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Research Article

Artificial Intelligence-based Remote Electrocardiogram Monitoring Improves the Diagnosis of Arrhythmias and Reduces Morbidity Caused by Fatal Arrhythmias

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- Artificial intelligence (AI)
- Arrhythmia
- Electrocardiogram (ECG) monitoring
- i-Holter

Abstract

Background: Remote ECG monitoring can provide valuable information for diagnosis in patients with cardiovascular diseases (CVD), but manually studying large amounts of ECG data can be tedious and time-consuming. The aim of this study was to evaluate the values of AI-based ECG monitoring and data analysis in clinical practice.

Methods: Between January 2018 and October 2019, a total of 16,408 patients evaluated for suspected CVD at Hefei Hi-Tech Cardiovascular Hospital and its associated community hospitals/clinics underwent i-Holter, a heart remote mobile monitoring device from Yocaly Information Science & Technology Co., Ltd, Lepu Medical, China. The i-Holter monitor is a remote, AI-based, real-time heart monitoring system with built-in pre-warning functions. The ECG data obtained from remote monitoring was screened and analyzed by this AI-based ECG analysis system and the final diagnosis was confirmed by ECG specialists. The number of pre-warning alerts, classification of arrhythmias, subsequent patient management, and outcomes were also analyzed.

Results: Of the 16,408 patients, 68.3% were detected to have different arrhythmias. The most common is supraventricular arrhythmia (40.7%), followed by ventricular arrhythmia (30.2%), ST-T segmental alternation (20.5%), cardiac pause (3.7%), atrial-ventricular blockage (2.5%), and branch blockage (2.2%). A total of 3,351 patients were alerted due to reaching critical ECG values and 8,874 phone calls were taken for the alerts. Among the alerts, 37.1% were supraventricular tachycardia, 36.4% were ST-T alternation, following by atrial flutter/atrial fibrillation (7.4%), ventricular tachycardia (6.4%), sinus tachycardia (6.1%), III° A-V block (3.3%), cardiac pause (1.98%), and ventricular flutter/fibrillation (0.03%). 1,229 patients (36.7%) with alerts needed promote management and obtained good outcomes.

Conclusion: AI-based remote monitoring can manage high volume ECG data, provide prompt diagnosis with high accuracy, initiate alert timely if critical values are reached. Patients in fatal situations can be managed in a timely manner, improving patient prognosis and leading to reduced mortality.

BACKGROUND

Cardiovascular disorders (CVD) are the leading cause of death in China, being the cause of 40% of deaths in the Chinese population according to the recent data from National Center for Cardiovascular Diseases (1). Cardiac arrhythmias are remarkably common in patients with CVD, some are life-threatening, but they routinely go undiagnosed because they are often unpredictable, transient, and asymptomatic (2,3). Prompt diagnosis of these life-threatening arrhythmias in symptomatic/asymptomatic patients and initiation of timely treatment can substantially reduce the morbidity and mortality rates associated with these arrhythmias. However, this is usually limited by several factors in clinical practice. Electrocardiogram (ECG) recordings were major tool for the diagnosis of cardiac arrhythmias and widely used by clinicians as a routine modality in hospitals, as it captures the propagation of the cardiac electrical signal from the body's surface. Many cardiac structural or electrophysiological abnormalities have a signature on the ECG, therefore ECG analysis can be a crucial first step to help diagnose, understand, and predict cardiovascular disorders. However, a growing body of evidence has shown that the morbidity and mortality rates associated with subclinical arrhythmias are often missed by ECG or conventional 24-hour monitors (Holter) because the occurrence of arrhythmia is usually transient and unpredictive (3, 4). Also, manually studying large amounts of ECGs or Holter data can be tedious and time-consuming; there is a long study-curve to give an accurate ECG

diagnosis. Furthermore, conventional 24-hour monitors (Holter) are retrospective analysis, which is unable to give a pre-warning when life-threatening arrhythmia is occurring. Therefore, the need for a powerful method or tool that is able to monitor patients in real-time, analyze high volume of ECG data, cover long-period ECG changes, and give prompt and accurate diagnosis becomes urgent. With the progress of science and technology, automatic analysis and diagnosis systems based on electrocardiogram (ECG) signals, such as artificial intelligence (AI), have been extensively investigated in the detection and diagnosis of cardiac arrhythmias (5, 6). Studies have shown that the use of an AI-assistant ECG automatic analysis and diagnosis system not only reduces the workload of doctors but also improves diagnostic efficiency and accuracy (5, 6, 14, 16-18).

