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Utility of mobile single-lead ECG device in hospital emergency department

Diagnostyka elektrokardiograficzna w warunkach SOR za pomocą mobilnego jednoodprowadzeniowego urządzenia EKG

Maciej Janusz Krajsman[1], Jakub Poliński[1], Kacper Pawlik[1], Emanuel Tataj[1], Gabriela Parol[2], Andrzej Cacko[1]

[1]Department of Medical Informatics and Telemedicine, Medical University of Warsaw, Warszawa, Poland
[2]I Cardiology Clinic, Medical University of Warsaw, Warszawa, Poland

Abstract

Introduction. Electrocardiography (ECG) is one of the basic diagnostic tests used in emergency departments and by emergency medical services. Life-threatening arrhythmias can be detected using a single-lead ECG. Therefore, single-lead ECG devices can be used for arrhythmia detection, as their availability steadily increases. Kardia Mobile from AliveCor is an example of such a device, recording a single-lead ECG and automatically detecting atrial fibrillation (AF) — the most common complex supraventricular tachyarrhythmia. The aim of our study was to evaluate the utility of a single-lead mobile ECG device in detecting AF in medical practice of emergency services.

Material and methods. Study included 118 patients (62 women and 56 men) who were hospitalized in a hospital emergency department and consented to examination with Kardia Mobile immediately after a standard 12-lead ECG. Results of both tests were subsequently compared. Ultimately, 121 different pairs of ECG recordings were analyzed (in 3 cases an additional ECG recording was performed after an electrical cardioversion).

Results. Sinus rhythm was identified in 99 patients and 22 were diagnosed with AF using a 12-lead ECG (reference). Kardia Mobile correctly detected AF in 19 of 22 patients with AF (sensitivity: 86.4%) and absence of AF in 96 of 99 people without AF (specificity: 97%).

Conclusions. Kardia Mobile device is effective in automated detection of AF among patients hospitalized in the emergency department.

Key words: electrocardiography, ECG, diagnostic, atrial fibrillation, emergency department

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Introduction

Electrocardiography (ECG) is one of the basic diagnostic tests utilized by emergency medical services (EMS) and emergency department (ED) staff. Apart from a standard 12-lead ECG, the so-called "quick look" ECGs, usually incorporated into a defibrillator or patient monitoring device, may be encountered in everyday practice of medical response teams. Diagnosis of ventricular or supraventricular arrhythmia is often made based on a telemetric ECG recording. Considering that all potentially life-threatening cardiac rhythms are visible in all ECG

Address for correspondence: dr n. med. Andrzej Cacko, Zakład Informatyki Medycznej i Telemedycyny, Warszawski Uniwersytet Medyczny, ul. Banacha 1a, 02–097 Warszawa, Poland, e-mail: andrzej.cacko@gmail.com

leads, a single-lead recording from defibrillator paddles may be used for rapid rhythm assessment during cardiopulmonary resuscitation [1].

Availability of mobile ECG devices is currently increasing. Kardia Mobile by AliveCor Co., a portable single-lead ECG recorder, is an example of such a device [2]. It holds a European Certificate of Conformity (CE, *Conformité Européenne*) and was approved by the American Food and Drug Administration (FDA) as a tool for acquiring, storing, displaying and transmitting a single ECG lead and for automatic detection of atrial fibrillation (AF) and sinus rhythm [3].

AF is the most common type of complex supraventricular arrhythmia. It is estimated that as much as 25% of adult patients in Europe and United States will develop atrial fibrillation over the course of their lives [4]. More importantly, a single-lead ECG is a sufficient tool for the diagnosis of AF. High availability and simplicity of this diagnostic modality supplemented by automatic algorithms for the diagnosis of AF suggests that tools such as Kardia Mobile will in the future become a standard component of home first aid kits or EMS equipment.

The main goal of this study is to determine the efficacy of AF detection using Kardia Mobile device in an emergency department. Moreover, we performed practical assessment of the utility of Kardia Mobile in an ED setting.

