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"Two for the Price of One": A Single-Lead Implantable Cardioverter-Defibrillator System with A Floating Atrial Dipole

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Abstract

In patients known to be a high risk for sudden cardiac arrest, implantable cardioverter defibrillators (ICD) are a proven therapy to reduce risk of death. However, in patients without conventional indications for pacing, the optimal strategy for type of device, dual- versus single-chamber, remains debatable. The benefit of prophylactic pacing in this category of patients has never been documented. Although available atrial electrograms in a dual chamber system improve interpretation of stored arrhythmia events, allow monitoring of atrial fibrillation and may potentially reduce the risk of inappropriate shocks by enhancing automated arrhythmia discrimination, the use of dual-chamber ICDs has a number of disadvantages. The addition of an atrial lead adds complexity to implantation and extraction procedures, increases procedural cost and is associated with a higher risk of periprocedural complications. The single lead pacing system with ability to sense atrial signals via floating atrial electrodes (VDD) clinically became available in early 1980's but did not gain much popularity due to inconsistent atrial sensing and concerns about the potential need for an atrial lead if sinus node fails. Most ICD patients do not have indications for pacing at implantation and subsequent risk of symptomatic bradycardia seems to be low. The concept of atrial sensing via floating electrodes has recently been revitalized in the Biotronik DX ICD system (Biotronik, SE & Co., Berlin, Germany) aiming to provide all of the potential advantages of available atrial electrograms without the risks and incremental cost of an additional atrial lead. Compared to a traditional VDD pacing system, the DX ICD system uses an optimized (15 mm) atrial dipole spacing and improved atrial signal processing to offer more reliable atrial sensing. The initial experience with the DX system indicates that the clinically useful atrial signal amplitude in sinus rhythm remains stable over time. Future studies are needed to determine reliability of atrial sensing during tachyarrhythmias, particularly atrial fibrillation as well as clinical utility and cost-effectiveness of this technology in different populations of patients.

Introduction

An implantable cardioverter defibrillator (ICD) is a proven life-saving therapy for patients at high risk of sudden death. However, device selection strategy, a single - versus dual-chamber system, in patients without conventional indications for pacing remains debatable. The majority of patients enrolled in the landmark clinical trials that evaluated the utility of ICDs for prevention of sudden death received single-chamber devices.[1] The concept of prophylactic pacing in ICD patients without pacing indications has been tested in a number of large randomized clinical trials. In the DAVID (Dual Chamber and VVI Implantable Defibrillator) trail, dual chamber pacing was associated with worse outcomes than VVI back up (40 beats/min) pacing, most likely due to ventricular desynchronization caused by right ventricular (RV) pacing.[2] In subsequent trials, dual-chamber programming that minimizes unnecessary RV pacing by using special pacing algorithms (AV Search Hysteresis, Boston Scientific or Managed Ventricular Pacing, Medtronic) or atrial based (AAI 60 beats/min) pacing have yielded no improved outcomes compared to VVI back up pacing.[3-5] Yet, about two thirds of patients meeting criteria for a primary prevention ICD are implanted with dual chamber devices in the US; the majority of them have no conventional indications for pacing.[6] An ICD system using a single lead with floating atrial dipole, which can provide diagnostic capability of a dual-chamber system without placing an additional atrial lead, has recently become available. In this article we discuss a rationale for its use in ICD candidates who do not require pacing and review initial clinical experience with this system.

Key Words:
Implantable Cardioverter-Defibrillator, Floating Atrial Electrodes, VDD Pacing, DX ICD System.

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Potential Advantages of an Atrial Lead in ICD Patients

Although there is no proven benefit of pacing in ICD patients without traditional pacing indications, recording of atrial electrograms has a number of potential diagnostic and therapeutic advantages. First, the distinction between supraventricular and ventricular arrhythmias using ventricular or far-field electrograms is limited and availability of atrial electrograms improves correct interpretation of

