

Level Accuracy of Automatic and Real Time Detection of Atrial Fibrillation with A New Wireless ECG Recorder (The SmartCardia)

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Abstract

Background: Atrial fibrillation (AF) is the most common cardiac arrhythmia but is currently under-diagnosed since it can be asymptomatic. Early detection of AF could be highly beneficial for the prevention of stroke, which is a major risk associated with AF, with a fivefold increase. The advent of portable monitoring devices can help uncover the underlying dynamics of human health in a way that has not been possible before.

Method: The purpose of this study was to validate the automated analysis of AF by the SmartCardia's proprietary health monitoring device (ScaAI patch, SmartCardia S.A., Lausanne, Switzerland). To this end, a model was created and tested on three publicly available databases comprised of 243,960 ECG segments of 30-seconds. The model was further tested against a set of 500 ECG streams of 30-seconds (recorded by ScaAI patch - across different clinical trials; annotated by 3 different cardiologists), especially representing problematic conditions, when determination the underlying rhythm was challenging.

Results: The created model obtained F1-scores of 94.42 against a test set from two published available databases, and an F1-score of 92.61 (average F1-scores w.r.t each cardiologist) on the SmartCardia assembled database.

Conclusion: We demonstrated that the new wireless ScaAI patch had a high capacity to automatically detect AF when compared with public database. Further studies will help identify the optimal role of the the ScaAI patch in the management of cardiac arrhythmias.

Keywords: Atrial fibrillation; arrhythmias; automatic arrhythmia detection; wireless system

Abbreviations

AF = atrial fibrillation.

AFDB = atrial fibrillation database.

LTAFD = long-term atrial fibrillation database.

MITDB = MIT-BIH arrhythmia database.

BLE = Bluetooth Low Energy.

HR = heart rate.

RR = respiratory rate.

PPG = plethysmography.

(SC_AFDB) = The SmartCardia Atrial Fibrillation Database.

PPV = positive predictive value.

Introduction

Atrial Fibrillation (AF) is the most common arrhythmia in clinical practice and is the leading cause for hospitalizations due to arrhythmias, heart failure and strokes. AF affects 2% of the general population [1]. Its prevalence increases with age, from 0.5% between 50-59 years to 9% between 80-89 years [2-4]. Importantly, AF is also associated with a 1.5- to 1.9-fold mortality risk [5]. With increasing life expectancy, the prevalence of AF is expected to double over the next fifty years. AF can persist for long periods of time. It is, therefore, crucial to prevent its progression from paroxysmal AF to persistent and permanent AF. There is a growing need to diagnose and develop curative strategies of AF, either by restoring sinus rhythm, or to prevent morbid and fatal complications such as stroke. Since its introduction, computer-aided interpretation has become increasingly important in the clinical ECG workflow. It represents a crucial adjunct to physician interpretation in clinical settings [6]. However, existing commercial ECG interpretation algorithms show high rates of interpretation mistakes [7-9]. The combination of widespread digitization of ECG data and the development of algorithmic analyzer is an opportunity to reexamine the standard approach to algorithmic ECG analysis and detection of AF and may provide improvements to automated ECG interpretation. Artificial neural networks (ANN) have dramatically improved the state of the art in medical applications [10-11]. The ability of ANNs to recognize patterns and especially AF from input data without requiring extensive data preprocessing, makes them well suited to interpret ECG data. Much of the previous work to employ ANNs toward ECG interpretation has mainly focused on artefacts or noise reduction [12-13] or detecting only a handful of abnormal contraction such as ventricular or supraventricular ectopies [14-17] or rhythm abnormalities such as AF or atrial or ventricular tachycardia [18-21].

Due to the unpredictable characteristics of AF and other abnormal rhythms, automatic classification of heart rhythms is still problematic. Generally, AF detection methods are based on atrial and/or ventricular activity analysis. This independent technique is extensively tested against well-known public available databases as well as recordings from a portable health monitoring solution developed by SmartCardia S.A. (Lausanne, Switzerland).

