**The ECG Endeavour: from the Holter single-lead recordings to multilead wearable devices supported by computational machine learning algorithms**

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**INTRODUCTION**

Since the time when the electrocardiogram was first introduced in its simplest form (Einthoven, 1902), this diagnostic procedure, which is one of the most common investigations in cardiology, has continued to evolve. The progressive introduction of new technologies and features has enabled it to address an increasing range of diagnostic needs.

Intermittent or continuous, extended, reliable, and of course portable (mobile) recording of an electrocardiogram has been a long-standing need and goal of all specialists dealing with paroxysmal cardiac disorders, including arrhythmias, syncopal episodes and ischemic attacks, symptomatic or not.

Since the pioneering work of Norman Holter culminated in the introduction of the portable electrocardiograph in the late 40s (when the device weighed 85 pounds), striking progress in electronic technology has brought us small, lightweight and smart mobile ECG devices with impressive capabilities.

Today, the developments are remarkable. Both wearable and implantable ECG recorders have high-volume information storage capabilities, allowing day-long—or, in the case of implantable recorders, year-long—recordings, high-resolution tracings, and in most cases, data transmission capabilities.

Further, the analysis of these data based on machine learning models using computational algorithms is expected to make a definitive contribution, by demonstrating specific ECG features and personalising the management of a significant number of cardiac disorders.

In this review, we present a comprehensive recapitulation of the continually evolving ECG technologies, the current advances, gaps and problems, with special reference to the value of multi-lead ECG tracings and wearable devices.

Additionally, we place emphasis on the rapidly developing reality, in which computational algorithms and artificial intelligence in general will play a decisive role in the detailed analysis of digital ECG data and in the enhancement of precision cardiovascular medicine.

**I. EXISTING MOBILE ECG TECHNOLOGIES: ADVANCES, GAPS AND CAVEATS**

Recently, a well-written expert consensus statement presented the current status in the field of ambulatory and external cardiac ECG monitoring. [1]

According to this document, existing modalities and technologies could be grouped as follows:

1. Continuous single- and multi-lead external recorders with wire-lead transmission (Holter monitors).

2. Continuous single- or two-lead external recorders with wireless transmission (patch ECG monitors).

3. Intermittent external patient- or event-activated recorders (external loop recorders).

4. Intermittent external patient-activated or automatic post-event recorders.

5. External real-time cardiac telemonitoring systems (mobile cardiac telemetry).

Any proper assessment of the diagnostic value and the usefulness of each of the previous modalities must take into account a number of specific parameters, such as the nature of the patient’s symptoms and the type of disease under investigation, the patient’s maturity and openness towards newer technologies, cost-effectiveness and the volume of monitoring data required to draw a reliable conclusion.

**II. TECHNICAL DATA RELATED TO THE METHODOLOGY OF ECG TRACING**

The quality and reliability of ambulatory ECG recorders depends on the quality of the recording and the number of channels that each recorder provides. The recordings can be in 2-channel (two independent bipolar leads), 3-channel, 12- channel or EASI lead formats.

Ideally, all ambulatory ECG (AECG) devices should use the classic 12-lead electrocardiographic architecture. However, because of technological and financial issues, only a minority of AECG monitors have 12-lead capability.

As the above-mentioned consensus document also points out, many AECGs use EASI reduced-lead systems, as an alternative to both the commonly used 5- electrode monitoring system and the traditional 12-lead ECG monitoring devices. The EASI 12-lead ECG is derived from a set of four recording electrodes and one reference electrode. It uses the E, A, and I electrodes from the Frank lead system and adds an “S” electrode at the top of the mid sternum, along with a body reference electrode to provide orthogonally oriented signals [2].

The following points should be noted:

- Most of the patch ECG monitors, external loop recorders, event recorders and mobile cardiac telemetry monitors available today feature only a single lead derived from two closely spaced embedded or wired electrodes.

- An ambulatory ECG recorded with torso placement of the extremity electrodes cannot be considered equivalent to the standard ECG for all purposes, and should not be used interchangeably with a standard ECG for serial comparison. [3]

- Gradually, over the past few decades, digital technology has contributed to a significant improvement in the quality of ECG recording and signal processing. Nowadays, all current technologies are digital and are subject to appropriate regulatory guidelines.

- The latest technology provides multichannel, simultaneous sampling, together with analogue-to-digital converters that have built-in programmable gain amplifiers, capable of resolving even very low-voltage signals.

**III. PROBLEMS IN ECG RECORDING AND PITFALLS IN THE INTERPRETATION OF AECG MONITORING**

Portable electrocardiographic monitoring equipment, even with modern and highly improved techniques, has to face various problems associated with the recording quality of the electrocardiogram and potential artefacts, as well as the methodology used for recording the ECG.