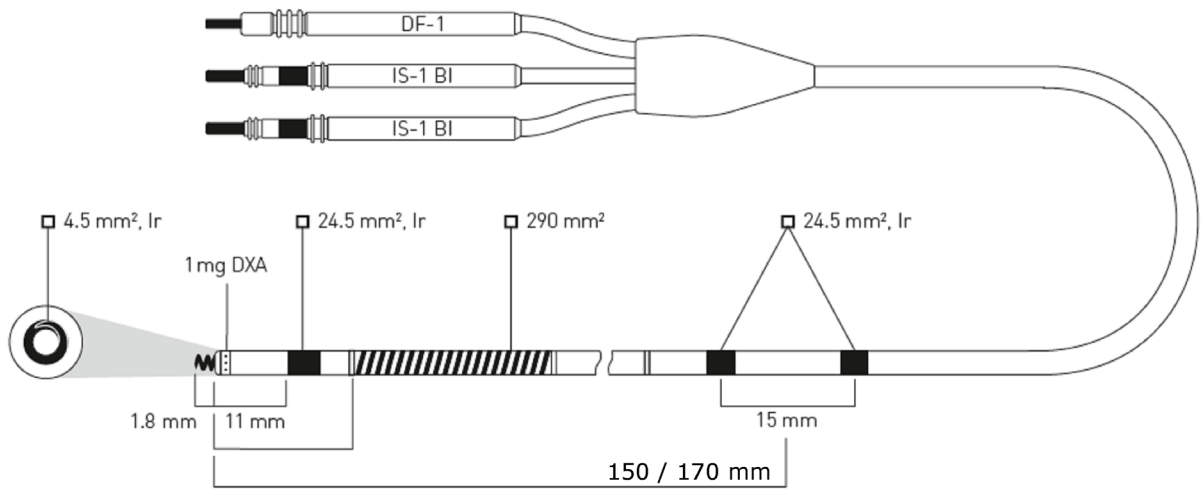

Figure 1: The Biotronik Linox Smart DX active fixation lead. The atrial dipole is mounted 15 -17 cm from the tip of the lead. Courtesy of Biotronik

stored arrhythmia events triggering ICD therapy.[7] Correct diagnosis of arrhythmia treated by ICD is critical for guiding an appropriate therapeutic approach.

Secondly, although published data are mixed, the presence of an atrial lead can potentially reduce the risk of inappropriate ICD therapies by enhancing automated arrhythmia discrimination.[8-11] While appropriate device programming with a relatively high detection cut off rate may significantly reduce the risk of inappropriate ICD shocks for supraventricular arrhythmias regardless of device selection (single versus dual), this strategy is not practical in patients with a relatively slow ventricular tachycardia (VT).[10] Inappropriate shocks predominantly for supraventricular arrhythmias have been reported in 11.5% - 17.4% of patients enrolled in major ICD clinical trials.[12, 13] Poorly tolerated high voltage ICD shocks can cause significant psychological stress and adversely affect patient's acceptance of the live-saving ICD therapy. Although the causality remains unclear, inappropriate ICD shocks have been associated with increased morbidity and mortality in heart failure patients.[12-15]

Finally, the presence of an atrial lead allows monitoring of atrial fibrillation (AF). This aspect of an ICD patient's management has become increasingly important with advent of remote monitoring with automatic wireless data transmission capability that allows early detection of clinically significant events such as AF, ventricular arrhythmias or device malfunction.[16] It is well recognized that AF is associated with adverse outcomes in heart failure patients and the most common trigger of inappropriate ICD shocks.[13-15] Asymptomatic AF is commonly found in ICD recipients.[10, 17] Although there is no consensus on the optimal anticoagulation strategy in patients with brief asymptomatic episodes of AF detected by implantable devices, there seem to be no argument that heart failure patients with sustained forms of AF should be managed with anticoagulation to reduce the risk of thromboembolic complications. In addition, early detection and prompt management of sustained AF by restoration of sinus rhythm or adequate control of ventricular rate can potentially prevent decompensation of heart failure and avoid inappropriate ICD shocks.

Disadvantages of the Addition of an Atrial Lead in ICD Patients

The addition of an atrial lead in ICD patients has a number of disadvantages. This adds complexity to implantation and extraction procedures, prolongs procedure and fluoroscopy time, increases procedural cost and is associated with higher rate of adverse outcomes.[1, 6, 10, 18] An outcome analysis of 104, 049 ICD implantation procedures using the National Cardiovascular Data ICD Registry found that selection of a dual- versus a single-chamber device was associated with increased risk of periprocedural complications and in-hospital mortality.[6] More recent analysis of data from the same registry by Peterson et al. revealed that the use of a dual-chamber ICD compared with a single chamber ICD was associated with almost two-fold higher risk of tamponade and mechanical complications requiring surgical correction while 1-year hospitalization and mortality rates were similar.[1]

A Single-Lead ICD System with Floating Atrial Electrodes

The single lead pacing system that affords atrio-ventricular (AV) synchrony through floating atrial electrodes (VDD) was introduced