Study design

The aim of this study was to test in vitro the algorithmic analyzer of the SmartCardia wireless ECG monitoring device to detect AF (SmartCardia S.A. Lausanne, Switzerland). For this purpose, we extract robust ECG-based features to detect episodes of AF efficiently and automatically in 30-sec real-time ECG recordings.

Methods

The data used in this study comprise of ECG recordings from public available databases, and those recorded from a wearable wireless cardiac monitoring device (ScaAI patch, SmartCardia S.A., Lausanne, Switzerland) in clinical settings. To detect AF, a window of ECG is considered for analysis. In this study, a sliding window of 30-second length, sliding every 10-seconds is used for detection of AF. In each 30-second window, in the training phase over 160 features from the ECG signal were extracted, such as the mean RR interval variations, standard deviation of RR intervals, polynomial fit of RR interval data. The description and processing of these databases are as follows:

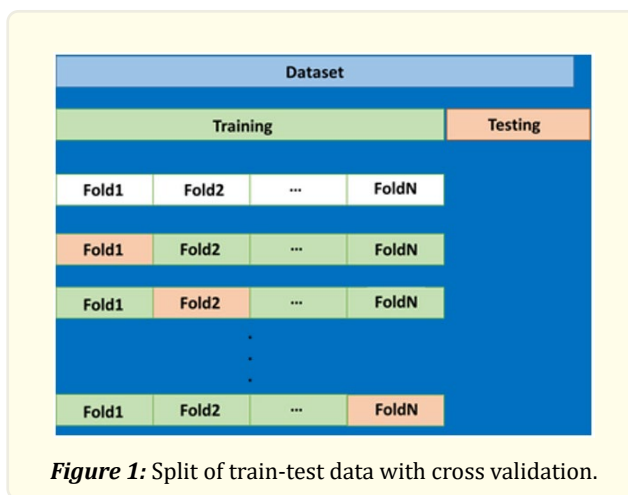
Public Databases

For this study, three publicly available databases were used for the purpose of training, and evaluation of the AF prediction model. The public databases namely, the Physionet MIT-BIH arrhythmia database (MITDB) [6-9], the Physionet MIT-BIH atrial fibrillation database (AFDB) [6-9], and the Physionet long-term atrial fibrillation database (LTAxFD) [6-9] contain two lead ECGs with cardiologist/expert manually annotated rhythms. These public databases were further processed to create training and validation sets. From the provided annotations, 30-second non-overlapping segments of ECGs were assembled for each class (i.e., AF vs non-AF). A final count of 2501 segments were created from the MIT-BIH arrhythmia database, while the AFDB and LTAxFD had respectively 27611 and 213848, 30-sec ECG recordings. The distribution of AF vs non-AF classes for these databases are reported in Table 1.

<i>Data Base</i>	<i>Total records</i>	<i>Episode of AF</i>	<i>Number of non AF</i>
MITDB	2501	228	2273
AFDB	27611	11062	16549
LTAxFD	213848	118311	95537

Table 1: Description of no. of 30-sec segments extracted from each publicly available database (AFDB = atrial fibrillation database, LTAxFD = long-term atrial fibrillation database, MITDB = MIT-BIH arrhythmia database).

The classifiers are trained using cross-validation to avoid the overfitting problem. This procedure consists of splitting the training data set in k smaller sets called k folds. A model is trained using k-1 folds as a training data and testing using the remaining part of the data, as shown in Figure 1.

