Detection Algorithms in Implantable Cardioverter Defibrillators

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Invited Paper

This paper presents a review of the evolution of tachycardia fibrillation detection algorithms designed for implantable cardioverter defibrillators (ICD) including those that have been incorporated into 1st, 2nd, and 3rd generation devices. The major emphasis of this review is an overview of the development of new and innovative means for improved detection in next-generation devices. Time-domain and frequency-domain methods of electrogram analyses are described, limitations are cited, and promising new proposals for increased specificity which address the false shock incidence are presented.

I. Introduction

The topic of this paper is the design of tachycardia/fibrillation detection schemes for implantable cardioverter defibrillators, the evolution of these methods from past to present, and a description of ongoing experimental work which holds promise for the future. Historical accounts of the design, development, and early clinical implementation of the implantable cardioverter defibrillator (ICD) abound in the literature [1]–[6] and we will not attempt to duplicate or elaborate on these extensive treatments, many written by participants, colleagues, and eyewitnesses to the early struggle to bring the ICD to realization.

Despite initial objections to the concept of an implantable defibrillator (technical, clinical, and even ethical), redemption has come with its overwhelming success in salvaging thousands and thousands of lives. No longer are there skeptics who shout epithets or pen nasty editorials. Michel Mirowski, who doggedly pursued the development of the ICD, endured humiliation with grace and an unflagging sense of purpose and fortunately lived to see his dream become a reality. It is in this spirit that this manuscript is prepared, and none of the material presented is meant to criticize or diminish the technological genius of the idea. The ICD is indeed the medical device *du jour*, and this paper is dedicated not only to Mirowski, but to the engineering expertise which brought this dream to fruition.

The first engineer to embark on this journey of imagination was Alois Langer, and those of us who follow in his footsteps marvel at his accomplishment. We continue to toil in engineering laboratories trying to improve on the original design, attempting to tinker and fix the technological problems, and devising new ways and means to make incremental modifications to correct the current limitations.

The implantable cardioverter defibrillator is a reality and the number of implants begs belief. The remaining problem to be solved is the refinement of detection criteria such that the device no longer offers a simple brute force solution (if in question, shock!). With over 75 000 implants to date, there is a growing demand to address needless delivery of false shock. This is a three-fold problem: false shocks are an unnecessary patient distress; false shocks deplete battery power rendering the device less capable of addressing true urgencies and forcing premature explantation; and false shocks (or antitachycardia pacing) frequently initiate ventricular tachycardia (VT) or ventricular fibrillation (VF) when none previously existed. New signal processing methods must be incorporated into ICD's if we are to achieve a reduction of false shocks yet improved specificity of diagnosis must come without sacrifice of sensitivity. Engineering tools to address this objective encompass low power digital electronics, more sophisticated processing capabilities, improved pattern recognition, and novel new computer algorithms designed for *minimization* and *miniaturization*.

A. Third-Generation Implantable Cardioverter Defibrillators

Third-generation ICD's offer high-energy defibrillation, low-energy cardioversion, antitachycardia and antibradycardia pacing, multiple programmable tachycardia detection zones which utilize the cardiac cycle length, onset, stability, and sustained high rate features which can be selected or deselected, noninvasive programmed stimulation, teleme-

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confirmed by Holter or telemetry monitoring, or stored electrograms. The rhythm preceding unnecessary shocks was atrial fibrillation (AF) in 30 patients (55%), and sinus tachycardia (ST) or supraventricular tachycardia (SVT) in 11 patients (22%). Third generation devices which allow examination of the electrical events eliciting therapy have provided more accurate statistics on the incidence of false shocks as well as acceleration of VT from pacing therapy [18]. Hook *et al* [19], reviewing stored electrograms from the Ventritex Cadence™, reported that 18/48 patients received appropriate device response for ventricular tachycardia and 20/48 patients received *non-VT* device intervention. Thirteen inappropriate interventions were due to atrial fibrillation and six were for SVT. In three patients with SVT, therapeutic pacing induced VT which required shock therapy. These authors assert that, despite advances in third generation ICD therapy, responses for non-VT rhythms still occur quite frequently. In this study of 48 patients, 41% of patients *which received device intervention* were paced or shocked falsely. A more recent study of 154 patients with third-generation devices [20] had 99/154 receiving device therapy of which 56 had appropriate and 43 had inappropriate therapies delivered. Thirty-two of these 43 patients had atrial fibrillation and in two cases of atrial fibrillation inappropriate pacing therapy delivered by the device initiated VT. Thus, the percentage of patients who are paced or shocked unnecessarily still exceeds 40% of those receiving therapy. Troup *et al* tabulated ICD complications that had been reported in ten publications from 1987–1990 for a total of 913 patients [21]. An average 57.4% of patients received shocks and 9–41% had inappropriate shock delivery. This continuing problem begs more sophisticated signal processing to be incorporated into device detection and decision.

II. Evolution and Trends

As early as 1982 [22], a plea was made for digital signal processing in tachycardia detection for implantable devices. This occurred at the time antitachycardia devices were already approved for SVT termination, and at the advent of the ventricular-based AICD™. Furman [22] proposed that two sensors (atrial and ventricular) be required for automatic diagnosis of tachycardia (with even a possible refinement of a third sensor for His bundle detection). He also suggested examining the QRS configuration for a match with sinus rhythm as a schema for diagnosing supraventricular tachycardia. These ideas were considered visionary in the early 1980's, but some of the ideas are being realized in the 1990's in experimental laboratories and more are on the immediate horizon. This paper will briefly review past and present signal processing strategies for tachycardia detection in implantable devices, and will more fully concentrate on novel signal processing techniques which are being developed by commercial and academic investigators to address the problem which still remains, *precise recognition and classification of cardiac arrhythmia.*

A. Early Algorithms for Tachycardia Detection

The first devices created for tachycardia interruption were designed primarily for pace-termination of supraventricular arrhythmias, but some had ventricular capability as well [23]. Despite initial excitement and a flurry of implants, the hazards associated with rapid atrial pacing, i.e., introduction of ventricular arrhythmias with possible lethal consequences, promptly halted this development until back-up ventricular rescue could be included. The appearance of the automatic implantable cardioverter defibrillator (AICD™) on the scene quickly shifted interest from SVT conversion to the more serious problem of reversion of ventricular fibrillation, the major cause of sudden cardiac death. The concentration on ventricular arrhythmias (as well as the design limitations of this invention) served to restrict the detection circuitry to ventricular electrodes only. In its successful infancy this limitation was greatly ignored because the promise and hope of this life-saving device were so dramatically realized. It should be no surprise that limitations of arrhythmia classification from a ventricular lead alone would closely parallel the classic weaknesses of automated coronary care monitors which derive diagnostic classification from the limited view of the surface leads [24].

A summary of detection schemes for early antitachycardia devices (ATD's) as well as methods in the experimental stage for both SVT and VT termination was given in Pannizzo *et al.* [25]. A tabular catalog of commercially available automatic ATD's was provided along with current (1988) status, i.e., released, in clinical evaluation, discontinued, etc. This paper presented a historical viewpoint of early development of algorithmic schemes, both practical and visionary. Multiple electrode measurements (both multiple ventricular mapping electrodes and dual chamber sensing) are discussed with prophetic vision. The rise and demise of the probability density function (PDF) as a discriminant for VF is nicely described. A more recent review of rate, timing, and morphology algorithms designed for ATD's and ICD's is provided by Lang and Bach [26].

The early probability density function (PDF) utilized the derivative of the signal to define the duration of time that the signal departed from baseline [1], [2]. It was empirically based upon the observation that the ventricular fibrillation signal spends the majority of its time away from the electrocardiographic isoelectric baseline when compared to sinus rhythm or supraventricular rhythms [2]. (See Fig. 1.) This was the original detection mechanism in the AICD™ but was supplanted at a very early stage by intrinsic heart rate measures. While the initial (predominantly hardware) implementation of PDF may have been less than robust, it's not surprising that modern digital versions have been introduced to address the early limitations [27].

The need to identify and cardiovert ventricular tachycardia in addition to detecting and defibrillating ventricular fibrillation, and the recognition that sufficiently "slow" VT might have rates similar to those which may occur during sinus rhythm or supraventricular tachycardias resulted in

try, and in some cases, stored electrogram capabilities. Most have either an automatic gain control or an auto-adjusting trigger threshold to address abrupt changes of signal amplitude. Rate detection algorithms of current versions of the Medtronic *PCD*™, Cardiac Pacemakers Incorporated *Ventak PRx*™, Ventritex *Cadence*™, Telectronics *Guardian ATP*™, and Intermedics *Res-Q*™ are described comprehensively in Olson [7]. The *Ventak PRx*, *PCD*, and *Res-Q*, each have stability criteria to separate atrial fibrillation with fast ventricular response from VT. Most devices allow selection of a noncommitted mode, i.e., redetection of the tachycardia must occur after charging and before therapy delivery. Only the *Ventak PRx* offers a morphology option in addition to rate, called probability density function (PDF). Results of early clinical trials of these devices and of the Pacesetter Systems *Siecure*™ are given in Klein *et al.* [8]. A new entry into clinical trials in 1995 is the ELA *Defender 9001*™, the first ICD to contain dual chamber sensing and pacing capabilities. In addition to rate, onset, and stability of the ventricular electrogram, the detection algorithm utilizes atrial timing to determine atrial-ventricular relationships. Acceleration of rate is identified by chamber of origin. The addition of atrial sensing is one of the most significant steps to be taken in this decade and this feature is expected to greatly enhance diagnostic specificity.