Artificial intelligence (AI) is a field of computer science that aims to mimic human thought processes, learning capacity, and storage of knowledge. This computational technique, and more specifically, machine-learning technique, is a powerful tool for classification, clustering and simulation, and they have recently been applied to address the analysis of medical data, especially ECG data (14-19). In this study, we evaluated the clinical value of an AI-based remote monitoring system, i-Holter, in investigating the epidemiology of arrhythmia, helping clinical diagnosis of ECGs, and assisting doctor's decision of treatment in patients with suspicious CVD. Our results indicated that use of this AI-based remote monitoring can provide prompt diagnosis with high accuracy, give timely alerts, and help initiate prompt treatment for severe patients.

MATERIALS AND METHODS

Patients

Consecutive patients who went to the Hefei Hi-Tech Cardiovascular Hospital and its affiliated hospitals/clinics from January 2018 to October 2019 for the evaluation of associated symptoms (such as palpitation, chest pain or discomfort) were included. Inclusion criteria included any age able to comply with continuous ECG monitoring and capable of providing informed consent by themselves or by their parents. The patients' general clinical information, including age, gender, height, weight, blood pressure, heart rate, past medical history, and personal habits (e.g., smoking, drinking) were collected. Written informed consent was obtained from all patients (or their parents if <18 years old) before enrollment. The study protocol was approved by the Ethics Committee of Hefei Hi-Tech Cardiovascular Hospital and was conducted in accordance with the ethical guidelines of the 1975 Declaration of Helsinki.

The Recordings, Monitoring and Analyzing of Remote ECG Data

i-Holter is a remote, mobile heart-monitoring system and heart real-time monitoring pre-warning device from Yocaly Information Science & Technology Co., Ltd, Lepu Medical, that has been approved by the US FDA and the EU CE certification in China. It is a three-channel Holter ECG system which can store a continuous and simultaneous recording of three-lead ECG for up to one week upon battery change (Figure 1). Patients were asked to perform their usual daily activities while wearing the

Figure 1 i-Holter (Lepu's AI- ECG platform ECG diagnostic system) has been approved by the US FDA and the EU CE certification in China.

device. The ECG data was transferred automatically or manually to the Data Analysis Center of Yocally Information Science & Technology, Co., Ltd (Jinan, Shandong Province, China). An AI-based ECG analysis system would perform the first-step screening and give a primary diagnosis, then the diagnosis would be confirmed by ECG specialists. If any conflict is present, three specialists would discuss and give a consistent diagnosis.

Alerts Initiation and Management

The alert value is set according to the following standards (**Table 1**). Any patient who meets the alert standards will be issued a pre-warning signal by the AI analysis system. The back-end ECG analysis expert will review it at once and a phone call will be given to the primary care physicians (PCP) or patient immediately. The PCP will determine if the patients need further management, including symptomatic management, going to emergency room (ER), or receiving other interventions.

RESULTS

Study population

16,408 (6 - 95 years old, average 52.3±38.4 years) were included in this study. 51.2% of them were male, 58.2% had hypertension, 30.6% had diabetes, 26.2% had active CAD, and 13.4% had history of stroke or transient ischemic attack. 69.7% patients are from affiliated hospitals or clinics (Level II and below hospital) of Hefei Hi-Tech Cardiovascular Hospitals, of which 7,536 (45.9%) were inpatient and 8,872 were outpatient. The clinical characteristics of the overall study population are listed in (Table 2).

ECG Data Analysis

The ECG data was analyzed with AI-based ECG analysis system, then confirmed by the back-end ECG analysis experts. The results showed that 78.3% patients were detected with differing arrhythmias. Among them, atrial/supraventricular arrhythmia was the most common arrhythmia, accounting for 40.7% of the group, followed by ventricular arrhythmia (30.2%), and ST-T changes (20.5%) (Figure 2). We also analyzed the gender differences of different arrhythmias between men and women. In general, there is little gender difference in various arrhythmias in different age groups, except for the ST-T segment changes in

Table 1: The ECG Standards for Alert Initiation.		
Severe Arrhythmia	Tachycardia	1. Ventricular flutter/Fibrilation 2. Ventricular/ wide QRS tachycardia, HR≥150bpm, last ≥ 30s or ≤ 30s but HR ≥ 180bpm 3. Torsades De Pointes, Polymorphic VT, Bidirectional VT 4. PSVT, HR ≥ 200bpm 5. Atrial fibrillation accompanied with W-P-W syndrome, HR ≥ 200bpm
	Bradycardia	6. Severe bradycardia, such as third- degree heart block, HR ≤ 35bpm 7. R-R interval ≥ 3s
Suspected ACS		8. New horizontal or down-sloping ST segment depression ≥ 0.5 mm at the J-point in ≥ 2 contiguous leads, or old depression becomes worse. 9. St segment depression ≥ 0.2mV at first time or become worse if ST depression present before 10. ECG changes indicating recurrence of AMI
Other Emergency Situations		11. ECG appearance of severe hyperkalemia/hypokalemia 12. Severe bradycardia, such as third-degree heart block, HR ≤ 35bpm 13. Long QT interval (≥ 480ms) 14. Premature ventricular contraction with R on T phenomena. 15. Significant T wave electric alternation

