

Comparison of the Specificity of Implantable Dual Chamber Defibrillator Detection Algorithms

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HINTRINGER, F., ET AL.: Comparison of the Specificity of Implantable Dual Chamber Defibrillator Detection Algorithms. *The aim of the study was to compare the specificity of dual chamber ICDs detection algorithms for correct classification of supraventricular tachyarrhythmias derived from clinical studies according to their size to detect an impact of sample size on the specificity. Furthermore, the study sought to compare the specificities of detection algorithms calculated from clinical data with the specificity calculated from simulations of tachyarrhythmias. A survey was conducted of all available sources providing data regarding the specificity of five dual chamber ICDs. The specificity was correlated with the number of patients included, number of episodes, and number of supraventricular tachyarrhythmias recorded. The simulation was performed using tachyarrhythmias recorded in the electrophysiology laboratory. The range of the number of patients included into the studies was 78–1,029, the range of the total number of episodes recorded was 362–5,788, and the range of the number of supraventricular tachyarrhythmias used for calculation of the specificity for correct detection of these arrhythmias was 100 (Biotronik) to 1662 (Medtronic). The specificity for correct detection of supraventricular tachyarrhythmias was 90% (Biotronik), 89% (ELA Medical), 89% (Guidant), 68% (Medtronic), and 76% (St. Jude Medical). There was an inverse correlation ($r = -0.9$, $P = 0.037$) between the specificity for correct classification of supraventricular tachyarrhythmias and the number of patients. The specificity for correct detection of supraventricular tachyarrhythmias calculated from the simulation after correction for the clinical prevalence of the simulated tachyarrhythmias was 95% (Biotronik), 99% (ELA Medical), 94% (Guidant), 93% (Medtronic), and 92% (St. Jude Medical). In conclusion, the specificity of ICD detection algorithms calculated from clinical studies or registries may depend on the number of patients studied. Therefore, a direct comparison between different detection algorithms based on clinical data is difficult. In contrast, simulation of supraventricular tachyarrhythmias using a uniform database may be a better tool for direct comparison of the specificity of ICD detection algorithms. (PACE 2004; 27:976–982)*

implantable device, inappropriate therapy, defibrillation, tachyarrhythmias

Introduction

Inappropriate therapy of supraventricular tachyarrhythmias by an implantable cardioverter defibrillator (ICD) is still a common problem occurring in 16–22% of patients with an ICD.^{1,2} Despite the introduction of more advanced detection algorithms, a substantial number of patients are still receiving inappropriate therapy.^{3–6} The specificity of ICDs (i.e., the correct classification of supraventricular tachyarrhythmias and the subsequent inhibition of therapy) is individually calculated for each algorithm from studies or registries mostly conducted by the manufacturers themselves in cooperation with clinical investigators.^{7–14} However, many factors may influence the results. One

of the most important factors may be the sample size of such a study that can be defined by the number of patients included into the study or by the number of episodes collected during the course of the study. A systematic comparison of studies reporting the specificity of individual ICD detection algorithms has not been performed so far. Thus, the first aim of the study was to compare the specificity of dual chamber ICD detection algorithms derived from clinical studies not only with respect to the specificity itself, but to compare the studies according to their size to detect an impact of sample size on the specificity. In contrast, simulation of tachyarrhythmias to test detection algorithms makes a direct comparison of specificity and sensitivity of these algorithms possible without the need for a clinical trial.¹⁵ However, it has not been studied if the specificity calculated from such a simulation correlates with the results from clinical studies or registries conducted for each algorithm individually. Therefore, the second aim of the study was to compare the specificities of dual chamber ICD detection algorithms calculated

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from clinical data and from the authors' simulation, respectively.

Methods

A survey was conducted of all available sources providing data regarding the specificity of the five dual chamber ICD algorithms on the market at the time of the simulation (Table I). The data sources included published clinical studies, multicenter registries, and reports by the manufacturers summarizing the results of multicenter market release studies.⁷⁻¹⁴ The specificity was correlated with data defining the size and determining the statistical power of these studies (i.e., number of patients included, total number of episodes, and number of supraventricular tachyarrhythmias recorded).

