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VIEWPOINT

Can we trust a smartwatch ECG? Potential and limitations

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The ability to record a 30 s single-lead electrocardiogram (ECG) at any time and as often as desired is a relatively new functionality of smartwatches that has been purported as a potentially useful medical technology advancement. Advertisers see this as the latest life-saving feature added to advanced smartwatches.[1] From a physician's perspective, this new technology is especially of interest since this may facilitate atrial fibrillation detection automatically in otherwise asymptomatic individuals, but this remains currently unconfirmed. Greater than 10% of individuals with the arrhythmias remain undiagnosed during their lifetime because they do not have any symptoms and among patients with acute cerebral stroke, about 20% have a new atrial fibrillation diagnosis.[2] The early detection of atrial fibrillation would allow early initiation of anticoagulation therapy, which may lead to a reduction in the number of cerebral strokes and other arrhythmia-related morbidity and mortality.[3]

Designed and introduced as tools for health monitoring, it was initially unclear whether ECG-enabled smartwatches are for diagnostic purposes. The manufacturers underscore explicitly that this is indeed not the case. According to the user manuals accompanying the devices, ECG is recorded for information purposes only and is not intended to replace traditional methods of electrocardiographic assessment for medical diagnosis. However, the manufacturers consider their apps which provide the ECG function to be medical products. All ECG apps (except those by Withings) have both CE certification in Europe, and Food and Drug Administration clearance as per the 510(k) pathway in the USA.[4–7] The fulfilment of regulatory requirements is a precondition for marketing. These inconsistencies have caused confusion, particularly among physicians. The recently updated version of the European Society of Cardiology (ESC) guidelines for the management of atrial fibrillation[3] explicitly state that a smartwatch-based ECG can be used to diagnose atrial fibrillation and that no confirmation by another ECG procedure is needed (provided that the arrhythmia lasts for 30 s, which is exactly the time needed for a smartwatch recording). The same guidelines also state that the devices may be used for screening for atrial fibrillation. The feasibility of such a screening has been demonstrated by two large studies published in 2019, the Apple Heart Study[8] with more than 400 000 participants, and the Huawei Heart Study[9] with more than 180 000 participants. However, even though both studies included larger numbers of patients, we contend that they do not necessarily provide definitive proof for the diagnostic accuracy of smartwatch ECGs under real-word conditions as they did not have a positive control. Indeed, the ESC atrial fibrillation guidelines highlight the need for further clinical studies aiming to validate the new technique.[3]

Since it will take years before the results of such studies will be available, in this viewpoint we sought to provide a closer look at the algorithms underlying the ECG function of the ECG-enabled smartwatches currently available in Europe (*Table 1*). These algorithms reflect and correlate with the diagnostic capabilities of the devices.

Diagnostic accuracy of the implemented algorithms

All ECG-enabled smartwatches are equipped with software applications that allow atrial fibrillation to be diagnosed automatically. Some of the smartwatches (Apple and Withings) allow atrial fibrillation screening using photoplethysmographic pulse wave analysis. If atrial fibrillation is suspected, the user is notified and asked to record an ECG. For the diagnosis of atrial fibrillation, sensitivities and specificities exceeding 95% have been reported.[4–7] However, it should be noted that these studies were performed under standardized research conditions and provide data on evaluable ECGs only; approximately 10–20% of ECGs recorded with a smartwatch are not evaluable (e.g. due to artefacts resulting from body motion or poor electrode contact).

The data compiled in *Table 1* suggest that diagnostic accuracy is likely to be significantly lower in everyday use and in clinically relevant higher rate scenarios. Atrial fibrillation with a ventricular rate below 50 bpm is not detected by any of the smartwatches. At high heart rates, there is a threshold above which atrial fibrillation is no longer tested for. This is 120 bpm for most watches. A revised

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Table 1 Electrocardiogram-enabled smartwatches available in Europe (only devices with CE marking are considered)

