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Electrophysiology

Shocks as Predictors of Survival in Patients With Implantable Cardioverter-Defibrillators

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OBJECTIVES The objective of the study was to determine whether the occurrence of shocks for ventricular tachyarrhythmias during therapy with implantable cardioverter-defibrillators (ICD) is predictive of shortened survival.

BACKGROUND Ventricular tachyarrhythmias eliciting shocks are often associated with depressed ventricular function, making assessment of shocks as an independent risk factor difficult.

METHODS Consecutive patients (n = 421) with a mean follow-up of 756 ± 523 days were classified into those who had received no shock (n = 262) or either one of two shock types, defined as single (n = 111) or multiple shocks (n = 48) per arrhythmia episode. Endpoints were all-cause and cardiac deaths. A survival analysis using a stepwise proportional hazards model evaluated the influence of two primary variables, shock type and left ventricular ejection fraction (LVEF <35% or >35%). Covariates analyzed were age, gender, NYHA Class, coronary artery disease, myocardial infarction, coronary revascularization, defibrillation threshold and tachyarrhythmia inducibility.

RESULTS The most complete model retained LVEF (p = 0.005) and age (p = 0.023) for the comparison of any shock versus no shock (p = 0.031). The occurrence of any versus no shock, or of multiple versus single shocks significantly decreased survival at four years, and these differences persisted after adjustment for LVEF. In the LVEF subgroups <35% and <25%, occurrence of multiple versus no shock more than doubled the risk of death. Compared with the most favorable group LVEF ≥35% and no shock, risk in the group multiple shocks and LVEF <35% was increased 16-fold.

CONCLUSIONS In defibrillator recipients, shocks act as potent predictors of survival independent of several other risk factors, particularly ejection fraction. (J Am Coll Cardiol 1999;34:204–10) © 1999 by the American College of Cardiology

Identification of high-risk patients undergoing implantable cardioverter-defibrillator (ICD) therapy is essential for the planning and implementation of appropriate therapy. One important question is whether ventricular tachycardia (VT) and ventricular fibrillation (VF) detected and treated by implanted defibrillators provide useful prognostic information. In some reports, the occurrence of shocks acted as a marker of poor outcome (1–3), but in several others it did not (4–8). In one study, ICD therapy was a risk factor only when more than one shock was delivered per arrhythmia episode (9). One difficulty in interpreting previous reports is that the occurrence of shocks was associated with a depressed left ventricular ejection fraction (LVEF) (2,9), an important predictor of survival (8,10,11). Therefore, shock therapies as an independent predictor of survival remained uncertain.

In the present study we performed a survival analysis in 421 consecutive patients receiving ICD treatment to determine whether the detection and treatment of ventricular tachyarrhythmias verified by an electrogram (EGM) are useful for the prediction of clinical outcome. The analysis included a stratification by LVEF and considered multiple variables of potential influence.

METHODS

Patients. Consecutive patients (n = 421) of either sex receiving first-time ICD implantation were included in the study. Indication for ICD therapy was at least one episode of aborted sudden cardiac death (SCD) or recurrent episodes of symptomatic VT. Contraindications for ICD therapy were ventricular arrhythmias associated with acute coronary syndromes, reversible causes of ventricular tachyarrhythmias, and diseases predicted to limit life expectancy to less than six months. All patients received an estimation of LVEF by radionuclide ventriculography, contrast angiog-

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Abbreviations and Acronyms

AMI = acute myocardial infarction
ATP = antitachycardia pacing
BMI = body mass index
CABG = coronary artery bypass graft
CAD = coronary artery disease
DFT = defibrillation threshold
EGM = electrogram
EPS = electrophysiologic study
ICD = implantable cardioverter-defibrillator
LVEF = left ventricular ejection fraction
MS = subgroup receiving multiple and possibly also single shocks
NS = subgroup receiving no shock
NYHA = New York Heart Association
SCD = sudden cardiac death
SS = subgroup receiving single but not multiple shocks
VF = ventricular fibrillation
VT = ventricular tachycardia

raphy or echocardiography, a coronary arteriography, and a preoperative electrophysiologic study (EPS).

