

Interactive Simulator for Evaluating the Detection Algorithms of Implantable Defibrillators

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Summary

Despite sophisticated implantable cardioverter-defibrillator (ICD) detection algorithms, inappropriate therapy for supraventricular tachyarrhythmias is still a common problem. A comparison of detection algorithms based on the specificity to detect supraventricular tachyarrhythmias reported from different clinical studies is of a limited value because the spectrum of tachyarrhythmias recorded during these studies may vary substantially. In addition, the values of specificity derived from simulations performed by each manufacturer separately do not allow a correct comparison of the performance of different detection algorithms unless the database of tachyarrhythmias is uniform for all devices compared. Based on tachyarrhythmias recorded during electrophysiological study, we created a database including supraventricular and ventricular tachyarrhythmias that may serve as such a uniform database for direct comparison of all available ICD detection algorithms. By customizing a simulator, we created a fully interactive device compatible with all ICDs via standard connectors that may serve as a uniform platform to evaluate and compare ICD detection algorithms. In addition, it is a valuable tool for selecting the optimum ICD for a patient with a specific spectrum of arrhythmias and training physicians.

Key Words

Tachyarrhythmia, specificity of detection algorithms, implantable cardioverter-defibrillator (ICD)

Introduction

Clinical data comparing the specificity for detection of supraventricular tachyarrhythmias by different dual-chamber implantable cardioverter-defibrillator (ICD) algorithms are scarce, and only preliminary data are currently available. These data include pre-market release studies, reports on the first clinical experience with a new device, or comparison of a single-chamber algorithm with that of a dual-chamber [1-6]. A comparison of algorithms based on the specificity derived from different clinical studies and reported by the manufacturers is of limited value because the spectrum of tachy-arrhythmias recorded during such a study may vary substantially from the spectrum recorded during another study.

In addition, the values of specificity to detect supraventricular tachyarrhythmias derived from simulations performed and reported by each separate manufacturer do not allow for a correct comparison of the performance of different detection algorithms unless the database used for tachyarrhythmia episodes is uniform for all devices compared [7]. However, the databases used by different manufacturers are different. There is a good reason that these databases are not the same. Different algorithms and different programming of single-chamber criteria lead to a markedly different success in distinguishing true ventricular tachycardia (VT)/ventricular fibrillation (VF) episodes from supraventricular tachyarrhythmias at the level of ven-

Atrial fibrillation
Atrial flutter with 1:1 AV conduction
Atrial flutter with n:1 AV conduction
Atrial tachycardia with 1:1 AV conduction
Atrial tachycardia with irregular AV conduction
Typical AV nodal reentrant tachycardia
Atypical AV nodal reentrant tachycardia with R-P > P-R
Atypical AV nodal reentrant tachycardia with R-P < P-R
Orthodromic AV reentrant tachycardia
Sinus tachycardia with normal AV conduction
Sinus tachycardia with AV block I°
Ventricular tachycardia with stable VA conduction occurring during sinus tachycardia with normal AV conduction
Ventricular tachycardia with stable VA conduction occurring during sinus tachycardia with AV block I°
Ventricular tachycardia with various but constant VA conduction
Ventricular tachycardia with VA dissociation

Table 1. Spectrum of tachyarrhythmias simulated. AV: Atrio-ventricular. VA = Ventriculo-atrial.



Figure 1. Arrhythmia Simulator (ARSI, HKP, Germany). The device consists of the simulator itself (top) and the ICD adapter (DFA - 2DS, bottom). Pressing the <PR> button and any of the numbers on the simulator will start a group of tachyarrhythmias, e.g., AV nodal reentrant tachycardias with varying VA interval. Single or multiple atrial or ventricular extrasystoles may be delivered by pressing one of the 4 buttons at the far right of the panel. Even noise generated by alternating current or skeletal muscle can be generated. The adapter accommodates the ICD through the pocket created during device implantation, and even facilitates testing of an active can device. The ICD is attached via standard DF-1 connectors, mimicking the defibrillation electrodes, and IS-1 connectors for the pacing and sensing leads.

tricular detection [8]. These differences result in a different spectrum of supraventricular tachyarrhythmias inappropriately classified by a single-chamber device and eventually stored in a database used to test the more sophisticated dual-chamber algorithms.

