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Use of digital health applications for the detection of atrial fibrillation

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Abstract

The advances in health care technologies over the last decade have led to improved capabilities in the use of digital health applications (DiHA) for the detection of atrial fibrillation (AFib). Thus, home-based remote heart rhythm monitoring is facilitated by smartphones or smartwatches alone or combined with external sensors. The available products differ in terms of type of application (wearable vs. handheld) and the technique used for rhythm detection (electrocardiography [ECG] vs. photoplethysmography [PPG]). While ECG-based algorithms often require additional sensors, PPG utilizes techniques integrated in smartphones or smartwatches. Algorithms based on artificial intelligence allow for the automated diagnosis of AFib, enabling high diagnostic accuracy for both ECG-based and PPG-based DiHA. Advantages for clinical use result from the widespread accessibility of rhythm monitoring, thereby permitting earlier diagnosis and higher AFib detection rates. DiHA are also useful for the follow-up of patients with known AFib by monitoring the success of therapeutic interventions to restore sinus rhythm, e.g. catheter ablation. Although some studies strongly suggest a potential benefit for the use of DiHA in the setting of AFib, the overall evidence for an improvement in hard, clinical endpoints and positive effects on clinical care is scarce. To enhance the acceptance of DiHA use in daily practice, more studies evaluating their clinical benefits for the detection of AFib are required. Moreover, most of the applications are still not reimbursable, although the German Digital Health Care Act (*Digitale-Versorgung-Gesetz*, DVG) made reimbursement possible in principle in 2019.

Keywords
Heart rhythm monitoring · AFib · Remote patient management · Screening · Telemedicine

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Introduction

The advances in health care technologies over the last decade have led to improved capabilities in the use of digital health applications (DiHA) for the detection of atrial fibrillation (AFib). [15]. Thus, home-based remote heart rhythm monitoring is facilitated by smartphones or smartwatches alone or combined with external sensors [15]. This allows for remote patient-initiated rhythm monitoring [15]. The technical solutions differ in terms of the sensors used for rhythm detection (electrocardiography [ECG] vs. photoplethysmography [PPG]) and by the type of application (wearable vs. handheld) [15]. Integration into telemedical approaches enables remote patient management [27]. This article summarizes technical aspects and clinical purposes of DiHA for the detection of AFib.

ECG-based technologies

The 12-lead ECG is the gold standard for the diagnosis of AFib but is not always available and, thus, has its limitations in the detection of paroxysmal episodes of AFib [17]. Its scope can be increased by DiHA, which most often derive a single-lead ECG [15]. While the majority of ap-

