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Experience in screening for atrial fibrillation and monitoring arrhythmia using a single-lead ECG stick

Introduction

For patients suffering from atrial fibrillation (AF), modern anticoagulation therapy is effective in reducing the risk of stroke with an acceptable range of side effects [1, 2]. Furthermore, the combination of current antiarrhythmic drugs with interventional and device therapy is able to control progress and aftermath of AF in many cases [1]. One challenging aspect of AF remains its early diagnosis, mainly due to the intermittent appearance and the asymptomatic character in many patients [3–7]. Recently available devices—stand-alone or integrated in mobile health technology—showed promising results for AF detection [3, 8–10]. However, available technology became confusingly diverse and fragmented, in particular when mainstream technology companies approached to the market [11]. This review focuses on a single-lead electrocardiogram (ECG) device and summarizes current literature, the authors' experience in large-scale screening for AF in pharmacies, and potential fields of application.

Technical aspects of the ECG stick

Several technologies are available to detect AF. In most cases, automated diagnosis depends on electrocardiographic [3, 12], mechanical [13, 14], or photoplethysmographic [8] identification of ventricular activity and an assessment of the heart rate and regularity to identify arrhythmia. An inherent advantage of ECG is that physicians of different areas of expertise are experienced in the interpretation of the recorded signals and robust knowledge exists about the appearance of arrhythmias in ECG. Furthermore, ECG recordings allow, at least during sinus rhythm, direct proof of normal atrial electrical activity.

The MyDiagnostick (Applied Biomedical Systems BV, Maastricht, the Netherlands) has a cylindrical shape (length 26 cm, diameter 2 cm, **Fig. 1**). On an

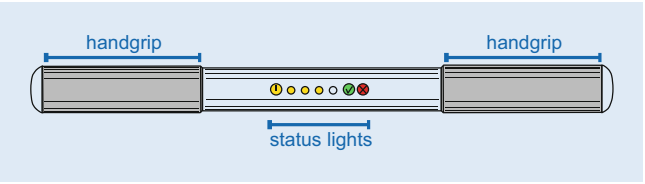

Fig. 1 ▲ MyDiagnostick device for electrocardiogram (ECG) recording. When the metal handgrips at both ends are touched simultaneously a 1-min ECG recording starts automatically. The progress of the measurement and the detected heartbeat is indicated by five yellow status lights in the middle of the stick. At the end of the measurement, the stick automatically indicates normal heart rhythm by a green and screen-detected atrial fibrillation by a red light

