

Fifth Generation Implantable Cardioverter Defibrillator

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Summary

Prototypes of the first fifth generation implantable cardioverter defibrillator (ICD), the Biotronik Phylax AV, have been successfully tested at the Bakulev Institute of Cardiovascular Surgery. The device's SMART Detection™ algorithm enables it to discriminate between ventricular tachycardia events and events of supraventricular origin, thus avoiding unnecessary therapy. It offers a dual chamber intracardiac electrogram recording capability for improved diagnostics. With the appropriate shock lead configuration, the Phylax AV can also be used for manual atrial defibrillation. Its small physical size enables subpectoral implantation.

Key Words

defibrillation, ICD, dual chamber defibrillator, ventricular defibrillation, atrial defibrillation, AV discrimination, supraventricular tachycardia, SVT, intracardiac electrogram, IEGM, dual chamber IEGM recording, subpectoral implantation

Introduction

Four fifth generation Phylax AV ICD's have been implanted at the Bakulev Institute of Cardiovascular Surgery in April and June 1996.

The characteristics of this fifth generation ICD are:

- dual chamber sensing/pacing
- SMART Detection™ for VT/SVT discrimination - avoiding unnecessary therapy when the tachycardia is of supraventricular origin.
- dual channel IEGM recording
- manual atrial defibrillation
- small size suitable for subpectoral implant - 76 x 63 x 17 mm, 69 cc, 109 g
- active housing for reduced shock electrode count

Background

An analysis of therapies delivered by a third generation ICD has indicated that in a group of 48 ICD implants, close to 40% have been inappropriately treated for episodes of SVT's^[1]. This causes unnecessary pain for the patient.

Most ventricular anti-tachycardia therapy starts with anti-tachycardia pacing (ATP). This is not effective against SVT's and may initiate a ventricular tachycardia, where none was there in the first place. Cardioversion (CV) is the only effective therapy against SVT's.

This points to the need for improved discrimination between VT and SVT's.

There have been attempts to classify the chamber of origin of the tachyarrhythmia using only ventricular signals^[2]. However, these have not been completely successful. In this report we will present an ICD with sense/pace leads in both the atrium and ventricle and an AV discrimination algorithm that uses the information obtained from these leads.

SMART Detection™ Algorithm

The Phylax AV uses a standard atrial lead, with active or passive fixation, to sense P-waves in the atrium. The rate of the P-waves along with the P-R intervals are used by the SMART Detection™ algorithm to perform the AV discrimination.

The following assumptions are made in the SMART Detection™ algorithm used in the Phylax AV:

- ventricular fibrillation detection is the highest priority. Thus, a separate rate based detector is used to initiate ventricular defibrillation therapy.
- no ventricular therapy will be initiated as long as the ventricular rate is below the VT detection threshold.
- when the ventricular rate is higher than the VT detection threshold, the chamber with the higher rate is the origin of the tachycardia. Thus, atrial flutter or atrial fibrillation with occasional AV conduction will not be treated.
- in the case of equal rate in the atrium and ventricle, for a given set of observations there can be many possible diagnostics. If VT is the likely cause, then therapy is initiated.

The following are qualifiers of ventricular tachycardia that are used in the SMART Detection™ algorithm of the Phylax AV:

- monomorphic VT is characterized by regular R-R intervals,
- polymorphic VT is characterized by irregular R-R intervals and the rate is typically fast.
- atrial fibrillation is characterized by irregular P-P intervals and regular P-R intervals.
- VT tends to occur spontaneously and typically results in a fast rate increase - sudden onset.

Because of the possibility of undersensing, therapy is initiated in the Phylax AV only after a specified number of intervals have been classified as VT. This avoids misdiagnostics that occur in algorithms that rely on the determination of the chamber where the initial rate acceleration occurred ^[3].

