Dual-Chamber Implantable Cardioverter-Defibrillator with Active Discrimination of Supraventricular Tachycardia

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Summary

Recent DDD-controlled implantable cardioverter-defibrillators (ICD) show enormous potential to reduce the high ratio (up to 41% incidence) of inappropriate shock delivery due to supraventricular tachycardias (SVT). This problem concerns all single-chamber ICDs and is related to the lack of reliable criteria to distinguish between ventricular tachycardias (VT) and SVT. Thus, dual chamber ICDs operate with discrimination algorithms in order to reliably discern the origin of the tachycardia episodes. The SMART Detection™ algorithm implemented in the Phylax AV (BIOTRONIK, Germany) is based on the concept that the chamber with the higher rate denotes the origin of the tachycardia. To differentiate in cases of equal heart rates in both chambers, additional criteria are analyzed, namely sudden onset, ventricular and atrial rate stability, and regularity of the P-R intervals. 12 Phylax AV were implanted up to today. All episodes of ventricular tachycardia (VT) or fibrillation (VF) were terminated by treatment with appropriate therapies. Analysis of the stored dual-chamber intracardiac electrogram (IEGM) showed that no episodes of atrial flutter (Af) or atrial fibrillation (AF) led to cardioversion/defibrillation. One episode of sinus tachycardia (ST) was inappropriately treated by delivery of a shock. With programming a more severe sudden onset criterion, no further inadequate therapy has been delivered. To further avoid delivery of inappropriate shocks in cases of 1:1 AV conduction, an additional active detection method has been developed and added to the original SMART Detection™ algorithm. In five patients, this new approach that replaces the sudden onset criterion was investigated. Premature ventricular extrastimuli (PVES) were delivered to test the hypothesis of VT with retrograde 1:1 VA conduction. The clinical investigations of the active detection procedure are reported in this article. Following the results, the SMART Detection™ algorithm - improved by an active discrimination method - has shown to be effective for AV discrimination with high specificity in a dual-chamber ICD which avoids inappropriate shocks in response to SVT.

Key Words

Implantable cardioverter-defibrillator, dual-chamber electrotherapy, ventricular and supraventricular discrimination, active discrimination, premature ventricular extrastimulus

Introduction

The highest priority of single-chamber ICDs was prevention of sudden cardiac death (SCD) as a result of life-threatening ventricular arrhythmias. Many randomized trials (MADIT, AVID, CASH, CIDS, etc.) have been performed; all studies have made it clear that, compared to drug therapy (Amiodarone, Sotalol, Cordaron etc.), ICD therapy significantly reduces the rates of SCD and total mortality.

The more sophisticated devices of the latest generation focus on a differentiated and individual therapy with additional information gained about the state of the atrium. Yet one of the most important challenges for dual-chamber ICDs is to increase the efficiency of discriminating between VT, supraventricular tachycardia (SVT), atrial flutter (Af), and atrial fibrillation (AF). This task is certainly the most relevant medical requirement to DDD ICDs - inappropriate shocks delivered by single-chamber devices number up to 41% [1-3]. Apart from being painful to the patient, this improper therapy harbors a danger of pro-arrhythmic effects [4].

Even if it is possible to adjust the ICD to the patient's individual arrhythmias by analyzing the Holter data gained from the IEGM, this procedure cannot reliably avoid inappropriate shocks [5]. Furthermore, such proceedings always include the possibility of delayed VT detection during simultaneous SVT episodes. In consequence, a safe discrimination algorithm is needed in dual-chamber ICDs [6-8] that enables higher specificity in the discrimination of VT and SVT episodes, thus lowering inappropriate shock delivery. To evaluate a new approach based on an active discrimination procedure, clinical studies have been conducted.

Materials and Methods

The Phylax AV is a subpectorally implantable ICD of the latest generation with a mass of 109 g and a volume of 69 cm^3. It provides up to 8 min of atrial and ventricular IEGM Holter monitoring.

A bipolar electrode (YP53-BP, Synox or Retrox, BIOTRONIK) with active or passive fixation for sensing/pacing and IEGM recording is used in the atrium. The ventricular lead contains tip and ring electrodes for sensing/pacing and a distal shock coil positioned in the right ventricle (Kainox SPS, BIOTRONIK) as shown in figure 1. An alternative configuration consists of a single lead (Kainox SL, BIOTRONIK) employing ventricular tip-ring for sensing/pacing and atrial and ventricular shock coils. This lead was implanted in 9 patients. The Phylax AV was implanted and tested in 12 patients (10 male, 2 female). The mean age was 51.9 ± 9.6 years (31 to 68 years). The postoperative follow-up period ranged from 4 to 19 months with an average of 13.3 ± 4.6 months.