In addition, the specificity of the devices (Table I) for the correct detection of supraventricular tachyarrhythmias was tested by means of simulation. The technique of simulating tachyarrhythmias, including the library and our interactive simulator, has been described elsewhere.^{15,16} Briefly, arrhythmias recorded from patients undergoing invasive electrophysiological studies, and in many cases catheter ablation at the authors' institution were used without any modifications to create a library consisting of 100 episodes of supraventricular tachyarrhythmias and nine episodes of ventricular tachycardias including the morphology of their QRS complexes. The library consists of episodes of atrial fibrillation, atrial flutter with different atrioventricular (AV) conduction, typical and atypical AV nodal reentrant tachycardia, AV reentrant tachycardia, and sinus tachycardia with normal and impaired AV conduction (Table II). In addition, nine episodes of ventricular tachycardia with constant

Table II.

Spectrum of Tachyarrhythmias Simulated and Tested

- 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 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

AV = atrioventricular; VA = ventriculoatrial.

but different ventriculoatrial (VA) intervals and without VA conduction were simulated (Table II).

All the devices were programmed for detection of:

1. Ventricular fibrillation at a cycle length <280 ms,
2. Ventricular tachycardia at a cycle length between 500 and 280 ms, and
3. The upper rate limit of antibradycardia pacing was always programmed below the detection window for ventricular tachycardia.

Table I.

Specificity for Correct Classification of Supraventricular Tachyarrhythmias Calculated From Available Clinical Data

| Manufacturer Model | BIO Phylax AV | ELA Defender | GUI Ventak AVIII | MED Gem DR | SJM Photon DR |
|--------------------|---------------|--------------|------------------|------------|---------------|
| Data sources (n) | 2 | 1 | 1 | 2 | 2 |
| Patients (n) | 78 | 95 | 148 | 1029 | 266 |
| Total episodes (n) | 362 | 559 | 661 | 5788 | 1045 |
| SVT (n) | 100 | 259 | 392 | 1662 | 402 |
| Spec. for SVT (%) | 90 | 89 | 89 | 68 | 76 |

BIO = Biotronik; ELA = Ela Medical; GUI = Guidant; MED = Medtronic; SJM = St. Jude Medical; Spec. for SVT = Specificity for correct classification of supraventricular tachyarrhythmias. For data sources, see references 7-14.

All detection enhancements for supraventricular tachyarrhythmias were activated at their nominal values.

The endpoint of each episode was:

1. Delivery of therapy, which was delivery of a 1-J shock if the tachyarrhythmia was classified as ventricular fibrillation or antitachycardia stimulation if the tachyarrhythmia was classified as ventricular tachycardia, and
2. The end of the simulated episode if the tachyarrhythmia was classified as supraventricular tachyarrhythmia.

Episodes and their classification by the ICD were recorded by interrogation of the device, documented by a printout of the programmer and, if possible, stored on a floppy disk or the hard disk of the programmer. If the classification of an episode by the DDD ICD was wrong, the test was repeated after optimization of the algorithm with the help of an engineer of the manufacturer.

In a second analysis, the simulated supraventricular arrhythmias were weighted according to their spontaneous clinical prevalence as reported in the literature,¹⁷⁻²⁰ and the specificity was recalculated. Weighting the arrhythmias was achieved by scoring each episode of supraventricular arrhythmia. For example, the most common supraventricular arrhythmia, atrial fibrillation was weighted with a value of 100 whereas a single episode of AV nodal reentrant tachycardia was weighted with a value of 0.4 due to the fact that this arrhythmia is far less common. In addition, 36 episodes of AV nodal reentrant tachycardia were simulated to cover the full spectrum of VA intervals seen in typical and atypical forms of this tachycardia in contrast to only three episodes of atrial fibrillation with different AV conduction.

Statistical Analysis

All data from clinical studies, multicenter registries, and reports by the manufacturers summarizing the results of multicenter market release studies regarding the same algorithm were pooled for each algorithm separately, and the specificity for correct classification of supraventricular arrhythmias was recalculated. This specificity and the specificity resulting from the simulation is expressed as the percentage of supraventricular arrhythmias correctly classified by the algorithm and, therefore, not treated by the device.

Spearman's correlation coefficient was calculated to assess the correlation between the specificity calculated from the survey as described above and the number of patients, the total number of episodes, and the number of supraventricular tachyarrhythmias, respectively. Comparison of

the specificity of the five different algorithms as assessed by simulation was performed using the McNemar test. A P value < 0.05 was considered statistically significant.

