Pacing Support

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Summary

The first DDÄ-DDDR (Ä=AE – Active discrimination & Electrogram) dual chamber implantable cardioverterdefibrillator (ICD) with left atrial pacing support was implanted on 24 January 2000. This is a true dual chamber ICD with three atrial tachyarrhythmia detectors and tiered therapies in the atrium. It can also detect junctional tachycardia that is treated with atrial therapies. Reliable atrial detection is possible with an enhanced atrioventricular (AV) discrimination algorithm in the ventricle. The original SMART Detection[™] algorithm, with 95.1% specificity at essentially 100% sensitivity, has been augmented with an active discrimination scheme, SMART Detection[™] II, that provides improved discrimination in the case of 1:1 AV rhythm. The device also incorporates a full feature DDDR pacemaker with enhanced hysteresis, PMT termination, mode switching. To prevent atrial fibrillation, the device also supports biatrial bipolar pacing.

Key Words

defibrillation, ICD, dual chamber defibrillator, active discrimination, atrial fibrillation, AV discrimination, supraventricular tachycardia, SVT, atrial therapy, junctional tachycardia, coronary sinus, biatrial pacing, high rate pacing, rate adaptive pace maker, dual chamber pacemaker, mode switching, PMT.

Introduction

Since the first dual chamber implantable cardioverter defibrillator (ICD) was implanted ^[1], a succession of dual chamber ICDs^[2-4] have appeared in the market. At least in the U.S., the majority of ICD implants are now with dual chamber devices^[5]. The primary indication for the dual chamber ICD has been the need or anticipated need for dual chamber pacing. However, with the addition of the atrial sensing lead, the dual chamber ICD makes possible enhanced AV discrimination that can reduce the incidence of inappropriate therapy due to supra-ventricular tachyarrhythmia (SVT). Inappropriate therapy due to SVT has been reported with an incidence rate as high as 41% in single chamber ICDs^[6-9].

One of the better atrioventricular (AV) discriminating dual chamber ICD^[10] has been the Biotronik Phylax AV®. In U.S. clinicals during 1999, ventricular tachycardia specificity of 95.1% with essentially 100% sensitivity has been reported. This compares

very favorably with other discrimination algorithms^{[11-} ^{18]}. The discrimination capability of the Phylax AV® was based on the SMART Detection[™] AV discrimination algorithm which, through extensive interval testing, can determine whether a high ventricular rhythm is of ventricular or supraventricular origin. The weak point of all these AV discrimination algorithm has been 1:1 AV rhythms. While sudden onset has been able to differentiate, somewhat successfully, between sinus tachycardia and other tachycardia, the further differentiation between ventricular tachycardia (VT) with retrograde conduction into the atrium and SVT conducting down to the ventricle is not possible if the SVT is paroxysmal.

The majority of the dual chamber ICDs available currently can be classified according to the NASPE/BPEG defibrillator code^[19], the NBD code, as VVE-DDD(R). They do not provide therapies for atrial tachyarrhythmia.

True dual chamber ICDs, with the NBD code of DDE-DDD, have been introduced recently^[14, 20, 21]. These true dual chamber ICDs use the same AV discrimination algorithm of their VVE-DDD cousins. Since these devices are implanted in patients with frequent episodes of atrial tachyarrhythmia, even with the relatively small percentage of inappropriate ventricular therapies, we expect the actual number of inappropriate ventricular therapies to become large. A significant improvement in AV discrimination is needed for an effective true dual chamber ICD.

Another concern that has been expressed with regard to atrial tachyarrhythmia therapy has been the release of thrombus into the circulatory system. The standard procedure is not to attempt automatic atrial fibrillation (AF) therapy, and maybe even atrial flutter (Afl) therapy, 72 hours after the onset of the tachyarrhythmia. Since it is desirable to wait, up to a day, in the hope that the AF episode terminates spontaneously^[21]. a concurrent episode ventricular tachyarrhythmia, e.g. VT, may develop during this wait. After successful termination of the ventricular arrhythmia, it is necessary to redetect the AF. It would be desirable that the delay for the AF therapy not be restarted to avoid running into the 72 hour limit due to repeated episodes of VT during the wait.

