

lead to abnormal vasoconstriction, coronary spasm and coronary thrombus. This report reviews current knowledge and speculates on possible mechanisms and links between the various clinical syndromes in patients with CAD. The work of many investigators including our own group and the daily care and evaluation in the cardiac catheterization laboratory of patients with CAD were important in formulating my thoughts.

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Ambulatory (Holter) Electrocardiography Using Real-Time Analysis

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The development of electronic technology during the past decade, with its accompanying microprocessor

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and microcomputer technology, has spawned a new generation of instrumentation capable of examining the ambulatory electrocardiogram using a technique known as real-time analysis.^{1,2} Using real-time analysis instrumentation, the patient wears a battery-operated, portable (Holter recorder size) microcomputer during ambulatory activity to analyze and record the ambulatory or long-term electrocardiogram. Because of the wide variety of capability and quality of such instruments, considerable misunderstanding and mis-

information surrounds the technology. Moreover, the specific lack of a clear definition and standardization of what constitutes an adequate ambulatory electrocardiographic report produced by such technology, and the economic reimbursement of all forms of real-time analysis ambulatory electrocardiographic examinations at a level comparable to that of conventional ambulatory (Holter) electrocardiographic recordings have resulted in an industry that ranges from producing dubious instrumentation with inadequate capability to developing instrumentation with promising technical capability.^{1,3}

In this editorial we include a definition of ambulatory electrocardiography, an explanation of real-time analysis technology, a discussion of the safety, efficacy and clinical effectiveness of real-time analysis technology, and examine issues concerning the use and abuse of real-time analysis technology.

Definition of Ambulatory Electrocardiography

Ambulatory or long-term electrocardiography is the recording of electrocardiographic data *continuous* as it occurs over a protracted period. This scientific method was originally applied clinically for 6 hours, extended to 12 hours, and then proved most useful for examination of the 24- or 48-hour diurnal cycle.⁴ The original application of this technology in humans utilized an electromagnetic tape (Holter) recording of continuous electrocardiographic data obtained from surface bipolar electrodes, coupled with playback analysis of these tape-recorded data. Thus, the conventional ambulatory electrocardiogram is defined as a continuous tape recording of all ambulatory electrocardiographic data for a minimum of 24 hours and its playback analysis.

Experience with ambulatory electrocardiography in the past 20 years has shown that some patient symptoms occur so infrequently and/or unpredictably that it was impractical to continuously record in persons for extended periods. Thus, there emerged the necessity of examining patients in a noncontinuous fashion using a variety of intermittent function or patient activated devices.⁵ These latter devices usually were patient initiated or activated to record electrocardiographic data, but a few used automatic time activation or a variety of sampling techniques over extended periods.⁵ This technology used either solid-state memory techniques or tape recording to record relatively limited electrocardiographic excerpts (1 to 3 minutes) of the continuous electrocardiographic events occurring in a patient. More recently, several of these intermittent devices have become capable of recording a sample of electrocardiographic data in solid-state memory, and at a later time transmitting that information by telephone to a receiver for playback of the stored data for subsequent analysis. This technology is known as transtelephonic monitoring. The shortcomings of noncontinuous sampling of ambulatory electrocardiographic data are widely appreciated. The inherent variability of cardiac arrhythmias, and the intermittent nature of the occurrence of specific forms of various arrhythmias (particularly complex ventricular arrhythmias), absolutely preclude use of noncontinuous

techniques in documenting the occurrence or frequency of arrhythmias in a specific person.⁴ Therefore, intermittent devices are usually used for examination of electrocardiographic events during rare or infrequent symptoms. However, rigorously supervised programs of transtelephonic monitoring in specific high-risk patients (malignant ventricular arrhythmias or sudden death) have proved to be of clinical value in certain situations.⁵⁻⁹ Many of these latter intermittent examination devices are often erroneously identified as "real-time" event recorders.

