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Assessment of a standalone photoplethysmography (PPG) algorithm for detection of atrial fibrillation on wristband-derived data

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ABSTRACT

Introduction: Atrial fibrillation (AF) is the most common cardiac arrhythmia in the developed world. Using photoplethysmography (PPG) and software algorithms, AF can be detected with high accuracy using *smartphone camera-derived* data. However, reports of diagnostic accuracy of standalone algorithms using *wristband-derived* PPG data are sparse, while this provides a means to perform long-term AF screening and monitoring. This study evaluated the diagnostic accuracy of a well-known standalone algorithm using *wristband-derived* PPG data.

Materials and Methods: Subjects recruited from a community senior care organization were instructed to wear the Wavelet PPG wristband on one arm and the Alivecor KardiaBand one-lead-ECG wristband on the other. Three consecutive measurements (duration per measurement: 60 s for PPG and 30 s for one-lead ECG) were performed with both devices, simultaneously. The PPG data were analyzed by the Fibricheck standalone algorithm and the ECG data by the Kardia algorithm. The results were compared to a reference standard (interpretation of the one-lead ECG by two independent cardiologists).

Results: A total of 180 PPGs and one-lead ECGs were recorded in 60 subjects, with a mean age of 70±17. AF was identified in 6 (10%) of the users, two users (3%) were not classifiable by the PPG algorithm and 1 user (2%) was not classifiable by the one-lead ECG algorithm. The diagnostic performance (sensitivity/specificity/positive predictive value/negative predictive value/accuracy) on user level was 100/96/75/100/97% for the PPG wristband and 100/98/86/100/98% for the one-lead ECG wristband.

Conclusions: In a small real-world cohort of elderly people, the *standalone* Fibricheck AF algorithm can accurately detect AF using Wavelet wristband-derived PPG data. Results are comparable to the Alivecor Kardia one-lead ECG device, with an acceptable unclassifiable/bad quality rate. This opens the door for long-term AF screening and monitoring.

1. Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia in the developed world with a prevalence of approximately 1.5–2% in the general population [1]. By 2030, 14–17 million AF patients are expected in the European Union, with 120,000–215,000 new diagnoses per year [2]. It is considered one of the major causes of stroke [3]. Diagnosing AF is hampered by the paroxysmal nature of the arrhythmia. Moreover, AF is often not accompanied by symptoms (silent AF) and an AF related complication can be the first manifestation of the disease. Since a standard 12-lead electrocardiogram (ECG) is an instantaneous measurement, ambulatory ECG monitoring (AECG) is often used for prolonged monitoring. However, such devices can be cumbersome to wear and recording time is limited, typically 48–72 h. Implantable loop recorders (ILRs) have been used to screen high-risk patients for atrial fibrillation, which is rather invasive and expensive. In 2017 the REVEAL AF trial, enrolling patients at risk for AF, reported an unprecedented high incidence of previously undiagnosed AF. Participants were monitored using an ILR. Detection rate of atrial fibrillation lasting more than 6 min was 6.2% at 1 month follow up and increased to 40% at

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Fig. 1. Wavelet wristband.

30 months follow up [4,5]. Importantly, the median time from device implantation to the first episode of AF was approximately 4 months and a standard ambulatory 2–7 days ECG (AECG) would hence not have detected atrial fibrillation in the majority of participants. This clearly shows the need for non-invasive long-term monitoring tools.

Recently, photoplethysmography (PPG) has gained significant interest. PPG is optical plethysmography, that can be used to detect blood volume changes in the microvascular bed of tissue. By analyzing PPG waveforms it is possible to assess heart rate (HR) [6]. At present, focus has shifted to medical applications using PPG to detect rhythm disorders, in particular AF [7].

Several PPG devices using *incorporated* software algorithms have been studied, showing relatively high sensitivity and specificity (sensitivity 86–100%, specificity 75–100%) [8–12] in a controlled clinical setting, and a moderate positive predictive value (PPV) in large real-world low-prevalence cohorts (PPV 71–87%) [13,14].

