

ORIGINAL ARTICLE

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The comparison of Kardia Mobile and Hartmann Veroval 2 in 1 in detecting first diagnosed atrial fibrillation

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Abstract

Background: Atrial fibrillation (AF) is the leading cause of stroke. The European Society of Cardiology (ESC) advises opportunistic AF screening among patients aged ≥ 65 years. Considering this, the aim herein, was compare the feasibility of two different systems of smartphone-based electrocardiogram (ECG) recordings to identify AF among those without a previous arrhythmia history.

Methods: Prospective AF screening was conducted at six pharmacies using Kardia Mobile and Hartmann Veroval 2 in 1. A single-lead ECG was acquired by the placement of fingers on the pads. A cardiologist evaluated findings from both devices.

Results: Atrial fibrillation was identified in 3.60% and previously unknown AF was detected in 1.92% of the study participants. Sensitivity and specificity of the Kardia application in detecting AF were 66.7% (95% confidence interval [CI] 38.4–88.2%) and 98.5% (95% CI 96.7–99.5%), and for Veroval 10.0% (95% CI 0.23–44.5%) and 94.96% (95% CI 92.15–96.98%), accordingly. Inter-rater agreement was k = 0.088 (95% CI 1.59–16.1%).

Conclusions: Mobile devices can detect AF, but each finding must be verified by a professional. The Kardia application appeared to be more user-friendly than Veroval. Cardiovascular screening using mobile devices is feasible at pharmacies. Hence it might be considered for routine use. (Cardiol J 2023; 30, 5: 762–770)

Key words: atrial fibrillation, mobile devices, screening, pharmacies, new technologies

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Introduction

Atrial fibrillation (AF) affects up to 34 million people worldwide [1, 2]. It is the most common cardiac arrhythmia with a prevalence of 1.5–2.0% in the general population. AF incidence has increased to almost 6% for those above 65 and 8.8% for those more than 80 years old [3–5]. AF is also the leading cause of stroke [1]. In many cases AF is asymptomatic and in 25% of patients, it is diagnosed after a thromboembolic event [1, 6, 7]. Thus, it contributes to the significant economic and public health burden, with annual costs accounting for more than 6.5 billion dollars in the United States [5, 6, 8–10].

Because the world's population is aging quickly [11, 12], the prevalence of AF is expected to double by 2060 [3]. One of the main challenges for healthcare is identifying AF as early as possible before a thromboembolic event occurs. There is a lot of data showing that adequate anticoagulation treatment reduces thromboembolic complications [3, 13]. The European Society of Cardiology (ESC) advises opportunistic AF screening in combination with the CHA₂DS₂-VASc score (Score for Atrial Fibrillation Stroke Risk [Congestive heart failure, Hypertension, Age \geq 75, Diabetes mellitus, Stroke, Vascular disease, Age 65-74, Sex]) among patients aged ≥ 65 years [14, 15]. Although it is still not routinely performed [16, 17], new technologies such as mobile electrocardiogram (ECG) devices may facilitate the implementation of common AF screening [16, 18]. These technologies can detect AF [16, 17, 19, 20] and are both convenient and inexpensive [11, 21]. In their studies, Lowres et al. [19] and Zaprutko et al. [17] confirmed the feasibility of AF detection using mobile ECG in public places (e.g., pharmacies). They identified an incidence of AF in 1.5% and 1.33% of subjects without previous history of arrhythmia in Australia and Poland, respectively [17, 19]. Besides, Lowres et al. [19, 20] reported Kardia Mobile to be cost-effective in screening patients for AF at pharmacies.

The objective of the present prospective study was to compare the feasibility of two different systems in identifying AF among those without a previous arrhythmia history. For that purpose, two different technologies were evaluated; Kardia Mobile with a dedicated smartphone application (app) and Hartmann Veroval 2 in 1 - ECG and Blood Pressure Monitor.

Methods

Atrial fibrillation screening was carried out between December 2018 and February 2020 at 6 pharmacies located in different regions of Poland. The study was approved by the Bioethics Committee of Poznan University of Medical Sciences and by the pharmacy owners who agreed to conduct the research.