Real-time analysis instruments, in contrast, purport to examine by microcomputer *continuous* ambulatory electrocardiographic data as it occurs beat by beat to determine a variety of decision analysis diagnoses within the capability of the algorithm of the specific instrument. Although this technique produces electrocardiographic data in a continuous manner, because of the constraints of data storage techniques, it can only record and document electrocardiographic data in an excerpted, noncontinuous manner (with rare exception). Thus, most real-time analysis instruments store their decision analysis of all continuous data examination in a computational or summary data format in solid-state memory or on tape storage and are forced to present the evidence of that decision analysis with noncontinuous excerpted electrocardiographic examples.

Recently introduced (November 1986), innovative data compression techniques that remove isoelectric baseline electrocardiographic data and intermittently sample the QRS waveform complex have resulted in the capability to store all "abbreviated" electrocardiographic complexes occurring during a continuous 24-hour examination. Playback computer techniques fill in these abbreviated waveforms, giving the appearance of storage of a continuous electrocardiographic recording. Whether important electrocardiographic data are lost with this technique has not been determined. Such techniques are perhaps misleadingly being presented as complete 24-hour data storage or full disclosure.

Real-Time Analysis Technology

Real-time analysis instrumentation emanating from several manufacturers (Tables I and II) usually consists of a real-time analysis recorder (a battery-operated microprocessor computer) that analyzes and records the ambulatory electrocardiogram, and a report generator that receives the data from the real-time analysis recorder and permits editing, generation of analog and graphic hard-copy records, and data storage and retrieval. More precisely, this technique analyzes each electrocardiographic complex as it occurs, i.e., during real-time, within the capability of its computer algorithm, and stores its decision analysis and summary or compressed data format in solid-state memory or on tape storage. The amount of data stored in such systems is limited primarily by the electronic memory used or some abbreviated form of tape recording found in such devices. Most often, such devices can only store about 30 minutes of selected information for electrocardiographic printout examples.

TABLE I Real-Time Analysis Recorder Instruments

Manufacturer Product Name/Model	Biosensor Multiday	Cardiac Care Units Compas	Circadian Circamed	Fukuda-Denshi Model SM-40	Grandcor Cardiport 1000	Hewlett-Packard Model 43410S
Hardware specifications						
Size (in.)	6X4X1	5X3X1.5	6X4X1.5	5.5X3.5X1.5	1.5X3X6	6.5X3.5X1.5
Weight, inc. batteries (oz.)	16	13.4	15	17	9	16
Microprocessor type	Intel 8051	*	*	*	*	Intel 8086
Memory size	32-64K	32K	*	*	*	256K
Time display (clock)	+	0	0	+	0	+
Battery type	Li or 1.5V aa	NiCad	1.5V AA	1.5V AAA	C cell	1.5V AA
Transtelephonic capability	+	+	0	0	0	0
Frequency response (Hz)	1-30	0.01-100	0.05-100	0.05-120	0.1-40	0.05-40
Solid-state memory	+	+	+	+(1)	+	+
Calibration	+	+	+	+	+	+
Software design						
Artifact filter	+	+	+	+(2)	+	+
Sampling rate (samples/s)	250	256	400	*	150	125
ECG strip memory (no.Xlength)	variable	42 X 6 s	140 X 10 s	100% retrievable	100 X 6 s	72 X 6 s
Ambulatory ECG features						
No. channels recorded	2	3	1 or 2	2	2	2
No. channels analyzed	2	3	1 or 2	2	2	2
No. categories defined	100	17	8	14	16	72
ST-segment analysis	+	+	+	+	+	+
Pacemaker detection	+	0	+	+	+	+
Maximum hours examined	24	24	30	24	24	25
Total hours of summarized data	120 (5)	24	30	48 (5)	24	25
Heart rate display	0	0	0	0	0	+
Static ECG display	0	0	0	0	0	+
Multiform beat recognition	+	+	+	+	+	+
Adjustable parameters	+	+	0	+	0	0
Event marker	+	+	+	+	+	+
Surveillance	0	+	0	0	0	0
	Litton Datamedix Pecgasys	Medicomp EPICardia PC	OCG Technologies Model RTS 2000H	Oxford Medilog 4500	QMED Monitor One HC	
Hardware specifications						
Size (in.)	7X4X1.5	6X4X1	6.5X4X1	6.5X4.5X1.4	7X3.5X1	
Weight, inc. batteries (oz.)	19.6	20	13	28	14	
Microprocessor type	Z-80	NSC 800	*	NSC 800	*	
Memory size	64-96K	168K	246K	16-32K	12K	
Time display (clock)	+	+	0	+	+	
Battery type	9V alkaline	1.5V AA	9V alkaline	1.5V AA	NiCad	
Transtelephonic capability	+	0	+	0	0	
Frequency response (Hz)	0.5-100	0.05-100	0.05-60	0.07-70	0.05-100	
Solid-state memory	+	+	+	+(1)	+	
Calibration	+	0	+	+	+	
Software design						
Artifact filter	+	+	+	+	+	
Sampling rate (samples/s)	250	250	256	128	256	
ECG strip memory (no.Xlength)	32 X 6-8 s for 64K 100X 6-8 s for 96K	Variable	Variable	100% retrievable	4 X 5 s	
Ambulatory ECG features						
No. channels recorded	2	2	2	2	1	
No. channels analyzed	1	2	2	2	1	
No. categories defined	(3)	40	22	40	10	
ST-segment analysis	+	+	+	+	+	
Pacemaker detection	(4)	+	+	+	0	
Maximum hours examined	24	24	24	24	24	
Total hours of summarized data	24	24	24	24	*	
Heart rate display	0	0	0	0	+	
Static ECG display	0	0	0	+	0	
Multiform beat recognition	+	+	+	+	+	
Adjustable parameters	+	0	+	0	+	
Event marker	+	+	+	+	0	
Surveillance	0	0	0	0	+	