The implemented SMART Detection^{TM} algorithm [9] is based on the following conditions:

1. The chamber with the higher rate indicates the origin of the tachycardia.

1.1 If the ventricular rate is the higher rate, then the diagnosis is VT.

1.2 If the atrial rate is higher, then a diagnosis of non-VT is declared.

We still have to consider the following cases:

2. If the AV rate is not exactly n:1 and the ventricular rhythm is stable, then the hypothesis is that a VT is occurring during an SVT episode. Consequently, VT diagnosis is declared.

3. The two rates are equal and the ventricular rhythm is stable and:

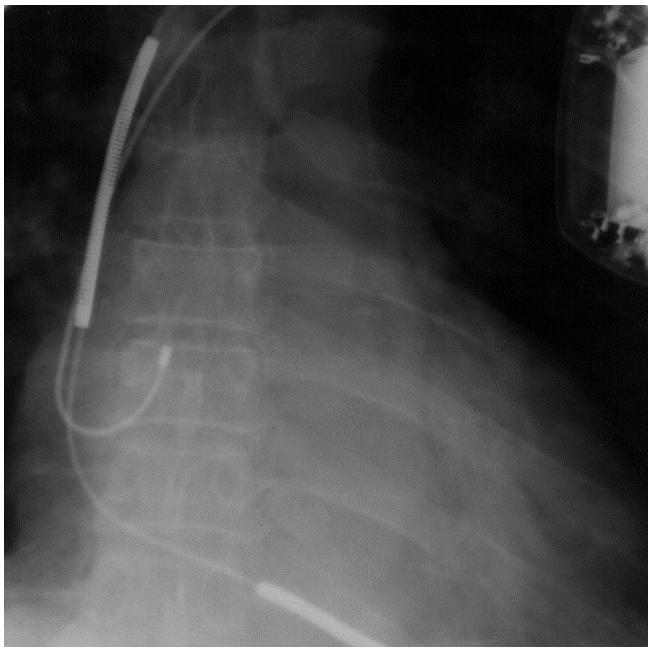

Figure 1. Standard electrode configuration of the subpectorally implanted Phylax AV.

3.1 the atrial rhythm is unstable; the diagnosis is VT.

3.2 the atrial rate is also stable; there are several possibilities, including VT with retrograde conduction, atrial tachycardia, ST or junctional tachycardia. In these cases, if the sudden onset criterion is additionally fulfilled, the occurrence of a VT episode is assumed.

4. If the two rates are equal and the ventricular rhythm is unstable with irregular P-R conduction, the diagnosis is VT.

Figure 2 illustrates the different branches of the SMART Detection^{TM} algorithm.

Depending on a calculated sliding average, the decision is made whether an R-R interval falls into a tachyarrhythmia class. The previous four R-R intervals are used to calculate the average ventricular rate, which is then used for VT detection and VT zone discrimination.

To detect VT episodes, three different criteria are foreseen. The high frequency (HF) criterion is combined with a counter, which is incremented whenever the average rate enters a VT class, and it is decremented if a following interval falls outside of the VT range, respectively. In case of VF the combination of the sliding average analysis with the counter allows the number of samples meeting the VF classification to be pro-

