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Implantable Defibrillator Event Rates in Patients With Idiopathic Dilated Cardiomyopathy, Nonsustained Ventricular Tachycardia on Holter and a Left Ventricular Ejection Fraction Below 30%

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OBJECTIVES This study investigated the incidence of appropriate implantable cardioverter defibrillator (ICD) interventions for ventricular tachycardia (VT) or ventricular fibrillation (VF) in patients with idiopathic dilated cardiomyopathy (IDC) and nonsustained VT in the presence of a left ventricular ejection fraction below 30%, versus in patients with syncope and patients with a history of VT or VF.

BACKGROUND To date, only limited information is available about the prophylactic use of ICDs in patients with IDC.

METHODS From January 1993 to July 2000, 101 patients with IDC underwent implantation of ICDs with electrogram storage capability at our institution. Patients were placed into one of three groups according to their clinical presentation: asymptomatic or mildly symptomatic nonsustained VT in the presence of a left ventricular ejection fraction ≤30% (49 patients, prophylactic group), unexplained syncope or near syncope (26 patients, syncope group) and a history of sustained VT or VF (26 patients, VT/VF group).

RESULTS During 36 ± 22 months follow-up, 18 of 49 patients (37%) in the prophylactic group received appropriate shocks for VT or VF, compared with 8 of 26 patients (31%) in the syncope group and with 9 of 26 patients (35%) of the VT/VF group. Multivariate Cox analysis of baseline clinical variables identified left ventricular ejection fraction, atrial fibrillation and a history of sustained VT or VF as predictors for appropriate ICD interventions during follow-up.

CONCLUSION Patients with IDC and prophylactic ICD implantation for nonsustained VT in the presence of a left ventricular ejection fraction ≤30% had an incidence of appropriate ICD interventions similar to that of patients with a history of syncope or sustained VT or VF. These findings indicate that ICDs may have a role in not only secondary but also primary prevention of sudden death in IDC. (J Am Coll Cardiol 2002;39:780–7) © 2002 by the American College of Cardiology Foundation

The implantable cardioverter defibrillator (ICD) has become the therapy of first choice to prevent sudden cardiac death in high-risk patients who have survived an episode of a hemodynamically poorly tolerated sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) in the absence of a reversible cause (1,2). In addition, prophylactic ICD therapy has been demonstrated to improve survival in selected postinfarct patients (3). Unlike in ischemic cardiomyopathy, arrhythmia risk stratification with regard to

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prophylactic ICD therapy is a completely unsolved issue in idiopathic dilated cardiomyopathy (IDC) (2,4). Although electrophysiologic studies currently have a central role in identifying high-risk patients with coronary disease in whom prophylactic ICD therapy is indicated (3), the result of programmed ventricular stimulation has not been found to be helpful for arrhythmia risk prediction in IDC (5,6). Two previous studies with small numbers of patients suggest that patients with IDC and unexplained syncope may benefit from ICD implantation (7,8). Several observational studies found an increased risk for sudden death in patients with IDC and nonsustained VT on Holter (9–11). To date, however, the usefulness of ICD therapy in these patients remains unknown (12,13). Accordingly, the present study investigated the incidence of appropriate ICD shocks as assessed from stored electrograms in patients with IDC, nonsustained VT on Holter and a left ventricular ejection fraction ≤30%, compared with the incidence in ICD patients with unexplained syncope and to patients with a history of sustained VT or VF.

METHODS

Patients. The study population consisted of 101 patients with IDC who underwent implantation of ICDs with electrogram storage capability and nonthoracotomy lead systems at our institution between January 1993 and July 2000. Patients were placed in one of three groups according to their clinical presentations: asymptomatic or mildly symptomatic nonsustained VT in the presence of a left

