New Concepts and Algorithms for Dual Chamber Defibrillators

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Abstract **--***Ventricular ICDs have not been capable of reliably discriminating SVTs from VTs. Thus the needs for a dual chamber ICD with, at a minimum, sensing in the atrium and with a detection algorithm that discriminates between episodes of SVT and VT. Such a device has been developed. Test results illustrating SVT rejection, SVT therapy along with possible extensions are presented.*

I. Introduction

An analysis of stored electrograms in 48 patients[1] with Implantable Cardioverter Defibrillator (ICD) has reported that up to 25% of therapies delivered were in response to non-ventricular arrhythmias, namely atrial fibrillation, and other supraventricular tachycardia. Up to 69% of patients who received therapies during the monitoring periods received at least one such inappropriate therapy. In another study [2] of an ICD without stored electrogram capability, it has been reported that in 1.6% of patients, defibrillation (DF) shocks were delivered in response to Supra Ventricular Tachycardias (SVT), and that 3.2% of patients received antitachycardia pacing (ATP) for SVTs.

Most ventricular antitachycardia therapy starts with ATP since this is a painless therapy. However, this is not effective against SVTs and may initiate a ventricular tachycardia or, worse, ventricular fibrillation. In a typical therapy progression, the ICD is programmed to start cardioversion (CV) shock therapy following unsuccessful ATP therapy attempts. Only shock therapy, be it CV or DeFibrillation (DF) shock can successfully terminate an episode of SVT. However, given that these SVTs are not life threatening and most are of a transient nature, the value of frequent uncomfortable shocks [3] is questionable.

The above arguments point to the needs for being able to discriminate between ventricular tachyarrhythmia and SVT and to initiate therapy only selectively for SVTs.

II. Atrial Signal

In current ICDs, with sensing limited to the ventricle, discrimination of ventricular tachyarrhythmia from SVTs has been limited to the following:

- Morphology: this is no longer in favor due to its poor specificity.
- Sudden onset: this has been successful in discriminating between sinus tachycardia and other form of tachycardia.
- R-R interval stability: this has been successful at discriminating monomorphic ventricular tachycardia from other tachycardia.

Even with these criteria, up to 25% of therapies are inappropriate[1]. Recently there have been proposals to improve the discrimination rate of success by using more sophisticated signal processing [4]. Even in these cases, the success rate is not high enough.

We have chosen to develop a dual chamber ICD with a dedicated atrial lead. At the present time the atrial lead is a regular pacemaker atrial lead. Either a passive "J" lead or an active fixation lead can be used. In our tests, we have used both types. As expected, the passive "J" lead offers better sensing and pacing capabilities. "J" lead dislodgment due to shocks has not been observed.

III. AV Detection Algorithm

With the atrial channel, the following information is now available to the atrioventricular (AV) detection algorithm:

1. R-R intervals
2. P-P intervals
3. P-R intervals

Combining the above information with the following assumptions, we have developed an AV detection algorithm.

4. Ventricular Fibrillation (VF) detection is the highest priority, due to the life-threatening nature of this tachyarrhythmia. Therefore a separate rate based detector is used to initiate ventricular defibrillation therapy.

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5. No ventricular therapy is initiated as long as the ventricular rate is below the ventricular tachycardia (VT) detection rate threshold.
6. When the ventricular rate is higher than the VT detection rate threshold, the chamber with the higher rate is considered to be origin of the tachycardia. Thus atrial flutter or atrial fibrillation with occasional AV conduction is not treated in the ventricle.
7. In the case of equal rates in the atrium and ventricle, many diagnoses can be made from the same set of information. If VT is a likely diagnosis, then therapy is initiated.

The following are qualifiers of VT that are also used:

8. Monomorphic VT is characterized by regular R-R intervals,
9. Polymorphic VT is characterized by irregular R-R intervals and the rate is typically fast.
10. Atrial fibrillation with conduction into the ventricle is characterized by irregular P-P intervals and regular P-R intervals.
11. VT tends to occur spontaneously and typically results in a fast rate increase.

Even with the best adaptation algorithm, undersensing is a problem. The amplitudes of both the atrial and ventricular signals can vary significantly during episodes of fibrillation or multi-foci tachycardia,. Therefore both sensing channels need to have the capability to adapt their sensitivities to the signals received. In our AV detection algorithm therapy is not turned on by any single event, but requires that a specified numbers of intervals be classified as VT intervals. This avoids the misdiagnoses that could occur in algorithms that rely on the determination of the chamber where the initial rate acceleration occurred [5,6].