Pharmacists, cardiologists, and students from the Student Scientific Society of Pharmacoeconomics and Social Pharmacy made up the research team. Students and non-physician researchers took part in a course on the basics of the used devices, thromboembolic risk assessment (the CHA₂DS₂--VASc score), and ECG basics.

The Kardia Mobile with a Kardia app (iOS/Android) is the Food and Drug Administration (FDA) approved device for recording, storing, and transfer of single-channel lead ECGs [16, 19].

A single-lead ECG from Kardia Mobile was acquired by placing fingers of both hands on the device pads for 30 s. The ECG's electrical signals were modified to an ultrasonic frequency modulation sound signal and then transmitted to a smartphone with the installed Kardia app [6]. The program demodulated the signal to a digital ECG trace (300 samples/s, 16-bit resolution), displayed it in real--time on the smartphone screen, and then transmitted and stored it on a password-protected server [22].

Veroval is dedicated to blood pressure measurement and for mobile ECG recording and conforms to European regulations based on the European Medical Device Directive 93/42/EEC. It bears the Conformité Européenne mark [23].

In this system, an ECG recording is acquired by placing a finger from the right hand on the upper electrode and one finger from the left hand on the lower electrode of the device. Veroval switches on automatically when the two fingers are placed on the electrodes. If the "ECG" notification appears on display, the device starts to record an ECG for 30-s. When the recording is complete, the final ECG finding appears on display but the tracing is not visible. To over-read Veroval's recordings, tracings are transferred via Bluetooth to software (Veroval medi.connect) on the user's computer.

Kardia provided 7 and Veroval 8 possible findings presented in Table 1 [22–25].

Inclusion criteria

Each patient visiting a pharmacy who looked to be 65 or more was asked to join the study. Younger patients or those with the previous history of AF were excluded from the study. A written informed consent with the patient's phone number and CHA_2DS_2 -VASc score was collected. Finally, an ECG was performed.

Table 1. Possible Kardia and Veroval findings.

K	ardia possible findings	Veroval possible findings		
ECG finding	Description	ECG finding	Description	
POSSIBLE AF	AF was detected based on of P-wave absence and R-R interval irregularity	ОК	Normal ECG recording	
NORMAL	The HR was regular and between 50 and 100 bpm, with shape, timing, and duration of every beat considered normal	FAST	HR was higher than 100 bpm	
UNCLASSIFIED	The quality of tracing was good but the Kardia application could not differentiate between "possible AF", and "normal" recordings (e.g., irregular rhythm due to premature complexes)	SLOW	HR was lower than 55 bpm	
UNREADABLE	Resulted from poor ECG quality (e.g., due to sound or electrical interference)	PAUSE	One or more brakes in the heart cycles that were longer than 2 s	
TACHYCARDIA	Regular HR faster than 100 bpm	RHYTHM	During the ECG recording supra- ventricular arrhythmia was detected (AF, atrial flutter, pathological sinus arrhythmia, paroxysmal atrial tachycardia, or supraventricular extrasystole)	
BRADYCARDIA	Regular HR was less than 50 bpm	WAVE	A changed ECG wave shape occurred (e.g., ventricular arrhythmias)	
NO ANALYSIS	There was no finding presented (e.g., due to the noise on the signal)	RHYTHM and WAVE	Indicated arrhythmia with changed wave shape (including singular ventricular extrasystole, bigeminy, trigemini, series of ventricular extrasystole, multifocal ventricular extrasystole, and ventricular tachycardia	
		ERROR	Occurs e.g., if there was insufficient skin contact to the upper and lower electrodes	

AF — atrial fibrillation; ECG — electrocardiogram; HR — heart rate

ECG recording

Each time, an ECG with the Kardia app was recorded first, followed by Veroval. ECG recordings from Kardia were saved as PDF files and password protected. For Veroval, the recordings were saved by the device (up to 64 measurements) and subsequently transferred via Bluetooth directly to the dedicated software.

