Clinical Results with the Dual-Chamber Cardioverter Defibrillator Phylax AV - Efficacy of the SMART I Discrimination Algorithm

B. MERKELY
Semmelweis University, Dept. of Cardiovascular Surgery, Budapest, Hungary

J. WITTE
Humboldt University, Charité, Dept. of Medicine, Berlin, Germany

Summary

Dual-chamber ICD therapy has several advantages over single-chamber ICDs, namely the positive hemodynamic effects of atrioventricular pacing, the possibility of atrioventricular discrimination, diagnostic capabilities, a decrease of inappropriate patient treatment, and the prevention of atrial tachyarrhythmias. Starting from April 1997, 52 patients (age: 56.8 ± 10.8 years, ejection fraction: 29.0 ± 7.9 %, NYHA: 2.8 ± 0.6) received a dual-chamber ICD (Phylax AV, Biotronik, Germany). Patient history revealed an ejection fraction < 35 % in 46 cases, bradycardia in 19 cases, paroxysmal atrial tachyarrhythmia in 10 cases and slow ventricular tachycardia (< 150/min) in 10 instances. The underlying diseases were coronary heart disease (30 patients), dilative and hypertrophic cardiomyopathy (22 patients). Indications were: prophylactic (8), sustained ventricular tachycardia (29), ventricular fibrillation or tachycardia with sudden cardiac death (15). Mean implantation time was 71.0 ± 12.2 minutes. Postoperative atrial electrode dislodgement was observed in 3 cases. Over the follow-up period (13.9 ± 8.1 months), 55 episodes of spontaneous ventricular fibrillation and 594 episodes of ventricular tachycardia were noted. These were terminated by cardioversion-defibrillation in 252 cases and by antitachycardia stimulation in 397 instances. Antitachycardia stimulation was effective in 88 % and cardioversion in 100 %. The analysis of the IEGM records revealed a VA dissociation in 85 %, partial retrograde conduction in 11 %, and 1:1 VA conduction in 5 % of the spontaneous ventricular tachycardias. Effective atrioventricular discrimination was observed in 74 cases. Inappropriate shocks were delivered in only 2 cases using the SMART™ discrimination algorithm because of atrial fibrillation. 30 patients were found to improve in NYHA class due to the echocardiographic AV-delay optimization. Dual-chamber ICDs provide optimal AV pacing, sensing and discrimination, and improve the efficacy of the ICD therapy.

Key Words

Implantable cardioverter defibrillator therapy, dual chamber

Introduction

The recently approved single-chamber ICDs provide reliable endocardial detection and termination of ventricular tachyarrhythmias (VT). However, data obtained from anamneses, stored intracardiac electrograms and Holter recordings of ICD patients showed about 25 % of the detected events to be supraventricular tachycardias (SVT) and, thus, treated inadequately [5]. These inadequate therapies are not only ineffective but may also induce new episodes of ventricular tachyarrhythmias. Thus, the challenge is to decrease or eliminate these therapies which burden the patients and increase the potential of ventricular-arrhythmia occurrence.

In order to further improve safety and efficacy of this device, the new fifth generation of implantable cardioverter/defibrillators are able to sense, pace and defibrillate both in the atria and in the ventricles. Thanks to an additional atrial electrode, these DDD-

devices are able to discriminate and treat ventricular and supraventricular tachyarrhythmias [8,9].
This article presents the clinical experience of two centers with an ICD, equipped with a dual-chamber pacing function, capable of dual-chamber detection for arrhythmia diagnosis.

Materials and Methods

Subjects
Fifty-two patients (mean age: 56.8 ± 10.8 years, ejection fraction: 29.0 ± 7.9 %, NYHA class: 2.8 ± 0.6.) implanted with a dual-chamber ICD (Phylax AV, Biotronik, Germany) at Semmelweis University, Dept. of Cardiovascular Surgery, Budapest, Hungary and Humboldt University, Charité, Dept. of Medicine, Berlin, Germany had been observed since January 1998. 9 patients (17 %) were in NYHA class II, 40 (77 %) in class III, and 3 patients (6 %) in class IV. Coronary artery disease was diagnosed in 30 cases, dilatative cardiomyopathy in 19 cases, and hypertrophic cardiomyopathy in 3 patients (pts). Patient history revealed an ejection fraction lower than 35 % in 46 cases, bradycardia in 19 cases, paroxysmal atrial tachyarrhythmia in 10 cases and slow VT (< 150/min) in 10 instances. Indications were: prophylactic (8 patients), sustained ventricular tachycardia (29 patients), ventricular fibrillation (VF) or tachycardia with sudden cardiac death (15 pts). According to the electrophysiological data and Holter information, atrial fibrillation, flutter or sinus tachycardia and sustained ventricular tachycardia resulted in identical ventricular rates in 20 pts. Only 2 pts had 1:1 retrograde conduction during slow VT and 14 pts had 1:1 retrograde conduction during 150/min ventricular stimulation.