Material and Methods

The first implant of the Biotronik Tachos DR[™]-M took place at the Bakoulev Institute for Cardiovascular Surgery, Moscow, Russia, on January 24, 2000. The patient, a 62 year old male, with chronic heart ischemia and coronary artery disease, was suffering from paroxysmal VT, resistant to antiarrhythmic drugs. The patient has a history of multiple coronary bypasses dating back to 1991. Sinus bradycardia and intraatrial conduction disturbance with 132 ms Pwave duration were aggravated by paroxysms of atrial fibrillation. The Tachos DR[™] was implanted into the patient to enable both synchronous dual chamber and biatrial pacing along with standard ICD therapy.

The Biotronik Tachos DR^{TM} has a volume of 48cc and weighs 88 grams. The Tachos DR^{TM} -M is the biatrial version of the device. It is illustrated in Figure 1. The M version shown in Figure 1 has a five port header (the standard Tachos DR^{TM} has a four port header) that provides built-in support for a coronary sinus lead for pacing the left atrium. The particular left atrial pacing configuration supported is tripolar with the right atrial tip and the coronary sinus ring being the cathodes and the right atrial ring the anode^[22]. This is the biatrial bipolar pacing scheme. It is depicted in Figure 2. The coronary sinus electrode, when activated, is coupled through a dc-current blocking capacitor to the rest of the circuit. This is a safety feature that is not available when using an external adapter^[23].



Figure 1. Biotronik Tachos DR™.



Figure 2. Biatrial bipolar pacing supports a regular right atrial lead (left) and a coronary sinus lead (right).

The coronary sinus electrode can be programmed to be switched in, biatrial mode, or out, right atrial mode. The programming is "permanent" (until a new program is sent down). The biatrial bipolar scheme was chosen because it is relatively cost effective from an energy point of view.

The Tachos DR^{TM} supports an enhanced SMART DetectionTM AV discrimination algorithm. In the case of a 1:1 rhythm, active discrimination is undertaken using isolated ventricular paces in the ventricle and analyzing its effect on the detected atrial P waves^[24]. This is illustrated in Figure 3.





The hypothesis under test in the active discrimination SMART Detection[™] II is that the 1:1 rhythm is caused by

- H0: VT with retrograde conduction
- H1: SVT

With an SVT, hypothesis H1, the ventricular pulse being only about 80 ms premature cannot penetrate the AV node to conduct retrograde to the atrial electrode in the RAA. Under hypothesis H0, the retrograde conduction disturbs the atrial rhythm. In our tests we found that, in the latter case, the disturbance can either increase or decrease the detected P-P interval. The tests are repeated a number of times with different amount of prematurity. We only need about 2 instances of P-P changes to confirm the H0 hypothesis. To avoid being proarrhythmic, the ventricular pacing pulses are delivered 6 QRS complexes apart.

The complete SMART DetectionTM algorithm is depicted in Figures 4 and 5.

In the enhanced 1:1 rhythm detection, junctional tachycardia (JT) is also detected by checking that either the P-R interval or R-P interval is within the programmed limit, typically 40 ms. Except for JT, the SMART DetectionTM does not influence the atrial detection process. The detection zones are illustrated in Figure 6.

In the ventricle, even though there are three therapy zones, only two detectors are used, namely the VT and VF detectors. With a single detector, episodes of VT can be detected and therapy, selected based on the last average rate, delivered promptly. In the atrium, since atrial tachycardias (AT) are not life threatening, we want to increase our specificity by using two detectors, AT-1 and AT-2, in the AT zone. The VT, AT-1 and AT-2 detectors use up-down counters. The VF and AF detectors use X out of Y criteria. When a junctional rhythm is detected, the AT-1 counter is incremented.



