# Critical Analysis of Dual-Chamber Implantable Cardioverter-Defibrillator Arrhythmia Detection

## Results and Technical Considerations

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***Background***—One of the perceived benefits of dual-chamber implantable cardioverter-defibrillators (ICDs) is the reduction in inappropriate therapy due to new detection algorithms. It was the purpose of the present investigation to propose methods to minimize bias during such comparisons and to report the arrhythmia detection clinical results of the PR Logic dual-chamber detection algorithm in the GEM DR ICD in the context of these methods.

***Methods and Results***—Between November 1997 and October 1998, 933 patients received the GEM DR ICD in this prospective multicenter study. A total of 4856 sustained arrhythmia episodes (n=311) with stored electrogram and marker channel were classified by the investigators; 3488 episodes (n=232) were ventricular tachycardia (VT)/ventricular fibrillation (VF), and 1368 episodes (n=149) were supraventricular tachycardia (SVT). The overall detection results were corrected for multiple episodes within a patient with the generalized estimating equations (GEE) method with an exchangeable correlation structure between episodes. The relative sensitivity for detection of sustained VT and/or VF was 100.0% (3488 of 3488, n=232; 95% CI 98.3% to 100%), the VT/VF positive predictivity was 88.4% uncorrected (3488 of 3945, n=278) and 78.1% corrected (95% CI 73.3% to 82.3%) with the GEE method, and the SVT positive predictivity was 100.0% (911 of 911, n=101; 95% CI 96% to 100%).

***Conclusions***—A structured approach to analysis limits the bias inherent in the evaluation of tachycardia discrimination algorithms through the use of relative VT/VF sensitivity, VT/VF positive predictivity, and SVT positive predictivity along with corrections for multiple tachycardia episodes in a single patient. **(*Circulation*. 2001;103:381-386.)**

**Key Words:** pacemakers ■ defibrillation ■ tachycardia ■ cardioversion ■ ventricles ■ atrium

The basic goal of implantable cardioverter-defibrillator (ICD) therapy is to preserve life by terminating life-threatening ventricular tachycardia (VT) and ventricular fibrillation (VF) episodes. However, the secondary goal is to do so in the least obtrusive manner, delivering VT and VF therapy only when required. The addition of the atrial lead, used in dual-chamber ICDs, provides an opportunity to improve detection accuracy.

Detection accuracy measurements are difficult and depend on many factors. Patients present with a diversity of ventricular and supraventricular rhythms, at differing frequencies, heart rates, and therapy responses. ICDs classify rhythms differently, depending on the algorithms available in the device. Finally, the mechanics of arrhythmia detection are programmable and thus represent a variable in dynamic tension with the patient characteristics, which also change over time.

Although they are desirable, randomized studies of a direct comparison of detection algorithms have limited usefulness because new devices and algorithms are quickly implemented and the results of such studies soon become irrelevant. However, some control over the bias introduced by nonrandomized trials is required to permit comparison with as little manipulation as possible. It was the purpose of the present investigation to report the arrhythmia detection clinical results of the Medtronic Inc GEM DR dual-chamber ICD and to propose methods to minimize bias in the evaluation of arrhythmia detection algorithms.

## Methods

Dual-chamber rate-responsive ICDs (model 7271 GEM DR ICD; Medtronic Inc) were implanted into 933 patients in a prospective multicenter evaluation of a tachycardia detection algorithm, PR Logic, between November 1997 and October 1998. The mean follow-up time was 3.9 months, with a cumulative follow-up of 3622