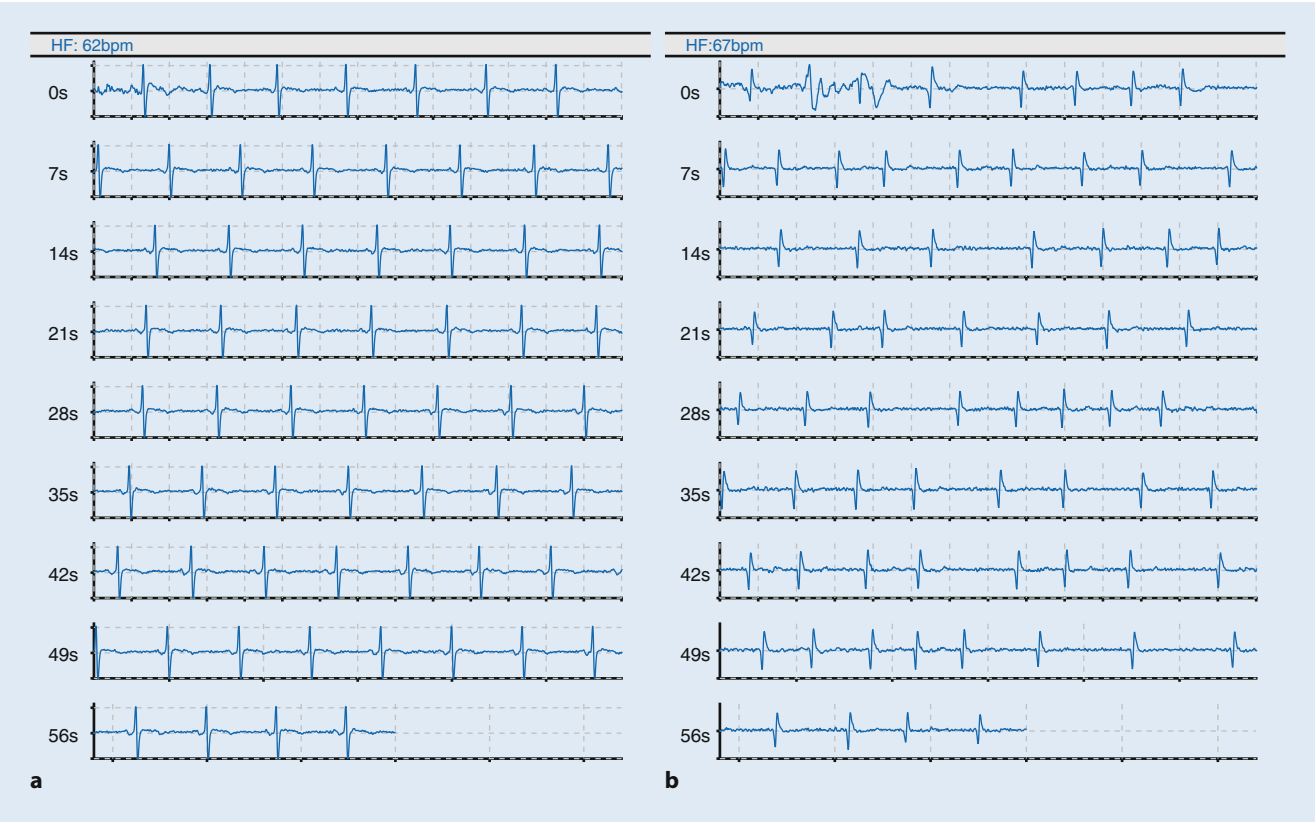

Fig. 2 ▲ Examples of electrocardiogram (ECG) stick recordings. After ECG recording in the pharmacy, the raw ECG signal recording was transferred to a University Hospital RWTH Aachen server. For human ECG expert heart rhythm validation, a file comparable to the original MyDiagnostick ECG file format was created without the result of the automated heart rhythm result. **a** ECG recording in sinus rhythm. **b** ECG recording in atrial fibrillation. *HF* heart frequency

integrated flash drive, storage of 140 measurements is possible. Each measurement is labeled with an ascending number, a time-stamp, and a unique serial number of the stick for later identification. In the case of repeated measurements and shortage of memory, stored measurements with faulty recordings and normal heart rhythm will be overwritten automatically, in order to keep recordings with screen-detected AF. A fully charged battery allows approximately 500 measurements. For battery charging and interrogation with a computer, the stick is equipped with a micro-USB connector. The company provides a dedicated program (MyDiagnostick Management Studio) to download, organize, and view the ECG recordings running on a local Windows computer.

When the metal handgrips (◘ **Fig. 1**) at both ends of the ECG stick are touched, a 1-min ECG recording starts automatically. The progress of the measurement is displayed by five status lights flashing yellow in the cadence of the detected heartbeat in the middle of the stick. After 1 min of ECG recording, the ECG stick automatically interprets the obtained rhythm by a RR interval analysis, indicating normal heart rhythm with a green and screen-detected AF with a red light. The ECG stick switches automatically to stand-by mode after the measurement if no contact to the handgrips is detected.

Screening for arrhythmia using the ECG stick

In the literature, the ECG stick was mainly investigated for its intended use of AF detection. Tieleman et al. [9] and Vaes et al. [15] showed good diagnostic accuracy with high sensitivity and specificity in cohorts with a high proportion of patients suffering from AF in a primary care environment. Based on these promising approaches, Kaasenbrood et al. [4] identified 1.1% of new AF cases in primary care units during seasonal influenza vaccination in 3269 patients. Furthermore, the screening for AF during seasonal influenza vaccination in primary care was considered cost effective in a Dutch population aged 65 years or older [16]. The yield of screen-detected AF is also proven in different environments from shopping centers [17] to approaches of in-hospital screening [12]. Besides screening for unknown AF, Pluymaekers et al. showed the capability of the ECG stick to monitor patients after cardioversion for recurrent AF by intermittent ECG stick measurements [18]. The ECG stick showed acceptable to good accuracy in AF detection in different study settings and comparable performance to other AF screening devices [11, 12].