Another consideration in the AV detection algorithm is the possibility that an atrial flutter or atrial fibrillation may lead to an independent ventricular tachycardia. Thus, constant monitoring is necessary to ensure that an episode of ventricular tachycardia does not go untreated because of the presence of a concurrent atrial tachyarrhythmia.

Another requirement for the detection algorithm is that:

12. Should the atrial lead fail (with no P-wave or with only noise) the AV detection algorithm must behave like a minimal VT detection algorithm. And VF detection must remain operational in this situation.

From these 12 requirements, an algorithm was developed and incorporated into an ICD. The detection algorithm is summarized in Figure 1.

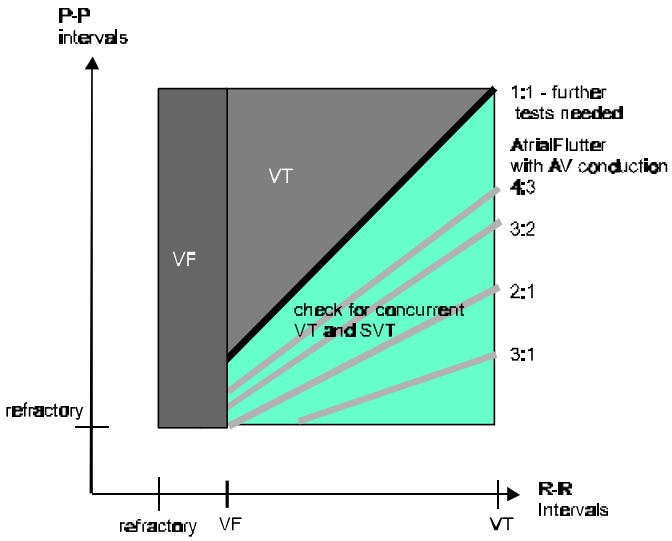

Figure 1. *Detection zones*

The algorithm was tested with the dual chamber electrograms from the Ann Arbor Electrogram data base [5]. We selected 67 files from 49 patients to develop and test our AV discrimination algorithm. They were selected on the following bases:

- Wide amplitude variation that would test our amplitude adaptation algorithm.
- Provide a large number of tachyarrhythmia situations:

  VT, VF, concurrent AF/VT, Atrial Flutter with 2:1 AV conduction, VT with 1:1 retrograde conduction.

We were successful in diagnosing 66 of these cases with a single set of detection parameters. The only case we failed involved a pathological case of concurrent arrhythmias.

Animal tests were conducted also with the device. The results show that our AV detection algorithm correctly diagnosed the following cases:

- Atrial flutter with 2:1, 3:1, 3:2, 4:3 AV conduction - diagnosed as SVTs, thus no treatment.
- VT with retrograde conduction into the atrium - diagnosed as VT, thus VT therapy was started.

IV. Leads

The recommended two lead system to be used with the new device is illustrated in Figure2. It consists of

- A single pass ventricular defibrillation lead with 4 electrodes:

- Tip and ring for bipolar sensing and pacing in the ventricular apex.
- Shock coil in the ventricle.
- Shock coil in the vena cava.

- A bipolar atrial lead.

The housing which acts as an active shock electrode

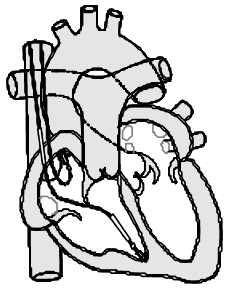

***Figure 2**. Intravenous electrodes*

V. ICD Test and Dual Chamber IEGM Storage

A dual channel Intracardiac ElectroGraM (IEGM) recording capability is also offered in this device. Multiple records can be stored inside the ICD for review. Each record consists of a pre-detection interval and a post-detection interval. The total record length along with the post-detection interval duration can be specified.

