The VDD Electrode for Dual-Chamber ICD Systems:
A Breakthrough in Discrimination Between Supraventricular and Ventricular Tachyarrhythmias in Single-Lead ICDs

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Summary

Detection of atrial signals improves the accuracy in identifying supraventricular tachyarrhythmias, to prevent inappropriate therapies in patients with implantable cardioverter defibrillators (ICDs). Since difficulties were found in dual chamber ICD systems with two leads, we designed a single-pass VDD lead for use with dual-chamber ICDs. The new single-lead dual-chamber ICD system was tested in ten patients in the acute phase. This system consists of a single-coil VDD lead with two additional sensing rings (15 mm spacing) for the atrium, connected to a Tachos MSV^{VDD} ICD. Atrial and ventricular signals were recorded during sinus rhythm, atrial flutter, atrial fibrillation and ventricular tachycardia or ventricular fibrillation. Terminations of ventricular arrhythmias were performed by internal DC-shock. The implantation of the lead was successful in all patients. Mean atrial pacing threshold was 2.9 ± 1.67 V at 0.5 ms, mean atrial impedance was 253 ± 25 W. The atrial amplitudes were greater during sinus rhythm (6.0 ± 0.72 mV) than during atrial flutter (2.6 ± 0.32 mV) or atrial fibrillation (0.62 ± 0.27 mV). During ventricular fibrillation atrial "sinus" signals had significantly lower amplitudes than during sinus rhythm (1.83 ± 0.22 mV). Mean ventricular sensing was 11.9 ± 3.9 mV, mean ventricular pacing impedance was 576 ± 63 W. Defibrillation was successful in all cases with a 20 J shock. 100 % of P-waves could be detected in sinus rhythm. During atrial flutter 99.8 % ± 0.4 % of flutter waves could be detected. Even during atrial fibrillation 91.5 % ± 4.3 % of atrial signals could be detected by the new Tachos MSV^{VDD} system. In conclusion the new single-lead dual-chamber ICD system provides stable detection of atrial and ventricular signals not only during sinus rhythm and atrial flutter but also during atrial fibrillation.

Key Words

Atrial tachyarrhythmia, VDD system, single-lead electrode, implantable cardioverter defibrillator, sensing amplitudes

Introduction

Detection of supraventricular arrhythmias is the predominant reason for inappropriate therapies of implantable cardioverter-defibrillators (ICDs). Single-chamber ICD systems use the ventricular rate criterion for decision to deliver therapy. While these devices provide high sensitivity, a lack of specificity in the detection of supraventricular and ventricular tachycardias (VT) using only the rate criterion in combination with the stability or sudden onset criterion has been demonstrated. This leads to an inappropriate electrical
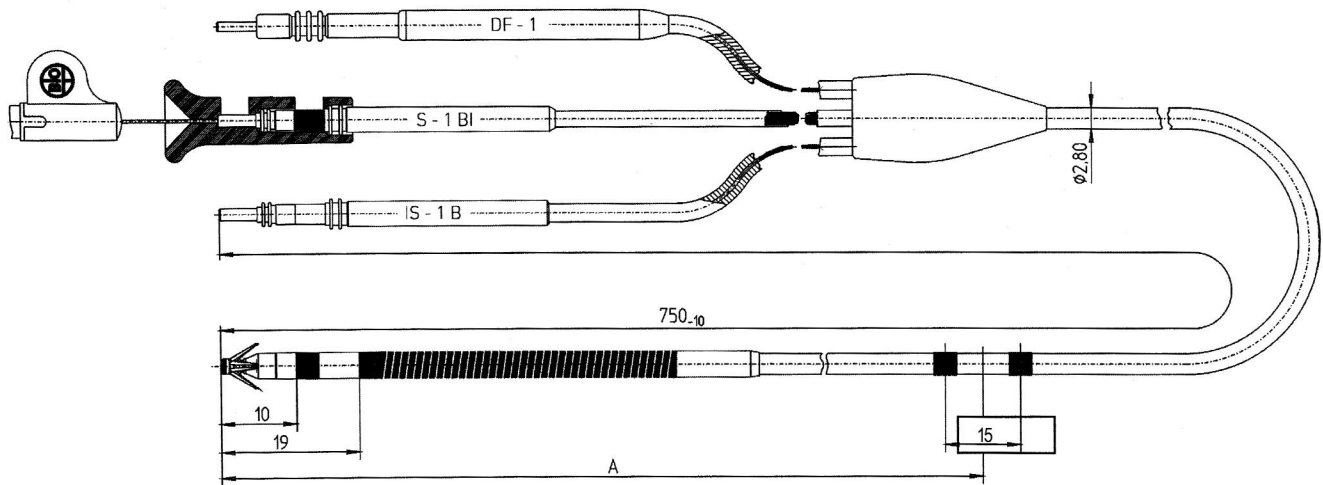
Figure 1. Technical drawing of the VDD lead. A = Distance between the tip and the middle of the two atrial rings (AV-distance) of the implanted VDD leads. Dimensions are given in mm.