ICD Implantation
The implantations were performed under local anesthesia using the tripolar Kainox RV shock electrode without any additional leads. The shock electrode was inserted into the left cephalic or subclavian vein and the Phylax AV was placed into a left intraclavicular pocket. Twenty-seven patients received active fixation J-shaped leads (Retrox J BP). The other 25 patients were implanted with passive fixation leads (Synox or Polyrox J BP, all Biotronik, Germany). Active fixation leads were mostly used in cases after coronary bypass surgery and in case the passive lead had no stable position in the right appendage.
DFT and device testing was performed under short acting intravenous general anesthesia. Minimal implantation criteria required two successful consecutive conversions of ventricular fibrillation using 20 Joules or less.
Doppler-mitral inflow, aortic outflow velocity were used to determine the optimal AV delay. The programming was controlled by Quality-of-Life questionnaires on cardiovascular symptoms (chest pain, dyspnea, physical capacity, dizziness, palpitations) or self-perceived health (well-being, mood and sleep disturbances).

SMART™ AV-discrimination Algorithm
The arrhythmia detection with the SMART is based on the examination of P-P-, P-R- and R-R-intervals extracted from the dual-chamber IEGM. Approximately 2,500 P-P and R-R intervals, about 16 minutes of dual-chamber electrogram, can be stored. The SMART detection algorithm investigates the average ventricular and atrial rate, the stability and onset of the atrial and ventricular rate, and the multiplicity of atrial compared to ventricular rate. The regularity and the monotonic change of P-R intervals are also included in the algorithm. Only ventricular arrhythmias are treated automatically.
As always, VF detection is top priority. Two VT and 1 VF zones are distinguished. Concerning lower ventricular rates, the main assumption of SMART is that the heart chamber with the higher rate is the source of the tachyarrhythmia. In this case, the discrimination algo-

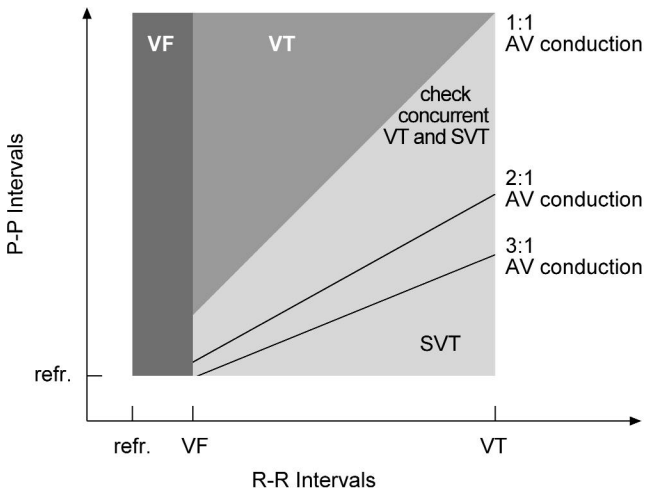

Figure 1. The basic detection strategy of SMART™ algorithm.

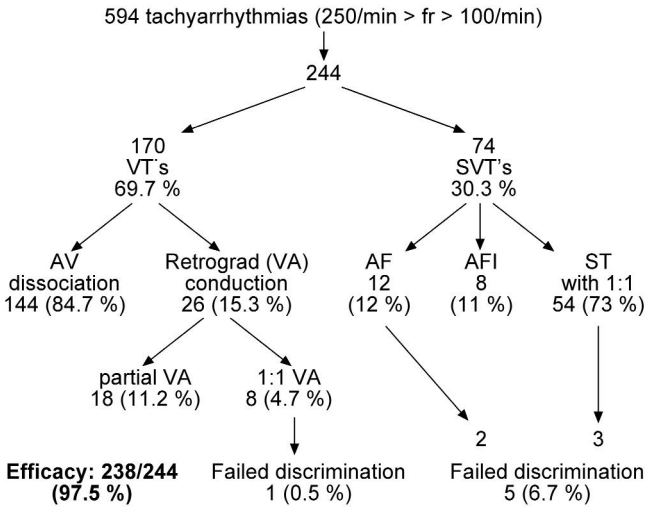

Figure 2. Analysis of IEGM data of 52 patients.