At our institution, arrhythmias recorded from patients undergoing invasive electrophysiological studies and catheter ablation were used without any modifications to create a "tachyarrhythmia" library. The data consists of 71 supraventricular and 15 ventricular tachyarrhythmias recorded on a standard personal computer (PC) by measuring the P-P and R-R intervals of each episode including the preceding rhythm and onset of the arrhythmia. There are episodes of atrial fibrillation, atrial flutter with different atrioventricular (AV) conduction, typical and atypical AV nodal reentrant tachycardia, AV reentrant tachycardia, sinus tachycardia, and ventricular tachycardia with and without ventriculo-atrial (VA) conduction (Table 1). In order to cover the full spectrum of R-P and P-R intervals of typical and atypical AV nodal reentrant tachycardia, the VA interval was increased by increments of 20 ms from episode to episode. The atrial and ventricular sensing input of each DDD-ICD was connected to a custom-built PC device that created rectangular impulses of a standardized amplitude of 20 mV and a duration of 10 ms at the intervals stored for each episode of tachyarrhythmia. Using this model, we compared the four DDD-ICDs available at this time: the Phylax AV (Biotronik, Germany), the Defender IV (Ela Medical, France), the Ventak AV III DR (Guidant, USA), and the Gem DR 7271 (Medtronic, USA). The results of this study have been reported elsewhere [9].

However, recently introduced dual-chamber detection algorithms include automatic delivery of a premature ventricular stimulus in order to test the presence of retrograde conduction or analysis of the morphology of the ventricular intracardiac electrogram (IEGM). This requires a more sophisticated simulation tool that has to be interactive in both directions and provides distinct ECG patterns for sinus rhythm and supraventricular, as well as ventricular tachycardia. For this purpose, we customized an Arrhythmia Simulator (ARSI, HKP, Germany).

Materials and Methods

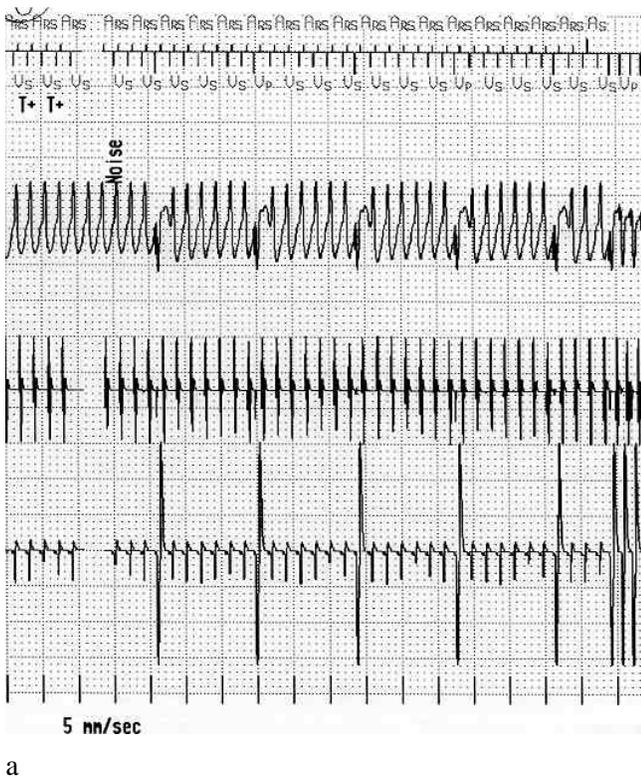
The ARSI device (Figure 1) consists of the simulator itself and the ICD adapter, a box that accommodates