B. Validation of Inappropriate Therapy by Stored Electrograms

Documentation of the event which initiates an ICD discharge is now possible with the emergence of stored electrograms (EGM) in device memory. The Ventritex *Cadence*™ and Medtronic *PCD Jewel*™, and the CPI *Ventak PRx*™ provide recovery of recorded signals which have been captured in random access memory (RAM). Storage capability and sampling rate of the digitized data are often treated as proprietary information by the manufacturers, but, for example, 60 s of the ventricular electrogram sampled at a rate of 128 Hz by an 8-b analog-to-digital converter would require approximately 64K RAM. Data compression techniques would further reduce this storage. Examples of device interrogation for evaluation of delivered therapy are given below.

In one study of 16 patients [9], three patients received out-of-hospital shocks and verification of the initiating event from the stored electrogram was recovered via telemetry. In one patient (three shocks in one day) atrial fibrillation was found responsible. Case two revealed a polymorphic ventricular tachycardia with appropriate device response. It was noted that "the cycle length of the tachycardia is 160–180 ms and is characterized by a continuously changing configuration." In case three, a determination of intermittent lead fracture was made by retrieval of the captured EGM. Electrical artifact was confirmed by reproducing oversensing through manipulation of the device pocket and body habitus. This study of three cases in which 2/3 patients received inappropriate shocks, further demonstrates the power of signal processing capabilities which are possible in future designs of ICD's. The observed signal characteristics of stored electrograms, such as in the first example whereby atrial fibrillation was deduced by RR variability and a constancy in electrogram configuration, and the second example in which polymorphic VT was visually verified, demonstrate the value of electrogram capture and storage for morphological assessment. Evaluation of the stored electrogram is presently done by a human observer but these methods can easily be duplicated by automated methods of morphological pattern recognition in future devices.

In another study, Roelke *et al.* [10] examined 73 stored events in 22 patients for evaluation of spontaneous monomorphic VT. They examined the morphology of the initiating events and of the subsequent VT in an attempt to identify mechanisms of initiation of VT. Morphological classification was performed (presumably by subjective means, since no description is given of the method of classifying morphologies A, B, C, etc.), but there is no question that waveforms of differing morphologies are apparent on these recordings. This study further confirms the evidence of changed morphology on ventricular bipolar RVA electrograms during VT, despite minimal analog-to-digital sampling rates, limited storage, and severely limited bandpass filtering. As we move into the future, we should expect to see the addition of morphological classifiers as an adjunct to standard rate classifiers.

C. Incidence of Inappropriate Therapy

A major limitation of both past and present devices is inaccuracy in differentiating benign and lethal tachycardias. Even third generation ICD's utilize predominantly ventricular cycle length and/or cycle length variation as the basis for identifying a tachycardia. Inappropriate electrical therapy from currently available commercial and investigational devices has been reported during documented periods of sinus rhythm, sinus tachycardia, and supraventricular tachycardias including atrial flutter and atrial fibrillation. The reported incidence of false shocks during the first decade of the initial AICD ranged from 27 to 41% [11]–[16]. The remarkable efficacy of the implantable defibrillator in preventing sudden death was confirmed in 1989 in a study of 65 patients, yet the one- and four-year cumulative incidence of spurious shocks was $17 \pm 5\%$ and $21 \pm 6\%$, and of receiving an "indeterminate" shock was $19 \pm 6\%$ and $52 \pm 10\%$, respectively [14]. Winkle *et al.* also reported in 1989 an incidence of 58% of patients receiving shocks in a cohort of 270 patients and 20% of patients (35% of those treated) receiving "problematic" shocks [16]. The most frequent complications cited in one study of 94 patients were device discharges for sinus tachycardia or supraventricular arrhythmias, usually atrial fibrillation with a rapid ventricular response (17 patients or 18%) [15]. Thus the prevalence of supraventricular events contributing to the false shock incidence was early established and remains (as we shall observe) predominant a decade later.

Grimm *et al* [17] reported that 54 of 241 patients received a total of 132 unnecessary shocks which were

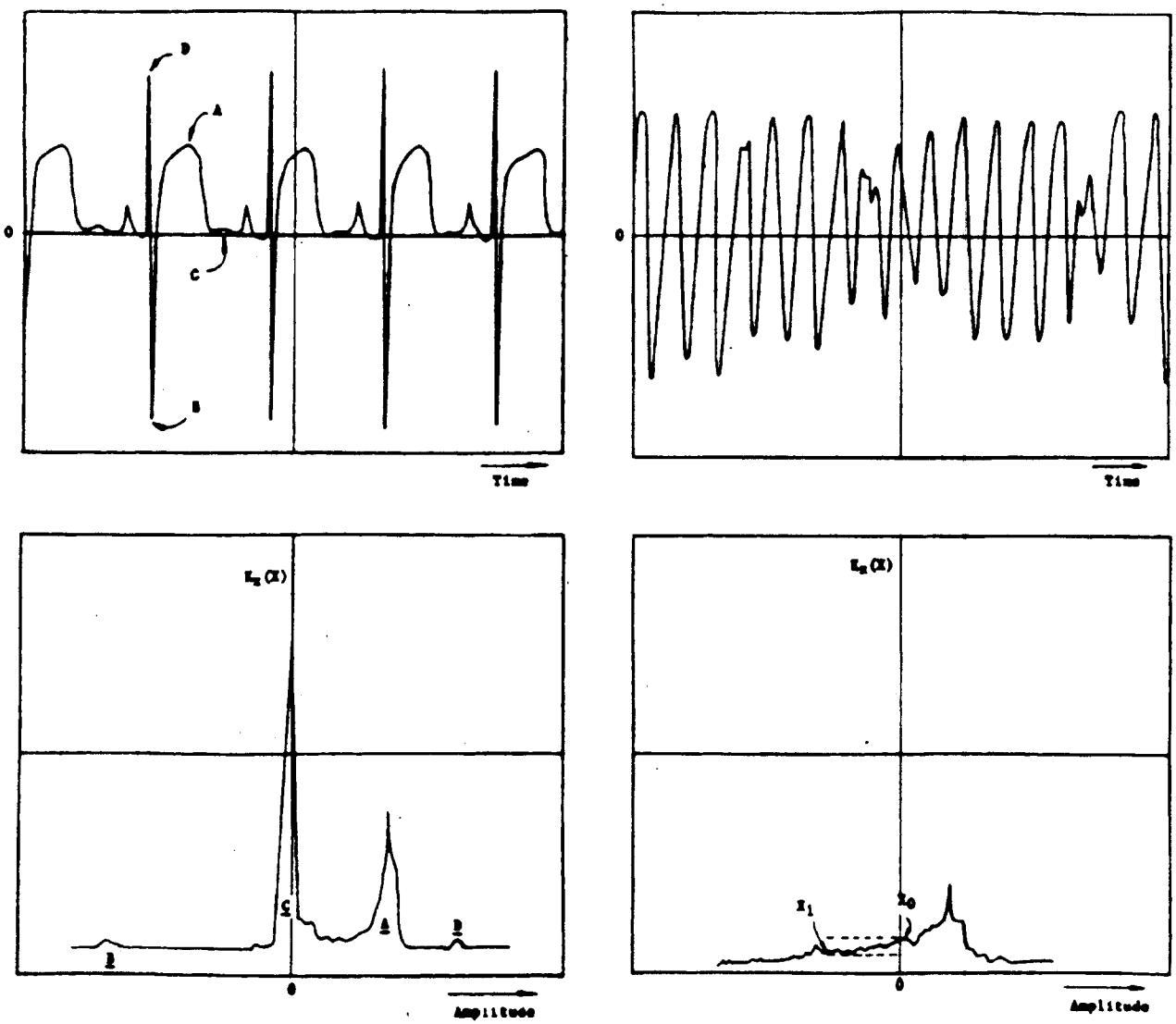

Fig. 1. The top graphs represent the intracardiac electrogram of sinus rhythm (left) and ventricular fibrillation (right). The bottom graphs are the corresponding probability density function, where the x-axis is amplitude and y axis is probability density function. The letters represent corresponding points on the left graphs.

several changes being incorporated into the second generation of devices. An alternative time-domain method called temporal electrogram analysis was incorporated into some second-generation devices [28]. This algorithm employed positive and negative thresholds, or "rails," placed upon electrograms sensed during sinus rhythm. A change in electrogram morphology was identified when the order of the excursion of future electrograms crossed the predetermined thresholds established during sinus rhythm. The combination of this morphologic method with ventricular rate was intended to differentiate ventricular tachycardia from other supraventricular tachycardias including sinus tachycardia. Initial testing of 27 arrhythmias in 25 patients gave correct classification of 26/27 nonsinus rhythms for a sensitivity of 96% when thresholds were adapted for each individual patient, but dropped to 81% following implementation of automated threshold settings. In sinus tachycardia 6/15 patients were incorrectly labeled as nonsinus (60% specificity).