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**TABLE 1. Patient Characteristics at Enrollment**

| Characteristic | |
|---|---|
| Male sex, n (%) | 739 (79.2) |
| Mean age, y | 64.1±12.6 |
| Primary indication (mutually exclusive), n (%) | |
| SCD | 134 (14.4) |
| VT | 488 (52.3) |
| SCD and VT | 294 (31.5) |
| MADIT | 17 (1.8) |
| Cardiovascular history (nonexclusive), n (%) | |
| CAD with MI | 559 (59.9) |
| CAD without MI | 125 (13.4) |
| MI without CAD | 36 (3.9) |
| Hypertension | 354 (37.9) |
| Cardiomyopathy-dilated | 363 (38.9) |
| Cardiomyopathy-hypertrophic | 41 (4.4) |
| Primary electrical disease | 26 (2.8) |
| Valvular heart disease | 143 (15.3) |
| Congestive heart failure | 288 (30.9) |
| Mean ejection fraction, % | 35.8±15.0 |
| NYHA class (mutually exclusive), n (%) | |
| I | 221 (23.7) |
| II | 497 (53.3) |
| III | 195 (20.9) |
| IV | 19 (2.0) |
| Antiarrhythmia medication (nonexclusive), n (%) | |
| Amiodarone | 285 (30.5) |
| $\beta$-Blockers | 292 (31.3) |
| Calcium-channel blockers | 38 (4.1) |
| Class I | 56 (6.0) |
| Digoxin | 281 (30.1) |
| Sotalol | 52 (5.6) |

n=933.

months. Follow-up examinations were conducted at 1, 3, and 6 months after device implantation and every 6 months thereafter. Eligible patients were recruited who had (1) cardiac arrest due to a ventricular tachyarrhythmia, (2) spontaneous sustained VT, or (3) inducible VT on electrophysiological studies at 1 of 82 centers in North America, Europe, and Australia. Voluntary participation was documented with a signed institutional review board–approved written informed consent.

Tachycardia episodes for rhythms classified as VT, VF, or supraventricular tachycardia (SVT) were automatically documented with stored atrial and ventricular electrograms. This information was copied to disk for investigator evaluation and confirmation of classification. The investigator's diagnosis was confirmed through a blinded review of a subset of the episodes and became the standard for the determination of the true nature of the rhythm. This review was performed on a subsample of 1845 of 4876 episodes (151 of 311 patients) by 1 of the ICD manufacturer's experts (J.M.G.), who was blinded to the physician classification. The reviewers agreed in 98.2% (1812 of 1845) of the episodes.

The stored events were classified as (1) VT or VF or (2) SVT without a coexistent ventricular tachyarrhythmia. Calculations were made from the perspective of the ability of the ICD to accurately detect VT or VF (true positive [TP]), accurately detect SVT (withhold VT/VF therapies) without coexistent VT or VF (true negative [TN]), falsely detect SVT as VT or VF (false-positive [FP]), and falsely detect VT or VF as SVT (false-negative [FN]).

## Device Description

The Medtronic model 7271 implantable defibrillator is a dual-chamber rate-responsive pacemaker and implantable defibrillator. The dual-chamber tachyarrhythmia detection algorithm in the ICD, PR Logic, has 3 independently programmable criteria (SVT criteria) to discriminate between SVT and VT/VF, with the goal of reducing the incidence of inappropriate VT/VF therapy. The 3 SVT criteria are programmed on or off for the detection of (1) sinus tachycardia, (2) atrial fibrillation (AF)/flutter, and (3) other 1:1 SVT episodes. In addition, the SVT limit parameter sets the fastest ventricular rate that can be identified as an SVT; tachycardias faster than the SVT limit are detected as VT or VF based on the ventricular rate criterion alone. Tachycardia discrimination with PR Logic is performed with the (1) atrial and ventricular rate, (2) pattern of atrial and ventricular events, (3) ventricular cycle length regularity, (4) atrioventricular (AV) dissociation, (5) evidence of AF, and (6) evidence of far-field R-wave sensing on the atrial lead. If SVT is confirmed and a double tachycardia, coexistence of a ventricular tachyarrhythmia during an SVT, has been excluded, then antitachycardia therapy is withheld.[1]

## Statistical Methods

All spontaneous episodes with stored electrograms, the investigating physician's classification of the rhythm, and ≥1 SVT criterion programmed ON were included in the analysis.

