

# Introduction of Wearable Device in Cardiovascular Field for Monitoring Arrhythmia

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There has been increasing adoption of wearable smart devices in health care field and they enable non-invasive continuous monitoring of various cardiac parameters. Lots of studies have demonstrated that ambulatory monitoring devices were able to provide data for reliable diagnostics for arrhythmia. Distinguishing features of wearables such as ubiquitous continuous monitoring make it a convincing alternative to traditional diagnostic devices. Additionally, this revolutionary technology does not only enhance the diagnostic utility of wearable devices, but has also facilitated remote health care using IOT (internet of things) capability. In this review, the authors aim to present the state of current technologic development of smart wearables for detection of arrhythmia and comment on future perspectives with reviewing recent studies focused on clinical utility.

**Key Words:** *Wearable Electronic Devices; Cardiac Arrhythmias; Delivery of Health Care*

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## INTRODUCTION

Various novel smart wearables have been introduced for monitoring biometric signals. Initially the fitness trackers were designed for monitoring simple biologic features such as physical activity and the quality of sleep, but nowadays the functions of smart wearables are not confined to such simple information. Evolution of technology has made it possible to collect and analyze a variety of vital physiological data with clinical usages. Those information include body temperature, oxygen saturation, respiratory rate and heart rhythm. Among them, monitoring heart rhythm is a key issue drawing the attention of health care professions and the general public. Technologic development has removed most of hurdles disturbing clinical application of wearable devices in the diagnosis of arrhythmia. These include the reduction of device size, improved energy efficiency, and a patient friendly interface. Combined with IOT (internet of thing) technology, a variety of smart wearable devices are ready for providing ubiquitous, continuous heart rhythm monitoring.

## LIMITATIONS OF CONVENTIONAL DEVICES FOR HEART RHYTHM MONITORING

There are several conventional technologies for invasive and noninvasive heart rhythm monitoring such as Holter monitoring, external event recorders, and implantable loop recorders. Holter monitoring provides continuous multi-lead ECG recordings for 24-72 hours with excellent signal quality, but has the limitation of low diagnostic yield especially in paroxysmal arrhythmia. External event recorders present symptomatic ECG with improved diagnostic yield as assuring more than 1 months of heart rhythm recordings, but also have limited clinical indications because ECG recording can be performed only by a patient triggering the device. Therefore there is possibility of missing diagnostic ECG sequence when a patient cannot trigger it. Such situations include very short arrhythmic event duration or arrhythmia associated with syncope.

The implantable loop recorder is designed for continuous ECG monitoring for about 3-4 years. ECG recording can be initiated by the patient or an automatic event recording mechanism. It showed superior diagnostic yield, especially when the patient was asymptomatic during arrhythmic

event. In Cryptogenic Stroke and underlying Atrial Fibrillation (CRYSTAL AF) trials, implantable loop recorders showed superior detection rates of subclinical atrial fibrillation in patients with cryptogenic stroke<sup>1</sup> and recent guidelines recommend implantable loop recorders in the case of cryptogenic stroke. However, it has only been applied in limited clinical settings because they require an invasive procedure.

## RATIONALE FOR DETECTION OF SUBCLINICAL ARRHYTHMIA

The burden of arrhythmic disease among the entire population is growing with aging and if not properly diagnosed, can lead to a number of comorbidities. In terms of atrial fibrillation (AF) this has become the most common arrhythmia disease, with comorbidities often associated with significant socioeconomic burden such as cerebrovascular accident. Analysis of Korean nationwide cohort data for 10 years by Lee et al.<sup>2</sup> demonstrated that AF-related hospitalization and outpatient clinic visits increased 2.19- and 3.06-fold, respectively, while the total cost increased from 3.6 to 11.3 billion won. However, detection of arrhythmia has been challenging since arrhythmic events are mostly episodic or even asymptomatic in many cases.

A number of studies have shown the clinical implications of subclinical atrial fibrillation. In the ASSERT study, subclinical AF (SCAF) was common in pacemaker patients without prior AF and was associated with increased risk of ischemic stroke or systemic embolism.<sup>3</sup> Recently, the European Society of Cardiology's statements include a rationale for screening subclinical AF<sup>4</sup> that can be summarized as below. 1) Increasing prevalence of AF within an aging population 2) previously unknown AF was detected in about 10% of all ischemic strokes 3) a high prevalence of asymptomatic AF 4) the potential to prevent AF-related strokes with appropriate treatment 5) the increasing availability of AF detection tools.