Fibricheck (Qompium, Hasselt, Belgium) is a well-known, and the first and only CE Class IIa and FDA approved, *stand-alone* algorithm to detect AF. When using a smartphone camera, it has a high accuracy (sensitivity 96%, specificity 97%) [15]. However, these (1-min) smartphone-camera measurements provide no means for continuous long-term screening and monitoring. Furthermore, the smartwatch community that wants to monitor their vital signs continuously is growing. For both preceding reasons it is necessary to be able to analyze wristband-derived PPG data. Nevertheless, these data might be different from smartphone camera-derived PPG data, due to motion artifacts and use of additional hardware. The use of the Fibricheck algorithm on wristband derived-data has never been studied. Therefore the present study aims to evaluate the *standalone* Fibricheck algorithm using wristband-derived PPG data (Wavelet wristband, Wavelet Health, California, US, Fig. 1) [16] with regard to diagnosing AF in a small real-world cohort of mostly elderly people.

2. Materials and methods

2.1. Study design and study population

An observational, prospective cohort study with randomly invited subjects was set up. Subjects were recruited from a community senior care organization in Belgium, both guests and employees. Exclusion criteria were age < 18 years and pacemaker dependent rhythm. Demographic and medical history data were collected. Written informed consent was obtained from every subject before inclusion. The study protocol was approved by the medical ethics committee of the Oost Limburg Hospital (Genk, Belgium, ID 14/090 U)

Fig. 2. Alivecor KardiaBand attached to Apple Watch.

2.2. Data acquisition

Subjects were instructed to wear the Wavelet wristband (Wavelet Health, California, US) on one arm and a one-lead-ECG device (the AliveCor Kardia Band, AliveCor, Mountain View, California, United States) in combination with an Apple Watch (Apple inc., Cupertino, California, United States) on the other one (see Figs. 1 and 2). The PPG- and ECG-based wearables were wirelessly connected to an Apple iPad using dedicated software. Three consecutive measurements were performed using both devices simultaneously. To obtain high-quality measurements, participants were instructed to adopt a sitting position with both arms resting on a firm surface and instructed not to move or speak during the registration process.

Raw 60-second PPG and 30-second one-lead ECG data (see Fig. 3) were sent to an online platform for analysis. PPG waveforms

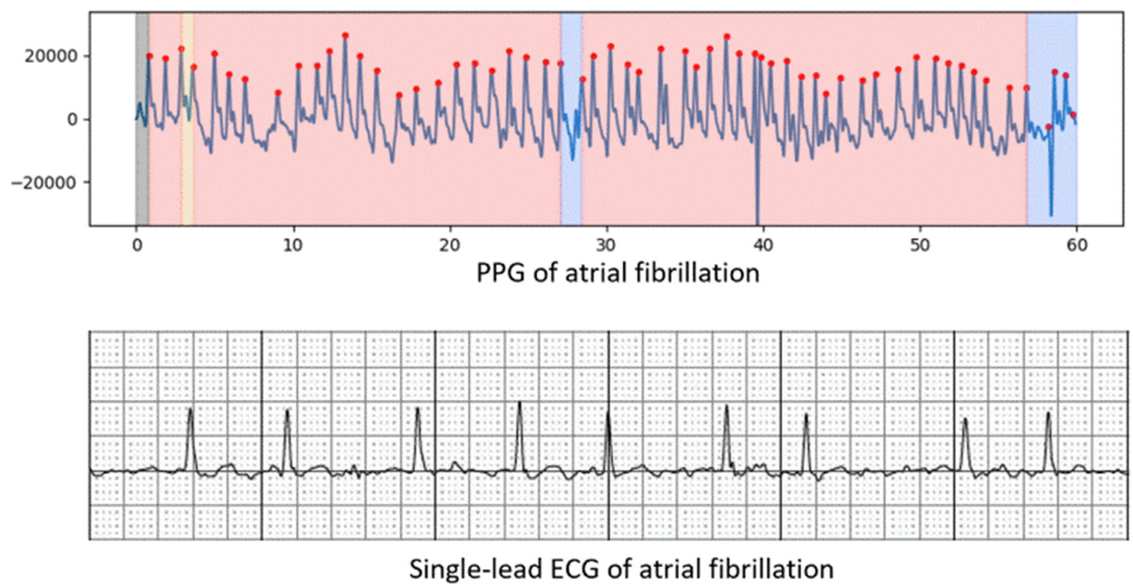

Fig. 3. Wavelet PPG registration with Fibricheck algorithm colors on top and Alivecor KardiaBand one-lead ECG registration. Pink = atrial fibrillation, blue = bad quality, yellow = extra systole, gray = start/end of a measurement. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