The sensitivity of a detection algorithm is the probability that VT/VF is detected when present. The absolute sensitivity of VT/VF detection cannot be computed from these data, because the ICD stores data only for those episodes that are rapid and long enough to be considered VT or VF based on the rate criterion. Therefore, we measured relative sensitivity defined as (sensitivity of detection with SVT criteria ON)/(sensitivity of rate-only detection). In this study, the sensitivity of rate-only detection is by definition 100% for episodes that are fast enough and long enough to be detected by the rate-only criterion. The relative sensitivity is [TP/(FN+TP)]× 100.

To determine the likelihood that a delivered ventricular arrhythmia pacing or shock therapy was appropriately required for treatment of a potentially life-threatening arrhythmia, the ventricular tachyarrhythmia (VT/VF) positive predictivity was calculated: [TP/(TP+FP)]× 100.

To determine the likelihood that ventricular arrhythmia pacing or shock therapy was appropriately not required during a rapid supraventricular rhythm, the supraventricular tachyarrhythmia (SVT) positive predictivity was calculated: [TN/(TN+FN)]× 100.

The specificity of a detection algorithm is the probability that VT/VF was NOT detected given that VT/VF was not present. The absolute specificity of VT/VF detection cannot be measured from these data for the same reasons that absolute VT/VF detection sensitivity cannot be computed. Therefore, we measured incremental specificity, which is the degree of improvement provided by the SVT criteria in reducing the number of FP VT/VF detections. VT/VF incremental specificity is defined as (specificity with SVT criteria ON)[minus](specificity with SVT criteria OFF). The specificity with SVT criteria OFF was 0%, because all episodes that meet rate detection criterion when enhancements are OFF will be detected and treated as VT/VF. Incremental specificity is equivalent to the observable specificity of detection with SVT criteria ON: [TN/(FP+TN)]× 100.

Bias is introduced in these performance numbers when an individual patient contributes multiple tachycardia episodes. Therefore, we corrected the algorithm performance calculations using the generalized estimating equations (GEE) statistical method[2,3] with an exchangeable correlation structure to remove this bias. This technique controls for multiple responses within a patient by assuming a common correlation between any 2 responses. The resulting corrected observed performance measures are estimates of the average patient performance of the algorithm.

**TABLE 2. Arrhythmia Characteristics**

| Tachycardia | Patients, n | Episodes, n | Ventricular Cycle Length, ms* | Tachycardia Detection Interval, ms* | Fibrillation Detection Interval, ms* | SVT Limit, ms* |
|---|---|---|---|---|---|---|
| VT/VF | 232 | 3488 | 329±75 | 401±57 | 314±24 | 307±28 |
| SVT | 149 | 1368 | 373±69 | 408±60 | 313±22 | 300±35 |
| All arrhythmias | 311 | 4856 | 343±56 | 400±56 | 313±23 | 305±31 |
| All patients | 916 | NA | NA | 395±40 | 314±21 | 260±112 |

*Values are mean±SD.

## Patients

The clinical characteristics of the 933 patients are similar to those of previously reported ICD populations and are listed in Table 1. There were 4856 spontaneous sustained tachycardias with ≥1 SVT criterion programmed ON that were recorded in 311 patients during the observation period. Physician classification defined 3488 episodes of spontaneous VT/VF from 232 patients (ventricular cycle length 329±75 ms) and 1368 episodes of spontaneous SVT from 149 patients (ventricular cycle length 373±69 ms).

## Programming

The ICDs were programmed to detect VT with a tachycardia detection interval (TDI) of 395±40 ms, VF with a fibrillation detection interval (FDI) of 314±21 ms, and SVT with an SVT limit interval of 260±112 ms. Table 2 lists the ventricular cycle lengths of the physician-classified VT/VF and SVT rhythms and the programmed TDI and FDI for the 311 ICDs that responded to arrhythmias.

The VT/VF and SVT rate detection parameters were clinically selected for each patient. The ventricular interval stability criterion was programmed off. The SVT criteria for sinus tachycardia and AF/flutter were programmed on at the time of discharge, and after the atrial lead was allowed to stabilize for 1 month, the "Other 1:1 SVT" criterion was usually enabled.

