

## Comparison of Two Smartphone-based Atrial Fibrillation Screening Application in an Indonesian Tertiary Care Population

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### Abstract

**Background:** Global longitudinal strain (GLS) was a proven predictor of systolic function improvement and myocardial remodeling after acute coronary syndrome (ACS) for a residual left ventricular function defined their prognosis. However, not all echocardiography devices are equipped by speckle tracking (STE) as compare to the availability of M-mode modality which capable on assessing fractional shortening (FS) instead.

**Methods:** This study was conducted in Mohammad Hospital General Hospital Palembang with a convenience sampling of 170 participants aged 18 years or older. The subjects underwent Fibricheck and KardiaMobile recordings followed by 12 lead electrocardiogram read by board-certified cardiologists as the diagnostic standard.

**Results:** After the exclusion of previous pacemaker implantation (n=7), 163 patients were included in the study. The mean age was  $51 \pm 15$  years with a gender distribution of 74.8% men and 25.2% women. Most of the subjects were asymptomatic (87.1%) with a mean blood pressure of 130/80 mmHg. The Fibricheck readings showed a sensitivity of 73% and specificity of 93%, meanwhile, KardiMobile was able to detect AF with a sensitivity of 77% and specificity of 98%.

**Conclusion:** In our study, KardiaMobile demonstrated overall greater sensitivity and specificity when compared to FibriCheck. However, KardiaMobile requires an external metal sensor that must be purchased separately. To the best of our knowledge, this is the first study to directly compare both methods in the Indonesian population.

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**Keywords:** atrial fibrillation, Kardia™ Mobile, FibriCheck®, Photoplethysmography, smartphone-based application

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## Introduction

**A**trial fibrillation is the most common arrhythmia found in clinical practice. The prevalence of atrial fibrillation (AF) is known to increase with age, starting from 2.2% in adolescents and young adults, up to 6.4% in people aged 60 and >8% in a population aged 80 or older.<sup>1</sup> Atrial fibrillation is a risk factor for several cardiovascular problems such as heart failure and stroke. The risk of stroke is five-fold in patients with AF when compared to the normal population.<sup>1</sup> Unfortunately, AF often went unrecognized and undertreated because of its natural history, which is usually asymptomatic. If AF can be detected properly at an early stage, giving upstream preventive therapies may be beneficial to reduce the risk of morbidities and the economic burden caused by complications of this disease. At present, electrocardiography (ECG) is still the main modality to detect various kinds of arrhythmias, including AF. However, not all 12 leads are needed to get the needed information in this kind of clinical scenario. Often, a smaller number of classic ECG leads are frequently sufficient for AF detection, as suggested by a recent study.<sup>2</sup>

Some previously published guidelines have recommended pulse palpation as opportunistic screening for AF, followed by an ECG examination to verify the diagnosis.<sup>3</sup> However, independent interpretation of pulse patterns may become quite a challenge for laypeople, and medical experts still need to play their roles. The concept of home ECG recording was initially introduced by Norman Holter in the early 1980s, using a simple portable radio receiver/recording unit for ambulatory monitoring. And since that day, ECG monitors for outpatient use has widely expanded and also included cardiac event monitors, loop recorder, and cardiac telemetry. Nowadays, smartphone devices for ECG recording have become a new, fashionable trend.

Advances in mobile technology make massive AF screening in the general population possible. It is estimated that as many as 33 million people worldwide use mobile phones in 2014, and it is predicted that the number of users will rise to nearly 100 million by the year 2019,<sup>4</sup> as the cost of such technology steeply lower. Smartphones, in their compact size, now clearly are more powerful than a room-sized supercomputer back

in the 1980s. An estimate of 2-3 billion people now can carry them around with ease.<sup>3</sup> The potential use of mobile phones as a mobile electrocardiography tool is promising, due to the abilities of smartphones that are ready to be connected with different sensors, extending their abilities to perform complicated analysis. In terms of remote mobile phone heart rhythm monitoring, currently, there are two major technologies widely used, i.e., photoplethysmography (PPG) utilizing the smartphone cameras and internet-enabled ECG (iECG).