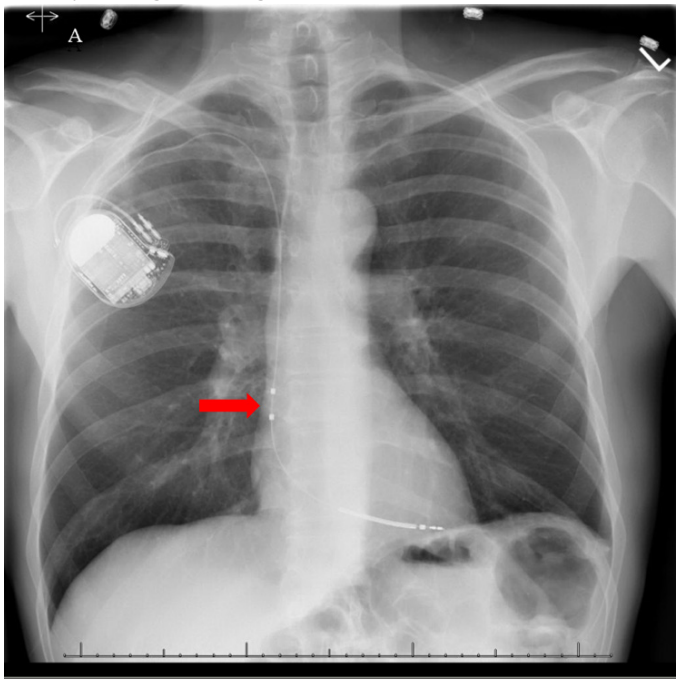

Figure 2A: A chest X-ray images showing placement of the Biotronik Linox Smart DX active fixation lead in the apex

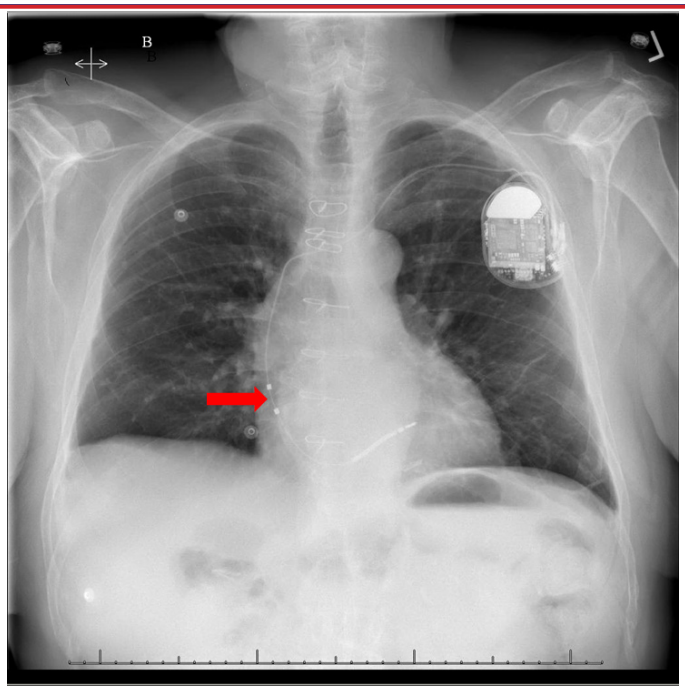

Figure 2B: A chest X-ray image showing placement of the Biotronik Linox Smart DX active fixation lead in the septum

into clinical practice in early 1980's as a simplified alternative to a dual chamber pacemaker for patients with complete AV block and preserved sinus note function.[19] While conceptually appealing, VDD pacing systems are implanted infrequently (< 1% of pacemaker implants in the US) primarily because of inconsistent atrial sensing causing intermittent loss of AV synchrony and a concern about the potential need for upgrade to a dual-chamber device if sinus node fails.[20] However, most ICD patients do not have indications for pacing at implantation and subsequent risk of symptomatic bradycardia seems to be low. In the Managed Ventricular Pacing Versus VVI 40 Pacing Trial, 5.5% of the 1030 enrolled ICD patients developed an indication for pacing over 2.5 years - some of them due to AV block.[5]