# Results

All 4856 sustained arrhythmia episodes in 311 patients, with ≥1 SVT criterion programmed ON, were included in the detection performance calculations. There were a total of 3488 episodes of VT/VF in 232 patients and 1368 episodes of SVT in 149 patients. The percentage of rhythms with ventricular cycle length at least equal to the SVT limit (eligible for SVT classification by PR Logic) was 85.5% (4154 of 4856) of all (VT+VF+SVT) episodes and 81.9% (2855 of 3488) of all VT/VF episodes. Table 3 lists the device classification of the sustained tachycardia episodes by number of episodes and the number of patients. Also shown is the average ventricular cycle length of the episodes. Figure 1 presents a waterfall diagram that outlines the detection result for each of the 4856 sustained tachyarrhythmia episodes.

**TABLE 3. Device Classification of Arrhythmias**

| Tachycardia | Patients, n | Episodes, n | Episodes per Patient, range | Ventricular Cycle Length, ms* |
|---|---|---|---|---|
| VT | 184 | 2868 | 1–167 | 373±58 |
| VF | 164 | 886 | 1–41 | 280±43 |
| Double tachycardia | 43 | 191 | 1–20 | 353±62 |
| Sinus tachycardia | 73 | 796 | 1–77 | 390±60 |
| AF or atrial flutter | 32 | 103 | 1–20 | 362±66 |
| Other 1:1 SVT | 5 | 12 | 1–4 | 330±36 |

*Values are mean±SD.

Figure 2 presents the PR Logic detection results compared with physician classifications for the 4856 episodes. All 3488 sustained ventricular arrhythmias in 232 patients were detected and treated with the ICD. There were 12 nonsustained episodes that did not receive VT/VF therapy (<21-second duration). The combined sensitivity for sustained VT and/or VF was 100.0% (95% CI 98.3% to 100%).

Detection was appropriate for 3488 VT/VF episodes from a total of 3945 VT/VF episodes, for a VT/VF positive predictivity of 88.4% uncorrected and 78.1% corrected (95% CI 73.3% to 82.3%) with the GEE method. Detection was appropriate for all 911 SVT episodes (101 patients), for an SVT positive predictivity of 100.0% (95% CI 96% to 100%).

Of the 1368 SVT episodes (149 patients) rapid enough to be detected as a ventricular arrhythmia, 911 were recognized as SVT, not VT or VF. None of these 911 device-classified SVT episodes accelerated to VF or caused patient harm. The VT/VF incremental specificity was 66.6% uncorrected (911 of 1368) and 56.1% corrected (95% CI 48.9% to 63.1%) with the GEE method.

There were 457 episodes (86 patients) for which the PR Logic SVT criteria did not withhold VT or VF detection

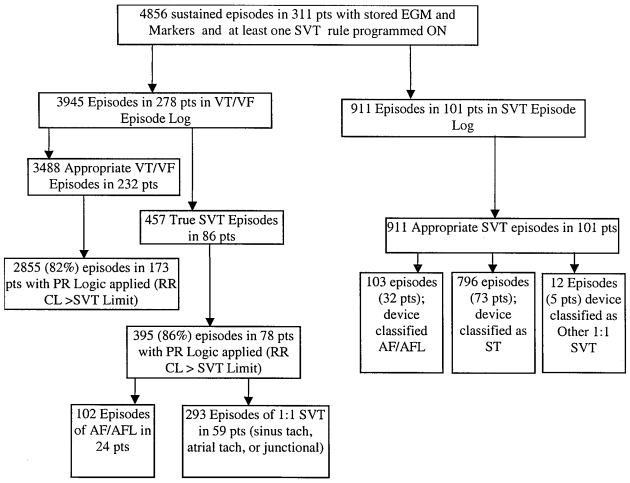


**Figure 1.** Result for each of 4856 sustained tachyarrhythmia episodes. EGM indicates electrograms; CL, cycle length; AFL, atrial flutter; pts, patients; and tach, tachyarrhythmia.