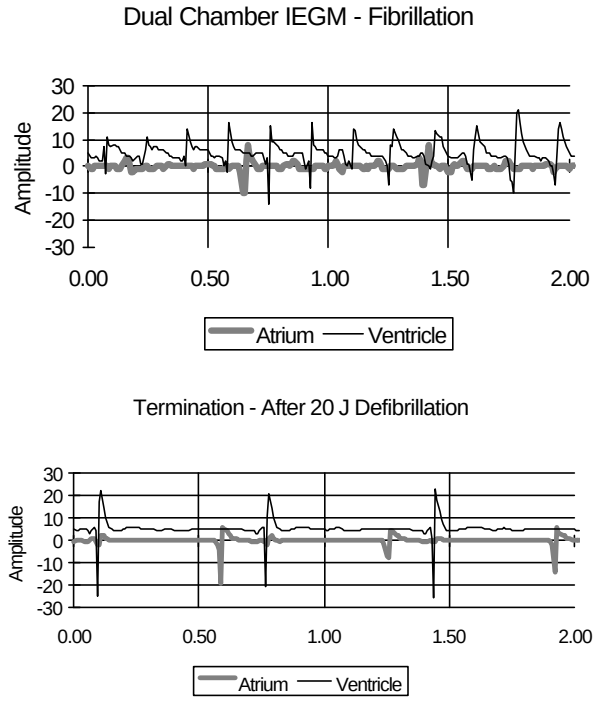

***Figure 3**. Fibrillation termination*

A record as long as one minute can be stored in the device. The physician can trade off recording length for the number of records. It is also possible to record just the ventricular IEGM and, thus, have twice the number of records.

An example of the IEGM recording in a patient for an episode of induced ventricular fibrillation that was successfully terminated with a 20 Joules shock is illustrated in Figure 3. It is interesting to note that the ventricular fibrillation induction has not affected the atrium, which is still subject to relatively slow, steady P-waves with a 600 ms average cycle length. In our tests, episodes of VF with cycle lengths of 188 ± 29 ms were detected in 2.3 ± 0.4 seconds.

IEGM recording of another patient for an episode of induced ventricular fibrillation is shown in Figure 4.

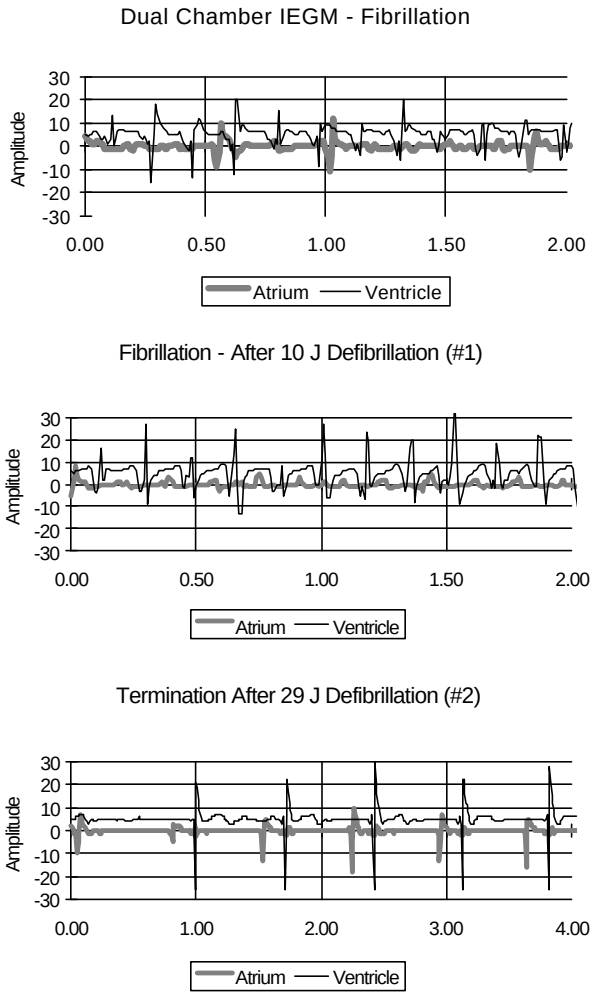

***Figure 4**. Ventricular fibrillation with retrograde atrial conduction*

The top IEGM shows that there is considerable retrograde conduction from the ventricle to the atrium. However, these retrograde waves are not able to capture the atrium, thus the atrial rate was still determined by the sinus node which continued to generate strong signals. The sinus node was apparently somewhat affected since its rate is no longer stable. RR cycle length is about 173 ms. In the middle IEGM, after the 10 Joules shock, there is no longer any strong atrial signal, just the retrograde waves, effectively causing atrium fibrillation. RR cycle length is essentially unchanged at 180 ms. The retrograde paths were terminated by the (second) 29 Joules defibrillation shock. Electro-Physiological (EP) studies have indicated that this patient has significant retrograde conduction from the ventricle to the atrium through an accessory pathway.

During the first fibrillation induction test, not shown, this patient was successfully terminated from a 169 ms fibrillation with a 20 Joules shock. We show in Figure 4, the IEGM's associated with the second test when an initial 10 Joules shock was not sufficient to terminate the 173 ms cycle length fibrillation. The fibrillation cycle length did not change appreciably but the amplitude variation has increased. A second shock of 29 Joules was required to terminate the fibrillation episode.