The concept of atrial sensing via floating electrodes was implemented in Biotronik ICDs (Biotronik, SE & Co., Berlin, Germany) in early 2000's in hopes to provide all of the potential advantages of available atrial electrograms without the risks and incremental cost of an additional atrial lead. The system has since undergone a series of device and lead modifications to optimize atrial signal recording and processing (optimization of atrial dipole spacing and distance from the RV tip, improvement of atrial signal processing and filtering, implementation of automatic atrial sensitivity control, adjustment of blanking periods, among others) prior to its commercial release (Biotronik, personal communication). The current generation of the system (DX system) consists of a VR-T DX device and a Linox Smart DX active fixation lead. The Linox Smart DX lead is a 7.8 French single coil true bipolar lead, which contains 15 mm spaced pair of atrial ring electrodes mounted 15 -17 cm from the lead tip (Figure 1). Atrial electrodes are floating and usually not in direct contact with myocardium. The DX ICD system has no atrial pacing capability but allows optional AV synchronous VDD pacing. Compared to a traditional VDD pacing system, the DX ICD system has a number of unique features that offer more reliable atrial sensing. The optimized atrial dipole spacing covers a relatively large area of atrial surface of 49 mm2. This provides better flexibility with its positioning within the atrium and improves stability of the atrial signal (Figure 2). To minimize atrial undersensing, the DX devices use a pre-amplifier, which progressively increases atrial gain up to four times. High gained atrial signals are then band-pass filtered to exclude signal frequencies outside the atrial component range (30-70 Hz) (Figure 3). While VDD pacemakers use a static sensitivity setting, the adaptive sensing feature implemented in DX ICDs helps to prevent oversensing of far-field noise. The DX ICD system received regulatory approval in Europe in 2011 and in the US in 2013.

DX ICDs are equipped with the SMART tachycardia discrimination algorithm, which is based on analysis of the tachycardia onset, average heart rate, heart rate stability and beat-to beat relation between atrial and ventricular signals (Figure 4). The algorithm has been described in details elsewhere.[21,22] Previous clinical studies have shown that the SMART algorithm allows discrimination between supraventricular and ventricular tachycardias with sensitivity of 100% and specificity of 64-89%.[21,23] In a simulation study, the algorithm showed 95% specificity for correct detection of supraventricular tachyarrhythmias.[24]

Recent studies evaluating the Biotronik DX ICD system have demonstrated stability of atrial signal within the clinically acceptable range over time.[22,25] In a study of 116 patients implanted with a DX ICD system, mean P wave amplitude varied from 5.0 to 6.1 mV during 6-month follow up in different body positions. None of the patients had P-wave amplitude lower then 0.4 mV. Appropriate atrial sensing was observed in 93.8% of sensing tests with sensitivity setting of 0.4 mV.[25] Iori et al. evaluated P-wave amplitude stability in 13 patients implanted with a DX ICD. The authors analyzed daily P-wave measurements using the Biotronik Home Monitoring™ system over a 200-day follow up. Mean P-wave amplitude was 4.2 ± 1.9 mV, whereas 95% of all daily measurements varied less than 50% of the mean P-wave value.[22]

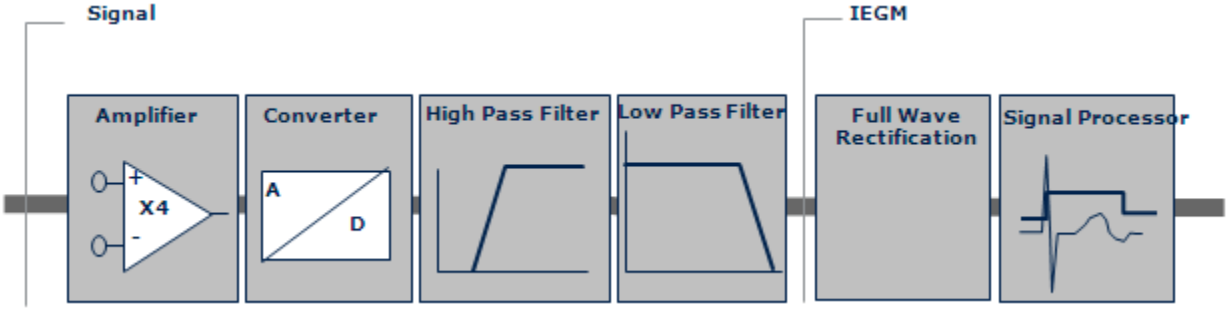

Figure 3: The schematic shows atrial signal processing in the Biotronik DX ICD system, which includes a dedicated atrial input stage with up to 4-fold signal amplification and noise filtering. Courtesy of Biotronik