Figure 5. Enhanced 1:1 Detection



Figure 6. Tachos DR detection zones

The VT detector uses the result of the SMART Detection[™] algorithm to increment its count. The AT-1 and AT-2 detectors just use atrial rate as the primary criterion.

SMART Detection[™], which uses both atrial and ventricular information, is the default VT detector. However, it is also possible to use a ventricular only detector, which is ventricular rate, stability and sudden onset based. The physician has the choices shown in Table I.

Options	VT-1	VT-2			
Standard	SMART Detection				
Polymorphic	SMART	Ventricular Only			

2 zone, stability is a therapy discriminator. If the rhythm is unstable (slow AF), atrial anti-tachycardia pacing (ATP) is skipped and the first therapy is an atrial high frequency (HF) burst.

The therapies modules available are shown in Table Ш.

VT-1	VT-2	VF	AT-1	AT-2	AF
ATP1	ATP3		ATP5	ATP7	
ATP2	ATP4		ATP6	HF1	HF2
CV1	CV2	DF	CV3	CV4	CV5

Table II. Therapy modules available

The HF burst, with pacing intervals of about 30 ms, can be programmed for improved effectiveness for durations up to 29 seconds. Since AV conduction may not be sustainable for such a long duration under an atrial HF burst, programmable VOO support is also provided.

The atrial cardioversion therapies, CV3-5, use the same shock electrode configuration as the ventricular shocks, namely right ventricular shock coil versus vena cava shock coil in parallel with device housing (RVS -> VCS+Hsg). All shocks are 60/55 (voltage-wise: 100% ->40% ->22%) biphasic. Since this shock coil configuration was found to be effective^[25] for atrial shocks and does not require the introduction of a coronary sinus lead, it was chosen to be the standard atrial shock configuration. A CS lead is used only with the M option of the Tachos DRTM.

To avoid thromboembolic events with atrial therapies, the Tachos DR™ provides a ratchet atrial redetection feature. Should atrial therapy progression be interrupted by a ventricular tachyarrhythmia, the device remembers the atrial tachyarrhythmia zone it was in. Following termination of the ventricular arrhythmia, the device redects in the atrium. It can only redetect an atrial termination, or an atrial acceleration. Until an atrial termination is detected, the device does not redetect in the same or a lower atrial tachyarrhythmia rate-zone. For example, assume that an episode of Afl is detected in the AT-2 zone. Atrial ATP is delivered but is not effective. Before the device can proceed to deliver an HF burst, a concurrent VT is detected. The device abandons atrial therapy and concentrates on terminating the VT. Assuming that a ventricular ATP is successful. The device then redetects in the atrium and is looking for an atrial return to sinus or an acceleration to AF. The device will not provide any addition AT-2 therapy.

This brings up another key feature of the Tachos DR[™]. With the reliability of the SMART Detection[™], it is now possible to use it during redetection. Ventricular therapy is withheld if an SVT-only condition, e.g. AF, is detected following the ventricular therapy. If the ventricular rate remains high, existing ICDs either deliver the next therapy or at best withhold therapy. In the latter case, the device remains in a limbo state with neither ventricular therapy delivered, nor termination declared. It is not unusual with patients with chronic AF episodes lasting days or weeks. While in this limbo state, if another ventricular arrhythmia is detected, the next ventricular therapy is delivered. Over time, all ventricular therapies are exhausted and the patient is no longer protected. The new feature of the Tachos DR[™] is a "forced" ventricular termination. If following a ventricular therapy, the device does not deliver any further therapy for a programmed duration, in the

order of minutes, then a ventricular termination is forced on the device. This allows the full set of ventricular therapy to be available for the next ventricular episode. This is an optional feature associated with "SMART redetection", as illustrated in Figure 7.

