

Digital health programme following rhythm control in patients with atrial fibrillation: comprehensive disease management by self-monitoring, coaching, and telemedicine

Georges von Degenfeld ^{1,*†}, Anke Langbein ^{2,†}, Alessandra Boscheri ³, Maximilian O. Ziegler ⁴, Jonas Demlehner⁵, Paul Weyh ⁵, Alexander Leber⁶, Sandra Schreier ⁷, and Stefan G. Spitzer ^{2,8}

¹Department of Internal Medicine I, Cardiology, University Hospital Augsburg, University of Augsburg, Augsburg, Germany; ²Praxisklinik Herz und Gefäße, 01099 Dresden, Germany; ³KIZ—Kardiologie im Zentrum, Munich, Germany; ⁴University of Münster, Münster, Germany; ⁵iATROS Digital Heart Center, Munich, Germany; ⁶Clinic for Cardiology and Internal Intensive Care Medicine, Isarkliniken GmbH, Munich, Germany; ⁷AOK PLUS—Die Gesundheitskasse für Sachsen und Thüringen, Dresden, Germany; and ⁸Brandenburg University of Technology Cottbus-Senftenberg, Institute of Medical Technology, 03046 Cottbus, Germany

Received 14 August 2024; revised 11 October 2024; accepted 19 November 2024; online publish-ahead-of-print 9 January 2025

Aims

Digital health is becoming increasingly powerful and available but is frequently not effectively integrated into daily practice. A hybrid programme was developed to provide holistic diagnostic and therapeutic patient care in atrial fibrillation.

Methods and results

Patients ($n = 68$) were recruited at the electrophysiology centre following successful interventional restoration of sinus rhythm. The 12-month programme consists of the key modalities: (i) self-recording of one-lead electrocardiograms (ECGs), (ii) short-term remote ECG diagnosis and medical advice by video consultation, and (iii) App-based education on lifestyle and risk factor optimization with video consultation. Patients recorded 29 092 ECGs, averaging 1.42 ECGs/day. Recurrent arrhythmia was found and confirmed in 39 patients. In all cases, arrhythmia was first diagnosed based on wearable ECG over the platform, rather than by standard in-office ECG/Holter. No false positive occurred. Patients with recurrent arrhythmia were treated by pulmonary vein isolation ($n = 17$), electric cardioversion ($n = 17$), antiarrhythmic medication ($n = 5$), or other interventional procedures ($n = 1$). Most patients ($n = 30$) scheduled a video consultation over the App as the first medical touchpoint after arrhythmia occurrence. In 21 patients with arterial hypertension, systolic blood pressure was reduced by 8.0 ± 8.6 mmHg (mean \pm SD), $P < 0.01$. In 25 patients with obesity (body mass index ≥ 30), body weight was reduced by 3.6 ± 5.5 kg (mean \pm SD), $P < 0.01$.

Conclusion

This real-world analysis indicates that the hybrid holistic programme is applicable in daily practice and is actively followed by patients and improves diagnostic and therapeutic outcomes. These promising data need to be confirmed in a controlled randomized study.

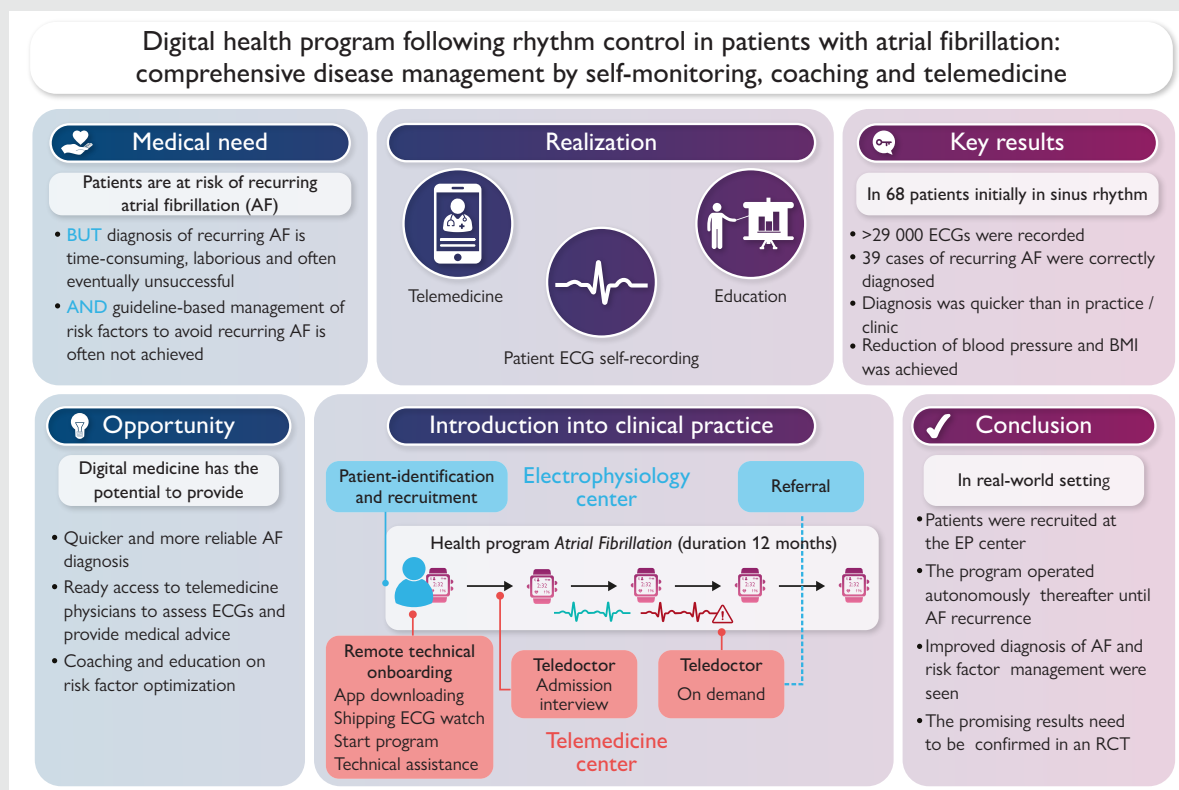
* Corresponding author. Tel: +49 163 2001298, Email: georges.degenfeld@outlook.de

[†]The first two authors contributed equally to the study.