*Manufacturer did not provide information.

Comments: (1) Combination solid-state memory and tape cassette. (2) Artifact filter has ON/OFF option. (3) Detects abnormality and documents it. (4) Pacemaker spike rejection. (5) With change of battery.

TABLE II Real-Time Analysis Report Generators

Manufacturer Product Name/Model	Biosensor Multiday	Cardiac Care Units COMPAS	Circadian Circamed	Fukuda-Denshi Model SM-40	Grandcor Cardiport 1000	Hewlett-Packard Model 43400A
Hardware specifications						
Microcomputer	IBM compatible	0	0	Custom	Custom	HP150/Vectra PC
CRT	+	0	0	0	+	+
Mass data storage	Floppy/hard disk	0	Floppy disk	0	0	Floppy disk
Printer type	Dot matrix	Dot matrix/laser	Thermal	Thermal	Dot matrix	Laser
Transtelephonic receiver	+	+	0	0	0	0
Multipurpose vs Dedicated	Dedicated	0	0	Dedicated	Dedicated	Multipurpose
Chart recorder	0	0	+	0	0	0
Software						
Report editing capability	+	0	0	+	0	+
Data management program	+	0	*	0	0	+
Ambulatory ECG features						
Report features:						
Tabular summaries	+	+	+	+	+	+
Graphics	+	+	0	+	+	+
Documenting ECG strips	+	+	+	+	+	+
Full disclosure	0	0	0	+	0	0
	Litton Datamedix Pecgasys	Medicomp EPICardia PC	OCG Technologies Model RTS 2000H	Oxford Medilog 4500	QMED Monitor One HC	
Hardware specifications						
Microcomputer	Custom	NEC PC	Custom	Custom	0	
CRT	+	0	+	+	0	
Mass data storage	0	Floppy/hard disk	Floppy disk	0	0	
Printer type	Dot matrix	Thermal	Thermal	Thermal	Dot-matrix	
Transtelephonic receiver	+	0	+	0	0	
Multipurpose vs Dedicated	Dedicated	Multipurpose	Dedicated	Dedicated	0	
Chart recorder	0	0	0	0	0	
Software						
Report editing capability	+	0	+	+	0	
Data management program	+	0	0	0	0	
Ambulatory ECG features						
Report features:						
Tabular summaries	+	+	+	+	+	
Graphics	+	+	+	+	0	
Documenting ECG strips	+	+	+	+	+	
Full disclosure	0	+	0	+	0	

* Manufacturer did not provide information.