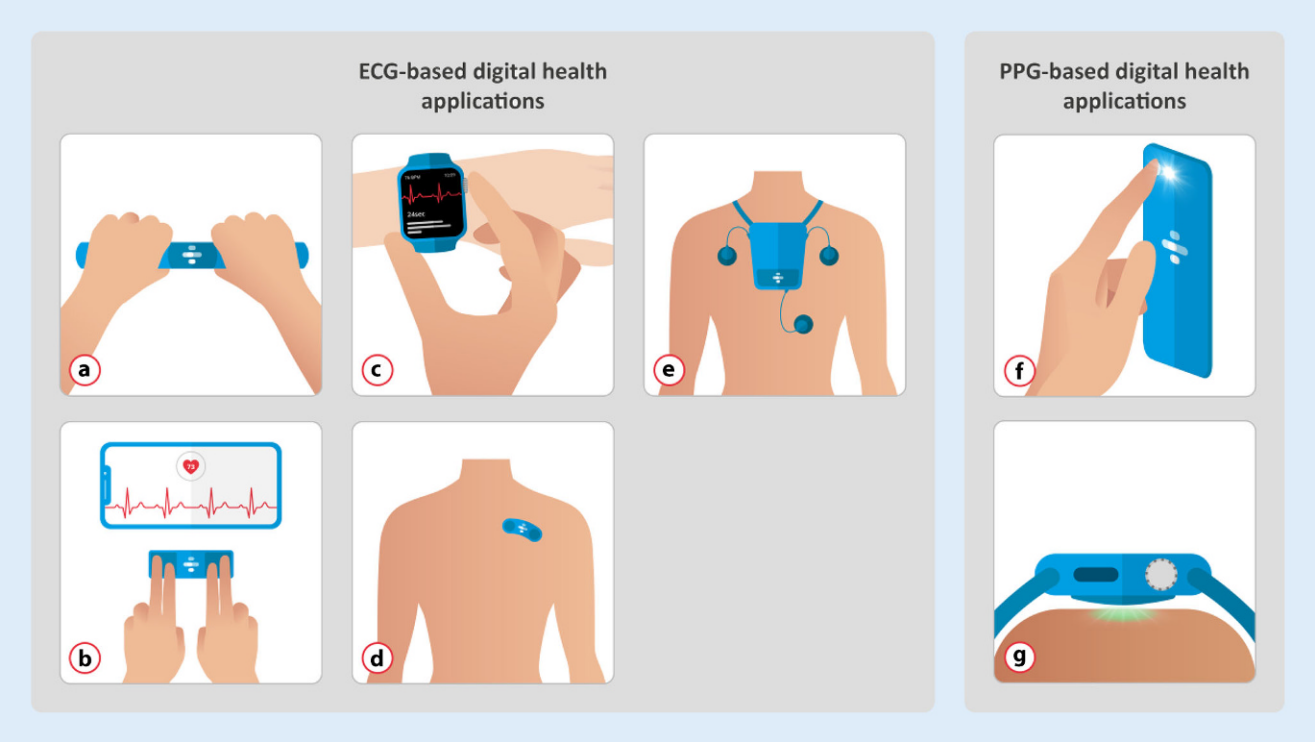

Fig. 1 ▲ Digital health applications for the detection of atrial fibrillation. **a** Electrocardiography (*ECG*) stick. **b** Handheld ECG plate. **c** Smartwatch with an integrated single-lead ECG. **d** ECG patch applied to the chest. **e** Multi-lead ECG. **f** Photoplethysmography (*PPG*) using common smartphones. **g** PPG using a smartwatch. © Department of Digital Medicine, Medical Faculty OWL, Bielefeld University; all rights reserved

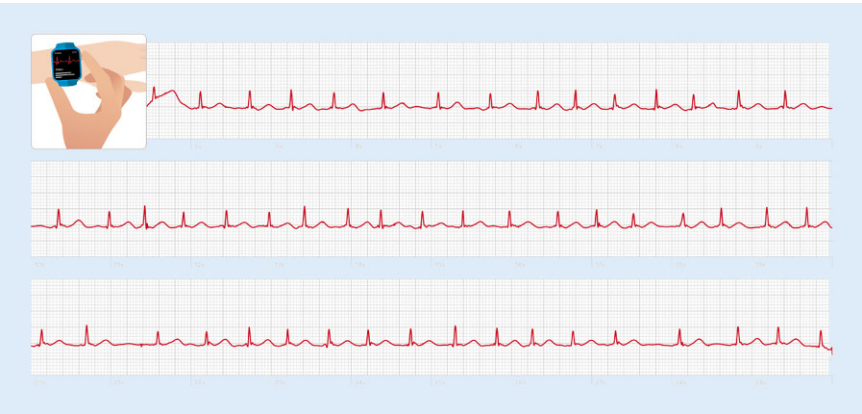

Fig. 2 ▲ Single-lead electrocardiogram (30 s) derived from an Apple Watch 6.1 (Apple) indicating atrial fibrillation (25 mm/s)

plications use dedicated handheld sensors applied on demand (e.g. in the case of palpitations), others can be used as wearables and facilitate continuous rhythm monitoring [15]. The hardware is complemented by algorithms using artificial intelligence to automatically detect AFib based on irregular RR intervals and the absence of P waves [28]. To evaluate whether such DiHA for the detection of AFib fulfil their purpose, three main questions need to be answered [12]:

1. Is the sensor precise and consistent (verification)?
2. Are the measurements and the processing algorithms comparable to high-quality reference systems (analytical validation)?
3. Does the application improve medical outcomes or confer positive effects on clinical care (clinical validation)?