Implantation of cardioverter-defibrillators and electrodes. Defibrillators implanted were new-generation tiered-therapy devices with EGM capability. All ICDs used were capable of delivering four or more therapies per episode of detected tachyarrhythmia. High-voltage electrodes consisted of a right ventricular electrode in combination with a superior vena electrode or a generator shell electrode (active can design). Other configurations included dual Endotak coil electrodes or a third high-voltage electrode.

Defibrillation threshold testing. For the determination of defibrillation thresholds (DFTs), a step-down scheme was used as previously reported (12,13). The requirement of a minimal 10-J margin of safety between the DFT and the maximum output of the generators was met in all cases. All devices were programmed to deliver biphasic defibrillation shocks at the maximum output of the generators (range of nominal outputs 29 J to 37.4 J).

Follow-up. Follow-up included visits at one and three months, and then at three-month intervals until the end of the study or death. The DFT was redetermined at the three-month visit. Additional visits were scheduled whenever patients experienced shocks or ICD-related complications.

Definitions. *Appropriate shock*: Shocks were called appropriate when stored EGMs met the programmed criteria of VT or VF detection. The EGM criteria for the diagnosis of VT included changes in the number and polarity of the QRS deflections during the tachycardia compared with that during the baseline rhythm (14). The EGMs were interpreted taking surface electrocardiographic information and clinical context into consideration (15). *Inappropriate shock*: Shocks were associated with EGM failing to exhibit interval and morphologic criteria of VT or VF. *Single shock (SS) subgroup*: patients who received appropriate successful single shocks, but never multiple shocks. *Multiple shock (MS) subgroup*: patients who received a rapid sequence of two or more appropriate shocks during a single episode of ventricular tachyarrhythmia. These patients may or may not have received single shocks at other times. Multiple shocks as defined here should be distinguished from shocks in clusters (storms, salvos), terms often used to denote frequent shocks elicited over short periods (minutes to hours) in response to temporally discrete, independently detected arrhythmic events. Single or multiple shocks delivered on the day of death were considered to be part of terminal arrhythmias and were not included in the analysis. *No shock (NS) subgroup*: patients who received neither SS nor MS. *Any shock (SS, MS) group*: sum of the nonoverlapping SS and MS subgroups. *Sudden cardiac death (SCD)*: the time-based definition of death within 1 h of onset of symptoms was used. *Ventricular tachycardia*: ventricular tachycardia was defined as $\geq$3 consecutive ventricular beats at a rate $\geq$110 beats/min.

Data collection. Selected demographic, historic and laboratory data totaling 112 variables were entered into a continually updated dBase database (versions IV or V, Borland). Although study end points were defined retrospectively, the data used, including those derived from electrograms, were entered prospectively into the data bank. Before data analysis, the data bank was independently edited by two investigators (L.L.F. and F.C-S.). Patient records were consulted in case of deficiencies or suspected entry errors detected during database review.

Statistical analysis. To determine the comparability of groups assembled according to shock therapies, data were subjected to one-way analysis of variance (continuous variables) or Pearson's chi-square test (categorical variables). Specific comparisons included those between patients receiving no shocks (NS) versus any shocks (SS, MS) or single shocks only (SS) versus multiple-shocks (MS).

Stepwise proportional hazard regression (16) was performed to model and determine the relationship between patient survival times and different shock therapies, controlling for selected prognostic factors, in particular categorical LVEF ($<$, $\geq$35%; $<$, $\geq$25%). Assessment was made of age, sex, body mass index (BMI), New York Heart Association (NYHA) class, coronary artery disease (CAD), acute myocardial infarction (AMI), coronary artery bypass graft (CABG), nonischemic cardiomyopathy, cardiac resuscitation (aborted sudden cardiac death), VT inducibility, DFT, antitachycardia pacing (ATP) and amiodarone or sotalol therapy as potential covariates in the model. A backward elimination procedure was used for the selection of candidate variables shown to be significant at $p < 0.25$ by the Wald test. The final model included variables that were