Present technology is at the brink of providing solid-state memory storage capable of holding 24 hours of electrocardiographic data, providing a continuous record similar to conventional tape recordings. One manufacturer (Table I) has overcome the latter limitation by simultaneously recording continuously all of the examined real-time analysis data on a conventional Holter recorder, while another manufacturer uses data compression techniques to provide full disclosure of all "abbreviated" electrocardiographic complexes (see earlier in this report). Stored real-time analysis data from the recorder is then delivered to a report generator (a general-purpose microcomputer with suitable keyboard terminals and graphic recorders) for editing, printing of hard-copy summary data and electrocardiographic examples and data management.

In general, this on-line analysis and preprocessing of electrocardiographic information as it occurs during real-time analysis reduces the time needed for completing a conventional Holter recording and removes the necessity for a well-trained and dedicated technician to interpret and interact with a conventional

Holter recording playback instrument. In contrast to the tape-recorded system, all of the preprocessed data provided by the real-time analysis recorder is immediately available upon the conclusion of the examination to a report generator, which generates the results of the examination. Although these results are said not to be heavily dependent on technician performance, so that the accuracy and precision are said not to be subject to human error and fatigue, they nevertheless also have required medical editing and review in our early studies.³ Because of this on-line analysis and preprocessing capability, there is emerging in the commercial marketplace the "surveillance" real-time analysis system (Table I). Such systems (with battery changes) purport to continuously examine patients over long periods (days to weeks) for selected abnormalities (such as episodes of ventricular tachycardia or ST changes of silent myocardial ischemia) and to alert either the patient directly (by recorder indicator) or the patient's physician (by daily telephone transmission) to the occurrence of such abnormalities for specific intervention. These instrument systems, more often than not,

are more limited instruments without state-of-the-art algorithm technology that examine only a single channel of electrocardiographic data for specific abnormalities (such as ST-segment depression or heart rate). While there is undoubtedly a valid indication for such examinations in selected patients, use of such devices to perform comprehensive 24-hour ambulatory electrocardiographic examinations is inappropriate.

Although real-time analysis systems permit more rapid access to the preprocessed data, most systems cannot retrieve most of the electrocardiographic data examined, which is the strength of the continuously Holter-recorded tape. Moreover, depending on the algorithm sophistication of the specific real-time instrument used, it will cease to record certain events that overwhelm its memory density capability, that is, certain systems are programmed to detect and record a finite number of specific events within 1 hour; otherwise, memory capability will be overutilized and memory capacity will not be available to examine all events over an entire 24-hour period. Thus, the accuracy of the final real-time analysis examination depends on the detection accuracy of the algorithm used for all electrocardiographic events, the ability of the specific real-time analysis instrument to recognize a variety of encountered artifact (such as baseline wandering and noise), and the ability of the particular instrument with its memory storage constraints to selectively document the decision analysis included in its final data summary. Unfortunately, the user of such instrumentation often cannot access those arrhythmic events that may be mislabeled or nondetected. This would only be possible in systems that simultaneously record all of the continuous data examined, or perhaps use the compressed abbreviated waveform storage technique. Other limitations of various real-time analysis systems include the general unproved ability of available algorithms to analyze atrial fibrillation, pacemaker rhythms, supraventricular rhythms, ST-segment changes (1 system excepted) and isolated P-wave detection, although many manufacturers purport to do so (Table I). These generic advantages and limitations are common to most real-time analysis systems available in the commercial and scientific marketplace.

Safety

Few clinical studies have reported use of real-time analysis ambulatory electrocardiographic instrumentation in clinical populations. Nevertheless, early clinical studies^{1,3,10} have not disclosed any untoward or unsafe conditions resulting from use of these miniature 8- or 16-bit microprocessor computer recorders, which usually have a battery power source of 9 V or less. Nevertheless, the standards recommended for conventional ambulatory Holter recording devices¹¹ are also directed at real-time analysis instruments to ensure that electrical malfunction and possible injury does not result to the patient being examined.