© The Author(s) 2025. Published by Oxford University Press on behalf of the European Society of Cardiology.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (<https://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact reprints@oup.com for reprints and translation rights for reprints. All other permissions can be obtained through our RightsLink service via the Permissions link on the article page on our site—for further information please contact journals.permissions@oup.com.

Graphical Abstract



Keywords

Atrial fibrillation • Digital medicine • Telemedicine • ECG wearable

Introduction

Atrial fibrillation (AF) is globally a significant burden on patients, physicians, and healthcare systems. It is the most frequent cardiac arrhythmia, and incidence is increasing as consequence of aging population.^{1,2} Despite recent advances in the diagnosis and treatment, AF is still a major cause of stroke and morbidity, leading to high healthcare costs.³

With the increasing possibilities of digitization and connected health, the almost ubiquitous availability of smartphones and mobile data, the introduction of wearable health trackers, electronic patient files, remote coaching, and telemedicine, a host of technical innovation has become broadly available.⁴ Leveraging these advances holds promise for improving diagnosis and treatment of patients with AF.^{3,5} Currently, however, digital healthcare innovation tends to be realized in the form of insular solutions that do not sufficiently leverage the synergistic potential of combined digital and analogue patient care.⁶ Often, digital health Apps and devices are used by the patients at their own discretion as add-on to the treatment received by their treating physicians, sometimes even against their recommendation.^{6–8} Furthermore, regardless of how powerful the technology may be, the unsupervised use of digital health solutions can have detrimental consequences such as medically unfounded patient anxiety and increasing alarm burden.^{6,9,10} Reluctance on both the patients' and physicians' sides contribute to slow uptake of these technologies. The introduction of digital health solutions has been further hampered by factors such as the lack of sufficient funding, difficulties in

finding scalable solutions, and technical solutions to process and display large data volumes. On the other hand, there have been recent advances, with, for example, the introduction of the digital health application (DiGA), telemonitoring of patients with heart failure, and reimbursement of teleconsultations in Germany—although still far from sufficient, these are promising advances.

We developed a fully hybrid digital health programme with the goal of leveraging the synergies between digital and analogue patient care in order to provide holistic disease management (*digital health programme AF*). Although the programme technically operates autonomously as a standalone, it was designed from the start as a hybrid approach that integrates itself into the existing care provider landscape. We performed a systematic real-world analysis of consecutive patients included into a programme sponsored by the AOK PLUS, the largest regional health insurance company in the German states of Saxony and Thuringia.

Methods

Patients

Patients were included into the programme following interventional treatment for AF by electric cardioversion (eCV) or pulmonary vein isolation (PVI) at the Praxisklinik Dresden. Key requirement was a primarily successful treatment with patients in sinus rhythm at the time point of recruitment. There was no limit on the number of interventional treatments the patients

had received before. Patients were either recruited after the procedure before discharge or by regular mail up to 3 months after discharge.

Digital health programme atrial fibrillation

The 12-month programme consists of the key modalities: (i) self-recording of one-lead electrocardiograms (ECGs) and monitoring of other vital parameters, (ii) short-term remote ECG diagnosis and medical advice by video consultation on demand, and (iii) patient education and coaching on health literacy, lifestyle optimization, and risk factor management via an App supported by video consultation. To ensure seamless integration into today's patient treatment trajectory, suited patients are identified and recruited directly by the interventional electrophysiology (EP) centre before discharge. Patients are then treated fully remotely via the App and with technical and medical support from the telemedicine centre. In case of diagnosed recurring arrhythmia, patients are referred back to the EP centre by the telemedicine centre, thereby closing the hybrid treatment loop.

The technical platform consists of an electronic health record connected to a patient App and to a dashboard for physicians and staff of the telemedicine centre (iATROS Digital Heart Center, Munich, Germany, with technical functionalities provided by Doc Cirrus, Berlin, Germany). The platform is a CE-certified medicinal product and complies with the German and European Union data protection regulations. The App serves as the interface between the patient and the platform and includes the following functions: (i) connecting wearable ECGs and other health devices via Bluetooth, (ii) manually entering additional vital parameters (e.g. blood pressure, body weight, height, and laboratory parameters), (iii) uploading of medical documents such as discharge letters, (iv) self-calculation of medical scores such as CHA2DS2-VASc score, (v) entering medication, (vi) scheduling appointments for video consultations with a telemedicine centre physician, (vii) rendering of educational content such as videos, texts, and short messages, and (viii) generating tasks such as reminders to record an ECG, watch a video, take medication, perform exercise, or follow nutritional advice (iATROS, Munich, Germany). The tasks (1–6) are performed by the patients, with support of patient support staff of the telemedicine centre if needed; tasks (7 and 8) are performed by the App. The dashboard for staff and physicians of the telemedicine centre displays ECGs and all other medical information that the patient has entered and the documentation of previous teleconsultations and information on which tasks were performed vs. skipped by the patient (iATROS, Munich, Germany).

The programme can be structured into three key medical functionalities:

- **Monitoring:** measurement of ECGs and other vital parameters. The data are displayed to the patient via the App, along with information on target values, and are made available to telemedicine physicians via the observation dashboard.
- **Patient education:** a core function of the system is to display the educational content of the digital health programme AF, which consists of >100 elements over 12 months to the patient over the App. The education programme includes content on health literacy (disease, diagnosis, and treatment) and lifestyle education including nutrition and physical activity (iATROS, Munich, Germany). This function is realized by a predefined series of consecutive contents including videos, texts, short messages, and tasks. While the sequence of the content is predefined, timing is dependent on the activity of the patient (e.g. a certain video is presented to the patient every day until the patient watches it; only then is the next video presented).
- **Telemedicine:** staff of the telemedicine centre provides remote technical assistance to help with any technical question or problem regarding the correct use of the device or the App and troubleshooting in case of problems. The physicians of the telemedicine centre have several years of experience in internal medicine or cardiology, have received specific training on the health programme and data safety, and are provided with standard operation procedures for the remote treatment of patients with AF. Telemedicine consultation via video or phone is provided to all patients initially at the start of the programme and thereafter when booked by the patient (Deutsche Telemedizin, Duisburg, Germany). The goal is to provide patients individually with specific recommendations and to modify the tasks as required to achieve optimal patient adherence as well as diagnostic and therapeutic benefit.