Experience with probability density function and temporal electrogram analysis in first- and second-generation devices was disappointing. Probability density function was found to be unable to differentiate sinus tachycardia, supraventricular tachycardia, ventricular tachycardia and ventricular fibrillation whose respective rates exceeded programmed device thresholds for tachycardia identification [29]. A similar experience was encountered with temporal electrogram analysis. As a result, these criteria were utilized less and less frequently as increasing numbers of second-generation devices were implanted. By 1992, less than 15% of all ICD's implanted worldwide utilized either algorithm for tachycardia discrimination [30].

Historically, measurements derived from rate have been utilized for detecting ventricular tachycardia in implantable

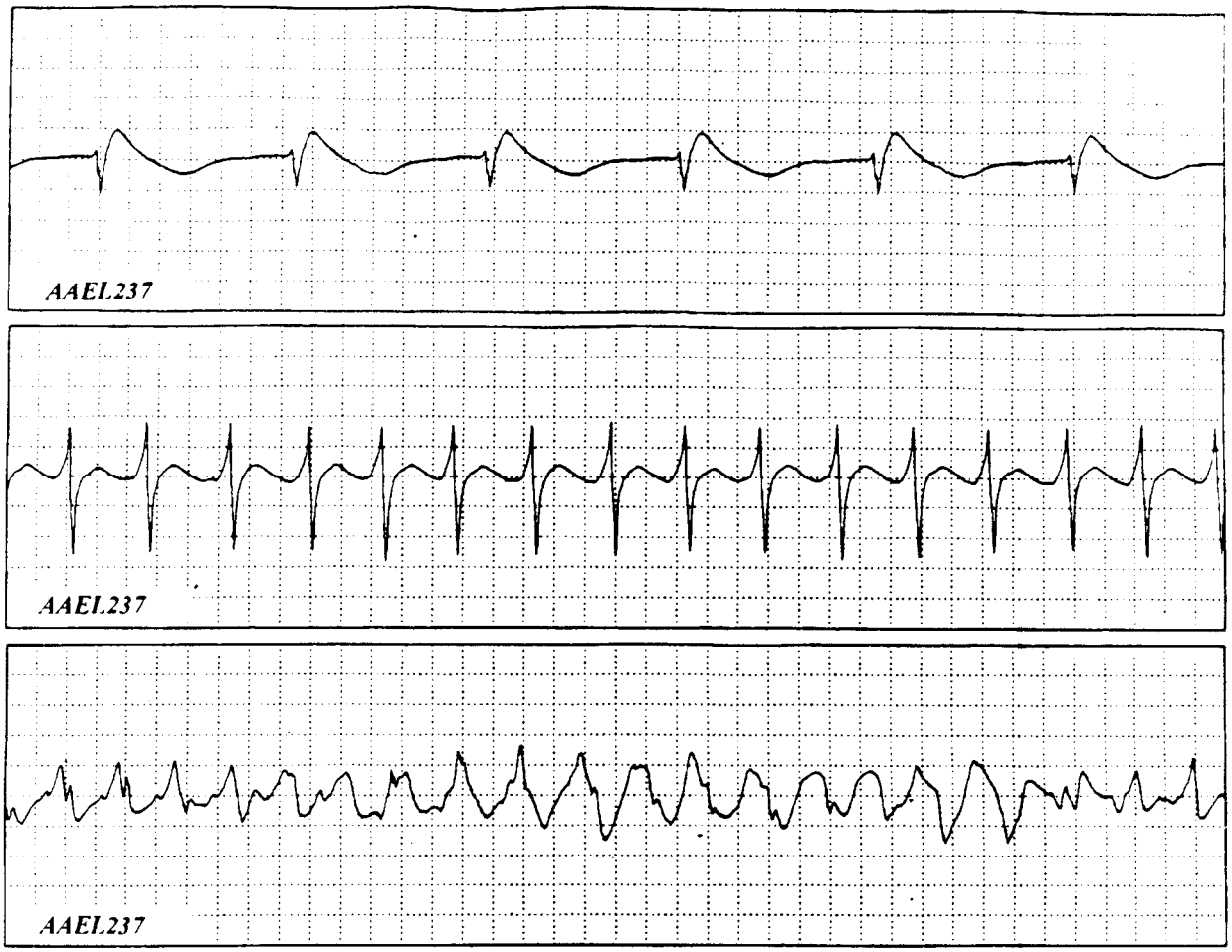

Fig. 2. Sinus rhythm (top), ventricular tachycardia (middle), and ventricular fibrillation (lower) recorded from the same patient. These unipolar electrograms were recorded (1–500 Hz, constant gain) from the right ventricular apex of patient AAEL237. Morphological configurations in each of the three rhythms exhibit distinct patterns.

devices, including the difference between the rate changes during the onset of sinus tachycardia compared to those of VT, as well rate stability during VT. Rate and rate-derived measures (based on cycle-by-cycle interval measurements) include average or median cycle length, rapid deviation in cycle length (onset), minimal deviation of cycle length (stability), and relative timing measures in one or both chambers or from multiple electrodes within one or more chambers. Among the methods most widely used for detection of VT in commercially available single chamber antitachycardia devices have been combinations of rate, rate stability, and sudden onset [31]–[36]. Pless and Sweeney published an algorithm for 1) sudden onset, 2) rate stability, and 3) sustained high rate [37] devised for early antitachycardia pacemakers designed for interruption of supraventricular tachycardia. This clever schema among others [38], [39] was a forerunner of many of the methods more recently reintroduced into tachycardia detection by ICD's. Another timing scheme proposed for tachycardia detection in electrograms suggested the use of dual ventricular electrodes to measure differences in timing and sequence of activation [40]. Intervals between deflection were 0–91 ms (mean 26 ms) during sinus rhythms and 13–141 ms (mean 66 ms) during VT. Locations of each electrode pair varied in different patients, but differentiation of normal and abnormal complexes was statistically significant in 14/15 ectopic morphologies.

Numerous electrogram signal analysis methods for discriminating ventricular electrograms during sinus rhythm (SR) and sinus tachycardia from those during VT have been proposed for improving accuracy in VT detection. These have included both time-domain and frequency-domain methods and have examined the possibilities of more sophisticated feature extraction and pattern recognition techniques than those currently in use. These proposed solutions for improved diagnostic specificity in future ICD's are described in the following sections.

B. Morphological Pattern Recognition

Morphology in our context refers to characteristics of the electrogram waveform itself which are easily identifiable and measurable. Such features might include peak-to-peak amplitude, slew rate (a measure of waveform slope), sequence of slope patterns, sequence of amplitude threshold crossings, and statistical pattern recognition of

total waveform shape by correlation coefficient measures. Fig. 2 is an electrogram recording taken from an annotated library of such recordings. It shows an example of distinctly different waveforms recorded from the right ventricular apex of AAEL237 [41] during SR, VT, and VF. Morphologic algorithms can exploit these inherent characteristics of the electrogram both with specialized analog circuits or digital processors. A feature extraction algorithm utilizing the product of the peak amplitude difference (maximum-minimum) and duration (time between maximum and minimum) was proposed but was tested on only four patients [42]. Another method for detecting VT combined bandpass filtering, rectifying, amplitude scaling, and signal integration over a 5 second moving time window with limited success [43].

In a search for better morphological classifiers, Lin *et al* [44], [45] investigated three techniques for morphologic analysis of ventricular tachycardia: correlation waveform analysis, amplitude distribution analysis, and spectral analysis. Correlation waveform analysis (CWA) is a classic method of pattern recognition applied to the surface electrocardiogram, but was first applied to intracardiac signals in this study. CWA uses the correlation coefficient between a template of sinus rhythm and the unknown cycle under analysis. The correlation coefficient, used by CWA, is computed as

$$\rho = \frac{\sum_{i=1}^{i=N}(t_i - \bar{t})(s_i - \bar{s})}{\sqrt{\sum_{i=1}^{i=N}(t_i - \bar{t})^2 \cdot \sum_{i=1}^{i=N}(s_i - \bar{s})^2}}$$

where ρ = the correlation coefficient, N = the number of template points, t_i = the template points, s_i = the signal points under analysis, $\bar{t}$ = the average of the template points, and $\bar{s}$ = the average of the signal points. The correlation coefficient falls within a range $-1 < \rho < +1$, where $+1$ indicates a perfectly matched signal and template. An example of CWA is shown in Fig. 3.

Amplitude distribution analysis (ADA) is a digital version of the probability density function (PDF) employed in a first-generation ICD, and spectral analysis of the ventricular depolarization uses Fourier transform methods. In this study, 30 induced monomorphic VT's were compared to sinus rhythm in the same patient. Morphology analysis by correlation (CWA) had 100% sensitivity and 100% specificity in classifying VT. In contrast, ADA differentiated only 15/30 (50%), and spectral analysis separated 18/30 (60%). Correlation waveform analysis has the advantage of being independent of amplitude and baseline fluctuations but requires heavy computational demands. All three methods require digital acquisition of the intraventricular signal by an analog-to-digital converter (A/D) and microprocessor-based waveform analysis.