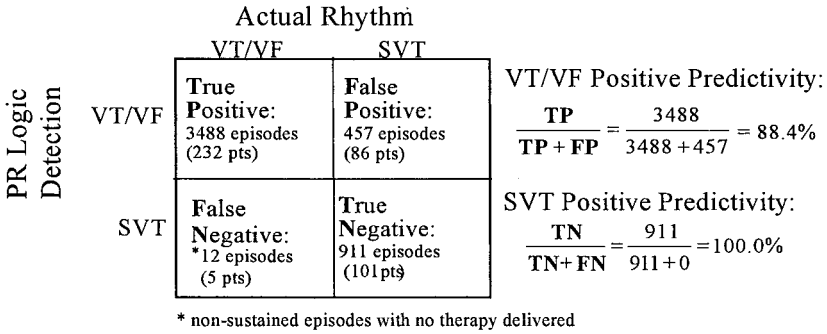


**Figure 2.** PR Logic detection results compared with physician classifications for 4856 episodes.

when the episode was SVT. The reasons are delineated in Table 4 and are related to (1) placement of the atrial or ventricular lead, (2) programming of the ICD, or (3) characteristics of the detection algorithm.

## Discussion

The development of sophistication and complexity in any technology implies improvement. The improvement does not have to be manifest as reduced cost, improved survival, or improved quality of life but does suggest that it can be measured. The addition of an atrial lead and its impact on tachyarrhythmia detection provide an example of technological advance that is in the process of evaluation. This comparison is prone to manipulation, and the results have been misleading. Results from other dual-chamber detection algorithm trials have been reported but not with sufficient detail to accurately compare and draw conclusions.[4-7] The essential issue is to determine the parameters that, when improved, make an important impact on the care of the patient. The second issue is to determine the assumptions made when the parameter is measured, so results can be accurately reported. The answers to these issues will change over time, but the development of standardized reporting methods must be initiated.

**TABLE 4. Reasons for Inappropriate Detection of 457 SVTs With Ventricular Rate in the VT/VF Detection Zone**

| Reason | Description |
|---|---|
| Lead placement: atrial or ventricular | |
| 9 patients, 84 episodes | Atrial: intermittent atrial oversensing of far-field R waves |
| 5 patients, 8 episodes | Atrial: atrial undersensing during AF |
| 1 patient, 1 episode | Ventricular: ventricular oversensing |
| ICD programming | |
| 18 patients, 61 episodes | SVT cycle length faster than programmed SVT limit (PR Logic not applied) |
| 3 patients, 7 episodes | Appropriate PR Logic rule programmed OFF |
| 14 patients, 44 episodes | Ventricular rate during AF in VF zone |
| Detection algorithm characteristics | |
| 46 patients, 174 episodes | Long PR SVT (atrial tachycardia or sinus tachycardia) |
| 7 patients, 26 episodes | AF with regular ventricular cycle lengths and AV dissociation |
| 13 patients, 52 episodes | Pattern syntax did not define SVT |

### Algorithm Performance Measures

When evaluating any ICD tachycardia detection algorithm, we propose that there are 3 prominent clinical questions that need to be answered. (1) Does the algorithm detect all dangerous ventricular tachyarrhythmias? (2) When therapy is delivered, how likely is it that the rhythm required treatment with antitachycardia therapy? (3) When therapy is withheld from a rapid rhythm, how likely is it that it was safe to withhold therapy? The use of relative VT/VF sensitivity (GEM DR results 100% [95% CI 98.3 to 100]), VT/VF positive predictivity (GEM DR results 88.4% uncorrected and 78.1% corrected [95% CI 73.3 to 82.3]), and SVT positive predictivity (GEM DR results 100% [95% CI 96 to 100]) addresses each of these questions. To remove bias introduced by patients who contribute multiple episodes to the results, statistical methods such as the GEE method should be used to correct the observed performance measures. Although there are many other questions, when these 3 questions are answered in a consistent manner, meaningful comparisons can then be made with other devices and algorithms. Incremental specificity may not be used for these comparisons because different ventricular rate-only algorithms may have different specificities. Incremental specificity is useful only to compare enhanced detection with the assumption of exactly the same ventricular rate-only algorithm.

