

Wearable Electrocardiograph (ECG) Technology: A Help Or A Hindrance To The Modern Doctor?

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Abstract

Electrocardiography is an essential tool in the arsenal of many medical professionals, used to diagnose potentially life-threatening dysrhythmias or identify ischaemic changes. Traditionally, patients were required to attend healthcare practitioners to have an electrocardiogram (ECG) to be performed. This meant that many intermittent arrhythmias were likely missed. Holter monitors allow for longer periods of home monitoring, but were still limited and results traditionally are delayed. The advent of wearable ECG devices built-in to smartwatches has allowed unparalleled access to ECG monitoring for patients, but this has its own challenges. Accuracy, managing patient expectations and incorporating into clinical guidelines and pathways have all arisen as challenges for the modern clinician. This article provides a primer on the basic science underpinning the ECG, how this has been applied in the wearable ECG and some future directions.

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Original Manuscript

Wearable Electrocardiograph (ECG) Technology: A Help Or A Hindrance To The Modern Doctor?

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Abstract

Electrocardiography is an essential tool in the arsenal of many medical professionals, used to diagnose potentially life-threatening dysrhythmias or identify ischaemic changes. Traditionally, patients were required to attend healthcare practitioners to have an electrocardiogram (ECG) to be performed. This meant that many intermittent arrhythmias were likely missed. Holter monitors allow for longer periods of home monitoring, but were still limited and results traditionally are delayed. The advent of wearable ECG devices built-in to smartwatches has allowed unparalleled access to ECG monitoring for patients, but this has its own challenges. Accuracy, managing patient expectations and incorporating into clinical guidelines and pathways have all arisen as challenges for the modern clinician. This article provides a primer on the basic science underpinning the ECG, how this has been applied in the wearable ECG and some future directions.

Introduction

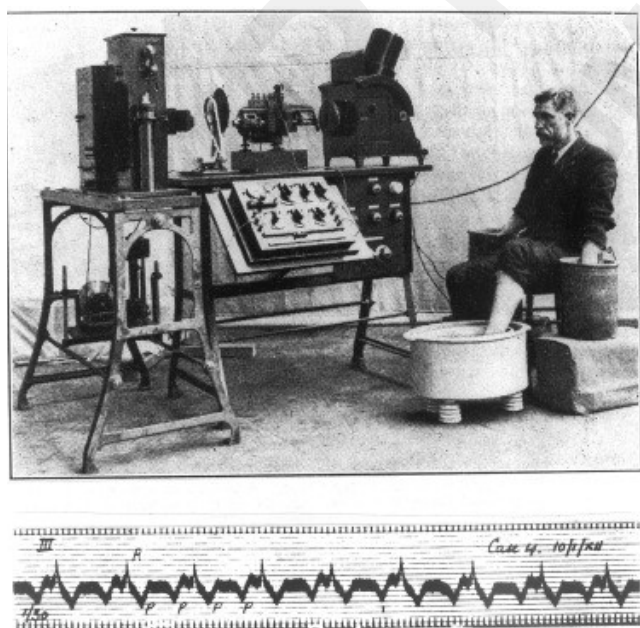
The electrocardiograph (or ECG) is one of the most commonly ordered tests in medical practice.^{1,2} By measuring the electrical activity of the heart, an ECG can indicate to a clinician cardiac arrhythmias and structural defects, respiratory disease, electrolyte disturbances, and even non-cardiac events such as subarachnoid haemorrhage.¹ The traditional 12-lead ECG is performed by placing ten electrodes connected to a digital ECG machine on the patient, and printing the ECG for interpretation.³ This process has been relatively unchanged since the inception of the modern ECG. However, with the modern explosion of portable digital technology, a single lead ECG can now be performed without placing any electrodes at all on a patient, and these digital ECGs can be sent across vast distances for real time clinician interpretation anywhere, at any time.³ With a range of popular wearable technologies incorporating this feature, more and more low cardiac risk patients have an ECG being taken from them at all times. This, plus the increasing role of deep learning and artificial intelligence (AI) in ECG

interpretation, have implications for medical practitioners. More patients will be presenting with possibly abnormal ECGs recorded by their home devices, and it will be up to their treating clinician to provide a second interpretation and explain how these new devices work. To do this effectively, clinicians require a thorough understanding of the basic sciences underpinning ECG acquisition. This essay will review the fundamentals of the ECG before examining the potential impacts of the digital age on electrocardiography for the modern doctor.