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Abbreviations and Acronyms

ACE = angiotensin converting enzyme
ICD = implantable cardioverter defibrillator
IDC = idiopathic dilated cardiomyopathy
LV = left ventricle
VF = ventricular fibrillation
VT = ventricular tachycardia

ventricular ejection fraction ≤30% (49 patients, prophylactic group), unexplained syncope or near syncope (26 patients, syncope group) and a history of sustained VT or VF (26 patients, VT/VF group). All patients in the syncope group were hospitalized after the episode of syncope that preceded defibrillator implantation and were included in this study only if the etiology of syncope remained undetermined after a thorough evaluation (14). Comprehensive echocardiographic examinations were performed by one experienced echocardiographer in all 101 study patients within one week before ICD implantation using a commercially available system (Sonotron VingMed CFM 700, Sonotron, Oslo, Norway). Left ventricular end-diastolic diameter and ejection fraction were measured according to American Society of Echocardiography guidelines (15). Three measurements were averaged for each value. To determine LV ejection fraction, the apical four-chamber view was optimized for maximum LV areas and frames. Then the largest and smallest LV cavity size was measured by tracing the endocardial borders to calculate end-diastolic and end-systolic volume obtained from paired apical views—that is, four-chamber view and orthogonal two-chamber view. The algorithm applied to these measurements was the disk summation method (modified Simpson's rule algorithm) (15). In eight patients, in whom echocardiographic determination of LV ejection fraction was difficult due to the inability to accurately trace the endocardial borders of the largest and smallest LV cavity size, LV ejection fraction was determined by radionuclide ventriculography for the purpose of this study. In addition to noninvasive cardiac evaluation, complete left and right heart cardiac catheterization, including coronary angiography, had been performed within three months before ICD implant in 70 patients (69%) and 24 ± 21 months before ICD implant in the remaining 31 patients (31%). None of the patients had coronary artery disease diagnosed by evidence of any coronary stenosis ≥50% by angiography or a history of myocardial infarction, systemic arterial hypertension, alcohol abuse, drug dependency, thyroid disease, malignancies or systemic diseases known to be associated with dilated cardiomyopathy. In patients in whom coronary angiography had been performed more than 12 months before ICD implant, a symptom-limited exercise stress test was used to screen for newly developed coronary disease. Of note, diagnostic cardiac catheterization included endomyocardial biopsy in 94 of 101 study patients (93%), which did not reveal any evidence for active myocarditis or specific heart muscle disease in any of these patients.

Defibrillator implantation and device programming. All patients gave written informed consent before ICD implantation. Patients received beta-blocking agents and antiarrhythmic drugs at the time of defibrillator implantation on the basis of their physicians' clinical judgement. Exclusively, ICDs with nonthoracotomy lead systems and biphasic shock waveforms with a maximum shock energy of 27 to 34 J were used and successfully implanted with an intraoperative defibrillation threshold of 11 ± 5 J. All ICD systems used in this study provided stored intracardiac electrograms in addition to beat-to-beat intervals of episodes triggering device therapy (Guidant, St. Paul, Minnesota: models Ventak P2, Mini2, Mini4, Prizm, Ventak AV; and Medtronic, Minneapolis, Minnesota: models 7202, 7219, 7220, 7221, 7223, 7227, 7229, 7271, 7272, 7273). In 65 of 101 study patients (64%), the implanted defibrillators were programmed to single-zone devices for VF detection at cycle lengths below 307 ± 12 ms (range 330 ms to 290 ms). In the remaining 36 patients (36%), the implanted defibrillators were programmed to two-zone devices for VT detection at cycle lengths below 319 ± 13 ms (range 350 ms to 300 ms) and for VF detection at cycle lengths below 247 ± 12 ms (range 300 ms to 240 ms).

The time an arrhythmia needed to persist for VF detection ranged from one to three seconds in Guidant devices; the majority of Medtronic devices were programmed to require 18 out of 24 beats below the programmed VF detection cycle length in order to initiate capacitor charging in the VF zone. Based on the preference of the attending physician and on the result of intraoperative defibrillation threshold testing, the first programmed shock energy in the VF zone ranged from 20 to 34 J in the noncommitted mode in order to avoid shocks for nonsustained VT. All subsequent shocks for VF detection were programmed to maximum shock energy. Of note, all ICDs in this study provided either ventricular demand pacing (in 95 patients) or dual chamber demand pacing (in the remaining 6 patients) with a programmed bradycardia escape rate ranging from 34 to 70 beats/min.

