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Latest Developments in Wearable Devices for the Screening and Management of Atrial Fibrillation

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【Abstract】 Atrial fibrillation（AF） is one of the two major bastions that need to be tackled in cardiovascular disease field. The rates of AF screening and standardized management are low, which are mainly due to the limitation of "no onset symptoms of AF at the time of detection and no detection at the time of having onset symptoms of AF" in the traditional screening. Wearable devices are technologies that can facilitate early detection and scientific management of AF, whose applicability, sensitivity and specificity in the screening AF have been gradually verified. We reviewed the latest developments in wearable devices for AF screening and management, including epidemiological characteristics of AF, and current application, applicable limitations and prospect of wearable devices, providing a theoretical basis for the use of wearable devices in the screening and management of AF.

【Key words】 Atrial fibrillation；Wearable devices；Internet of things；Screening；Management

Atrial fibrillation（AF） is an important public health problem with a high prevalence and great harm, affecting more than 37 million people worldwide[1-2]. Atrial fibrillation is one of the main risk factors for thromboembolic events such as stroke, and early screening of atrial fibrillation is particularly important for improving patient outcomes[3]. The traditional Holter ECG, also known as Holter monitoring ECG, has the limitations of difficulty in identifying asymptomatic AF. Studies have suggested that if the accuracy of screening technology can be improved, the detection rate of atrial fibrillation is expected to increase by 2.3 times[4]. In recent years, wearable devices have many advantages of non-invasive detection, stable performance, safety and reliability, etc. They are gradually applied in health monitoring, disease treatment, remote management and other fields, which is of great significance for AF screening and management. This article aims to review the progress of wearable devices in the screening and management of AF, so as to provide a theoretical basis for the screening and management of wearable devices for AF.

1 Epidemiological characteristics and harm of AF

AF is a supraventricular tachyarrhythmia associated with uncoordinated atrial electrical excitation and ineffective atrial contraction. From 2014 to 2015, data from China National Stroke Screening and Prevention Program (CNSSPP) showed that the standardized prevalence of AF in adults aged 40 years old and above was 2.31%, aged 40-49 years old was 1.13%, increased to 4.57% in adults aged 70 years old and above, the prevalence of AF in women was higher than men (2.72% vs 1.90%), in rural residents was higher than urban residents (2.42% versus 2.219%)[5-6]. For the three generations, participants in the Framingham heart study results showed that one in three European people of 55 years were with AF[7].

Atrial fibrillation not only affects the quality of life of patients, but also easily causes serious complications such as heart failure and stroke, and increases the mortality rate[3]. In the 2002-2012 Oxford vascular study, a prospective survey of vascular events in 92 728 Oxford residents (Oxford Vascular Study) showed that 43.9% of fatal or disabling stroke were associated with atrial fibrillation[8]. The results of a prospective study of more than 15, 000 emergency AF patients in 47 countries showed that the proportion of emergency AF patients dying from stroke was 8%[9]. According to the fourth National Health Service Survey report in China, the treatment cost of stroke caused by atrial fibrillation reaches over 4.9 billion yuan per year[10].

2 AF screening

2.1 Limitations of traditional AF screening AF is only a small proportion of all AF patients. The early episodes of AF are mostly paroxysmal, with short duration and low seizure frequency. It is difficult to preserve the conventional ECG in time[11]; the dynamic electrocardiogram can only observe the internal electrical changes from 24 to 48 h, and the ability to detect atrial fibrillation is limited[12]; although the implantable electronic devices can realize real-time ECG monitoring, it is difficult to be widely promoted and applied[13] due to the limitation of its invasive and high cost. The results of the national epidemiological survey of AF participated by our team showed that patient aged 45-year-old and above with AF was unaware of the presence of AF before receiving ECG screening[14]. Data from the US Commercial and Medicare Administrative Claims Database showed that approximately 15% of patients with AF are currently undiagnosed and 75% of them may need to receive anticoagulation therapy[15]. Therefore, more continuous and long-range ECG data monitoring methods are urgently needed to improve the sensitivity and specificity of atrial fibrillation screening.

2.2 Application of wearable devices in AF screening Wearable devices are sensor-based lightweight portable devices that transmit information about body signals to external devices by wearing close to the skin surface, detection and analysis, and provide biofeedback. The intelligent ECG analysis system based on radio communication, Internet and cloud platform has created the technical conditions for atrial fibrillation screening, there are three main types of wearable devices on the market currently: photoplethysmographic(PPG) equipment (including watch / wrist band, arm band, finger band and earlobe sensor, etc.), electrocardiography(ECG) equipment (including patch, chest band, wireless recorder, etc.) and mechanocardiography(MCG) device (such as sphygmomanometer).