Patient journey

In the EP centre, written consent was obtained, patients were handed a flyer with a personalized QR code to download the App and self-register (Figure 1), and the clinic uploaded the discharge letter to the platform. All subsequent steps were handled remotely via the App with assistance by the staff of the telemedicine centre up until a recurrent arrhythmia occurred. All patients were provided with a free Withings Move ECG watch to self-record one-lead ECGs (Withings, Issy-les-Moulineaux, France). However, the iATROS platform is by design sensor-agnostic, so patients were free to connect other supported ECG wearables with CE approval such as the Apple Watch, the Withings ScanWatch, the Withings BPM Core, or the Beurer BM 96. If required, remote initial technical onboarding assistance was available, and in all cases, a remote video admission interview with a physician of the telemedicine centre was performed (Deutsche Telemedizin, Duisburg, Germany).

Patients were instructed and reminded by the App to record an ECG at least twice daily and additionally every time they felt palpitations. A first telemedicine consultation was always scheduled at the beginning of the programme to acquire complete anamnesis and inform the patient on the individual programme goals. Patients were instructed to book an appointment for a video consultation in case of an ECG-labelled 'AF' by the device or to go to their general practitioner (GP). Patients were informed that their data were not routinely reviewed by physicians of the telemedicine centre, unless they took action. The patient's GPs were informed regarding the programme and given contact information in case of questions. Patients were instructed to measure arterial blood pressure three times daily for at least 2 weeks; further measurements were recommended by the telemedicine physician based on the blood pressure values. All patients were instructed to enter their height at the beginning of the programme and their body weight once weekly in order to calculate the body mass index (BMI). Patients received reminders through the App to perform the measurements. Throughout the 12-month duration of the programme, they received tasks to watch an educational video or read a text and to perform activities, e.g. 30-min daily moderate exercise.

Management in case of recurring arrhythmia

Within the video consultation, the ECG was assessed. If arrhythmia was confirmed, the patients' medication was checked, in particular to ensure that the importance of anticoagulation medication was understood and medication was diligently taken, and slight adaptations were done when needed (e.g. adaptation of beta-blocker or antihypertensive medication dosage). A report was then written for the EP centre with a summary of findings and symptoms, featuring the original ECG tracings to enable data-based decision-making. Patients received the report via the App and were instructed to contact the EP centre the following business day for further therapy.

Data analysis

Patient activity at the end of the programme was defined as having recorded at least one ECG in the time window 365 ± 7 days after the start of their individual health programme.

ECGs were analysed based on the label attributed by the device algorithm. In the subset of patients in whom eventually no recurring arrhythmia was diagnosed, ECGs labelled as 'AF' were analysed by two physicians with >7 years of experience in cardiology to identify false positives.

Blood pressure was analysed as the mean values of the first 3 weeks after start of the programme and the last 3 weeks recorded. A mean systolic blood pressure of 130 mmHg or higher in patients with known arterial hypertension was qualified as not sufficiently controlled based on the current European Society of Cardiology/European Society of Hypertension (ESC)/ESH guidelines on arterial hypertension.¹¹ Body weight in patients with obesity at baseline (defined as BMI ≥ 30) was analysed as the first and the last value reported. Data were tested for normal distribution with the Kolmogorov–Smirnov test followed by either the t-test or the Wilcoxon test; a $P < 0.05$ was considered statistically significant.

The study conforms to the Declaration of Helsinki. All analyses were performed retrospectively on anonymized data, and for this reason, the competent ethics review board does not require approval of studies using these data.

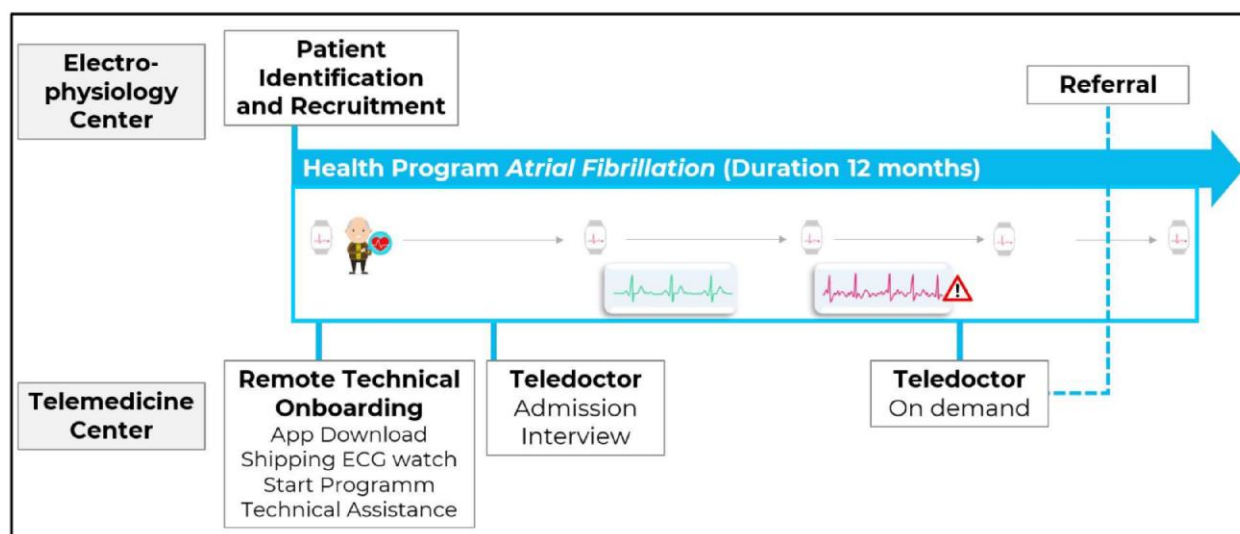


Figure 1 Patient journey.

Results

Patient population

A total of 68 patients were included into the programme. Patients were on average 63.1 years old (range 38–83 years), and 30.9% were female and 69.1% male (Table 1). The majority of patients were included following successful treatment for persistent AF ($n = 41$) vs. paroxysmal AF ($n = 27$). The last EP procedure preceding inclusion into the programme (= trigger intervention) was PVI in 60 patients and eCV in 8 patients. The distribution and frequency of accompanying diseases was as expected (Table 1).² Of 51 patients with known arterial hypertension, 23 were insufficiently controlled at the beginning of the programme. Obesity was seen in 28 patients, with the distribution: Class 1 ($\text{BMI} \geq 30\text{--}35$, $n = 20$), Class 2 ($\text{BMI} \geq 35\text{--}40$, $n = 5$), and Class 3 ($\text{BMI} \geq 40$, $n = 3$).