rithm is applied in two different zones (Figure 1):

- A VT is declared and appropriate therapy initiated if the ventricular rate in the VT-zone exceeds the atrial rate.
- An SVT is detected when the atrial rate is faster than the ventricular rate. However, concurrent VT episodes might occur beside the SVT or as a result of the SVT. Thus, while in general ventricular therapy is withheld, constant monitoring of the ventricular rhythm is carried out in order to detect the occurrence of VTs. This is the case for atrial flutter with 2:1 or 3:1 conduction block. The requirements are stable rates and an integer ratio relationship between both rates.
- Further tests are required to detect the source of the tachyarrhythmia when rates in the atria and ventricles are identical. In this case, rate and P-R interval stability and sudden onset criteria can discriminate between sinus tachycardia, AV nodal tachycardia, low rate atrial tachycardia with 1:1 conduction rate, and VT with retrograde conduction. In case of 1:1 AV-ratio, the ICD can also differentiate by giving a

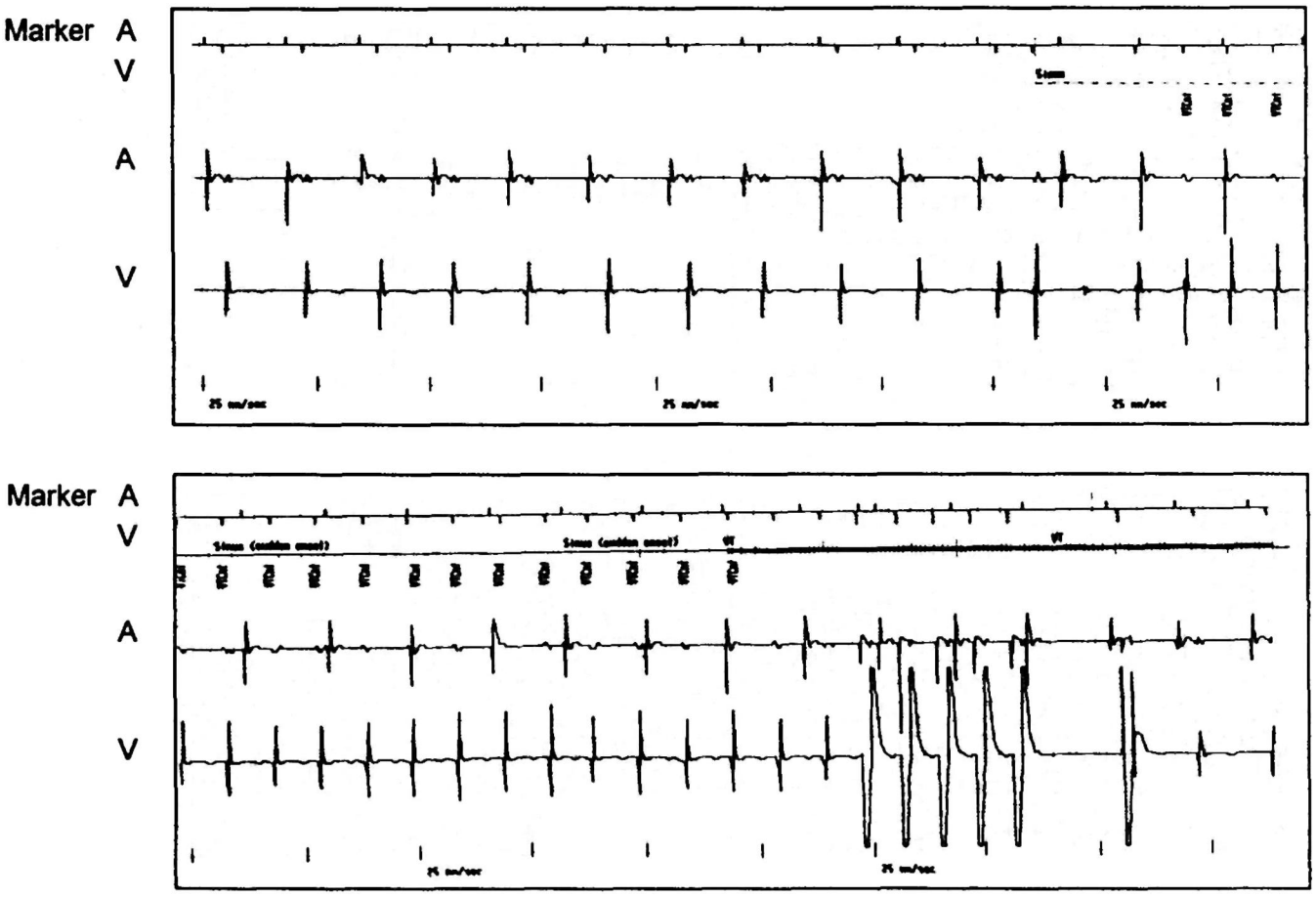

Figure 3. VT with VES-induced VA-dissociation and effective ATP therapy.

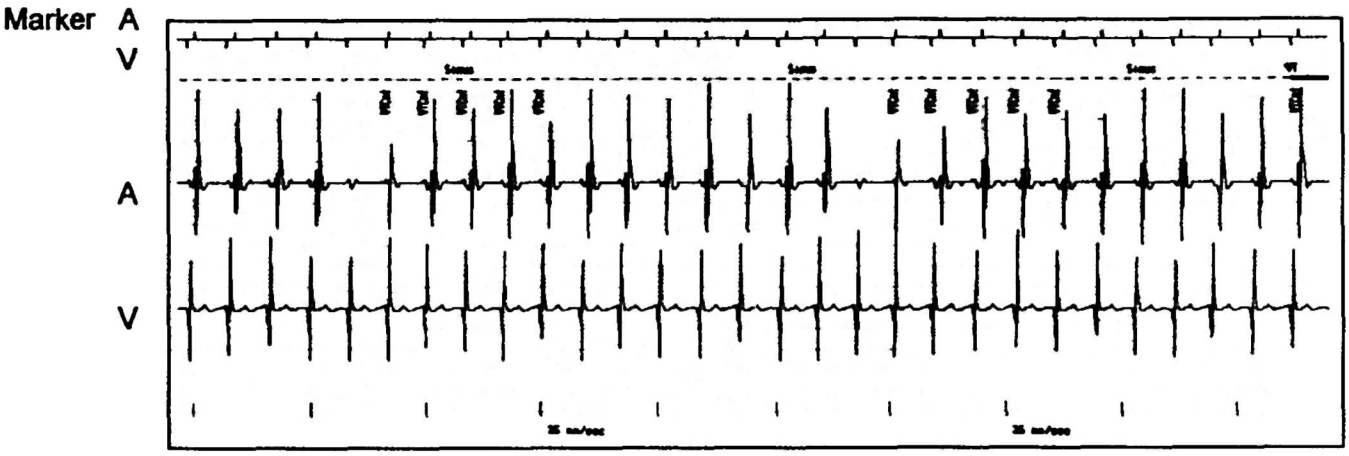

Figure 4. VT (170/min) with 1:1 and Wenckebach type VA conduction. The device detected the VT correctly.

premature ventricular stimulus. The premature ventricular stimulus does not change the PP-intervals during sinus tachycardia, but influences them during VT with retrograde conduction.

If necessary, the Phylax AV provides full DDD bradycardia support with automatic mode conversion.

Results

Mean implantation time was 71.0 ± 12.2 min. Postoperative atrial electrode dislodgment was observed in 3 cases.

30 patients were found to improve in NYHA class due to the individual echocardiographic AV-delay optimization after the ICD implantation. At the time of the last outpatient clinic visit, 37 patients (71.1 %) were in NYHA class II, 12 patients (23.1 %) in NYHA class III, and 3 patients (5.8 %) in NYHA class IV. Only 2 patients suffered from an increased degree of heart failure after implant.