Table 1. Clinical Characteristics

Characteristic	Total	No Shock (NS)	Single Shock (SS)	Multiple Shock (MS)	p-Values*/†
Number of cases	421	262	111	48	—
Age (yrs)	63 ± 11	64 ± 11	61 ± 12	61 ± 10	0.029/0.844
Male (%)	84	82	86	90	0.237/0.494
BMI (kg/m^2)	27 ± 4	27 ± 4	27 ± 4	27 ± 4	0.766/0.853
CAD (%)	82	84	75	90	0.261/0.035
SCD (%)	46	47	45	42	0.560/0.694
AMI (%)	54	56	49	52	0.175/0.691
CABG (%)	47	47	51	44	0.683/0.798
Class I/II/II (%)‡	32/62/6	39/55/6	21/72/7	19/79/2	<0.001/0.397
LVEF (%)	34 ± 12	36 ± 12	31 ± 11	31 ± 11	<0.001/0.954
<35% (%)	52	42	66	71	<0.001/0.532
<25% (%)	32	26	46	38	<0.001/0.324
Follow up (days)§	756 ± 523	637 ± 489	925 ± 483	1015 ± 594	—
Total deaths	55 (13%)	16 (6%)	19 (17%)	20 (42%)	—
Cardiac deaths	44 (10%)	12 (5%)	16 (14%)	16 (33%)	—

Continuous data are presented as mean ± SD.
*p-Value for comparison NS vs. (SS+MS). †p-Value for SS vs. MS. ‡New York Heart Association functional class. §Follow-up days from implant to death or end of study.

statistically significant, at least at the 5% level. End points of interest were all-cause mortality and cardiac mortality.

Survival probabilities were assessed using the Kaplan-Meier product limit method. Adjusted estimates of survivor functions were based on alive and dead counts reweighted according to the relative hazards estimated by the Cox proportional hazards covariate model. These adjustments should not be viewed to have the same meaning as those in an ordinary regression problem. Survivor functions for the shock subgroups were stratified by LVEF (<, ≥35%; <, ≥25%) and compared for equality by the stratified log-rank test. All statistical calculations were performed using STATA statistical software (Stata Corporation, College Station, Texas).

RESULTS

Patient characteristics. Clinical characteristics for the entire cohort and for the shock treatment subgroups are shown in Table 1. Characteristics in the subgroups were generally similar and resembled those of 18 ICD studies recently analyzed (12). There were no significant intergroup differences for male prevalence, BMI, angiographically verified CAD, and histories of AMI, CABG and aborted SCD. The mean LVEF was 34 ± 12% in the entire cohort, 36 ± 12% in the no shock subgroup (NS), and 31 ± 11% both in the single (SS) and multiple shock (MS) subgroups. The LVEF values for MS or SS compared with NS were significantly depressed ($p < 0.001$) (Table 1). Compared with NS, there were a significantly ($p < 0.001$) greater proportion of patients with any shock (SS, MS) under the stratifications of LVEF <35% (107/159 = 67%) and LVEF <25% (69/159 = 43%) (Table 1).

Electrophysiologic study. At preimplantation EPS, programmed stimulation in 421 patients induced monomorphic VT in 77% (325), VF in 3% (13), polymorphic VT in 0.7% (3), and no inducible arrhythmia in 19% (80) of the patients. Corresponding percents were 78% (204), 3% (9), 0.7% (2), and 18% (47) for the NS subgroup (n = 262); 78% (87), 4% (4), 0.8% (1), and 17% (19) for the SS subgroup (n = 111); and 91% (44), 3% (1), 0% (0), and 6% (3) for the MS subgroup (n = 48).

Device programming. Programmed interval limits for the detection and treatment of VT in the NS, SS, and MS subgroups averaged 344 ± 32, 349 ± 35, 356 ± 34 ms, and corresponding limits for VF were 296 ± 13, 298 ± 14, and 299 ± 19 ms. Intergroup differences were not significant. The ATP was "on" at some time during follow up in 48% of the patients (201/421), and 44% of these (88/201) received at least one appropriate ATP therapy. In the NS, SS and MS subgroups, the percentages of patients with ATP programmed "on" were 45% (118/262), 51% (57/111), and 54% (26/48). In the corresponding groups, the percents for ATP used at least once were 42% (49/118), 44% (25/57) and 54% (14/26). The ATP treatment was successful in the NS, SS and MS subgroups in 96%, 92%, and 86% of the episodes. Acceleration of the tachycardia in response to ATP was below 2% in all groups. None of the intergroup differences between parameters of ATP therapy were significant.

