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Differences in amiodarone efficacy in relation to ejection fraction and basal rhythm in patients with implantable cardioverter defibrillators

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ABSTRACT

Background: Atrial fibrillation (AF) and ventricular arrhythmias (VAs) are associated with increased morbidity and mortality. However, data are lacking concerning the association of AF and VAs. This study aimed to clarify the association between AF and VAs and to investigate the effect of amiodarone on the incidence of VAs in patients with implantable cardioverter defibrillators (ICDs).

Methods and results: We enrolled 612 patients who had ICDs or who underwent cardiac resynchronization therapy with a defibrillator (CRT-D) and classified them into two groups (sinus rhythm [SR] group, n = 427; AF group, n = 185) according to their basal rhythm at enrollment. Patients with paroxysmal AF were grouped into the AF group. The incidence of VAs, i.e., ventricular tachycardia (VT) and ventricular fibrillation (VF), was significantly lower in the AF group than in the SR group (0.54 vs 0.95 episodes/person/year, P = 0.032). Furthermore, amiodarone use was significantly higher in the AF group than in the SR group (P = 0.003). Non-use of amiodarone was associated with a significant increase in the occurrence of VT/VF in the two groups. This beneficial suppressive effect of amiodarone on the incidence of VT/VF was present in the AF group regardless of left ventricular ejection fraction (LVEF). However, this effect of amiodarone was present only in patients with LVEF ≥ 40% in the SR group.

Conclusions: Amiodarone was negatively associated with VT/VF occurrence and was frequently used in ICD/CRT-D patients with AF. VT/VF was controlled by amiodarone in all cases in the AF group but only in patients with an LVEF ≥ 40% in the SR group.

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Introduction

Implantable cardioverter defibrillators (ICDs) are widely recognized as effective devices for preventing sudden cardiac death from fatal arrhythmias [1,2]. Despite the effectiveness of ICD therapy, shock delivery may have a poor prognosis; thus, avoiding shock therapies is critical [3,4].

Atrial fibrillation (AF) is independently associated with an adverse prognosis in patients with an advanced age and structural heart disease [5–7]. About 20–25% of ICD patients have AF before the implantation and up to 50% may develop AF during the lifespan of the device [8]. Therefore, it is not surprising that atrial tachyarrhythmias, including AF and atrial tachycardia/flutter (AT/AF), are common in ICD patients [5]. ICD shocks, in particular, can have significant effects on the quality of life and disease-related morbidity and mortality. For instance, the Antiarrhythmics Versus Implantable Defibrillators (AVID) trial showed that AF is an independent predictor of mortality in ICD patients [9]. Moreover, AF may be related to hemodynamic impairment and the occurrence of ventricular arrhythmia (VA), i.e. ventricular tachycardia (VT) and ventricular fibrillation (VF) [10]. There are at least two pathophysiological factors which may help explain how AF can influence the recurrence rate of VT/VF episodes. First, the irregularity of RR intervals

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can cause short-long-short sequences, which immediately precede VT/VF episodes in up to a third of VT/VF episodes [11]. Second, AF can cause and be caused by hemodynamic deterioration, which is also a known risk factor for recurrences of VT/VF episodes [12]. It has been demonstrated that the termination of AT/AF significantly delays the occurrence of VT/VF. Amiodarone has been recognized as effective for both the termination of ongoing VAs, as well as for the prevention of recurrent VT/VF during electrical storms [13]. Furthermore, amiodarone has been proven to be effective in reducing AT/AF and inappropriate ICD therapies in patients with structural heart disease [12,13]. However, data are lacking concerning the association of AF and VAs. The objectives of this study were to clarify the association of AF and VAs and to determine the effect of amiodarone on the incidence of VAs in ICD patients.

Materials and methods

Study design

This study was a subanalysis of the Survey on AnTItachycardia pacing Strategy for the termination of FAst ventricular tachycardia in Japanese implantable Cardioverter defibrillator populaTION (SATISFACTION) trial [14]. The SATISFACTION trial was a prospective multicenter study of patients who had an ICD or received cardiac resynchronization therapy with a defibrillator (CRT-D) that had an antitachycardia pacing (ATP) function during capacitor charging (ATP During Charging; Medtronic, Minneapolis, MN, USA). We enrolled 760 patients from January 2009 to May 2011 and the analysis was conducted on 715 patients (45 patients were excluded because of loss to follow-up). All patients were followed up until November 2011 and were seen at least every 3 months and at least twice during the follow-up period. Patients who underwent ablation treatment for AF and VT were excluded from this study. Moreover, patients with atrial pacing were also excluded from this study because atrial pacing might suppress AF, and it was not sinus rhythm (SR). The patients were classified into two groups according to their basal rhythm: the SR and AF groups. AF was ascertained from ECG or Holter ECG records.