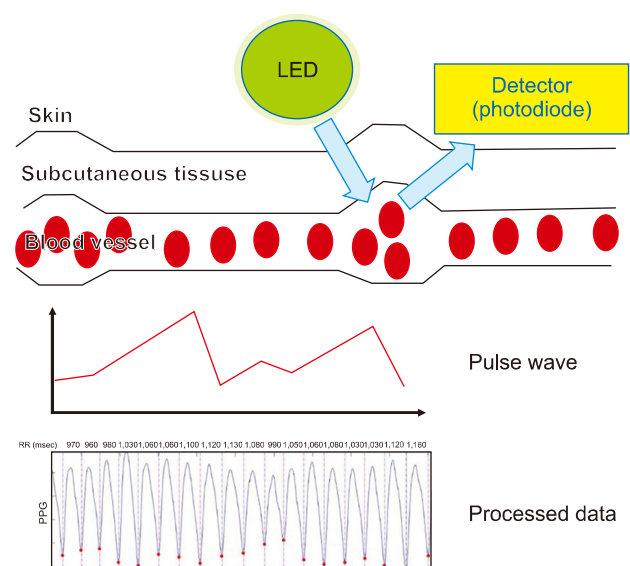
There have been several studies for proving the efficacy of wearable monitoring devices in the detection of asymptomatic AF. In the mSToPS trial, authors showed immediate monitoring with a home-based wearable ECG sensor patch, compared with delayed monitoring, resulted in a higher rate of AF diagnosis after 4 months.<sup>5</sup> Recently mid-term data of VITAL-AF trial presented at the American Heart Association conference showed the feasibility of single lead ECG as a screening tool in the elderly primary care population.<sup>6</sup> Population based mass screening of AF have the potential to relieve socioeconomic burdens that have resulted from AF associated comorbidity. A study for cost effectiveness of mass screening showed 11 more life-years, and 12 more quality-adjusted life years with screening of 1000 individuals.<sup>7</sup>

## DIAGNOSIS OF ARRHYTHMIA IN PATIENTS WITH SUSPICIOUS SYMPTOM

A number of patients visited outpatient clinic and emergency department because of arrhythmia associated symptoms such as palpitation and syncope. Unfortunately, it is not common to preserve diagnostic electrocardiograms in initial work ups. Wearable devices could be tools for extended ECG monitoring in this clinical setting. In one multicenter study of enrolled patients visiting emergency departments, a smartphone-based event recorder using AliveCore increased the number of patients in whom an ECG was captured during symptoms over five-fold to more than 55% at 90 days.<sup>8</sup> Most of them showed sinus rhythm during events but several newly detected atrial tachyarrhythmia events were documented in the interventional group. Wearable devices also showed feasibility for detection of ventricular arrhythmia and supraventricular tachycardia. In one case report, two cases of ventricular tachycardia were detected with prolonged ECG monitoring using apple watches and subsequent electrophysiology confirmed diagnosis that guided appropriate intervention.<sup>9</sup>

## PHOTOPLETHYMOGRAM BASED HEART RHYTHM MONITORING

There are various biometric signals used to determine for heart rate and regularity. The photoplethysmogram (PPG) is one of the most widely used techniques for heart rhythm monitoring and provides a simple and inexpensive tool for detection of arrhythmia. The PPG device has two components including the infrared light emitting source and photodetector. It measures changes of blood volume in capillary blood vessel below subcutaneous layer resulted from cardiac cycle of systolic and the diastolic phase (Fig. 1).



**FIG. 1.** Brief diagram of Photoplethysmogram (PPG) based heart rhythm monitoring.

Heart beat data can be extracted from detection of the peak values during pulsatile nature of blood vessels and it could be matched with QRS wave of electrocardiogram. Previous studies showed pulse detection based values were well correlated with information from conventional ECG monitoring during both sinus rhythm and arrhythmic events.<sup>10</sup> PPG methods have lots of potential for applying to wearable device because they of the usually small apparatus size, inexpensive price, and very low electrical energy consumption. It has an easily modifiable nature fitting different shapes of devices such as wristwatch, smartphone camera, or fingertip detector. Indeed, most smart wearables for health care are equipped with a PPG based monitoring function. However, there are several major drawbacks limiting clinical usage of PPG. Despite excellent correlation with conventional ECG, PPG recordings cannot be used as a definite diagnostic modality because only a ECG recording can be accepted for diagnostic purpose. Therefore, PPG data might be a useful screening tool with a high probability, but cannot justify interventions for treatment purposes. The other obstacles for PPG based ECG recordings are related with the size of the data collected. PPG devices generate large amounts of data making it difficult to interpret the data's entirety manually. Recent developments in artificial intelligence provide a realistic solution to overcoming this hurdle though. One study using a deep neural network technique for interpreting smartwatch based PPG data showed excellent sensitivity and specificity compared to other AF detecting modalities.<sup>11</sup>

### PATCH TYPE ECG MONITORING DEVICE

Recently, several newly designed patch type, monitoring devices have been introduced. They have small and light profiled and water proof features for minimizing daily life interruption and guaranteed longevity during ECG monitoring with efficient energy usage. They can also transfer data wirelessly enabling clinicians to analyze data without visiting the patient directly.