Dual Chamber IEGM - Fibrillation

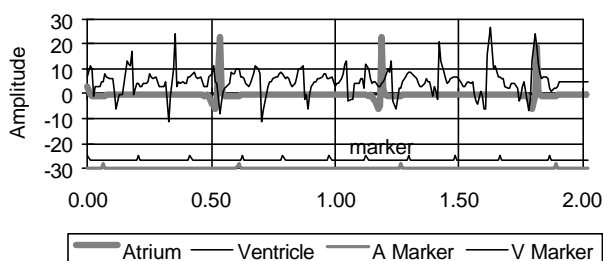


Figure 1. Dual Channel IEGM recording.

Dual Chamber IEGM

Both atrial and ventricular IEGM's can be stored inside the ICD for later retrieval. An example of the IEGM's during fibrillation and after successful defibrillation are shown in Figure 1. Both a pre-trigger segment and a post-therapy segment can be stored for each episode. Multiple records can be stored in the ICD. Each record can be as long as one minute. Pace/sense markers are also stored with the IEGM's.

Atrial Defibrillation

Atrial fibrillation is a common occurrence in patients with ICD implants. Since it is not life threatening, there is no urgency to terminate atrial fibrillation, unlike ventricular fibrillation.

With the atrial lead information, it is now possible to correctly diagnose atrial tachyarrhythmia. Thus, atrial therapy can be undertaken. As a first step, the Phylax AV offers a manual atrial defibrillation capability..



Figure 2. Active Housing Phylax AV with defibrillator SL lead

This is possible with the conventional vena cava and Right Ventricle shock electrodes as shown in Figure 2, where the ICD is an active housing device. Low energy (<4 Joules) R-wave synchronous cardioversion is used to achieve atrial defibrillation.

In Figure 3, an atrial flutter IEGM with 2:1 AV conduction is shown. With SMART Detection™ enabled, this atrial arrhythmia would be correctly classified and not treated. A manual atrial defibrillation was attempted with a 1 Joule cardioversion. The result of a successful 1 Joule atrial defibrillation is shown in the lower panel of Figure 3.

With low energy atrial defibrillation, the arrhythmia does not convert immediately. In a number of cases observed, like that in Figure 3, the atrial defibrillation disrupts the arrhythmia which then terminates on its own. This is a type II cardioversion^[4]. Higher energy atrial defibrillations tend to achieve immediate conversion, type I cardioversion. In the same patient with the type II cardioversion at 1 Joule shown in Figure 3, type I cardioversion has been achieved at 2 Joules.

Since atrial arrhythmias tend not to be life threatening, a strategy to delay treatment and to use only low level energy is desirable from a patient comfort perspective^[5].

References

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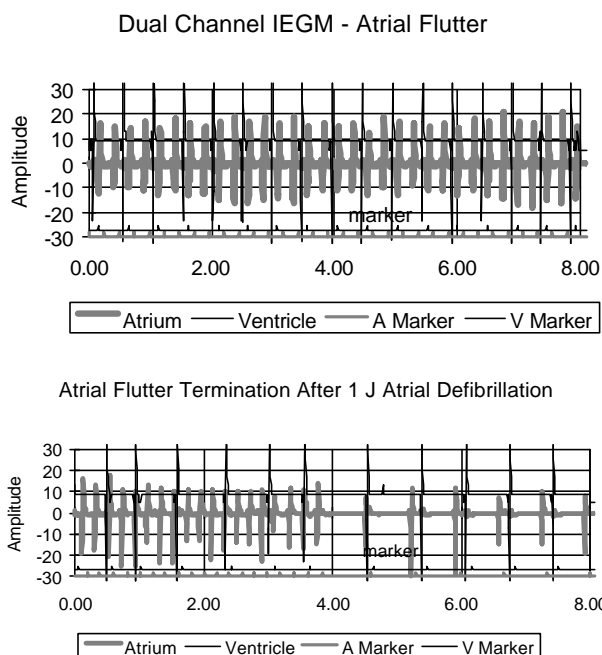


Figure 3. Atrial Defibrillation

Conclusion

Fifth generation ICD's with their atrial sensing capability and an effective VT/SVT discrimination algorithm should lead to improved patient life style due to the avoidance of unnecessary painful shocks and the availability of atrial defibrillation.