Antiarrhythmic drug therapy. At discharge, the percentages of patients receiving amiodarone in the NS, SS and MS subgroups were 5% (13/262), 14% (16/111), and 29% (14/48) ($p < 0.05$ for NS vs. MS). The percentage of patients receiving amiodarone was 9% (34/366) in survivors compared with 16% (9/55) in nonsurvivors ($p > 0.05$). The percentage of patients discharged on beta-adrenergic blocking agents did not differ between groups, averaging 22% (58/266) for NS, 19% (21/111) for SS, and 21% (10/48) for

Table 2. All-cause Mortality for Groups Receiving Different Shock Therapies After Adjustment for Categorical LVEF

Shock Therapy	Proportion Surviving		
	1 Year	2 Years	4 Years
No Shock (NS)	0.99 (0.98)	0.97 (0.95)	0.89 (0.82)
Any Shock (SS, MS)	0.98 (0.95)	0.94 (0.86)	0.83 (0.64)
Single Shock (SS)	0.98 (0.97)	0.93 (0.91)	0.80 (0.71)
Multiple Shocks (MS)	0.94 (0.92)	0.85 (0.78)	0.67 (0.55)

Numbers in parentheses denote corresponding unadjusted proportions.

MS. Compared with values at discharge, values at 12 and 24 months did nor differ significantly.

Shock therapies. Among the 421 patients, 195 (46%) experienced shocks. These were appropriate in 159 patients and inappropriate in 36, with 4 patients assessed to have received both appropriate and inappropriate shocks. Major causes of inappropriate shocks included atrial fibrillation/flutter in 16 cases and lead complications in 12 cases. All but one patient receiving MS (n = 48) experienced additional SS. Among the 47 patients receiving both shock types, SS preceded MS in 15 patients, SS followed MS in 15 patients, and SS occurred on the same day as MS in 17 patients. Repeated shocks received as part of a terminal syndrome were by definition excluded.

Survival analysis. The numbers of total (all-cause) deaths and total cardiac deaths (nonsudden/sudden) were 16 and 12 (8/4) for NS, 19 and 16 (13/3) for SS, and 20 and 16 (13/3) for MS. The mean intervals from implant to the end of the study or death in the entire cohort and in shock subgroups are shown in Table 1. The intervals from implantation to first appropriate shock averaged 398 ± 395 days for any shock (SS, MS), 416 ± 402 days for SS and 408 ± 402 days for MS. For deaths due to all-cause, the average intervals from first SS to death and first MS to death were essentially the same, averaging 354 ± 288 (n = 19) and 348 ± 280 (n = 20) days. In patients receiving both SS and MS, the subgroups with SS occurring before (6 deaths), after (9 deaths), or on the same day as MS (5 deaths) had similar survival (respective Kaplan-Meier estimates at three years 0.81, 0.73 and 0.85).

The occurrence of any shock versus NS, or MS versus SS decreased survival at four years, and this difference persisted after adjustment for categorical LVEF (Table 2 and Fig. 1). A stratified log rank test (Table 3) indicated a significant difference in the survival functions between any shock versus NS ($p = 0.0520$) and between MS versus SS ($p = 0.0058$). Within each stratum, the difference is mostly attributed to LVEF ≥35% for the comparison of any shock versus NS ($p = 0.0034$, Fig. 2) and to LVEF <35 for the comparison of MS versus SS ($p = 0.0055$, Fig. 3). Similar intergroup relations were obtained when LVEF was stratified at the 25% level (survival curves not shown).