There is much evidence with regard to verification and analytical validation. However, data are lacking with regard to clinical validation [15].

Handheld ECG-based applications

Most of the ECG-based devices allow for the recording of a single-lead ECG (mostly lead I) by external sensors being held between two extremities [19, 28]. For instance, the ECG stick MyDiagnostick (**Fig. 1a**; Applied Biomedical Systems, Maastricht, Netherlands) is held between the user's right and left hand for a measurement lasting 60 s [28]. The software for the automated rhythm analysis is integrated in the device [28]. Tielemann et al. assessed the diagnostic accuracy for the detection of AFib by MyDiagnostick and found a sensitivity of 100.0% and a specificity of 95.9% [28].

AliveCor Inc. (San Francisco, CA, USA) provides the ECG plate KardiaMobile which is connected with the user's smartphone (**Fig. 1b**; [19]). This handheld device allows for recording of lead I by putting one finger of each hand onto the plate's elec-

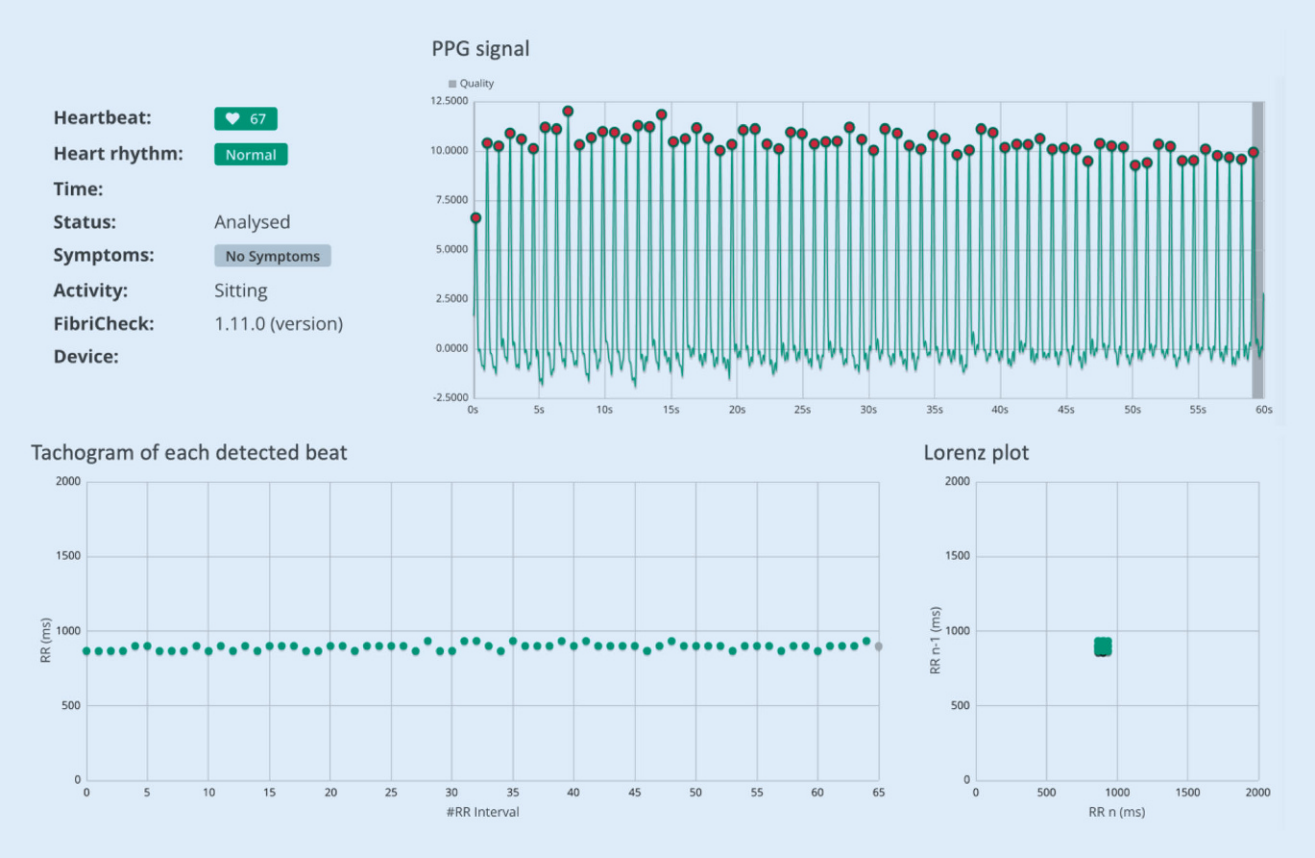

Fig. 3 ▲ Results from the photoplethysmography (*PPG*)-based smartphone algorithm Fibricheck indicating sinus rhythm. The time intervals of consecutive pulse waves are presented in the tachogram and the Lorenz plot

trodes [19]. Several studies have validated the quality of the measurements and the accuracy of the algorithm [15]. Sensitivity and specificity were 95.3% and 97.5%, respectively [19]. By placing the device onto the left leg while holding it in the right or left hand, leads II and III can be recorded [27]. This may enhance visibility of the P wave [27].

Recently, the manufacturer upgraded the ECG plate by adding an additional electrode to the back of the plate [18]. In this way, a 6-lead ECG can be recorded by putting the back of the plate onto the left leg [18]. The KardiaBand by AliveCor Inc. is an alternative wrist band for the Apple Watch and has an integrated electrode [9]. An ECG recording of lead I can be derived between the wrist and a finger of the contralateral hand [9].

The Apple Watch (Apple, Cupertino, CA, USA) combines ECG and PPG in a single device and operates without the need for an external sensor (**Fig. 1c**; [8, 20]). While the watch is worn on the left wrist, a single-lead ECG (lead I) can be recorded by establishing contact between the right index finger and the crown of the watch (**Fig. 2**; [8]). Its algorithm has been shown to detect AFib with a sensitivity and specificity of 96.0% and 91.0%, respectively [8]. Limitations for the detection of AFib result from an upper frequency threshold above which the algorithms of the Apple Watch and other smartwatches do not check for AFib [14]. For instance, the automated algorithm of the latest version of the Apple Watch detects AFib only in measurements with heart rates up to 150 beats per minute [14].