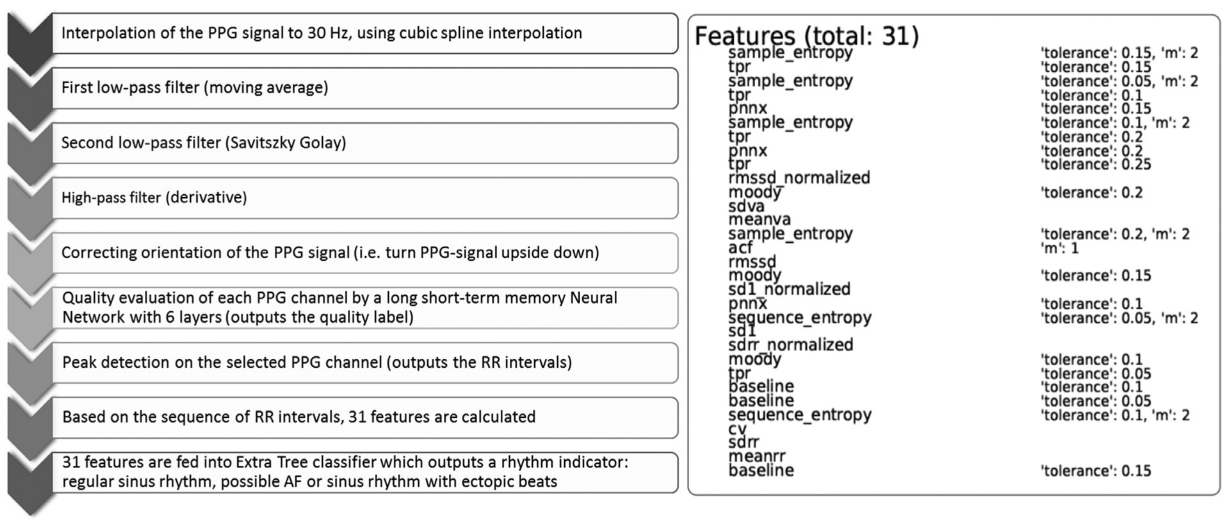

Fig. 4. Fibricheck algorithm flow. PPG = photoplethysmography, tpr = Turning Points Ratio, pnnx = Proportion of pairs of successive NNs that differ by more than x ms, rmssd = Root Mean Square of the Successive Differences, moody = Percentage of pairs of RR intervals that are not "normal-normal". Sd1_normalized = Standard deviation based on Poincaré plot divided by the mean RR interval, meanva = Mean vector angle (measures the mean departure of all Poincaré dots from the diagonal line, $y = x$), sdva = Standard deviation vector angle, acf = Auto Correlation Function, meanrr = Mean RR interval, sdrr = Standard deviation RR intervals, baseline = Ratio of RR intervals that fall on the mode of RR intervals (+/- tolerance), cv = Coefficient of variation.

were analyzed by the Fibricheck AF Algorithm and automatically categorized as 1) regular sinus rhythm, 2) possible AF, 3) sinus rhythm with ectopic beats or 4) insufficient quality. The single-lead ECG signals were analyzed by the AliveCor Kardia algorithm and categorized as 1) regular sinus rhythm, 2) possible AF, 3) unclassified or 4) noise. The single-lead ECG tracings were interpreted offline by two blinded, independent cardiologists providing the reference diagnosis, categorized as 1) regular sinus rhythm, 2) atrial fibrillation, 3) sinus rhythm with ectopic beats or 4) unreadable. Inconsistencies were evaluated by a third reviewer.

