Dual-Chamber Implantable Cardioverter-Defibrillator

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Summary

The presented paper reports on the clinical experience with the PHYLAX AV (BIOTRONIK). The device offers SVT/VT discrimination, DDD pacing, and the full range of atrial and ventricular therapy. The PHYLAX AV ICD (BIOTRONIK) was tested and implanted in 10 patients (2 female, 8 male). During a follow-up period of 4 to 19 months (13.3±4.6 months) 84 episodes of SVT and VF/Vf were observed. Using a novel algorithm (SMART™, BIOTRONIK), AF/Af was discriminated from VT with 100 % specificity. Intraoperative results with atrial defibrillation using a coronary sinus shock coil are promising with respect to a fully automated device for dual chamber antitachycardiac

Key Words

Automatic implantable cardioverter-defibrillator (ICD), dual-chamber electrotherapy, ventricular (VT) and supraventricular tachyarrhythmia (SVT) discrimination

Introduction

The implantable cardioverter-defibrillator (ICD) presents new therapy options for patients with stable VT and SCD (sudden cardiac death) episodes (ventricular fibrillation (VF) or flutter (Vf)) unresponsive to conventional antiarrhythmic therapy. Current research spanning follow-up periods of 1 to 3 years shows that such VT and SD patients possess a 20 to 25% improved chance of survival after ICD implantation. Survival rates also increase with higher left ventricular ejection fractions [1][2]. In addition to adequately terminating VT and/or of life-threatening ventricular arrhythmias, the ability to discriminate between SVT, Af, and AF is a profoundly pertinent medical requirement in treating tachycardia patients. According to intracardiac electrogram (IEGM) data collected during electrotherapy, 15 to 40% of all patients require differentiating tachyarrhythmia diagnostics so that inappropriate shocks are avoided during SVT and AF episodes. Clinical needs defining the tasks for the next generation of ICDs are shown in Table 1.

The clinical data cited above leave no doubt of the necessity for the 5th generation dual-chamber ICD. By design, the dual-chamber ICD can administer DDD and DDDR mode physiologic pacing and multifunctional dual-chamber electrotherapy (ATP, cardioversion, defibrillation). With both atrial and ventricular sensors, the algorithm of the device can also discriminate between SVT and VT. The added atrial feature affords AF prevention by atrial and/or biatrial pacing; atrial ATP for the termination of re-entry SVT and Af, and atrial cardioversion and defibrillation in cases of Af/AF. The inclusion of both chambers eliminates the proarrhythmic effects (i.e., ventricular arrhythmia) possible with a defibrillator that is solely atrial. The vanguard dual-chamber ICD combines this range of therapy options with subpectoral implantation and an active housing configuration.

Additional Therapy Options	Rate of Demand
DDD pacing	10% to 42%
SVT/VT discrimination	34% ± 13%
AAI pacing and/or bi-atrial pacing for AF prevention	16% to 56%
Dual-chamber electrotherapy (ATP, cardioversion, defibrillation)	10% to 35%

Table 1. Clinical basis for dual-chamber ICDs.

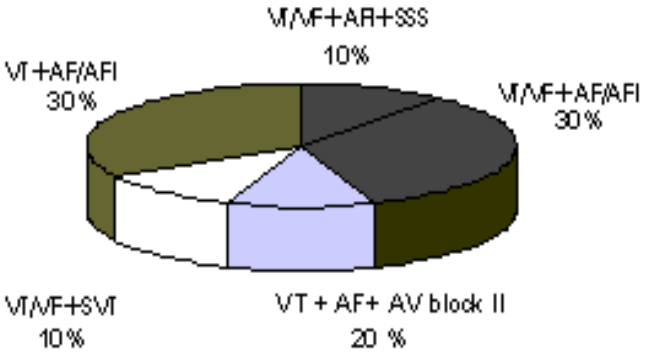

Figure 1. Distribution of arrhythmia types in patients who received the dual-chamber PHYLAX AV ICD.