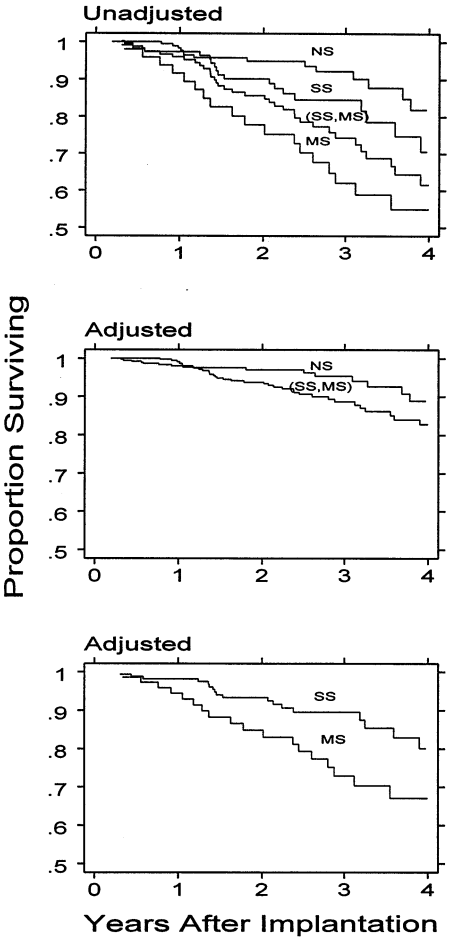

Figure 1. Kaplan-Meier survival curves for patient groups receiving different types of ICD shock therapies. **Top panel:** unadjusted for LVEF. **Lower panels:** adjusted for categorical LVEF. In this and in subsequent figures, NS, SS, MS and (SS, MS) indicate no shock, single shock, multiple shocks and any shock as defined in Methods section.

The results of initially fitting the full model on all prognostic variables considering all-cause mortality with the retention of any shock (compared with NS) and LVEF <35% (compared to LVEF ≥35%) in the model demonstrated three variables to be significant: any shock (p =

Table 3. All-Cause Mortality for Groups Receiving Different Shock Therapies With Stratification by Categorical LVEF

Shock Therapy	Log-rank p-Value		
	Total	<35%	≥35%
No Shock (NS) vs. Any Shock (SS, MS)	0.0520	0.4649	0.0034
Single Shock (SS) vs. Multiple Shocks (MS)	0.0058	0.0055	0.5452

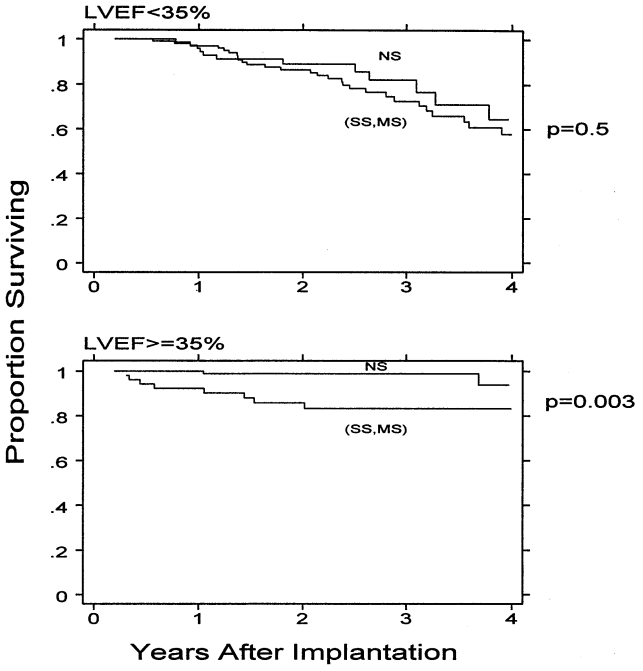

Figure 2. Kaplan-Meier survival probability stratified according to LVEF: comparison of any versus no shock. **Upper panel:** LVEF <35%. **Lower panel:** LVEF ≥35%. Abbreviations as in Figure 1 legend.