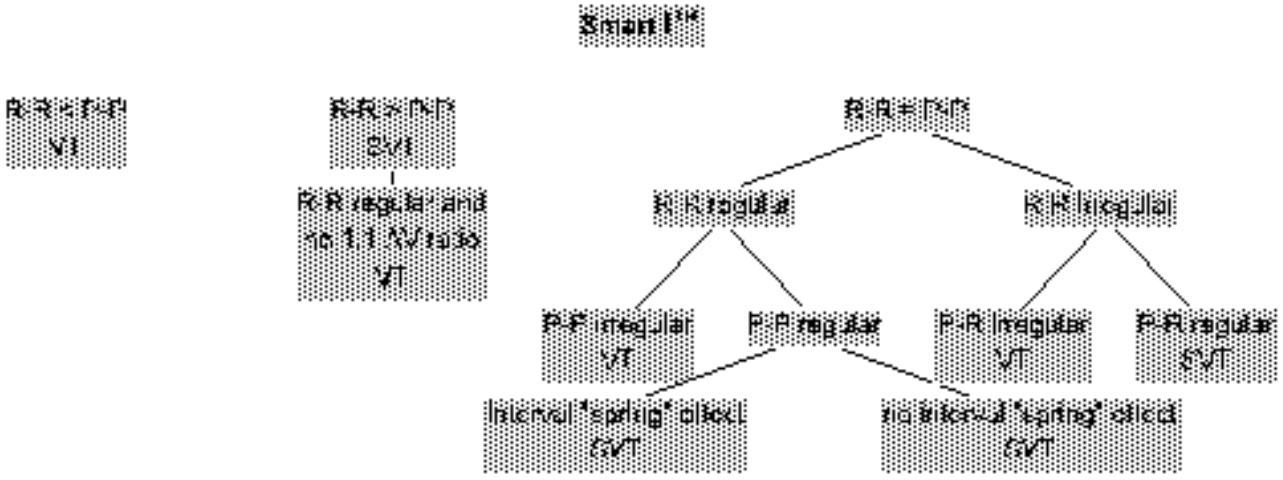

Figure 2. Diagram of the SMART Detection™ algorithm based on the analysis of the R-P, P-P, and P-R time intervals.

grammed before a VF detection is declared by 'x out of y' means. Thus, if 'x out of y' events belong to the VF class, this type of arrhythmia is diagnosed. The values of x and y are freely programmable and, thus, enable the criterion to be set more or less strictly. Therefore, a few mistakes in classification of VF, due to alternating R-wave amplitudes, for instance, do not present a risk of a false final diagnosis.

The stability criterion is used to differentiate between stable monomorphic VT and SVT episodes, which are irregularly conducted to the ventricle. The ventricular rhythm is considered to be stable if all of the differences calculated from the most recent ventricular interval (RR_1) and each of the previous ventricular intervals (RR_2, RR_3, and RR_4) are less than or equal to the programmed stability limit.

Furthermore, the onset criterion is analyzed. Onset is classified as 'sudden' if the difference between the previous four-interval average and the current four-interval average is greater than or equal to the programmed onset limit. This feature is used in the origin SMART Detection™ algorithm only in cases of stable 1:1 rates. The sudden onset criterion has been shown not to be optimal. It was found that in a case of a stable 1:1 rate, VT may be declared for the following episodes: atrioventricular nodal re-entry tachycardia, atrioventricular re-entry tachycardia, and VT with retrograde conduction. Thus, branch 3.2 represents the point of the SMART algorithm for which ambiguous interpretations may arise. Therefore, the physician is offered the choice of selecting the severity of the sudden onset criterion by programming a threshold for the rate variation. In this manner, the sudden onset can be adapted with respect to the individual patient's rhythm. Nevertheless, the best compromise has to be struck between a low sudden onset threshold for prompt VT detection and a value large enough to avoid inappropriate therapy, and consequently an accelerated sinus rhythm, during exercise periods.

However, an alternative approach based on an active discrimination procedure has been developed and added to the original SMART Detection™ algorithm for clinical tests. In general, there are two different possibilities for such an active detection method. Firstly, the hypothesis of ST can be tested using premature atrial extrastimuli [10][11]. Secondly, premature ventricular extrastimuli (PVES) allow the hypothesis of retrograde conduction, from the ventricle to the atrium, to be tested. Both methods are based on the delivery of an extrastimulus during an episode classified as VT. If the tachycardia is atrial with a 1:1 conduction ratio to the ventricle and an extrastimulus is applied in the atrium, it is expected that the corresponding R-R interval will be modified when compared to the previous one. If the tachyarrhythmia is of a ventricular origin, there should be no great discrepancy in R-R intervals since there is a negligible probability that the pulse could reach excitable tissue in the ventricle due to still refractory ventricular tissue. However, premature ventricular extrastimuli are expected to provide

a suitable means in answering the relevant question whether the detected tachycardia is of ventricular origin and whether the high atrial rate is due to the retrograde conduction of the ventricular events. In such a case, a PVES is likely to propagate toward the AV node, infiltrating the atrium, where this particular event is promptly detected. Then, the current P-P interval is different than the previous one, indicating VT. If an SVT is in progress, it is most likely that the retrograde propagation of the PVES will be blocked in the AV node or in the atrium, at the latest, by antegrade conduction of the atrial events. As a consequence, there is no variation in the respective P-P intervals. In this event, a non-VT is diagnosed; no ventricular therapy is delivered.