2.3. PPG algorithm details

The processing of PPG data using the Fibricheck algorithm is shown in Fig. 4. Firstly, the PPG signal is interpolated to 30 Hz, using cubic spline interpolation, followed by a first low-pass filter (moving average), a second low-pass filter (Savitszky Golay) and a high-pass filter (derivative). Subsequently the orientation of the PPG signal is corrected (i.e. turn PPG-signal upside down). The next step is a strict quality evaluation of each PPG channel by a long short-term memory (LSTM) Neural Network with 6 layers, trained on 10.000+ manually annotated PPG-signals, collected in 2018. The PPG channel (red or infrared) with least amount of insufficient quality is kept for peak detection. The interval between each consecutive beat is called the RR-interval. Based on the sequence of RR intervals, a set of 31 features is calculated (eg. mean RR interval, SD of RR intervals, root mean square of successive differences and entropy). These features are fed into an Extra Tree classifier which then outputs a rhythm indicator: regular sinus rhythm, possible AF or sinus rhythm with ectopic beats. The quality label is given by the LSTM neural network. The algorithm runs on consecutive 1-min patches of PPG data, both the pre-processing (i.e. filtering) and the analysis itself.

Table 1
Patient characteristics.

	N = 60
Demographics	
Age	69.6 (±16.9)
Male	19 (32%)
Medical History	
Hypertension	24 (40%)
Hyperlipidaemia	23 (38%)
CVA / thrombosis	17 (28%)
Vascular disease	8 (13%)
Diabetes mellitus	7 (12%)
Obesity	7 (12%)
Smoking	2 (3%)
Congestive heart failure	6 (10%)
Cardiothoracic surgery	5 (8%)
Extrasystole	7 (12%)
Atrial fibrillation	3 (5%)
Atrial flutter	3 (5%)
Electrocardioversion	3 (5%)
Rhythm ablation	2 (3%)
CHA_2DS_2-VASc	2.9 (±2.1)

2.4. Statistical analysis

The sensitivity (sens), specificity (spec), positive predictive value (PPV), negative predictive value (NPV) and accuracy (acc) were assessed for both wearable technologies. Recordings in the categories insufficient quality, unclassified and noise were reported as percentage of the total recordings, but not included in the analysis, comparable to previous analyses [17]. Regular sinus rhythm and sinus rhythm with ectopic beats were considered one group.

Outcome was reported on measurement level, and on user level (3 measurements per user, based on majority vote (MV) after unclassifiable exclusion, a draw was considered not classifiable). Continuous variables are expressed as mean +/- standard deviation and compared using the independent Student's *t*-test. Categorical data are expressed as counts (percentages) and compared using the Pearson's Chi square test. Statistical significance was always set at a 2-tailed probability level of <0.05. Statistics were performed using IBM SPSS Statistics 27, Python 3.7 and Microsoft Excel 2016.

3. Results

A total of 180 PPGs and 180 one-lead ECGs were recorded in 60 subjects with a mean age of 70±17 years (Table 1). AF was identified in 6 (10%) subjects, of which 4 were previously undiagnosed.

3.1. Quality assessment

Of the PPG recordings, 43 (24%) were not classifiable by the Fibricheck algorithm because of bad quality. In the one-lead ECG group 14 recordings (8%) were not classifiable by the algorithm. On user level (MV) this resulted in 2 users (3%) that were not classifiable by the PPG algorithm and 1 user (2%) by the one-lead ECG algorithm. See Tables 2 and 3.

3.2. Diagnostic performance

On measurement level, the diagnostic performance for detecting AF (sens/spec/PPV/NPV/acc) after unclassified exclusion was 79/98/85/98/96% for the PPG wristband and 93/98/81/99/98% for the one-lead ECG wristband. On user level (3 measurements, MV) the diagnostic performance was 100/96/75/100/97% for the PPG wristband and 100/98/86/100/98% for the one-lead ECG wristband. No inconsistencies were observed between both reviewers. For details, see Tables 2, 3 and Fig. 5.