therapy by the device [1]. Inappropriate shocks for fast ventricular rates during atrial fibrillation (AF) occur in up to 12 % to 25 % of ICD patients having a history of AF [2]. Additional discrimination algorithms like morphology detection [3,4] have been developed but they have shown a limited sensitivity and specificity with potential underdetection of ventricular arrhythmias. Schuger et al. [5] have shown an improved discrimination between atrial and ventricular tachyarrhythmias by incorporation of atrial signals in the sensing algorithms in dual-chamber ICDs. Single-chamber ICDs do not have direct access to information of the atrium. The ability to operate with dual-chamber detection in order to classify both atrial and ventricular signals allows the device to better identify the rhythm and deliver appropriate ventricular therapy [6]. Therefore, in these ICD systems the specificity for ventricular tachyarrhythmias is improved without decreasing the sensitivity [7,8]. In addition, patients requiring concomitant pacing could take advantage of the hemodynamic benefit of DDD pacing [9]. However, the rate of complications in dual-chamber ICDs due to the additional atrial lead is higher compared to single-chamber ICD systems [10]. The aim of the present study was to evaluate and to optimize an ICD system that incorporates true bipolar atrial sensing in a single lead construction for dual-chamber ICDs to utilize the advantages of additional atrial sensing without the problems related to the additional atrial lead.

Materials and Methods

On the basis of promising results during animal experiments we conducted a clinical study to test the VDD lead in the acute human evaluation. The protocol was approved by the institutional review board and by the ethical committees of each clinical center.

VDD Defibrillation Lead

To realize a true bipolar sensing in atrium and ventricle we developed a 5-lumen tube consisting of silicone with a fixation tip for the right ventricle with four tines (Figure 1). The distance between the two atrial rings is 15 mm. Tip and ring of the ventricular channel and both lead rings for atrial sensing are fractally coated. For the presented study, the VDD lead was constructed with two different distances of 15 and 17 cm between atrial rings and the right ventricular (RV) tip (Figure 1: size A). The lead diameter is 10.5 F and the lead was introduced by a standard 11 F sheath. The criterion of a successful placement was defined as a lead position with atrial sensing rings in contact with the lateral right atrial wall and stable atrial signals > 1 mV during sinus rhythm (SR), a ventricular sensing > 4 mV and a ventricular pacing threshold < 2 V at 0.5 ms.