Control for clinical and technical variances is very difficult. Future technological advances may obsolete some of the currently important parameters, but we propose that there are $\geq$4 ICD and $\geq$4 clinical parameters that are essential for any comparison. The ICD parameters are (1) the slowest tachycardia detection rate, below which no tachycardia is detected; (2) the fibrillation detection rate, above which the rules for detection change; (3) the number of intervals or time for detection to take place; and (4) the SVT limit, or rate above which SVT tests are no longer applied. The clinical parameters are (1) the inclusion of all arrhythmias; (2) the number, type, and ventricular rate of arrhythmias presented to the algorithm (ventricular versus supraventricular); (3) the mechanism of the supraventricular rhythms presented to the algorithm (sinus tachycardia, AF, atrial flutter, atrial tachycardia, AV node reentry tachycardia, etc); and (4) the frequency and distribution of each tachycardia in the population tested.

## ICD Parameters

The tachycardia detection rate influences the number and type of tachycardias presented to the detection algorithm. The tachycardia detection rate not only affects the relative distribution of the SVT mechanism for episodes being evaluated (eg, slower rates will result in more sinus tachycardia presented to the algorithm) but also may influence the relative challenge that the SVT presents to the algorithm. Kühlkamp et al[8] demonstrated that AF becomes more regular (and thus more similar to VT) as ventricular rate increases.

Some manufacturers have intentionally designed less capability for discrimination of SVT and ventricular tachyarrhythmias for rhythms with ventricular rates faster than the fibrillation detection rate. For some algorithms, this limit is tied specifically to 1 of the programmed ventricular tachyarrhythmia detection zones; others, such as PR Logic, have a separately programmable SVT limit parameter. Regardless of the detection algorithm design, all fast SVT rhythms should be included in detection algorithm performance evaluation because the results will be influenced by the number of rhythms (supraventricular or ventricular in origin) that are faster than the fibrillation detection rate.

The duration or number of intervals to detect tachycardia will depend on the programmed detection parameters and the type of ventricular interval counting algorithms used for detection (eg, consecutive count or probabilistic counting), which in turn influences the number and type of tachycardias presented to the detection algorithm. Shorter detection times may yield more tachycardias per patient and may skew the distribution of SVT or VT/VF episodes depending on which type of episodes are more likely to be the result of short runs of tachycardia.

## Clinical Parameters

Bias in the detection performance numbers will be introduced when any subset of episodes is excluded. This bias can cause discrepancies in the observed performance measures and the actual clinical performance. The measures that describe detection algorithm performance (positive predictivity, relative sensitivity, incremental specificity) are probabilities that are derived from the number, type, and detection result for the rhythms presented to the algorithm. Without full disclosure of the number and type of tachyarrhythmias presented, these probabilities are less relevant (eg, 1/1=1000/1000=100%).

The frequency and distribution of the arrhythmia mechanisms represented in the clinical trial and their match or mismatch to the strengths of the particular algorithms will determine the performance of the defibrillator. If an algorithm is weak in distinguishing sinus tachycardia from VT and there is little sinus tachycardia represented in the trial, then the weakness will not be identified. The outcome of the evaluation will depend on the weakness and strength of an algorithm and its opportunity in the clinical population.

## Clinical Observations

A complete picture of detection algorithm performance is not provided by statistical measures alone. An analysis of algorithm weaknesses with corresponding clinical observations and occurrence rates serves to complement the statistical performance measures. The clinical observations for PR Logic are presented in Table 4 with potential weakness being the inability to consistently withhold VT/VF detection for certain types of SVT with ventricular rates in the VT/VF detection zones, including (1) sinus or atrial tachycardia or with intermittent far-field R-wave oversensing on the atrial lead, (2) AF with ventricular rates in the VF zone, and (3) sinus tachycardia or atrial tachycardia with long PR intervals (PR interval $\geq$50% RR interval).

The influence of intermittent far-field R-wave oversensing on the atrial lead during SVTs in VT/VF zones may permit VT/VF detection to occur despite the dual-chamber algorithm. Intermittent far-field R-wave oversensing was the reason for 17% (84 of 457) of all inappropriate detections. The clinical solution to this problem is careful placement of atrial lead with close tip-ring spacing[9] and/or careful programming of atrial sensitivity.