The ECG stick in a large-scale screening

Community pharmacies provide access to medical diagnostics and therapy all

Abstract · Zusammenfassung

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Experience in screening for atrial fibrillation and monitoring arrhythmia using a single-lead ECG stick

Abstract

Atrial fibrillation (AF) is the most common arrhythmia and is highly associated with increased morbidity and mortality. Since many AF episodes remain subclinical, screening for AF is considered a desirable approach for timely diagnosis, prevention of sequelae and effective treatment. Recently, devices for AF detection—stand-alone or integrated in mobile health technology—have become available and show promising preliminary results in the detection and monitoring of arrhythmia. This review describes the technical aspects of a single-lead ECG stick and summarizes the current literature, experience in large-scale screening for AF in pharmacies and potential fields of application.

Keywords

Atrial electrical activity · Arrhythmia · Atrial flutter · Single-lead electrocardiography · Pharmacy

Erfahrungen mit dem Screening auf Vorhofflimmern und der Überwachung von Herzrhythmusstörungen unter Einsatz eines 1-Kanal-EKG-Sticks

Zusammenfassung

Vorhofflimmern ist die häufigste Herzrhythmusstörung und in hohem Maße mit erhöhter Morbidität und Mortalität verbunden. Da viele Vorhofflimmerepisoden subklinisch verlaufen, ist die aktive Suche nach Vorhofflimmern eine wichtige Grundlage für die rechtzeitige Diagnose, Prävention von Folgeerkrankungen und wirksame Behandlung. Seit Kurzem sind Geräte zur Erkennung von Vorhofflimmern – als eigenständige Lösung oder integriert in mobile (Gesundheits-)Geräte – verfügbar und zeigen erste vielversprechende Ergebnisse bei der Erkennung und Überwachung von Herzrhythmusstörungen. Diese Übersicht beschreibt die technischen Aspekte eines 1-Kanal-EKG-Sticks und fasst die aktuelle Literatur, Erfahrungen in einem groß angelegten Screening auf Vorhofflimmern in Apotheken und mögliche Anwendungsgebiete zusammen.

Schlüsselwörter

Elektrische Aktivität des Vorhofs · Herzrhythmusstörung · Vorhofflattern · 1-Kanal-Elektrokardiogramm · Apotheke

over the world and have been proven to be a cornerstone of manifold screening programs [19, 20]. Thus, the authors designed a study for AF screening in a pharmacy setting with a commercially available single-lead ECG device. The aim of this AF screening study was to determine the incidence of AF and investigate clinical outcome and health service-associated key points [21].

In all participating pharmacies, the staff was educated regarding clinical aspects of AF, to obtain medical data in a custom-built database system, and to perform an ECG stick measurement. Any customer aged 65 years or older was eligible to participate in the study and was actively invited by the pharmacy staff. After informed consent was obtained, the ECG stick analyzed the heartbeat for 1 min and baseline medical and epidemiological data were taken by the pharmacy staff. In the case of screen-detected AF indicated by a red light after the measurement, the participants received additional information about AF and were advised to consult a general practitioner for further diagnosis and treatment. The measurement took place over 4 weeks in January and February 2017 at 90 pharmacies in the city ($n = 44$) and urban region ($n = 46$) of Aachen, Germany. The measurement phase was accompanied by a media campaign consisting of press releases, posters at bus stops, posters and leaflets in pharmacies, an information website, information sessions, and radio spots. A team of seven students, three study nurses, a computer and IT specialist, and a cardiologist were available for telephone and on-site assistance.

Handling of the ECG stick

In preliminary tests on healthy volunteers and eligible participants, different measurement conditions were tested to minimize artifacts and improve signal quality. The pharmacy staff was advised to follow the recommendations to provide reliable measurement conditions.

