

Kardia Mobile applicability in clinical practice: A comparison of Kardia Mobile and standard 12-lead electrocardiogram records in 100 consecutive patients of a tertiary cardiovascular care center

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Abstract

Background: Mobile devices are gaining a rising number of users in all countries around the globe. Novel solutions to diagnose patients with out-of-hospital onset of arrhythmic symptoms can be easily used to record such events, but the effectiveness of these devices remain unknown.

Methods: In a group of 100 consecutive patients of an academic cardiology care center (mean age 68 ± 14.2 years, males: 66%) a standard 12-lead electrocardiogram (ECG) and a Kardia Mobile (KM) record were registered. Both versions were assessed by three independent groups of physicians.

Results: The analysis of comparisons for standard ECG and KM records showed that the latter is of lower quality ($p < 0.001$). It was non-inferior for detection of atrial fibrillation and atrial flutter, showed weaker rhythm detection in pacemaker stimulation ($p = 0.008$), and was superior in sinus rhythm detection ($p = 0.02$), though. The sensitivity of KM to detect pathological Q-wave was low compared to specificity (20.6% vs. 93.7%, respectively, $p < 0.001$). Basic intervals measured by the KM device, namely PQ, RR, and QT were significantly different (shorter) than those observed in the standard ECG method (160 ms vs. 180 ms [$p < 0.001$], 853 ms vs. 880 ms [$p = 0.03$] and 393 ms vs. 400 ms [$p < 0.001$], respectively).

Conclusions: Initial and indicative value of atrial fibrillation and atrial flutter detection in KM is comparable to results achieved in standard ECG. KM was superior in detection of sinus rhythm than eye-ball evaluation of 12-lead ECG. Though, the PQ and QT intervals were shorter in KM as compared to 12-lead ECG. Clinical value needs to be verified in large studies, though. (Cardiol J XXXX; XX, X: XX–XX)

Key words: arrhythmia, telemedicine, mobile, electrocardiogram, atrial fibrillation

Introduction

Increasing versatility of mobile devices provides an opportunity to implement them in the diagnosis and follow-up of patients with cardiovascular disorders. Kardia Mobile (KM) (AliveCor Inc., San Francisco, CA, USA) is a portable, mo-

bile, connected electrocardiogram (ECG) device available to iOS and Android platform smartphone owners. It consists of a small device with two conducting plates that wirelessly connect with a smartphone, and an application installed on user smartphones. It enables one-lead ECG recording e.g. in cases of the onset of unsettling symptoms

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Received: 12.06.2018

Accepted: 22.11.2018

(palpitations, chest pain, dyspnea, and others). KM was designed to detect periods of atrial fibrillation (AF), which, if confirmed by the Food and Drug Administration (FDA)-approved algorithm, can then be reported to the physician responsible for the follow-up of a given patient. The accessibility of KM has prompted the present evaluation of its usefulness in comparison with 12-lead ECG recordings in assessing the underlying rhythm and basic ECG parameters (PQ, RR, and QT intervals). The aim herein was to establish protocol, according to evidence-based medicine, on whether it has acceptable sensitivity and specificity, and thus, useful and reliable for medical professionals.

Methods

Recruitment

A total of 100 consecutive patients of mean age 68 ± 14.2 , with male subjects constituting 66% of the group of a tertiary cardiovascular care center were included in the study. Baseline characteristics can be found in the Table 1.

The patients were admitted to hospital elective diagnostic and treatment procedures for various cardiac conditions (arrhythmias, conduction disorders, stable coronary disease, hypertension and others). The group consisted of 100 patients consecutively admitted to the documented center between July 1st and July 31st 2015. The inclusion criterium was undergoing regular 12-lead ECG due to standard diagnosis on admission in stable state. All patients who urgently needed medical care were excluded. Upon referral for a 12-lead ECG, each patient was asked to provide informed consent for additional KM ECG recording. All patients agreed to take part in the study. The subjects' clinical state was stable at the time of ECG recording. First a 12-lead ECG was performed and KM ECG was recorded directly after this procedure. Two technicians were responsible for 12-lead ECG measurements and one physician to record KM ECGs.

