Performance of a new single-chamber ICD algorithm: discrimination of supraventricular and ventricular tachycardia based on vector timing and correlation

Raffaele Corbisiero1*, Michael A. Lee2, David R. Nabert3, James A. Coman4, David J. Breiter5, Mark Schwartz5, Edward Mckittrick5, and Yunlong Zhang5

1 Deborah Heart and Lung Center, 200 Trenton Road, Browns Mills, NJ 08018, USA; 2 John Muir/Mt. Diablo Health Systems, Walnut Creek, CA, USA; 3 Baptist Medical Center, Jacksonville, FL, USA; 4 Hillcrest Medical Center, Tulsa, OK, USA; and 5 Guidant Corporation, St Paul, MN, USA

Received 2 June 2006; accepted after revision 28 August 2006; online publish-ahead-of-print 14 November 2006

Aims Interval- and morphology-based algorithms have been used in modern implantable cardioverter defibrillators (ICDs) to discriminate supraventricular tachycardia (SVT) from other rhythms. A newly developed ICD discrimination algorithm, Rhythm ID™ (Guidant Corporation, St Paul, MN, USA), uses both interval-based metrics and an electrogram vector timing and correlation (VTC) algorithm in a dual-chamber ICD. In a single-chamber ICD, Rhythm ID contains only the VTC component. This study conducted a retrospective analysis of the performance of Rhythm ID for the detection of induced and spontaneous rhythms in a single-chamber ICD.

Methods and results This study gathered the data from a prospective, multicentre clinical trial. Ninety-six patients were implanted with a dual-chamber ICD. For this study, each episode was analysed to determine the performance of the single-chamber ICD Rhythm ID algorithm. The mean age of the patients implanted with the device was 67 ± 11 years. Seventy-eight patients were male. The primary cardiovascular disease was coronary artery disease and the primary tachyarrhythmia was monomorphic ventricular tachycardia (VT). The mean follow-up time was 11.4 months. A total of 369 induced and spontaneous ventricular arrhythmias was analysed. The algorithm detected 100% of ventricular arrhythmias. Four hundred and forty-two SVT episodes were analysed, including 145 induced and 297 spontaneous. The SVTs were atrial fibrillation (n = 199), atrial flutter (n = 135), and 1:1 SVT (n = 108). The single-chamber ICD Rhythm ID algorithm successfully discriminated 403 SVT episodes and achieved a specificity of 91%.

Conclusion The single-chamber version of Rhythm ID demonstrated high specificity without compromising sensitivity.

KEYWORDS
ICD; Ventricular tachyarrhythmia; Detection algorithm; Supraventricular arrhythmias

Introduction
Sudden cardiac death (SCD) affects nearly 300 000 people each year in the USA.1 In patients who have survived SCD, implantable cardioverter defibrillators (ICDs) have been repeatedly proven to be an effective means to prevent SCD.2-5 Implantable cardioverter defibrillators have also proven to be cost-effective.6 Additionally, the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II)7 further demonstrated that ICDs could be used as a primary prevention of SCD for patients with a prior myocardial infarction. As a tool for primary prevention, a single-chamber ICD requiring the implantation of only a single intravenous lead may be desirable because of the cost and complexity considerations,8 but the use of dual-chamber capabilities may improve the specificity and sensitivity of arrhythmia detection.9 Previous publications have reported that as many as 40% of patients implanted with a single-chamber ICD may receive inappropriate therapy for supraventricular tachycardia (SVT).10-16 Conventional single-chamber ICDs have used interval-based methods such as sudden onset or stability to discriminate SVT episodes. Programming of these features comes with the associated risk or trade-off between sensitivity and specificity.17-19

In an attempt to improve discrimination performance and reduce the complexity of programming offered by conventional methods, Rhythm ID™ was developed. In

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single-chamber ICDs. Rhythm ID uses a vector timing and correlation (VTC) algorithm for rhythm discrimination. In dual-chamber ICDs, Rhythm ID uses a combination of VTC and conventional interval-based SVT discrimination methods [V > A, atrial fibrillation (AF) rate threshold, and stability]. In a smaller study, tape testing of the dual-chamber Rhythm ID ICD algorithm showed promising results (100% sensitivity and 97% specificity). In this study, the performance of Rhythm ID’s single-chamber ICD algorithm was analysed from a larger data set, which included both induced and spontaneous rhythms.

Methods

Algorithm descriptions

In single-chamber ICDs, Rhythm ID uses the VTC algorithm to discriminate SVTs from ventricular tachycardias (VTs) (a detailed description of the algorithm can be found in Gold et al.20). The VTC algorithm requires the ICD to acquire a normal sinus rhythm (NSR) reference vector. The reference vector uses information from the pace/sense channel (to determine timing of depolarization) and also uses the shock-channel electrogram conduction features (providing overall direction and speed of the depolarization). The reference vector is automatically collected at periodic intervals to account for changes in the reference. The Rhythm ID algorithm is available only in VT zone(s), not in ventricular fibrillation (VF) zone.