Follow-up. All data of baseline clinical characteristics, including the results of noninvasive and invasive cardiac evaluation and implant data, had been collected prospectively in the Marburg Defibrillator Database. Follow-up started at the time of defibrillator implantation and ended in December 2000. Follow-up could be completed for all 101 study patients. Patients were followed up primarily in our defibrillator outpatient clinic in three- to four-month intervals or as soon as possible after spontaneous ICD shocks for device interrogation and retrieval of stored electrograms. All stored electrograms of episodes triggering ICD therapy were classified by two experienced electrophysiologists as appropriate or inappropriate using previously described criteria (16–18). Using these criteria, the interobserver agreement in the present study was 100% for VT or VF with

Table 1. Characteristics of the 101 Study Patients at the Time of Cardioverter-Debrillator Implantation

Characteristic	All Patients (n = 101)	Prophylactic Group (n = 49)	Syncope Group (n = 26)	VT/VF Group (n = 26)
Mean age, years	51 ± 14	49 ± 13	51 ± 15	55 ± 13
Range	17–75	17–72	23–72	24–75
Male gender (%)	82 (81)	41 (84)	21 (81)	20 (77)
New York Heart Association class (%)				
I	4 (4)	1 (2)	1 (4)	2 (8)
II	62 (61)	26 (53)	18 (69)	18 (69)
III	35 (35)	22 (45)	7 (27)	6 (23)
Duration of symptoms, months†	36 ± 45	35 ± 45	33 ± 37	41 ± 51
Symptom duration ≥ 12 months (%)	55 (54)	26 (53)	17 (65)	12 (46)
Echocardiographic study				
LV end-diastolic diameter, mm	70 ± 8	71 ± 7	69 ± 9	68 ± 7
Range	57–97	58–85	57–97	58–88
LV ejection fraction, %	25 ± 8*	22 ± 6	27 ± 9	31 ± 8
Range	10–45	10–30	13–45	10–45
12-lead electrocardiogram (%)				
Atrial fibrillation	21 (21)	9 (18)	4 (15)	8 (31)
Left bundle branch block	32 (32)	14 (29)	7 (27)	11 (42)
Right bundle branch block	1 (1)	1 (2)	0 (0)	0 (0)
Nonsustained VT on Holter or telemetry (%)	82 (81)*	49 (100)	21 (81)	12 (46)
Rate of nonsustained VT, beats/min	173 ± 32	172 ± 35	175 ± 28	170 ± 24
Range	124–295	125–295	124–240	136–230
Length of nonsustained VT, beats/min	8 ± 5	8 ± 5	8 ± 6	8 ± 5
Range	3–34	3–25	3–34	3–16

*$p < 0.05$ for differences among the 3 groups, †including the duration from the time of first diagnosis of IDC in asymptomatic patients.
LV = left-ventricular; VT = ventricular tachycardia; VF = ventricular fibrillation.

rates ≥240 beats/min; disagreement occurred in three arrhythmia episodes with rates <240 beats/min. For the purpose of this study, these three episodes were subsequently classified as supraventricular arrhythmias triggering inappropriate device therapy.

Statistical analysis. Baseline clinical characteristics of the prophylactic group, the syncope group and the VT/VF group were compared using the Kruskal-Wallis test. Event-free survival probabilities were estimated with the Kaplan-Meier method, with transplant candidates being censored at the time of transplantation. Multivariate Cox proportional-hazards regression analysis was used to evaluate the association between the baseline clinical variables and the occurrence of appropriate ICD interventions during follow-up. Because the implant procedure may lead to an exacerbation of ventricular tachyarrhythmias, episodes of VT or VF occurring within one week after the operation in four patients were excluded from further analysis. In addition, we excluded episodes of VT or VF occurring in five patients within one week of death; no prognostic benefit can be derived from ICD shocks with a close time relationship to death, which was predominantly caused by end-stage heart failure. The final Cox regression model was built by a stepwise procedure with a significance level of 0.15 as criterion for entry into the model. Results are expressed as mean ± SD unless otherwise specified. All p-values reported are two-sided, and a p-value <0.05 was considered to be statistically significant. SAS software (SAS Institute, Cary, North Carolina) was used for statistical analyses.

RESULTS

Patient characteristics. All 101 patients with IDC were in a clinically stable state, with New York Heart Association classification of I, II or III at the time of ICD implantation and a mean LV ejection fraction of 25 ± 8% (Table 1). By definition, all patients in the prophylactic group had an LV ejection fraction ≤30% and nonsustained VT on Holter or telemetry monitoring before ICD implantation. The longest episode of nonsustained VT in the prophylactic group was a mean of 8 ± 5 beats with a mean rate of 172 ± 35 beats/min. Left ventricular ejection fraction was lower in the 49 patients in the prophylactic group, compared with that in the 26 patients in the syncope group or the 26 patients in the VT/VF group (22 ± 6% vs. 27 ± 9% and 31 ± 8%, respectively). Medical therapy at the time of hospital discharge and at follow-up is summarized in Table 2. Of note, beta-blocker use was similar in all three groups at the time of hospital discharge; amiodarone was used more frequently in the VT/VF group.