0.031), LVEF <35% (p = 0.005) and age (p = 0.023) (Table 4). The interaction term of any shock by LVEF <35% was evaluated and shown to add only a slight improvement to the model (G = 3.68, p < 0.10). There was a slight increase in the risk of dying the older the patient was, with an estimated hazard ratio of 1.4 (per 10-year increase). Very similar modeling results were seen when considering cardiac mortality, though without significant contribution of age.

When fitting the full model with MS (compared to SS) and with LVEF <35% retained in the model, MS (p = 0.013) but not LVEF <35% (p = 0.136) was significant for all-cause mortality (Table 4). No significant interaction was detected. The risk of cardiac mortality was increased about twofold for patients with the occurrence of any shock (vs. NS, p = 0.051) or with the occurrence of MS (vs. SS, p = 0.035).

Hazard ratios stratified on both categorical LVEF and shock subgroup are listed in Table 5. Compared with the most favorable prognostic group with LVEF ≥35% and NS, depression in LVEF below 35% increased the risk of dying about 7-fold, and when LVEF <35% was combined with MS, the risk was increased 16-fold. Compared with the reference group LVEF ≥25% and NS, the hazard ratios were 11.2 for the group LVEF <25% with NS, and 23.4 for the group LVEF <25% with MS. Thus, both at the <35% and <25% LVEF depression levels, occurrence of multiple shocks versus no shock more that doubled the risk of dying.

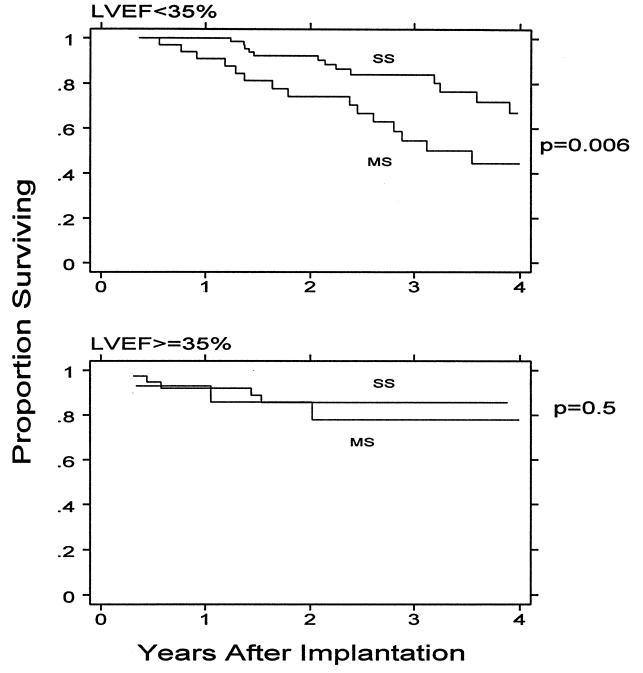

Figure 3. Kaplan-Meier survival probability stratified according to LVEF: comparison of multiple versus single shocks. **Upper panel:** LVEF <35%. **Lower panel:** LVEF ≥35%. Abbreviations as in Figure 1 legend.

DISCUSSION

Our study is in agreement with previous reports indicating the importance of LVEF as a prognostic indicator of survival in patients receiving ICD therapy (1–3). Conversely, our results do not support the conclusion that appropriate ICD shocks for ventricular tachyarrhythmias have no or little prognostic implications (4–8). Both the occurrence of any shock versus no shock and multiple shocks for single arrhythmia episodes versus single shocks were associated with significantly lower survival probabilities.

This report is the first to examine in detail the interactions between LVEF and shock therapy on survival. The results demonstrate that an increased risk of dying persisted after adjustment for LVEF and that both shock and shock types acted as potent independent risk factors. Compared with the prognostically most favorable group (no shock and LVEF ≥35%), the occurrence of single shocks increased the risk of death more than 5-fold irrespective of whether LVEF was more or less than 35%. Also, the combination of an LVEF of less than 35% and a history of multiple shocks for single arrhythmia episodes identified a group with a 16-fold increased risk of dying. Controlled trials indicate that ICDs are effective in preventing sudden cardiac death (17,18), and in large series refractoriness to ICD therapy occurred in less than 2% of the patients (19). Here, we demonstrate that it is possible to identify special subsets of patients at high risk despite ICD therapy.

