

# Smart mobile devices in health care—smart enough to detect atrial fibrillation?

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Automated detection of atrial fibrillation (AF) is a major research focus worldwide.

Since the introduction of the Holter ECG by Norman J. Holter in the 1960s, technical progress was substantial (1). As a result, modern long-term electrocardiography (ECG) devices are small and lightweight and record multiple leads for seven days and more. In addition, implantable loop recorders were introduced to the health market, enabling remote 24/7 ECG monitoring for more than 1 year. Nevertheless, both technologies do have downsides, be it the need for sticker electrodes, which limit the length of the maximal recording time due to skin irritations and electrode deterioration, or the invasiveness and costs related to implantable loop recorders.

Driven by the goal to identify AF patients who could profit from anticoagulation therapy to prevent strokes, new strategies are developed and tested for their performance in clinical trials. In the context of the global availability of smartphones and increasing availability of other smart devices worldwide, the use of these devices as medical grade diagnostic tools represents an attractive option, that has to be validated in state-of-the-art trials. The fact, that these devices and the related software algorithms are subject to frequent updates which most likely influence its performance, make traditional clinical validation especially challenging. If certification would only cover the version tested, probably none of the devices from the consumer market would make it in the healthcare environment. Regulatory authorities in different countries are still

developing valid approaches to address this problem and hopefully harmonization between the different standards will happen within the near future.

The Kardia Band, linked to the Apple Watch, represents a very good example of a device that made its way from the consumer market to an FDA approved medical grade device. Its core consists of a small ECG, integrated in the wristband of an Apple Watch. This ECG does not need sticker electrodes or gel, but works by plain skin contact. To record an ECG, the individual actively has to put a finger of his opposite hand on the wrist worn device and remain calm to prevent artefacts. Therefore, continuous screening, comparable to a Holter ECG, is not possible with this tool. Once the ECG is recorded it is analysed in an automated fashion by an algorithm providing, given that the quality is good enough, instant feedback if the rhythm is “normal” or “possible atrial fibrillation”. So far, this system is only compatible with the Apple Watch.

Bumgarner *et al.* tested the performance of this device and the underlying automated AF detection algorithm, in the setting of elective patients presenting for cardioversion (2). This setting provides a good environment to test such tools and was used by Mc Manus in the past to validate an AF detection tool, based on the signals of a smartphone camera (3). It is obvious though, that with an expected prevalence of AF close to 100% pre-cardioversion, this does though not represent a real-world scenario.

In the trial of Bumgarner *et al.*, the performance of the device was well in line with previous trials using the

AliveCor algorithm: In roughly a third of all ECGs (57/169) it did not give any interpretation and in the remaining two thirds, it performed with a high sensitivity and specificity (4). Taking into account, that the trial setting stands for optimal quality ECG recordings, the data cannot be extrapolated to a population-based setting, where we would expect a higher percentage of technical problems and artefacts, leading to a higher percentage of ECGs without interpretation.

This hypothesis should be tested in upcoming population-based trials though.

Based on the data available, we do see the major advantage of the tested device not in the automated detection of AF in an outpatient setting, but in the increasing availability of ECG documentation to be used by symptomatic patients. Another possible use case could be an easy to use quick pre-cardioversion check for sinus rhythm as suggested by the authors.

Two caveats have to be mentioned in this context:

There is no clear evidence yet, that present recommendations for anticoagulation therapy apply to patients, which only have short episodes of AF documented with smart devices. Although it is along the guidelines to start life-long anticoagulation therapy in every 75-year-old woman with a one-minute mobile ECG showing 30 s. of AF is at least debatable (5).

A second caveat concerns the fact, that health related personal data is sent to, and can be processed by, a commercial company, and not by a health care institution. From a data protection and privacy point of view this will be an issue in the near future.

To conclude, we congratulate Bumgarner *et al.* to their important clinical trial and valuable scientific contribution. The optimal use case for the tested device in its present form has still to be identified. For the time being it represents a very attractive tool to increase the availability

of ECG documentation outside the regular healthcare environment. Further trials testing mobile devices in a population-based setting are needed to define the role of these tools for AF screening and other medical purposes.

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## Footnote

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