Another template matching algorithm based on raw signal analysis measured the area of difference between electrograms, i.e., adding absolute values of the algebraic

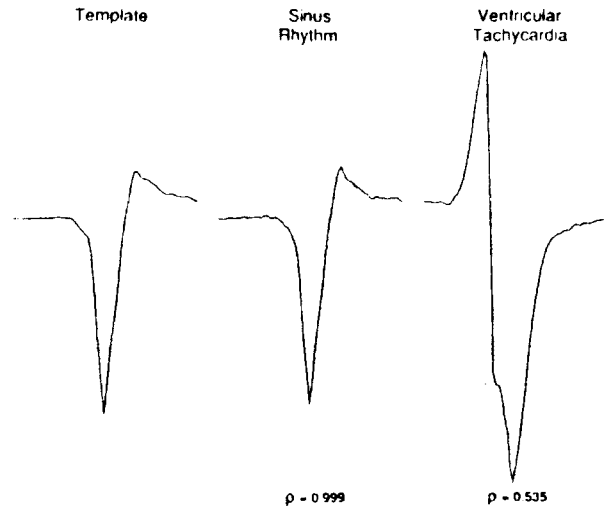

Fig. 3. Example of correlation waveform analysis of a ventricular intracavitary electrogram. A template of ventricular depolarization (left) was created from a 10-s passage of signal-averaged ventricular depolarizations. A typical ventricular depolarization during sinus rhythm (center) has a correlation coefficient $\rho > 0.90$ while a ventricular depolarization during ventricular tachycardia (right) exhibits a change in morphology with resultant $\rho = 0.535$. The sampling rate is 1000 Hz and the window size is 65 ms.

differences between each point on the electrogram and corresponding point on the SR template.. This technique was shown effective in discriminating VT from SR in animals [46] and in 10 patients [47]. Area of difference was expressed as a percent of the total area of the template and complete separation was possible in all 10 patients in both unipolar and bipolar configurations. Measures of peak amplitude and slew rate were less successful for classification purposes. The measurement of an area of difference is simple computationally but has the disadvantage of producing erroneous results in the face of baseline and amplitude fluctuations, and this method fails to produce a bounded measure. (Percentage values in [47] ranged from 1.4 to 423.) An improvement on this technique by signal normalization and scaling to create a metric bounded by ± 1 was utilized by Throne *et al.* [48].

The utility of unipolar versus bipolar electrograms in tachycardia recognition was examined by two groups. Langberg *et al.* utilized 10-cycle passages of filtered and unfiltered electrograms from 10 patients and reported that unipolar electrograms may be preferable to bipolar electrograms for analysis of areas of difference [47]. A second study of unipolar versus bipolar intraventricular electrogram classification of VT employed correlation waveform analysis (CWA) in 15 consecutive patients with induced sustained monomorphic ventricular tachycardia [49]. Successful separation required that there be no overlap in the ranges of values generated by CWA for SR and VT. CWA distinguished 14/15 VT's from SR in unipolar electrograms and 14/15 VT's from SR using bipolar electrograms. Thirteen of the VT's were common to both groups. Results gave the conclusion that 1) neither bipolar nor unipolar electrograms were superior in distinguishing VT from SR; and 2) for individual patients, either a unipolar

or a bipolar electrogram might be preferable for greater reliability.

In a further study of correlation waveform analysis (CWA), this template matching technique was applied to resolve the confusion that paroxysmal bundle branch block (BBB) might pose in the possible morphological misdiagnosis of ventricular tachycardia. Results showed that there existed a major overlap of ranges of correlation values seen in VT and paroxysmal BBB which preclude reliable separation of these arrhythmias by either a global or patient-specific threshold [50]. Thus CWA as well as other morphological techniques can easily be confounded by rate-related BBB and further classifiers are required for this case.

Template matching by CWA was further examined for distinction of multiple VT's of unique morphologies in the same patient. It was hypothesized that, in addition to a SR template, a second template acquired from the clinical VT could provide confirmation of a later recurrence of the same VT. Nineteen patients with 23 reinductions of the initial monomorphic VT were compared on a case-by-case basis [51]. A VT template constructed from the initially induced VT was used to classify electrograms of sinus rhythm and the same VT (identical in 12/12 surface ECG leads) when induced a second time. CWA identified 23/23 of the reinduced VT's. This technique of creating an abnormal template (as well as a normal) is based on similar methods used in computer analysis of Holter recordings in which "families" of templates are stored for classification of abnormal activations. The multiple template method was proposed as an effective means for separating sinus rhythm, ventricular tachycardia, and paroxysmal SVT with bundle branch block (BBB), but this would hold only in the case where BBB differed substantially from the VT waveform [50].

This work has been revisited by a new study of differentiation of distinct monomorphic VT's using morphological methods [52]. In response to tiered-therapy modalities which allow therapeutic alternatives for different tachycardias, the distinction of a variety of unique VT configurations provides better classification than underlying heart rate alone. This study of 23 patients exhibiting 36 distinct VT's demonstrated 100% correct classification of identical VT's and 94% classification of different VT's. The recognition of two or more different VT's within the same patient could play an important role in future devices in the selection of therapy to be delivered to hemodynamically stable versus unstable VT's.

Steinhaus *et al* [53] modified correlation analysis of electrograms to address computational demand through applying data compression of filtered data (1-11 Hz) by retaining only samples with maximum excursion from the last saved sample. The average squared correlation coefficient (ρ^2) was used for separation of SR and VT in both unipolar and bipolar configurations. In all 23 patients, ρ^2 values showed large separation using template lengths of 80% of the SR cycle length. Comparison with noncompressed correlations demonstrated that data compression had negligible effects on the results.

The paced depolarization integral (PDI) has been proposed as a metric for recognition of VT at the stimulus site. A cardiac action potential propagation model was developed to demonstrate a reduced conduction velocity (θ) of 46% and an increased PDI of 39% in the presence of suprathreshold stimuli [54]. In vivo studies (22 patients) showed increased PDI during VT while PDI decreased or remained unchanged in SR, and in a subgroup of seven patients, an 11% decrease in sinus tachycardia [55]. Animal studies with overdrive pacing at 200 bpm showed stable PDI values in SR and significantly lower PDI in induced VF, thought to be due to lack of capture [56].

To address the problem of power consumption, computationally efficient methods have been sought which would match the performance of correlation (CWA) but at greatly reduced execution speeds. Throne *et al.* designed four fast algorithms and compared discrimination results to CWA performance [48]. These morphological methods were: the bin area method (BAM); derivative area method (DAM); accumulated difference of slopes (ADIOS); and normalized area of difference (NAD). All four techniques are independent of amplitude fluctuations and three of the four are independent of baseline changes.

BAM is a template matching algorithm which compares corresponding area segments or bins of the template with the signal to be analyzed. Each bin (average of three consecutive points) is adjusted for baseline fluctuations by subtracting the average of the bins over one cycle and normalized to eliminate amplitude variations. The BAM calculation is given in the following equation:

$$\rho = 1 - \sum_{i=1}^{i=M} \left| \frac{T_i - \overline{T}}{\sum_{k=1}^{k=M} |T_k - \overline{T}|} - \frac{S_i - \overline{S}}{\sum_{k=1}^{k=M} |S_k - \overline{S}|} \right|$$

where the bins are, $S_1 = s_1 + s_2 + s_3, S_2 = s_4 + s_5 + s_6, \cdots, S_M = s_{N-2} + s_{N-1} + s_N$ and the average of M bins is $\overline{S} = (1/M)\Sigma_{k=1}^{k=M} S_k$. The bins and average of the bins is calculated similarly for the template. The BAM metric falls between -1 and $+1$, allowing a comparison to CWA.

Normalized area of difference (NAD) is identical to BAM except that the average bin value is not removed. By not removing the average value the algorithm avoids one division which would otherwise increase computational demand each time the BAM algorithm is applied. NAD is independent of amplitude changes.

The derivative area method (DAM) uses the first derivative of the template and the signal under analysis. The method creates segments from zero crossings of the derivative of the template. It imposes the same segmentation for analysis of the derivative of the signal to be compared. The segments are normalized, but are not adjusted for baseline variations since derivatives are by their nature baseline

independent. The DAM metric is calculated as follows:

$$\rho = 1 - \sum_{i=1}^{i=M} \left| \frac{\dot{T}_i}{\sum_{k=1}^{k=M} |\dot{T}_k|} - \frac{\dot{S}_i}{\sum_{k=1}^{k=M} |\dot{S}_K|} \right|$$

where $\dot{T}_k$ represents the kth bin of the first derivative of the template. The value of the DAM metric falls between -1 and $+1$.

Accumulated difference of slopes (ADIOS) is similar to DAM in that it also employs the first derivative of the waveforms. A template is constructed of the sign of the derivative of the ventricular depolarization template. This template of signs is then compared to the signs of the derivative for subsequent depolarizations. The total number of sign differences between the template and the current ventricular depolarization is then computed as

$$\rho = \sum_{i=1}^{i=N} \operatorname{sign}(\dot{t}_i) \dot{+} \operatorname{sign}(\dot{s}_i)$$

where $\dot{+}$ is the exclusive-or operator. The number of sign changes is bounded by 0 and the maximum number of points in the template (N), i.e., $\rho \in \{0, \cdots, N\}$.

Evaluation of these four algorithms was performed on 19 patients with 31 distinct ventricular tachycardia morphologies. Three of the algorithms (BAM, DAM, and NAD) performed as well or better than correlation waveform analysis but with one-half to one-tenth the computational demands.

A morphological scheme for analysis of ventricular electrograms (SIG) was devised for minimal computation [57] and compared to normalized area of difference (NAD). SIG is a template based method which creates a boundary window enclosing all template points that form a signature of the waveform to be compared. Equivalent results of VT separation were seen in the two techniques at two thresholds, but at an increased safety margin of separation SIG outperformed NAD (13/16 versus 9/16, respectively) and yielded a four-fold reduction in computation. Reduction of algorithmic complexity will be the essential ingredient for future implementation of automated signal analysis, particularly now that electrogram acquisition is a feature of third-generation commercial devices and morphological classification is certain to follow.