Wearable ECG-based applications

Some applications use sensors which are applied to the skin and allow for continuous heart rhythm recording for a defined period of time (**Fig. 1d,e**; [27]). These devices do not need to be activated on demand and, thus, may also be helpful for the detection of asymptomatic episodes of AFib. These solutions are most commonly provided as ECG patches which are applied to the chest (e.g. Zio Patch, iRhythm Technologies Inc., San Francisco, CA, USA) [29]. The advantage of these devices is that they are self-adhesive, wireless and water-resistant and, thus, the patients' compliance is high [27]. Other wearable ECG applications are comparable to usual Holter ECGs but allow for longer periods of rhythm monitoring [24].

PPG-based technologies

The blood volume of the skin's vessels varies between systole and diastole [15]. These variations lead to changes in the light absorption of the skin [15]. In PPG devices a light source illuminates the skin and a camera detects the pulse-synchronous variations in light absorption, thereby allowing for visualization of the pulse wave [15]. This can be achieved by placing the smartphone's camera on the tip of a finger or by using sensors embedded in the back

Fig. 4 ▲ Results from the photoplethysmography (*PPG*)-based smartphone algorithm Fibricheck indicating atrial fibrillation. The tachogram and the Lorenz plot illustrate the high variability of the pulse wave intervals

of a smartwatch (**Fig. 1f,g**; [15, 27]). The algorithms of PPG-based applications assess the pulse wave intervals for irregularity indicating the presence of AFib (**Figs. 3 and 4**; [21]). By using existing technology, most PPG-based DiHA do not require additional sensors which in turn reduces costs and allows for widespread accessibility [15].

Smartphone-based PPG applications

The Heartbeats (Preventicus GmbH, Jena, Germany) and Fibricheck (Qompium Inc., Hasselt, Belgium) applications provide software to perform PPG-based rhythm diagnosis using common smartphones [4, 22]. By analyzing the intervals between the detected pulse waves, AFib can be accurately diagnosed [4, 22]. Heartbeats reported a sensitivity of 92.0% and a specificity of 100.0% in analytical validation studies [4]. FibriCheck was found to have a sensitivity of 96.0% and a specificity of 97.0% [22].