Stored ECG recordings were analyzed by cardiologists (after logging in). One of the cardiologists analyzed the recordings and gave a diagnosis of "AF", "non-AF," or "non-interpretable". If artifacts were present on the ECG recording or there was no ECG tracing despite the ECG finding presented on Veroval's display, the recording was evaluated as "non-interpretable". If the cardiologist had doubts about the diagnosis a second cardiologist was consulted with the tracing to provide a final diagnosis. If the cardiologist diagnosed AF, the patient was contacted by phone and advised to contact their general practitioner for a further evaluation. All of the patients were presented with an option to get their ECG tracing by e-mail or to pick up a printout at the pharmacy where it had been carried out (**Suppl. Figs. 1–3**).

Statistical analysis

A comparison of an AF diagnosis made by the analyzed application and the cardiologist was performed using the Fisher exact test. The sensitivity and specificity, and predictive powers were calculated for the Kardia app, and Veroval took the cardiologist's diagnosis as the gold standard. The Bland-Altman plot was used to describe the agreement between heart rates recorded by the applications. The difference in mean heart rate (HR)

values was tested by using the paired t-Student test. Additionally, the kappa coefficient was calculated to assess the agreement in the diagnosis of AF between the analyzed applications (inter-rater agreement).

Statistical analysis was performed using TIBCO Software Inc. (2017) and Statistica (data analysis software system), version 13. All tests were considered significant for p < 0.05.

Results

Out of 878 potential participants asked to join the study, 230 refused, and 115 were younger than 65. Moreover, 94 patients were excluded due to their previous arrhythmia diagnoses, inability to fulfil the CHA₂DS₂-VASc protocol, or refusal to be subjected to a second (Veroval) ECG recording. In addition, 22 patients were excluded from further analysis because they could not operate the device, e.g., due to shaking hands. Finally, 417 patients were included in the study, and the study group structure is presented in Table 2. In addition, a distribution of the findings from the Kardia app and Veroval and cardiologists' diagnoses is presented in Tables 3 and 4.

After the over-read of each recording (Kardia first followed by tracings from Veroval), AF was identified in 15 (3.60%) patients. However, the cardiologist's interview revealed 7 (1.68%) patients admitted to the AF history. Hence, the study identified 8 (1.92%) patients with newly diagnosed AF. Importantly, due to the different quality of tracings, the Kardia app allowed us to detect 15 AF cases. whereas Veroval revealed 10. Inter-rater agreement (kappa coefficient) between the devices was k = 0.088 (95% confidence interval [CI] 1.59-16.1%).

Sensitivity and specificity of the Kardia app in detecting AF were 66.7% (95% CI 38.4-88.2%) and 98.5% (95% CI 96.7-99.5%), respectively. Positive predictive value (PPV) and negative predictive value (NPV) were 62.5% (95% CI 35.4-84.8%) and 98.7% (95% CI 97.1-99.6%), respectively.

For Veroval the sensitivity and specificity of detecting AF were 10.0% (95% CI 0.23-44.5%) and 94.96% (95% CI 92.15-96.98%), accordingly. PPV and NPV were 5.23% (95% CI 0.12-26.03%) and 97.41% (95% CI 95.15-98.81%), respectively.

Atrial fibrillation diagnosed by a cardiologist was frequently classified by Veroval as ventricular arrhythmia (simultaneous "rhythm" and "wave" finding). It resulted from the presence of isoelectric line artifacts (also unknown), which the device identified as changed wave shapes. Hence,

	Š	вх	Age		CHA ₂ DS ₂ -	VASc	Heart rate (Kardia	application)	Heart rate (Ve	eroval)
	Female	Male	Mean ± SD	Median	Mean ± SD	Median	Mean ± SD	Median	Mean ± SD	Median
All* (n = 417)	322 (77.22%)	95 (22.78%)	72.58 ± 6.25	71	3.22 ± 1.29	ო	78.30 ± 14.00	77	83.40 ± 21.53	79
Non-AF (n = 402)	312 (74.82%)	90 (21.58%)	72.46 ± 6.23	71	3.21 ± 1.29	ო	78.21 ± 13.82	77	83.64 ± 22.57	79
AF (n = 15)	10 (2.40%)	5 (1.20%)	75.8 ± 6.06	75	3.47 ± 1.19	ო	95.13 ± 26.52	92	90.73 ± 9.22	88
Newly identified AF (n = 8)	5 (1.20%)	3 (0.72%)	77.25 ± 7.55	78.5	3.37 ± 1.50	3.5	93.91 ± 22.87	83	105 ± 10.26	91.5
*All patients included in the s ase, Age 65–74, Sex); SD —	tudy; AF — atrial fi standard deviation	brillation; CHA ₂ D:	S ₂ VASc — Score fo	r Atrial Fibril.	lation Stroke Risk (Congestive h	eart failure, Hypertensior.	ı, Age ≥ 75, Diabet	ss mellitus, Stroke, V	ascı