The Zio Patch (iRhythm Technologies, San Francisco, CA, USA) is a single-use patch type ECG monitoring device. It can be attached to the left anterior chest and provide continuous ECG monitoring for more than 2 weeks (Fig. 2). This device received FDA approval in 2011 and has been prescribed to more than 400,000 patients so far. It has several clinical indications. One of them is detection of atrial fibrillation without symptoms. Monitored individuals, compared with non-monitored controls, had higher rates of AF diagnosis, greater initiation of anticoagulants, but also increased health care resource utilization at 1 year.<sup>10</sup> There are also small numbers of developing patch type devices in Korea trying to enter medical system. One of patch type ECG monitoring devices named the 'ATP100' (ATsens, Seongnam, Korea) showed eligibility for continuous ECG monitoring in a small study with comparable accuracy compared to conventional devices.<sup>12</sup>

### PATIENT TRIGGERED SINGLE LEAD ECG

Several wearable devices have been introduced for patient triggered single lead ECG. For ECG recordings, two different polarities should be connected with a device. In



FIG. 2. Examples of patch type single lead ECG recording devices. ATP100 (ATsens, Seongnam, Korea) (A), Zio Patch (iRhythm Technologies, San Francisco, CA, USA) (B), ECG recording from Zio patch (C).

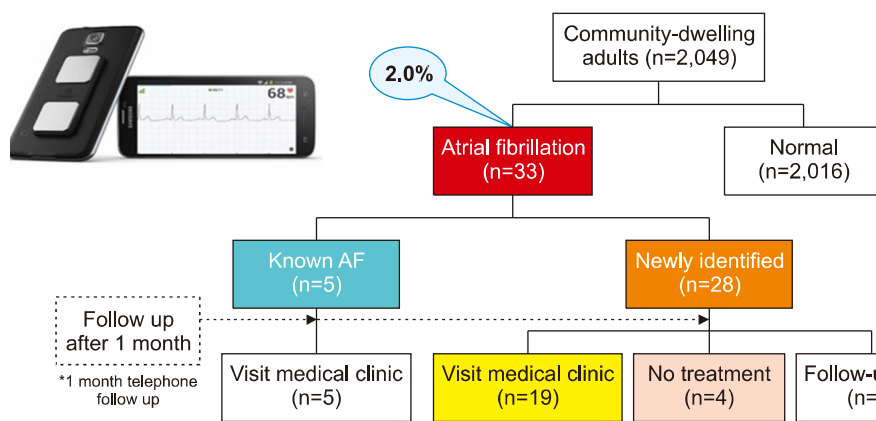
the case of AliveCor KardiaMobile (AliveCor, San Francisco, USA), a patient puts two fingers from each hand on pocket sized device. With minimal training, most individuals can easily make a single lead ECG recording for 30 seconds which can be transmitted to the application installed on a smartphone. It has an automatic detection algorithm for diagnosis of AF with excellent sensitivity (96.6%) and specificity (94%).<sup>13</sup> When patient delivered their ECG recording, health care professions could make clinical decisions based on the data. It is very useful for mass screening of AF. In one series of mass screenings for 2,049 community dwelling adults, 28 newly identified AF patients were discovered and followed up on by medical clinic visit (Fig. 3).

Single lead ECG devices can be applied to the wristbands of smartwatches. Kardia Band (AliveCor, Mountain View, California) was introduced as FDA cleared Apple Watch accessory (Apple, Cupertino, California). Patients can record 30 seconds of an ECG by just putting their thumb on the wristband (Fig. 4). An automated algorithm differentiated AF with 93% of sensitivity and 84% of specificity.<sup>14</sup> in the