Programme adherence

Most patients measured ECGs regularly, and 45 out of 68 patients were found to have recorded at least one ECG at the predefined time point 365 ± 7 days after the start of their programme. Mean programme adherence duration according to these criteria was ~ 10.5 months (320.3 ± 78.3 days, mean \pm SD). In patients for which evidence was available, the reason for not having recorded ECGs at the time point 365 ± 7 days included only temporary pause (programme was resumed later on), ECG recordings having become obsolete (e.g. permanent AF without planned attempt at rhythmization), long periods of sinus rhythm, technical reasons (e.g. loss or damage of cell phone or ECG wearable and software problems), and medical reasons (e.g. new cancer diagnosis).

ECG recordings

The majority of patients used the Withings Move ECG device provided within the programme. However, several patients used an Apple Watch ($n = 2$), the Withings ScanWatch ($n = 3$), or the Withings BPM core ($n = 1$). During the active period, a total of 29 092 ECGs was recorded, corresponding to 1.42 ± 1.09 ECGs recorded per day (mean \pm SD) (median 1.14 ECGs/day). In order to rule out undetected

Table 1 Patients baseline characteristics

Age (years)	Mean	63.1 (range 38–83)
Sex (n, %)	Female	21 (30.9)
	Male	47 (69.1)
Initial atrial fibrillation (n)	Persistent	41
	Paroxysmal	27
Procedure before start (n)	Pulmonary vein isolation	60
	Electric cardioversion	8
Accompanying diagnoses (n, %)	Arterial hypertension	51 (76.1)
	Obesity	28 (41.8)
	Heart failure	14 (20.9)
	CAD	12 (17.9)
	Diabetes	11 (16.4)
	Heart valve disease	9 (13.4)
	Kidney failure	6 (9.0)
	OSA	6 (9.0)
	Chronic obstructive pulmonary disease	6 (9.0)
	Stroke	3 (4.5)
	PAD	1 (1.5)

CAD, coronary artery disease; OSA, obstructive sleep apnea; PAD, peripheral artery disease.

prolonged periods of arrhythmias, it is desirable in principle to ensure that at least one ECG is recorded daily, which was the case on 61.4% of days; specifically, no ECG was recorded on 124 of the 320 days within the active participation period (equivalent to 38.6% of days).

Of the 29 092 ECGs recorded, 20 224 (69.5%) were labelled by the devices as *sinus rhythm* and 4338 (14.9%) as *AF*, whereas 4530 (15.6%) were labelled as *inconclusive*.

An additional analysis was done in the subgroup of 29 patients who did not have an arrhythmia as eventually diagnosed and confirmed by 12-lead ECGs and/or Holter ECG performed in office and/or clinic.

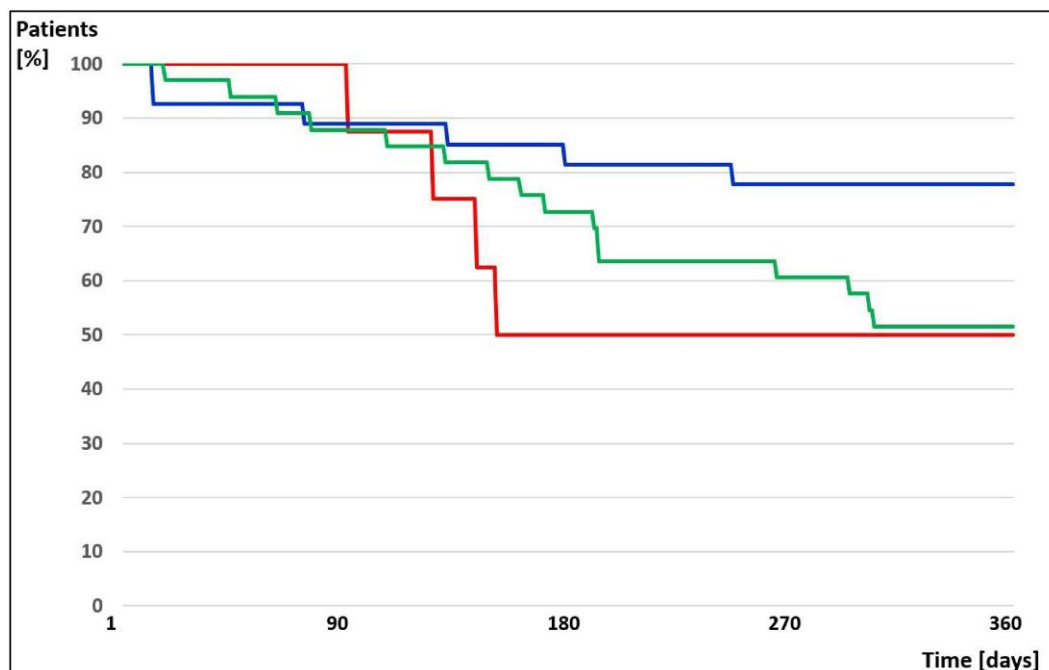


Figure 2 Time to first retreatment. Blue line: patients following pulmonary vein isolation for paroxysmal atrial fibrillation. Green line: patients following pulmonary vein isolation for persistent atrial fibrillation. Red line: patients treated by electric cardioversion for persistent atrial fibrillation.

The goal was to determine whether false positive AF labels were generated by the ECG watch algorithm. This subgroup had recorded 10 770 ECGs over the duration of the programme, of which the vast majority was correctly labelled as *sinus rhythm* by the device algorithm (84.0%), whereas 15.5% were labelled as *inconclusive*. Importantly, 0.5% of ECGs were wrongly labelled as AF, as analysed by two physicians. Whereas this would seem technically a low number of false positives, they were distributed to 7 of 29 patients without arrhythmia. In other words, 24.1% of patients who never had an arrhythmia during the 12-month programme period had at some point in time at least one ECG that was wrongly labelled as AF by the device algorithm. If patients are left alone, this rather high percentage may lead to patient anxiety, poor adherence and difficulties in patient management.¹⁰ Within the programme, patients had the possibility to book a video consultation to receive medical review—this led to the correction of the incorrect label of the ECG device. Hence, false positive labels of the ECG algorithms could be successfully corrected by telemedicine consultation in all cases—this is in line with the current ESC guidelines on AF that require physician review of one-lead ECGs for definitive AF diagnosis.²

Impact of ECG monitoring on retreatment

As described above, one purpose of the holistic digital health programme is to empower the patient to (i) self-record ECGs as needed, (ii) understand the implications of (re-)occurring arrhythmias, and (iii) take appropriate action by seeking medical advice. We evaluated how the detection of arrhythmias by wearable ECGs impacted patient journey and, ultimately, clinical decision-making and retreatment.