- *Preparation:* Before the measurement, informed consent was obtained, the participant was taken to the place of measurement, and a baseline questionnaire was answered, in order to get the participants in a calm mood.
- *Body position:* Ideal measurement was in sitting position, an alternative position was standing. In both cases the participant had to rest the forearms on a solid support like a table or desk. This was important to reduce transmission of upper body movement or tremor to the measurement device.
- *Explanation of the ECG stick:* The pharmacy staff held the ECG stick at the plastic part in the middle (**Fig. 1**) with one hand and explained the ECG stick to the participant prior to the measurement. The status lights pointed upwards and the labels on the ECG stick were readable for the participant.
- *Start of the measurement:* The pharmacy staff asked the participant to grab one side of the stick at the metal handgrip. The participant was advised to hold the ECG stick as firmly as a bicycle handlebar. After the participant felt comfortable with the device, the handgrip at the other side of the ECG stick was gripped and the measurement started. This step was important since the measurement of the ECG stick starts automatically as soon as both handgrips are touched, but in preliminary tests artifacts appeared in particular in the first seconds of the measurement. The

Fig. 3 ▲ Sinus rhythm with ventricular and supraventricular premature contractions with reduced signal quality. *HF* heart frequency

authors figured out that, in the first second, the volunteers who were not familiar with the device slightly moved the ECG stick in their hands and changed pressure to it in order to have a comfortable hand position with the consequence of impaired signal quality and artifacts.

- *During the measurement:* The pharmacy staff was advised to inform the participant on the progress of the measurement indicated by the status lights in the middle of the ECG stick. The participant was asked to breathe calmly and keep silent during the measurement.
- *End of the measurement:* The end of the measurement was indicated by a green or red light.
- *Interrupted measurement:* If the measurement was interrupted, the stick was cleaned electronically by the database and the entire measurement procedure had to be repeated.
- *Download of the ECG recording by the custom-built database:* The database checked a connected ECG stick automatically for stored ECG recordings and in the case of more than one recording, all files were deleted since assignment of the recordings to the correct participant could not be guaranteed and recurrent measurement was not allowed. In the case that one complete measurement was found, the file was downloaded from the ECG stick, the storage was cleaned, and the measurement and the patient data were uploaded to a University Hospital RWTH Aachen server.
- *Cleaning the stick:* The ECG stick had to be cleaned in the case of visible contamination or at the discretion of the pharmacy staff or participant.
- *Improvement of signal quality with fluid:* There was no fluid to improve signal quality significantly in the authors' preliminary tests or reported in literature [12].

In total, 7295 participants were screened and 7107 eligible participants identified with full baseline data and results of automated ECG stick AF analysis. There were no reports of participants that were not able to use the ECG stick, as reported in comparable investigations [12]. In the case of a technical problem, the study team replaced the entire measurement setup (laptop and ECG stick) on-site to avoid interruption of the participant acquisition. The replaced measurement setup was brought for maintenance to the study center. Reasons for technical problems included: No internet connection, no connection to the database with available internet connection, and technical problems with the laptop. No technical or usability problems with the ECG stick were reported during the pharmacy measurement.

Recorded ECGs

All recorded ECGs were stored on a University Hospital RWTH Aachen server for validation of the automatically detected heart rhythm by human ECG experts. For human analysis, files comparable to the original ECG stick file format were created without the information of the automated analysis (**Fig. 2**). In **Figs. 3**, **4**, **5** **and** **6**, examples of premature ventricular beats, pacemaker activity, atrial flutter, sinuatrial conduction block, and low signal quality are shown. To assist ECG experts in heart rhythm diagnosis, an algorithm to automatically mark R-peaks was developed [22]. This algorithm was inspired by the approach of the dedicated MyDiagnostick algorithm and comparable single-lead ECG devices. The ECG experts could switch between the two ways of visualization with or without R-peak marking.