Table 2: Patient's Demographic and Clinical Characteristics.	
Age (years)	52.3 ± 38.4
Gender (%, male vs female)	51.2% vs 48.8%
Weight (Kg)	42.5 ± 20.6
Height (cm)	158.2 ± 19.5
Systolic BP (mmHg)	150.66 ± 19.63
Diastolic BP (mmHg)	83.78 ± 17.59
HR (bpm)	76.42 ± 20.15
Hypertension (%)	58.2
Diabetes (%)	30.6
Hyperlipidemia (%)	40.6
Active CHD (%)	26.2
Stroke or TIA (%)	13.4
COPD (%)	15.5
Renal insufficiency (%)	19.8
Smoking (%)	20.8
Alcohol (%)	19.9

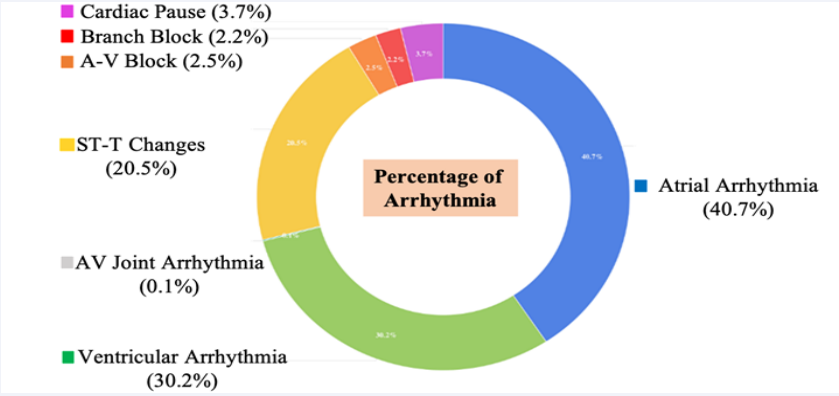

Figure 2 The Classification of Cardiac Arrhythmias Detected with i-Holter.

the 20-29 age group, which was seen more in female than in male (data not shown).

Alert Initiation

Alerts were initiated in 3,351 patients due to meeting the pre-warning standards. Among them, 52.7% were men and a total of 8,874 calls were made for the warning. The classification of initiating alert is shown in the table (Table 3). Supraventricular tachycardia is the most common causes for alert initiation, accounting for 43.4% of the cases, followed by ST segment changes (27.5%), atrial flutter/fibrillation (9.6%), atrioventricular block (6.0%), and severe bradycardia (5.3%).

Table 3: The Cardiac Arrhythmias Initiating Alerts (n = 3351).	
Supraventricular Arrhythmias	1454 (43.4%)
ST Segment changes	921 (27.5%)
Artial flutter/ fibrillation	322 (9.6%)
High degree A-V block	201 (6.0%)
Severe Bradycardia	175 (5.2%)
Ventricular Tachycardia	174 (5.2%)
Cardiac Pause	54 (1.6%)
Long QT interval (≥ 480ms)	44 (1.3%)
Ventricular flutter/ Fibrillation	6 (0.18%)

Among all alerts, 1,229 patients (36.7%) received urgent management, including medical observation and management, transferring to emergency room, receiving early intervention (e.g pacemaker implantation, coronary angiography/PCI intervention, radiofrequency ablation, electric defibrillation, etc.) (Figure 3). All patients have achieved good outcome except for four sudden deaths. A representative case initiating alerts due to ST-T elevation (acute myocardial infarction) is shown on (Figure 4).