4. Discussion

This study demonstrates that AF detection by the Fibricheck standalone algorithm on Wavelet wristband-derived PPG data is feasible and has a high sensitivity and specificity, in a small real-world cohort. On user level it shows comparable results to the use of a one-lead ECG wristband and algorithm. As outlined in the introduction, for detecting AF, especially paroxysmal AF, there is a clear need for non-invasive long-term monitoring tools. The current available options, pulse taking, 12-lead ECG, AECG or even the one-lead ECG devices [17–19] do not meet these requirements. This has fueled the development and improvement of PPG wearable devices and algorithms for heart rhythm evaluation. The results of this study encourage further development of PPG AF algorithms in combination with wristbands by demonstrating high diagnostic accuracy and acceptable unclassifiable rate.

4.1. PPG signal quality and PPV

This study shows a substantial 24% of unclassifiable measurements using PPG wristband-derived data, compared to 8% in the one-lead ECG group, and 7% in an earlier PPG analysis using Fibricheck smartphone camera-derived data [15]. Bad quality signals are a common finding in PPG-AF studies, especially when using wristband-derived data, due to motion artefacts. As long as multiple measurements are conducted, this is not a problem. By using a PPG-wristband, continuous AF monitoring is possible, where 10,000+ measurements per user are normal. In this study, by obtaining 3 consecutive measurements the percentage unclassifiable was already reduced from 24% (measurement level) to 3% (user level). Furthermore, all subjects with AF were identified with the PPG algorithm-wristband combination, while maintaining a high specificity, confirming feasibility of this method of AF detection. In comparable studies, up to 40% of the acquired data were classified as bad quality [20,21]. This is contributable to the strict quality check of the PPG algorithms, which is necessary to obtain high specificity and thus a low number of false positives. Negative predictive values in PPG studies are typically close to 100%, whereas PPV is generally much lower (despite the strict quality checks). The Apple Heart trial was the first large PPG-AF study, and showed their algorithm to provide a PPV (with regard to detecting AF) of 71% in 419k relatively young real-world participants who wore an Apple Watch 4 (of 2089 AF-positive tachograms, 1489 were confirmed as AF by means of an ECG patch) [13]. In the second large study, the Huawei Heart trial, 188k individuals (mean age 35 years, 87% male) used smart devices to monitor their heart rhythm. Of those individuals, 424 (0.23%) received a "suspected AF" notification. Of those, 262 (61%) were effectively followed up and 227 (87% of 262) were confirmed as having AF [14]. Although these studies are conducted in young people (mean age 35–41y) and ours in an elderly group (mean age 70y), our PPV of 75% is comparable.

4.2. Potential barriers

Wristbands using PPG technology only indirectly evaluate the heart rhythm by derived pulse wave analysis. A major concern is loss of PPV due to inferior ability to distinguish other pulse wave irregularities such as premature supraventricular and ventricular contractions. Another potential concern is an increase in healthcare utilization of patients having no AF. This may occur due to loss of PPV as a result of 1) screening populations with a low AF prevalence (as is the case in large-scale AF screening programs for early detection of silent AF in a 'healthy' population), and 2) motion artefacts in ambulant patients, especially in case of long-term screening. Furthermore, hospitals are not used to handling such large data sets, so workflow will have to be adapted.

Table 2
2 × 2 tables of PPG Fibricheck algorithm with 2-cardiologist one-lead ECG interpretation as reference.

Measurement level		Cardiologist interpreted KB recording		User level		Cardiologist interpreted KB recording	
		AF	SR			AF	SR
Fibricheck algorithm	AF	11	2	Fibricheck algorithm	AF	6	2
	SR	3	121		SR	0	50
	Not classifiable	43 (24%)			Not classifiable	2 (3%)	

Table 3
2 × 2 tables of one-lead ECG Kardia algorithm with 2-cardiologist one-lead ECG interpretation as reference.