Smartwatch-based PPG applications

By integrating a light source and a camera into the back of a smartwatch, PPG-based applications can be used as wearables that enable semi-continuous heart rhythm monitoring [20]. As mentioned above, the Apple Watch provides PPG technology by a light source and a sensor integrated in its back [20]. In the case of pulse irregularities the user is requested to record a single-lead ECG [20]. The Apple Heart Study demonstrated how the scope of community screening for AFib can be expanded by using algorithms integrated into wearables [20]. The study enrolled 419,297 probands (mean age 40 years) and calculated a positive predictive value for the detection of AFib of 0.84 [20].

In summary, DiHA based on PPG showed comparable results when compared to ECG-based algorithms in the analytical validation studies [4, 19, 22, 28]. However, the latest guidelines of the European Society of Cardiology still require a single-lead ECG of more than 30 s for the diagnosis of AFib [17]. Thus, alerts from PPG-based devices suggesting AFib require confirmation by intensified ECG monitoring before the diagnosis of AFib can be established. Of note, all data derived from DiHA should be carefully evaluated for artefacts before confirming any type of arrhythmia [27].

Settings for clinical use

There are many analytical validation studies indicating a high accuracy of ECG- and PPG-based DiHA for the detection of AFib [4, 19, 22, 28]. However, evidence is scarce regarding clinical validation, e.g. the improvement of hard clinical endpoints, such as mortality or hospitalizations and positive effects on clinical care.

Two main clinical settings seem appropriate for the use of DiHA in the setting of AFib:

1. Screening (e.g. in asymptomatic patients at high risk for AFib or in patients with palpitations)
2. Monitoring of patients with known AFib after interventions to restore sinus rhythm (e.g. cardioversion, catheter ablation)

In most of the DiHA used for the detection of AFib patients are requested to inform their physicians about symptoms experienced during a measurement, thereby allowing for symptom–rhythm correlation. The results are presented to the user and can additionally be transmitted to the physician. The integration into telemedical approaches enables remote patient management [27].

Screening for AFib

A significant proportion of patients suffering from AFib are asymptomatic and, thus, the diagnosis of AFib is either made with a delay or not at all [17]. There is ample evidence that the detection rates of AFib can be increased by intensified screening with DiHA [19, 20, 23, 26]. The prevalence of AFib differed between those trials depending on the population used for screening [19, 20, 23, 26]. For instance, the mean age of the 419,297 probands enrolled in the Apple Heart Study was 40 years [20]. The study used a PPG sensor in the back of the Apple Watch to screen for AFib [20]. Only 0.5% of probands received a notification for pulse irregularities during a median monitoring period of 117 days and were provided with an ECG patch for additional rhythm monitoring [20]. The positive predictive value to detect episodes of AFib after notification of an irregular pulse was 0.84 in this young and healthy cohort [20]. The detection rates for AFib were higher in older participants [20].

In the SEARCH-AF study, conducted in Australian pharmacies, screening with the ECG plate KardiaMobile (AliveCor Inc., San Francisco, CA, USA) in patients aged ≥ 65 years led to the primary diagnosis of AFib in 1.0% [19]. Rivezzi et al. carried out screening using the MyDiagnostick device in 1820 patients aged ≥ 65 years without any history of AFib [23]. The prevalence of AFib in this population was 5.5% [23]. The mean CHA_2DS_2-VASc score in this cohort was 3.3 ± 1.2 and, thus, the diagnosis of AFib would trigger the initiation of anticoagulation for stroke prevention [23]. However, the study was not conducted to investigate the impact of AFib screening on stroke rates [23].

The above-mentioned studies indicate that screening for AFib using DiHA is able to detect unknown AFib, especially in older patients at higher risk for cerebrovascular events [19, 20, 23, 26].