Arrhythmias

Over the follow-up period (13.9 ± 8.1 months), 55 episodes of VF occurred spontaneously and 594 episodes of VT were noted (Figure 2). These were terminated by cardioversion-defibrillation in 252 cases and by antitachycardia stimulation (ATS) in 397 instances. ATS was effective in 88 % and cardiover-

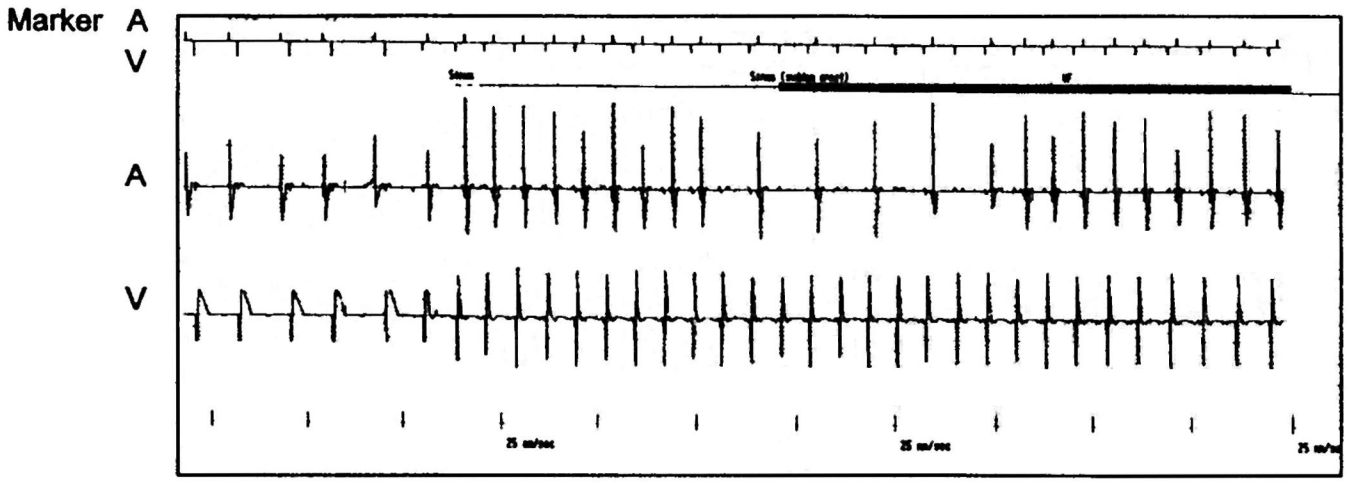

Figure 5. VT (200/min) with 1:1 - 2:1 - 1:1 retrograde conduction. While 1:1 conduction occurred, the device inappropriately detected supraventricular arrhythmia. When this ratio changed to 2:1 (proving the ventricular origin of the arrhythmia), the diagnosis was revised.