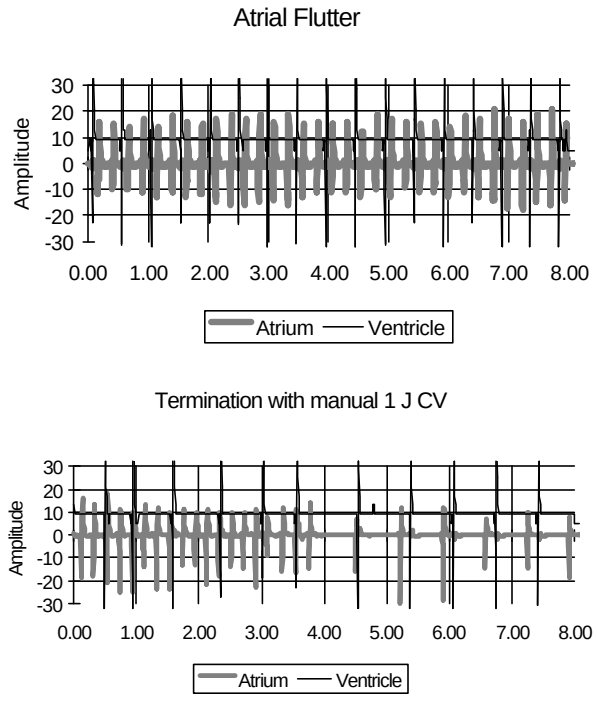

Figure 5*. 2:1 atrial flutter - normally not treated.*

During the course of our series of tests, a stable atrial flutter with a cycle length of 244 ms was induced in the patient. This flutter exhibited a 2:1 AV conduction, resulting in an R-R interval of 488 ms. Our AV detection algorithm correctly diagnosed this to be an SVT and no treatment was performed. The IEGM for this episode of atrial flutter is shown in Figure 5. A 1 Joule manual cardioversion successfully terminated this atrial flutter.

VI. Atrial Defibrillation

The ICD can also perform atrial defibrillation using the standard lead system [7] shown in Figure 2.The preferred electrode electrical setup is for the ventricular shock electrode to be the main electrode and the vena cava electrode and the ICD housing to act as the counter electrodes. This is illustrated in Figure 6. Atrial defibrillation is achieved using a cardioversion shock pulse between these electrodes.

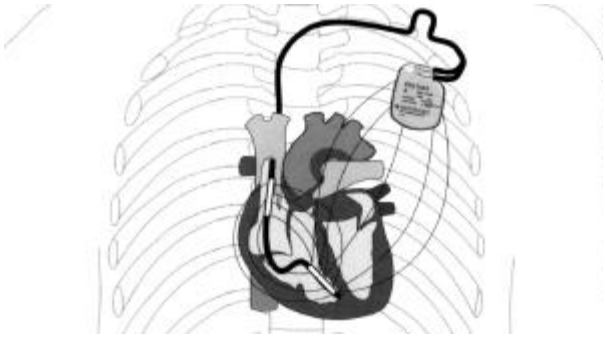

Figure 6*. Current path under shock.*

With the proposed electrode configuration, the current will cover both atria fairly uniformly. Our experience with the above configuration is that atrial defibrillation can be achieved with energy under 2 Joules. With the introduction of an electrode in the coronary sinus, we found that defibrillation can be achieved with energies under 1 Joule. However, given that shocks from 0.4 to 2 Joules are equal in the level of discomfort to the patient [3], we feel that the hardware and potential medical complications of adding a coronary sinus lead to the system is not worth the reduction in the atrial defibrillation threshold.

Atrial Fibrillation (AF) is a common occurrence in patients with ICD implants. Since it is not life threatening and most episodes self-terminate, the urgency to treat AF is minimal. However, persistent atrial fibrillation that lasts over 48 hours can create blood clots and thus lead to stroke. Current practice [7] for the treatment of persistent atrial fibrillation is to perform cardioversion if the episode has lasted less

than 48 hours. Beyond this duration, anticoagulation drugs need to be administered prior to cardioversion.

Initially, we offer only a manual atrial defibrillation capability. This capability was used in the test illustrated in Figure 5. We plan to offer automatic atrial defibrillation. If atrial fibrillation is detected using a simple high rate criterion then, after a set interval of time predetermined by the physician but typically on the order of tens of hours, atrial defibrillation will be initiated. The advantage of using the device is that the 48-hour limit can be strictly observed, thus making the use of anticoagulant unnecessary. With the ventricular defibrillation capability of the device, complications like VT or VF can be treated.

Another advantage of using the shock electrode configuration shown in Figure 6 is that we can also cardiovert AV Nodal Reentrant Tachycardia (AVNRT). Thus, this is a general shock electrode configuration that can be used to deal with almost all tachyarrhythmias.