Patients

Ten patients (eight male, two female) scheduled for ICD implantation were enrolled in the study. The mean

Shock impedance	$59.6 \pm 12.8 \, \Omega$
Pacing threshold (at 0.5 ms)	0.58 ± 0.37 V [range 0.3 - 1.5 V]
Sensing	11.9 ± 3.9 mV [range 6.0 - 16.0 mV]
Slew-rate	1.50 ± 0.35 V/s

Table 1. Ventricular parameters (VDD channel)

age was 58 ± 13 years, the NYHA-class 2.6 ± 0.5. The left ventricular ejection fraction was 30 ± 15 %. The underlying heart diseases were typical for ICD-patients (seven coronary artery disease [CAD], two dilatative cardiomyopathy [DCM] and one other). The indication for ICD implantation was VT in 60 % and VT or ventricular fibrillation (VF) in 40 %. In 30 % of the tested patients a history of atrial flutter (Afl) or paroxysmal AF was documented. Patients with chronic AF were excluded from the study. All ICDs were implanted in the left pectoral region.

Study Protocol
All patients gave written consent to the study. During general anaesthesia the tests were performed acutely during a routine ICD implant procedure. Initially, a bipolar stimulation catheter was placed in the right atrium. Subsequently, the VDD lead was implanted in the right ventricle through the left subclavian vein and was positioned in the way that atrial sensing rings contact the lateral wall of the middle right atrium. After recognition of a stable position of the VDD lead by fluoroscopy, atrial and ventricular channels were connected to the Tachos MSV^{VDD} ICD (commercial name: Deikos A+, Biotronik, Germany). The measurements started with recordings of sinus rhythm (SR) for 60 s. Then, the atrial stimulation catheter was connected to the HF-generator to induce Afl or AF with rapid pacing of 20 – 50 Hz. Atrial and ventricular signals were recorded continuously by the pacemaker programmer TMS 1000. VF was induced by 50 Hz burst and terminated by a standard 20 J biphasic shock. During this procedure, atrial signals were recorded before, during and after termination of the ventricular arrhythmia.

Statistical Analysis
Measurements of the atrial and ventricular signals were carried out as a peak-to-peak analysis by the

printouts of the EGMs of the Tachos MSV^{VDD}. The detection feasibility was evaluated by counting the markers set by the ICD and the P- or R-waves in the surface ECG. The data are presented as mean $\pm$ one standard deviation. Continuous variables were analyzed with student´s t-test for unpaired data and categorical variables by Fisher´s test. A P-value < 0.05 was considered statistically significant. Far-field sensing of ventricular signals in the atrial channel was defined as amplitudes > 0.3 mV.

Results

Implantation Procedure
The VDD lead could be implanted successfully in 100 % of the cases. In one patient with successful implantation, a change of the lead with respect to the distance between the RV-tip and the atrial sensing rings (Figure 1, size A) was necessary to improve stability and amplitude of the atrial signal. The mean duration of implantation of the VDD lead was 12 ± 7 min and the mean fluoroscopy time 9.1 ± 7.3 min.

According to the experiences during the animal experiments the best results with stable atrial sensing and without far-field sensing of ventricular signals were obtained in a position of the atrial sensing rings in contact to the middle lateral wall of the right atrium. Moreover, in this position no far-field sensing of ventricular signals was observed.

The AV distance is determined between the tip of the lead and the middle between the two atrial sensing rings. Predominantly the 17 cm sized lead was implanted. One patient (female) required a smaller size (15 cm).

Electrophysiological Values at Implantation
For the electrical characteristics of the ventricular channel see Table 1. Sensing and pacing characteristics do not differ from those of the standard RV lead.