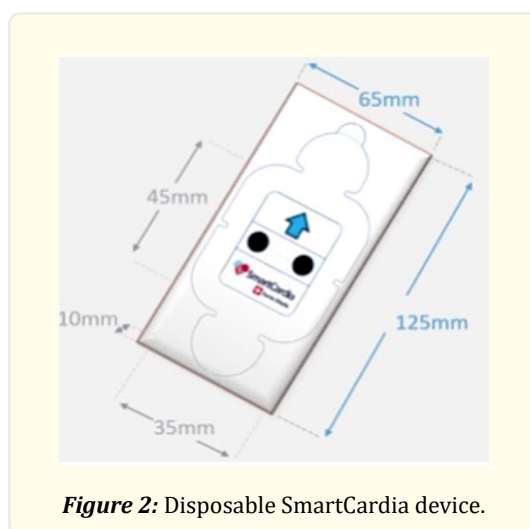


The AF detection algorithm is based on extracting R-R intervals from the ECG in the window and deriving features (40 features) from the R-R intervals. As a first step, the ECG signal delineation is performed either on device or on cloud, where the QRS complex R-peaks are detected. From the detected R-peaks, several features of RR intervals (such as the mean of all RR intervals) are derived. The 40 features are chosen by testing over 200 features of RR intervals and selecting the best-performing ones, which provide the highest predictive values. With respect to the initial set of 200 features, the selected 40 features provide very similar accuracy while significantly improving the algorithm latency.

To get the maximum accuracy and minimize the number of false positives and false negatives, different types of classifiers, such as the Random Forest, Support Vector Machines (SVM) and Logistic Regression were tested. The ADABOOST classifier with RandomForest provided the best results and was chosen as the ANN model.

Description of SmartCardia Portable Health Monitoring Device

The ScaAI patch (SmartCardia, Lausanne, Switzerland) is a medical-grade lightweight, wireless and wearable adhesive biosensor that measures a number of vital signs continuously such as, single-lead ECG, green/red/infrared photoplethysmography (PPG), heart rate (HR), respiration rate (RR), HR variability, skin temperature, and body posture (Figure 2). ScaAI patch designed to facilitate long-term remote monitoring of vital signs and activities in hospital environments as well as in post discharge period at home. The device uses a disposable adhesive patch that houses two ECG electrodes. A rechargeable battery as well as other sensors namely, a skin temperature sensor, reusable sensor modules containing the electrocardiogram, green/red/infrared PPG sensors, a tri-axial accelerometer, and Bluetooth Low-Energy (BLE) transceiver, are built into the device. The patch can be applied on the chest and/or the arm and measures vital signs continuously up to 7 days. The device records these vital signs on its internal memory, with the capability of real-time streaming of vital signs, via BLE to a relay device (for this work we used android phones) through the “SmartCardia Health” mobile application. Patient identification information is not entered on the mobile device to ensure privacy protection. Moreover, patient data can be viewed on a web cloud-based server in an on-line fashion, to monitor long-term trends. The system is CE-approved: It is a wireless patch with a low-cost disposable component and a re-chargeable/re-usable electronic unit (65 over 125 mm) (Figure 2). The patch records a single-lead ECG and evaluates HR, HR variability, and arrhythmias. The data are transmitted by Bluetooth to a mobile phone or router. The recorded signals and parameters are also stored on the device placed on the upper left quadrant of the patient’s chest. The patch-based device offers up to 7-days monitoring and storage and 3.5-days real-time connectivity with the cloud through a smartphone on a single battery charge. The ability to receive, store and interpret a broad range of signals offers the opportunity to go far beyond monitoring individual parameters. If the patient’s vitals reach a pathological value, the system give an alert on the cloud and the physician can see the real-time parameters and ECG signals. The device is also equipped with a mark event button and patients are instructed to push it in case of symptoms.

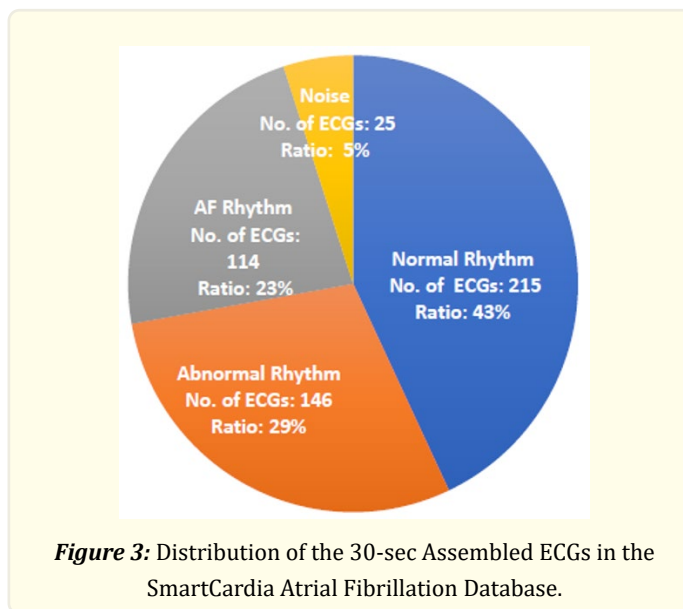


The SC_AFDB

This database comprises ECG recordings from cardio-respiratory patients across three different clinical trials: Madrid Ramón y Cajal hospital in cardiac ICU patients, patients undergoing polysomnography testing in Kamenica and Kragujevac (Serbia) hospitals.