The timing of the PVES delivery should be selected such that its retrograde propagation would be blocked by the refractory period of the His bundle in cases of normal, antegrade 1:1 conduction. Only with an absence of SVT and thus an absent His bundle refractory period, are the PVES able to propagate back to the atrium. The corresponding prematurity value during a VT episode, therefore, has to be set to a value between 30 ms and 120 ms. Otherwise, a pro-arrhythmic effect is possible with an increasing interval.

Preliminary tests revealed that premature atrial extrastimuli need a very long burst for ventricular capture during an SVT episode. This is due to the high probability that extrastimuli are blocked by refractory atrial substrate. Additionally, long burst duration may be dangerous for the patient since VT can be initiated during an ongoing SVT. Consequently, our approach has focused on delivering premature ventricular extrastimuli.

Results

During the follow-up period, 84 electrotherapy episodes due to SVT and VT/VF were observed. It should be emphasized that endocardial defibrillation was performed in 10 episodes due to Af/AF by manual activation. Seven patients needed dual-chamber pacing because of bradyarrhythmia episodes or AV conduction disturbances. To prevent frequent VT attacks, 7 patients were prescribed antiarrhythmic drugs (amiodarone 200 mg/day) during the postoperative period.

During all 12 implantations of the Phylax AV, intraoperative tests have been done to determine the defibrillation threshold (DFT) in the ventricle (average 8.5 ± 3.8 J) and the atrium. For the latter, an additional lead (SPS, BIOTRONIK) was temporarily placed in the coronary sinus position. Atrial flutter or fibrillation was induced by rapid atrial pacing. Episodes of AF with 2:1 AV conduction appeared most frequently. Using the shock coil of the coronary sinus lead as the different electrode and the shock coil of the intra-atrial lead as the indifferent electrode, the mean value of the atrial DFT was determined to be 1.2 ± 0.3 J.

After programming the device, induced VF episodes were all correctly classified and successfully terminated by the implant. For all induced SVT episodes, no ventricular therapy was delivered by the Phylax AV when operating with the SMART Detection^{TM} algorithm. However, when the Phylax AV was used as a conventional single-chamber ICD (by disengaging the SMART Detection^{TM} algorithm), SVT episodes were classified as VT. They were successfully terminated by low-energy cardioversion shocks (1 to 5 J) with the temporary, additional coronary sinus lead. Otherwise, higher energy (15 J) shocks between the right ventricular shock coil, the right atrial coil, if available, and the ICD housing were necessary to terminate the SVT.

In the next stage, the Phylax AV was again used as a dual-chamber ICD. The active discrimination method's use of PVES was investigated. To this end, PVES were tested in patients showing SVT, Wolff-Parkinson-White (WPW) syndrome, and VT episodes. A premature stimulus was applied to the ventricle when accelerated rhythm had been detected. The intervals between consecutive atrial events were measured prior to (A1-A1) and after (A1-A2) the extrastimulus delivery (figures 3 and 4).

As previously described in this article, differences in the intervals between atrial events are caused by the reaction to the ventricular extrastimulus and, thus, may help indicate the origin of the tachycardia. In the case of an SVT episode, figure 5 illustrates that the A1-A2 and A1-A1 interval values are equal and do not change, i.e. the interval remains stable. This corresponds with the fact that retrograde propagation of the ventricular extrastimulus is blocked by the antegrade conduction of the atrial events. In patients suffering from a VT, the P-P intervals change significantly. A1-A2 is shorter than A1-A1 by more than 20 ms. This information is used to declare the diagnosis of a tachyarrhythmia of ventricular origin. Patients with WPW are an exception, as excitation is conducted through faster accessory pathways. Here, it is possible that the ventricular