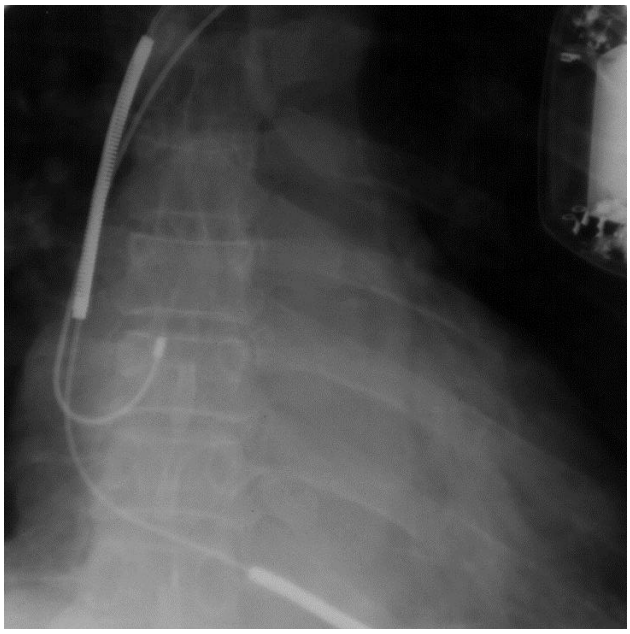

Figure 2. Standard electrode configuration of the sub pectorally implanted PHYLAX AV.

Material and Methods

From April 1996 to July 1997, the dual-chamber PHYLAX AV (BIOTRONIK) ICD was tested and implanted in 10 patients (8 male, 2 female) ranging from 31 to 68 years of age (mean 50.8 ± 10.6 years). The postoperative follow-up period lasted 4 to 19 months (mean 13.3 ± 4.6 months).

Table 2 illustrates the clinical characteristics of the patients who underwent PHYLAX AV implantation.

The distribution of the patients' arrhythmia types is presented in Figure 1, as revealed by invasive and non-invasive diagnostics.

The PHYLAX AV, with a mass of only 109 g and a volume of 69 cm^3 (76 x63 x17 mm), is the world's first subpectorally implanted 5th generation ICD. It offers DDD pacing with automatic mode switching and atrial and ventricular 8-min IEGM Holter monitoring. The ICD service life is estimated to be 4 to 5 years, depending on the pacing mode and the delivered antitachy-

#	Age/ Gender	Implantation Date (month/year)	VT Cycle Length (ms)	VF	SVT Type (cycle length in ms)	Cardiac Pathology	LVEF (%)
1	33/m	04/96	350-270	+	Atrial tachycardia (380-330)	ARVD	55
2	31/m	04/96	330-290	+	Af (240)	DCMP	20
3	63/m	06/96	400-280	-	Af/AF (480)	CAD	20
4	43/m	06/96	330-280	-	Af (480-240)	ARVD	58
5	68/m	06/96	500-350	+	AF (480)	CAD	30
6	51/f	09/96	330 (irreg.)	-	Af/AF (500-250)	AHF	40
7	59/f	01/97	400-330	+	Af, SSS, second-degree AV block	ARVD	43
8	44/f	03/97	440-270	+	Af (440)	ARVD	50
9	55/m	03/97	450-360	-	AF (500), first- to second-degree AV block	CAD	17
10	62/m	07/97	400-300	-	AF (400), first- to second-degree AV block	CAD	25

Table 2. Patient data implanted with PHYLAX AV (m - male, f - female, ARVD - arrhythmogenic right ventricular dysplasia, DCMP - dilated cardiomyopathy, CAD - coronary artery disease, AHF - acquired heart failure).