In the abovementioned trials, a conventional bedside monitor or a portable ECG monitor (Philips Intelliview or Philips Alice system) (Philips, Amsterdam, Neederland) as well as a ScaAI patch simultaneously recorded patient ECGs. The ScaAI patch ECG was sampled at 250 Hz with a resolution of 24-bits and a range of ± 400 mV. From the three trials, a set of 500 30-sec ECG recordings were assembled

to represent oisy as well as problematic and borderline ECG rhythms, such as an ECG excerpt with an underlying AF rhythm and a short duration (8 sec) ventricular tachycardia. An expert was instructed to select a balanced set of ECGs with normal, abnormal, and AF, selected these segments. Segments were then sent to three cardiologists for rhythm and heartbeat annotation. The purpose of these segments was to further test the created model against perturbations, especially rare and problematic conditions to have a comprehensive performance evaluation. The distribution of the 30-sec Assembled ECGs in the SmartCardia Atrial Fibrillation Database is reported in Figure 3.



Statistics

To compare the relative performance of the ANN to the cardiologist committee labels, we calculated the F1 score. It is the harmonic mean of the PPV and sensitivity. It ranges from 0 to 1 and rewards algorithms that maximize both PPV and sensitivity simultaneously, rather than favoring one over the other. The F1 score is particularly helpful in the setting of multi-class prediction. To obtain estimates of how the database compares to an average cardiologist, the characteristics of cardiologist performance were averaged across cardiologists who individually annotated each record. Among the individual cardiologist annotations in the test dataset, we calculated inter-annotator agreement as the ratio of the number of times two annotators agreed that a rhythm was present at each output interval and the total number of pairwise comparisons.

Sensitivity was defined as the percentage of people who test positive for the presence of the arrhythmia that really have the arrhythmia in other words AF. PPV was defined as the probability that subjects with a positive screening test truly have the arrhythmia. ACC was defined as.

Results

The AF detection model was trained on the Physionet LTAfDB and subsequently evaluated against MITDB and AFDB. Table 2 reports detailed results of the created model on the publicly available databases. In this table performance metrics such as the accuracy, sensitivity, specificity, and average F1-score of the model is reported for each class. As results in Table 2 suggest, the created model efficiently identifies ECG segments with AF episodes. It is worth mentioning that the recordings provided in the validation set do not have the same class distribution as the training set. Of course, as the distributions were unbalanced, the F-score is more representative of performance compared to classification accuracy and therefore, is a suitable choice for the scoring function.

<i>Classification</i>	<i>ACC</i>	<i>Sensitivity</i>	<i>PPV</i>	<i>F-Score</i>
AF	95.76	94.41	94.43	94.42
Non-AF	95.76	96.58	96.57	96.58

Table 2: Performance of the created model against AFDB+MITDB.

With results on the publicly available databases at hand, the created model was tested on SC_AFDB and its performance was compared to annotations provided by the cardiologists. The agreement between the created model and each annotator, as well as their majority and unanimous voting are reported in Table 3. In this table, results are given for two classes of AF vs non-AF, i.e., Normal/Abnormal rhythms. Moreover, noisy ECGs are discarded from analysis. As cardiologists decided whether ECG segments were of high quality, the total no. of correctly classified segments, as well as the F1-score and the total no. of non-noisy segments are reported in Table 4. Therefore, in time, by obtaining cardiologist annotations on recordings which are more representative of real-life scenarios, one can expect a better, closer to “cardiologist level” performance from the created model.