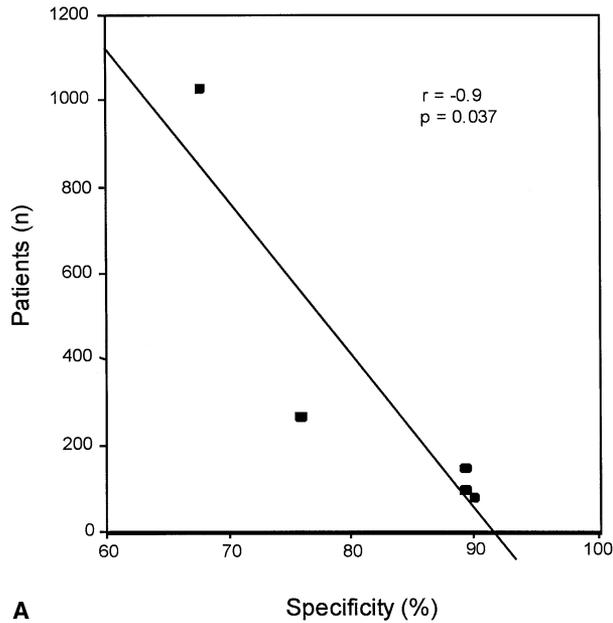
After weighting the simulated supraventricular arrhythmias according to their spontaneous clinical prevalence, the specificity was recalculated. However, weighting supraventricular arrhythmias does not result in a representative sample. Therefore, the statistical significance of the different specificity achieved by the algorithms tested was not calculated. The Statistical Package for the Social Sciences (SPSS) for Windows 11.5 (SPSS, Inc., Chicago, IL, USA) was used for all analyses.

Results

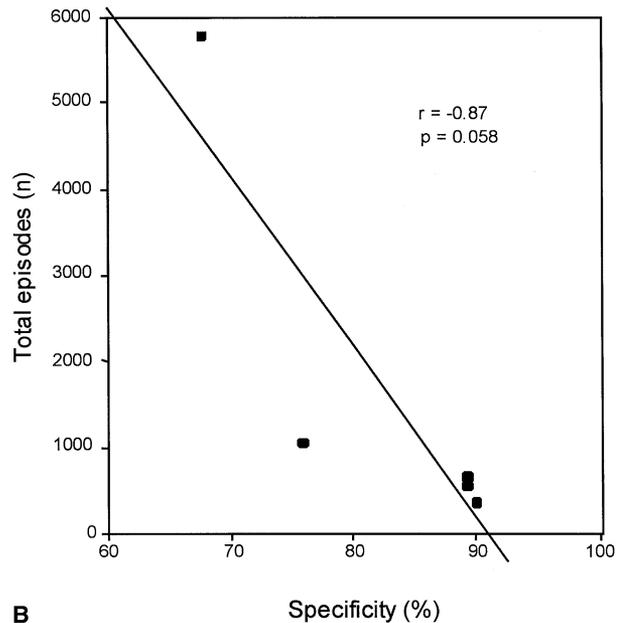
The results of the analysis of the data from published clinical studies, multicenter registries, and reports by the manufacturers summarizing the results of multicenter market release studies are shown in Table I. The range of the number of patients included into the studies was 78 (Biotronik) to 1,029 (Medtronic, Inc., Minneapolis, MN, USA), the range of the total number of episodes recorded was 362 (Biotronik) to 5,788 (Medtronic), and the range of the number of supraventricular tachyarrhythmias used for calculation of the specificity for correct detection of these arrhythmias was 100 (Biotronik) to 1,662 (Medtronic). The specificity for correct detection of supraventricular tachyarrhythmias calculated by pooling all available data for each ICD was 90% (Biotronik), 89% (ELA Medical), 89% (Guidant, St. Paul, MN, USA), 68% (Medtronic), and 76% (St. Jude Medical, St. Paul, MN, USA) (Table I). There was an inverse correlation between the specificity for correct classification of supraventricular tachyarrhythmias and the number of patients (Fig. 1A), total number of episodes (Fig. 1B), and number of supraventricular tachyarrhythmias (Fig. 1C), respectively. However, only the correlation between the specificity for correct classification of supraventricular tachyarrhythmias and the number of patients reached statistical significance.