First, we looked at the occurrence and time point of first reintervention for arrhythmia, defined as PVI, eCV, and/or antiarrhythmic medication. At the end of the 12-month programme duration, the

following percentage of patients initially treated by PVI had been re-treated for arrhythmia in an EP centre: 6 of 27 patients initially treated for paroxysmal AF (22.2%), and 16 of 33 patients initially treated for persistent AF (48.5%) (the time course is shown in Figure 2). We also looked at the reintervention for arrhythmia in patients who had been initially treated by eCV, with 50.0% of patients requiring reintervention (Figure 2).

Clinical decision-making

Next, we evaluated the patient journeys following ECG recordings within the health programme. Although the ECG and the algorithms of the wearables used in this programme are of good quality, there are a non-negligible number of false negatives and false positives and a substantial number of ECGs labelled as *inconclusive*. We therefore sought to evaluate how the patients acted on the ECG diagnoses and what actions were subsequently taken. We evaluated the patient journey from screening to retreatment, if applicable, for the 39 patients in whom recurring arrhythmia was seen, and compared them with the 29 patients in whom no arrhythmia was seen until the end of the programme with either method (12-lead ECG or Holter ECG in-office, or self-recorded one-lead ECG following correction by experienced physicians) (Figure 3).

- Step 1: Initial identification of recurring arrhythmia. Recurring arrhythmia was successfully and accurately first detected by the wearable ECGs in all 39 cases. By contrast, no arrhythmia was diagnosed first by in-office procedures (12-lead ECG or Holter ECG).
- Step 2: Confirmation of recurrent arrhythmia by physician. Once recurring arrhythmia was signalled by the ECG wearable, the patients had the possibility to seek medical advice either by booking a video consultation with a tele-physician over the App or to go to their GP or cardiologist. Video consultation was the first medical touchpoint in 30 patients, vs. office GP, cardiologist or clinic in nine patients.

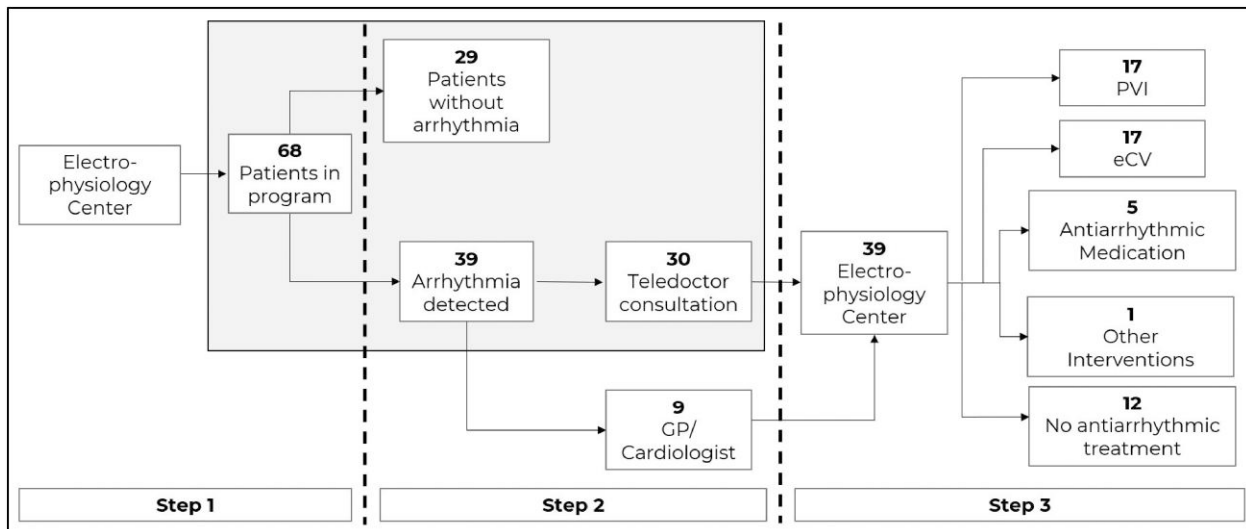


Figure 3 Patient recruitment in the electrophysiology centre and treatment within the health programme (Step 1), detection of first arrhythmia and first consultation (Step 2), and treatment in the electrophysiology centre (Step 3). The grey box denotes actions taking place autonomously within the health programme atrial fibrillation via the platform. eCV, electric cardioversion; GP, general practitioner; PVI, pulmonary vein isolation.

The tele-physician was able in all cases to correctly either confirm or dismiss the diagnosis of recurring arrhythmia; within the video consultation, the physician had the opportunity to check their current medication and adapt if necessary and refer the patients to the EP centre if required. In cases with documented arrhythmia, a report including the ECG tracings was generated for the EP centre. Thus, the receiving EP centre was provided with comprehensive information on symptoms, medication, and, most importantly, the documented one-lead ECG of the arrhythmia, allowing swift and data-based decision-making.

- Step 3: Further therapy in the EP centre. The EP centre decided based on the documented ECGs and reports whether additional diagnosis was needed and/or whether antiarrhythmic therapy was recommended. Treatments performed within the 12-month duration of the programme were PVI ($n = 17$), eCV ($n = 17$), other ablation procedures ($n = 1$), and/or antiarrhythmic medication ($n = 5$). In 12 patients, decision was either taken to no longer attempt rhythm control, or patients were not clearly motivated, intervention was not necessary due to very low AF burden or intervention was delayed by various reasons beyond the 12-month observation time frame.