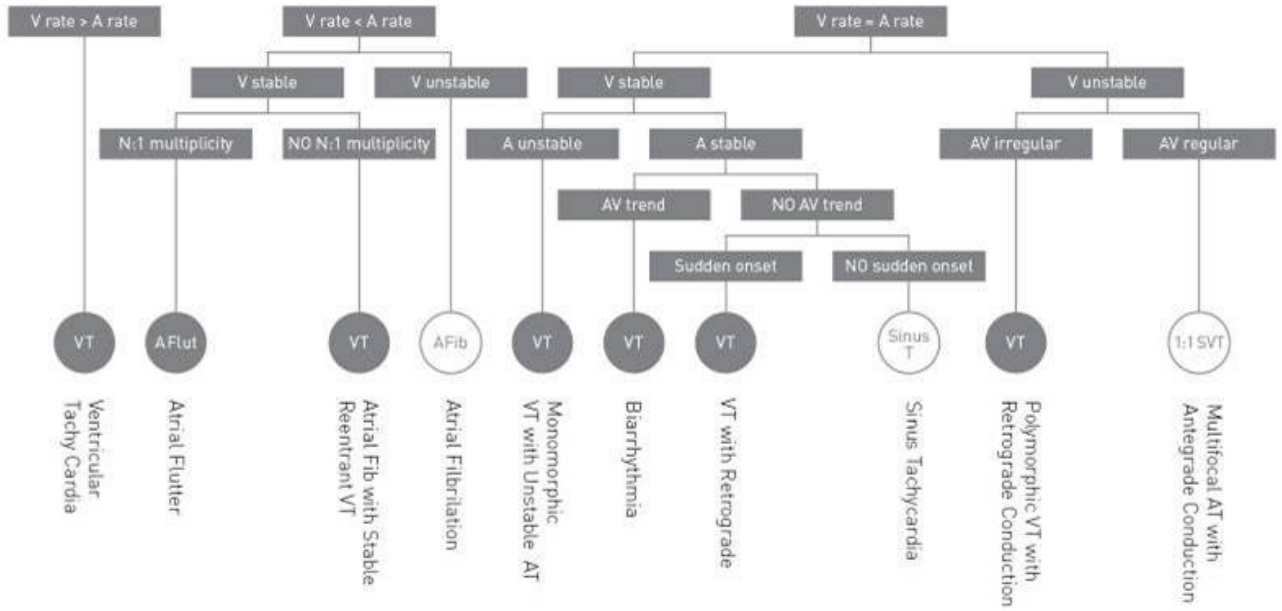

Figure 4: **Rhythm discrimination criteria employed in the SMART Detection algorithm. A and V denote atrial and ventricular, respectively. Courtesy of Biotronik**

The ADRIA (Belos A+ versus DR Clinical Investigation of Arrhythmia Discrimination) multicenter study randomized 249 patients without indications for pacing to either a single lead atrial sensing (A+) system (an early generation of the Biotronik single lead with floating electrode system which is now called DX ICD) or to a conventional dual chamber ICD.[23] The A+ system was found to be equivalent to a dual chamber ICD in terms of arrhythmia discrimination (specificity of supraventricular tachycardia discrimination: 61.8% and 66.2% for the A+ group and dual chamber group, respectively) while required significantly shorter implantation time. The vast majority of the misclassified supraventricular tachyarrhythmias were relatively slow sinus tachycardia. Low specificity of the SMART discrimination algorithm found in this study was attributed to a combination of low programmed VT detection cut off rate (≤ 130 bpm per study protocol), a relatively high incidence of abnormal atrial sensing (over- or under sensing) during supraventricular events, and definition of the Onset criterion to be triggered by a single ventricular premature beat (once the Onset criteria is met, the algorithm classifies the rhythm as VT regardless of other SMART criteria). The Onset criterion has been refined in later generation of devices (Biotronik, personal communication). Analysis of 492 misclassified sinus tachycardia episodes revealed that the percentage of patients with atrial over-or undersensing was significantly higher in the A+ arm compared to the dual chamber arm (36% versus 11% of patients, respectively).[23] As discussed earlier, the system has since undergone a series of modifications to optimize atrial sensing prior to its commercial release. Published clinical experience with current generation of devices (DX) is limited. In the Linox DX Study, 23 patients had total 88 spontaneous tachyarrhythmia events. All 15 ventricular events were appropriately diagnosed and treated by the device. In 54 out of 73 (74%) non-ventricular events, ICD therapies were appropriately withheld. Inappropriately treated events were due to supraventricular tachycardia (7 events), sinus tachycardia (4 events), T-wave oversensing (7 events), or electrocautery noise (1 event).[25] In the study by Iori et al., twenty spontaneous tachyarrhythmia events (3 ventricular and 17 supraventricular) were recorded in the VT zone. All events were correctly diagnosed by the device.[22]