ECG assessment

Both 12-lead and KM ECG records were analyzed by three independent teams comprised of two cardiologists each. ECG interpretation was carried out according to a previously elaborated online form, consistent with the Polish ECG Description Guidelines [1], which required assessment of the following: ECG quality (good, acceptable, poor), rhythm (sinus rhythm, AF, atrial flutter [AFI] or pacemaker rhythm), presence of pathological Q wave as well as PQ, RR and QT measurements.

Table 1. Patient characteristics.

Baseline demographics	N (%) or mean \pm SD
Gender [male]	66 (66.0%)
Age [years]	68.0 \pm 14.2
Body mass [kg]	80.7 \pm 15.9
Height [m]	1.7 \pm 0.1
Body mass index	28.0 \pm 4.8
Medical history	
Nicotinism (history):	40 (43.5%)
Nicotinism active	9 (9.8%)
Packyears cumulative	33.4 \pm 22.5
Diabetes mellitus	20 (20.4%)
Hypertension	67 (68.4%)
Dyslipidemia	45 (46.4%)
Chronic kidney disease:	32 (32.7%)
CKD G2	2 (2.0%)
CKD G3	23 (23.5%)
CKD G4	7 (7.1%)
CKD G5	1 (1.0%)
Thyroid dysfunction:	18 (18.4%)
Hypothyroidism	9 (9.18%)
Hyperthyroidism	9 (9.18%)
COPD:	6 (6.12%)
Parkinson's disease	1 (1.02%)
Cerebrovascular disease	17 (17.35%)
Peripheral artery disease	12 (12.24%)
Cardiovascular history	
Stable angina (angina pectoris)	46 (47.4%)
ACS (admission)	15 (15.31%)
Myocardial infarction (history)	25 (25.5%)
PCI/CABG (history)	27 (27.6%)
Cardiac surgery (other than CABG)	3 (3.1%)
Heart failure:	43 (43.9%)
NYHA II	28 (28.6%)
NYHA III	9 (9.2%)
NYHA IV	6 (6.1%)
LVEF [%]	49 \pm 14
Atrial fibrillation:	34 (34.7%)
Paroxysmal	16 (16.33%)
Persistent	4 (4.1%)
Chronic	14 (14.3%)
CIED implanted	34 (34.7%)
Pacemaker:	24 (24.5%)
AAI	2 (2.0%)
VVI	7 (7.1%)
DDD	15 (15.3%)
ICD	5 (5.1%)
CRT	5 (5.1%)
Ablation	6 (6.1%)

ACS — acute coronary syndrome at the time of admission; CABG — coronary artery bypass grafting; CIED — cardiac implantable electronic device; CKD — chronic kidney disease (G2-G5 — CKD stages); COPD — chronic obstructive pulmonary disease; CRT — cardiac resynchronization therapy device; ICD — implantable cardioverter-defibrillator; LVEF — left ventricular ejection fraction measured during the hospitalization; NYHA — New York Heart Association functional classification; PCI — percutaneous coronary intervention

In order to avoid cognitive and measurement bias, all KM ECG records were printed out in 1:1 ratio and assessed in paper-based form. A database comprised of answers provided by the teams. The study protocol and informed consent form was approved by the local bioethics committee.

Statistical analysis

The data were analyzed using adequate statistical tests with the aim of looking for agreement between the two diagnostic methods. In case of disagreement, ECGs were reevaluated by a data committee consisting of three ECG experts, who then provided a final report.

Continuous variables were expressed as mean \pm standard deviation, and categorical variables were stored as number of cases or percentage. The Student t-test was used for comparison of continuous variables, while categorical variables were compared using the χ^2 test or the Fisher exact test, as appropriate among the groups. All tests were two-tailed and a p-value of < 0.05 was considered significant. All statistical analyses were performed using MedCalc 17.6 software (MedCalc Software, Ostend, Belgium).

Results

A total of 99 KM ECGs and 100 12-lead ECGs were analyzed. In 1 patient, KM recording was not possible due to an underlying condition (tremors secondary to Parkinson's disease). Comparison of KM ECGs and 12-lead ECGs revealed that the overall quality of the latter was superior (6 vs. 0 — poor, 41 vs. 1 — acceptable, 52 vs. 99 — good, $p < 0.001$). Effectiveness evaluation of KM with regards to rhythm determination was performed by comparing it with 12-lead ECG interpretation. Sensitivity and specificity were tested for the following rhythms:

- sinus rhythm — 98.4% and 74.2% ($p = 0.02$);
- atrial fibrillation — 92.8% and 100% ($p = 0.32$);
- atrial flutter — 100% and 100% (p value not applicable);
- pacemaker rhythm — 53.6% and 100% ($p = 0.008$).