Surface ECG	12-channel standard leads
	Amplitude resolution: 8 bits
	Sampling rate: 1 kHz
	Signal bandwidth: 500 Hz
Endocardial electrogram	Heart rate: 10 ... 225 bpm (+/- 1%)
	Output resistance: 1 k Ω
	Pacing threshold: 0.7 V at 0.5 ms, bipolar
	Pacing spike: 3 mV/1 ms
Defibrillation	Impedance: 500 Ω
	Amplitude of intracardiac atrial electrogram: 3 mV
	Amplitude of intracardiac ventricular electrogram: 10 mV
Defibrillation	Defibrillation threshold: 2 J
	Defibrillation impedance: 57 Ω

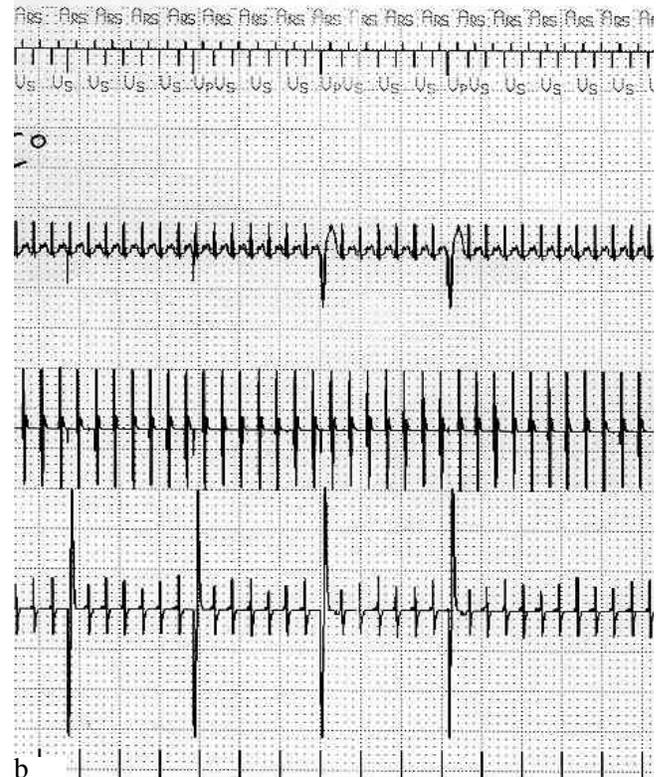
Table 2. Technical data of the Arrhythmia Simulator (ARSI, HKP, Germany).

the ICD (similar to the pocket created during device implantation) and even facilitates the testing of an active can device. The ICD is attached via standard DF-1 connectors, mimicking the defibrillation electrodes, and IS-1 connectors for the pacing and sensing leads. The simulator is a battery-driven device providing both a 12-lead surface ECG and an atrial and ventricular IEGM. Surface ECG and ventricular IEGMs provide different morphologies depending on the rhythm being simulated [10].

Each of the episodes of supraventricular rhythms can be delivered with narrow or wide QRS complexes. The simulation is fully interactive, i.e., in addition to simulating arrhythmias that are analyzed by the ICD connected to the simulator, the simulator responds to electrical impulses delivered by the ICD (stimulation, defibrillation). This even includes premature beats delivered after the effective refractory period that result in transient changes of tachycardia cycle length, thereby facilitating the evaluation of ICD algorithms that analyze the response to single premature beats.



a



b

Figure 2. SMART II algorithm of the Tachos (Biotronik, Germany) : Delivery of premature ventricular extrastimuli during two episodes of tachycardia with identical, stable cycle length and VA interval may result in shortening of the A-A interval indicating a ventricular tachycardia (panel a) or may leave the atrial cycle length unchanged indicating sinus tachycardia with first degree AV block (panel b).