Risk factor management

An additional aim of the programme was to optimize risk factors known to be associated with AF as recommended in the 2020 American Heart Association (AHA) statement and the current 2024 ESC guidelines.^{2,12} The importance of rigorous managing of cardiovascular risk factors is increasingly recognized as an approach to reduce the occurrence of AF; this includes HbA1c, dyslipidaemia, obstructive sleep apnea (OSA), diabetes, alcohol excess, smoking, and physical inactivity.^{2,12} This was addressed by a combined approach including video consultations, in which antihypertensive medication was adjusted if required, and education to improve lifestyle (in particular on health literacy, nutrition, and physical activity). In 21 patients with insufficiently controlled hypertension at the beginning of the programme who entered their blood pressure values over time, mean systolic blood pressure was 135.9 ± 6.4 mmHg at Day 0 and was reduced to 127.8 ± 8.7 mmHg at the end ($n = 21$, $P < 0.01$) (Figure 4). All patients with

diagnosed hypertension had antihypertensive medication at the beginning of the programme. In nine patients, antihypertensive medication was increased, whereas antihypertensive medication was not changed in 11 patients and was reduced in one patient. In patients with obesity who entered their body weight values over time, body weight was 105.5 ± 17.1 kg at baseline and was significantly reduced to 101.9 ± 14.0 kg at the end of the programme ($n = 25$, $P < 0.01$) (Figure 4).

Discussion

A hybrid holistic digital health programme was developed with the goal of leveraging the potential of digital technologies for improved diagnosis and treatment by integrating it into today's clinical treatment pathway of patients with AF. Real-world data were gained by systematically analysing a programme with 68 consecutive patients enrolled after intervention for AF. The main findings were as follows:

- Adherence: patients actively participated in the programme over a prolonged period of time (mean participation duration was 10.5 months, close to the overall programme duration of 12 months), during which time 1.42 ECGs were recorded daily on average (vs. goal of ≥ 2 ECGs daily).
- Diagnosis of recurring arrhythmia: the combination of self-recorded one-lead ECGs and access to short-term medical assessment by video consultation led to an early detection of recurring arrhythmia in all 39 cases with no false positive. In all cases, diagnosis preceded that by the conventional approach (12-lead ECG or Holter ECG in-office).
- Decision-making: the diagnosis and ECG documentation through the health programme enabled data-based clinical decision-making in the EP centre regarding potential reinterventions.
- Cardiovascular risk factors: within the combined approach of medication adjustments via video consultation and the 12-month coaching and education programme, the cardiovascular risk factors arterial hypertension and obesity were significantly improved.

The introduction of patient self-recording of ECGs by wearables has been a milestone in the management of patients with arrhythmias, and a

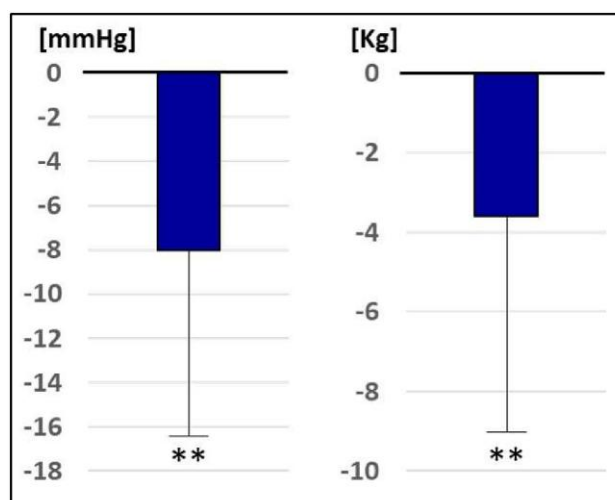


Figure 4 Reduction of blood pressure in patients with insufficiently controlled hypertension (left panel, $n = 21$) and of body weight in patients with obesity (right panel, $n = 25$). Data are mean \pm standard deviation; ** $P < 0.01$.

growing number of certified medical devices is available.^{4,13,14} An alternative approach is that of rhythm analysis using photoplethysmographic (PPG) approaches as shown in a recent publication¹⁵; however, the current clinical standard in accordance with the relevant guidelines requires that AF be documented by ECG for final diagnosis and as basis of further treatment (e.g. PVI or eCV) and it remains to be seen, if PPG recordings will be accepted as an alternative in the future.^{2,16}

A recent study comparing five wearable ECG devices, including the Apple Watch and the Withings ScanWatch, has shown rather poor sensitivity (between 58 and 85%) and specificity (between 69 and 79%, respectively),¹³ and other groups have reported similar findings.^{17,18} These underwhelming numbers are driven in part by a substantial percentage of recordings labelled by the device algorithms as *inconclusive*.¹³ This is mirrored by our findings, in which 16.5% of ECGs were labelled by the devices as *inconclusive*. A recent European Heart Rhythm Association practical guide was recently published in which physician oversight was recommended when using ECG wearables in clinical practice,¹⁹ which is also recommended in the 2024 ESC guidelines.² However, ECG assessment by a physician with cardiology training has the potential to increase the overall accuracy and to fully leverage the potential of this technology, especially if patients are trained and multiple ECGs are obtained.^{20–22} This has been investigated previously in studies in which self-recording of ECGs by patients was combined with physician review.²³ Unfortunately, unlike the situation in clinical studies, in routine practice, there is no low-threshold access for patients to physicians who are able to technically view and are medically trained and experienced to assess one-lead ECG short term.⁷ Also, technically transferring the ECGs to a doctor's office to make it available for medical assessment can be challenging in today's practice for various reasons. Importantly, a recent survey among caregivers has shown that most physicians sometimes or regularly use digital devices such as wearables, even though 22.1% said they did not²⁴; lack of reimbursement was cited as the main reason for this underuse.²⁴ Hence, a main goal of the hybrid digital health programme was to establish a platform making short-term medical assessment of the recorded ECGs readily available through appointment booking via the App and subsequent video consultation, with reimbursement secured by the AOK PLUS health insurance. With this combined approach, we have seen in a real-world setting in patients who were in sinus rhythm at

the beginning of the programme that the presence vs. absence of arrhythmia could be clinically correctly identified in all 39 cases in the present programme. Furthermore, the diagnosis came earlier than standard in-office ECGs in all cases. Of the 39 cases of recurrent arrhythmia, AF was diagnosed in 36 cases and later confirmed by the EP centre. In three remaining cases, the presence of arrhythmia was correctly identified, even though the specific nature of the arrhythmia could not be established based on the one-lead ECGs alone - these patients were referred to the EP centre based on the diagnosis of unspecified arrhythmia, where eventually atrial tachycardia ($n = 2$) and typical atrial flutter ($n = 1$) were diagnosed.