History of the Electrocardiogram

This history of the ECG is really the history of electrophysiology, which can be traced back to Galvani's experimentation in the 18th century, whereby he discovered the electrical basis of the nervous system by applying electrical stimulation to a dead frog's leg, causing movement.⁴ More researchers followed him, adding more pieces to the electrophysiological puzzle and in 1902, Einthoven broke new ground by accurately recording the electrical activity of the heart using his string galvanometer.^{5,6} The string galvanometer was not without its drawbacks- it required the patient to place their hands and one foot into a salt water solution, five assistants to operate, and weighed over 300 kilograms (Figure 1).⁷

Figure 1. An early commercial string galvanometer:⁷ The patient can be seen placing his hands and left foot into solutions of salt water to aid conductance and record the ECG tracing seen at the bottom of the image (Reprinted from BMJ 1950; 1:720, British Medical Association, London).



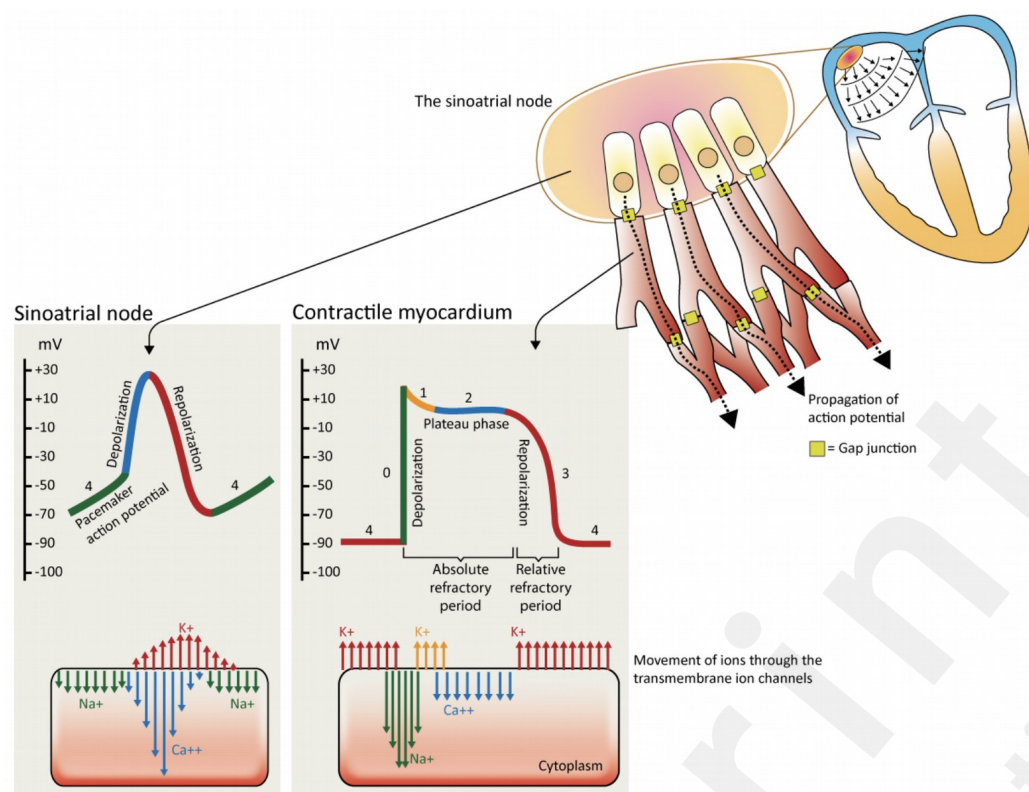
Thankfully modern ECG machines have evolved, and now require only 10 small electrodes to be placed on the patient to obtain an almost complete view of the heart. Despite this, the basic principles underpinning ECG acquisition and interpretation remain unchanged since its 1902 inception- an understanding of cardiac anatomy and physiology, and physics.