Kardia application findings		After cardiologists over-read	
Kardia finding	Number of findings	Diagnosis	Number of findings
Normal	347 (83.21%)	Non-AF AF Non-interpretable	343 (98.85%) 1 (0.29%) 3 (0.86%)
Possible AF	16 (3.84%)	Non-AF AF Non-interpretable	4 (25%) 10 (62.5%) 2 (12.5%)
Unclassified	34 (8.15%)	Non-AF AF Non-interpretable	26 (76.47%) 2 (5.88%) 6 (17.65%)
Unreadable	8 (1.92%)	Non-AF AF Non-interpretable	3 (37.5%) 5 (62.5%)
Tachycardia	6 (1.44%)	Non-AF AF Non-interpretable	5 (83.33%) 1 (16.67%) –
No analysis	2 (0.48%)	Non-AF AF Non-interpretable	1 (50%) 1 (50%) –
Without notification	4 (0.96%)	Non-AF AF Non-interpretable	4 (100%) _ _

Table 3. Findings from Kardia application (n = 417) and diagnoses after the cardiologist's over-read.

AF — atrial fibrillation

Table 4. Findings from Veroval (n = 417) and diagnoses after the cardiologist's over-read.

Veroval findings		After cardiologists over-read	
Veroval finding	Number of findings	Diagnosis	Number of findings
Rhythm	19 (4.56%)	Non-AF AF Non-interpretable	16 (84.21%) 1 (5.26%) 2 (10.53%)
Rhythm/Wave	84 (20.14%)	Non-AF AF Non-interpretable Lack of tracing	39 (46.43%) 8 (9.52%) 31 (36.91%) 6 (7.14%)
Ok	259 (62.11%)	Non-AF AF Non-interpretable Lack of tracing	235 (90.73%) 1 (0.39%) 1 (0.39%) 22 (8.49%)
Fast	37 (8.87%)	Non-AF AF Non-interpretable Lack of tracing	12 (32.43%) 19 (51.35%) 6 (16.22%)
Slow	7 (1.68%)	Non-AF AF Non-interpretable Lack of tracing	7 (100%) _ _ _
Error	11 (2.64%)	Non-AF AF Non-interpretable Lack of tracing	- - - 11 (100%)

AF — atrial fibrillation



Figure 1. The agreement between heart rates recorded by Kardia application and Veroval; HR — heart rate.

considering "rhythm" and simultaneous "rhythm" and "wave" findings collectively and as a warning of supraventricular or ventricular arrhythmias, the sensitivity and specificity in detecting AF were 90.0% (95% CI 55.52–99.75%) and 74.79% (95% CI 69.93–79.18%), respectively. The PPV and NPV were 9.09% (95% CI 4.25–16.55%) and 99.63% (95% CI 97.94–99.99%) respectively.

The mean heart rate for the Kardia app was 78.30 ± 14.00 ; median 77 and for Veroval it was 83.40 ± 21.53 ; median 79 (p < 0.001). The distribution of heart rate results is presented on the Bland-Altmann plot (Fig. 1).

Discussion

The most important result of the present study was that AF was identified in 3.60% of patients. Previously unknown AF was detected in 1.92% of the study participants. The Kardia app achieved this with an acceptable level of sensitivity and high specificity. For Veroval, the sensitivity was low, but specificity was high. According to the McHugh [26] study about inter-rater reliability, the k coefficient between the used devices was very low (k = 0.088).

