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Original Article

Utilization and Clinical Feasibility of a Handheld Remote Electrocardiography Recording Device in Cardiac Arrhythmias and Atrial Fibrillation: A Pilot Study

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SUMMARY

Background: Remote cardiac rhythm monitoring and diagnosis has been well incorporated in the telehealth service model. The prevalence and incidence of abnormal ventricular beats, based on utilizing a symptom-driven portable remote electrocardiography (ECG) device, remains less well explored.

Methods: We studied 339 consecutive study participants, which included 192 individuals from outpatient clinics who were enrolled via a symptom-driven protocol; 147 participated in a heart rhythm screening program. All participants underwent 24-hour data transfer using a handheld portable electrocardiogram (ECG) device (DailyCare Biomedical Inc., Taoyuan City, Taiwan) with automatic ECG wavelet data extraction software (InstantCheck, version 4.0; DailyCare Biomedical Inc., Taoyuan City, Taiwan).

Results: Among 1152 data transferred (98.4% success rate), we noticed 32.5% of the study participants had evidence of cardiac arrhythmias with permanent or paroxysmal atrial fibrillation (AF) constituting 50.9% of arrhythmias. Individuals with a history of heart failure (odds ratio [OR], 3.37; 95% confidence interval [CI], 1.69–6.74), diabetes (OR, 3.03; 95% CI, 1.67–5.49), and cardiovascular disease (OR, 3.71; 95% CI, 2.05–6.7) had a higher AF risk. Both populations had an age-related increase in AF, even in multivariate models (OR, 1.72; 95% CI, 1.31–2.24 per +decade).

Conclusion: The handheld ECG device shows clinical feasibility with high rate for AF detection with a similar trend toward a higher prevalence with aging from different settings. These data suggested that portable ECG device *via* remote care system may aid in clinical diagnosis, therapeutic interventions, or patient referral for cardiac arrhythmias.

1. Introduction

The standard 12-lead electrocardiogram (ECG) has been used clinically for more than 10 decades for the diagnosis of myocardial ischemia or cardiac arrhythmias[1]. Conventional 12-lead ECG on the body surface may provide useful information with more detailed electrical activity, although simplified bipolar connections of limb leads can be easily reproduced, based on Einthoven's triangle[2]. A bipolar device can also theoretically create multiple combinations in clinical use, which include augmented limb leads, which are useful and feasible[3].

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In the recent era, increasingly more elderly populations in developed countries are experiencing one or more cardiovascular disease[4]. Current ambulatory ECG monitoring systems must be performed on site with a 12-lead patch and take considerable time and effort for subsequent diagnostic interpretation[1]. A portable ECG recorder with rapid data transmission and real time assessment to report sporadic or chronic cardiac events (e.g., tachyarrhythmias featured by a rapid and irregular cardiac cycle length) may be clinically feasible[5–7], whereas efforts to broaden its clinical use and value via a standardized protocol may be worthwhile. To meet the requirement and demand for potential rapidly growing populations and a large amount of data transfer for clinical interpretation, a remote monitoring or wireless data transmission of rate and rhythm profiles to the specialist based on more advanced technology may allow early intervention that can prevent clinical events[8].

Atrial fibrillation (AF), an emerging cardiac arrhythmia in an elderly society, has recently been a primary target for the use of such device implementation, with the aim of preventive stroke treatment and heart rate control because of its association with worse clinical outcomes and stroke[9–12]. In our current work, we examined the data by using a handheld palm-sized ECG device for clinical use, and explored data precision and its clinical correlation and efficacy in our pilot study.

2. Materials and methods

From June 2012 to December 2014, we consecutively enrolled study participants from outpatient clinics who underwent population screening programs via our remote care center in a tertiary medical center in Northern Taiwan. In total, 339 consecutive participants were collected. Study participants without baseline demographics were excluded ($n = 42$). We examined several ECG parameters using a handheld ECG device, and further analyzed its feasibility, frequency of use, and clinical associations among the study participants.