Electrical parameters of the atrial channel during SR: SR could be recorded in all successfully implanted patients. The pacing impedances of the atrial sensing rings were significantly lower compared to those of common atrial leads. The pacing threshold of the atrial rings was 2.9 ± 1.6 V at 0.5 ms which is higher compared to common atrial leads. No exit block was found. Detection of atrial signals during SR by the ICD (sensing floor 0.25 mV) was reliable: 100 % of the P-waves were markered and no oversensing was found. No sig-
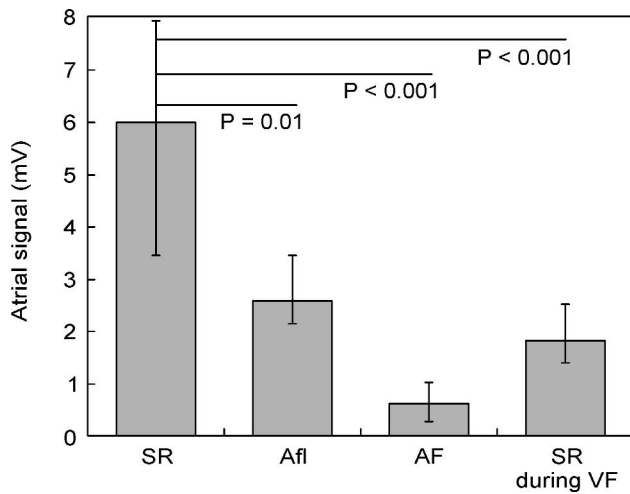
Figure 2. Atrial signals measured by the ICD Tachos MSV^VDD during sinus rhythm (SR) and during atrial arrhythmias. Afl = atrial flutter, AF = atrial fibrillation, VF = ventricular fibrillation.

nificant breathing-caused change of the amplitudes was found.

Detection Feasibility during Different Arrhythmias

- After recording SR, several atrial arrhythmias were induced. Afl could be induced in six patients and AF in all patients. Atrial signals recorded during Afl (Figure 2) were significantly lower 2.6 ± 0.32 mV, (P < 0.01) than those during SR (6.02 ± 0.72 mV). The feasibility of detection by the ICD was nearly 100 % (Figure 3). This detection rate does not differ significantly from the detection during SR (Figure 4). During AF atrial signals were 0.62 ± 0.27 mV and the rate of detected atrial signals by the ICD

decreased to 91.5 ± 4.3 % (P < 0.001 versus SR). Nevertheless, even during AF no malfunction of the discrimination algorithm SMART was found (Figure 5).

- VF could be induced in all patients. In seven of ten patients (70 %) atrial SR could be observed during VF. The induction of VF also induced AF in 3 patients. The atrial signals during these arrhythmias during atrial SR (1.83 ± 0.22 mV) and during AF (0.86 ± 0.35 mV) were significantly lower compared to those during normal ventricular rhythm. In all patients, VF could be terminated with an energy of 20 J. Shock impedances (59.8 ± 13 Ω) did not differ significantly from those of commonly used ICD-leads.
- After defibrillation of VF, eight of ten patients were in SR; in other patients AF was observed. The mean atrial VDD sensing during SR was 1.83 ± 0.22 mV. Atrial sensing (SR) was observed immediately after shock delivery in 100 % (Figure 6).

Discussion

The main purpose of a single-pass dual-chamber VDD defibrillation lead is to improve the discrimination between atrial and ventricular tachyarrhythmias. For reliable functioning of this system, stable detection of atrial signals even during atrial tachyarrhythmias is necessary. The VDD defibrillation lead used in our study was easy to implant; the mean implantation time was in between the time of a single-chamber and a dual-chamber ICD system.

The detection feasibility of atrial signals in the atrial

Figure 3. Detection of atrial and ventricular VDD signals by the ICD Tachos MSV^VDD ICD during atrial flutter.
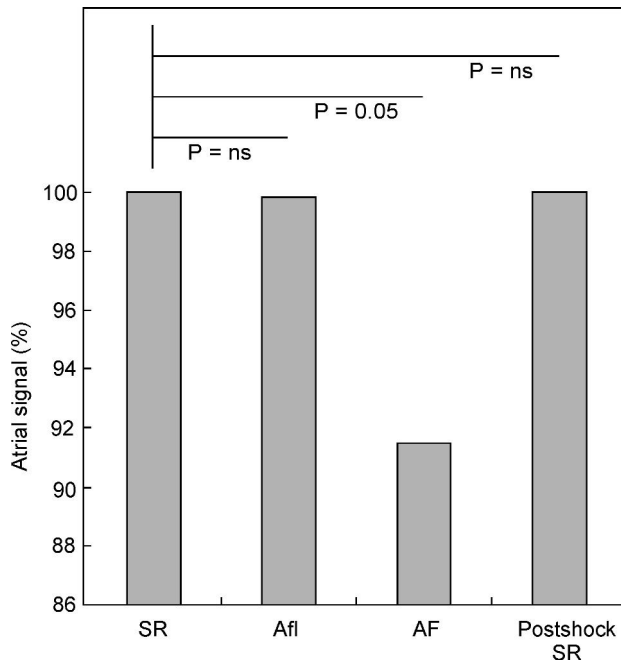
Figure 4. Detection of atrial VDD signals by the ICD Tachos MSV^VDD during sinus rhythm (SR), and during atrial arrhythmias. Afl = atrial flutter, AF = atrial fibrillation.