Material and methods

The study included 118 consecutive patients (62 women and 56 men) admitted to the ED of a large clinical hospital, who consented to examination with Kardia Mobile immediately after a standard 12-lead ECG. Patient age ranged from 18 to 95 years, mean 57.3 years (61.5 in women and 52.6 in men).

Each patient underwent a single-lead immediately after 12-lead ECG examination. Finally, 121 different pairs of ECG recordings were examined (in three patients ECG was acquired before and after electrical cardioversion)

Study was acknowledged by the Bioethical Committee at the Medical University of Warsaw (declaration no. AKBE/181/17).

Kardia Mobile

The Kardia Mobile device reads an ECG signal using two electrodes (each with an area of 9 cm^2) and connects to a phone or a tablet. Recorder is supplied by a 3V CR2016 cell, which allows for at least 200 hours of continuous work.

Kardia Mobile system is simple to use. An adapter with the electrodes should be located no further than 30 cm from the mobile device with dedicated software. Patient should touch the electrodes with both ends in such a way that the fingers of one hand touch only one electrode. Also, hands should not be in contact with each other. This arrangement corresponds to lead I on ECG (Figure 1). Theoretically, it is also possible to obtain readings from lead II and III by placing the electrodes between right hand and left thigh or left hand and left thigh.

Figure 1. AliveCor Kardia Mobile: mobile application and dedicated adapter (own source)

Measurement lasts 30 s, but may be extended up to 5 minutes if necessary. Each uninterrupted reading is automatically recorded by software in order to be assessed for AF and designated as **normal**, **possible AFib**, or **unclassified.** ECG reading may be also observed during acquisition — it is displayed on the screen of a phone or a tablet.

According to the documentation [5] only sinus rhythm of 50–100/minute without or with a small number of significant abnormal beats is considered normal. The documentation states also that Kardia Mobile device was not designed to work with pacemakers.

Analyzed ECG parameters and statistical method

A standard 12-lead ECG was assessed with regard to the presence of AF by two cardiology specialists and each time the diagnosis was made as a result of expert consensus.

Results were presented as a mismatch matrix for automatic detection of AF.

Results

Sinus rhythm was identified in a 12-lead (reference) ECG in 99 patients and 22 subjects were diagnosed with AF. Based on automatic analysis of single-lead ECG Kardia Mobile identified possible AF in 22 subjects, normal ECG in 78 subjects and in 21 patients heart rhythm could not be classified. Kardia mobile properly diagnosed AF in 19 of 22 patients with arrhythmia (sensitivity: 86.4%) and absence of AF in 96 of 99 patients (specificity: 97%). Results are presented in Table 1.

Table 1. Mismatch matrix for automatic detection of atrial fibrillation (AF)

Reference → Observations ↓	AF present		AF absent	
AF present	19	TP	3	FP
AF absent	3	FN	96	TN
ACC: 115/121 = 0.95	19/22 = 0.86	TPR	96/99 = 0.97	TNR

TP — true positives; FP — false positives; TN — true negatives; FN — false negatives; TPR — true positive rate; TNR — true negative rate; ACC — accuracy

Among probable reasons for the lack of automatic classification of the ECG recording in 22 patients we should mention: too low or too high heart rate (12 cases), presence of ventricular stimulation (two cases), bundle branch block — broad QRS complexes (five cases), poor quality of the recording (three cases).

A number of abnormalities were recorded and identified by the Kardia Mobile device:

- ventricular extrasystoles;
- ventricular stimulation (Figure 2A);
- broad QRS complexes (Figure 2B);
- prolonged atrioventricular conduction (Figure 2C).

During data collection we observed situations that might significantly impede acquisition and analysis of the ECG signal:

- patient cannot hold the device with both hands (*e.g.* patients after stroke);
- significant difference in amplitudes of QRS complexes in the recordings from Kardia Mobile compared to the reference recording;
- presence of sources of interference may make the recording illegible;
- low QRS amplitudes may impede their detection, especially in the presence of high-frequency interference (Figure 2D);
- P waves may be poorly visible or almost undetectable when the investigator has only one lead at his disposal (Figure 2E);
- hand tremor, e.g. in the course of Parkinson's disease or in patients with electrolyte imbalance (Figure 2F, 2G).