DISCUSSION

Remote real-time ECG monitoring is a technology that has developed rapidly in the medical field in recent years. Studies have shown that it has great advantages in health service improvement, disease diagnosis, and patient transfer (7, 8). ECG remote monitoring can be used for many diseases, such as patients with heart device implantation, chronic lung disease, diabetes, and particularly the patients with cardiovascular and cerebrovascular diseases (7-11). Rapid and accurate alerts during ECG monitoring in patients with life-threatening situations, such as acute myocardial infarction, fatal arrhythmias, etc., are very important in saving the patient's life and improving prognosis through initiating the therapeutic process in a timely manner. However, traditional ECG monitoring equipment, such as the Holter detector, is a retrospective diagnosis (4, 12); the diagnostic report usually comes out 24 hours later, and the positive rate of diagnosis is only 5-18% (12-14), therefore it cannot provide accurate, early alerts of critical events in time. Recent studies have shown that AI-based ECG analysis has several advantages when compared to traditional Holter monitoring:

1) the diagnostic speed of arrhythmias by AI is significantly higher than that by specialists,

2) it can analyze high-volume ECG data in a short period of time, and

3) the accuracy of diagnosis by AI is equal to or even higher than that by professionals (6, 14, 15).

In this study, we analyzed the data from an AI-based ECG remote monitoring equipment (i-Holter). Among 16,408 patients, 3,350 patients were alerted due to critical ECG values and subsequently, 8,874 phone calls were made for the alerts. All fatal situations were managed properly (e.g., pacemaker implantation, stents for AMI, defibrillation for fatal ventricular arrhythmias, and medical treatment for supraventricular tachycardia). Our results suggested that AI-based ECG remote monitoring can monitor patients large-scale, analyze high volumes of data, detect and diagnose the arrhythmias in a rapid and accurate manner, and initiate the alert for fatal arrhythmias in time, therefore saving lives and reducing mortality.

AI-ECG technology can effectively process interference signals and reduce the impact of interference on the accuracy of image judgment, support 72 special ECG diagnosis types with more detailed judgment, high accuracy and stability, and it will not suffer from quality degradation due to long working hours as well (6, 16-18). The average time for traditional manual analysis of a 24-hour Holter electrocardiogram is 20-30 minutes, while the AI-ECG algorithm analysis time for a 24-hour Holter electrocardiogram is about 1-5 minutes (15). Fast speed and high accuracy rates can greatly reduce the overall analysis time. This i-Holter AI-based ECG analysis system comes from nearly 30 million accurately labeled data fragments of 300,000 patients. Using 1 million independent test data for testing, the accuracy rate can reach 95.2%. For some special arrhythmias, such as atrial fibrillation, the positive prediction rate can reach 99%, which is significantly higher than traditional analysis (~70%) (15). The analysis and early warnings can automatically track the dynamic change trend of patient data according to the different physical conditions of each patient, and deduce the personalized alarm threshold, which greatly improves the effective early warning rate and reduces false alarms (15).

In conclusion, i-Holter is a reliable real-time ECG remote

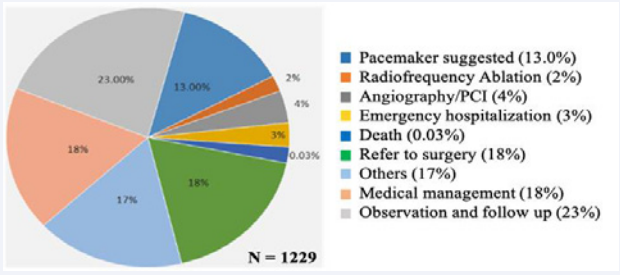

Figure 3 The Management of Patients with Alerts Initiation.

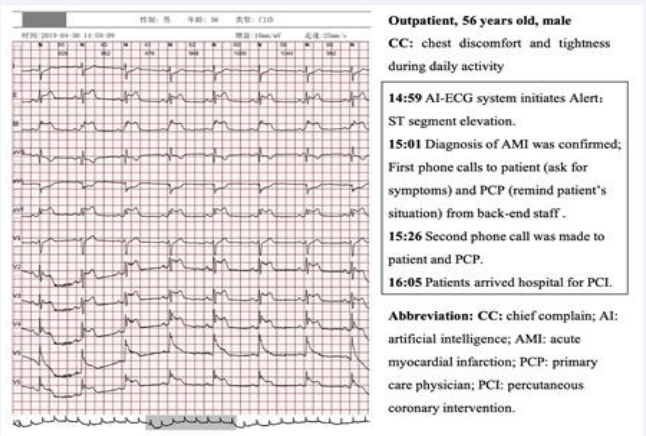

Figure 4 A representative case of i-Holter monitoring, alert initiation and patient management.

monitoring equipment that can provide rapid early warning and accurate diagnosis, and help clinicians manage patients efficiently, thus improving patients' prognosis and reducing mortality. This AI-based ECG monitoring system can provide a low-cost and effective solution to the challenges of high-volume ECG data analysis and the need for a rapid and accurate diagnosis.

CONFLICT OF INTERESTS STATEMENT

The authors declare no conflict or competing interest with respect to the authorship and publication of this article. The authors have no financial relationship with any organization.

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