving appropriate ICD therapy equates to a number needed to treat of 1.8 patients to achieve an appropriate ICD therapy within 5 years and reflects careful patient selection. Furthermore, our study confirmed that there is still a quantifiable, although small, risk for late appropriate first ICD therapy even in patients without arrhythmic events within the first 5 years after implantation. However, it needs to be emphasized that 43% of the appropriate ICD therapies that occurred in our study were only for VT but never for VF or FVT. It might be speculated that many of these VT episodes would have terminated spontaneously or might have been hemodynamically stable.[24] If so, ICD therapy cannot be considered life saving in these patients,[25] reducing the overall mortality benefit provided by ICD therapy. Furthermore, the proportion of ICD's implanted for primary prevention indications is rising continually with a lower survival benefit demonstrated in these patients.[2,4]

Effective segregation of patients at high risk for SCD from low risk patients is an unmet clinical need. Earlier observational studies examining mixed ICD populations have reported on unused ICD rates of 82% after a mean follow-up of 13 months,[17] 82% after 18 months[15] and 51% after 30 months.[16] In the only other large cohort with a longer follow-up reported so far, Tandri *et al.*[26] found a proportion of 47% of patients with unused ICD at a mean of 5.8 years after ICD implantation. Selection of ICD patients as recommended by current guidelines in primary prevention is based almost exclusively on a

Table 3 Comparison of the study population to the populations in the primary and secondary prevention randomized controlled ICD trials

	BASEL	2° Prevention trials		1° Prevention trials	
		MADIT I[a]	AVID[b,c]	MADIT II[d,e]	SCD-HeFT[f]
Patients in ICD group (*n*)	322	95	449	720	829
Age (years)	60	62	65	64	60
Gender: male (%)	90	92	79	84	77
Coronary artery disease (%)	66	100	81	100	52
Ejection fraction (%)	35	27	32	23	24
1° Prevention indication (%)	27	–	–	100	100
2° Prevention indication (%)	73	100	100	–	–
Appropriate ICD therapy in 1° prevention patients	45% in 5 years	–	–	35% in 3 years	21% in 5 years
Appropriate ICD therapy in 2° prevention patients	61% in 5 years	90% in 5 years	69% in 3 years	–	–
Appropriate ICD therapy overall	57% in 5 years	–	–	–	–

[a]Moss AJ. *N Engl J Med* 1996; **335**:1933.
[b]The AVID Investigators. *N Engl J Med* 1997; **337**:1576.
[c]Raitt MH. *Am J Cardiol* 2003; **91**:812.
[d]Moss AJ. *N Engl J Med* 2002; **346**:877.
[e]Moss AJ. *Circulation* 2004; **110**:3760.
[f]Bardy GH. *N Engl J Med* 2005; **352**:225.

low EF.[5] As shown by our study, other variables such as a primary prevention indication and negative EPS testing prior to implantation significantly and independently predicted use or nonuse of the device, but the clinical value of these factors for patient selection is limited due to rather small HRs. Promising strategies to further improve the selection of ICD patients include dynamic risk profiling using repeated measures before implantation and risk reassessment before device replacement on one hand side as well as the use of additional risk markers on the other hand side. The occurrence of nonsustained VT, T-wave alternans, magnetic resonance imaging, heart rate turbulence, QT variability or genetic risk profiling are promising novel risk markers currently under investigation.[27–32] None of these testing modalities has proven its value for patient selection in prospective clinical trials yet, but some may complement the ejection fraction for the selection of ICD patients in the future.

Among the patients not receiving appropriate ICD therapy within the first 5 years, 25% received inappropriate shocks in our study. Inappropriate shocks are known to result in multiple adverse effects including psychiatric disturbances,[33] impaired quality of life[34] and provocation of subsequent ventricular arrhythmias.[35] The use of longer detection intervals has recently been shown to lower the number of inappropriate ICD shocks and should be helpful here.[24]

Potential limitations of the current study merit consideration. First, even though this is a single-center study, patient demographics are comparable to several other studies including consecutive ICD patients.[16,26,36] Second, our population received ICD implantation per definition from 1994 to 2004. ICD indications have expanded meanwhile[5] and the majority of ICDs nowadays are implanted for primary prevention indications. We therefore assume that the proportion of patients with unused ICDs will be higher in patients currently undergoing ICD implantation. Third, we did not reassess the patients at time of device replacement. Hence, it is possible that the patients who received late first appropriate ICD therapy >5 years after ICD implantation developed new risk factors. Careful reassessment of the arrhythmic risk profile should be carried out at the time of replacement. And fourth, different types of devices from different manufacturers were used throughout the study period. Although unlikely, we cannot exclude that this has to some minor extent influenced our data.

Conclusion

About half of ICD patients seen in daily practice receive appropriate ICD therapy within 5 years after implantation, and there is a small, yet significant proportion of patients receiving late first shocks

after five uneventful years. Knowledge of these numbers from a real-world cohort are important both for careful patient selection before ICD implantation and for reassessment of patients before generator replacement.

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Conflict of interest: Dr Kühne has received research grants from Sanofi Aventis, Bayer and Boehringer Ingelheim, has served as a consultant to MSD and has served on the speakers' bureau for Boston Scientific and St Jude Medcial. Dr Sticherling has received research grants from Boston Scientific and Biotronik and has served on the speakers' bureau for Medtronic, Biotronik, Boston Scientific, Sorin and Sanofi Aventis. Dr Osswald has received research grants from Medtronic, Boston Scientific, Biotronik, St Jude Medical, Sanofi Aventis and Astra Zeneca and has served on the speakers' bureau for Medtronic, Biotronik, Boston Scientific, St Jude Medical, Sanofi Aventis and Astra Zeneca. Dr Schaer has received research grants from Medtronic, Boston Scientific, Biotronik, St Jude Medical and Sorin and has served on the speakers' bureau for Medtronic and Boston Scientific. Dr Reichlin reports no conflicts.

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