Appropriate defibrillator interventions. During 36 ± 22 months mean follow-up after ICD implantation, 18 of 49 patients (37%) in the prophylactic group received appropriate ICD interventions for VT or VF, compared with 8 of 26 patients (31%) in the syncope group and 9 of 26 patients

Table 2. Medication at the Time of Hospital Discharge After Defibrillator Implant and at Most Recent Follow-Up

	All Patients (n = 101)	Prophylactic Group (n = 49)	Syncope Group (n = 26)	VT/VF Group (n = 26)
Medication at hospital discharge (%)				
Digitalis	85 (84)	42 (86)	22 (85)	21 (81)
Diuretics	88 (87)	42 (86)	23 (88)	23 (88)
Angiotensin converting enzyme inhibitors	89 (88)	44 (90)	24 (92)	21 (81)
Angiotensin II receptor antagonists	3 (3)	2 (4)	0 (0)	1 (4)
Spironolactone	5 (5)	2 (4)	1 (4)	2 (8)
β-Blockers without d,l-sotalol	32 (32)	16 (33)	7 (27)	9 (35)
D,l-sotalol	6 (6)	1 (2)	2 (8)	3 (12)
Amiodarone	22 (22)*	10 (20)	2 (8)	10 (38)
Class I antiarrhythmic drugs	2 (2)	0 (0)	0 (0)	2 (8)
Medication at follow-up (%)				
Digitalis	89 (88)	46 (94)	23 (88)	20 (77)
Diuretics	87 (86)	45 (92)	19 (73)	23 (88)
Angiotensin converting enzyme inhibitors	89 (88)	41 (84)	24 (92)	24 (92)
Angiotensin II receptor antagonists	8 (8)	6 (12)	1 (4)	1 (4)
Spironolactone	24 (24)	13 (27)	6 (23)	5 (19)
β-Blockers without *D*,l-sotalol	49 (49)	30 (61)	9 (35)	10 (38)
D,l-sotalol	8 (8)	2 (4)	3 (12)	3 (12)
Amiodarone	24 (24)	7 (14)	7 (27)	10 (38)
Class I antiarrhythmic drugs	3 (3)	1 (2)	0 (0)	2 (8)

*$p < 0.05$ for differences among the 3 groups.

(35%) of the VT/VF group (Table 3, Figs. 1 and 2A). The incidence of appropriate ICD shocks for rapid VT or VF ≥240 beats/min was also similar in the three groups (Fig. 2B). The mean duration of VT or VF episodes triggering appropriate device therapy from the onset of the arrhythmia until arrhythmia termination by the device was 10 s ± 7 s (median 10 s, range 4 s to 46 s) for VTs with rates <240 beats/min, and 13 s ± 5 s (median 12 s, range 8 s to 37 s) for rapid VTs or VF with rates ≥240 beats/min, without significant differences among the three groups. The mean duration from device implant until the first appropriate ICD intervention was 12 ± 11 months in the prophylactic group, compared with 9 ± 13 months in the syncope group and 15 ± 11 months in the VT/VF group. Multivariate Cox regression analysis of baseline clinical variables identified left ventricular ejection fraction, atrial fibrillation and a

Table 3. Appropriate and Inappropriate ICD Interventions and Transplant-Free Survival During Follow-Up