Fig. 4 ▲ Sinus rhythm with intermittent ventricular pacing and premature ventricular contractions in reduced signal quality. *HF* heart frequency

Strengths and limitations

Based on the authors' data, they found strengths and limitations of the utilized ECG stick. All participants were capable of holding the ECG stick and there were no reports of handling problems. The ECG stick is able to operate as a standalone device for automated AF detection. After the measurement, the ECG stick was controlled via the micro-USB interface and a custom-built database to download all data and clearance of local storage after the upload to a University Hospital RWTH Aachen server. Thus, there was no participant related data—personal or ECG—after the measurement was finished and uploaded to the server in the pharmacy. The usability allowed structured training for the pharmacy staff and reliable measurement conditions for the acquisition period. The main advantage was the direct availability of AF analysis after the measurement without ECG experts had to be presented to determine heart rhythm. In human ECG validation, the vast majority of the recorded ECGs provided good or excellent signal quality in which the identification of heart rhythm was possible by electrical atrial activity only.

There are several limitations of the ECG stick that need to be mentioned. There is no direct feedback implemented in the case of low signal quality; in the case of an aborted measurement or very bad signal quality, a yellow blinking light should indicate a faulty measurement. In the authors' data there was no file with a yellow measurement or a report from participating pharmacies of yellow measurements if the protocol was followed. However, human ECG experts found differing ECG signal quality, which had an impact on the diagnosis of correct heart rhythm for the automated ECG stick and for human analysis. However, although the ECG stick provided a result for all ECG recordings, in a minority of the recordings the signal quality was so bad that the ECGs were considered uninterpretable for human read-out. The ECG stick provides no information about battery charge and capacity of free storage. To prevent the battery or memory from running out, the workflow was designed