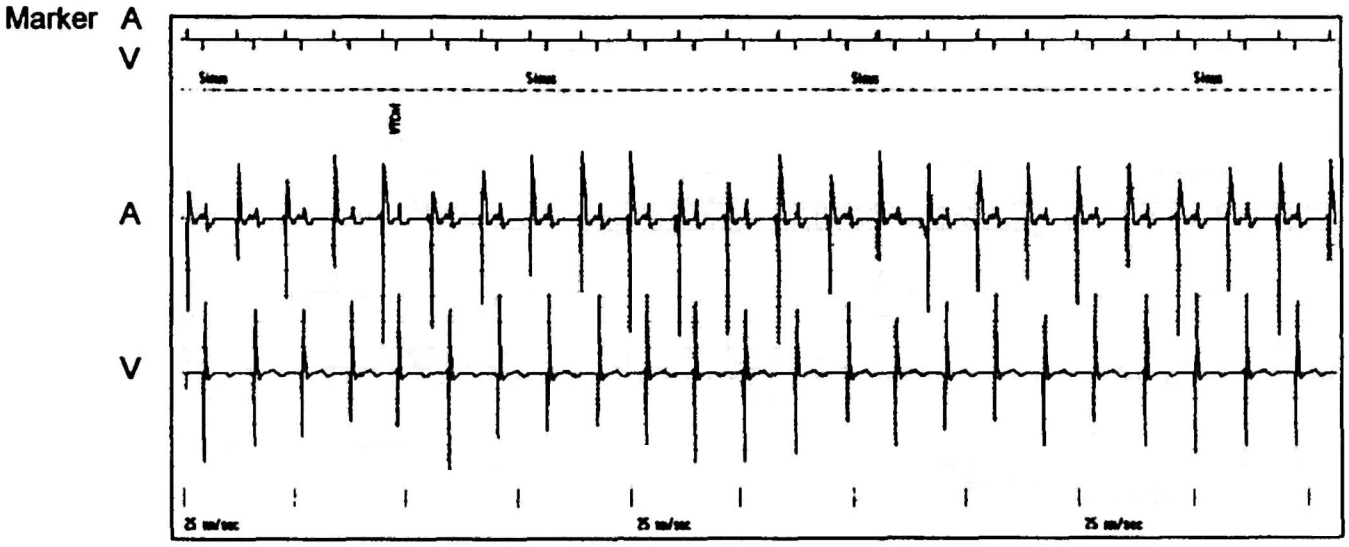

Figure 6. Sinus tachycardia (140/min) with 1:1 AV conduction. Due to the appropriate discrimination, no ventricular therapy was given.

sion in 100 %. The analysis of 244 IEGM records (170 VTs and 74 SVTs) revealed a VA dissociation (Figure 3) in 85 % of the spontaneous VTs, partial retrograde conduction in 11 % and 1:1 VA conduction (Figure 4, Figure 5) in 5 % (Figure 2).

Effective AV discrimination deduced from Holter records and stored SMART IEGM have been observed in 74 cases (54 sinus tachycardia, 12 atrial fibrillation and 8 atrial flutter). Figure 6 shows appropriate discrimination of a sinus tachycardia with 1:1 conduction. Figure 7 shows appropriate therapy due to the simultaneous occurrence of atrial fibrillation and VT. Following the termination of the VT, the atrial fibrillation continued and no inappropriate shocks were delivered. Inappropriate shocks were delivered only in 5 cases because of atrial fibrillation or sinus tachycardia (Figure 2). Due to failed discrimination, 1 VT was not treated but spontaneously terminated. The efficacy of

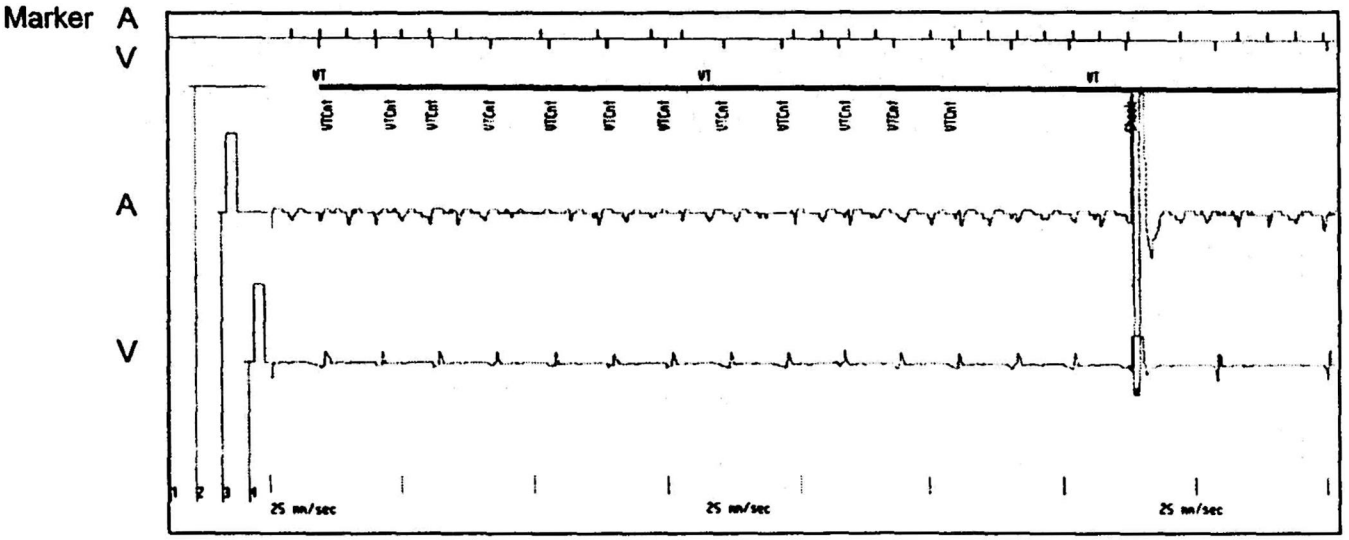

Figure 7. Simultaneous occurrence of atrial fibrillation and a VT (140/min). The therapy terminated VT while atrial fibrillation continued.

the Phylax AV proved to be 97.5 %, specificity (97.1 %) and sensitivity (99.4 %) of the discrimination were high.
46 patients (82 %) needed DDD or VDD bradycardia support or AV-delay optimization due to sick sinus syndrome or I to III degree of AV-block or intraventricular conduction block.