The Electrocardiogram: Underlying Physiological Fundamentals

Cardiac cells (cardiomyocytes) all have a positive charge on their outside membrane resulting from the distribution of ions inside and outside of the cell. At rest, potassium (K^+) ions are at a high concentration inside the cell whilst sodium (Na^+), calcium (Ca^{2+}) and chloride (Cl^-) have a higher concentration outside of the cell. The resting membrane potential (RMP) of cardiomyocytes is predominantly determined by the outward diffusion of potassium, mediated by a favourable chemical gradient and high membrane permeability to potassium ions at rest. This diffusion of the positively charged potassium ion leaves the inside of the cell relatively negatively charged when compared to the outside membrane. Contractile cardiomyocytes therefore typically have a resting membrane potential between -90mV and -80mV. Pacemaker cardiomyocytes have a different cell membrane whereby there is no stable RMP- instead, there is a constantly slowly increasing membrane potential mediated the so-called “funny current” (I_f).⁸

When depolarisation of contractile cardiomyocytes occurs (triggered by action potentials of nearby pacemaker cardiomyocytes), the membrane potential increases. Fast- Na^+ channels, then open and allow an influx of positive sodium ions, depolarising the cell to about +20mV and opening slow L-type Ca^{2+} channels. Once these channels close, active transports for sodium and calcium will begin removing these ions to restore ionic equilibrium and a potassium rectifier channel will open, allowing potassium to leave the cell again, repolarising the cell (Figure 2).^{9,10}

Figure 2. Cardiac depolarisation:¹⁰ This image shows depolarisation of conductile cardiomyocytes (e.g. sinoatrial node cells) and contractile myocytes, showing the movement of various ions across the cell membrane and their relationship to the action potential. The difference in ion flow between the two cell types can be readably appreciated, as can the contributions of ions to cell RMP (i.e. potassium efflux) and action potential. Some simplifications have been made, for example not showing the active Na^+/K^+ transporter pump that restores equilibrium after depolarisation.



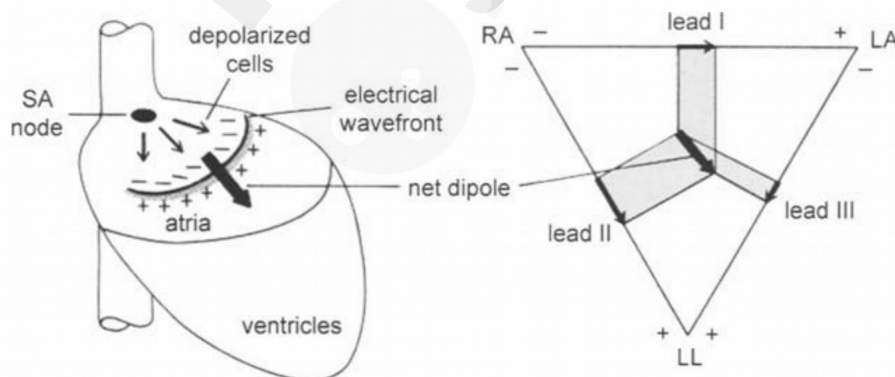
As each cell's membrane becomes positively charged during depolarisation, they propagate their action potentials to other nearby cells, who then depolarise, transmit the action potential to more nearby cells, and so on. In each wavefront of depolarisation, there will be a positive end (where the cells are depolarising and thus have a more positive membrane potential) and a negative end (where the membranes are repolarising, and thus more negative), which results in a moving electrical dipole (Figure 3).¹¹

A moving electrical dipole will create an electrical current. By virtue of the body's ability to act as a volume conductor, the current-field created by the flow of electricity (caused by cardiac depolarisation) is conducted to the thoracic cavity, and from there the surface of the body.^{11,12} This current flow is thus detectable as an electrical field on the skin by surface electrodes. As the electrical field moves toward a positive electrode it causes a positive deflection, and as it moves away, it causes a negative deflection.¹³ The view given between a positive and negative electrode is known as a lead. The two electrodes essentially act as voltmeters at their respective points and measure the potential difference between the two (which can be considered the "view" of the lead). For example, Lead I represents the potential difference between voltages measured at the right arm (RA; negative

electrode) and left arm (LA; positive electrode).¹³ As an electric field moves towards the left arm, a positive potential difference (or voltage) is recorded, which would be reported as an upstroke in the ECG trace.¹¹

