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Prophylactic implantable cardioverter defibrillator therapy in dilated cardiomyopathy: Impact of left ventricular function☆

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Abstract

Background: The value of an implantable cardioverter defibrillator (ICD) for primary prevention in dilated cardiomyopathy (DCM) is unclear, as randomized trials could not show a survival benefit compared to drug therapy. It has not been investigated if patients with a very poor left ventricular function (LVEF) could profit from an ICD.
Methods: Consecutive patients with DCM who received an ICD between December 1996 and November 2003 were included in this analysis. Patients were divided in group A (secondary prevention) and group B (primary prevention). Both groups were stratified in subgroups with left ventricular ejection fraction (LVEF) below and above 20%.
Results: Fifty eight patients were included (male 50, age 56.4±12.7 years). Follow-up was 34±19 months. There was no difference regarding death (18% vs. 11%), but significant differences (p value <0.05) regarding any adverse events (55% vs. 22%), any ICD intervention (48% vs. 17%) and ICD interventions for life-threatening arrhythmias (27% vs. 0%) between group A and B. LVEF was not predictive for events in group A, whereas in group B only patients with a LVEF <20% had events (p value 0.02). Over time there was an increase of the LVEF of more than 15% determined by echocardiography in 36% of patients, significantly more often in group B.
Conclusions: Indication for primary prevention with an ICD in DCM should be made with caution. Larger studies are needed to determine if patients with LVEF of <20% might benefit from an ICD.

Keywords: Implantable cardioverter defibrillator; Left ventricular function; Sudden cardiac death

The efficacy of an implantable cardioverter defibrillator (ICD) for primary prevention of sudden cardiac death (SCD) in patients with coronary artery disease (CAD) has been shown in several large-scale randomized trials [1–3]. More than 2000 patients were included in these trials and the reduction in the relative risk of SCD or aborted SCD was always significantly lower in the ICD group (24–54%). In contrast, four primary prevention trials performed in 1876 patients with idiopathic dilated cardiomyopathy (DCM) showed no benefit of the ICD [4–7] compared to optimal drug therapy or amiodarone. Two trials were terminated prematurely because the mortality in the conventional arm was lower than predicted and there were divergent trends towards a better survival once in the ICD arm [4] and once in the amiodarone group [5]. In the third trial, only a reduction of the rate of sudden death in the ICD group was observed, but overall mortality, the primary endpoint, was not significantly lower in the ICD group than in the control group [6]. In SCD-HeFT, modes of death were not reported, but again overall mortality was not reduced in the ICD arm. Thus, current guidelines for ICD implantation do not recommend its use for primary prevention in DCM patients [8].

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However, in three of the trials no subgroup analysis stratifying patients in groups with poor or very poor left ventricular ejection fraction (LVEF) was performed [4,5,7]. Therefore, we analyzed all our DCM patients with an ICD implanted for primary or secondary prevention of SCD regarding appropriate ICD interventions, overall mortality, drug therapy and LVEF during follow-up and stratified them into subgroups of LVEF above or below 20%.

1. Methods

1.1. Patient population

All patients with the clinical diagnosis of idiopathic dilated cardiomyopathy who received an ICD at our institution were included in this analysis. Cardiac drug therapy at the time of ICD implantation and at the latest follow-up visit was recorded. Significant (>70% stenosis) CAD as a potential cause for the left ventricular dysfunction and dilatation was excluded by angiography. Patients with recent myocarditis, alcohol abuse and drug or tachycardia induced cardiomyopathy were excluded by means of history, resting ECG and laboratory tests, as far as this was reasonably possible. Transthoracic echocardiography was performed in all patients at baseline. LVEF was estimated using the disc-summation method (modified Simpson's rule) [9]. Since electrophysiological testing has a low sensitivity and specificity for risk stratification in DCM patients, this test was not routinely performed and results are not considered.

1.2. Follow-up

All patients were exclusively followed at our institution 1, 3, 6, 12, 18 . . . months after implantation. All ICD interventions were registered and classified as ventricular tachycardia (VT) (terminated by antitachycardia pacing), fast ventricular tachycardia (FVT) (tachycardia with regular RR-intervals, terminated by cardioversion) and ventricular fibrillation (VF) (fibrillatory R-waves according to intracardiac electrogram recordings, terminated with defibrillation). Death was categorized as due to congestive heart failure, sudden cardiac death or not cardiac.

Patients were divided in two groups, group A (secondary prevention; patients with either syncope suggestive of VT, documented VT or survivors of sudden death due to VF) and group B (primary prevention; no arrhythmias or only nonsustained VT during ambulatory electrocardiography). Subgroup analysis was done with further stratification in patients with LVEF below and above 20%.

At the end of the observation period reassessment of the LVEF by echocardiography was obtained in all patients who were still alive, did not undergo heart transplantation and had a follow-up of at least 12 months. An improvement of more than 15% in LVEF was considered relevant.

1.3. Statistical analysis

Continuous data are expressed as the mean value ± SD. The chi-square test was used to compare categorical data presented in Tables 2 and 3. Group comparisons of all continuous variables presented in Table 1 were calculated using unpaired Student's *t*-test. Survival curves were prepared according to the method of Kaplan–Meyer, and univariate survival distribution was compared by the log-rank test. For the Kaplan–Meyer curves drawn, patients were censored either at the time of the first adequate ICD interventions and/or at the time of death, if they did not have ICD interventions before. Statistical analysis was done with StatView software, version 5 (SAS). A p value of <0.05 was considered to be significant.

2. Results

Between December 1996 and March 2004 an ICD was implanted in 58 patients with DCM. Of these, 50 were male, and the mean age was 56.4 ± 12.7 years. Overall follow-up time was 34 ± 19 months. The clinical characteristics of the patients are shown in Table 1, stratified according to indication for ICD implantation in group A (secondary prevention) and B (primary prevention). The concomitant drug therapy of the patients is described in Table 2. Overall, therapy with beta-blockers at the time of ICD implantation was 78%. Apart from spironolactone therapy, with which significantly (p value 0.04) more patients were treated with in group B, there were no significant differences in medical therapy between groups. At the latest follow-up, 90% of patients were on beta-blockers and 98% on ACE-inhibitors/AT-II-antagonists.

Events during follow-up are depicted in Table 3. There was no significant difference regarding overall mortality. However, patients in group A had consistently more events than those in group B regarding any events (ICD interventions and/or death), any ICD intervention and ICD interventions for potentially life-threatening arrhythmias (p value <0.05).

Table 1
Clinical characteristics of patients

	Group A	Group B	p value
n	40	18	
Age (years)	58 ± 13	54 ± 11	0.3
Follow-up (months)	38 ± 20	25 ± 14	0.01
LVEF	0.27 ± 0.9	0.21 ± 0.7	0.01
EF < 0.20	35%	61%	0.06
Indication:			
VF	6	–	
VT	23	–	
Syncope	11	–	
NSVT*	–	18	

* Non-sustained VT.