Sensitivity and specificity of KM for pathological Q wave detection was 20.6% and 93.7%, respectively ($p < 0.001$). Mean PQ, RR and QT measurements in KM ECGs and 12-lead ECGs were as follows:

- PQ — 160 ms vs. 180 ms ($p < 0.001$);
- RR — 853 ms vs. 880 ms ($p = 0.03$);
- QT — 393 ms vs. 400 ms ($p < 0.001$).

Discussion

Principal results

With regard to the fact that many life-threatening arrhythmias are non-sustained and occur infrequently, it is justified to search for relatively cheap solutions giving the patient a chance to record an ECG at the onset of unsettling symptoms. Apart from the conventional, clinically-approved methods, recent years have brought a few breakthroughs regarding smartphone-dependent devices enabling such a procedure. Versatility of mobile phones and general access to the Internet has created the possibility to remotely provide the practitioners with information of possible clinical significance, and thus enable them to react in case of an emergency.

Although reliability of such solutions has not yet been thoroughly investigated in randomized clinical trials, some data suggests good compliance and improved patient management. The most obvious application of smartphone-compatible ECG devices that has been brought up is the possibility of screening for patients with paroxysmal AF especially for those who need antithrombotic therapy [2–4].

The present study confirmed that KM, despite its simplicity, provides a record of sufficient quality to diagnose periods of AF. KM has also proven to be reliable while supervising QTc period in patients on dofetilide [5] and in pediatric patients with various arrhythmic disorders [6]. In contrast study revealed that QT measurements in KM ECGs are shorter on average by an average of 7 ms, whereas PQ intervals tend to be shorter by as much as 20 ms (more than a 10% difference compared to the conventional ECG). This phenomenon has not as yet been described in the literature available and may potentially mimic arrhythmia, e.g. pre-excitation syndrome in extreme cases or conceal atrioventricular blocks, but this tendency was not confirmed in this study.

Extremely high sensitivity compared to relatively lower specificity of KM detection of sinus rhythm is a characteristic that potentially was previously heralded by Narasimha et al. [7] who reported that nearly one third of patients declaring alarming symptoms while the ECG was assessed normal by the algorithm. One in four patients in our population ascribed by KM to sinus rhythm category should in fact have been described differently. Based on the construction of the KM device, it is not surprising that it has low sensitivity in detecting pacemaker rhythm, this supports Desteghe et al. [8] findings and recommendations.

According to available research, this is the first study to investigate and compare selected parameters in KM records and conventional 12-lead ECGs. New studies, currently with protocols available [9, 10] will shortly verify the usefulness of the method and the present findings.

New studies being currently conducted can be also groundbreaking in respect to ischemia detection, and thus rapid detection of myocardial infarction in symptomatic patients [11, 12].

Limitations of the study

Despite the prospective design of this study there are some important limitations. Firstly, this is a single center study. Secondly, ECG interpretation is subjective and thus there may have been certain discrepancies. There were only three teams analyzing the records and assessments of ECG quality were subjective according to their expertise which may somehow bias this study. Furthermore, a group of stable subjects were analyzed, which made it impossible to verify KM applicability for cases of acute cardiac events. Finally, the number of patients included in the study is relatively small and a larger group would enable more reliable conclusions.

Comparison with prior work

The onset of certain clinical symptoms such as syncope, palpitations and chest pain may indicate an underlying cardiovascular etiology. Among others, paroxysmal arrhythmias are a potential culprit. Long-term ECG monitoring has proven to be an important measure in diagnosing elusive periods of AF, supraventricular arrhythmias and ventricular arrhythmias [4, 13, 14]. To confirm the relation between the symptoms and arrhythmias, the European Society of Cardiology (ESC) guidelines recommend continuous or intermittent ambulatory ECG monitoring. This procedure also makes it possible to verify if the arrhythmic events are secondary to an ischemic heart disease [13, 15]. An appropriate, long-term ECG screening may warn the clinician of a series of potential adverse clinical events. Sudden cardiac death (SCD), one of the leading direct causes of mortality in the western world, whether secondary to ischemic heart disease or to congenital malfunctioning of the electrical conductance system of the heart, could be in many cases prevented by pharmacotherapy or implantable cardioverter-defibrillator (ICD) implantation [13]. Furthermore, paroxysmal AF is a proven risk factor for stroke, another important cause of mortality and disability in developed