It is important to remember that there are many thousands of myocardial fibres, each with their own electrical wavefront. Surface electrodes will not be able to distinguish the electrical field generated by each wavefront, and so the electrical field detectable on the surface of the chest wall is determined by the vectoral sum of the electromotive field strength of all active components of the myocardium.¹² It is this overall vector sum (or cardiac dipole) that is represented by the ECG trace (Figure 3).¹¹ What this vector will look like on an ECG trace at any given timepoint depends on the view of the respective lead and whether it is parallel to the flow of electricity at that moment. Each view will also look at certain areas of the heart depending on the direction of the lead vector. Traditionally, a 12-lead view is used in clinical electrocardiography. This includes Einthoven's original three lead view, as well as three augmented leads (which are unipolar with a neutral central terminal) and six precordial leads (whose leads lie in a transverse plane).¹³ This requires the placement of ten separate electrodes to create an electrical window for each lead.¹²

Figure 3. The cardiac dipole and Einthoven's triangle:¹¹ In the image to the left, the dipole associated with the depolarisation wavefront can be seen. The net (or cardiac) dipole is the sum of the multiple dipoles found along the electrical wavefront. It is this net dipole that is measured by an ECG. In the image to the right, Einthoven's triangle is presented, which shows the derivation of leads I, II and III. It can be deduced that the normal cardiac dipole (represented by the central arrow) will be positive in these three leads at this moment owing to the fact that it largely aligns with the positive electrode associated with each lead.



Thus, even the highly clinical process of ECG acquisition (and as logically follows, interpretation) is

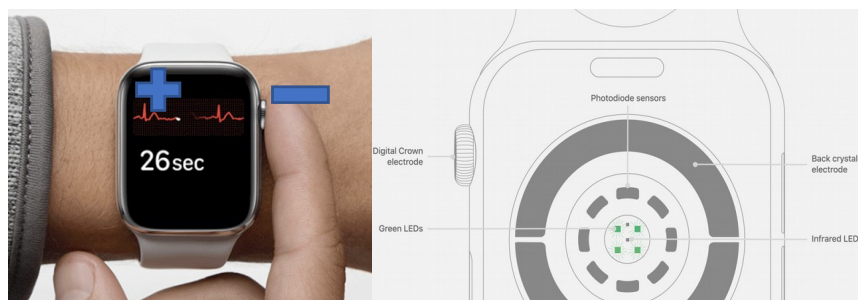
dependent on a thorough knowledge of basic science principles. It is impossible to fully understand the waveforms of the ECG if one does not understand both the cardiac physiology that creates the electrical wavefronts secondary to depolarisation, and the physics that allows electrodes to pick up the resultant electrical field. Without understanding the concept of leads or vector analysis, one would not fully understand the importance of multiple leads. This will prove to be an important concept when discussing the modern wearable single lead ECG.

A Modern Take

Recently, breakthroughs in both the hardware and software of mobile devices have drastically changed the paradigm of ambulatory ECG monitoring, allowing electrode-free ECG monitoring using wearable devices, and improved analysis of ECGs using AI. Mobile devices are almost ubiquitous in modern society and are used daily by 2-3 billion people.¹⁴ In a society where patients are eager for more involvement in their health and have a smartphone at their fingertips, it should come as little surprise that technology for home health monitoring has developed at a rapid pace. The wearable ECG device is an example of this, available using such devices as Kardia Band (AliveCor) and the Apple Watch (Apple).

The basic science principles behind these devices are the same as the traditional ECG. The device (whether it be a phone case, watch case or other portable device) will have two metal plates that create the positive and negative electrodes of Lead I. When the right and left hands (or a wrist) touch both of these electrodes, a bipolar Lead I is created, as per Einthoven's original triangle (Figure 4).¹⁵ The signal is detected using the same principles of volume conductance and net vector analysis as the traditional ECG.