Efficacy and Clinical Effectiveness of Real-time Analysis Instrumentation

Few clinical studies concerning the efficacy or clinical effectiveness of real-time analysis instruments in

the clinical setting have been reported.^{1,3,12,13} Moreover, standards of accuracy for arrhythmia detection by conventional Holter recording instruments have only recently been addressed by an American Heart Association Task Force¹¹ and were simultaneously directed at real-time analysis instrument systems. Suffice it to say that early reports^{1,3,10,12} of real-time analysis accuracy indicate that the technology appears to be promising with respect to detecting and identifying ventricular arrhythmias, and has a high correlation ($r = 0.95$) in detection of normal QRS complexes compared with simultaneously tape-recorded data. There is no consensus regarding the method of standardizing the accuracy assessment of supraventricular arrhythmias, ST-segment detection, pacemaker evaluation and various conduction abnormalities.

One early clinical study that addressed the clinical effectiveness of real-time analysis ambulatory electrocardiography found it comparable to conventional Holter recording for patient applicability and technical reliability in obtaining information during examination.³ In that study, technical failure occurred in 2% of both real-time analysis and conventional Holter recording examination. Although the study showed overall acceptable accuracy for detection of ventricular arrhythmias, it also disclosed lower sensitivities in detection of low prevalence repetitive forms of ventricular arrhythmia.³ Significant inaccuracies in detection of supraventricular arrhythmias were also found.³

To our knowledge, no clinical studies have indicated that real-time analysis ambulatory electrocardiography is specifically recommended for any specific population or cardiac condition, and data with regard to algorithm accuracy or efficacy for supraventricular rhythms, conduction abnormalities, atrial fibrillation or pacemaker rhythms is nonexistent or unsubstantiated.

Use and Abuse of Real-Time Analysis Technology

As a result of the lack of a standard of what constitutes a valid ambulatory electrocardiography report and the economic opportunity presented by insurance reimbursement of "ambulatory electrocardiographic examinations," there has evolved a spectrum of real-time analysis systems that report only heart rate, isolated ST-segment changes or only isolated arrhythmias, and consider such reports a comprehensive valid 24-hour ambulatory electrocardiographic examination. Unabashedly, such instrument systems are often claimed and advertised to return the "investment" of their physician users with little risk involved. This latter practice has led to the development of many limited-capacity real-time analysis systems of dubious efficacy.

Such instances, bordering in some cases on fraudulence for economic purposes, are apparent to workers in the field. They exist for too many of the devices designated as "real-time analysis" instruments, and tarnish the credibility of the technology and the responsible manufacturers seeking valid real-time analysis instruments. These practices could be limited by a definition of the components required for a valid 24-hour ambulatory electrocardiographic examination

using a real-time analysis device, and a decrement in the scale of reimbursement for devices that do not provide all the data as detected by conventional 24-hour ambulatory electrocardiographic examination. Such consideration is in progress at the national agencies responsible for assessment of health technology and third-party reimbursement.

Use of real-time analysis ambulatory electrocardiography in specific clinical circumstances and populations is undefined. Although there are promising aspects to reliable preprocessing of ambulatory electrocardiographic data, the American College of Cardiology considers the technology available as not sufficiently documented and evaluated to be recommended for general use.¹⁴ However, real-time analysis technology is a "moving target," as indicated by the recent introduction of the data compression techniques for storing 24 hours of "abbreviated" QRS complexes and the emergence of new memory technology. These latter innovations, once assimilated, will surely mitigate in large part the greatest criticism of the technology: the inability to substantiate the electrocardiographic data examined. We can anticipate the need to review this technology frequently in the coming years.

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Rethinking Sensitivity and Specificity

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The concepts of the sensitivity and specificity of diagnostic tests were introduced in 1947,¹ and over the past decade have become familiar to most physicians.

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These test parameters have 2 major applications. First, they can be used in Bayes' rule to compute the "post-test probability" of disease (i.e., the probability a patient with a given test result actually has the disease in question). Such probability computations may be applied to individual patients or used in formulating general clinical strategies for groups of patients. Second, sensitivity and specificity are often regarded as the benchmarks of test performance and are used to compare the diagnostic value of alternative tests. The importance of both applications is being increasingly recognized.

While clinicians may use the concepts of sensitivity and specificity, most do not appreciate that these concepts imply a simplified probability model of diagnostic testing that contains some important assumptions. A key assumption is that sensitivity and specificity have constant values that are independent of the population