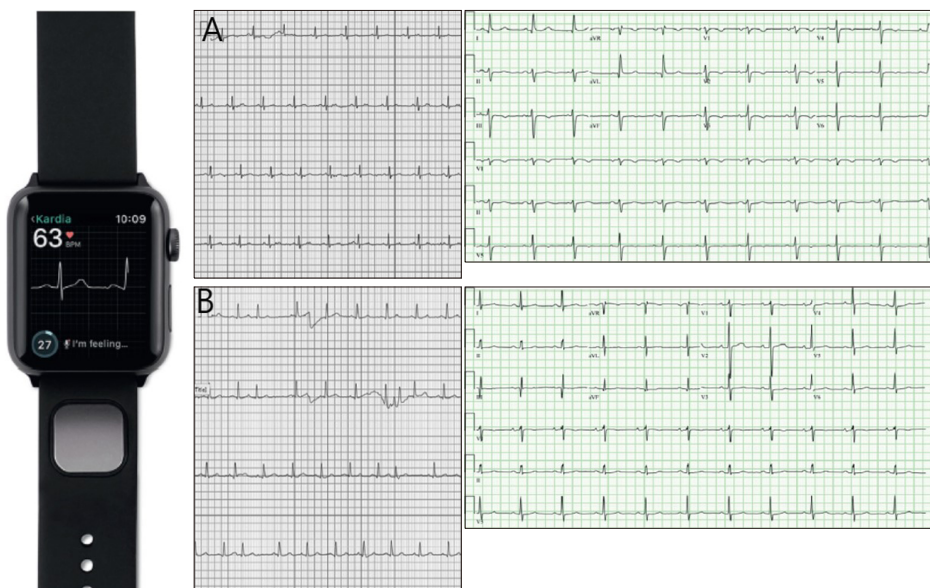
REHEARSE-AF Study, 1001 patients were enrolled and tested the feasibility of the Kardia Band in mass screening of AF and it showed superior detection of AF compared with conventional monitoring.<sup>15</sup>

### A HYBRID APPROACH USING PPG AND PATIENT TRIGGERED ECG RECORDING

There are pitfalls in both of PPG based devices and patient triggered ECG devices. PPG based devices can provide continuous ambulatory heart rhythm recording and increase the chance to detect asymptomatic arrhythmia, but diagnosis should be confirmed by checking the ECG by visiting clinic. In contrast, patient triggered ECG devices can offer confirmative diagnostic recordings, but the lack of a continuous monitoring feature limits utility for the diagnosis subclinical arrhythmia. There have been trials for filling these gaps by combining these device together. In one study, participants without atrial fibrillation used a smartphone (Apple iPhone) application to engage in mon-



**FIG. 3.** Result of mass screening performed in single center for detecting atrial fibrillation with single lead ECG device (not published).



**FIG. 4.** Examples of ECG recording from Kardia Band (AliveCor, Mountain View, California). Recording of normal sinus rhythm (A) and atrial fibrillation (B) in smartwatch and conventional ECG.

itoring. If a smartwatch based irregular pulse notification algorithm identified possible atrial fibrillation, an ECG recording was performed with a mailed ECG patch. 2161 among all of 419,297 enrolled patient received notification, Patch type single lead ECG detected AF in significant proportions.<sup>16</sup> Other studies using smartwatches (Galaxy Gear-fit) and Alivecor Kardiamobile also made diagnoses of AF with 93.7% of sensitivity and 98.2% of specificity.<sup>17</sup>

## WEARABLE DEVICES AS A DECISION MAKING TOOL

Tracings from wearable rhythm devices suggestive of arrhythmias could initiate further diagnostic evaluation and detection by wearable devices of various arrhythmia as has been described above, but, to date, they have not been endorsed as a diagnostic rhythm detection approach by the Heart Rhythm Society or American and the European Societies of Cardiology. Furthermore, therapeutic interventions based on wearable device have not been approved. An online survey conducted by questioning physicians showed that majority of participants expect these devices to facilitate diagnostics and arrhythmia screening, but fear data overload and expect scientific society recommendations on the use of these wearables.<sup>18</sup> Accumulation of data from ongoing studies will likely provide evidence of a potential supporting role of wearable data as a decision making tool and will change the consensus about legal issues.

## CONCLUSION

The introduction of smart wearable devices shows a promising future for early detection and treatment of arrhythmic disease. Furthermore it has the potential for relieving the massive socioeconomic burden that is consequence of lethal arrhythmia. However, there are several remaining obstacles delaying widespread clinical applications. Those include technical issues or legal issues about telemedicine. The advancement of technology based on clinical trials and the careful resolution of legal regulation about privacy issues are necessary for the continued, future evolution of smart wearables but their potential as a medical resource are undeniable.

## CONFLICT OF INTEREST STATEMENT

None declared.