These could be classified as follows:

**a) The number of leads used in each of the various existing systems and the reliability of the ECG tracing.**

It is obvious that recorders using only one or a limited number of leads are not able to reliably record any episodes of ischaemia with accompanying ST- segment changes. All previous recorders, either external or implantable, have contributed excellent diagnostic services in the investigation of episodes of paroxysmal arrhythmia or unexplained syncope. Wearable ECG monitoring patches using two closely spaced electrodes, provide 1- or 2-lead recordings, for several days, thus increasing the diagnostic yield of arrhythmia detection. However, the performance of single-lead devices is limited by the lower voltage amplitude of the recorded ECG, thus impairing accurate recognition of the arrhythmia type and origin. In the same context, external loop recorders record a single-lead ECG without providing information on the precise orientation of P, QRS and T waves as well as on changes of ST segment [1].

**b) Electrocardiographic artefacts, which make interpretation questionable and unreliable.**

Here we can distinguish two main categories that lead to more or less the same problem.

*The first category relates to body movements, appropriate skin preparation for skin electrode placement and, more generally, the functionality of the electrodes.*

All of the above are capable of generating deviations that make interpretation difficult, while these artefacts are not infrequently perceived incorrectly as arrhythmias.

*The second category of artefacts are associated with deficient contact between the electrodes and the skin.*

Bad skin–electrode contact is quite likely to cause pseudopauses to appear on the recording, while pacemaker spikes may disappear. Larger portions of an electrocardiogram, such as the QRS complex, are also often distorted. [4,5]

**It should be stressed at this point that, whenever there is a need to monitor the functionality of a pacemaker with an AECG recording, this must be highly reliable.**

It is clear that, in order to justify its value and its cost, continuous electrocardiographic monitoring equipment, though certainly extremely useful, must provide highly reliable ECG tracing in order to avoid incorrect diagnosis and potentially wrong treatment.

**IV. THE ROLE OF 15-LEAD RECORDERS IN IMPROVING THE DIAGNOSTIC CAPABILITY OF LONG-TERM AMBULATORY ELECTROCARDIOGRAPHY**

As mentioned above, continuous ambulatory 12-lead electrocardiographic monitoring equipment, or devices that use the EASI 5-electrode system, are traditionally applied for 24 or 48 hours, for specific diagnostic purposes.

Of course, this older modality, which is traditionally called Holter monitoring, cannot reliably detect a large percentage of paroxysmal events associated with either arrhythmias or myocardial ischaemia, since their detection requires a longer period of recording and/or a higher resolution tracing. [6,7]

It is also important to note that supraventricular arrhythmias, which are based on atrial activity, or arrhythmological problems associated with the length of the PQ or QT interval, are often not detected by recordings that use a limited number of electrodes. [8,9]

In addition, even greater problems arise when the continuous electrocardiogram is required for the study of symptomatic or mainly asymptomatic episodes of myocardial ischaemia.

The majority of ischemic attacks—especially in certain categories of patient, such as diabetics—are known to occur without pain, asymptomatic or minimally symptomatic, and the reliable recording of ST changes would of course be particularly useful if they were associated with only mild or atypical symptoms. Unfortunately, continuous electrocardiographic monitoring equipment that has only one, three or five ECG leads usually proves insufficient and is not very reliable when it comes to ST-segment changes. [10,11,12]

In contrast, the use of 12- and 15-lead AECG recording, assuming the resolution of technical difficulties to ensure a high-quality tracing, could prove an extremely important tool, not only for the diagnosis of sporadic arrhythmias and the determination of their anatomical origin, but in particular for episodes of myocardial ischaemia, particularly when it occurs in the inferior-posterior wall. [13]

Of course, the concept of a portable 12- or 15-lead system entails technology fundamentally different from that used for the continuous 12-lead electrocardiographic monitoring of cardiac inpatients in coronary care units.

It is of interest to consider here the findings of a study by Zalenski, who studied the diagnostic value of an ECG containing leads V4R, V8 and V9 from 149 patients with suspected myocardial infarction or unstable angina who were admitted to a university-affiliated hospital. [14]. The authors found major abnormalities (ST-segment deviation, T-wave inversion, Q waves) on the three extra leads in 28.9% (43 of 149) of patients. The sensitivity of ST-segment elevation for acute MI on 12 versus 15 leads increased from 47.5% to 58.8%, respectively, with no decrease in specificity. In the same paper, the authors concluded that the 15-lead ECG provided better sensitivity and odds in detecting ST-segment elevation; its use could thus contribute to the better selection of patients for thrombolytic therapy.