[16,17,18], although VF induction and termination by the VDD lead has not been performed in these studies. During Afl, an insignificant decrease of the atrial signal amplitude was found. This observation is similar to a study by Neuzner et al. [19] who described a decrease of 26 % between SR and AFlu. with the use of the new Tachos MSV^VDD ICD an adequate classification of Afl by the ICD is possible.

During AF, more than 90 % of the fibrillation waves could be detected by the ICD. While AF still remains – in accordance with other VDD studies – a problem of the VDD technique, the combination of the new VDD lead with the 15 mm spacing of the atrial rings and the Tachos MSV^VDD improves the detection of AF and provides a reliable discrimination between atrial and ventricular tachyarrhythmias by the SMART algorithm incorporated in the Tachos series for the first time. This is in contrast to our experiences with VDD systems that show a marked decrease of atrial signals during AF that made adequate detection of AF impossible [20].

In our study, stable sensing of atrial signals was possible even during VF and directly after shock delivery. This will ensure the discrimination of atrial and ventricular arrhythmias directly after shock delivery.

Conclusions

The newly designed VDD dual-chamber lead in combination with the Tachos MSV^VDD ICD provides stable detection of atrial and ventricular signals during SR, Afl, AF, VT and VF in the acute phase. Reliable detection of atrial signals is possible only with modifications of the sensing amplifier. However, the correlation of ampli-
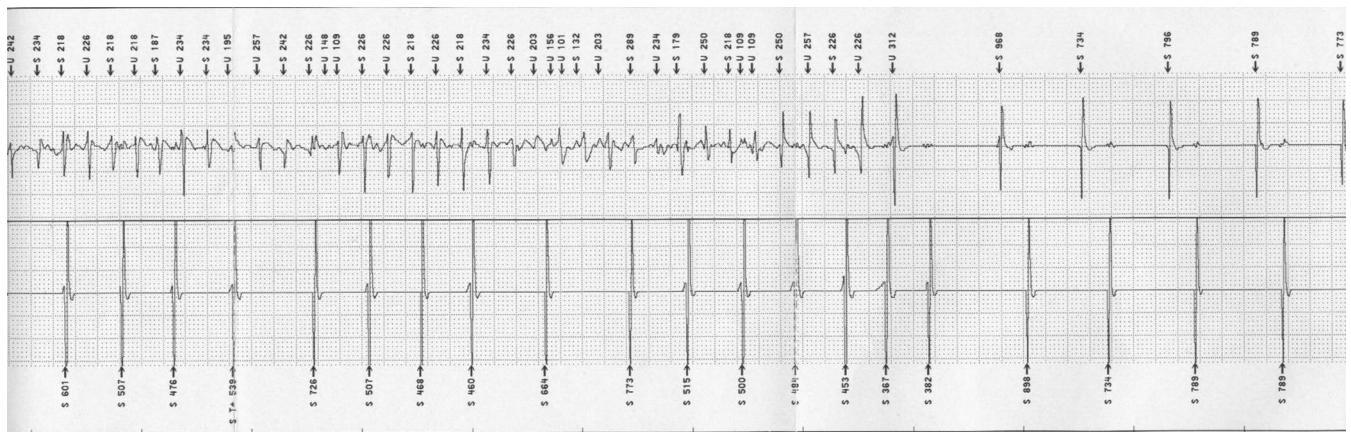
VDD-channel was comparable to those in antibradycardia VDD systems [11,12]. During SR, 100 % of the P-waves could be detected by the Tachos MSV^VDD ICD. The mean sensing amplitudes of SR are comparable to those observed in VDD pacemaker trials [13,14,15], but the upper range of the measured values is higher than in those studies. Furthermore, the mean amplitudes of atrial signals were comparable to preliminary data of three studies with small patient populations