societies [16–18]. Up until recently it has been estimated that even 20–40% of ischemic strokes remain idiopathic, but some clinical trials have shown a higher prevalence of paroxysmal AF detectable on a long-term ECG analysis in comparison with a standard 24 h Holter monitoring in this group of patients [19–22]. The KM system was assessed in a study conducted by Halcox et al. [22] in a randomized control trial (REHEARSE-AF study) in a group of patients older than 65 years with an elevated risk of cerebral thromboembolism ($\text{CHA}_2\text{DS}_2\text{-VASc}$ score ≥ 2). The results presented a proactive approach of regular weekly iECG monitoring with the use of KM system may not only be preventive in a medical sense, but also cost-effective in AF detection. This observation opens the discussion over the possibility of a more routine implementation of KM in clinical practice to remotely monitor QT periods.

Rapid diagnosis of AF can prevent cerebral thromboembolic events, and according to recent publication by Rattanawong et al. [23], it can also reduce overall SCD rate. As AF has been reported to provide higher risk of SCD than other associated factors, such as previous myocardial infarction, heart failure or coronary artery disease, preventive measures using quick and easy diagnostic tools such as KM could be undertaken to avoid unnecessary hospitalizations and reduce mortality in this subgroup.

Another important feature of every telemonitoring device that needs to be discussed is its availability. Surveys gathered from subjects enrolled in the SPEAR trial showed a high level of satisfaction and willingness to continue implementing KM ECG testing in the future [4]. Furthermore, all the patients that took part in the present study showed a positive attitude towards KM as well. Such attitudes have also been observed in a recent study by Halcox et al. [22] with patients of advanced age being enthusiastic about such methods.

Patients can be subjected to more personalized care due to the possibility of remote transmission of their ECG records to their physician. In recent years a proactive attitude was positively tested by Klein-Wiele et al. [24], who provided data of successful cooperation between patients, general practitioners and cardiologists. The KM device could be part of a cross-sector telemetric network with rapid response to a patients' worsening state of health by qualified professionals.

Apart from clinical reliability, it also needs to be verified whether smartphone-based ECG controls are not an excessive financial burden for the

health care system. Initial data suggest that there is no long-term difference in cost-efficiency between conventional monitoring and smartphone supervision, while patient self-awareness seems to benefit from remote self-controls [25]. Nevertheless, this is still a matter of debate as the information at hand are scarce.

Kardia Mobile aside, smartphone-based ECG device market constantly expands, offering new solutions for mobile phones with Android operating systems [26], or enabling a context-aware ECG monitoring [27]. Moreover, specifically oriented systems such as Remote Cardio Control (RCC) designed to diagnose signs of myocardial infarction, continue to be created [28]. It can be conceived that in the following years devices encompassing those standards of diagnostic procedures will become a part of routine approach.

It should be also noted that the number of reports considering mobile ECG record is rising. Apart from arrhythmias considered in this study, there is a possibility to record and diagnose other heart rhythm disturbances, including atrioventricular block [29]. This poses even greater area for implementation of these devices into general practitioner practice.

Conclusions

The usefulness of KM is unquestionable in the prevention and rapid detection of AF and AFls in a standard comparable to the conventional method, namely 12-lead ECG. Applying this novel device to routine diagnostics is rather preemptive, as discrepancies in sensitivity of the algorithm may present a possible misinterpretation of the outcome. The clinical need for an easy-to-use mobile ECG is immense, however it is concluded herein, that further studies are needed to confirm diagnostic value.

Acknowledgements

The research was performed within the statutory fund of the First Chair and Department of Cardiology of the Medical University of Warsaw and received no external funding.

The authors would like to acknowledge the 9 physicians who assessed ECG recordings during the study and the technicians for recording the ECGs and thus, for making the study possible. Many thanks to the participants for their involvement in the study.

Conflict of interest: Lukasz Koltowski and Pawel Balsam are consultants to Medtronic, and Abbott. Lukasz Koltowski is a consultant to Boston Scientific, and Shareholder of SmartMedics Ltd.

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