Depolarization width (i.e., duration) in ventricular electrograms has been postulated as a discriminant of supraventricular rhythm (SR) from ventricular tachycardia (VT) [58]. Measurements were made on the 8 last beats during VT detection and compared to a patient-specific width threshold. Authors found a significantly greater VT width (ms) compared to SR width in 13 patients. These findings were not in agreement with a subsequent study of depolarization duration in patients with two or more monomorphic VT configurations [59]. In this study only 5/15 patients (34 distinct VT's) yielded separation between SR and VT.

C. Frequency Analysis

Frequency-domain analysis is often proposed for classification of rhythms but little success has been solidly demonstrated for the recognition of VT. In surface electrocardiography, there has been some success in separating patients subject to VT from normals by spectral analysis of the terminal 40 ms portion of the QRS complex combined with the ST segment of the signal-averaged high resolution X, Y, Z leads [60]. In general, frequency analysis for recognition of ventricular tachycardia in electrograms has not been as straightforward. Distinctly different morphological waveforms (SR versus VT) which are easily classified in the time domain, can exhibit similar or identical frequency components if one focuses on the depolarization component alone. Examination of longer segments of 1000 ms–15 000 ms yields the same phenomenon because the power present in small visually distinctive high frequency notches is insignificant compared to the remainder of the signal, and changes in polarity of the waveform, easily recognized in the time domain, are simply not revealed by frequency analysis [45].

The success of this technique applied to recognition of VT in intracardiac signals yielded initially promising results in a small number of patients [60]. In other studies however, it was found to be ambiguous [45]. Pannizzo *et al.* found the spectral peak to be 15 ± 11 Hz for SR and 13 ± 11 Hz for VT in a study of 33 patients. No statistically significant difference was found and peak frequency was greater in SR for only 20/30 patients. Frequency-domain methods were applied only to a single ventricular depolarization from each class and the effect of variations over a number of ventricular depolarizations was not examined [61].

The case for frequency-domain recognition of atrial fibrillation [62] and ventricular fibrillation [63], [64] is perhaps more promising. In atrial electrograms the per cent power in the 4–9 Hertz band was found to exceed 28% in 93/100 (92%) of signals acquired during atrial fibrillation and to fall below that value in 190/195 (97%) of regular rhythms [62]. Similar identifying frequency characteristics of ventricular fibrillation have been cited [63], [64].

A magnitude-squared coherence function was developed by Ropella *et al.* which utilizes filtering and Fourier transformation of the intracardiac electrograms with a sliding window to distinguish monomorphic ventricular tachycardia from polymorphic ventricular tachycardia and ventricular fibrillation [65]. This method, while elegant, requires multiple electrode sites and is at present too computationally demanding for consideration in battery operated devices. As technology advances, the possibility of hardware implementation of frequency-based methods such as magnitude-squared coherence and time-domain correlation waveform analysis (CWA) may become feasible. A discussion of this will appear in a later section on digital signal processing (DSP) chip implementation of morphological metrics and software triggering algorithms.

D. Amplitude

Measurement of electrogram amplitude was postulated as a means of detecting VT and VF. A study of mean ventricular electrogram amplitude changes in VF versus SR showed a decrease from $15.3 + 5.4$ mV (SR) to $8.3 + 3.6$ mV (VF) in 37 episodes [66]. There was a significant relationship between initial amplitudes in SR and subsequent VF on a patient-by-patient basis, suggesting that SR amplitude might be useful for programming device sensitivity levels. In another study (41 episodes of VF in 15 patients), mean amplitude in endocardial leads decreased from 14.9 ± 0.9 mV in SR to 8.8 ± 0.7 mV (at 1 s), and 9.7 ± 0.7 (at 10 s) in induced VF. In epicardial leads (173 episodes in 43 patients) mean amplitude in sinus rhythm of 10.4 ± 0.3 mV decreased to 7.8 ± 0.3 mV (at 1 sec), 8.3 ± 0.3 mV (5 s) and 8.0 ± 0.3 mV (10 s) in VF. Changes of amplitude in monomorphic VT were not found to be consistent, i.e., $\leq 25\%$ decrease in 11 episodes, $\leq 10\%$ increase or decrease in 9 episodes, and $\geq 10\%$ increase in 11 episodes [67]. The significant decreases of amplitude in ventricular fibrillation in endocardial electrograms are consonant with findings of diminished amplitudes in atrial electrograms during atrial fibrillation (42% decrease) in an animal study of chronic implanted atrial leads [68].

DiCarlo *et al.* [69] examined the impact of electrogram amplitude on four typical detection schemes (counting) employed by commercial devices, by incrementally varying the sensing threshold from 0.1 to 2.0 mV. Ventricular electrogram amplitude (25 patients) was 6.3 ± 3.4 mV during SR/AF and 3.9 ± 2.8 mV during VF. The maximum threshold allowing completely accurate VF detection was 0.1 mV for two of the counting methods and 0.25 mV and 0.5 mV for the others. The interplay of diminished amplitudes seen in VF and choice of sensitivity settings to prevent "dropout" or "undersensing" was nicely demonstrated by this study. The study focused on the largely ignored problem of discriminating between VT and VF for the case of third-generation devices which allow unique zone settings for choice of therapy. The tradeoff leads physicians to artificially expand the VF detection zone to eliminate the possibility of misdiagnosing VF. Once again, more sophisticated digital signal processing techniques could be applied to overcome these deficiencies (separation of VT and VF) by methods more intelligent than counting alone.

E. Atrial Analysis for Recognition of Retrograde Activation

Morphological recognition of retrograde atrial depolarization in the electrogram was reported by Amikan and Furman [70] with a 17/25 (68%) success rate. The most common configuration seen in retrograde conduction was the RS shape (first upward deflection followed by an equal second downward deflection). The second most common was rS shaped signal. Amplitude was also assessed and 14/16 patients exhibited greater antegrade peak-to-peak amplitude than that measured in retrograde. In six patients in which slew rate was used as a feature, all had faster slew rates in antegrade conduction.

Another scheme to detect retrograde (V-A) activation from antegrade employed a feature detection algorithm which examined sequential slew rate changes in bipolar atrial electrograms [71]. This automated signal recognition method characterized each signal by a sequence of amplitudes with different maximum and minimum turning points (first differential coefficient of slew rate). For each patient, average signal polarity, amplitude ratio, and initial deflection were used for differentiation. In all 10 patients, separation of retrograde and antegrade was possible from one and usually two [HRA and RAA] lead sites. Davies *et al.* [72] examined electrogram morphology from digitized signals which were converted to a form in which the amplitudes were proportional to the rates of change of the original electrograms (equivalent to a time derivative). The derived signal was analyzed by a gradient pattern detection (GPD) program. Retrograde atrial activation was recognized in all 11 patients.

McAlister *et al.* [73] measured amplitude and slew rate of atrial electrograms from the right atrial appendage for recognition of retrograde conduction. Mean antegrade amplitude was 4.2 ± 2.2 mV and mean retrograde was 2.4 ± 1.5 mV ($p < 0.001$). Antegrade amplitude exceeded retrograde by 0.5 mV in 81% of patients. Authors asserted that amplitude criteria reliably distinguished antegrade and retrograde atrial activation, while morphology and slew rate contributed little to discrimination. CWA was also utilized for detection of morphological changes in the atrial electrogram in the presence of retrograde conduction [74]. Atrial electrograms in 19 patients were recorded from bipolar endocardial electrodes during sinus rhythm and 1:1 retrograde atrial depolarization produced by right ventricular pacing. In all 19 cases, a patient-specific threshold could be derived to separate anterograde from retrograde atrial depolarizations using 1000 Hz or higher sampling rates.

Other examinations of the power of atrial activation analysis included a study of P-wave detection from a right intraventricular apical lead [75]. Each electrode member of a bipolar catheter was used in a unipolar configuration with an electrode in the right subclavian vein as the indifferent electrode. Signal processing of the intraventricular P-wave was performed by computing the mean normalized area of difference. At the proximal electrode 75% of patients had P-waves detected, and at the distal electrode, 50%. The study demonstrated the possibility of atrial synchronous pacing and atrial rate response in pacemakers with standard ventricular leads. Techniques described above may be important in prevention of pacemaker mediated tachycardias, and could also be an essential ingredient for two-channel ICD detection of ventricular tachycardias with 1:1 or N:1 retrograde atrial activation.