Discussion

Nowadays a large share of the society has access to mobile devices (smartphone, smartwatch), which have increasingly more potent functions [6]. There are no technological impediments that would prevent from using them for assessment of health status [7]. Mobile electrocardiography has great potential, taking into consideration that cardiovascular disorders constitute the most common cause of death in Europe [8].

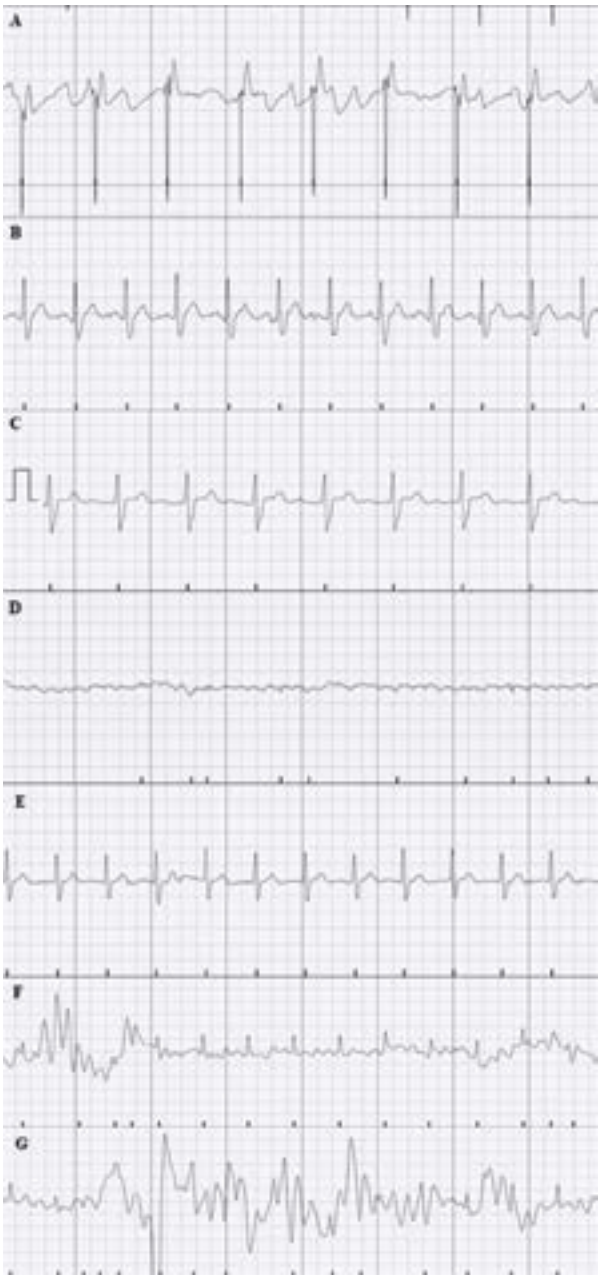

Figure 2A–G. Examples of recordings where automatic analysis could be impaired (own source)

Table 2. A compilation of characteristics of electrocardiography (ECG) recording modalities depending on the number of leads

Parameter	12-lead ECG	3/6-lead ECG	1-lead ECG
Diagnostic capabilities	Full	Limited	Limited
Duration of examination	The longest	Short	The shortest
Resistance to interference	High	High	Low
Personal devices	No	No	Yes
Availability of long-term acquisition	Low	High	High
Available leads	I, II, III, aVR, aVL, aVF, V1–V6	I, II. III, aVR, aVL, aVF, modified precordial	I, modified precordial

Aside from a 12-lead ECG we have at our disposal devices with a smaller number of leads. Absence of precordial leads is a significant impediment to the diagnosis of ischemia. Nevertheless, mobility of testing devices and their broader availability increase with the reduction in the number of leads. Devices with a reduced number of leads are often used for long-term ECG monitoring or so-called "ECG on demand", "event ECG" or "quick look" examinations. Table 2 demonstrates a comparison of available ECG recording systems.