Kardia™ Mobile (AliveCor, Inc., Mountain View, US) is an example of an iECG device that implements automated AF detection. Kardia™ Mobile uses metal sensors on an external product (like a case or a card) to generate a lead I rhythm strip, which can be used to detect atrial fibrillation, paroxysmal supraventricular tachycardia, or ventricular tachycardia in both adults and children. After the conversion of the cardiac electric signal into ultrasound (18-24 kHz), the smartphone application will demodulate it into a digital ECG tracing.<sup>1</sup> Meanwhile, FibriCheck® (Qompium NV, Hasselt, BE) is a modality that only uses a downloadable application without additional apparatus. FibriCheck® works through receiving the signal that is recorded using the pulse photoplethysmography (PPG) mechanism. FibriCheck® is developed to detect heart rhythm irregularities using the flashlight and camera which are standard components on a smartphone. The received signal received will further be processed using two distinct statistical techniques for its particular algorithm. The first, called root mean square of the successive difference of RR intervals (RMSSD), calculate the variability of R-R intervals during atrial fibrillation. Shannon entropy (ShE), is the second one, which synthesizes the complexity of the RR variability.<sup>5</sup>

## Methods

### Study population

A consecutive sampling of 170 participants aged 18 and older was conducted in Mohammad Hoesin General Hospital Palembang. People who came to the cardiology clinic or waited in the hospital hall between May 2018 until July 2018 were randomly enrolled in the study,

comprising of both patients and accompanying persons. All participants provided written informed consent. Secondary data taken to describe the study population were: age, sex, blood pressure, and symptoms. Pacemaker rhythm is an artificial rhythm resulting from previous pacemaker device implantation, therefore it is unnatural and thus we make it as an exclusion criterion for our study. The order of sample selection can be seen in Figure 1.

to lead I on a conventional 12-lead ECG. After the recording, the application will instantly show the result of the rhythm analysis. The possible readings that will show on the Kardia™ by AliveCor, Inc. application are : “Normal”, “Unspecified” and “Possible Atrial Fibrillation”. In this study, we interpret “Unspecified” as “Not Atrial Fibrillation”, because the “Unspecified” result will turn up if the underlying rhythm from the patient does not fit into either the atrial fibrillation

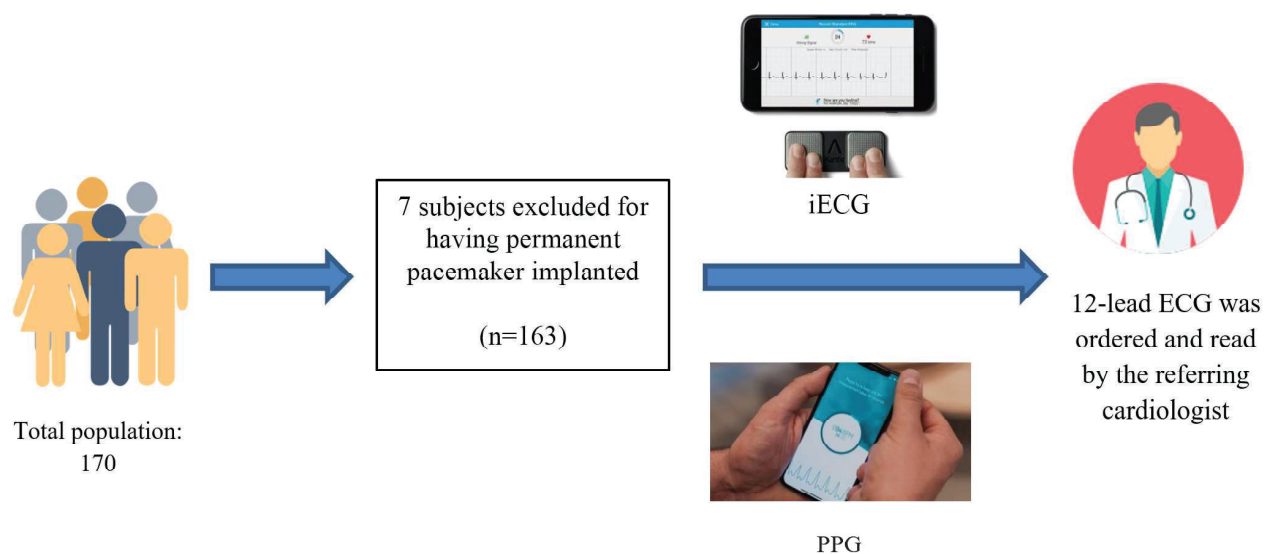


Figure 1. Diagram of study population selection and flowchart.

### Mobile iECG and PPG recording

Kardia™ Mobile is a special ECG recorder device that looks like a card with two metal pieces on it. We paired the iECG system with an android phone Samsung Galaxy S5 (Samsung Electronics Co. Ltd , South Korea) where Kardia™ by AliveCor, Inc. application version 5.0.4 was already installed beforehand. Users will put their index and middle fingers on each of the metal pieces (electrode) for thirty seconds. The measurements were performed in a quiet surrounding, and patients were instructed to remain in a stable, relaxed sitting position to minimize movement artifacts. The detector then sends data using ultrasound to the user’s smartphone microphone, where the Kardia™ by AliveCor, Inc. application will render the data and display a single ECG lead most similar

or normal algorithm. Afterward, all of the recorded iECG files were saved into a PDF format for our study reference, as recommended by European Heart Rhythm Association (EHRA) consensus and approved by the US FDA for AF screening method 6.