This study was approved by the institutional review board/medical ethics committee of each participating center and all patients provided signed informed consent before participation.

Device description and programming

All patients had an ICD or CRT-D equipped with the ATP During Charging function (Virtuoso VR, Virtuoso DR, Secura VR, Secura DR, and Concerto C154DWK and C174AWK; Medtronic). The tachyarrhythmia detection and therapy settings are described in Table 1. The definition of VT (cycle length [CL] > 320 ms), FVT (240 ms ≤ CL ≤ 320 ms), very FVT (vFVT; 200 ms ≤ CL < 240 ms), and VF (CL < 200 ms) first depended on the CL of the tachycardia detected by the ICD.

Statistical analysis

Continuous data are summarized as the mean ± SD and categorical data are expressed as the count and percentile. Pairwise group comparisons were tested using Student's *t*-test for continuous variables and Fisher's exact test or Cochran-Mantel-Haenszel test for categorical data. Device intracardiac electrogram episodes adjudicated as true VT (appropriate) by investigators were analyzed for the primary and secondary endpoints. The risk for VT with respect to the various predictive factors was evaluated based on the hazard ratio, which was the ratio of the episodes per person per year. Poisson regression models adjusted for overdispersion were used for univariate and multivariate analyses. For the multivariate analyses, the variables were selected using a purposeful selection method based on the stepwise elimination method with a selection criteria alpha value of 0.120. To estimate the episode rates, Poisson regression analysis adjusted for overdispersion was used. All tests were performed with a 5% type I error level. The statistical analyses were performed with the SAS software package (version 9.2) (SAS Institute, Cary, NC).

Table 1
Device programming.

Parameter	Programmed setting
Required programming detection	
VF DI	320 ms
VF NID	18/24
VF redetect NID	12/16
FVT detection	OFF
Prologic	ON (dual chamber only)
SVT -limit	320 ms (dual chamber only)
Therapy	
ATP during charging	ON
Deliver ATP last 8 R-R≥	200 ms
Amplitude	8 V
Pulse width	1.5 ms
Therapy type	Burst
Initial no. pulses	8
R-S1 interval = (%RR)	88%
Minimum ATP Interval	170 ms
Optimal programming detection	
FVT detection	ON-via VF
FVT DI	240 ms
Therapy	
Therapy type	Burst
Amplitude	8 V
Pulse width	1.5 ms
Initial no. pulses	8
R-S1 interval = (%RR)	88%

ATP, antitachycardia pacing; DI, detection interval; FVT, fast ventricular tachyarrhythmia; NID, no. intervals to detect; SVT, supraventricular tachyarrhythmia; VF, ventricular fibrillation.

Results

Baseline characteristics

The mean follow-up period was 11.3 ± 5.4 months. Of 715 patients, 103 were excluded because of atrial pacing. Among the 612 remaining patients, 427 were assigned to the SR group and 185 (paroxysmal AF: 111 patients; persistent/permanent AF: 74 patients) were assigned to the AF group (Fig. 1). The demographic and clinical data of the two groups are shown in Table 2. The patients in the SR group were younger than those in the AF group (63 ± 14 vs. 68 ± 10 years, P < 0.001). The patients in the SR group more frequently had a previous syncope than those in the AF group (54% vs. 42%, P < 0.001). The patients in the AF group more frequently had a previous heart failure than those in the SR group (67% vs. 44%, P < 0.001). There was no significant difference between the SR and AF groups regarding the percentage of beta-blocker use (69% vs. 74%, P = 0.249). In the AF group, amiodarone was more frequently used than in the SR group (48% vs. 35%, P = 0.003).

We compared the frequency of VT/VF in the SR and AF groups (Table 3). Patients in the AF group had a significantly lower frequency of VT/VF than the SR group (P = 0.032).

We compared the VT/VF frequency according to the ejection fraction and amiodarone administration in the SR and AF group. In the SR group, VT/VF was controlled by amiodarone only in the group with an LVEF ≥ 40% (P < 0.001) (Table 4). However, in the AF group, VT/VF was controlled by amiodarone both in the group with an LVEF < 40% (P = 0.016) and in that with an LVEF ≥ 40% (P = 0.049) (Table 5).

The univariate and multivariate analyses of VT/VF risk in the SR group are shown in Table 6. In the multivariate regression analysis, the clinical characteristics associated with an increased risk for VT/VF in the SR group were the male sex (P < 0.001), absence of ischemia (P < 0.001), New York Heart Association (NYHA) classification (P =

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