Whether community screening for AFib with DiHA in high-risk patients may prevent strokes was investigated in the STROKESTOP study [26]. A total of 28,768 patients aged between 75 and 76 years were enrolled in Sweden and randomized to either routine care or to a screening group [26]. In the screening group the patients without any history of AFib were provided with a single-lead handheld ECG plate and invited for intermittent self-initiated recordings of their ECG during the monitoring period of 14 days [26]. The screening group showed a small but significant reduction in the primary combined endpoint of ischemic or hemorrhagic stroke, systemic embolism, bleeding and all-cause death after a median follow-up of 6.9 years [26]. In a per-protocol-analysis the benefit of screening was stronger for the secondary endpoint of ischemic stroke in the 51.3% of patients that actually participated after the invitation for screening [26].

Hence, the use of DiHA is recommended by the European Heart Rhythm Association for AFib screening in patients with prior stroke, age ≥ 75 years or younger patients that are at high risk for cardiovascular events due to comorbidities [27].

Follow-up of patients with known AFib

Recurrence rates after restoration of sinus rhythm remain a challenge; arrhythmia recurrence has been found in 43% of patients after catheter ablation and 68.0% after initiation of antiarrhythmic drug therapy [2]. Semi-continuous heart rhythm monitoring in AFib patients undergoing antiarrhythmic interventions may improve their management during follow-up through earlier and more reliable detection of AFib relapses. In the iHEART study, 238 patients undergoing catheter ablation or electrical cardioversion were randomized to an intervention group consisting of daily self-recordings for 6 months using the ECG plate KardiaMobile or to standard of care [11]. Relapses of atrial tachyarrhythmias were detected significantly more frequently and earlier in the intervention group [11].

Hermans et al. found that detection rates of AFib relapses after catheter ablation were higher using a handheld ECG device three times daily for 4 weeks compared to Holter ECG ≥ 24 h [16]. Moreover, Aljuaid et al. showed that the use of an ECG-based DiHA for self-monitoring after catheter ablation for AFib led to a significant reduction in outpatient department visits [1].

Of interest is the integration of DiHA into interdisciplinary and telemedical therapeutic approaches. The TeleCheck-AF trial aimed to implement on-demand smartphone-based heart rhythm monitoring for 7 days using the Fibricheck application for patients suffering from AFib [10]. Participating patients, who were directly involved into their own care process, were embedded in a network comprising multiple health care providers [10]. The smartphone application as well as teleconsultations served as vehicles for the remote management of AFib [10]. In this way, 1930 patients with AFib were managed during the COVID pandemic [10].

The iCARE-AF study assessed the individualized management of anticoagulation in patients with paroxysmal AFib and a CHA_2DS_2-VASc score ≥ 1 [25]. In all, 58 patients were randomized to either continuous anticoagulation or intermittent anticoagulation based on the results of a daily 30-s rhythm strip which was self-recorded by the patients with a DiHA and transmitted via a telemedical platform [25]. In the intervention group anticoagulation was only initiated in the case of detected AFib episodes during self-measurements [25]. Patients randomized to the intervention group had less bleeding events and no strokes after a follow-up of 20 months [25]. This concept is appealing but requires confirmation in larger studies to prove the safety of such a concept.

Moreover, DiHA provide other positive side effects by their incorporation of clinical decision-support tools (e.g. assessment of CHA_2DS_2-VASc score), educational material and patient involvement strategies with self-care protocols [13]. Guo et al. found that the use of such applications enhanced patients' knowledge, quality of life, drug adherence and anticoagulation satisfaction [13].

Reimbursement and implementation in routine care

The use of DiHA as a medical product for the detection of AFib requires CE certification [3]. It is worthy of note that a directory including all DiHA approved as medical products is lacking. Moreover, the CE certificate only guarantees compliance with technical standards and does not test for accuracy of the device. Thus, medical applications need to be evaluated for quality before clinical use [27]. In 2019, the Digital Health Care Act (*Digitale-Versorgung-Gesetz*), which approved the reimbursement for DiHA (risk classes I and IIa), was passed into law in Germany [7]. Beyond that, the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*, BfArM) regulates the reimbursability of such applications by health insurances [7]. Approved applications are listed in the directory for DiHA [7]. For approval to the directory the manufacturers have to pass the Fast-Track-Process of the BfArM in which the validity of the applications, their functionality and safety as well as privacy aspects are verified [6]. Beyond that, the manufactures need to provide evidence regarding the improvement of medical endpoints and positive effects on clinical care [6]. A lack of evidence for the latter aspects often limits final approval. To date, DiHA for the detection of AFib are not listed in the directory (accessed 15 June 2022) [5]. Thus, DiHA are often reserved for patients with sufficient socioeconomic status given that reimbursement by healthcare insurances is not yet possible.