FibriCheck® is a smartphone application utilizing pulse photoplethysmography (PPG) to calculate the blood volume pulse variation in local arterioles, based on the amount of reflected light on the camera. Patients will hold the smartphone in a vertical position on their right hand then cover the flashlight and camera on the back using their index finger. Afterward, the index finger will be illuminated for a countdown of sixty seconds. The result will be sent back to the users after some time of blinded automatic analysis by the application through a process that needs an internet connection. The possible

reading that will show on FibrCheck® is “Normal” or “Possible Atrial Fibrillation”. For our study, we used Fibrcheck® version 1.20 application installed to an android-based mobile phone Xiaomi Redmi Note 4 (Xiaomi Corp, Beijing, CN).

A standard 12-lead ECG using Kenz™ ECG-305 (Suzuken Kenz Company, Nagoya, JP) electrocardiogram machine is recorded from each patient as the gold standard for atrial fibrillation diagnosis. The ECG strips were evaluated for AF diagnosis by two board-certified cardiologists, and a third cardiologist (an electrophysiologist) was consulted in cases of uncertainty to reach a consensus. Cohen’s kappa coefficient of 0.862 showed an acceptable inter-rater reliability. All the cardiologists were blinded for iECG, PPG, and previous 12-lead ECG analysis results.

### 2.3 Statistical analysis

Both of internet-enabled ECG and PPG analysis results were compared to standard 12-lead ECG cardiologists’ diagnoses as the gold standard. The sensitivity and specificity of each modality were calculated using SPSS v24 software (IBM Corporation, New York, US).

## Result

A total of 170 subjects participated in this study. Seven subjects were excluded due to the previous history of cardiac pacemaker implantation. The characteristics of the patients are shown in Table 1. Of the remaining participants, 122 were men (74.8%), and 41 were women (25.2%). The mean age of the participants was 51 (range: 36-66). Most of the subjects were asymptomatic (87.1%) and had a mean blood pressure of 130/80 mmHg. We found a significant correlation between patient’s characteristics such as age, symptoms, and blood pressure with the occurrence of atrial fibrillation, except for gender.

Atrial fibrillation was diagnosed in 22 patients (13,5%) by 12-lead ECG read by cardiologists. The sensitivity and specificity of iECG were 77% and 98%, respectively, and the sensitivity and specificity of PPG were 73% and 93% (Table 2). Both methods yielded a similar negative predictive value (NPV) of 96%, while iECG demonstrated a higher positive predictive value (PPV) of 85% compared to PPG with PPV of 62%. The diagnostic accuracy was higher for iECG (95%) compared to PPG (90%).

**Table 1.** Study subject characteristics (n = 163)

| Characteristic      | Study Subject Classification |  |   | P      |
|---------------------|------------------------------|--|---|--------|
|                     | All<br>(n = 163)<br>n (100%) | Atrial Fibrillation<br>(n = 22)<br>n (13.5%) | Non-Atrial Fibrillation<br>(n = 141)<br>n (86.5%) |        |
| Sex                 |                              |  |   |        |
| Male, n (%)         | 122 (74.8)                   | 17 (77.27)                                   | 105 (74.47)                                       | 0,986  |
| Female, n (%)       | 41 (25.2)                    | 5 (22,73)                                    | 36 (25.53)  |        |
| Age, mean±SD        | 51.07 ± 14.95                | 44.32 ± 18.29                                | 52.13 ± 14.15                                     | 0,032  |
| Symptoms            |                              |  |   |        |
| Palpitation, n (%)  | 21 (12.9)                    | 10 (45.45)                                   | 11 (7.8)  | <0,001 |
| Asymptomatic, n (%) | 142 (87.1)                   | 12 (54.55)                                   | 130 (92.2)  |        |
| SBP (mmHg), mean±SD | 130.49 ± 13.78               | 140 ± 10.23                                  | 129.01 ± 13.7                                     | <0,001 |
| DBP (mmHg), mean±SD | 81.66 ± 6.21                 | 85 ± 5.97                                    | 81.13 ± 6.1                                       | 0,011  |

SBP: Systolic Blood Pressure

DBP: Diastolic Blood Pressure

**Table 2.** Comparison of diagnostic accuracy for both PPG and iECG methods.

| Study Population<br>(n=163) | Sensitivity (95% CI) | Specificity (95% CI) | Positive Predictive Value (95% CI) | Negative Predictive Value (95% CI) | Diagnostic Accuracy |
|-----------------------------|----------------------|----------------------|------------------------------------|------------------------------------|---------------------|
| PPG                         | 73% (50-88)          | 93% (87-96)          | 62% (41-79)                        | 96% (90-98)                        | 90% (85-94.5)       |
| iECG                        | 77% (54-91)          | 98% (93-99)          | 85% (61-96)                        | 96% (92-99)                        | 95% (90.5-98)       |

## Discussion

Early detection of atrial fibrillation is one of the most important pillars in the primary prevention of stroke. The mobile phone as a practical and widely used device has the potential to be utilized as a cost-effective mass screening tool for AF in the general population. We tested the abilities of a novel iECG method (Kardia™ Mobile) and PPG analysis algorithm (Fibrichck®) to detect AF, compared with cardiologists' diagnosis using standard 12-lead ECG recording.