Figure 4. The Apple Watch Series 4: A photo and schematics for the Apple Watch Series 4, an example of a wearable ECG device. The underside of the watch acts as the positive terminal, whilst the digital crown electrode acts as the negative terminal for Lead I. When the user touches both simultaneously, a tracing from the view of Lead I can be recorded.



The ECG tracing is then sent to an app on the user's smartphone, where automatic diagnostic algorithms analyse it and can provide diagnoses.¹⁶ This ECG can then be sent to any number of destinations; stored on the patient's computer, sent to a wireless printer for a physical copy, or sent directly to their personal physician.

Ambulatory cardiac monitoring is by no means a new development; Holter first reported the use of his eponymous cardiac monitor in 1961.^{17,18} However, this new hardware represents a large step forward in making it more accessible and has several advantages over the traditional Holter monitor. Whilst portable, Holter monitors are still bulky and uncomfortable to wear; they require the patient to visit technicians for the placement and removal of electrodes; they are costly to both health systems and patients; they cannot be given to patients indefinitely; and they require patients to take the initial step of visiting a physician.¹⁷ This is particularly important, as the asymptomatic patient unaware of their arrhythmia will not present until serious sequelae (e.g. stroke secondary to atrial fibrillation (AF)) occur. Furthermore, even with continuous ECG monitoring for a period of weeks, many arrhythmias may still be missed.¹⁷ Finally, whilst some Holter monitors can send their data to a central terminal, the majority save their data to a memory drive, which is then collected and interpreted when the monitor is returned. Thus, there is great interest in using these modern wearable devices for arrhythmia detection.

As mentioned, with these newer designs there is no need to place further electrodes on a patient. The device can be put on as easily as a watch by the patient, and a single lead ECG taken by merely touching the negative electrode. Not only does this mean it is easier to set-up for the patient in general, but it also negates the necessity for a patient to attend a healthcare centre to set up the ECG recording device. Additionally, these devices can be bought by patients themselves for a fraction of the cost of a Holter monitor, at no cost to health systems.¹⁹ The devices are exceptionally small and generally more comfortable to use, and, perhaps most importantly, they can be bought without a

referral or prescription, increasing the likelihood that asymptomatic patients with serious arrhythmias can be detected early. Whilst a full head to head comparison of these two diagnostic methods has yet to occur, a preliminary analysis has shown that for a fraction of the cost and inconvenience, wearable ECG devices such as the Kardia Band are superior or concordant with Holter monitors in 82% of patients.¹⁹

Not only has the physical hardware become more portable and acceptable to patients, but the underlying software interpreting the acquired ECG has also improved drastically over the recent years. Traditional ECG interpretations are fraught with error. Diagnostic interpretations from traditional machines have been reported as incorrect between 9-35% of interpretations, however this depends on what rhythm is being evaluated (with AF a particularly troublesome arrhythmia to diagnose).^{20,21} Whilst the newer diagnostic algorithms use similar diagnostic criteria as previous auto-interpretations, the difference is in the ability of the algorithm to learn and adapt when exposed to a new “learning set” of patient results. For instance, in one of the seminal papers to describe this breakthrough, a learning set of 109 patients was used which resulted in the algorithm adjusting its weighting for P-wave absence as indicating AF.¹⁶ This optimised algorithm had a sensitivity of 100% and a sensitivity of 96% compared to the initial values of 87% and 97% respectively, using the interpretation of two cardiologists as gold standard.¹⁶ This demonstrates how the deep learning that can now be utilised in real time for ECG analyse has the potential to far surpass previous automatic ECG interpretations.