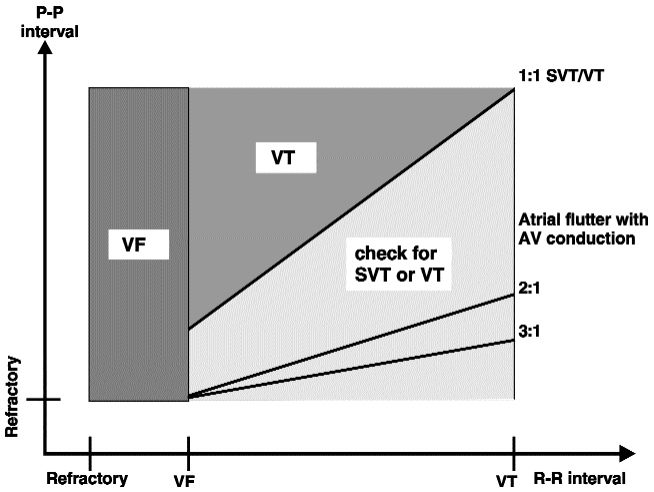

Figure 3. Detection zones of the SMART™ algorithm in classifying heart rhythms on the basis of both P-P and R-R intervals for SVT, VT, and VF discrimination.

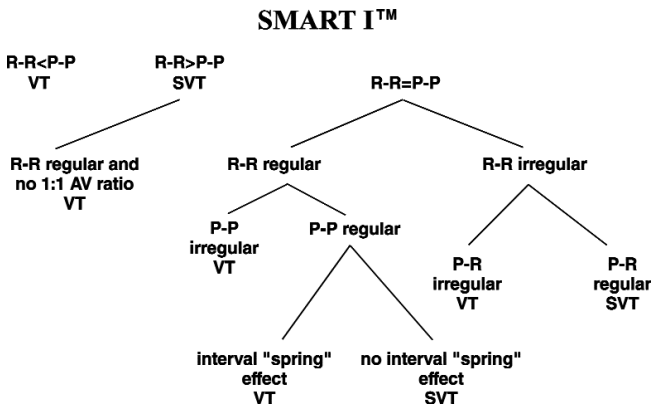

Figure 4. Diagram of the SMART™ algorithm based on the analysis of the R-P, P-P and P-R intervals.

cardia therapy. The PHYLAX AV possesses the same basic technical premise of the PHYLAX 06 in regard to VT/VF detection and therapy [3][4]. The device is implanted with a bipolar atrial electrode (with active or passive fixation) for pacing and IEGM recording. The standard electrode configuration for dual-chamber implantation is illustrated in Figure 2.

Six of the 10 patients had passively fixated electrodes implanted in the atrium, while the remaining 4 patients had electrodes actively fixated. The SL-ICD electrode (BIOTRONIK) with atrial and ventricular shock coils was used in 6 patients. The SPS electrode (BIOTRONIK) with one distal shock coil was used in 4 patients. Atrial and ventricular signal amplitudes were measured in all 10 patients during sinus rhythm and after SVT and VT induction. The atrial defibrillation threshold (DFT) during stable Af/AF and the ventricular DFT were measured conventionally. During the atrial measurement, the electrode was placed in the coronary sinus position. A permanent lead placement in this position has not yet been attempted however. During the ventricular DFT measurement, the PHYLAX AV active housing served either as an anode or cathode.

The device algorithm, SMART™, differentiates between SVT and VT episodes (Figures 3 and 4). The algorithm is based on the analysis of the P-P, R-R, and P-R intervals and their respective ratios. If the atrial rate exceeds the ventricular rate and the R-R interval duration is not within the VF zone, the arrhythmia is considered an SVT [4].

Algorithm sensitivity and specificity have been tested in the clinic and with 67 patient files from the Ann Arbor electrogram database (Table 3).

Arrhythmia	Sensitivity	Specificity
VT/VF	100%	100%
SVT	100%	95%
VT/VF+SVT/AF	92%	100%

Table 3. Results of the SMART™ algorithm testing.

Results

The implantation time necessary for 3 electrodes (i.e. in the coronary sinus (SPS), the right ventricle (SL-ICD), and the right atrium (SYNOX or Y 53-BP, all BIOTRONIK)) and the main testing was 120 ± 35 min on average. No complications were observed during PHYLAX AV implantations.

Mean values of the PHYLAX AV defibrillation thresholds and sensing amplitudes determined in the 10 patients are listed in Table 4.