The sensitivity and specificity comparison of several wearable devices currently used for AF screening is shown in Table 1[16]. ECG monitoring patch was an early wearable device used to provide continuous 14-d heart rate monitoring. In a study in Taiwan in 2020 used ECG monitoring patch on 32 patients with suspected paroxysmal arrhythmia to screen for atrial fibrillation, The results showed that the detection rate of atrial fibrillation/atrial flutter in the ECG monitoring patch was higher than Holter (66% vs 9%) after removing the patch[17]. In 2017, the United States FDA approved for the first time with the ECG sensor smart bracelet (Kardia Band) and dedicated APP (Kardia APP), the device using Kardia algorithm, automatically detecting whether P wave is missing and rhythm change, which is more convenient, comfortable, with 93% sensitivity and 84% specificity, but this application technology has disadvantages including low monitoring signal available data, long monitoring interval and power consumption[18].

The average application time of the wearable devices supported by PPG is 6.7 d, and the periodic monitoring time interval is 10 min, which is better than the Kardia technology. Increasing evidence supports that wearable devices based on PPG technology for AF screening have good feasibility, sensitivity and specificity[19-21]. Due to the advantages of simple PPG signal and easy wearing of the measurement device, it has gradually become the main method of measuring blood oxygen, pulse and heart rate in non-hospital conditions. Both Apple Heart Study[22] and Huawei Heart Study[21] have confirmed that smart wearable devices based on PPG technology can be used as simple and easy feasible AF screening tools for large populations. Apple Heart Study recruited 419, 039 healthy people, conducted an 8-month prospective AF screening study based on PPG technology apple Watch and Apple Watch / Apple Heart Study matching mobile phone APP, and finally concluded that the positive predictive value of AF in PPG-supported wearable devices was 84%[22]. Huawei Heart Study Using PPG, supported Huawei watch/bracelet for health adults aged 18 year old and above (n=187 912) for AF screening, 424 (0.23%) subjects received a prompt of "suspected AF" and then followed up by the researchers, 87% of them were diagnosed with AF with a positive predictive value of 91.6%after 14-day monitor[21]. Currently, more than 71% of wearable devices support PPG sensors, enabling the large-scale application[23].

Table 1 Comparison of sensitivity and specificity of six atrial fibrillation screening tools（with the sensitivity and specificity of the standard 12-lead ECG as the "gold standard"）

The AF screening tool/method	sensitivity	specificity
palpation	87~97	70~81
automatic blood pressure monitor	93~100	86~92
smart mobilephone APP	91.5~98.5	91.4~100.0
ECG wearable devices	94~98	76~95
MCG wearable devices	67	99
PPG wearable devices	97~99	83~94

3 AF management

3.1 Current status of AF management There are still challenges and weak links in the management of AF in China. The national survey showed that only 6.0% of AF patients with high risk of stroke (according to CHA2DS2-VASc score) received anticoagulation[14]. WHO proposed that one of the main tasks of cardiovascular disease prevention and treatment is community-based comprehensive management[24]; UK primary care experts proposed the "GP-specialist joint management of AF" model[25]. The 2020 European Society of Cardiology (ESC) guidelines for the management of AF, where A represents anticoagulation/avoidance of stroke, B represents better symptom management, and C represents cardiovascular and comorbid optimization[16]. Implementation of the ABC pathway was associated with a reduced risk of all-cause death, composite endpoint event[26] of stroke/bleeding/cardiovascular death and first hospital admission, lower cardiovascular event incidence[27-28], and lower health-related cost[29] compared to usual care.

3.2 Current application status of wearable devices in AF management The rapid development of wearable device support technology provides technical support for the comprehensive management of AF. Currently, the commonly used wearable devices on the market can be divided into three categories according to the types of built-in sensor technology. The sensing technology of wearable devices and its application in AF monitoring and management are shown in Table 2[18, 21, 30-31].