In Figure 7, an example of a possible behavior of the Biotronik Phylax AV® with SMART redetection is shown at the top. Therapy is withheld during the atrial tachycardia. When the concurrent VT develops, it is treated with ventricular ATP which accelerates the rhythm into VF. A low energy shock terminates the VF. Unfortunately, it also accelerates the AT into an AF.With the ventricular rate remaining high, the device enters the "limbo" state. At some later time another concurrent VT develops. Because of ratcheting therapy, it is treated with the next programmed VF shock. With the ventricular rate remaining high due to the conducted AF, the VT episodes may repeat, leading to ventricular shock therapy exhaustion. In the case of the Tachos DR[™], a forced termination occurs, allowing the full therapy suite to become available. Thus ATP is used for VT.

An associated feature is the SVT re-evaluation idle parameter. One of the concern of any atrial therapy is that it causes a ventricular tachyarrhythmia. The Tachos DRTM does not initiate atrial redetection immediately after an atrial therapy. It will wait a programmable time, on the order of 10's of seconds, to allow a ventricular arrhythmia to be detected and treated. If a ventricular therapy is delivered during this wait time, then the assumption is that the atrial therapy has been the cause of the ventricular tachyarrhythmia. Then, any further atrial therapy will be withheld for a programmed period of at least 4 hour, the SVT therapy idle time.

At the bottom of Figure7, since the VT was detected within the SVT re-evaluation idle period, no further therapy is delivered for the programmed SVT therapy idle time of at least 4 hours. Following this, atrial redetection takes place and therapy is delivered.

Since it is not convenient to test devices during implant with the SVT re-evaluation idle feature, when the physician uses the EP Test screen monitoring mode, these delays are ignored.

The Tachos DR[™] also makes it possible to delay, on the order of seconds, the initial AT-1 and VT-1 therapies. This feature is useful in the case of transient episodes of AT-1 or VT-1.

Unlike ventricular shocks, there is little urgency in delivering atrial shocks. Thus, all atrial shocks can be

delayed up to 36 hours. After the delay, the atrial shocks are delivered only during a programmable time window. The expectation is that this time window is programmed for early morning so that the shocks are delivered while the patient is asleep to minimize pain perception^[21].

In order to be able to detect AF, the atrial detector needs to have a short refractory. Far field QRS

oversensing then becomes a problem^[26-29]. While the majority of far field QRS signals can be ignored by adjusting the minimum atrial threshold^[29], cases where the far field signal is larger than the P wave has also been encountered. An example of such oversensing is illustrated in Figure 8. In this case, threshold adjustment cannot avoid the far field signal without affecting P wave sensing.



Figure 7. Ventricular forced termination.



Figure 8. Example of far field QRS sensing. Top trace: atrial(above line) and ventricular markers. Second trace: suface ECG. Third trace: atrial intracardiac electrogram. Bottom trace: ventricular intracardiac electrogram.

In recognition of this oversensing problem, an Ablank-Vsense is available. This is referred to as tachy PVARP. This is in contrast to the conventional pacemaker (brady) PVARP, which is normally long, and which is available in the Tachos DR[™] for the bradycardia function. The tachy PVARP is typically short, only 25 ms. Not only is the atrial detector blanked during this time, but at the end of the blanking time, the atrial threshold is also increased and then allowed to decay normally. This is illustrated in Figure 9.

Occasionally, far field QRS signals are detected in the atrium before the actual QRS are detected in the ventricle^[30]. This occurs in less than 1% of the patients. The tachy PVARP feature described above cannot help in this case. An analysis of this problem indicates that the only time the SMART Detection[™] algorithm improperly withholds therapy is when a VT with retrograde is active.

Thus, the SMART Detection[™] algorithm was further modified to **t**reat a 2:1 rhythm where the P-R interval is shorter than a programmed value, nominally 8 ms, as if it were a 1:1 rhythm. Unfortunately in this case, the active discrimination SMART Detection[™] II is not effective in making the difference. For these patients, the SMART Detection[™] II should be turned OFF and sudden onset is the main discriminator.

A useful diagnostic feature of the Tachos DR[™] is its ability to create and save an IEGM record when no therapy is delivered in the course of an episode of high ventricular rate due to inhibition by the AV discrimination algorithm, be it the SMART Detection[™] algorihm or the simpler ventricular-only criteria.