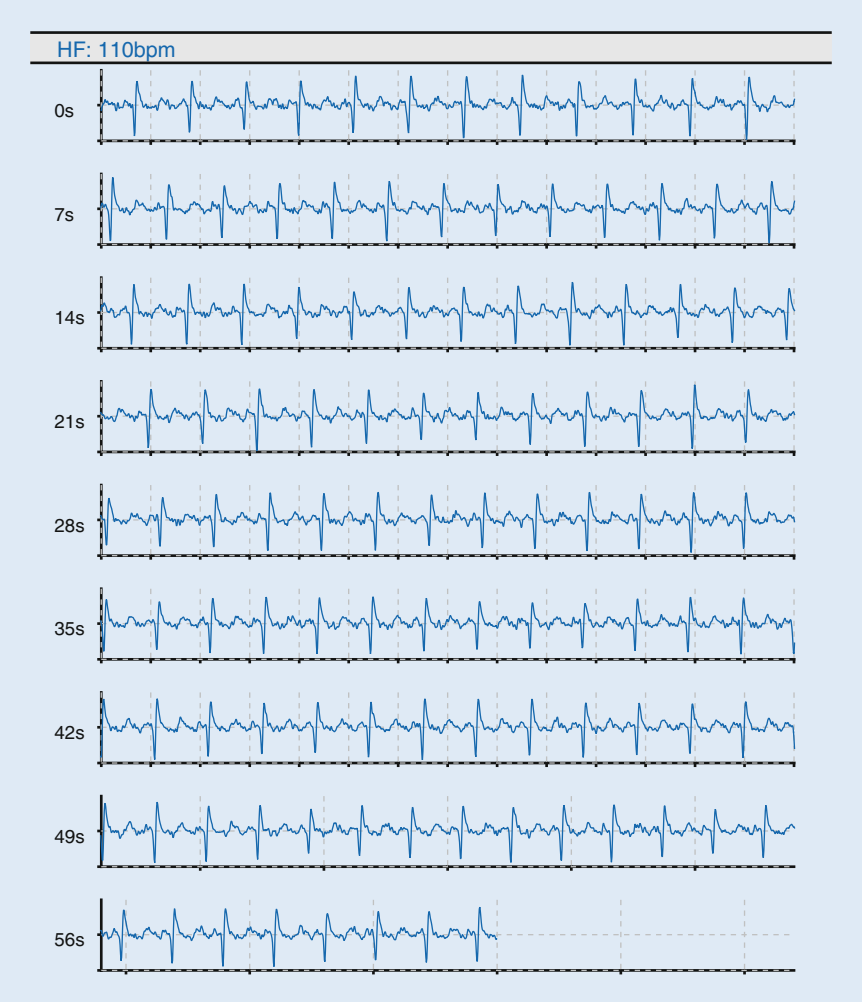

Fig. 5 ▲ Atrial flutter with 2:1 conduction. *HF* heart frequency

for frequent connection of the stick to the laptop to charge the internal battery and clear the storage. However, in a more uncontrolled situation, like handing the ECG stick to a patient for outpatient heart rhythm monitoring, this could lead to empty battery and overwritten ECG recordings by low remaining storage. There is an inherent limitation of 1-min ECG recording and the pragmatic study setting of single-time-point measurement for patients with paroxysmal AF. Patients suffering intermittent AF episodes could have been missed, since measurements were performed only once during a pharmacy visit by the participants. Repetitive measurements—or alternatively—continuous ECG recordings with implanted loop recorders would increase the sensitivity to detect all clinical appearances of AF.

The main disadvantage in the authors' perspective is the single-lead ECG nature of the signal, which correlates with a lead Einthoven I signal in a 12-lead ECG. In some cases, a lead I-related ECG recording offers no ideal ECG deflection in particular for P-wave detection. Since direct feedback is not visible to the researcher or participants during the recording, this limitation will first be recognized during the manual inspection of the ECG recording. However, this is a technical limitation for most available single-lead ECG devices.

In summary, there were no technical or handling problems in the authors' cohort for the ECG stick. The limitation to a lead I ECG deflection and the ECG signal quality influencing the automated analysis are in the authors' perspective the main limitations. The decision for or against one of the available single-lead ECG devices for screening of AF should be made in the context of the intended use and the target population of screening. The intended use of the ECG stick is automated AF detection, which predestines it for any screening for unknown AF, but also for monitoring of recurrent AF after medical intervention. Furthermore, it may provide an ECG to symptom correlation in patients with a suspected but not yet detected underlying arrhythmia. Besides automated AF detection, the ECG stick has several potential fields

Fig. 6 ▲ Intermittent 2:1 sinuatrial block. *HF* heart frequency

by virtue of the ECG signal quality it is able to provide in an ideal measurement situation. The authors see potential for detection of other arrhythmias, whether supra- or ventricular, and for more sophisticated ECG analysis like monitoring of conduction properties.

Practical conclusion

- **The MyDiagnostick offers easy-to-use single-lead ECG recording and is capable of detecting AF automatically in a large-scale screening approach, but a strict protocol for ECG recording should be followed.**
- **Single-lead ECG devices generate in most cases lead I-related ECG recording, which is for some subjects not ideal to detect atrial and ventricular electrical activity.**
- **ECG signal quality was good to excellent in most cases in a large-scale screening study for AF, but in the case of low signal quality feedback should be provided.**
- **Based on these data, the authors recommend human ECG validation of the automated analysis in single-lead ECG recording**

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Compliance with ethical guidelines

Conflict of interest. M.D. Zink, A. Napp and M. Gramlich declare that they have no competing interests.

For this article no studies with human participants or animals were performed by any of the authors. All studies performed were in accordance with the ethical standards indicated in each case.