In our center, we followed 35 patients who were implanted with the DX ICD system. We found that the atrial signal amplitude remained in the clinically useful range (mean 5.4 - 8.7 mV) over a mean follow up of 432 ± 197 days. There was no difference in atrial signal amplitude between apical and septal lead positions. All stored arrhythmia events showed readily interpretable atrial electrograms (Figure 5). The majority of the supraventricular events (82%) were correctly classified by the device and ICD therapies were appropriately avoided.[26]

Conclusions

A single lead ICD system with floating atrial dipole, which can provide the benefit of available atrial electrograms without the risks and incremental costs of an additional atrial lead, is a promising alternative to a dual chamber ICD in patients without conventional pacing indications. The initial experience with the Biotronik DX system indicates that the clinically useful atrial signal amplitude remains stable over time. However, since this is a relatively new technology many questions remain. Future studies are needed to determine: (1) long-term lead durability, (2) impact of floating electrodes on complexity of lead extraction comparing to a conventional single coil

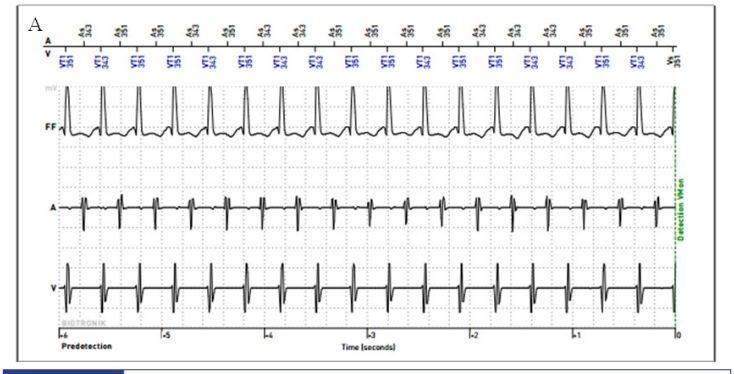

Figure 5A: **An examples of stored arrhythmia events during supraventricular tachycardia**

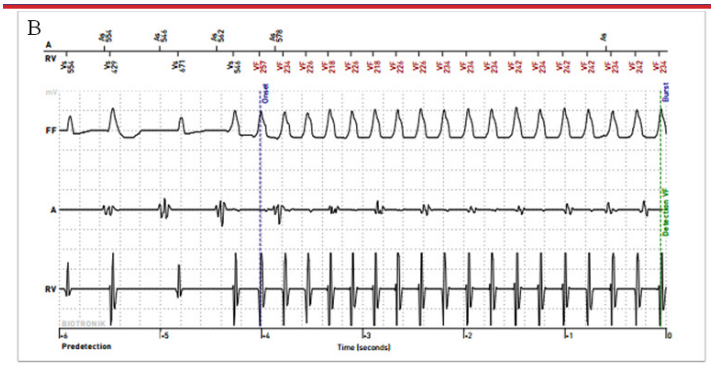

Figure 5B: An examples of stored arrhythmia events during ventricular tachycardia

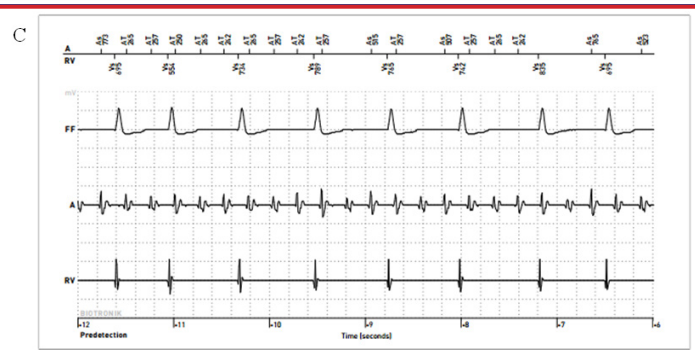

Figure 5C: An examples of stored arrhythmia events during atrial flutter

ICD lead, (3) reliability of atrial sensing during tachyarrhythmias, particularly atrial fibrillation, (4) subsequent need for atrial pacing and device upgrades in patients implanted with this system, and (5) clinical utility and cost effectiveness of this technology in different patient populations (primary versus secondary prevention indication, primary arrhythmogenic syndromes such as Long QT or Brugada, etc.).

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