In our study, both iECG and PPG showed high specificity, but only modest sensitivity. This finding is consistent with a previous publication performed by Hund et al. reporting the sensitivity and specificity of Kardia™ Mobile iECG as 71.4% and 99.4%, respectively.<sup>7</sup> Another study by Haberman et al. found a somewhat higher sensitivity of 94% and a specificity of 99% in a cardiology clinic setting for iECG.<sup>8</sup> Similarly, Lau et al. reported a high sensitivity of 98% and a high specificity of 97% of iECG method in community screening to detect AF.<sup>9</sup>

As for the diagnostic ability of the PPG system, our study yielded a significantly lower sensitivity and PPV compared to another study by Proesmans et al., which showed the sensitivity and specificity of Fibrichck® at 100% and 98% respectively.<sup>10</sup> McManus et al. also reported a specificity of 97.5% and sensitivity of 96%.<sup>5</sup> This difference of findings may be explained by the known limitations for PPG-based devices, such as the potential influence of extrasystoles, worse signal-to-noise ratio in patients with tremor, and reduced PPG pulse wave tissue penetration in subjects with intense skin pigmentation. Indonesians, like other Southeast Asian descents, have a characteristic and diverse melanin index compared to the European counterparts.<sup>11</sup>

Apart from the aforementioned shortcomings, PPG systems like Fibrichck® may become more appealing because no additional external device for signal acquisition is usually needed, and currently this technology is also being integrated into smartwatches.<sup>12</sup> However, some authors conducted post-participation surveys showing high levels of satisfaction and the willingness of users to use the iECG system regularly, despite the extra cost.<sup>7,8</sup>

Our study is a single tertiary center study with several limitations. The relatively small sample size

may not give enough power for a direct head-to-head comparison of both methods, although in our study iECG did show slightly higher sensitivity and specificity compared to PPG. The considerably low PPV, especially in the PPG method was probably consequent to the lack of sensitivity of the device, despite a higher AF prevalence (13,5%) in our study compared to the general population. The tendency to a lower sensitivity for AF detection read by the automatic algorithm of iECG devices compared to when being read by experts had been noticed in other studies, probably contributed by a critical amount of artifacts.<sup>13</sup>

There were several false positive and false negative results, some due to technical difficulties such as bad contact and heat sensation in the finger in PPG method, or poor signal quality in iECG due to noise and other mechanical interference. The troubleshooting of iECG is in line with what was stated by Evans et al in their study that for a few patients, the background noise was too excessive so that the sampling had to be redone.<sup>14,15</sup>

By the time this manuscript is published, the Kardia™ Mobile and Fibrichck® have not officially entered the Indonesian market yet. However, considering their high specificity, and presumably low false-positive rate, both technologies are very attractive for mass-scale atrial fibrillation screening, especially during imminent pandemics, where direct physical contact should be minimized.<sup>16</sup> Extending this study to some additional health centers including general practitioner clinics, district hospitals or even primary care centers would provide an insight on how to implement this kind of technology in the Indonesian health care system. Furthermore, the addition of artificial intelligence and big data management to the existing screening platform had shown great promise for the future.<sup>17</sup>

## Conclusion

The iECG and PPG are alternative diagnostic methods for detecting atrial fibrillation. With their high specificity, modest sensitivity, and ease of use, both modalities can be considered as a new portable AF screening tool for the general public. In this study, the iECG method demonstrated a higher diagnostic accuracy compared to PPG, despite the need for external apparatus for signal acquisition. However, the accuracy of the algorithm of both apparatus in detecting

AF was assessed separately using 12 lead ECG read by cardiologists as the gold standard, thus reflecting an indirect comparison of iECG vs PPG. To the best of our knowledge, our study is the first to compare these two distinct mobile phone-based AF screening applications in the Indonesian population.

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## Conflict of interest

Authors declare no Conflict of Interest for this article.

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## Ethical approval

Dr. Mohammad Hoesin General Academic Hospital conferred ethical clearance for this study. Compliance with ethical standards, this research proposal was approved by the ethical committees of Dr. Mohammad Hoesin General Academic Hospital (Ref: No.32/kepkrsmh/2020).

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