Seven patients required dual-chamber pacing due to

Ventricular DFT (RV-RA-ICD electrode configuration)	8.5±3.8 J
Atrial DFT (RA-CS-ICD electrode configuration)	1.2±0.3 J
R-wave amplitude	14.5±5.2 mV
P-wave amplitude	3.2±1.7 mV

Table 4. Clinical data of PHYLAX AV tests in 10 patients (RV-right ventricle, RA-right atrium, CS-coronary sinus).

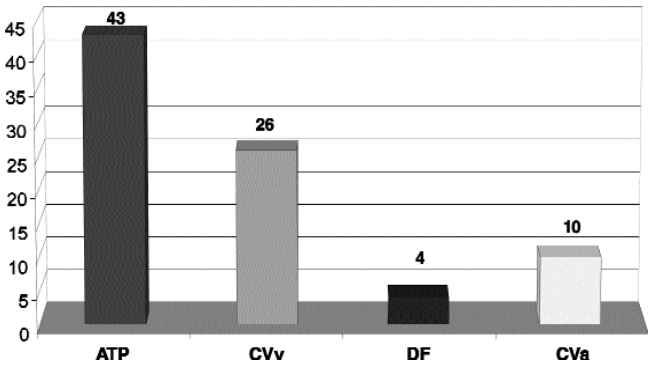

Figure 5. Incidence of different modes of dual-chamber electrotherapy performed after PHYLAX AV implantation during the 4- to 19-month follow-up periods (CVv - ventricular cardioversion, CVa - atrial cardioversion, DF - ventricular defibrillation).

bradyarrhythmia episodes or AV conduction disturbances. In preventing frequent VT attacks, antiarrhythmic drugs (cordaron 250-300 mg/day) were prescribed to 70 % of the patients during the postoperative period. Endocardiac defibrillation was performed for 10 episodes of Af/AF. In discriminating Af/AF from VT, SMART™ was proven to possess 100% specificity by the PHYLAX AV testing results and Holter IEGM analysis. Patients with life-threatening ventricular arrhythmia and bradyarrhythmia benefited from DDD pacing.

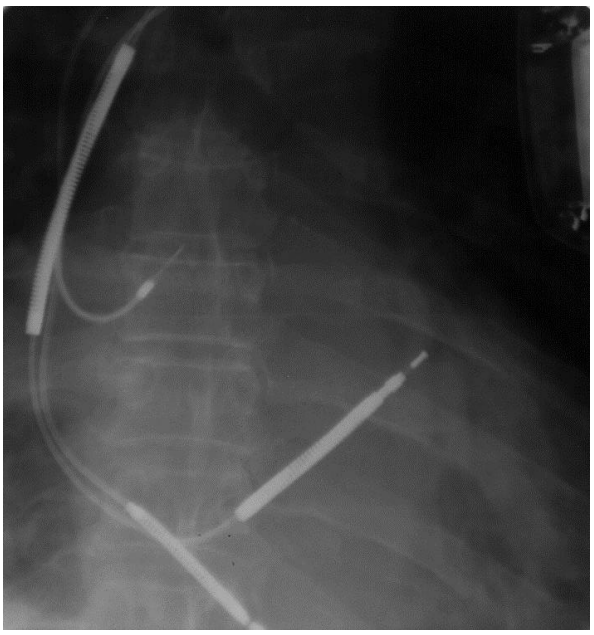

Figure 6. X-ray diagram of the 3-electrode shock configuration used to measure the atrial DFT intraoperatively.