Discussion

Our results show that dual-chamber ICDs provide optimal AV pacing, sensing and discrimination, thus, further improving the efficacy of ICD therapy. The main advantages of dual-chamber ICD therapy over single-chamber ICDs are the possibility of AV discrimination, AV diagnostic capabilities, a decrease of inappropriate patient treatment, the prevention of atrial and ventricular tachyarrhythmias, and the positive hemodynamic effects of AV pacing.
The specificity and sensitivity of the discrimination with the SMART algorithm proved to be high. However, the case of a 1:1 ratio of atrial and ventricular rate is still a problem. With any passive discrimination algorithm, a success rate of 100 % will never be achieved. Thus, using an active discrimination algorithm with stimulation in the ventricle might bridge this gap.
The preservation of atrioventricular synchronization may have a positive effect on morbidity and possibly even on the mortality of patients with depressed left ventricular function. AV-pacing has also proved to have positive effects on patients with bradycardia and congestive or hypertrophic cardiomyopathy [2,4,6]. Patients with dilated cardiomyopathy, severe mitral regurgitation, and prolonged atrioventricular conduction, and patients with hypertrophic obstructive cardiomyopathy may significantly benefit from DDD pacing with an individual short atrioventricular interval [6,7]. Approximately 11 % of ICD patients require concomitant pacing for sinoatrial or atrioventricular conduction disturbances [3]. Drug induced sinus bradycardia is a common finding in ICD patients requiring additional pharmacological therapy. Even these patients may benefit from dual-chamber pacing. But the true incidence of the need for additional pacing in ICD patients is still unknown.
Dual-chamber pacing may also prevent supraventricular tachyarrhythmias, particularly atrial fibrillation, resulting in inappropriate ICD shocks. Data from prospective and retrospective studies have suggested that atrial pacing was associated with less atrial fibrillation and thromboembolic events than VVI pacing [1]. In addition, pacing with slightly higher rates than the spontaneous rhythm may suppress the initiation of VT and VF by decreasing the number of premature beats and short-long-short periods that trigger arrhythmia. This has been demonstrated in VVI pacing. Dual-chamber pacing may be even more effective for a variety of arrhythmias. However, future studies comparing conventional ICDs and dual-chamber ICDs will be necessary to prove these questions.

References

[1] Andersen HR, Nielsen JC, Thomsen PE, et al. Long-term follow-up of patients from a randomised trial of atrial versus ventricular pacing for sick-sinus syndrome. Lancet. 1997; 350(9086): 1210-1216.

[2] Auricchio A, Salo RW. Acute hemodynamic improvement by pacing in patients with severe congestive heart failure. PACE. 1997; 20: 313-324.

[3] Epstein AE, Kay GN, Plumb VJ. Combined automatic implantable cardioverter-defibrillator and pacemaker systems: implantation techniques and follow-up. J Am Coll Cardiol. 1989; 3: 121-131.

[4] Neuberger HR, Mewis C, Dornberger V. Implantation of a dual chamber pacemaker-defibrillator (DDD-ICD) in a patient with hypertrophic obstructive cardiomyopathy. Z Kardiol. 1999; 88: 521-525.

[5] Maloney J, Masterson M, Khoury D, et al. Clinical performance of the implantable cardioverter defibrillator: electrocardiographic documentation of 101 spontaneous discharges. PACE. 1991; 14: 280-285.

[6] Romano S, Pagani M, et al. Which patients with dilated cardiomyopathy may really benefit from dual-chamber pacing? In: Cardiac Arrhythmias. Springer, Milano, 1997.

[7] Rossi R, Muia N, Turco V, et al. Short atrioventricular delay reduces the degree of mitral regurgitation in patients with a sequential dual-chamber pacemaker. Am J Cardiol. 1997; 80: 901-905.

[8] Schaumann A. Managing atrial tachyarrhythmias in patients with implantable cardioverter defibrillators. Am J Cardiol. 1999; 83(5B): 214D-217D.

[9] Trappe HJ, Achtelik M, Pfitzner P, et al. Single-chamber versus dual-chamber implantable cardioverter defibrillators: indications and clinical results. Am J Cardiol. 1999; 83(5B): 8D-16D.