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New Technologies for Detection and Management of Atrial Fibrillation

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Abstract

Atrial fibrillation (AF) is a common and prevalent form of arrhythmia. It is associated with various morbidities with stroke being the major hazard. Since AF is often reported to be asymptomatic, many individuals remain unaware of their condition and may not receive the requisite treatment. Hence, screening for AF has gained substantial attention recently. Growing advancement in technology has paved way for numerous approaches for AF screening using medical-prescribed devices as well as consumer electronic devices. However, there still lies scope for large-scale randomized trials which would explore additional aspects associated with AF. This review very concisely summarizes AF, screening, present technology, current literature and clinical studies associated with it.

Keywords: Atrial fibrillation, Medical devices, Stroke, Technology

1. Introduction

Atrial fibrillation (AF) is the most common and prevalent form of cardiac arrhythmia. It is widely associated with varied consequences from impairment of quality of life to substantial complications such as heart failure, vascular dementia, stroke, enhanced risk of thromboembolic events, depression and mortality [1]. AF as defined by European Society of Cardiology (ESC) Guidelines 2020, is 'supraventricular tachyarrhythmia with uncoordinated atrial electrical activation and consequently ineffective atrial contraction' [2]. This hemodynamic instability of AF depends on the interplay of various factors, such as pathophysiological mechanisms, anatomical and electrophysiology associated abnormalities [3,4].

Around 46.3 million individuals were estimated to be suffering from AF according to the Global Burden of Disease project [4]. It has been reported that about one-third of the total AF population is asymptomatic (silent AF) hence awareness and early detection of AF is important. Diagnosis of AF is widely done using an electrocardiogram (ECG) which is the current gold standard for diagnosis. However, early detection of AF is hampered in case of Silent Atrial Fibrillation (SAF) owing to the absence of symptoms and silent nature of rhythm disturbances. Patients with symptomatic AF are furnished with medical attention as a result of symptoms arising due to hemodynamic instability. Whereas, SAF patients may only present after serious complications have taken place such as ischemic stroke or heart failure. Therefore, timely detection of AF is crucial to safeguard patients from the consequences of arrhythmia and progression of AF into fatal conditions [5]. In this review, we summarize the screening for AF detection, newer technologies and clinical studies associated with AF.

2. Screening

Public health screening has enhanced dramatically over the last few years owing to the need and desire to address the growing burden of disease [6].

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Advancement in digital technology is highly contributable to this exponential growth. Screening results into detection of disease at its budding stage and treating it at the right time in order to reduce morbidity, mortality and associated healthcare and societal costs [7]. This remarkable shift has derived a more proactive approach whereby early detection of disease has renewed importance over the diagnosis of clinically overt disease. AF screening is considered as one of the best strategies to enhance detection rates in individuals. Population-based AF screening has various benefits, including identification of patients with unrecognized AF who would potentially benefit from oral anticoagulants (OAC) to prevent stroke, as well as the beginning of requisite treatment regimen early in high-risk patients [8]. Different consensus guidelines recommend screening strategies of AF which includes ESC guidelines that recommend opportunistic screening by pulse palpation or ECG in patients aged 65 or older [2]. The National Heart Foundation of Australia, the Cardiac Society of Australia and New Zealand recommend opportunistic point-of-care screening in clinic or community in individuals aged ≥65 years [9]. Over the years, there has been vast progress in the development of diagnostic tools, ranging from devices which detect persistent or paroxysmal AF to devices which offer long-term continuous identification of brief asymptomatic AF [10]. Nowadays, the term 'Digital Health' is popularly used to describe the use of digitalization and communication technology to gather and analyze information for improvement of health. This involves electronic health records (EHRs), implantable device monitoring, wearable sensor data, analytics and artificial intelligence (AI), behavioral health, and personalized medicine. Amongst these, mobile health (mHealth) which is a part of digital health is defined by the World Health Organization as health practice supported by mobile devices, such as mobile phones, patient-monitoring devices, personal digital assistants, and other wireless devices [11]. In recent years, these devices have become popular among health-conscious consumers and will continue to rapidly expand. There has been extensive use of cardiac implantable electronic devices (CIEDs) such as permanent pacemakers (PPM), implantable cardioverter defibrillators (ICDs), cardiac resynchronisation therapy (CRT) devices [pacemakers (CRT-P) and defibrillators (CRT-D)] which have resulted in early detection of brief AF asymptomatic episodes. CIEDs with an atrial lead are equipped to detect atrial arrhythmia irrespective of the appearance of symptoms. Implantable cardiac monitors (ICMs) and wearable monitors (wristbands, watches and shirts with imbedded leads/sensors and adhesive patches with sensors worn on the chest) are also being used recently. In case of wearable heart rate devices, subsequent monitoring by ECG is necessary for AF diagnosis to eliminate chances of false positives or artifacts. For devices which offer continuous monitoring, generated data is analyzed and processed by algorithms programmed in the device and utilized by manufacturer for report preparation.