VII. Atrial Flutter

In the atrium, the plan is also to offer atrial ATP to treat Atrial flutter (Af). Detection will rely on the AV detection algorithm discussed earlier, rather than rely solely on an atrial rate detector[9]. Atrial defibrillation by means of CV shocks can also be used to terminate these episodes of Af. These should be used as backup for ATP only.

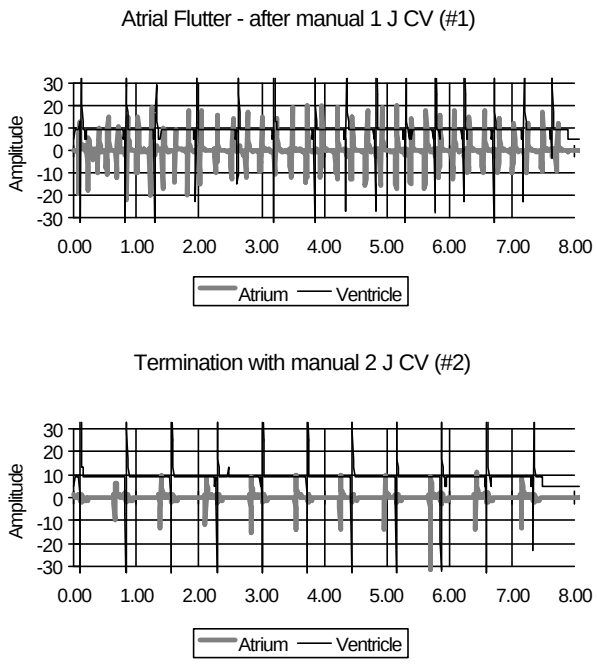

Figure 7. *2:1 atrial flutter - terminated after 2nd cardioversion*

Figure 5 shows an episode of Af treated with (manual) CV shock. Unlike ventricular tachycardias that are either immediately terminated by a CV shock or continue on, the Af shown first accelerates to a cycle length of about 195 ms following the CV shock before terminating. The same Af was induced again in the patient. Figure 7 shows the IEGMs after the first 1 Joule CV shock. The Af accelerates to a cycle length of less than 180 ms before settling back down to a cycle length of 242 ms. During this time, the R-waves are uncoupled from the P-waves. AV 2:1 synchronization is re-established by T=3 seconds. The next 2 Joules atrial defibrillation then converts this atrial flutter.

In our tests, we found that the redetection time for Af following an atrial defibrillation (by means of a low-energy CV) must be set for longer than in the ventricle to give the atrial flutter a chance to terminate (see Figure 5).

VIII. Extensions

The problem of improved classification of 1:1 tachyarrhythmia still remains. The timing information used does not allow us to discriminate between VT and SVT. The following are possible research areas:

- Morphology: templates of the R-wave under sinus and sinus tachycardia, induced atrial flutter, and other inducible SVTs are stored and compared with the current R waves.
- Active discrimination: premature stimulus [10] are used to actively discriminate between VT and SVTs.
- Monophasic action potential (MAP) measurement, made possible by the fractal coating of electrodes [11]: to determine the state of the myocardium
- Intracardiac impedance measurement [12]: to assess the state of the myocardium.

A research area is the prevention of tachyarrhythmia through monitoring of the P- and R-waves and detecting significant rate variability, a predictor of impending tachyarrhythmia [13,14]. With a pacing capability in both chambers, rapid pacing can be used to prevent the onset of tachyarrhythmia in the two heart chambers. Such a preventive system always run the risk of initiating a tachyarrhythmia. Thus, the availability of atrial and ventricular defibrillation makes such a system safe.

The termination of AF with high frequency burst pacing [15] is another topic that we plan to investigate with the new device.

Another area of research is the development of a single lead system. As a ventricular device, it is not necessary for the ICD to pace in the atrium. Thus, only sensing is needed. A single lead system with bipolar sensing rings floating in the atrium could also be developed along the lines of the single lead system for pacemaker. Since it is known from pacemaker research that pacing from floating rings is possible [16,17,18], a single lead dual chamber ICD can be developed for patients who only need occasional atrial pacing.

IX. Conclusions

In this paper we have presented a description of the requirements for an AV detection algorithm. Such an algorithm has been implemented in the Biotronik Phylax AV. With the appropriate lead system, this ICD can also be used as an automatic atrial defibrillator with backup ventricular tachyarrhythmia therapy. The IEGM's collected from a set of tests have provided us insights into the behavior of the atrium during low energy cardioversion shocks and high energy defibrillation shocks.

Some possible research topics for improved AV discrimination and for tachyarrhythmia prevention have been presented.

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