2.1. Study protocols and study participant enrollment

We adopted two clinical protocols in this study: (1) the long-duration protocol, which is a symptom-driven clinical protocol implemented in accordance with the institution outpatient visits ($n = 192$) and (2) the short-duration protocol, which is rhythm screening for a generally elderly population ($n = 147$, 75%, >65 years old)], which supposedly has a higher risk of cardiac arrhythmias prevalence (e.g., AF in a community-dwelling population, or for screening purposes in an elderly population). For the long-duration symptom-driven clinical protocol, we confirmed a negative 24-hour Holter or multiple body surface 12-lead ECG study before using the handheld ECG device. This protocol aimed to test the feasibility of using the handheld ECG device for certain symptom-driven cardiac arrhythmias on a monthly basis. For the screening program, we enrolled individuals who were willing to have their baseline heart rhythm recorded and studied (for continuous 30 seconds) during each public educative activity for the device from June 2012 to December 2014. The aim was to identify the prevalence of AF and other cardiac arrhythmias in a cross-sectional survey. This study was approved by the institutional review board committee, Taipei, Taiwan (approval number 15MMHIS018) for data analysis and conduction.

2.2. Electrocardiography data acquisition and recording

A portable, handheld ECG device that had a large liquid crystal display panel with validated signal processing was used uniformly in this study design and may render convenient data recording and transportation (Figure 1). The body R-wave related to the ventricular depolarization and mechanical contraction was defined by the most significant deflection wavelet and feature extraction from ECG recordings. Routine reports for users and patients will be made for each single data transfer, and will primarily focus on abnormal findings, if any. Software-based automatic quantification of several output ECG wavelet parameters such as heart rate (HR), PR interval, QRS duration, ST segment, QT, and corrected QT interval were all displayed by the software by DailyCare Biomedical Inc. (InstantCheck, ReadMyHeart Handheld ECG Recorder V2.0; Taoyuan City, Taiwan; Figure 2). Participants were referred back to clinics for a complete survey and next stage management if they had a suspected arrhythmia underlying the ECG data such as AF, flutter, widened QRS complex, premature atrial contractions, premature ventricular contractions, paroxysmal supraventricular tachycardia or atrioventricular block that may necessitate pharmacological or medical interventions. The nursing assistant in charge of the patient had monthly phone-based clinical follow up, based on the patient's clinical conditions or symptoms, medication use, and schedule for next visit.

2.3. Statistical analysis

In our study, continuous data were expressed as the mean and standard deviation and categorical information was expressed as the frequency and proportion of prevalence. These two sets of data were then compared by the Chi-square test or Fisher's exact test, as appropriate. Baseline continuous data were compared by the Student t test between groups. Trend analysis was used for continuous data across ordered categories (e.g., age groups). Univariate and multivariate models were conducted to examine the role of age in predicting AF identification, and baseline clinical covariates such as sex distribution, medical history, and frequency of data transfer were considered confounding factors.

All data were analyzed using a commercial software STATA 9 package (Stata Corporation, College Station, TX, USA). The significance of p level (α-value) for all analysis was two-sided, and a value of less than 0.05 was considered statistically significant.

3. Results

3.1. Baseline demographics

Table 1 displays the baseline demographics of the study participants collectively and in the different study protocols. Our table shows that, among all symptom-driven study participants ($n = 192$; mean age, 70.6 ± 18.3 years; 42% female), individuals tended to be younger and tended to have a lower prevalence of diabetes and cardiovascular diseases, compared to the screening population ($n = 147$; mean age, 75.8 ± 17.2; 55.8% female). The overall mean age of all study participants was 72.9 ± 18 years ($n = 339$, 48.1% female), and 44% of participants had hypertension; 26.3% had diabetes, 13.6% had heart failure, and 33% had cardiovascular diseases. The age-stratified differences in service months, total times of data transfer and prevalence of AF or associated cardiac arrhythmias based on study protocols were further displayed (Tables 2 and 3).

3.2. Evaluation of the clinical efficacy and outcomes

Among all study participants, we observed that 110 (32.5%) study participants had evidence of cardiac arrhythmias of all types and 50.9% of the arrhythmias were AF. Participants with a known medical history of heart failure (OR, 3.37; 95% CI, 1.69–6.74; $p = 0.001$), diabetes (OR, 3.03; 95% CI, 1.67 –5.49), and