Mobile health (mHealth) technology has developed rapidly in recent years, mobile phones and wearable devices and other mobile technologies have been more and more applied, especially in China, showing a strong vitality[32]. According to the Statistical Report on Internet Development in China, as of June 2022, the number of mobile Internet users in China has reached 1.047 billion, providing a convenient[33] for the technology research and development of wearable devices (continuous symptom monitoring) and its application (contact with providers outside health care facilities). For example, the outstanding advantages of smart phones are that when used with wearable devices, health data can be monitored without affecting the life and work of the users, and automatically transmitted and transmitted to the central big data cloud platform. After that, the relevant health information can be timely feedback to the tested people and doctors through algorithm analysis. MHealth Technology can build a "bridge" between specialists, general practitioners, patient-community collaboration. A Comprehensive Management of AF (IMPACT-AF) study demonstrated: After 1 year of remote education management of AF based on wearable devices, the proportion of patients taking anticoagulants and thromboembolic events decreased significantly decreased[34]. SHACHAM et al. [35] also demonstrated that the rate of AF recurrence was significantly lower than that of traditional management (70% versus 80%). In a prospective mAFA II (mobile Atrial Fibrillation App II) randomized controlled trial, 3 324 18-year-old patients with atrial fibrillation were randomly divided into intervention group (mHealth based integrated management of ABC pathway) and conventional treatment group, the intervention group was mainly managed comprehensively through the mAFA platform and the PPG Huawei bracelet, the mean follow-up was about 280 d, showed that the composite outcomes of ischemic stroke / systemic thromboembolism, death, and rehospitalization were significantly reduced in the intervention group compared with the control group[31].

Table 2 Application of several types of wearable devices classified by the type of built-in sensor in monitoring and management of atrial fibrillation

Built-in sensor technology type	Built-in sensor technology	Measurement index	Clinical application
Type of movement	accelerometer	Steps, impact force, speed, sedentary time, exercise	Risk assessment in patients with AF[1], physical activity intervention in primary and secondary prevention, cardiac telerehabilitation[2]
	barometer	Number of stair climbs (determined by variation in altitude)	
	GPS	Distance from exercise, heat consumption, etc	
Biometrics	PPG	HR, HRR, HRV, blood pressure, blood oxygen saturation, stroke volume, stroke volume, pulse-based rhythm detection, sleep and its stage	Risk prediction of related diseases in patients with AF, screening and management of AF[3], cardiac telerehabilitation, acute coronary syndrome diagnosis, electrolyte abnormality diagnosis (such hyperkalemia), QTc interval extension diagnosis, drug titration
	ECG	Single-lead and multi-lead ECG, continuous or on-demand ECG, interval measurement of QTc interval, arrhythmia conditions, abnormal	

		electrolyte changes, etc	(such as β -blockers)
	MCG	Wrist band blood pressure	
Other types	Biochemical sensor	With continuous monitoring of invasive blood glucose and electrolyte abnormalities, non-invasive (combined with clothes/shoes) sweat, saliva electrolyte and hydration status monitoring	Electrolyte abnormality detection (such as hyperkalemia), continuous glucose monitoring, AF management[4]
	Biomechanical sensors	Cardiac volume, stroke volume, body vibration, body mass, etc	

4 Application challenges

There are still many challenges in the application of wearable devices in clinical practice: (1) the accuracy and effectiveness of the data still need to be improved. For example, PPG wearable devices still have limitations in terms of data accuracy and effectiveness. Their sensors work the best in direct contact with the skin, while wearable devices fixed with bands can not ensure that the device is always close to the skin. Skin color, humidity and even tattoos will also affect the accuracy of PPG[30]. In addition, wearable devices also have limitations in the identification of atrial flutter, interrhythmic preventricular contraction or pre-atrial contraction, etc. When AF is detected by wearable devices, further diagnosis should still be combined with 12-lead ECG and expert diagnosis. To further understand the limitations of wearable devices and improve their performance, clinical practice[31] with large samples and different populations is still needed.(2) There is currently a lack of a unified standard for the clinical use of wearable devices[30, 33].(3) Some studies have questioned the value of wearables in guiding behavior change[36-37]. (4) Hardware cost indirectly affects the users. Studies have shown that the higher use of wearable devices in people with high socioeconomic status may cause new health inequality problems in[38].(5) Data security and management need to be standardized. If wearable devices are used in clinical practice on a large scale, network security[35-38] need attention from the aspects of sensitive information and data protection and data sharing of patients.

In conclusion, wearable devices have created the technical conditions for wearable devices for the early detection and scientific management of AF.

Early screening of paroxysmal AF and early intervention of thrombotic events can be realized through connecting patients and medical institutions, and the application effect has been preliminarily verified, which is expected to solve a series of problems such as high prevalence rate, low detection rate and low standard management rate of AF in China, and open a new model of chronic disease prevention and control in China. However, the current use of wearable devices for chronic disease screening and management is still in the early stage of exploration, and there are still challenges in data accuracy, effectiveness, safety and clinical standards. It still needs to be further explored and verified in combination with Internet medical treatment and large-scale population application research.

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