## REFERENCES

- Sanna T, Diener HC, Passman RS, Di Lazzaro V, Bernstein RA, Morillo CA, et al. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med* 2014;370:2478-86.
- Lee H, Kim TH, Baek YS, Uhm JS, Pak HN, Lee MH, et al. The trends of atrial fibrillation-related hospital visit and cost, treatment pattern and mortality in Korea: 10-year nationwide sample cohort data. *Korean Circ J* 2017;47:56-64.
- Van Gelder IC, Healey JS, Crijns HJGM, Wang J, Hohnloser SH, Gold MR, et al. Duration of device-detected subclinical atrial fibrillation and occurrence of stroke in ASSERT. *Eur Heart J* 2017;38:1339-44.
- Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomström-Lundqvist C, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): the Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *Eur Heart J* 2020. doi: 10.1093/eurheartj/ehaa612.
- Steinhuyl SR, Waalen J, Edwards AM, Ariniello LM, Mehta RR, Ebner GS, et al. Effect of a home-based wearable continuous ECG monitoring patch on detection of undiagnosed atrial fibrillation: the mSToPS randomized clinical trial. *JAMA* 2018;320:146-55.
- Khurshid S, Chang Y, Guan W, Lipsanopoulos A, Borowsky LH, Ellinor PT, et al. Real-world diagnostic performance of single-lead handheld electrocardiograms for atrial fibrillation screening: the Vital-af trial. *Circulation* 2020;142(Suppl\_3):A15336.
- Aronsson M, Svennberg E, Rosenqvist M, Engdahl J, Al-Khalili F, Friberg L, et al. Cost-effectiveness of mass screening for untreated atrial fibrillation using intermittent ECG recording. *Europace* 2015;17:1023-9.
- Reed MJ, Grubb NR, Lang CC, O'Brien R, Simpson K, Padarenga M, et al. Multi-centre randomised controlled trial of a smartphone-based event recorder alongside standard care versus standard care for patients presenting to the Emergency Department with palpitations and pre-syncope: the IPED (Investigation of Palpitations in the ED) study. *EclinicalMedicine* 2019;8:37-46.
- Burke J, Haigney MCP, Borne R, Krantz MJ. Smartwatch detection of ventricular tachycardia: case series. *HeartRhythm Case Rep* 2020;6:800-4.
- Hochstadt A, Chorin E, Viskin S, Schwartz AL, Lubman N, Rosso R. Continuous heart rate monitoring for automatic detection of atrial fibrillation with novel bio-sensing technology. *J Electrocardiol* 2019;52:23-7.
- Tison GH, Sanchez JM, Ballinger B, Singh A, Olgin JE, Pletcher MJ, et al. passive detection of atrial fibrillation using a commercially available smartwatch. *JAMA Cardiol* 2018;3:409-16.
- Choi W, Kim SH, Lee W, Kang SH, Yoon CH, Youn TJ, et al. Comparison of continuous ECG monitoring by wearable patch device and conventional telemonitoring device. *J Korean Med Sci* 2020;35:e363.
- William AD, Kanbour M, Callahan T, Bhargava M, Varma N, Rickard J, et al. Assessing the accuracy of an automated atrial fibrillation detection algorithm using smartphone technology: the iREAD Study. *Heart Rhythm* 2018;15:1561-5.
- Bumgarner JM, Lambert CT, Hussein AA, Cantillon DJ, Baranowski B, Wolski K, et al. Smartwatch algorithm for automated detection of atrial fibrillation. *J Am Coll Cardiol* 2018;71:2381-8.
- Halcox JPJ, Wareham K, Cardew A, Gilmore M, Barry JP, Phillips C, et al. Assessment of remote heart rhythm sampling using the AliveCor heart monitor to screen for atrial fibrillation: the REHEARSE-AF study. *Circulation* 2017;136:1784-94.

16. Wasserlauf J, You C, Patel R, Valys A, Albert D, Passman R. Smartwatch performance for the detection and quantification of atrial fibrillation. *Circ Arrhythm Electrophysiol* 2019;12:e006834.
17. Dörr M, Nohturfft V, Brasier N, Bosshard E, Djurdjevic A, Gross S, et al. The WATCH AF trial: SmartWATCHes for Detection of Atrial Fibrillation. *JACC Clin Electrophysiol* 2019;5:199-208.
18. Manninger M, Kosiuk J, Zweiker D, Njeim M, Antolic B, Kircanski B, et al. Role of wearable rhythm recordings in clinical decision making-the wEHRables project. *Clin Cardiol* 2020;43:1032-9.