When a tachycardia occurs in the single-chamber ICD, for the device to declare and store an episode, 8 of 10 fast beats must occur above the programmed VT rate cutoff. The Rhythm ID algorithm then compares the tachycardia vector with the NSR reference vector on a beat-to-beat basis. If the tachycardia beat is highly correlated with the NSR reference vector, it is considered to be an SVT beat. If the tachycardia beat does not correlate, it is considered to be a VT beat. In order for the Rhythm ID algorithm to classify the rhythm as an SVT and withhold therapy, at least 3 of 10 consecutive beats must be correlated. Otherwise, the rhythm is classified as VT and therapy will be delivered.

Data collection

This study analysed the data collected from a prospective multicentre trial. In the trial, 96 patients were implanted with a dual-chamber ICD from December 2002 to January 2003 at 21 US centres. Patients met the standard indications for an ICD. All induced and spontaneous SVT and VT episodes with stored electrograms were saved on patient disks and used in this analysis. Tachyarrhythmia episodes were annotated by physicians at the 21 centres and classified as VT or SVT. Arrhythmia episode information was analysed by a LabVIEW™ (V6.0, National Instruments, Austin, TX, USA) software application. This application had the ability to retrieve the decision-making information of the individual components of Rhythm ID for a tachycardia episode (i.e. the individual contributions of V > A, AF threshold, stability, and VTC separately). Figure 1A–C shows the examples of this analysis. The application was used to determine which episode was classified as an SVT or VT by the VTC component alone. For example, all tachycardias with VTC uncorrelated are considered VT and all tachycardias with VTC correlated are considered SVT regardless of the V > A, AF rate threshold, and stability as used in the dual-chamber ICD.

Data analysis

From the stored episode database, the performance of the single-chamber ICD Rhythm ID algorithm was assessed for sensitivity and specificity. Sensitivity was calculated by the number of Rhythm ID-declared VT episodes divided by the number of physician-annotated VT episodes. Specificity was calculated by the number of Rhythm ID-declared SVT episodes divided by the number of physician-annotated SVT episodes. For continuous variables [e.g. patient age, ejection fraction (EF), etc.], the data
were summarized using means and SDs. For discrete variables (e.g. patient gender, primary arrhythmia, etc.), frequency distribution and cross tabulation were used.

Results

Patient demographics, programming, and follow-up

The mean age of the 96 patients implanted with the ICD was 67 ± 11 years. Seventy-eight patients were male (81.3%). The primary cardiovascular disease was coronary artery disease (CAD) and the primary tachyarrhythmia was monomorphic VT (MVT). Twenty-three patients (24.0%) had a history of SVTs. Table 1 lists the details of patients’ demographics. The average follow-up time was 11.4 ± 3.2 months.

Device arrhythmia zone

The median rate cutoffs were 200, 150, and 135 bpm for VF, VT, and VT-1 zones, respectively. At implant, devices were required to be programmed to two zones with a VF zone rate cutoff of 200 bpm and a VT zone rate cutoff of 90 bpm. During follow-up, the detection zone cutoffs were as per physician’s discretion.

Arrhythmia distributions

A total of 810 stored tachyarrhythmia episodes with Rhythm ID information was analysed. Three hundred and sixty-eight were VT episodes [146 MVT, 24 polymorphic VT (PVT), 4 ventricular flutter (VFL), and 194 VF], of which 88 were spontaneous episodes in 19 patients. Four spontaneous MVT episodes were non-sustained and excluded from the analysis. Four hundred and forty-two were SVT episodes [199 AF, 135 atrial flutter (AFL), and 108 1:1 SVT], of which 297 were spontaneous episodes in 35 patients. The mean ventricular rates recorded by devices were 208 ± 46 bpm for MVT/PVT, 293 ± 53 bpm for VF/VFL, 140 ± 29 bpm for AF, 129 ± 28 bpm for AFL, and 144 ± 28 bpm for 1:1 SVT.

Performance of the Rhythm ID algorithm

The sensitivity to VT/VF of the single-chamber ICD Rhythm ID algorithm was 100%. Table 2 lists the sensitivities of the single-chamber version Rhythm ID algorithm for each category of ventricular arrhythmia. The specificity to SVT of the single-chamber version Rhythm ID algorithm was 91.2% [403/442, 89.4% generalized estimating equations (GEEs) adjusted], which was similar to 91.4% (404/442, 90.3% GEE adjusted) of dual-chamber clinical performance in the data set. The specificities were 90.1% (127/141, 90.8% GEE adjusted) for the induced episodes and 91.7% (276/301, 88.4% GEE adjusted) for the spontaneous episodes. Table 3 lists the specificities for each category of SVT. The majority of the SVTs was AF and AFL, with specificities of 98.5 and 98.3% to spontaneous episodes, respectively.