Current results of new AF detection are in line with other studies. For example, using the Kardia app, Zaprutko et al. [17] found previously unknown AF in 1.33% of patients. In turn, Lowres et al. [19], and Halcox et al. [27] revealed new AF in 1.5% and 1.84% of individuals, respectively. In the review provided by Ramkumar et al. [28], the average AF detection rate using portable ECG monitoring was 1.7% (95% CI 1.4–2.1%).

In the present study, the sensitivity of the Kardia app was 66.77%. Alternatively, Zaprutko et al. [17] and Koshy et al. [29] revealed a sensitivity of 100%. Lau et al. [22] reported a sensitivity of 98%. A sensitivity of (71.4%) was presented by Chan et al. [16], this was close to the present result, but Desteghe et al. [30] reported sensitivity of the Kardia app at 36.8%. Thus, specificity was high in the current study and was in line with results revealed by Zaprutko et al. (98.7%), Lau et al. (97.0%), and William et al. (94.1%) [17, 22, 31].

The Kardia app's PPV (62.5%) was lower than the result revealed, e.g., by Selder et al. (80%) [32]. PPV for Veroval (5.23%) was very low, and it was probably the effect of common artifacts in ECG tracings. Low PPV might be a drawback of portable ECG devices because they rely on a patient's ability to perform the test accurately. The device might interpret any noise during an ECG recording as arrhythmia. These devices provide a finding, not a diagnosis, and all those true and false-positive tests should be re-evaluated by professionals [16]. Contrary to PPV, both the Kardia app and Veroval achieved a very high level of NPV (~99%). Chan et al. [16], screening tests should have both high specificity and NPV, and is convergent with the current results.

During the last decade, there has been significant development of mobile health applications, with approximately 3.7 billion downloaded globally between 2013 and 2017. These included many for detecting AF. Despite this, only a few of the apps have undergone a formal assessment [33]. Although we used approved devices, a very low inter-rater agreement (k = 0.088) between them was revealed. Contrary to this finding. Desteghe et al. [30] revealed no difference in the agreement between the Kardia app and MyDiagnostick (a handheld ECG device). It may result from differences in the methodology of these studies and automated algorithms used by the producers of such devices. Besides, Mant et al. [34] noticed that differences in diagnoses were possible when the interpretation was made by dedicated software or by different operators.

There was also a difference in heart rate measurements between devices (Table 1). Veroval was used as a second device in each case, so the study participants should have been calmer. However, Veroval provided higher heart rate results. Considering findings revealed by Coppetti et al. [35], this is not surprising. They noticed that in smartphone applications for heart rate measurement, a difference of over 20 bpm occurred in more than 20% of all cases. Observed differences in bpm may also result from imperfections of the equipment used. For instance, Koshy et al. [36] found that smartwatches demonstrated strong agreement for heart rate estimation in sinus rhythm, but the value was surprisingly underestimated in AF patients.

In the current study, the CHA₂DS₂-VASc score was lower in the group of non-AF patients (3.21 \pm \pm 1.29) compared to those with newly identified AF (3.37 \pm 1.51). Although it is in line with other studies, the difference obtained in the present study was lower than that revealed by Lowres et al. [19] (3.2 \pm 1.1 for non-AF participants and 3.7 \pm 1.1 for those with newly identified AF) and by Yan et al. [3] (3.1 \pm 1.9 for non-AF participants and 4.5 \pm \pm 2.0 for those with present AF). Nevertheless, the presented results confirm that all AF patients are potential candidates for oral anticoagulants due to high stroke risk [19].

After a cardiologist assessment, there were 16 (3.84%) non-interpretable Kardia app findings and 53 (12.71%) such notifications from Veroval. The number of non-interpretable tracings may result from the fact that using the equipment for the first time could have been stressful for older people. Some issues may also have occurred due to the evaluation of ECG quality by non-professionals

[30, 37]. Moreover, tracings from handheld devices often have an unstable baseline and noise [30].