Wearable ECG Monitoring in Clinical Practice

The main utility of these devices in clinical practice is the detection or exclusion of arrhythmias. KardiaPro has been approved in the U.S. for the screening and detection of atrial fibrillation (AF), but has been studied in various other conditions, including myocardial infarction, atrioventricular node re-entrant tachycardia, congenital heart disease and electrolyte disturbances.^{16,22-25} AF is one of the most investigated applications as it is commonly asymptomatic, has a high prevalence (up to 1.4% of all patients aged >65%) and can lead to devastating consequences, such as stroke and death.²⁶ Studies examining the use of wearable ECG technology for screening of AF are broadly supportive; the SEARCH-AF Study utilised wearable ECG screening in pharmacies and found newly-diagnosed AF in 15 (1.5%) patients, with an overall prevalence of 6.7%.²⁷ A theoretical analysis based off of this, supposing screening were extended into the community using this wearable ECG, suggested a potential cost-effectiveness ratio of US\$4,066 per quality adjusted life year gained, and \$USD20,695

for the prevention of one stroke.²⁷ When compared to the average inpatient costs of stroke (US\$20,396 \pm \$23,256) plus the associated outpatient costs (US \$17,081 for the first-year post stroke plus US\$16, 689 for every year after), this represents potentially an enormous cost saving.^{28,29} An Australian study using similar technology in introduced smartphone based AF screening to general practices during nurse led influenza vaccination clinics. The sensitivity and specificity of the automated algorithm was 95% (95% confidence interval: 83–99%) and 99% (95% confidence interval: 98–100%) respectively, and new diagnosis of AF occurred in 0.8% of patients. The evidence base for using these devices in screening at risk populations is steadily increasing, and several further trials are planned examining wearable ECG technology in other populations.^{22,30}

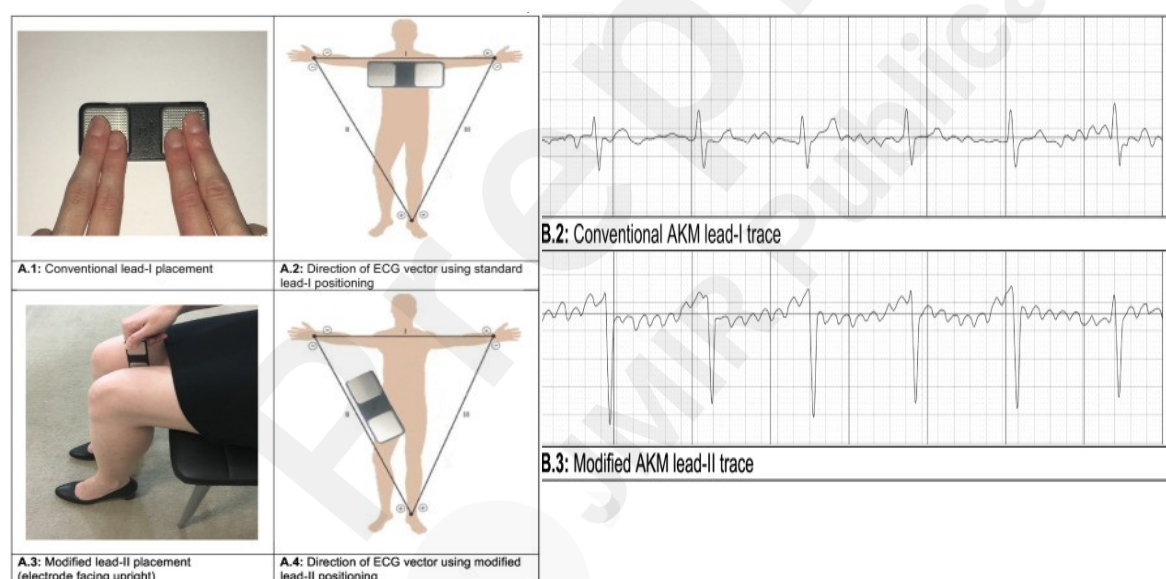
The reasons for these potential benefits over existing methodologies of AF screening and diagnosis have already been discussed; patients are more likely to wear these more comfortable, easily accessible devices, improved analysis of ECGs using smartphone AI algorithms increase diagnostic accuracy, and data can be read in real time by physicians being some of the biggest advantages. Patients themselves are also enthusiastic; a survey of 88 people found 82% found the device useful and use of the device prompted a doctor's visit in 25% of patients.²³ While this obviously has a benefit if those patients did have arrhythmia, it does lead to questions surrounding resource utilisation. This leads us to consider the potential limitations of this new technology.