F. Distinction of Ventricular Tachycardia and Ventricular Fibrillation

For separation of VT and VF, correlation waveform analysis (CWA) using a sinus rhythm template was tested

on a passage of monomorphic ventricular tachycardia and a subsequent passage of ventricular fibrillation in each patient [76], [77]. The standard deviation of the correlation coefficient (ρ) of each class (VT and VF) was used as a discriminant function. This scheme was based upon the empiric knowledge that correlation values are more tightly clustered in the cycle-by-cycle analysis of monomorphic VT and more broadly distributed in the dissimilar waveforms in VF. In 12 patients, values of the standard deviations of ρ for VT ranged from 0.018–0.176 (mean 0.076) and for VF 0.104–0.820 (mean 0.613). A global threshold midway between these values (0.345) yielded a distinction of 11/12 occurrences (93%) of VT and VF. In each patient individually, the standard deviations were well separated between VT and VF using a patient-specific threshold. A similar study applied CWA and the newer fast algorithms to the same problem [78]. These algorithms included normalized difference of area (NAD), a bin area method (BAM), and the derivative area method (DAM). Results showed easy separation of sinus rhythm from VT and VF; however in the VT/VF separation, standard deviation was only successful in 13/16 for CWA, 9/16 for NAD, 13/16 for BAM, and 11/15 for DAM. Standard deviation requires patient-specific thresholds, may not hold for all template-based algorithms, and adds further computational requirements to the algorithm; therefore, it is not a promising algorithm in its present form for discrimination of VT from VF. Other morphological measures which can swiftly perceive the similarity of waveforms in monomorphic VT and the dissimilarity in VF (or polymorphic VT) must be sought and these measures must be computationally simple if this technique is to be considered feasible.

Throne *et al.* addressed the problem of separating monomorphic and polymorphic VT/VF by using scatter diagram analysis [79]. A moving average filter was applied to rate and morphology channels and plotted as corresponding pairs of points on a scatter diagram with a 15×15 grid. The percentage of grid blocks occupied by at least one sample point was determined. Investigators found that monomorphic VT's trace nearly the same path in 2-D space and occupy a smaller percentage of the graph than nonregular rhythms such as polymorphic VT or VF. Thirteen episodes of monomorphic VT were distinguished from 27 episodes of polymorphic VT or VF, with overlap in one monomorphic VT and one polymorphic VT or VF.

Thakor *et al.* [80] utilized a sequential hypothesis test procedure for separating SR, VT, and VF. This method allows a tradeoff between detection time and specificity/sensitivity. A binary sequence is created using a comparison with a threshold which is 20% of the peak amplitude for each 1-s segment. An overall probability density function (pdf) of a metric derived from the binary sequence, called tachycardia crossing threshold (TCI), was generated from all patients in the study where SR, VT, and VF each have their respective pdf's. The SR pdf was easily separated from the VT and VF pdf's by a simple threshold; however, VT could not be separated from VF with this method thereby requiring a more sophisticated statistical technique, sequential hypothesis testing. This method delays diagnosis until there is sufficient information available (enough TCI's) to achieve the desired error probabilities; therefore, each passage has a different detection time. Results showed 100% separation of VT and VF (170 cases) after 7 s. A major limitation of this study was that the *training set* used to generate the pdf's was also used as the *test set*. It is unknown whether a general set of pdf's can be created that will be valid for all patients.

III. Other Electrogram Considerations

A. Electrogram Stability

Computer algorithms designed for tachycardia detection are typically tested on data acquired from supine patients undergoing electrophysiology studies during a resting state, i.e., with stable drug levels and steady sinus rhythm heart rate, and during induced ventricular tachycardia. In order to examine whether increases in *heart rate* with and without accompanying increase in sympathetic tone affect the stability of sinus rhythm electrograms (and possibly confound detection algorithms utilizing morphology), correlation (CWA) was used to evaluate consistency of intraventricular electrograms from 25 patients acquired during routine electrophysiology studies [81]. A template derived during sinus rhythm at rest was compared to electrograms during acceleration in heart rate from atrial overdrive pacing (600 ms, 10 patients; 500 ms, 10 patients; 450 ms, nine patients; 400 ms, nine patients) and during increased heart rate associated with an increase in sympathetic tone caused by physiologic doses of epinephrine (50 ng/kg/min, 13 patients) or infusions of isoproterenol (2 μg/min, 17 patients). Correlation values remained stable (change $< 4\%$) in all cases of atrial overdrive pacing when compared to normal sinus rhythm. During pharmacologic testing, correlation values remained stable in all but three of 30 patients. These results suggest that intraventricular electrogram morphology remains relatively unchanged in the majority of patients during increases in heart rate with or without accompanying changes in sympathetic tone.

Template matching algorithms also rest on the assumption that sinus rhythm morphology remains stable during *patient activity*. A study was undertaken to test this assumption by observing the impact of body position and physical activity on sinus rhythm morphology. Previous studies, using temporary electrodes in active patients, had suggested that the morphology [82] and amplitude [81], [83], [84] change with changes in rate. Caswell *et al.* examined *chronic* (24 ± 21 mos) bipolar electrograms (EGM's) sensed from a pacemaker in 10 patients while supine, sitting, and standing before and after limited exercise, simulating routine physical activity ($26\% \pm 16\%$ increase in heart rate) [85]. EGM's were recorded by telemetry and compared using correlation waveform analysis (CWA) and normalized difference of area (NAD). No significant difference was found in intrapatient EGM morphology ($p > 0.05$) using

CWA but moderate changes were found in amplitude and in NAD, which is an amplitude dependent morphologic algorithm.

B. Statistics

Many of the pilot studies and developmental work cited here have had small population samples on which to test the algorithms. In addition, there has been minimal statistical validation of the many frequency-domain and time-domain methods proposed for tachycardia discrimination by anti-tachycardia devices. When statistical methods *have* been employed, a normal (Gaussian) distribution of the morphometric values has been assumed. To test the validity of the assumption of a Gaussian distribution of morphological metrics, two time-domain methods for electrogram analysis were evaluated in 29 patients with 33 distinct sustained monomorphic ventricular tachycardias: Correlation waveform analysis (CWA) which is independent of electrogram baseline and amplitude fluctuations, and area of difference (AD) which is dependent upon these fluctuations [86]. A sinus rhythm template was used to analyze subsequent SR passages and VT passages containing a minimum of 50 consecutive depolarizations for deriving 95% confidence intervals. The values (morphometrics) derived from analysis of each of the individual passages were examined for skewness (symmetry) and kurtosis (shape) using two-tailed tests ($p < 0.02$). For passages of SR a Gaussian distribution of the metric under analysis was present in only 24% (CWA) and 45% (AD). For passages of VT, Gaussian distribution was present in only 58% for both CWA and AD. Therefore, the assumption of a Gaussian distribution of measures of selected time-domain analysis methods was found questionable, and statistical testing with nonparametric tolerance intervals was recommended as preferable. An expanded study (16 patients) using similar methods considered the Gaussian characteristics of four metrics CWA, NAD, BAM, and peak-to-peak amplitude (PAMP) for sinus rhythm, ventricular tachycardia, and ventricular fibrillation. This study also determined that Gaussian distribution could not be assumed in approximately 50% of the passages evaluated [87].

As an adjunct to the important problem of statistical validation, it should be appreciated that triggering and alignment are crucial to results of morphological analyses of intraventricular electrograms. Using nonparametric tolerance intervals to evaluate the same 29 patients as in [86] at the original (peak) alignment of a sinus rhythm template with subsequent cycles, 90% of all VT depolarizations could be distinguished from 90% of all corresponding SR depolarizations with 95% confidence in 27/35 (77% CWA) to 31/35 (89% AD) instances, depending on the template matching method applied. At the *best fit* alignment, VT could be distinguished from the corresponding SR in 30/35 (86% CWA) to 32/35 (91% AD) instances. Misalignment by only ±1 ms led to failure to discriminate VT from SR in 6/35 (17%) instances. Thus, triggering methods and alignment remain an important component of the morphological methods proposed and should not be ignored in future experimental studies [48].

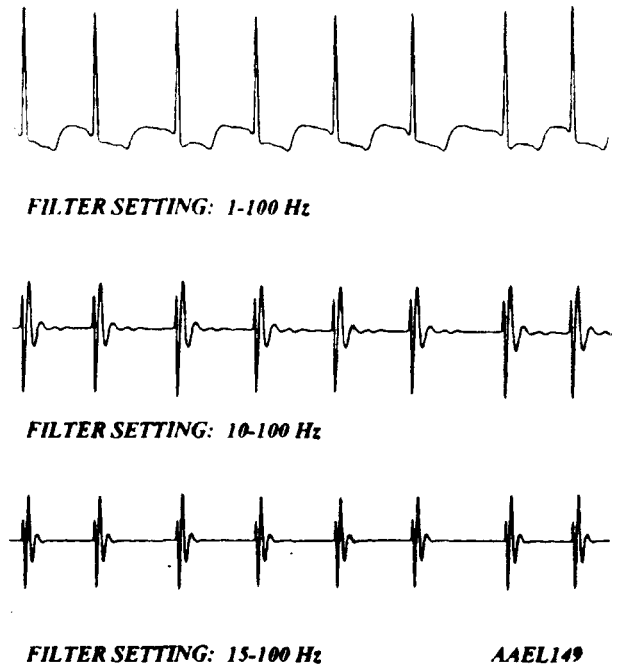

Fig. 4. Effect of filter settings on electrogram morphology. Traces of patient AAEL149 (recorded at an initial bandwidth of 1-500 Hz) are shown after bandpass filtering at 1-100 (top trace), 10-100 (middle trace), 15-100 Hz (lower trace). High pass-filtering at low frequency cutoffs of 10 and 15 Hz dramatically alter the waveform configuration. Filter characteristics: 4-pole Butterworth.