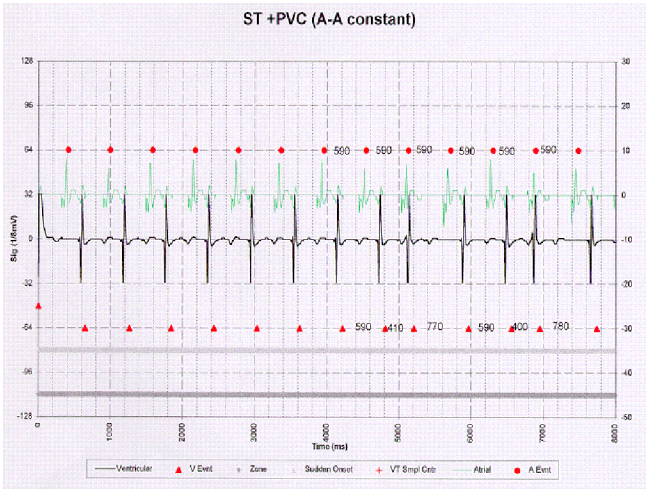

Figure 3. Atrial and ventricular IEGMs during a sinus tachycardia episode, before and after a premature stimulus is delivered to the ventricle. The atrial interval A1-A1 equals the A1-A2 interval. Holter IEGM data from the implanted ICD.

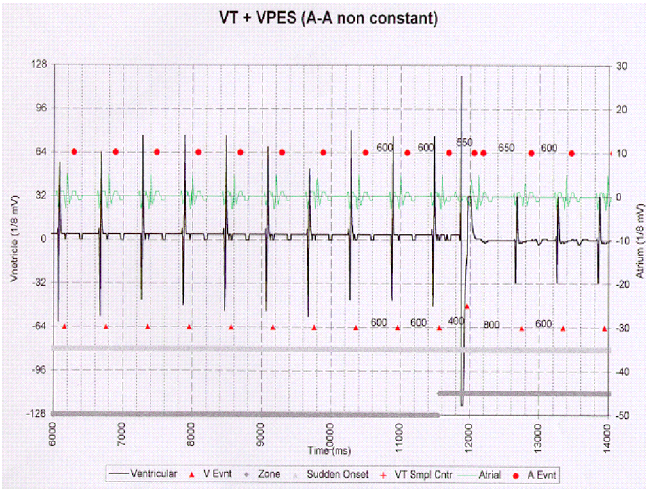

Figure 4. The A1-A2 interval is changed when the ventricular extrastimulus is delivered during VT with 1:1 VA conduction, A1-A2 < A1-A1. Holter IEGM data from the implanted ICD.

extrastimulus can be detected by the atrial electrode as indicated by the results shown in figure 5.

Given the capability of actively discriminating between arrhythmias with 1:1 conduction ratios, the sole point in the SMART Detection™ algorithm which may lead to ambiguous interpretations has been eliminated. It should be noted that these are preliminary data gained from ongoing clinical tests; the data still must be confirmed in Phylax AV implants that implement both the original SMART Detection™ algorithm and the advanced active discrimination algorithm.

Conclusion

The original SMART Detection™ algorithm already offers a reliable means of discrimination of SVT while not altering the sensitivity for VT detection. This statement has been verified through the analysis of recorded IEGM data. Even if the programmed parameters may still lead to delivery of inappropriate shocks in special cases, reprogramming the sudden onset criterion is possible, thus helping to avoid such inadequate therapies.

The enhanced SMART algorithm, which provides active discrimination instead of analyzing 'sudden onset' in the case of stable 1:1 AV conduction, has shown promising results during the first preliminary clinical tests. All SVT episodes were correctly classified, and no therapy was delivered in the ventricle. Furthermore, all VF episodes were classified as VF and terminated by a shock. Therefore, the new active discrimination method seems to improve the specificity of detecting tachycardia episodes, and we expect that it will lead to further improved patient comfort.

The next step is to combine the efficient and highly specific AV discrimination capability with the delivery of appropriate atrial therapy concepts, thus achieving a truly dual-chamber ICD.

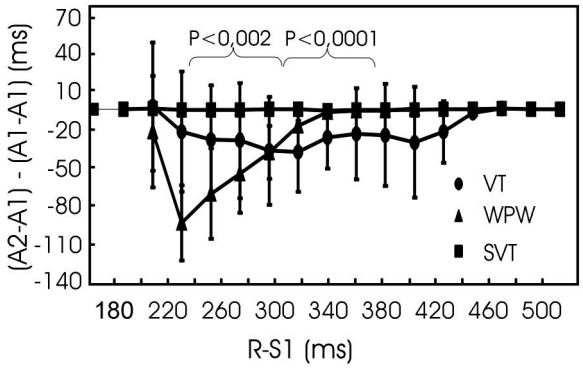

Figure 5. Difference of the atrial intervals (y-axis) [(A2-A1)-(A1-A1)] in ms correlated to R-S1 interval (x-axis) in ms during ventricular stimulus delivery with decreasing coupling interval.

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