The specificity for correct detection of supraventricular tachyarrhythmias calculated from the present simulation was 32% (Biotronik), 88% (ELA Medical), 18% (Guidant), 30% (Medtronic), and 57% (St. Jude Medical). After correction for the clinical prevalence of the simulated supraventricular tachyarrhythmias the specificity was 95% (Biotronik), 99% (ELA Medical), 94% (Guidant), 93% (Medtronic), and 92% (St. Jude Medical) (Fig. 2). For the present simulation, the Biotronik Tachos DR and the Guidant Prizm II DR were used, whereas the authors collected clinical data from the Biotronik

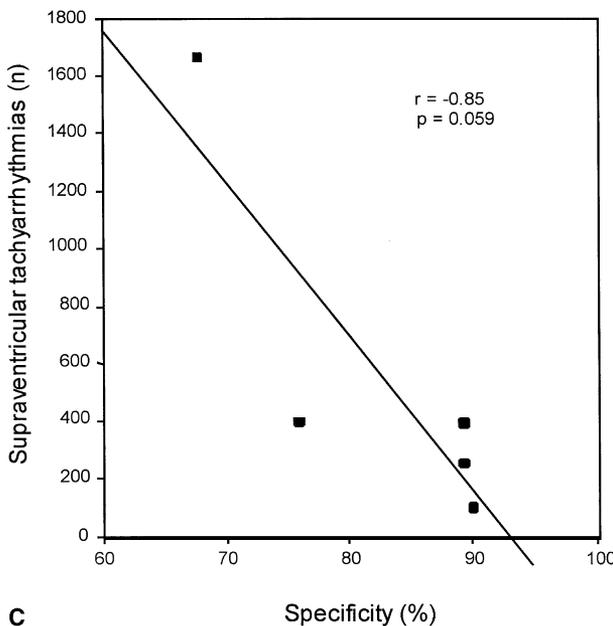
COMPARISON OF THE SPECIFICITY OF IMPLANTABLE DEFIBRILLATORS



A



B



C

Figure 1. Correlation between the specificity for correct classification of supraventricular tachyarrhythmias calculated from available clinical data and the number of patients (panel A), total number of episodes (panel B), and number of supraventricular tachyarrhythmias (panel C).

Phylax AV and the Guidant Ventak AV III. However, the detection algorithms of the Phylax AV III and the Tachos DR are identical and also the detection algorithms of the Ventak AV III and the Prizm II DR.

The Biotronik Tachos DR DDD

The ICD correctly classified all stable supraventricular tachyarrhythmias with n:1 AV conduction ($n > 1$). In addition, due to the timing of delivery of the ventricular premature beat, the P-P interval during typical AV nodal reentrant tachycardia was not affected by the stimulus and

the tachycardia was correctly classified. All other supraventricular tachycardias with 1:1 AV conduction were classified as ventricular tachycardia. Sinus tachycardia with or without impairment of AV conduction was correctly classified.

The ELA Defender IV DDD

The ICD classified AV nodal reentrant tachycardias induced by an atrial ectopic beat and a VA interval longer than the minimum atrial blanking interval (47 ms) as supraventricular tachycardia, whereas episodes of AV nodal reentrant tachycardia with a VA interval shorter than the minimum

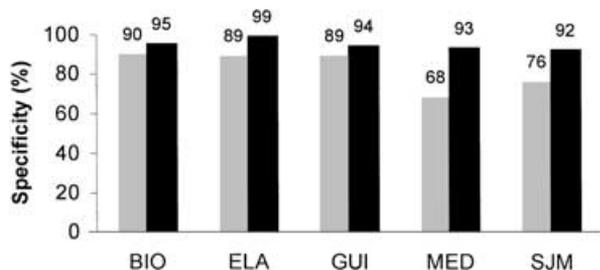


Figure 2. Comparison of the specificity for correct classification of supraventricular tachyarrhythmias of the five different dual-chamber defibrillators. Grey bars: Specificity resulting from clinical data. Black bars: Specificity resulting from the simulation when weighting the supraventricular tachyarrhythmias according to their spontaneous incidence. BIO = Biotronik; ELA = Ela Medical; GUI = Guidant; MED = Medtronic; SJM = St. Jude Medical.

blanking interval and AV reentrant tachycardias induced by ventricular ectopic beats were classified as ventricular tachycardia. Supraventricular tachyarrhythmias with n:1 AV conduction were correctly classified. Sinus tachycardia with or without impairment of AV conduction was correctly classified. However, ventricular tachycardia with VA conduction following sinus tachycardia with first-degree AV block was not detected, and thus no therapy was delivered.

The Guidant Prizm II DR DDD

The ICD classified all supraventricular tachycardias with 1:1 AV conduction and a stable ventricular rate as ventricular tachycardia. Supraventricular tachyarrhythmias with an irregular ventricular rate or n:1 AV conduction ($n > 1$) were correctly classified. Sinus tachycardia with or without impairment of AV conduction was correctly classified.