This altogether has resulted into a newer category of atrial arrhythmias called atrial high-rate episodes (AHREs) also known as, subclinical atrial tachyarrhythmias or subclinical AF. AHREs can be defined as the detection of asymptomatic AF episodes by implantable devices and confirmed by electrogram or by review of recorded rhythm on the ECG [12,13]. In case of AF detection using any screening tool such as mobile or wearable device which are capable of ECG recording, a single-lead ECG tracing of ≥30 s also enables direct analysis of results. However, if AF detection is not based on ECG recording (e.g. with devices using photoplethysmography) or in case there is uncertainty about diagnosis and interpretation provided by device ECG, a confirmatory ECG is required with additional ECG recording using a 12-lead ECG or Holter monitor, etc. [2] Screening modalities which detect AF by intermittent assessment of cardiac rhythm include 12-Lead ECG, pulse palpation, smartwatch, smartphone extension and home blood pressure monitor. AF detection by continuous monitoring includes implantable loop recorder,

Abbreviations

AF	Atrial Fibrillation
AHRE	Atrial High-Rate Episodes
AI	Artificial Intelligence
BMI	Body Mass Index
CIED	Cardiac Implantable Electronic Devices
CRT	Cardiac Resynchronisation Therapy
DM	Diabetes Mellitus
ECG	Electrocardiogram
EHRs	Electronic Health Records
ESC	European Society of Cardiology
ESUS	Embolic Stroke Of Undetermined Source
HF	Heart Failure
HM	Holter Monitors
ICM	Insertable Cardiac Monitor
MI	Myocardial Infarction
OAC	Oral Anticoagulants
PPG	Photoplethysmography
PPM	Permanent Pacemakers
SAF	Silent Atrial Fibrillation
TIA	Transient Ischemic Attack

ambulatory patch ECG and multi-lead Holter monitor [8].

3. New device technology for AF detection

With ongoing advancement, there has been the development of a wide range of patient-friendly technology focused on improving the accuracy and detection rates of AF. It ranges from new devices to several applications on smart phones. These devices offer advanced screening along with enhanced specificity and sensitivity. They also offer convenience and ease to patients so that they can self-test with immediate diagnosis of AF if present.

Traditional ambulatory Holter monitors (HM) which are connected by electrodes to the chest, are still regularly used but have several limitations. They can be used for varying lengths of time but can cause inconvenience and difficulty in result analysis [14]. Recently, wrist-worn wearables have accumulated significant attention for AF detection. Smart phones and watches are equipped to capture personalized health data and most commonly used. They can analyze heart rhythm and detect AF using photoplethysmography (PPG). It is an easy, convenient and widely available technology to detect AF in asymptomatic patients [15]. PPG technology is usually more susceptible to motion artefact. The most commonly used smart watches include the Apple Watch and Fitbit [16]. The sensitivity and specificity of PPG technology from various clinical findings was found to be 95–98% and 95–99.6% respectively [17]. Blood pressure monitors offer pulse rhythm detection, making this another technology for AF screening which is cost-effective and easy to use in daily routine. These devices have been used increasingly owing to the prevalence of hypertension [18]. Latest innovations have enabled the recording of electric impulses from the heart without conventional ECG machines. Handheld device or smartphone compatible ECG recorder is wearable, small in size and can record cardiac impulses for extended periods of time [19]. A single lead is used in majority of these devices. One of the best known is AliveCor or Kardia. A summary of clinical findings suggests sensitivity to be 66.7–98.5% and specificity to be 99.4–99% [17]. The generated data is wirelessly transmitted to a smart phone and produces a tracing. The limiting factors include requiring access to smartphone, not recommended for use in children and those with implanted electronic devices [19,20]. A simple alternative to Holter or loop recorders for AF screening are Patch ECG monitors. Though the 'gold standard' for assessing abnormalities of cardiac rhythm is 12-lead Holter, there has been an increasing demand for portable devices which allow monitoring of cardiac rhythm in real-world settings such as home or workplace. To facilitate this, patch ECG monitors are designed to be waterproof, having wireless communication and containing patch carrier for skin adhesion [21]. Amongst wearable devices, as of now, adhesive patches are mostly used for detection of AF in an embolic stroke of undetermined source (ESUS) or evaluating AF burden after invasive interventions. Nevertheless, consumer-grade devices exhibit good potential for AF detection outside the traditional medical settings, their accountability and performance in AF detection is currently uncertain. Interpretation and management of patients on its basis is yet to be established concretely (Table 1) [22,23].