Characteristic	All Patients (n = 101)	Prophylactic Group (n = 49)	Syncope Group (n = 26)	VT/VF Group (n = 26)
Follow-up duration, months	36 ± 22	35 ± 20	41 ± 23	32 ± 26
Range	3–84	3–79	9–80	7–84
Appropriate ICD Interventions* (%)				
Any ICD intervention for VT/VF	35 (35)	18 (37)	8 (31)	9 (35)
≥2 interventions for VT/VF	29 (29)	15 (31)	8 (31)	6 (23)
≥1 ICD shock for VT/VF ≥240 beats/min	27 (27)	12 (24)	8 (31)	7 (27)
Inappropriate ICD Interventions* (%)				
Any inappropriate ICD intervention	16 (16)	9 (18)	5 (19)	2 (8)
ICD shocks for AF or SVT	10 (10)	6 (12)	4 (15)	0 (0)
ICD shocks for nonsustained VT	5 (5)	3 (6)	1 (4)	1 (4)
ICD shocks due to electrode fracture	1 (1)	0 (0)	0 (0)	1 (1)
Time to 1st ICD therapy for VT/VF, months	12 ± 11	12 ± 11	9 ± 13	15 ± 13
Range	1–40	1–32	1–40	1–33
Mortality during follow-up (%)				
Death from any cause	18 (18)	11 (22)	3 (12)	4 (15)
Death due to progressive heart failure	13 (13)	8 (16)	2 (8)	3 (12)
Sudden cardiac death	1 (1)	1 (2)	0 (0)	0 (0)
Noncardiac death	4 (4)	2 (4)	1 (4)	1 (4)
Heart transplant (%)	11 (11)	5 (10)	4 (15)	2 (8)

*Exclusively episodes as documented by stored electrograms were included for analysis.

AF = atrial fibrillation with rapid ventricular response; ICD = implantable cardioverter defibrillator; SVT = supraventricular tachycardia; VT = ventricular tachycardia; VF = ventricular fibrillation.

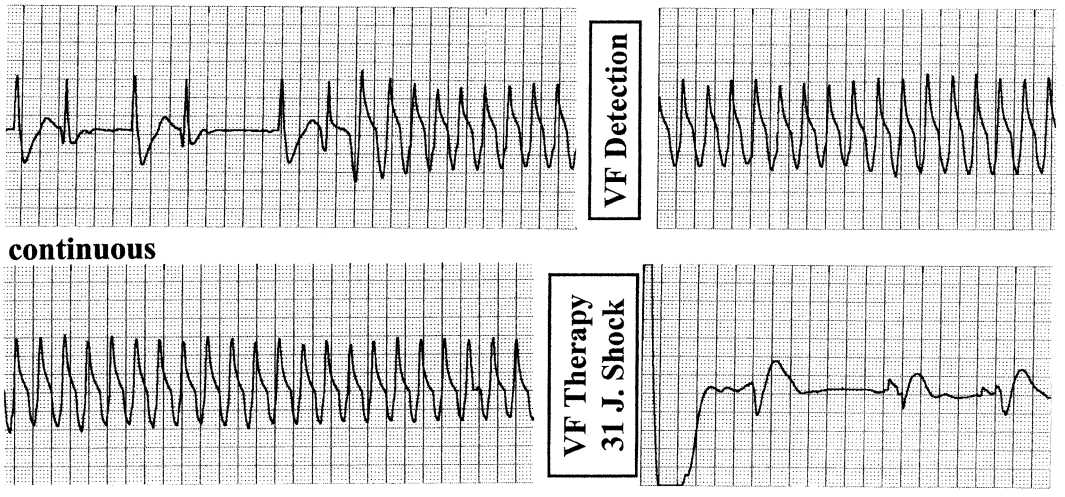

Figure 1. Stored electrogram (25 mm/s) of spontaneous ventricular tachycardia terminated by a 31 J shock in a patient with idiopathic dilated cardiomyopathy and prophylactic defibrillator implantation. VF = ventricular fibrillation.

history of sustained VT or VF before defibrillator implantation as predictors for appropriate ICD interventions during follow-up, as summarized in Table 4.

Sudden death and transplant-free survival. During 36 ± 22 months of follow-up, 18 patients died (18%) and 11 patients (11%) underwent successful heart transplant (Table 3, Fig. 2C). Only one patient died suddenly at home, 24 months after prophylactic ICD implantation while waiting for heart transplantation. Unfortunately, sudden death was not witnessed in this patient, and the device was not available for retrieval of stored ECGs after the patient died.

Complications related to ICD therapy. During 36 ± 22 months of follow-up, 29 of 101 study patients (29%) had one or more of the following complications: inappropriate shocks (16 patients, 16%), as summarized in Table 3; bleeding or pocket hematoma (2 patients, 2%); generator malfunction, including inappropriate charge time prolongation necessitating generator replacement (4 patients, 4%); periarthritis humeroscapularis (2 patients, 2%); and lead-related complications, including endocardial lead migration, lead fracture or insulation defect (8 patients, 8%). No patient died perioperatively (30-day). In addition, no ICD infection and no thromboembolic complications were observed at implant and during follow-up.