Later, in a similar publication, the results from a prospective multi-centre trial were presented, where the posterior (V7 to V9) and right ventricular (V4R to V6R) leads were studied to assess their accuracy compared with standard 12-lead ECGs in the diagnosis of acute myocardial infarction (AMI). In this publication, the authors concluded that the standard ECG was not optimal for detecting ST-segment elevation in AMI, while its accuracy was modestly improved by the addition of posterior and right ventricular leads. [15] Additionally, Michailides et al. demonstrated that the use of right precordial leads along with the standard six left precordial leads during exercise electrocardiography improved the diagnostic accuracy of exercise testing for detection of coronary artery disease [16].

Finally, it appears that there are major developments in this direction, as systems for 15-lead continuous ambulatory ECG monitoring are being developed, with the following advantages:

* Standardised electrode placement (not supported by electrodes of the older, user-unfriendly technology).
* No special preparation of the patient is required (such as shaving before attaching the electrodes).
* Recording quality is high.
* Capability for real-time ECG electronic transmission to special analysis stations, which can obviously accelerate decision-making concerning the therapeutic management of patients.

Today’s technology is mainly provided in the form of smart textiles, woven into a T-shirt, thus providing a wearable 15-lead ECG for continuous ambulatory monitoring (Figure). There can be no doubt that ECG monitoring over longer periods offers significant new diagnostic possibilities, not only for investigating a particular disease, either arrhythmia or ischaemia, but also for assessing the burden of the existing disease to a significant degree.

In addition, it is expected that all these smart wearable ECG systems will progressively be enriched with special sensors to record additional parameters, such as respiratory rate, skin temperature and oximetry, enabling these new devices to perform more comprehensive cardiopulmonary monitoring of outpatients. [17]

It should also be noted here that, with the evolution of previous technology, there will certainly be a need for reliable cost-effectiveness analysis to confirm the value of the new systems, not only as reliable clinical instruments, but also as contributors to reducing hospitalisation costs.

**V. ARTIFICIAL INTELLIGENCE AND COMPUTATIONAL TECHNIQUES FOR ECG ANALYSIS**

The steadily improving techniques for continuous and long-term ECG recording, and consequently the great mass of accumulated digital data, will be hard to evaluate without a parallel development in the techniques of non-invasive analysis and diagnosis.

Various machine-learning models based on computational algorithms allow computers to learn directly from data and perform a specific task efficiently without using explicit programmed instructions. This field of artificial intelligence has been widely used in ECG recording analysis.

In the last decade, deep learning has produced major breakthroughs in various medical conditions such diabetic retinopathy and skin cancer and has also gained enhanced popularity in ECG interpretation and the identification of heart rhythm abnormalities [18-20]. Deep learning is a type of machine learning that mimics biological brain interactions and behaviour. In other words, it is based on specific algorithms that operate through a network of interconnected neurons comprising a neural network; hidden layers of computation are added in order to model more complex behaviours and data structures. A major advantage of the deep learning approach to the automatic detection of cardiac abnormalities is that they do not require the extraction of any ECG features. The implemented diagnostic criteria are incorporated in a continuing process of learning as part of the algorithm’s training, based on the analysis of provided ECG data.

Recent studies have shown that deep learning models exhibit high performance in the automatic detection of atrial fibrillation on long-term ECG recordings [21-22]. Additionally, Xiao et al. have demonstrated that deep learning approach can be also used to detect myocardial ischemia early and accurately with high sensitivity and specificity. [23] In another study the researchers hypothesized that asymptomatic patients with left ventricular systolic dysfunction can be identified using a 12-lead ECG. The authors used a large database of ECGs (from approximately 45000 patients) to train a convolutional neural network that was then tested on 52,870 patients. The study concluded that deep learning applied to an ECG can detect asymptomatic left ventricular dysfunction with high accuracy [24]. Furthermore, long-term monitoring of patients and automatic disease diagnosis can be achieved rapidly and accurately by using this technology for ECG analysis [25]. The design of more sophisticated and deeper networks permits the efficient, rapid and reliable real-time classification of even the most complex signals on wearable devices [26]. Finally, modern technological advances and the development of telemonitoring is applicable in patients with heart failure using telerehabilitation systems, such as heart rate telemonitoring, transtelephonic electrocardiographic monitoring and remote supervised exercise training devices [27].

**VΙ. CONCLUSIONS**

Technologies and capabilities for continuous electrocardiographic recording and analysis are continuing to evolve, supported by the great potential of modern digital technology.

Wearable AECG monitoring devices capable of continuous recording for two or more weeks, with 12 or 15 leads, will contribute decisively to the diagnostic possibilities in patients with paroxysmal heart episodes of arrhythmia and/or ischaemia. Beyond the multi-lead ECG tracing, when one observes the rapidly developing computational techniques, and specifically those based on machine learning algorithms, it is certain that these techniques will contribute definitively to a more detailed classification and clustering of many cardiac diseases, promoting the whole concept of precision cardiovascular medicine.

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