Limitations

This technology is not without its potential drawbacks, to both the patient and clinician. By far the biggest drawback of this technology is its limit to only taking a Lead I view. When one considers the basic science underpinning ECG acquisition, this limitation makes perfect sense; one positive and one negative electrode will only ever be able to provide a one lead view as the potential difference cannot be measured at more points (and thus obtain more leads) without more electrodes. It is not even possible to obtain augmented limb leads (which are unipolar and so could practically be created using only one positive electrode) as the neutral central terminal (Wilson's Central Terminal) is created by the average of Lead I, Lead II and Lead III. However, one way that this could be improved whilst keeping the desired principle of ease of use is by changing the positioning of the positive terminal of the electrode (Fig 6). By keeping the negative terminal still in the right hand and moving the positive terminal to the left leg, the potential difference being measured is in line with Lead II, providing now a two-lead view of the heart. Whilst this may not seem like an enormous improvement (compared to the standard 12-lead ECG), as can be seen in Figure 5 it assists

considerably in the diagnosis of some cardiac arrhythmias, in this case, atrial flutter (AFL).³¹ By simply moving this electrode, the sensitivity for AFL from 27.3% to 72.7%. This is one potential way to increase the utility of this advance, and one that relies simply on the basic science underpinning this device.

Figure 5. Example of repositioning and resultant ECG:³¹ It can clearly be seen that by placing the positive electrode on the right leg, Lead II view is created. This has the resultant effect of improving image quality and revealing atrial flutter (B.3, right hand image).



The other major limitation is the practicality of physician access. Ironically, one of the greatest strengths of these devices (24-hour continuous monitoring for as long as the patient wants) can also be a weakness. Whilst a patient who has this technology now has the ability to record an ECG at any point in the day (or night), that does not necessarily mean that they will have timely access to a physician across the same hours. Patients who detect a possible arrhythmia outside of their doctor's availabilities may be left with two options: wait until an appointment becomes available, worrying

all the while about potential stroke or cardiac event; or visit their nearest emergency department. From a resource utilisation standpoint this becomes worrisome as in some studies, up to 7.3% of normal ECGs were reported as abnormal (sensitivity 97.1%, specificity 78.5%). Applied to the real world, that means 7 of every 100 normal ECGs may be reported as abnormal, resulting in 7 potentially unnecessary hospital visits per 100 normal ECGs. The question of what to do with patients who present with an abnormal ECG taken on a single lead private device is a vexing one. One potential solution could be rotating on-call physicians to review ECGs as they come through (as these can be sent in real time). However, this will leave open questions of compensation for the physician, and the eternal question raised above: how confident can a physician be based off a one-lead ECG that there is no further pathology to exclude? What are the medicolegal implications of not fully working up a patient with a single positive trace who then has a devastating cardiovascular event? These issues need to be considered for the clinician to provide safe and sound medical treatment and advice to patients and as the prevalence of these devices rises, these are issues that will be faced by more and more clinicians.

Conclusions

This topic was chosen because of the strong links between the clinical topic and the basic sciences. To understand basic ECGs, it is necessary to have a good grasp not only of cardiac physiology, but also anatomy and physics. If a clinician is then to have an informed discussion with a patient regarding use of a wearable ECG device, then they must have confidence in their basic sciences to explain the mechanisms and potential limitations of such a device. With the anticipated explosion of these devices in people's private lives, questions surrounding this are almost a given, and thus all clinicians should be well acquainted with the basic sciences of electrocardiography.

The ECG is one of the most ordered clinical tests for good reason; it is an affordable, easily performed test with minimal discomfort and a large potential for guiding further care. The electrophysiological principles underpinning its use are straightforward, but important to understand for clinical interpretation. Wearable ECG devices have many advantages over existing methods of trace acquisition, but also many potential drawbacks. The ease of use, patient centred care and increased availability of ECG monitoring must be balanced with a physician's duty of care and potential for false positives, creating unnecessary unease and overtesting. Additional research and

guidelines regarding the placement of a potential Lead II view, as well as thorough guidelines regarding data management, confidentiality, and physician workload need to be developed quickly, before this technology becomes the standard.

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