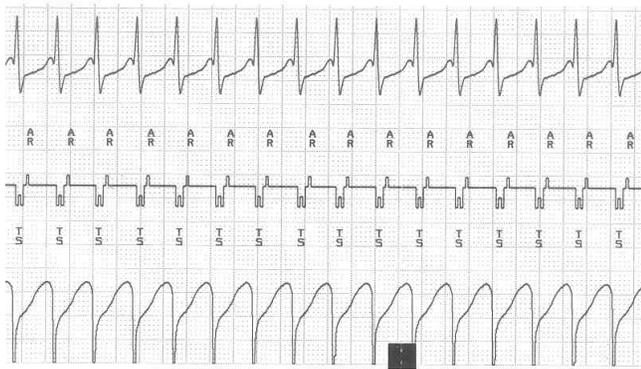


Figure 3. P-R Logic algorithm of the Gem DR 7271 (Medtronic, USA). See text for further details.

Results

In the customized version of the simulator, there are more than 150 episodes from our library, covering the spectrum of tachyarrhythmias listed in Table 2. Some examples are sinus rhythm including supraventricular rhythm with normal, narrow QRS complexes, or wide QRS complexes in the presence of intraventricular conduction delay; ventricular tachycardia with wide QRS complexes with a different morphology as compared to supraventricular rhythms with wide QRS complexes, and irregular morphology in the presence of ventricular fibrillation.

After the device is switched on, sinus rhythm is simulated. Amplitude of the surface ECG, basic heart rate, and the P-R interval may be varied. By pressing single buttons, transient AV block can be simulated or atrial or ventricular extrasystoles up to non-sustained tachycardias can be delivered. In addition, even noise generated by alternating current or skeletal muscle can be generated.

Variation of the AV and VA interval of the simulated supraventricular and ventricular tachyarrhythmias reveals the impact of variations in the blanking time or zones defined for presumed antegrade or retrograde conduction during tachycardia.

In the Parad+ algorithm of the Defender IV (Ela), the atrial signal in case of a typical AV nodal reentrant tachycardia with a VA interval less than the atrial blanking period is not detected and therefore the arrhythmia is classified as ventricular tachycardia. However, if the VA interval during AV nodal reentrant tachycardia is longer than the atrial blanking period,

the arrhythmia will be correctly classified as supraventricular tachycardia.

The P-R Logic algorithm analyses the two previous R-R intervals for each ventricular event. The number of atrial events and their timing relative to the ventricular events are used to assign one of 19 couple codes to the most recent ventricular event. Zero, one, or more atrial events are classified within the first or second half of each R-R interval. If an atrial event is detected within 80 ms before or within 50 ms after a R wave, then that P wave should not be related to the ventricular event by either antegrade or retrograde conduction. However, any supraventricular tachycardia with a VA interval greater than 50 ms and less than 50% of the tachycardia cycle length will be classified as ventricular tachycardia with 1:1 VA conduction. Sinus tachycardia with AV block I° and a P-R interval greater than 50% of the tachycardia cycle length will be classified as ventricular tachycardia with 1:1 VA conduction, too (Figure 3).

Discussion

Our simulator provides a convenient tool for easy assessment of the specificity of different ICD detection algorithms and a direct comparison of ICDs from different manufacturers. It may serve as the common universal database as suggested by Malik [7]. Wide acceptance of a database such as this would provide a uniform standard for evaluating the specificity for the correct classification of supraventricular tachyarrhythmias, and would result in values that are comparable among manufacturers.

Due to its fully bi-directional interaction with the ICD, even testing of sophisticated detection algorithms that evaluate the response to a premature ventricular stimulus is feasible and the impact of the AV and VA interval on the accuracy for classification of tachyarrhythmias can be analyzed. While the accuracy of IEGM morphology analysis performed by the ICD algorithm cannot be studied, different electrogram morphologies can be simulated and the contribution of a morphology criterion to the overall performance of the algorithm can be assessed.

Conclusion

Sophisticated ICD algorithms may be difficult for a physician to understand without any specific arrhyth-

mias illustrating the timecourse of application of the different detection criteria. Our device may help to train physicians by demonstrating the way a specific algorithm works. In addition, it is a valuable tool that aids the physician in choosing the ICD system with the optimal detection algorithm for a specific patient. The device simulates tachyarrhythmias similar to the patient's spontaneous arrhythmias and can help in determining which specific device should be implanted.

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