Prompt feedback in case of recurring arrhythmia is important to patients.¹⁰ Many patients are highly concerned or even anxious and frequently go to an emergency department, even though it is medically unnecessary.^{1,25} A major albeit underappreciated drawback of available ECG tools is that information on whether an arrhythmia has occurred or not is delayed, often by weeks or months. Indeed, Holter ECGs often need to be repeated several times until diagnosis is secured. Even with the technical gold standard, implantable monitors, feedback to the patients is not immediate but delayed until the next scheduled device interrogation or visit to the cardiologist.^{26,27} In our experience, patients value the short-term diagnostic feedback provided by the programme, along with the security that medication is checked, and recommendations are given as to whether further medical care is needed and with what degree of urgency. This may help to promote patient adherence and informed shared decision-making between patients and physicians and reduce patient anxiety. Possibly, this was also due to the education programme in which understanding of the disease, therapy, and risk management is fostered (importance of anticoagulation, heart rate control, and others).

Once an ECG was recorded that was labelled by the device as AF, a large majority of patients opted to speak with a teledoctor first ($n = 30/39$). Although going to a doctor's office first is a medically valid option, the teledoctors offer a number of practical advantages: the ECGs are already on file at the time of teleconsultation (whereas transferring ECGs to a GP can be challenging and time-consuming, depending on the individual setting), the teledoctors are familiar with interpreting one-lead ECGs and the programme itself, and they are available short term (i.e. following business day).

One additional goal of the holistic digital health programme AF was to improve modifiable cardiovascular risk factors according to the 2020 AHA scientific statement and the AF-Care approach recommended in the recent 2024 ESC guidelines on AF.^{2,12} To achieve this, an educational programme was developed featuring > 100 elements over the course of 12 months and including content on health literacy (disease, diagnosis, and treatment) as well as lifestyle education including nutrition and physical activity. Educational content is delivered via the Patient App, using different functions: entering blood pressure and body weight values, entering medication, rendering of educational content such as videos, texts, and short messages, and generating disease and lifestyle-related tasks such as reminders to watch a video, take medication, perform exercise, or follow nutritional advice. The programme was supported by video consultation, in which the goals were proposed and agreed upon, patients were encouraged, the educational programme was adapted if required, and medication was changed as needed. A recent study has concluded that patients with AF request from a programme aimed at managing modifiable risk factors: (i) person-centred information, (ii) support in managing healthy lifestyle habits, and (iii) more regular communication.²⁸ These criteria were overall largely met in this programme, which most likely has supported the seen achievements of high patient adherence and improved risk factors blood pressure and body weight.

The EP centre was provided with the ECG tracings of the documented arrhythmia along with a description of symptoms and circumstances, which streamlined data-based decision-making regarding further diagnostic and therapeutic procedures. However, communication between the telemedicine centre and the EP centre required patients' participation, which proved to be challenging in some cases due to lacking technical versatility. We expect that with the advent of secure communication channels in Germany and other countries, direct communication will be easier between medical centres.

In the present real-world cohort, the programme was provided to patients in sinus rhythm after interventional treatment for AF, which is a patient group with high likelihood of recurrence and therefore high medical need to optimize risk factors and allow smooth retreatment in case of recurrence. Other potential applications include patients with suspected but not yet confirmed AF or patients following thromboembolic stroke of unknown origin. Clinical application will need to show whether the acceptance, adherence, and diagnostic and therapeutic efficacy in these other patient groups also show benefit.

Limitations and outlook

The current analysis is a report based on real-world data from an actual patient care programme and is exploratory in nature. By design, we analysed the overall effects of a holistic programme, which leaves questions as to the relative contributions of individual factors unanswered (e.g. whether blood pressure reduction was mainly due to the coaching or teleconsultation or both or whether ECG recording vs. assessment by video consultation were the main drivers of efficacy). Also, the programme almost certainly can be optimized, e.g. by reducing the frequency of blood pressure/ECG measurements to avoid fatigue, etc. and by evaluating the optimal programme length (24 vs. 12 months); each change will have to be evaluated against the current benchmark. Some of the findings are currently being validated in a clinical study, which will provide more definitive answers to the advantages and potential limitations of the approach (NCT05375877). Ultimately, a prospective randomized controlled trial (RCT) will be required comparing the hybrid digital approach with standard of care. An additional limitation of the current report is that no cost-effectiveness analysis was performed in this cohort. The costs are in the range of 40€/month including the device (which the patients keep), access to the platform,

technical support, education programme, and telemedicine services, but whether this approach is truly cost-effective remains to be shown.

Conclusion

The current data show that such a hybrid programme can be successfully implemented into today's patient care. The data are promising but need to be confirmed in an RCT. If confirmed, this approach could improve the diagnosis and therapy of patients with AF.

Lead author biography



Georges von Degenfeld, MD PhD, FESC, University Lecturer at the University of Augsburg, Germany. Physician with over 7 years of experience in cardiology patient care at the Ludwig-Maximilians-University München, Germany. Internationally acknowledged researcher with over 20 years of experience, in particular at Stanford University Medical School, USA. Over 10 years of experience in pharma drug discovery and early clinical development in cardiovascular research

and as global head of drug discovery ophthalmology at Bayer Pharma, Wuppertal and Berlin, Germany. Over 6 years of experience in telemedicine and digital health at Medgate AG, Basel, Switzerland, iATROS Digital Heart Center, München, Germany (founder and CEO/CMO), and DT Deutsche Telemedizin, Duisburg, Germany (CEO and CMO).

Funding

The programme was funded by AOK PLUS - Die Gesundheitskasse für Sachsen und Thüringen, Dresden, Germany.