Figure 5. Detection of atrial and ventricular VDD signals by the ICD Tachos MSV^VDD during atrial fibrillation.
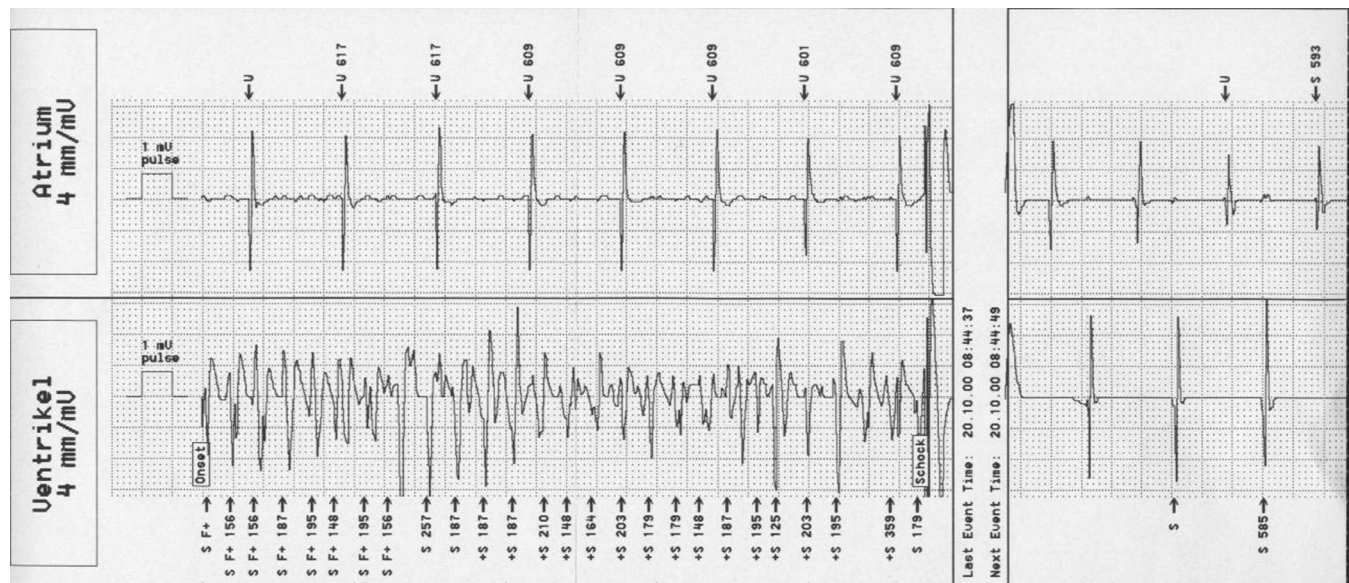
Figure 6. Detection of atrial and ventricular VDD signals by the Tachos MSV^VDD ICD during ventricular fibrillation (atrium: sinus rhythm) and after therapy.

tudes of AF was significantly lower compared to SR. The VDD lead may provide additional information for discrimination algorithms in dual-chamber ICDs to increase specificity of the detection of supraventricular tachycardias. The majority of patients with single-chamber ICD systems may benefit from the new VDD-ICD system without the problems related to a secondary atrial lead.

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