Discussion

The single-chamber ICD version of the Rhythm ID algorithm showed 100% sensitivity and 91.2% specificity by a retrospective analysis of 810 induced and spontaneous episodes. The present single-chamber algorithms with interval-based criteria have provided mixed results. The initial intention of developing dual-chamber ICDs was to provide physiological pacing and to add atrial information to the arrhythmia detection algorithm. However, dual-chamber ICDs with interval-based arrhythmia detection algorithms did not achieve the level of improvement that was desired. Multiple factors affected the performance of interval-based dual-chamber algorithms including undersensing or oversensing of atrial activity and 1:1 tachycardias, especially with slow AV conduction. One-to-one conducted tachycardia has been one of the biggest challenges for interval-based SVT discrimination algorithms. It was the single most significant factor (63%), with inappropriate detection in one study where all 1:1 SVT rhythms with slow AV conduction were erroneously detected as VT. Another dual-chamber device study reported an overall

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Measure</th>
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<tbody>
<tr>
<td>Age at implant (years, n = 96)</td>
<td>Mean ± SD 67.3 ± 10.8</td>
</tr>
<tr>
<td>Gender [n (%)]</td>
<td>Male 78 (81.3%) Female 18 (18.8%)</td>
</tr>
<tr>
<td>LV EF (% (n = 90)</td>
<td>Mean ± SD 30.4 ± 12.3 MVT 37 (38.5%)</td>
</tr>
<tr>
<td>Primary tachyarrhythmia [n (%)]</td>
<td>Non-sustained VT 29 (30.2%) VF 6 (6.3%) PVT 3 (3.1%) VFL 3 (3.1%) Torsades de pointes 1 (1%) Other 17 (17.7%) Atrial fibrillation 18 (18.8%) PSVT 4 (4.2%) Paroxysmal atrial tachycardia 2 (2.1%) Sinus node dysfunction (brady-tachy syndrome) 4 (4.2%)</td>
</tr>
<tr>
<td>History of atrial arrhythmias</td>
<td>CAD 75 (78.1%) Ischaemic cardiomyopathy, CAD 59 (61.5%) Valvular heart disease 10 (10.4%) Non-ischaemic cardiomyopathy 8 (8.3%) Congenital heart disease 1 (1.0%) Other 25 (26.0%)</td>
</tr>
</tbody>
</table>

*Patients may have more than one co-morbidity arrhythmia and cardiac disease.
specificity of 66.6% (n = 1368 SVT episodes), with inappropriate detection of 1:1 SVTs accounting for 64% (293/457) in an episode-based analysis and 69% in a patient-based analysis. Recent studies reported dual-chamber ICD specificities ranging from 96 to 76%; however, a significant inverse correlation between specificity and the number of patients studied was observed; therefore, there is a need for caution when comparing results from two trials.

Development of morphology-based algorithms to discriminate arrhythmia has been tested. These algorithms work under the general assumption that the shape of the ventricular electrogram during ventricular arrhythmias is different from that of the supraventricular-conducted rhythms. An early morphology-based single-chamber algorithm using an EGM width criterion was associated with a reduction in sensitivity, leading to a recommendation that it not be used in patients with long baseline QRS durations (i.e., bundle branch block). Two more recent morphology-based algorithms were also reported. One algorithm based on morphology and interval metrics showed an improvement in specificity, but a reduction in sensitivity. It was recommended that this algorithm only be used in combination with other interval-based algorithms and an extended high rate criterion to correct the reduction in sensitivity. A morphology algorithm using wavelet transformation was reported to have 100% sensitivity and 78% specificity in a single-chamber device. The Rhythm ID algorithm in this analysis achieved an overall 91.2% (89% GEE adjusted) arrhythmia discrimination specificity without compromising sensitivity.

Study limitations

This study was a retrospective analysis of the single-chamber Rhythm ID algorithm based on data collected from a prospective dual-chamber ICD study. For consistency, the analysis used ICD data from a single point in time. This may not reflect the actual clinical device performance of the single-chamber ICD for episodes that continue for an extended period. Only episodes with stored electrograms were used in this analysis, episodes without stored electrograms were excluded. Also, programming of rate zones was left at the discretion of the physician investigators and was not uniform across the patients.

Conclusions

In this analysis, the single-chamber ICD Rhythm ID algorithm had 100% sensitivity and 91.2% specificity to induced and spontaneous tachyarrhythmias. It also showed 98.5, 98.3, and 79.4% specificity to spontaneous AF, AFL, and 1:1 VT, respectively. These results indicate that the single-chamber ICD version of the Rhythm ID algorithm may achieve a high specificity without compromising sensitivity. However, further prospective study is needed to confirm these results.

Table 3 Rhythm ID specificity to SVT

<table>
<thead>
<tr>
<th>Rhythm</th>
<th>Spontaneous episodes</th>
<th>Induced episodes</th>
<th>Overall (%)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Annotation</td>
<td>Specificity (%)</td>
<td>Annotation</td>
</tr>
<tr>
<td>AF</td>
<td>135</td>
<td>98.5</td>
<td>64</td>
</tr>
<tr>
<td>AFL</td>
<td>59</td>
<td>98.3</td>
<td>77</td>
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<tr>
<td>1:1 SVT</td>
<td>107</td>
<td>79.4</td>
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<tr>
<td>Overall</td>
<td>301</td>
<td>91.7</td>
<td>141</td>
</tr>
</tbody>
</table>

*GEE-adjusted specificities were 88.4, 90.8, and 89.4% for spontaneous, induced, and overall episodes, respectively.

References