Smartwatch	Rhythms detected by the ECG function[a]	Comment
Apple Apple Watch Series 4, 5 and 6	Version 2.0: - Sinus rhythm: 50–100 bpm - AF: 50–150 bpm - Inconclusive Version 1.0: - Sinus rhythm: 50–100 bpm - AF: 50–120 bpm - Inconclusive	ECG app and AF screening app cleared by FDA (08/2018) and CE certified (03/2019). Updated ECG app (version 2.0) available in Europe since 01/2021.
Fitbit Sense	- Sinus rhythm: 50–120 bpm - AF: 50–120 bpm - Inconclusive	ECG app CE certified (08/2020) and FDA cleared (08/2020). AF screening not yet available.
Samsung Galaxy Watch Active 2, Galaxy Watch 3	- Sinus rhythm: 50–100 bpm - AF: 50–120 bpm - Inconclusive	ECG app FDA cleared (08/2020) and CE certified (12/2020). Announced to be available in Europe in spring 2021.
Withings Move ECG, Scanwatch	- Sinus rhythm - AF[b] - Inconclusive	ECG app CE certified (MOVE ECG: 06/2019, Scanwatch 06/2020). FDA clearance is pending.

AF, atrial fibrillation; CE, Conformité Européenne; ECG, electrocardiogram; FDA, Food and Drug Administration.
[a]For further details please refer to the cited references.
[b]The available information is inconclusive, according to the manufacturer no limits for AF detection, no validation data.

version of the Apple algorithm now detects atrial fibrillation at ventricular rates up to 150 bpm.[10] However, the accuracy of the algorithm is significantly lower at ventricular rates above 100 bpm than at ventricular rates of 50–99 bpm (98.3% vs. 83%).[7] In this context, it is important to note that new-onset atrial fibrillation clinically has ventricular rates above 120 bpm in about one-third of cases, and it is not uncommon for the rate to exceed 150 bpm.[8] *Figure 1* gives examples showing that atrial fibrillation may remain undiagnosed by a smartwatch when heart rate exceeds a certain limit.

Some devices use photophlethysmography to detect pulse irregularities (*Table 1*). Photophlethysmography is a simple optical technique, which is based on the detection of changes in blood volume in the peripheral circulation.[11] It is highly accurate at measuring heart rate in sinus rhythm at rest (correlation coefficient of 0.96).[12] However, it is sensitive to artefacts (e.g. body movement and poor sensor contact). Diagnosing atrial fibrillation can be quite challenging, particularly at higher heart rates.[13] Other types of arrhythmias reduce the diagnostic accuracy.[10] False positive result may occur. One episode of pulse irregularity detected by photoplethysmography is not enough to inform the patient that atrial fibrillation might be present. In the case of the Apple watch, five out of six consecutive photoplethysmographic measurements (performed at rest) need to fulfil the criteria for possible atrial fibrillation before the patient receives a message.[10] Thus, smartwatch-based screening for atrial fibrillation is a relatively complex procedure. It is particularly important that measurements are not performed continuously, as one may expect, but only intermittently, the protocols for which depend on the manufacturer. This is because such measurements consume significant power and the battery life of most ECG-enabled smartwatches is relatively short.

Clinical implications

The algorithms currently used by ECG-enabled smartwatches show particularities, which are manufacturer-dependent and significantly limit their diagnostic accuracy. They may lead to both false positive and negative diagnoses, resulting in anxiety and unnecessary further diagnostic testing. Physicians using this new technology today should be aware of these limitations. These should be discussed with patients presenting with an ECG-enabled smartwatch. Physician overreading remains mandatory, even when the patient presents repeatedly with numerous ECG recordings. It has been known for decades that computerized interpretation of atrial fibrillation is a challenge and that incorrect computerized interpretation, combined with the failure to correct the erroneous interpretation, can result in the initiation of unnecessary and potentially harmful medical treatment as well as inappropriate use of medical resources.[14] The outlined limitations should also be appreciated when the devices are used in the context of clinical studies. It is likely that there will be an improvement in diagnostic accuracy in the future, probably in parallel with an increased use of algorithms based on artificial intelligence. It is also difficult in some cases to obtain information regarding the way the algorithms of the ECG function work. When it comes to trusting new technologies, it is important to have a detailed knowledge about their algorithms and processes. This holds also true for ECG-enabled smartwatches.