DISCUSSION

This is the first study to report the incidence of appropriate ICD interventions exclusively based on stored electrograms by the device in a relatively large patient population with IDC and prophylactic ICD therapy compared to patients with unexplained syncope and patients with a history of sustained VT or VF. The major finding of our study is that patients with IDC in whom prophylactic ICD implantation was performed for asymptomatic or only mildly symptomatic nonsustained VT in the presence of a left ventricular ejection fraction ≤30% had a similar incidence of appropriate ICD interventions as did patients with unexplained syncope or patients with a history of sustained VT or VF. The results of multivariate Cox regression analysis of baseline clinical variables strongly suggest that the comparable incidence of appropriate ICD interventions in the prophylactic group and the VT/VF group is due to the significantly lower LV ejection fraction in the prophylactic group compared with that in the VT/VF group. The low LV ejection fraction appears to have outweighed the history of sustained VT or VF as a risk factor for subsequent adequate ICD interventions in this patient population. Because not every episode of spontaneous sustained VT or VF would lead to sudden cardiac death in the absence of device therapy, Böcker and colleagues (19,20) have previously suggested using the occurrence of ICD shocks for fast VT or VF >240 beats/min to estimate the potential benefit from ICD therapy in different patient groups. Of note, analysis of stored electrogram data restricted to rapid VT or VF in our study also revealed a similar incidence of these rapid ventricular tachyarrhythmias in the prophylactic group versus in the syncope group and the VT/VF group (Fig. 2B).

Prior studies in patients with IDC and a history of VT or VF. Three prior studies focused on the outcome of patients with IDC and a history of sustained VT or VF treated by implantable defibrillators (21–23). Fazio et al. (21) found appropriate ICD shocks in 24 of 39 patients (62%) with IDC and a history of sustained VT or VF during a mean follow-up of 30 months. Grimm et al. (22) observed appropriate shocks in 25 of 49 patients (51%) with IDC and a history of VT or VF (n = 43) or syncope in the presence of nonsustained VT (n = 6) during a mean follow-up of 25 months. Finally, Bänsch and coworkers (23) noted appropriate ICD interventions in 73 of 106 patients (69%) with IDC during 33 ± 23 months follow-up. In contrast to these three previous reports (21–23), only 9 of 26 patients (35%)