The Medtronic Gem DR 7275 DDD

ICD correctly classified AV nodal reentrant tachycardias with an atrial signal sensed within the junctional zone (50 ms), whereas episodes with a VA interval exceeding 50 ms and AV reentrant tachycardias were classified and treated as ventricular tachycardia. However, atypical AV nodal reentrant tachycardias with an R-P interval exceeding the P-R interval were correctly classified. Sinus tachycardia with first-degree AV block with a P-R interval longer than the R-P interval was misclassified as ventricular tachycardia.

The St. Jude Medical Photon DR DDD

The ICD correctly classified all supraventricular tachycardias with a stable ventricular cycle length and a QRS morphology matching the mor-

phology during sinus rhythm. However, supraventricular tachycardias with a mismatch of morphology as compared to sinus rhythm, were classified as ventricular tachycardia, and subsequent therapy was delivered. Sinus tachycardia with or without impairment of AV conduction was correctly classified. An episode of atrial fibrillation with single R-R intervals < 280 ms was inappropriately classified.

Rapid supraventricular tachyarrhythmias resulting in a cycle length < 280 ms, like atrial flutter with 1:1 AV conduction were classified and treated as ventricular fibrillation by all DDD ICDs, except the Medtronic Gem DR 7275 DDD ICD. The P-R LOGIC algorithm allows to apply detection enhancements even in the ventricular fibrillation detection window down to a minimum cycle length of 260 ms, while keeping the border between the ventricular tachycardia and the ventricular fibrillation detection window at a cycle length of 280 ms, as it was standardized for all devices tested.

Options to further optimize the detection algorithm when all detection enhancements are active at their highest specificity are not available (Biotronik, St. Jude Medical) or are limited (Guidant) in three of the five devices tested. Therefore, the second test after an attempt to optimize the classification of supraventricular tachyarrhythmias revealed different results in the ELA and the Medtronic algorithm, only. In the case of the ELA algorithm, shortening of the postventricular atrial refractory period from its nominal value to the minimum value resulted in correct classification of all AV nodal reentrant tachycardias with a VA interval exceeding 47 ms. Reprogramming of the border between the zone of retrograde and antegrade conduction closer to the previous QRS complex in the Medtronic algorithm resulted in correct classification of sinus tachycardia with first-degree AV block. However, episodes of ventricular tachycardia with slow VA conduction were not detected.

Discussion

The analysis of data retrieved from published clinical studies, multicenter registries, and reports by the manufacturers summarizing the results of multicenter market release studies⁷⁻¹⁴ revealed major differences in the specificity for correct classification of supraventricular tachyarrhythmias. This clinical specificity shows an inverse correlation to the number of patients, total number of arrhythmias, and number of supraventricular tachyarrhythmias included in these studies. The range of specificity is between 68% (Medtronic) and 90% (Biotronik). While the specificity calculated for the Medtronic algorithm is based on a

large database with 1,029 patients, a total number of 5,788 arrhythmias, and 1,662 episodes of supraventricular arrhythmias, the specificity calculated for the Biotronik algorithm is based on data of 78 patients, a total number of 362 arrhythmias, and 100 episodes of supraventricular tachyarrhythmias. In addition, the specificity of the St. Jude Medical algorithm (76%) is lower as compared to the specificity of the Biotronik (90%), the ELA medical (89%), and the Guidant (89%) algorithm. Again, similar to the Medtronic algorithm, the calculation is based on data of a relatively high number of patients and arrhythmias. However, it needs to be stressed that only the correlation of the specificity with the number of patients included into these studies reached statistical significance. In addition, the large differences in the sample size of different studies (i.e., number of patients included, number of episodes analyzed) may raise further concerns if a comparison of the results is statistically correct. However, these differences in sample size constitute an important factor for the major differences in the specificity for correct classification of supraventricular tachyarrhythmias as the present survey revealed. A small sized database can not cover the same spectrum of supraventricular tachyarrhythmias as compared to a database consisting of more than 5,000 episodes, with a probably far more comprehensive spectrum of arrhythmias. Therefore, the authors could clearly demonstrate that a reliable comparison of different ICD detection algorithms based on such different databases is impossible. Even if ICD manufacturers are using their own databases for assessment of the specificity of their algorithms by simulating supraventricular tachyarrhythmias they have been collecting for many years, the results are not comparable because each database is different. As shown by Malik,²¹ the episodes contained in such a database are dependent on the performance of previous generations of detection algorithms used by a manufacturer. In other words, earlier detection algorithms of the same manufacturer contribute to selection of episodes by eliminating supraventricular tachyarrhythmias that have been correctly classified and by collecting arrhythmias that were not correctly classified. The more evolutionary steps in designing a detection algorithm a manufacturer has taken before, the more episodes easy to correctly classify for a specific algorithm might have been eliminated. This process may lead to substantial differences in the spectrum of supraventricular tachyarrhythmias stored in each database. In addition to the fact that the results of simulations performed by the manufacturers individually are not comparable to each other, they may be confidential and not intended for publication. Therefore,

simulation of supraventricular tachyarrhythmias using a uniform database is a valuable tool for direct comparison of the specificity of ICD detection algorithms.