Conflict of interest: W.H. declares that he has received fees from Abbott, Amicus, AstraZeneca, Bayer, Bristol Myers Squibb, Daiichi-Sankyo, Medtronic, Pfizer, and Sanofi. J.B. declares that he serves as a consultant for Abbott, Adrenomed, Amgen, Array, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb,

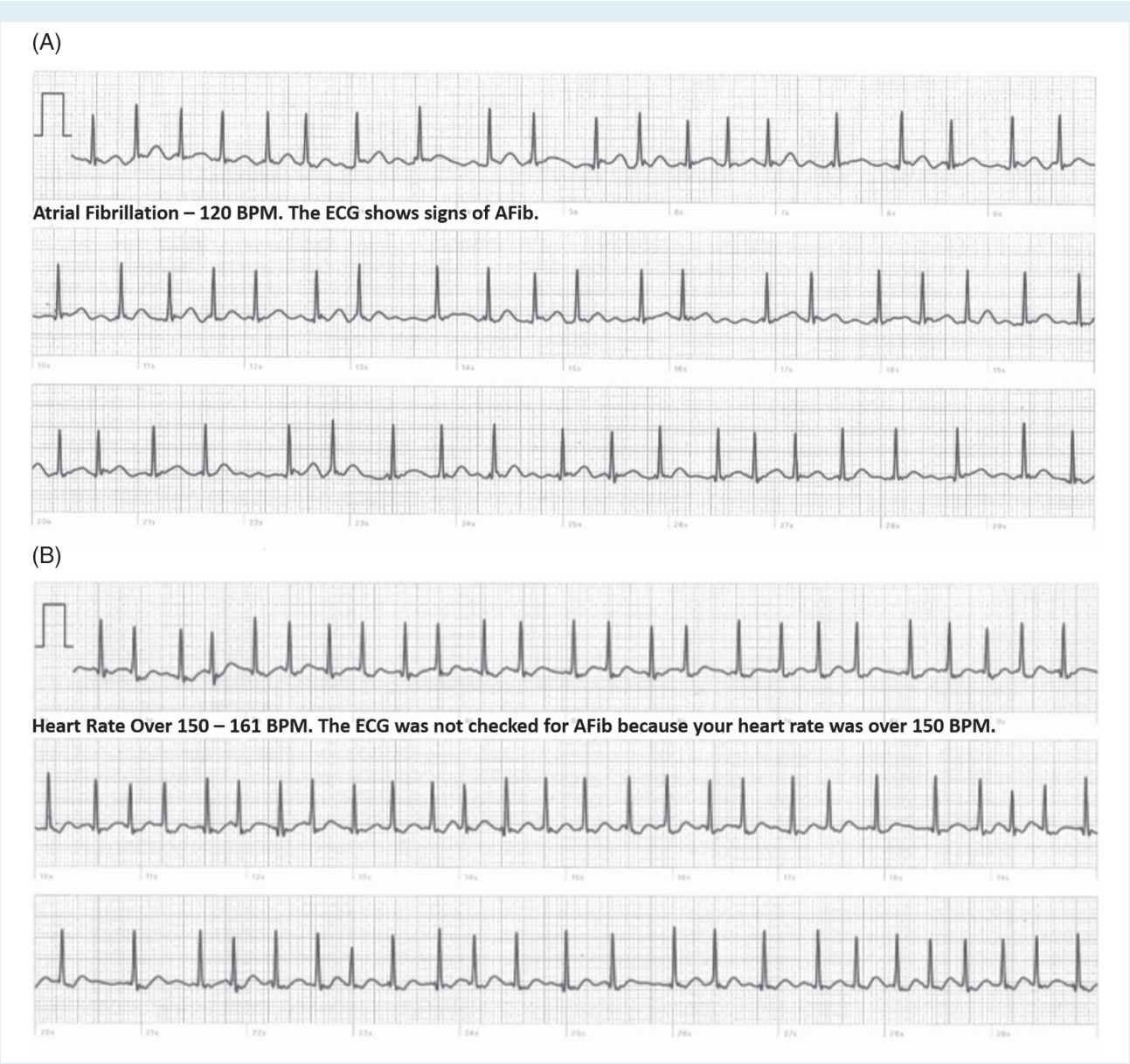

Figure 1 Example of two electrocardiograms (ECGs) in the same 56-year-old patient at ventricular rate of 120 bpm (*A*) and 161 bpm (*B*). Apple Watch Series 5. (*A*) The automatic algorithm diagnoses 'atrial fibrillation' at a ventricular rate of 120 bpm. The patient is informed that the ECG shows signs of atrial fibrillation. (*B*) Atrial fibrillation persists. The diagnosis is no longer atrial fibrillation, but 'heart rate over 150 bpm'. The patient is informed that the ECG is not checked for signs of atrial fibrillation, because heart rate exceeds 150 bpm.

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