Discrimination of AF with a conducted ventricular rate in the VF detection zone is another potential point of vulnerability for PR Logic. No other manufacturer's dual-chamber detection algorithms are in effect in the VF zone, so this is a point of vulnerability for all dual-chamber ICDs. In this study, 9.6% (44 of 457) of inappropriate detections were due to rapidly conducted AF in the VF zone despite the SVT limit being programmed appropriately to allow PR Logic to reject the rhythm. PR Logic can discriminate SVTs with AV association (eg, 2:1 atrial flutter) from true VF; however, PR Logic cannot discriminate rhythms with AV dissociation (eg, rapidly conducted atrial fibrillation) from true VF. One clinical solution is to reprogram the ICD detection zones such that the ventricular rates during AF are in the VT detection zone (or fast VT via VT), where the VT/AF discrimination algorithm is more powerful. However, care must be taken in making this change so the true VF is not underdetected.

PR Logic may interpret sinus or atrial tachycardia with long PR intervals (PR interval $\geq$50% RR interval) for VT with 1:1 VA conduction and not withhold VT/VF detection. Long PR intervals during 1:1 SVTs were the reason for 38% (174 of 457) of all inappropriate VT/VF detections. In theory, VT with 1:1 VA conduction with long RP intervals (such that the resulting PR interval is $<$50% of the RR interval) may have therapies withheld inappropriately by the PR Logic algorithm. Although there were no sustained tachycardia episodes of VT with 1:1 VA and long RP intervals, there were 8 nonsustained episodes (all $<$21 seconds in duration). The clinical incidence of SVT with long PR intervals is low: 3% of patients in this study and in the single-center experience reported by Wolpert et al.[10]

## Alternative Methods

An alternative to comparisons of detection algorithm performance that result from clinical evaluations is to perform in vitro studies with recordings of induced tachycardia episodes during electrophysiology studies or during the implantation of implantable defibrillators. This methodology has advantages in that it is easier to control detection algorithm and clinical parameters. However, this method is questionable in its ability to generate clinically meaningful detection algorithm performance estimates, because the results will be

highly dependent on how closely the induced tachycardia recordings match the clinically observed spontaneously occurring tachycardias for cycle length, type, and distribution.

### Study Limitations

Despite attempts to limit bias, there are limitations to the techniques used in this evaluation. This was an observational study of consecutive patients. Tachycardias below the detection rate or persisting for less than the programmed detection duration were excluded from this analysis regardless of the tachycardia mechanism, ventricular or supraventricular, because they are by definition not collected by the ICD. Tachycardia episode classification was based on investigator classification according to symptoms, clinical presentation, electrograms, and marker channel analysis. The programming of the parameters was not prospectively prescribed but individualized according to the clinical situation. Therefore, programming to the mean values reported here may not produce similar results.

### Conclusions

A structured framework is required for valid comparative analyses of tachycardia discrimination algorithms. This report of the clinical results of the GEM DR PR Logic tachycardia detection algorithm has been structured to answer 3 clinical questions: (1) Does the algorithm detect all dangerous ventricular tachyarrhythmias? (2) When a therapy is delivered, how likely is it that the rhythm needed to be treated with antitachycardia therapy? (3) When therapy is withheld from a rapid rhythm, how likely is it that it was safe to withhold therapy? The use of relative VT/VF sensitivity, VT/VF positive predictivity, and SVT positive predictivity and the correction for multiple tachycardia episodes in a single patient address each of these questions in a responsible fashion and may be applied generally to all ICD detection algorithms. In addition, it is essential to thoroughly characterize the clinical arrhythmias and the defibrillator programming used to evaluate the algorithm so useful comparisons can be made. Finally, it was valuable to characterize the rhythms that proved difficult for the algorithm in identifying areas of vulnerability and the mechanism of the detection failure. This analytical process produced a firm foundation for future evaluations and avoided much of the bias inherent in the clinical evaluation of new therapies.

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