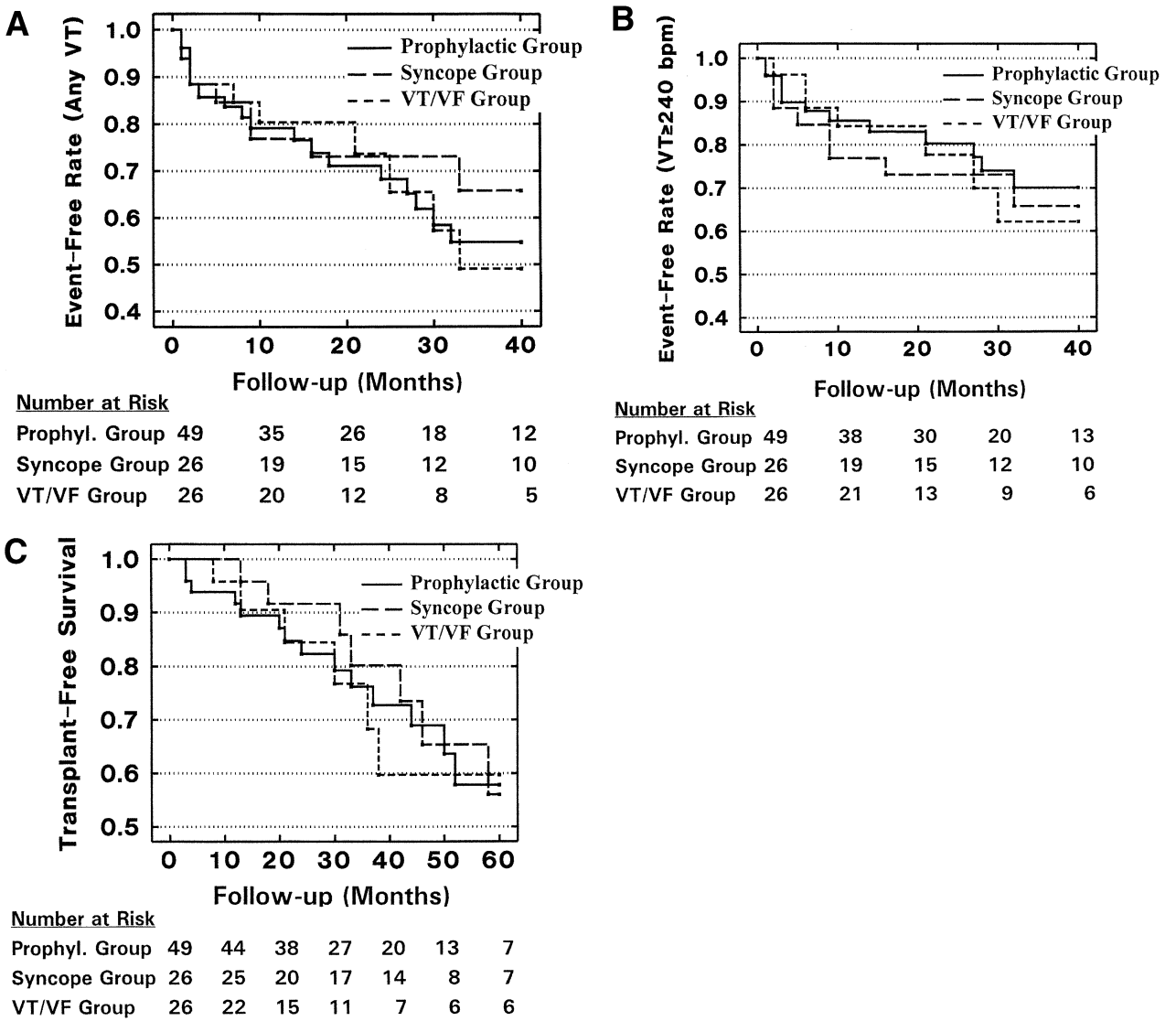

Figure 2. Kaplan-Meier curves showing the event-free survival rates for: **(A)** appropriate implantable cardioverter defibrillator (ICD) interventions for any ventricular tachycardia (VT) or ventricular fibrillation (VF) as documented by stored electrograms; **(B)** appropriate ICD shocks exclusively for rapid VT or VF with a mean rate ≥240 beats/min; **(C)** transplant-free survival.

with IDC and a history of VT or VF received appropriate ICD interventions during a mean follow-up of 32 months in the present study. This discrepancy may, in part, be due to differences in patient selection, as well as concomitant medical therapy in these three studies. In addition, the definition of appropriate shocks in the present study was based exclusively on electrograms stored by the device; previous investigators had to rely to a great extent on symptoms preceding spontaneous shocks to define appropriate shocks.

Prior studies in patients with IDC and unexplained syncope. Knight et al. (7) observed appropriate ICD shocks in 7 of 14 patients (50%) with IDC and unexplained syncope during 24 months follow-up, compared with 8 of 19 patients (42%) with IDC and a history of cardiac arrest during 45 months follow-up. Fonarow et al. (8) found appropriate shocks in 10 of 25 patients (40%) with IDC and unexplained syncope during 22 months follow-up. In contrast to these two previous studies, a slightly lower incidence of appropriate ICD interventions for VT or VF was found in 8 of 26 patients (31%) with unexplained syncope during 41 months follow-up in the present study.

Studies using prophylactic ICD implantation in IDC. Levine et al. (12) observed appropriate ICD shocks in eight of nine patients (89%) with IDC in whom prophylactic ICD implantation had been performed for asymptomatic nonsustained VT in the presence of a left ventricular ejection fraction of 28 ± 14% during 35 months of follow-up. In contrast to the study of Levine et al. (12), we observed appropriate ICD interventions in 37% of patients with prophylactic ICD therapy for asymptomatic or only mildly symptomatic nonsustained VT and an ejection fraction of 22 ± 6%. This discrepancy may be due to the larger number of patients in our study, as well as to the fact that

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Table 4. Association Between Baseline Clinical Characteristics and Appropriate Defibrillator Interventions During Follow-Up