In four of the five devices tested, the specificity for detection of supraventricular tachyarrhythmias calculated from the present simulation after weighting arrhythmias according to their prevalence is much smaller as reported from the clinical studies the authors analyzed. In addition, differences were found in specificity between the devices greater than expected from the comparison of clinical data. These findings are due to the fact that the simulation covers the full spectrum of supraventricular arrhythmias collected in the authors' electrophysiology laboratory regardless of how frequently they will occur spontaneously. Atrial fibrillation, the most common supraventricular tachyarrhythmia in patients with an ICD, was detected by all five devices. However, major differences were found in the classification of supraventricular arrhythmias resulting in a stable ventricular rhythm, resulting in differences of the specificity by far greater than expected from clinical studies and the authors' own clinical experience. Therefore, in a second analysis the results had to be corrected by weighting the simulated episodes according to their spontaneous clinical prevalence as reported in the literature¹⁷⁻²⁰ and to recalculate the specificity. This weighted specificity makes a direct comparison of all algorithms possible.

The weighted specificity resulting from the present simulation is higher as compared to the specificity calculated from clinical studies. One could argue that this improved specificity results from optimization of the algorithms in the process of simulation, while ICDs tested in clinical studies may have been programmed at their nominal settings. However, options to further optimize the detection algorithm when all detection enhancements are active at their highest specificity are limited. Reprogramming the algorithm improved in one device only the overall specificity without the risk of underdetection of ventricular arrhythmias. Since the authors completed their simulations, most of the manufacturers have launched new models. However, the detection algorithms are still the same in four of the five manufacturers. Only Guidant has recently introduced a new detection algorithm with an additional criterion analyzing changes in the axis of the bipolar electrogram. The electrogram is acquired by the tip of the ventricular lead and the distal defibrillation coil, and the distal defibrillation coil and the proximal defibrillation coil and the ICD itself, respectively. Whereas a morphology analysis using a single bipolar electrogram, like performed by the St. Jude Medical algorithm, can be

tested by the authors' simulation, this detection enhancement cannot be evaluated by their current simulator.

Study Limitations

One could argue that the raw data of the publications used for the comparison are necessary for exact reanalysis and comparison of the ICD algorithms. However, comparisons and the choice of a specific ICD model by clinicians are based exactly on these publications used for the analysis.

Weighting supraventricular arrhythmias according to their clinical prevalence still does not result in a representative sample. Therefore, the statistical significance of the different specificities achieved by the algorithms tested could not be calculated. The specificity calculated after weighting supraventricular arrhythmias is not identical with the values reported from clinical studies. Despite the fact that multiple data sources were used to determine the prevalence of supraventricular arrhythmias as exact as possible, one has to keep in mind that the prevalence of supraventricular arrhythmias may be different in a population representative of ICD patients.

Despite the fact that all available data sources were used to collect the maximum number of episodes for each algorithm, there may be stud-

ies that were not included into the survey because they are confidential.

Testing ICD detection algorithms using tachyarrhythmias collected in the electrophysiology laboratory by intracardiac recordings from the right atrium and the right ventricle exactly mimics sensing by an implanted device. However, the simulation is not a clinical study. Therefore, problems with respect to electrode position, undersensing due to poor wall contact, or sensing of far-field signals that may influence the results of clinical studies cannot be addressed by the simulation.

Conclusions

The specificity of ICD detection algorithms calculated from clinical studies or registries may depend on the number of patients studied. Therefore, a direct comparison between different detection algorithms based on these differently sized data sets is difficult. In contrast, simulation of supraventricular tachyarrhythmias using a uniform database may be a better tool for direct comparison of the specificity of ICD detection algorithms. The weighted specificity for all the episodes simulated makes a direct comparison of all algorithms possible and suggests that the differences in specificity are much smaller as they appear to be if different single data sources are used.

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