C. Effect of Filtering on Morphological Analysis

In many of the publications which report detection schemes using amplitude, slew rate, morphological features, and template matching, little information is provided about the signal characteristics of the test set under analysis. Of particular interest are the filter settings used during signal acquisition because these dramatically impact the fidelity of the signal under analysis as well as the robustness of a given algorithm in different settings. Filtering of an electrogram has long been known to alter both its amplitude and morphology [88]. Fig. 4 shows three filtered versions of a ventricular electrogram which was originally recorded at 1-500 Hz. The effect of filtering at 1-100, 10-100, and 15-100 Hz in the morphology of the waveform is evident.

Many of the morphological techniques have been tested and evaluated on intracardiac signals acquired with restricted passbands (30-250 Hz) while others have been applied to wideband signals (1-500 Hz). Both of these cases disregard filter settings which are typically used for signal conditioning in commercial devices, typically 15-20 Hz low frequency cutoff and 40-50 Hz high frequency cutoff. In a study undertaken to assess the reliability of CWA in the presence of reduced bandwidths, Jenkins *et al.* analyzed bipolar ventricular electrograms (16 patients, 20 distinct VT's) using two bandwidths: the originally recorded signal (1-500 Hz), and the same passages digitally filtered at

10–80 Hz. Separation of SR and VT was 17/20 at the wideband setting and 18/20 at the filtered setting [89]. The original sampling rate of 1000 Hz was retained both for the wideband signal and the digitally filtered signal; thus results (using 1 ms samples in both cases) are probably positively biased.

A more exhaustive study (10 patients each with SR, VT, and VF passages, recorded in bipolar and unipolar configurations) was performed in which 16 distinct analog filter settings were applied and subsequent sampling rates were reduced appropriate to each filter setting [90]. Correct classification of the three rhythms by CWA was used as a measure of signal fidelity which might be suitable for waveform analysis in practical next-generation devices. The minimum acceptable bandwidth for morphometric analysis of unipolar data was found to be 1–50 Hz, and for bipolar data, 10–50 Hz. If microprocessors and A/D converters are to be considered for signal analysis in next generation devices, minimal sampling rates and storage requirements are a necessity. These values, plus the choice of computationally simple detection algorithms, will define the power requirements needed for more effective classification.

D. Dual Chamber Sensing

The previous sections have dealt with single chamber analysis of arrhythmias (predominantly ventricular because that remains the state of the art) but inventive schemes which advanced two-chamber analysis appeared as early as 1984 [38], [39]. These methods were designed for tachycardia detection in antitachycardia devices (ATD's) intended for termination of supraventricular tachycardias, but even now they remain the most promising solution to reduction of false shocks in ICD's. The most prevalent cause of delivery of false therapy is atrial fibrillation which accounts for over 60% of all false shocks according to the literature. The simple addition of an atrial sensing lead can dramatically change the false detection statistics. Dual chamber pacemakers have been available for decades and the addition of two-chamber detection and analysis can be anticipated in next-generation ICD's.

The first two-channel algorithm for intracardiac analysis incorporated timing of atrial activation as well as ventricular into the diagnostic logic of arrhythmia classification [38], [39]. This scheme was based on earlier work in which an esophageal pill electrode [91] provided P-wave identification as an adjunct to surface leads in coronary care and Holter monitoring [24]. For ATD application, atrial and ventricular endocardial leads yielded intervals between successive depolarizations in both chambers. Recognition of a run of short intervals was followed by a comparison of atrial versus ventricular rate. With both chambers (atrial and ventricular) under analysis, most supraventricular arrhythmias could be detected by an n:1 (A:V) relationship, and most ventricular arrhythmias could be detected by a 1:n (A:V) relationship. Ambiguity occurred in tachycardias characterized by a 1:1 relationship, where SVT with 1:1 ventricular conduction could be confounded with ventricular tachycardia with retrograde 1:1 atrial conduction. The two-channel scheme also employed a sudden onset criterion to separate 1:1 SVT's and ST's. The two-channel algorithm successfully diagnosed 21/22 arrhythmias.

An imaginative scheme to clarify the case of 1:1 tachycardia was the proposal of an active device which incorporated the provocative delivery of an atrial extrastimulus (AES) late in the tachycardia cycle and examined the ventricular response [39], [92]. A related (early) ventricular response would evoke a diagnosis of ST and a nonrelated response would indicate AV reentrant tachycardia, AV nodal reentrant, or ventricular tachycardia with retrograde conduction. In 28/29 patients with sinus tachycardia, the atrial extrastimulus elicited an early ventricular response, and in 22/22 patients with paroxysmal 1:1 tachycardia AES failed to produce a significant change in ventricular cycle length. It remains curious that given the proactive capabilities of implantable devices nothing of this genre has ever since been considered. It's clear that the introduction of a simple active intervention could easily elucidate a variety of clinical scenarios, with little or no risk to the patient.

Schuger *et al.* [93] proposed that inclusion of atrial sensing in ICD's and the imposition of a simple criterion (that VT cycle length be less than atrial cycle length) would facilitate differentiation of VT from SVT. In 25/30 induced VT's (83%) the rule held. Four of the five failures were due to 1:1 VA conduction and the fifth case had a concurrent atrial flutter. Interestingly, all four cases of 1:1 VA conduction had VT cycle lengths below 350 ms, despite claims in the literature that only slow ventricular tachycardias conduct retrogradely with 1:1 relationships [94], [95]. No patients were studied during concurrent atrial fibrillation (the most prevalent arrhythmia appearing simultaneously with VT).

The early argument for adding atrial sensing for improvement of ICD tachycardia detection was advanced conceptually by Furman in 1982 [22], was demonstrated algorithmically by Arzbaecher *et al.* in 1984 [38], and was further confirmed by Schuger [93]. This simple two-channel analysis offers a first-pass method for confirming a VT diagnosis when the ventricular rate exceeds the atrial. The two-channel rate-only method still has limitations in separation of 1:1 tachycardias which could be either SVT or VT with 1:1 retrograde and is not always robust in the face of competing atrial and ventricular tachycardias. Thus the limitations of even two-channel timing analysis, although powerful, needed to be addressed by more advanced logical relationships.

In the dual chamber analysis category, a promising look at AV and VA relationships has been postulated as a feature of interest. LeCarpentier *et al.* attempted to differentiate sinus tachycardia and ventricular tachycardia (VT) with retrograde conduction using atrioventricular conduction time [96]. Ventricular pacing was used as a model for VT with retrograde, and sinus tachycardia was modeled by catecholamine stimulation. The thesis was that if the AV interval were longer than a "normal" AV interval, conduction began in the ventricle giving a diagnosis of VT with retrograde. This criterion works only for VT which has a

cycle length longer than the crossover cycle length, defined as the cycle length where the AV interval during ventricular pacing equals the normal AV interval. Limitations include beat-to-beat AV variability due to polymorphic. VT and prolongation of VA interval (therefore, a decrease in AV) during VT with retrograde due to drugs, stress, or disease. Other limitations include prolongation of the AV interval during ST and intraatrial tachycardias with 1:1 ventricular response.

A system designed for two-channel analysis using rate in both chambers plus three supplemental time features (onset derived by median filtering, regularity, and multiplicity) was designed for real-time diagnosis [97] of spontaneous rhythms. This system was an integration of previously tested stand-alone timing schemes [98], [99]. The combined system was able to recognize competing atrial and ventricular tachycardias and produced joint diagnoses of the concurrent rhythms. Simultaneous VT and atrial flutter was classified via atrial rate, ventricular rate, and a lack of multiplicity. Fast ventricular response in atrial fibrillation was detected via the regularity criterion. Onset (employed in 1:1 tachycardias) utilized a new median filter technique [98]. Twenty-five arrhythmia passages (11 patients) were processed with 21 correct classifications, where correct was defined as accuracy in all cycles of the passage.

E. Two-Channel Morphological Analysis

The use of morphological classifiers on intraventricular signals has been amply demonstrated [28], [44]–[57], [76]–[78] and similar methods have been applied to the intraatrial signal for recognition of retrograde conduction [70]–[74]. A two-channel classifier was designed by Caswell *et al.* [100] using CWA employing the morphology of concurrent atrial and ventricular intracardiac signals without employing rate information. A least squares minimum distance classifier was applied to atrial and ventricular CWA coefficients plotted in 2-D space, and automated decision boundaries were derived to separate four classes: SR, VT, SVT, and VT with retrograde. The method correctly recognized 48/48 SR cycles, 47/48 VT cycles, 39/48 SVT, and 40/48 VT with retrograde. The system demonstrated the power of two-channel waveform classifiers even in the absence of underlying rate.

Morphological analysis of both the intraatrial signal and the intraventricular signal was incorporated into a two-channel arrhythmia classifier [101] based on strategy developed previously for surface and esophageal signals [102]. A five-feature vector was derived for each cycle containing an atrial and a ventricular waveform metric (ρ_a, ρ_v, where ρ is the correlation coefficient for each depolarization), and AA, AV, and VV interval classifiers (short, normal, and long). Single-cycle codes were mapped to 122 diagnostic statements. The eight most current cycles were employed for a contextual interpretation of the underlying rhythm. Thirty-six patient recordings (3417 cycles with six distinct arrhythmias) were processed in real-time with 95.3% accuracy. This addition of morphological analysis of both atrial and ventricular channels combined with rate determination in each channel on a cycle-by-cycle basis, dramatically demonstrated the power of modern signal processing in the interpretation of arrhythmias.