References

1. Kirchhof P, Benussi S, Kotecha D, Ahlsson A, Atar D, Casadei B et al (2016) 2016 ESC guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J 37(38):2893–2962
2. Freedman B, Potpara TS, Lip GY (2016) Stroke prevention in atrial fibrillation. Lancet 388(10046):806–817
3. Svennberg E, Engdahl J, Al-Khalili F, Friberg L, Frykman V, Rosenqvist M (2015) Mass screening for untreated atrial fibrillation: the STROKESTOP study. Circulation 131(25):2176–2184
4. Kaasenbrood F, Hollander M, Rutten FH, Gerhards LJ, Hoes AW, Tieleman RG (2016) Yield of screening for atrial fibrillation in primary care with a hand-held, single-lead electrocardiogram device during influenza vaccination. Europace 18(10):1514–1520
5. Chan PH, Wong CK, Poh YC, Pun L, Leung WW, Wong YF et al (2016) Diagnostic performance of a smartphone-based Photoplethysmographic application for atrial fibrillation screening in a primary care setting. J Am Heart Assoc 5(7):e3428
6. Chan PH, Wong CK, Pun L, Wong YF, Wong MM, Chu DW et al (2017) Diagnostic performance of an automatic blood pressure measurement device, Microlife WatchBP Home A, for atrial fibrillation screening in a real-world primary care setting. BMJ Open 7(6):e13685
7. Lowres N, Neubeck L, Redfern J, Freedman SB (2013) Screening to identify unknown atrial fibrillation. A systematic review. Thromb Haemost 110(2):213–222
8. Perez MV, Mahaffey KW, Hedlin H, Rumsfeld JS, Garcia A, Ferris T et al (2019) Large-scale assessment of a smartwatch to identify atrial fibrillation. N Engl J Med 381(20):1909–1917
9. Tieleman RG, Plantinga Y, Rinkes D, Bartels GL, Posma JL, Cator R et al (2014) Validation and clinical use of a novel diagnostic device for screening of atrial fibrillation. Europace 16(9):1291–1295
10. Mairesse GH, Moran P, Van Gelder IC, Elsner C, Rosenqvist M, Mant J et al (2017) Screening for atrial fibrillation: a European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), and Sociedad Latinoamericana de Estimulacion Cardiaca y Electrofisiologia (SOLAECE). Europace 19(10):1589–1623
11. Freedman B, Camm J, Calkins H, Healey JS, Rosenqvist M, Wang J et al (2017) Screening for atrial fibrillation: a report of the AF-SCREEN International Collaboration. Circulation 135(19):1851–1867
12. Desteghe L, Raymaekers Z, Lutin M, Vijgen J, Dilling-Boer D, Koopman P et al (2017) Performance of handheld electrocardiogram devices to detect

atrial fibrillation in a cardiology and geriatric ward setting. Europace 19(1):29–39
13. Zink MD, Bruser C, Winnersbach P, Napp A, Leonhardt S, Marx N et al (2015) Heartbeat cycle length detection by a ballistocardiographic sensor in atrial fibrillation and sinus rhythm. Biomed Res Int 2015:840356
14. Brueser C, Diesel J, Zink MD, Winter S, Schauerte P, Leonhardt S (2013) Automatic detection of atrial fibrillation in cardiac vibration signals. IEEE J Biomed Health Inform 17(1):162–171
15. Vaes B, Stalpaert S, Tavernier K, Thaels B, Lapeire D, Mullens W et al (2014) The diagnostic accuracy of the MyDiagnostick to detect atrial fibrillation in primary care. BMC Fam Pract 15:113
16. Jacobs MS, Kaasenbrood F, Postma MJ, van Hulst M, Tieleman RG (2016) Cost-effectiveness of screening for atrial fibrillation in primary care with a handheld, single-lead electrocardiogram device in the Netherlands. EP Europace 20(1):12–18. https://doi.org/10.1093/europace/euw285
17. Battipaglia I, Gilbert K, Hogarth AJ, Tayebjee MH (2016) Screening for atrial fibrillation in the community using a novel ECG recorder. J Atr Fibrillation 9(2):1433
18. Pluymaekers NAHA, Dudink EAMP, Luermans JGLM, Meeder JG, Lenderink T, Widdershoven J et al (2019) Early or delayed cardioversion in recent-onset atrial fibrillation. N Engl J Med 380(16):1499–1508
19. Blenkinsopp A, Anderson C, Armstrong M (2003) Systematic review of the effectiveness of community pharmacy-based interventions to reduce risk behaviours and risk factors for coronary heart disease. J Public Health Med 25(2):144–153
20. Lindsey L, Husband A, Nazar H, Todd A (2015) Promoting the early detection of cancer: a systematic review of community pharmacy-based education and screening interventions. Cancer Epidemiol 39(5):673–681
21. Zink MKM, Keszei A, Rummey C, Freedman B, Neumann G, Tolksdorf A, Frank F, Wienströer J, Kuth N, Schulz JNM (2020) Screen-detected atrial fibrillation predicts mortality in elderly subjects. Europace. https://doi.org/10.1093/europace/euaa190
22. Kashif M, Jonas SM, Deserno TM (2017) Deterioration of R-Wave Detection in Pathology and Noise: A Comprehensive Analysis Using Simultaneous Truth and Performance Level Estimation. IEEE Trans Biomed Eng 64(9):2163–2175