Measurement level		Cardiologist interpreted KB recording		User level		Cardiologist interpreted KB recording	
		AF	SR			AF	SR
Kardia algorithm	AF	13	3	Kardia algorithm	AF	6	1
	SR	1	149		SR	0	52
	Not classifiable	14 (8%)			Not classifiable	1 (2%)	

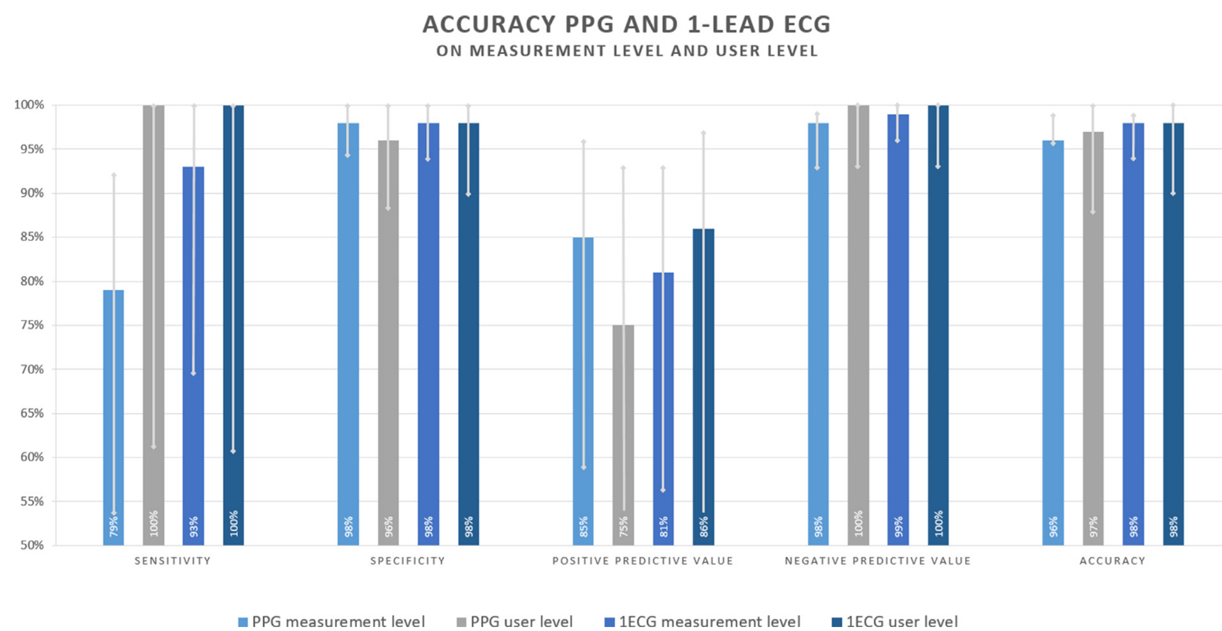

Fig. 5. Accuracy of PPG and 1-leads ECG (1ECG) on measurement level and user level. Bars are estimates. gray lines are confidence intervals.

4.3. Limitations of this study

A first limitation is the relatively small group of subjects. A second limitation is that this study was conducted in a semi-supervised setting, it is therefore unknown whether the algorithm-wristband combinations perform the same in an unsupervised home setting for long-term screening of atrial fibrillation. A third limitation is the use of a one-lead ECG device with consensus of two independent experts as reference instead of a 12-lead ECG. A fourth limitation is the combined use of one specific software algorithm and one specific wristband, other combinations might provide different results.

5. Conclusion and future perspectives

This feasibility study demonstrates that the standalone Fibricheck algorithm has a high accuracy for detection of AF, with an acceptable unclassifiable/bad quality rate, when using Wavelet wristband-derived PPG data. On user level, it shows comparable results to the Alivecor Kardia one-lead ECG device and its algorithm.

To assess clinical value, larger scale AF screening trials with PPG-wristbands need to be conducted in elderly subjects, using stroke, heart failure, systemic embolism and myocardial infarction as endpoints. In addition, studies are needed to assess long-term AF screening after cryptogenic stroke with PPG-wristbands. Furthermore machine-learning algorithms need to be trained distinguish motion artefacts from true cardiac arrhythmias. And eventually these devices need to be incorporated in a General Data Protection Regulation-compliant platform for communicating results to relevant parties.

Author disclosure statement

No disclosures.

Declaration of Competing Interest

All authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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