The expectation of dual chamber ICD's has now become a reality. Luceri *et al.* reported initial clinical experience with a dual lead endocardial defibrillation system with atrial pace/sense capability [103]. The atrial sensing examination was limited to intraoperative observation only and no details are give about plans for algorithmic incorporation of the signal into tachycardia recognition except for the predictive comment that "Newer generations of ICD's are expected to provide atrial pacing and sensing as well." One might surmise that other ICD manufacturers will soon follow suit given the recent publication of a dual chamber ICD detection algorithm by Kaemmerer and Olson [104]. Evaluation of this algorithm in 322 rhythms from 52 patients showed a 37% decrease of inappropriate SVT detections and 32% decrease in the number of overtreated VT rhythms as compared to the ventricular rate with stability detection by the *Jewel PCD*™.

An actual realization of a two-channel ICD has appeared with the introduction into clinical trials (1995) of the ELA *Defender*™, a dual chamber sensing and pacing ICD which uses both atrial and ventricular signals for its tachycardia diagnoses. Algorithmic logic resembles work published by independent investigators over a decade ago [38], [39] which demonstrated that simple comparison of atrial and ventricular rates during tachycardia yielded 96% correct classification. If one wonders why something so simple, so logical, and so obvious took so long to come to fruition, one need only consider the regulatory implications of adding another lead and of adding more complex (albeit straightforward) two-channel logic to the detection strategy. It should come as no surprise that a non-US pacemaker company took the giant-step first.

IV. New Analysis Methods

A. Time-Frequency Analysis

Time-frequency analysis has recently emerged as a tool for interpretation of surface electrocardiograms for prediction of patients at risk of VT [105]–[108]. In a recent study, time-frequency methods applied to the intraventricular electrogram characterized SR and monomorphic VT using a neural network classifier with unsupervised learning [109]–[110]. Bipolar ventricular electrograms (1–500 Hz) of SR and monomorphic VT (16 patients) were submitted for classification, with ten cycles of both SR and VT from each patient reserved as a test set and the remaining cycles used for training the neural network. Three feature values were extracted from the time-frequency distribution plot and used as inputs to a three layer backpropagation neural network. In 12 patients, there was 100% sensitivity and 100% specificity in classifying SR and VT: two patients had 100% specificity and 90% sensitivity: one patient had 90% specificity and 100% sensitivity, and in one case, the neural network did not converge.

B. Neural Networks

Farrugia *et al* [111] also designed an artificial neural network classifier to recognize tachycardias from the ventricular intracardiac electrogram. It performed classification on a set of easily extracted features that characterize waveform morphology and rate. The six-input neural network (NN) used rectified and scaled bins of ventricular electrogram samples (inputs 1-3), two probability distribution function estimates, and the mean of the interevent intervals. The NN contained five neurons in the hidden layer and a three-neuron output layer representing the three classes ST, VT, and VF. Of 26 patient recordings, 18 were used for training and eight for testing. Error rate of diagnosis was 8.8%. An advantage of the neural network was its ability to generalize on patients on which it had not been trained as well as the use of features easily extracted from electrograms without significant computational burden.

Another use of a neural network was employed by Leong *et al* [112] in their classification system, called morphology and timing classifier (MATIC). Timing between atrial and ventricular channels is examined using a decision tree, and a neural network based morphology classifier is used for cases such as VT with 1:1 retrograde conduction where timing alone is insufficient. MATIC achieved 99.6% correct classification in 67 patients (12 483 QRS complexes). MATIC utilized the morphology classifier only for VT 1:1 patients and this selection process was performed in advance by a human. The value of the method remains ambiguous since the neural network morphology classifier was only tested on known true positives and not on the remainder of the cases.

C. Digital Signal Processing Chip Implementation

An alternative solution to the algorithmic complexity of correlation waveform analysis (CWA) was addressed via the new technology of digital signal processing (DSP) microchips [113]. DSP chips are designed to perform fast multiply and accumulate operations and are uniquely suited to digital filtering, fast Fourier transforms (FFT's), correlation, and autocorrelation. Correlation waveform analysis (CWA), an algorithm developed and previously tested in experimental studies of classification of ventricular tachycardia and fibrillation [44], [45], [48]-[52], [76]-[78], [81], [85]-[87], [90], [101], [102] plus a software trigger employing digital filtering and adaptive thresholding [114], were implemented in real-time on a single DSP chip (Motorola 56001). All calculations associated with the trigger alignment (21 separate sliding windows for each depolarization for optimal trigger placement) and 21 correlation coefficients computed within each 64 ms window (1000 Hz sampling rate) for each depolarization were completed within 30 μs. Overall accuracy was 2943/2978 (98.8%) depolarizations correctly classified. The test set included 1781 abnormal waveforms. This movement to new hardware technology to address software limitations is yet another example of engineering solutions which are on the horizon. Generic DSP chips in their present form are still too power-consumptive for incorporation into ICD's, but special purpose microprocessor architectures can and will be designed for signal processing problems such as this which demand speed, accuracy, and minimal power expenditure.

V. Summary

A. Signal Processing Methods

The purpose of this manuscript was to chronicle the history of development of tachycardia recognition algorithms and mechanisms which span over 15 years of ICD history. There are cautionary issues which should be raised in our future pursuit of this work. A variety of investigators, both in industry and in research laboratories, are designing, redesigning, and testing experimental algorithms for future consideration. Unfortunately, often the signal we process has dramatically different characteristics from those others process. In the interest of scientific methodology, it's imperative that authors reveal all signal conditioning stages that precede any pattern recognition and classification of electrograms. These include filter settings of the initial recording amplifiers, any subsequent filtering or electronic conditioning of the signal, and methods of capture of analog signal (FM or digital recording) including tape speed and bandwidth characteristics of that device. If direct computer digitization is performed, information should include description of data acquisition system used, sampling rate, analog-to-digital (A/D) resolution in bits/sample, type of software control of acquisition (custom software versus commercial software), and type of analysis software (custom versus commercial). These are absolutely minimal requirements that need to be reported for any serious study of signal analysis, whether classification is performed subsequently by visual interpretation or automated analysis.

B. Precepts of Pattern Recognition

All of the computer methods or automatic classification schemes described above are exercises in pattern recognition. The discipline of pattern recognition has well-established precepts which should be observed if the audience is to place credence in stated performance measures of the classifier. The most important rule is the separation of the data into *training set* and *test set*. The training set is used for design and development of an algorithm and it is during this stage that fine-tuning takes place to perfect the performance of the algorithm. These same data *should not be reused* for evaluation of the success of the classifier. The use of a training set for evaluation of a detection algorithm does not give valid statistics about performance. A separate and independent test set of data is required for validation if confidence is to be placed in predicted outcome [115].

C. Sample Size for Statistical Validation

Sample sizes of test sets reported in the literature are often small and statistical conclusions should be drawn cautiously when only a handful of patients have been processed

by these algorithms. Methods of statistical validation should be chosen judiciously and appropriately for the measures under analysis. (See *Statistics* section above.)

D. Electrogram Library

There now exists a collection of electrophysiologic signals acquired prospectively under a well-defined protocol which is intended for use in scientific investigation and evaluation of tachycardia recognition [41]. This library of recordings is available for licensing in both analog and digital (1000 Hz) format. These recordings, which have been proposed as an industry standard, allow scientists and ICD developers alike to utilize identical data for testing and device design. Each recording consists of surface electrocardiograms (ECG's) and intracardiac (atrial and ventricular) bipolar and unipolar electrograms of diverse cardiac arrhythmias. The recording protocol specifies wideband filter settings (1-500 Hz) for fidelity of morphological characteristics, and constancy of amplifier settings between control (sinus rhythm) and test passages (ventricular tachycardia or fibrillation) in the same patient. Each recording has been annotated and reviewed by a cardiac electrophysiologist and an electrical engineer to ensure an accurate interpretation of each arrhythmia and consistent quality with regard to recording of the electrograms. Patient demographics and antiarrhythmic agents, when utilized, are included in the annotation of each recording. Each patient recording has been assigned a number (such as AAEL001). Since the use of this library of patient recordings requires citation in the Methods section of any published paper and since the patient number of each recording (or corresponding digital file) utilized must be cited specifically in any tabular listing of results, a comparison is possible of the results of any published paper with those of previous as well as future studies which also utilize the licensed database.

VI. Conclusion

The thread that we have tried to weave in this historical hike through ICD arrhythmia detection schemes reveals certain underlying patterns. Early schemes for morphological signal analysis were scrapped for simpler and kinder rate rules. (Well, simpler and kinder to designers if not to patients.) The sensitivity and therapeutic success of simple rules were realized, but in the meantime more and more real people were enduring more and more real false shocks. We engineers improved the rate algorithms (adding onset, stability, sustained high rate) yet all the while yearning for a second (atrial) sensing lead, for more computing power to revisit morphology, for A/D conversion of the signal, and for increased RAM storage for electrograms and related data. Dual chamber timing schemes emerged, and finally two-channel schemes employing morphology were proposed. These ideas were novel and inventive, or perhaps radical, when they were first advanced. Fortunately, technology marches forward and many of the worthier creations may find realization within the near future. We salute those who pushed the limits, designed the improbable, and proposed the impossible, because that is the true engineering spirit.

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This paper is dedicated to Alois Langer, who was responsible for the engineering design and realization of the first implantable defibrillator. His contribution and vision inspire our continuing efforts at perfecting this device.

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