	VT/FV During FU (n = 35)	No VT/VF (n = 66)	Multivariate Cox Regression Analysis		
			p Value	Relative Risk	95% CI
Clinical characteristics at implant					
Age, years	52 ± 13	50 ± 14	NS		
Male gender (%)	30 (86)	52 (79)	NS		
NHYA class III	13 (37)	22 (33)	NS		
Indication for ICD implant					
Prophylactic implant	18 (51)	31 (47)	NS		
Unexplained syncope	8 (23)	18 (27)	NS		
History of sustained VT/VF	9 (26)	17 (26)	0.036	2.85	1.07 to 7.58
Antiarrhythmics at hospital discharge					
β-blockers without sotalol	8 (23)	24 (36)	NS		
D,l-sotalol	3 (9)	3 (5)	NS		
Amiodarone	8 (23)	14 (21)	NS		
Antiarrhythmics at follow-up					
β-blockers without sotalol	15 (43)	34 (52)	NS		
D,l-sotalol	1 (3)	7 (11)	NS		
Amiodarone	13 (37)	11 (17)	NS		
Echocardiographic study at implant					
LV end-diastolic diameter, mm	70 ± 6	69 ± 6	NS		
LV ejection fraction, %	23 ± 7	27 ± 9	0.0002	1.76* 3.11†	1.31 to 2.38* 1.71 to 5.66†
Electrocardiography at implant (%)					
Atrial fibrillation	11 (31)	10 (15)	0.009	2.76	1.28 to 5.97
Left bundle branch block	10 (29)	22 (33)	NS		
Nonsustained VT on Holter or telemetry	31 (89)	51 (77)	NS		

*Relative risk and 95% confidence interval per 5% decrease of LV ejection fraction. †Relative risk and 95% confidence interval per 10% decrease of LV ejection fraction.

CI = confidence interval; FU = follow-up; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association; LV = left ventricular; VT/VF = ventricular tachycardia or fibrillation.

only episodes with stored electrograms showing VT or VF triggering device therapy were accepted as appropriate ICD interventions in our study. Recently, the preliminary results of the AMIOVIRT trial have been reported (4). A multicenter, randomized trial, AMIOVIRT examined the total mortality rate associated with amiodarone versus ICD therapy in patients with nonischemic dilated cardiomyopathy, an ejection fraction <35% and asymptomatic nonsustained VT. The trial was stopped early after 102 patients were randomized because the number of patients surviving during 20 ± 13 months follow-up were similar in the amiodarone and ICD treatment groups (4).

Study limitations. The study had some limitations. 1) It was an uncontrolled observational study with the incidence of appropriate ICD interventions for VT or VF and ICD interventions for rapid VT or VF with rates ≥240 beats/min as surrogate endpoints for a potential benefit from defibrillator therapy, as previously suggested by Böcker et al. (19,20). This study does not have the same value or power as a properly designed, randomized, multicenter study with total mortality as primary end point in order to prove that prophylactic ICD implantation is warranted in patients with IDC and nonsustained VT in the presence of a low LV ejection fraction. 2) Quality of life issues and cost-effectiveness analyses have not been performed in this study. 3) Because this study started in January 1993, the use of beta-blockers was not included as standard heart failure therapy in the majority of patients at study entry. In addition, beta-blocker dosing was not standardized in the majority of patients but varied considerably between patients according to the attending physician's preference. Therefore, we cannot make any valid conclusions with regard to the value of beta-blocker therapy for arrhythmia risk reduction in this patient population with IDC.

Clinical implications. The present study showed that a substantial number of patients with IDC in whom prophylactic ICDs were implanted for asymptomatic or only mildly symptomatic nonsustained VT in the presence of an ejection fraction ≤30% had appropriate discharges during 36 months mean follow-up. In addition, multivariate analysis of baseline clinical variables suggests that the comparable incidence of appropriate ICD interventions in the prophylactic group and the VT/VF group is due to the significantly lower LV ejection fraction in the prophylactic group compared to the VT/VF group, which appears to have outweighed the history of sustained VT or VF as a risk factor for subsequent adequate ICD interventions. Thus, our data support the view that ICD implantation may be a valuable tool for both secondary and primary prevention of sudden death in IDC. It is also important, however, to recognize that ICD therapy is expensive and not free of complications

(24). Therefore, the results of properly designed, randomized, multicenter studies (13,25,26) are needed before any valid recommendations with regard to prophylactic ICD implantation in IDC can be made. In addition, several noninvasive strategies for arrhythmia risk stratification have recently been introduced, which may allow for a more precise selection of patients who may benefit most from prophylactic ICD implantation (27).

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