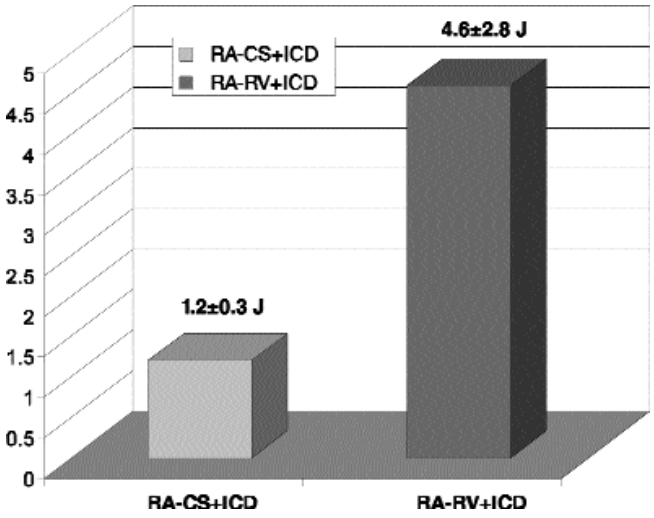

Figure 7. Atrial DFT testing results with different lead configurations and the ICD active housing (RA - right atrium, CS - coronary sinus, RV - right ventricle).

During the 4- to 19-month follow-up period, 83 electrotherapy episodes due to SVT and Vf/VF were observed (Figure 5).

Figures 6 and 7 demonstrate the significance of coronary sinus electrode placement to obtain lower energy atrial defibrillation for terminating induced and stable AF. The atrial DFT was reduced from 4.6 ± 2.8 J to 1.2 ± 0.3 J ($p < 0.025$) in this position as compared to atrial electrode placement. Atrial fibrillation and flutter were either induced or occurred spontaneously during the implantation procedure. The DFT was determined within 5 min after the onset of Af/AF.

The case of efficacy for the coronary sinus electrode is well taken in patient 6 from Table 2. Atrial cardioversion was performed in this patient, who suffered from Af/AF and irregular VT. When the lead was placed in the coronary sinus, a 1-J shock was sufficient to terminate the Af/AF episode. Figure 8 illustrates atrial and ventricular IEGMs interrogated from the implanted ICD storage memory. Without the coronary sinus electrode, the atrial DFT rose only a 15-J shock led to successful termination.

Perspectives and Future Applications of Dual-chamber ICDs

A dual-chamber ICD with DDD capabilities and also bi-atrial pacing will benefit the great number of patients who require differentiating tachyarrhythmia diagnostics in the therapy.

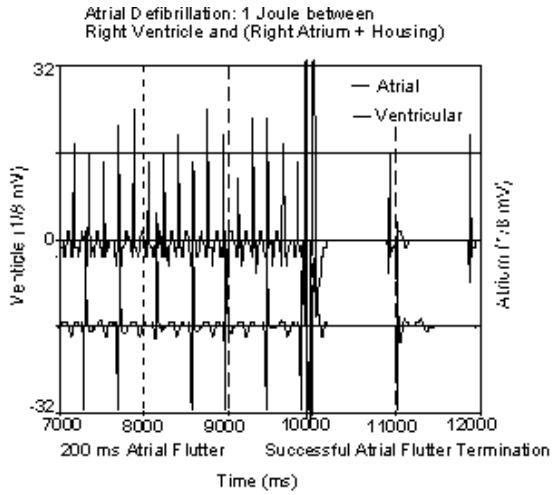

Figure 8. Atrial and ventricular IEGMs record effective termination of Af/AF by a 1-J shock with the coronary sinus electrode during the ICD test in patient 6.

Applying a coronary sinus electrode or a patch electrode implanted at the left atrium via the minimally invasive thoracoscopic approach, as well as fractal coated and/or floating electrodes, will provide lower atrial DFTs and a reduction in the number of endocardial leads. Although these designs are still mostly of a theoretical and experimental kind, the modern state of research is now close to solve the problem: to develop a fully automatic device capable of reanimating a patient after a total cardiocirculatory collapse. Furthermore, automatic electrotherapy of tachyarrhythmias will indubitably be of great value in preventing and treating forms of re-entry tachycardia.

The significant progress in ICD development and the highly increased ICD efficiency in preventing sudden arrhythmic death do not undermine the prerogative of the physician in deciding on a method for eliminating arrhythmias. Multi-component or "hybrid" therapies are possible, combining antitachycardia pacing, catheter ablation, tachyarrhythmia surgery, and/or dual-chamber ICD implantation.

References

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