Importantly, for Veroval, it was impossible to view the recording on display (only findings were presented) and thus, an evaluation of the tracing quality. Unfortunately, it was quite common (n = 45; 10.79%) that there was no ECG tracing after transferring an ECG recording to a computer, but the device provided a finding during the test.

The number of non-interpretable recordings from Veroval and those without tracings recorded might be the main reason for less (10 compared to 15 from the Kardia app) AF cases diagnosed after a cardiologist's evaluation. It could also partially explain the low k between devices. Besides, the number of Veroval's tracings of poor quality may partly result from the chosen recording method. For Veroval, the first-choice option is the "right index finger-chest", and the measurement stability is higher for this method. Despite this, the "left handright hand" method was chosen, which is more comfortable [23], and ensured that the measurement method by both devices was similar. Secondly, more patients were expected to refuse taking part if the recording would require partial undressing. However, electrodes pressed too firmly onto the skin, and the resulting muscle tension could lead to imprecisely measured values [23].

Ramkumar et al. [28] pointed out that the screening tool should also be affordable and cost-effective. Both devices might be considered in expensive and enable numerous recording repetitions. The official price of Kardia Mobile is US\$ 89 (June 2020). External entities distribute Veroval; thus, the price might vary and is usually between US\$ 120 and US\$ 145 in Poland. Notably, several authors evaluated handheld ECG devices as cost-effective [14, 19, 30, 38]. For the Kardia app, Lowres et al. [19, 20] revealed an incremental cost-effectiveness ratio of €3142 per gained quality-adjusted life years (QALY). In turn, Jacobs et al. [4] showed that AF screening with a handheld mobile device provided an additional 0.27 QALYs with cost savings of EUR 764 per patient.

Despite possible advantages and drawbacks of mobile health technologies, the use of new technologies in AF screening may significantly impact the future of healthcare [39]. It could also support traditional healthcare delivery [33], especially during a pandemic. Furthermore, high specificity, high NPV, and affordability of the used devices may lead to the opportunistic AF screening becoming common and feasible, e.g., at pharmacies. Besides, formally evaluated apps and devices demonstrate improvements in patient knowledge of AF and oral anticoagulants. Hence, it contributes to medication adherence, a better quality of life, and more effective treatment [33].

Limitations of the study

The study sample could have been larger. However, the present study was suddenly stopped due to the COVID-19 pandemic. The subsequent lockdowns of the country and severely limited physical contact between people after the gradual opening of the national economy were significant obstacles for the study. Besides, the study was not advertised anywhere to avoid pharmacy advertising, which is unlawful in Poland [40, 41]. It would be worthwhile to conduct the screening with Veroval using the first-choice option from Veroval's manual to have a possibly better quality of recordings. Opportunistic and one-time ECG screening may miss patients with paroxysmal AF.

Implications for future research

Although both devices provide similar usefulness for ECG recordings, there are differences between them. In our opinion, the Kardia app is more user-friendly, i.e., the Veroval is more challenging to use. For the Kardia app, the transfer of recordings is more convenient, and the quality of recordings is better. Although smartphones are common right now [42, 43], Veroval, contrary to the Kardia app, does not require a smartphone to provide an ECG recording. However, tracing provided by Veroval is visible after transfer to the computer's software. Therefore, it does not allow one to evaluate if tracing is of good quality in an instant. Veroval is simultaneously a blood pressure monitor, which makes the device multifunctional. The low level of Veroval's sensitivity in detecting AF should be relevant motivation for the producer to improve the algorithms used for supraventricular arrhythmia/AF detection.

Conclusions

Atrial fibrillation was identified in 3.60% of patients and in 1.92% of patients (\geq 65 years old) with a previously undiagnosed AF. Mobile devices are capable of detecting AF but with different levels of sensitivity and specificity. The very low interrater agreement between devices confirmed that each finding must be verified by a professional. The Kardia app appeared to be more user-friendly than Veroval. Due to a better quality of ECG tracings, cardiologists confirmed more new AF cases based on the tracings from the Kardia app than solely based on Veroval. Cardiovascular screening using mobile devices is feasible at pharmacies; hence it might be considered for routine use.

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Conflict of interest: None declared

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