In the report by Villacastin et al. (9), 80 patients were grouped without the availability of EGMs into those

Table 4. Proportional Hazards Regression

Event	Model	Predictors	β (SE)	Hazard Ratio (95% CI)	p-Value
All-Cause Mortality	I	Any shock*	0.67 (0.31)	1.9 (1.1, 3.6)	0.031
		LVEF <35%†	0.97 (0.35)	2.6 (1.3, 5.2)	0.005
		Age	0.31 (0.13)	1.4 (>1.00, 1.8)	0.023
	II	MS‡	0.80 (0.32)	2.2 (1.2, 4.2)	0.013
		LVEF < 35%†	0.59 (0.40)	1.8 (0.8, 3.9)	0.136
Cardiac Mortality	I	Any shock*	0.68 (0.35)	2.0 (<1.0, 3.9)	0.051
		LVEF <35%†	1.15 (0.40)	3.1 (1.4, 6.9)	0.004
	II	MS‡	0.75 (0.36)	2.1 (1.0, 4.2)	0.035
		LVEF <35%†	0.50 (0.43)	1.6 (0.7, 3.8)	0.244

*vs. NS. †vs. ≥35%. ‡vs. SS.

receiving no shock (n = 38), single shocks (n = 26), and multiple consecutive shocks for single arrhythmia episodes (n = 16). In agreement with our findings, results of their proportional hazards regression analysis suggested that the occurrence of multiple shocks was a marker of poor prognosis (9). In contrast, they (9) concluded that single shocks did not influence survival compared with no shock, a result that appeared to confer prognostic significance exclusively to multiple consecutive shocks. However, the numbers of deaths in the no-shock (3 deaths), single-shock (2 deaths), and multiple consecutive shock groups (7 deaths) appeared small to perform valid survival analyses. A confounding feature of the study by Villacastin et al. (9) was that the mean ejection fraction in the multiple consecutive shock group was substantially depressed compared with that in either the single or no-shock groups (26 ± 4% vs. 39 ± 3% or 43 ± 2%).

In the study by Zilo et al. (2), 32 patients receiving shocks compared with 21 receiving no shocks had a lower three-year survival rate, but patients with a history of shocks again exhibited lower ejection fractions compared with shock-free patients (27 ± 14% vs. 36 ± 15%). In these studies (2,9), it remains unclear whether shock therapy was a risk factor independent of depressed ventricular function, an established risk factor in patients receiving ICD therapy (8,10).

In our analysis, the only variable associated with a change in survival besides LVEF and shock therapies was the age of the patients. Our results indicate that the arrhythmic history before implantation (presenting arrhythmia) did not act as an important prognostic factor, in apparent agreement with the ESVEM trial (11). Our results are also in agreement with those of the AVID trial (17,20), suggesting that inducibility of VT at baseline EPS is not prognostic of increased total mortality. The value of VT inducibility as a prognostic factor of sudden death independent of left ventricular function remains a controversial issue (21,22).

Table 5. Stratification for Ejection Fraction

Shock Group	Ejection Fraction	Deaths	Hazard Ratio	(95% CI)
No Shock	≥35%	3/151	1.0	
	<35%	13/111	7.0	(2.0, 24.4)
Single Shocks	≥35%	5/38	5.2	(1.2, 21.8)
	<35%	14/73	6.1	(1.7, 21.1)
Multiple Shocks	≥35%	3/14	5.6	(1.1, 27.6)
	<35%	17/34	16.1	(4.7, 54.9)

Study limitations. This mortality study was not designed as a prospective trial. However, data used were based on a continually updated data bank. Because the study included consecutive patients, we believe that data collection was not biased or restricted to subsets fitting special prerequisites.

Conclusions. In consecutive ICD recipients not selected according to special inclusion/exclusion criteria, single or repetitive shocks for single episodes of ventricular tachyarrhythmias were risk factors for total and cardiac mortality independent of ventricular function. In addition, combined occurrence of multiple shocks and a low ejection fraction identified a subgroup with a poor prognosis.

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