4. Clinical trials

There has been a rapid development in mobile health technologies for detection of AF (Table 2). Currently, there are >100,000 mobile health apps available and >400 wearable monitors [24]. Since the majority of these devices are not clinically validated, caution is needed in their clinical use. Different studies evaluated detection of AF using smartwatches. The Apple Heart Study [25,26], over a period of eight months recruited 419,297 smartwatches users in the United States of America (USA). It was observed that 0.5% of participants received notification of an irregular pulse. Amongst them, upon subsequent ECG patch readings, 34% of participants had atrial fibrillation. The Huawei Heart study [27] included 187, 912 individuals, of which, 0.23% received notification for suspected AF. Out of those who were effectively followed up, 87% of individuals were confirmed as having AF. The SEARCH-AF trial was a randomized, open-label, parallel-group study with 336 patients randomized to receive either 30 days of continuous ECG monitoring ($n = 163$) or usual care ($n = 173$). All patients were followed up for a period of 9 months. It was found that AF was detected ten times higher in the monitoring group than those who received usual care [28]. The Cryptogenic Stroke and Underlying AF (CRYSTAL-AF) was a randomized (1:1 ratio), parallel-group trial of 441 patients comparing time to detect AF with an insertable cardiac monitor (ICM) versus conventional follow-up in patients with cryptogenic stroke or transient ischemic attack

Table 1. Technology used for atrial fibrillation detection.

Type of technology	Device	Functioning	Advantages	Disadvantages	Performance
Photoplethysmography: - Wristband-type - Forehead-type - Ear-type	Apple watch Fitbit Simband HuaweiBand2 GearFit2 CardioSense	Utilizes infrared light to measure the volumetric variations of blood circulation. This information is then analyzed by an algorithm in the device and the user is notified [22,32]	- Low-cost - Non-intrusive modality for continuous heart rate monitoring	- Recognizing arrhythmia in a PPG signal can be challenging in the presence of motion artifacts [33]	- Positive predictive value of AppleWatch notification and tachogram was 84% and 71% respectively [26]. - DETECT AF PRO reported sensitivity of 91.5% and specificity of 99.6% for AF detection by photoplathysmography [34].
Blood pressure monitor	Omron HealthSense Beurer Rossmax Microlife WatchBP Home-A	Detects vibrations produced in the arterial wall as a result of blood flow between systolic and diastolic pressures and its transduction into electrical signals [35]	- Reliable screening tool in the elderly - Widely available - Paroxysmal AF might also be detected [36]	- Irregular heart-presumed AF	- WatchBP reported AF detection sensitivity of 95% and specificity of 86% [37].
Handheld device or smartphone compatible ECG recorder	KardiaMobile by AliveCor Zenicore EKG	Presence of electrodes which transmit ECG rhythms to smartphone [19]	- Good diagnostic accuracy - Ease of use	- Short ECG duration	- Kardia reported a sensitivity of 98.5% and specificity of 91.4% for diagnosis of AF [38].
Patch ECG monitors	ZioPatch MCOT Patch BodyGuardian-Heart BodyGuardian-MINI Nuvant MCT-Monitor Carnation Ambulatory Monitor Cardiodiagnostics MCT	Involves processing of analog and digital ECG data and its transmission to smart phone or computer [21]	- Water proof - Patient friendly - Continuous monitoring for up to 14 days	- Skin irritation - Single-channel ECG	- A pilot study of Zio patch with 75 participants ($\geq$55 years old) with $\geq$2 AF risk factors reported new silent AF in 5.3% [39].

ECG- Electrocardiography, PPG- Photoplethysmography.

(TIA). Upon 12 months, it was observed that in ICM group, AF had been detected in 12.4% of patients versus 2.0% patients in the control group. This concludes that ECG monitoring with an ICM was found to be superior to conventional follow-up for detecting AF post cryptogenic stroke [29].

5. Future directions

Digitalization in health technology has revolutionized the concept of health screening. There has been a constant development and increase in the number of new technologies that can be used in screening of AF. Several of these are even beginning to generate a meaningful evidence base. These devices offer advantages like ease of use along with specificity and sensitivity as compared to traditional methods. Available evidence suggests that digital technologies are more accurate for detection of undiagnosed AF in existing device users.

Provided the enhanced smart device ownership rates across the globe, development of applications for AF detection using PPG technology will likely play a large role in coming years. It will likely help patients in identifying AF along with other potential rhythm abnormalities in the future, but at the risk of warranting significant downward testing in healthy population. Additionally, companies are expected to

Table 2. Studies on devices used for atrial fibrillation screening.