Figure 9. Tachy PVARP. Top: atrial intracardiac electrogram. Bottom: ventricular intracardiac electrogram.

From previous experience with the dual chamber Biotronik Phylax AV®, a "giant T-wave" option is made available. In a few patients, even with the high pass filtering of the device, a T wave with amplitude greater than $\frac{1}{2}$ of the QRS amplitude can still get through to the detection system. To supplement the peak tracking automatic threshold detection system, an option is offered, whereas normally the threshold changes to $\frac{1}{2}$ the peak amplitude after the holdoff and then decays to $\frac{1}{4}$ of the peak amplitude, with this new option, the initial decrement is to only $\frac{3}{4}$ of the peak amplitude with decay to $\frac{1}{4}$ of the peak amplitude. This can be used to avoid the detection of large T wave complexes.

Another feature that is offered is the programmable shock reconfirmation bradycardia/asystole flag. Since this is a dual chamber ICD, one can expect that a large portion of the patient population is bradycardic. A common phenomenon observed with this patient population is that episodes of VT or VF can terminate spontaneously during the time the device charges for a shock. Following the charging of the capacitors, the device enters a reconfirmation period. Depending on whether the device is programmed to recognize bradycardia or not during shock reconfirmation, the absence of ventricular sensed events during this time is flagged as bradycardia (no shock to be delivered) or asystolic (shock to be delivered).

In addition to these tachyarrhythmia detection and therapy features, the Tachos DR[™] also offers a full feature DDDR pacemaker, which is PVARP based for improved PMT avoidance.

Some of the advanced bradycardia features offered are:

- Separate normal and post-shock bradycardia parameter sets
- Mode switching with programmable rates. A programmable up-down counter is used. Switch can occur with just 4 fast atrial events.
- PMT termination. After 16 paced events, if the R-P interval is longer than the programmed (bradycardia) PVARP and the PVARP extension (used when a PVC is detected), then the next ventricular pace is skipped.
- Enhanced hysteresis: night rate, scan hysteresis and repetitive hysteresis^[31], as illustrated in Figures 10 and 11.

Improved diagnostic features are:

- Up to 34 minutes of stored dual channel IEGM. The memory can be divided into 7 127 records (one for each detection/redection) with programmable post detection duration.
- Up 13.6 hours of PP, PR and RR interval storage.



Figure 10. Scan hysteresis Every 180 cycles, the system will search for an intrinsic rate between the basic rate and the hysteresis rate.



Figure 11. Repetitive hysteresis. After 180 sensed cycles, the system will allow the intrinsic rate to drop lower than the hysteresis rate without going to the basic rate.

Conclusions

The Biotronik Tachos DR^{TM} is a true dual chamber ICD. Its active discrimination feature makes it the first ICD with an active sensor. Thus, our claim that it is the first DDÄ-DDDR device. This is not the standard NBD code. The Ä (German A umlaut), which can also be written as AE, is used to indicate that we have here an **Active** discrimination device based on **Electrogram** measurement.

To date, we have tested this active discrimination feature in human under sinus and atrial tachycardia conditions. Our first patient unfortunately did not exhibit VT with retrograde. As we expand the patient population, we expect to achieve confirmation under all 1:1 rhythm conditions. This has been verified already in animal studies.

In summary the Tachos DR[™] key features are:

Dual chamber tachyarrhythmia detection and therapy

- Active AV discrimination for improved performance with 1:1 rhythms, making it a DDÄ-DDDR device.
- Three atrial detection zones
- Long HF burst with ventricular support for improved effectiveness
- Forced ventricular termination
- Detection of atrial therapy caused ventricular tachyarrhythmia, and mitigation

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- Atrial redetection ratchet with intervening ventricular tachyarrhythmia
- Far field QRS oversensing mitigation and avoidance
- Giant T wave avoidance
- Up to 34 minutes of stored dual channel IEGM and up to 13.6 hours of PP. PR, RP interval storage.

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