<i>Performance</i>	<i>Agreed segments</i>	<i>F1-score</i>	<i>Non-noisy segments</i>
SC vs Ann1	406	93.01	467
SC vs Ann2	400	92.49	465
SC vs Ann3	396	92.31	464
SC vs Maj Vot	420	95.01	464
SC vs Unan. Vote	377	88.6	464
Disagreement	45	-	464

Table 3: Performance of the SmartCardia AF Prediction Model against Cardiologist Annotations.

<i>Annotator</i>	<i>Agreed segments</i>	<i>F1-score</i>	<i>Non-noisy segments</i>
Ann 1 versus Ann 2	443	96,83	472
Ann 1 versus Ann 3	452	97,94	471
Ann 2 versus Ann 3	434	95,91	471
Majority Vote	471	100	471
Unanimous Vote	429	95,33	471
Disagreement	0	-	471

Table 4: Inter-Cardiologist Agreement on Underlying Rhythms, on SmartCardia Testset.

Discussion

Atrial fibrillation is the leading cause of stroke, and its detection remains challenging because of its asymptomatic nature and paroxysmal frequency (1-2). Accessible means to detect silent and paroxysmal AF are needed. The ideal instrument for that purpose is a non-invasive recorder like Holter monitoring or smartwatches. Previous trials have shown that smartwatch coupled with a deep neural network can passively detect AF but with some loss of sensitivity and specificity when compared with standard twelve leads electrocardiogram [23]. The features were chosen from literature survey, as well as accounting for the ability to detect them in real time at ultra-low latency. During the training phase, the most important features were identified for detecting AF, and the top 40 features were chosen. For each sliding window, if AF is detected, the middle 10-seconds of the 30-second window is marked as AF. We deliberately chose a machine learning approach with extracted features rather than a deep learning approach that usually doesn't involve explicit feature extraction. In ECG signals, the QRS peak is usually distinctive and detectable in noisy ECG segments as well, and the feature-based approach provides a robust tolerance in real-world ECG signals that may be affected by a variety of noise sources, such as movement artefact and muscle noise. Moreover, a feature-based approach could provide insights to the clinicians on the reasoning

for an AF call, rather than a black-box approach of classification.

In this study, we measured the performance of the new SmartCardia enhanced AF detection algorithm in a multicenter clinical trial for remote monitoring of patients with known or suspected arrhythmias from cardio-respiratory patients across three different clinical hospitals. We have tested the agreement between the created model and each annotator, as well as their majority and unanimous voting. Results are given for two classes of AF vs non-AF, i.e., normal/abnormal rhythms. Moreover, noisy ECGs are discarded from analysis. As cardiologists decided whether ECG segments were of high quality, the total number of correctly classified segments, as well as the F1-score and the total number of non-noisy segments are reported (Table 4). Results suggest that, although not as good as inter-cardiologist agreement, the created model can efficiently identify AF presence in the ECG. It is important to note that these results are obtained on problematic cases. Therefore, in time, by obtaining cardiologist annotations on recordings which are more representative of real-life scenarios, one can expect a better, closer to “cardiologist level” performance from the created model. In addition to our results, the reduced size, improved electrode coating, and simplified insertion procedure makes this new wireless cardiac monitor system as a reliable tool for diagnosis of patients with asymptomatic or symptomatic AF and for long-term management of patients with a known history of intermittent and symptomatic AF.

Limitations

Our study has some limitations. Validation was done against a public available database which does not fully replicate the real life situation. In addition, the device was not worn by patients during the trial thus avoiding disturbances induced by patients’ movements.

Conclusion

The new AF detection algorithm in the SmartCardia system showed acceptable AF detection capabilities showing high sensitivity, specificity, and PPV values. The SmartCardia device represents a valuable diagnostic tool in patients with suspected AF. The presented model was able to accurately provide near cardiologist level of performance, efficiently determining the underlying rhythm of the ECG. The purpose of these segments was to further test the created model against perturbations, especially rare and problematic conditions to have a comprehensive performance evaluation.

Conflict of Interest

S. Murali, R. Braojos and F. Rincon are members of the board of SmartCardia.

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