As a result of this and, furthermore, due to low acceptance rates among physicians and lack of evidence for the improvement of hard clinical endpoints and care effects, DiHA for the detection of AFib are only rarely implemented in routine care. Moreover, attention should be paid to barriers resulting from patients' fears, e.g. anxiety resulting from alerts, reimbursement, concerns regarding privacy and data protection as well as a lack of technical skills.

Practical conclusion

There is ample evidence pointing to high accuracy of DiHA for the detection of AFib (analytical validation). While ECG-based algorithms often require additional sensors, PPG utilizes techniques integrated in smartphones or smartwatches. The advantage for clinical use results from the widespread accessibility for rhythm monitoring, allowing for earlier diagnosis and higher detection rates of AFib. Most available studies indicate a benefit for the use of DiHA. However, the evidence regarding hard clinical endpoints and positive care effects (clinical validation) still requires improvement. Thus, such applications are only rarely implemented in routine care.

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Declarations

Conflict of interest. D. Lawin, S. Kuhn, S. Schulze Lammers, T. Lawrenz and C. Stellbrink declare that they have no competing interests.

No studies using humans or animals were performed for this review article. For the studies cited, the authors refer to the ethical guidelines stated in the articles.

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Zusammenfassung

Einsatz digitaler Gesundheitsanwendungen zur Erkennung von Vorhofflimmern

Die technischen Fortschritte der letzten Jahre erleichtern uns mittlerweile die Diagnose von Vorhofflimmern (VHF) unter Einsatz digitaler Gesundheitsanwendungen (DiGA). Dadurch wird eine häusliche Herzrhythmusdiagnostik mit Smartphones oder Smartwatches allein oder in Kombination mit externen Sensoren möglich gemacht. Die verfügbaren Produkte unterscheiden sich in ihrer Art der Anwendung (Wearable vs. Handheld) und in der Technik zur Rhythmusdetektion (Elektrokardiogramm [EKG] vs. Photoplethysmographie [PPG]). Während EKG-basierte Algorithmen häufig externe Sensoren benötigen, bedient sich die PPG der in Smartphones oder Smartwatches integrierten Techniken. Auf künstlicher Intelligenz basierende Algorithmen erlauben die automatisierte Diagnose von VHF. Dies führt zu einer hohen diagnostischen Treffsicherheit EKG- und PPG-basierter DiGA. Der Vorteil in der klinischen Nutzung resultiert aus der großen Reichweite des Rhythmusmonitorings, wodurch frühere Diagnosestellungen und höhere Detektionsraten erzielt werden können. Darüber hinaus können DiGA für Patient*innen mit bekanntem VHF zur Überwachung des Therapieerfolgs nach Rhythmisierung von Nutzen sein, beispielsweise nach Katheterablation. Obwohl einige Studien stark auf einen Nutzen bei VHF hindeuten, besteht noch wenig Evidenz bezüglich der Verbesserung harter, klinischer Endpunkte und hinsichtlich positiver Versorgungseffekte durch DiGA. Um die Akzeptanz für die Implementierung in die tägliche Routine zu erhöhen, sind weitere Studien zur Evaluation des klinischen Nutzens in der VHF-Erkennung nötig. Außerdem sind die meisten Anwendungen bisher nicht erstattungsfähig, obwohl durch das Digitale-Versorgung-Gesetz seit 2019 die Erstattungsfähigkeit von DiGA prinzipiell gegeben ist.

Schlüsselwörter
Rhythmusmonitoring · VHF · Telemedizinische Versorgung von Patienten · Screening · Telemedizin