The goal of this study was to assess the efficacy of application of a single-lead ECG recording by emergency medical services. By definition it cannot replace cardiomonitors or 12-lead ECG devices, which currently constitute the diagnostic gold standard in emergency medical services and emergency departments. However, it is possible to assess the utility of this device in the diagnosis of certain cardiac rhythms and the prospects for incorporating wireless ECG devices into healthcare standards in the future.

Automatic ECG analyses are widely used in automatic external defibrillators (AED). Numerous publications corroborate high efficacy of automatic single-lead in the diagnosis of shockable heart rhythms [9–11].

Results obtained with AliveCor Kardia mobile demonstrate that a device of this kind is capable of effective automatic detection of atrial fibrillation in an ED setting. Automatic ECG assessment toward AF was characterized by 95% accuracy (115/121). Moreover, Kardia makes it possible to observe a number of other possible ECG abnormalities under the condition that the test is conducted properly according to manufacturer's recommendations and obtained readings are uninterrupted. Some of the errors of automatic analysis can be detected based on human interpretation of the ECG curve. Using the system for screening of all patients awaiting admission to the ED is also an idea worth investigating.

It should be noted that none of the patients refused participation in the study. Patients generally showed positive attitude to the idea of wireless electrocardiography. Examined subjects as well as ED staff exhibited great interest in the device itself as well as capabilities. Following short training, all patients were enthusiastic toward the examination.

Conclusions

The work of a paramedic rarely provides optimal conditions for patient examination with Kardia Mobile. However, our work illustrates a great potential of mobile ECG devices. Tools, such as Kardia Mobile, show that a mobile phone may perform ECG assessment, supporting the use of mobile devices in the diagnostics of acute conditions.

Streszczenie

Wstęp. Elektrokardiografia (EKG) jest jednym z podstawowych badań wykorzystywanych w praktyce szpitalnych oddziałów ratunkowych (SOR) i zespołów ratownictwa medycznego. Zaburzenia rytmu mogące powodować zatrzymanie krążenia należą do najważniejszych dla zdrowia pacjenta nieprawidłowości wykrywanych w badaniu EKG. Są one widoczne we wszystkich odprowadzeniach EKG, co pozwala używać do ich wykrywania jednoodprowadzeniowych aparatw EKG, których dostępność na rynku istotnie się zwiększyła. Przykładem takiego urządzenia jest Kardia Mobile firmy *AliveCor*, zdolne do akwizycji pojedynczego odprowadzenia EKG oraz do automatycznej detekcji rytmu zatokowego oraz migotania przedsionków (AF), najczęściej występującej złożonej tachyarytmii nadkomorowej. Celem pracy jest określenie przydatności mobilnych jednoodprowadzeniowych rejestratorów EKG detekcji AF w warunkach SOR.

Materiał i metody. Do badania włączono 118 osób (62 kobiety i 56 mężczyzn) hospitalizowanych na SOR, które wyraziły zgodę na wykonanie badania urządzeniem Kardia Mobile bezpośrednio po wykonaniu standardowego 12-odprowadzeniowego badania EKG. Wyniki obu badań porównywano. Ostatecznie analizowano 121 różnych par odczytów EKG (u 3 pacjentów wykonano akwizycję EKG przed zabiegem kardiowersji elektrycznej i po nim).

Wyniki. W 12-odprowadzeniowym (referencyjnym) zapisie EKG rytm zatokowy rozpoznano u 99 badanych, u 22 badanych rozpoznano AF. Urządzenie Kardia Mobile prawidłowo rozpoznało AF u 19 spośród 22 badanych z arytmią (czułość: 86,4%), a brak AF — u 96 z 99 badanych (swoistość: 97%).

Wnioski. Urządzenie Kardia Mobile jest w efektywnym narzędziem w diagnostyce AF w warunkach SOR.

Słowa kluczowe: elektrokardiografia, EKG, diagnostyka, migotanie przedsionków, szpitalny oddział ratunkowy

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