Study name	Country	Number of patients	Status	Modality	Outcomes
Photoplethysmography					
Apple Heart Study [25,26]	USA	419,297	Completed	Wrist-type PPG	34% diagnostic yield of AF; 71% patients detected with simultaneous AF during irregular tachogram
Huawei Heart study [27]	China	187, 912	Completed	Wrist-type PPG	New atrial fibrillation Detection Rate- 0.23% abnormal pulse notification; 0.12% (confirmed AF)
Fitbit Heart Study [40]	USA	100,000	Ongoing	Wrist-type PPG	New onset AF
Patch Monitor					
mSToPS [41]	USA	2659	Completed	Zio patch monitor	New AF Detection Rate- screened period (3.9%); unscreened period (0.9%)
SCREEN-AF [42]	Canada	856	Recently completed	- Zio patch monitor, - Watch BP oscillometric device	Detection of new atrial fibrillation or flutter
GUARD-AF [43]	USA	52,000	Ongoing	Zio patch monitor	Stroke, major bleeding
Single-Lead Handheld ECG					
Engdahl et al. [44]	Sweden	848	Completed	– 12-lead ECG - Single lead handheld ECG	New AF Detection Rate- Initial Assessment (1.0%); 3.5% (2 wk)
Lowres et al. (SEARCH-AF) [38]	Australia	1000	Completed	Single-lead handheld ECG	New AF Detection Rate-1.5%
Kearley et al. [45]	United Kingdom	1000	Completed	- Single-lead handheld ECG - Blood pressure monitor	New AF Detection Rate-1.4%
STROKESTOP [46]	Sweden	7173	Completed	– 12-lead ECG - Single lead handheld ECG	New AF Detection Rate- 0.5% (initial assessment); 3% (2 wk)
Kaasenbrood et al. [47]	Netherlands	3269	Completed	Single-lead handheld ECG	New AF Detection Rate-1.1%
Chan et al. [48]	Hong Kong	13,122	Completed	Single-lead handheld ECG	New AF Detection Rate-0.8%
PIAAF-Pharmacy Study [49]	Canada	1145	Completed	Single-lead handheld ECG	New AF Detection Rate-2%
Chan et al. [50]	Hong Kong	5969	Completed	- Single-lead handheld ECG - Blood pressure monitor	New AF Detection Rate-1.2%
Quinn et al. [51]	Canada	2171	Completed	- Pulse palpation - single-lead handheld ECG - blood pressure monitor	New AF Detection Rate- 0.6%
REHEARSE-AF [52]	United Kingdom	1001	Completed	Single-lead handheld ECG	New AF Detection Rate-3.7%
STROKESTOP II [53]	Sweden	28,712	Completed	Zenicor single-lead ECG	New AF Detection Rate-2.6%
AF-CATCH [54]	China	7641	Ongoing	AliveCor single-lead ECG	New-onset AF
D2AF [55]	Netherlands	19,200	Ongoing	- My Diagnostick single-lead ECG - Watch BP oscillometric device	New-onset AF
VITAL-AF [56]	United States	35,000	Ongoing	AliveCor single-lead ECG	New-onset AF
SAFER [57]	United Kingdom	120,000	Ongoing	Zenicor single-lead ECG	Stroke

AF- Atrial Fibrillation, BP- Blood Pressure ECG- Electrocardiography, PPG-Photoplethysmography.

produce more wearables in the future, thus leading to people having access to home monitoring first and then referring to physicians for further investigations. However, it is not well understood whether older adults who are at risk for AF will adhere to mobile or digital technologies. On the contrary, wearable devices are likely to be used majorly by young healthy individuals who might be at very low risk of AF. Therefore, the overall risk of a false positive notification of AF will be higher than the elderly population, who might be less likely to use a smart watch. Furthermore, recent advancements in AF detection technology offers cost-effectiveness and informed preference, as well as equity and screening access to the complete target population [20].

Hence, clinical evidence generated from ongoing multiple clinical trials would be a major help. However, there still needs to be further research proposing different objectives involving these devices. Further studies are also needed comparing different devices to each other, especially in a screening capacity [20,30,31].

6. Conclusions

AF is a common and important health problem with an increase in prevalence over the years. The consequences of undetected AF are wide-ranging from impairment of quality of life to stroke and even death. It is reported that the majority of AF patients suffer from asymptomatic episodes, which is one of the major concerns. To overcome this problem, early detection with the help of screening tools can be considered as the best option. Potential approaches for AF screening are varied with noninvasive methods being the most feasible and highly acceptable by patients. Despite the upcoming trend for AF screening, there lie certain key issues which remain unanswered. These include the type of population to be screened, a device to be used, a methodology for screening, screening duration and AF burden warranting the use of OAC. Currently, there seems less concrete evidence available demonstrating direct improvement in health outcomes in terms of morbidity or mortality based on screening. However, with the emerging user-friendly smart technology and innovations, it is likely that individuals will be able to self diagnose and become aware of their health data. In-depth research is mandatory to determine the best risk stratification tool. Randomized trials with large patient pool, powered endpoints along with analysis of cost-effectiveness will aid in addressing these evidence gaps.

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