Conflict of interest: none declared.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

References

1. Sadlonova M, Salzmann S, Senegés J, Celano CM, Huffman JC, Borggrefe M, et al. Generalized anxiety is a predictor of impaired quality of life in patients with atrial fibrillation: findings from the prospective observational ARENA study. *J Psychosom Res* 2024; **176**:111542.
2. Van Gelder IC, Rienstra M, Bunting KV, Casado-Arroyo R, Caso V, Crijns H, et al. 2024 ESC guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J* 2024; **45**: 3314–3414.
3. Linz D, Gawalko M, Betz K, Hendriks JM, Lip GYH, Vinter N, et al. Atrial fibrillation: epidemiology, screening and digital health. *Lancet Reg Health Eur* 2024; **37**:100786.
4. Varma N, Han JK, Passman R, Rosman LA, Ghanbari H, Noseworthy P, et al. Promises and perils of consumer mobile technologies in cardiovascular care: JACC scientific statement. *J Am Coll Cardiol* 2024; **83**:611–631.
5. Svennberg E, Caiati EG, Bruining N, Desteghe L, Han JK, Narayan SM, et al. The digital journey: 25 years of digital development in electrophysiology from an *Europace* perspective. *Europace* 2023; **25**:euaad176.
6. Giebel GD, Abels C, Plescher F, Speckemeier C, Schrader NF, Borchers K, et al. Problems and barriers related to the use of mHealth apps from the perspective of patients: focus group and interview study. *J Med Internet Res* 2024; **26**:e49982.
7. Manninger M, Zweiker D, Svennberg E, Chatzikiyiakou S, Pavlovic N, Zaman JAB, et al. Current perspectives on wearable rhythm recordings for clinical decision-making: the wEHRAbles 2 survey. *Europace* 2021; **23**:1106–1113.

8. Sinner M, von Falkenhausen AS, Steinbeck G. [Screening for atrial fibrillation—what to do if the patient presents with atrial fibrillation on a smartwatch ECG?]. *MMW Fortschr Med*. 2024;**166**:50–53.
9. Pastapur A, Pescatore NA, Shah N, Kheterpal S, Nallamothu BK, Golbus JR. Evaluation of atrial fibrillation using wearable device signals and home blood pressure data in the Michigan Predictive Activity & Clinical Trajectories in Health (MIPACT) study: a subgroup analysis (MIPACT-AFib). *Front Cardiovasc Med* 2023;**10**:1243574.
10. Rosman L, Lampert R, Zhuo S, Li Q, Varma N, Burg M, et al. Wearable devices, health care use, and psychological well-being in patients with atrial fibrillation. *J Am Heart Assoc*. 2024;**13**:e033750.
11. Williams B, Mancia G, Spiering W, Agabiti Rosei E, Azizi M, Burnier M, et al. 2018 ESC/ESH guidelines for the management of arterial hypertension. *Eur Heart J*. 2018;**39**:3021–3104.
12. Chung MK, Eckhardt LL, Chen LY, Ahmed HM, Gopinathannair R, Joglar JA, et al. Lifestyle and risk factor modification for reduction of atrial fibrillation: a scientific statement from the American Heart Association. *Circulation* 2020;**141**:e750–e772.
13. Mannhart D, Lischer M, Knecht S, du Fay de Lavallaz J, Strebel I, Serban T, et al. Clinical validation of 5 direct-to-consumer wearable smart devices to detect atrial fibrillation: BASEL wearable study. *JACC Clin Electrophysiol* 2023;**9**:232–242.
14. Garikapati K, Turnbull S, Bennett RG, Campbell TG, Kanawati J, Wong MS, et al. The role of contemporary wearable and handheld devices in the diagnosis and management of cardiac arrhythmias. *Heart Lung Circ* 2022;**31**:1432–1449.
15. Calvert P, Mills MT, Howarth K, Aykara S, Lunt L, Brewer H, et al. Remote rhythm monitoring using a photoplethysmography smartphone application after cardioversion for atrial fibrillation. *Eur Heart J Digit Health* 2024;**5**:461–468.
16. Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomstrom-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* 2021;**42**:373–498.
17. Peppinkhuizen S, Hoeksema WF, van der Stuijt W, van Steijn NJ, Winter MM, Wilde AAM, et al. Accuracy and clinical relevance of the single-lead Apple Watch electrocardiogram to identify atrial fibrillation. *Cardiovasc Digit Health J* 2022;**3**:S17–S22.
18. Wasserlauf J, Vogel K, Whisler C, Benjamin E, Helm R, Steinhaus DA, et al. Accuracy of the Apple Watch for detection of AF: a multicenter experience. *J Cardiovasc Electrophysiol* 2023;**34**:1103–1107.
19. Svennberg E, Tjong F, Goette A, Akoum N, Di Biase L, Bordachar P, et al. How to use digital devices to detect and manage arrhythmias: an EHRA practical guide. *Europace* 2022;**24**:979–1005.
20. Malmqvist J, Engdahl J, Sjolund G, Doliwa P. Sensitivity and specificity of handheld one lead ECG detecting atrial fibrillation in an outpatient clinic setting. *J Electrocardiol* 2024;**83**:106–110.
21. Hibbitt K, Brimicombe J, Cowie MR, Dymond A, Freedman B, Griffin SJ, et al. Reliability of single-lead electrocardiogram interpretation to detect atrial fibrillation: insights from the SAFER feasibility study. *Europace* 2024;**26**:euae181.
22. Alnasser S, Alkalthem D, Alenazi S, Alsowinea M, Alanazi N, Al Fagih A. The reliability of the Apple Watch's electrocardiogram. *Cureus* 2023;**15**:e49786.
23. Lambert CT, Patel D, Bumgarner JM, Kanj M, Cantillon D, Saliba W, et al. Atrial fibrillation future clinic. Novel platform to integrate smart device electrocardiogram into clinical practice. *Cardiovasc Digit Health J* 2021;**2**:92–100.
24. Boriani G, Svennberg E, Guerra F, Linz D, Casado-Arroyo R, Malaczynska-Rajpold K, et al. Reimbursement practices for use of digital devices in atrial fibrillation and other arrhythmias: a European Heart Rhythm Association survey. *Europace* 2022;**24**:1834–1843.
25. Shih P, Prokopovich K, Degeling C, Street J, Carter SM. Direct-to-consumer detection of atrial fibrillation in a smartwatch electrocardiogram: medical overuse, medicalisation and the experience of consumers. *Soc Sci Med* 2022;**303**:114954.
26. Nölker G, Mayer J, Boldt LH, Seidl K, van Driel V, Massa T, et al. Performance of an implantable cardiac monitor to detect atrial fibrillation: results of the DETECT AF study. *J Cardiovasc Electrophysiol* 2016;**27**:1403–1410.
27. Reiffel JA, Verma A, Kowey PR, Halperin JL, Gersh BJ, Wachter R, et al. Incidence of previously undiagnosed atrial fibrillation using insertable cardiac monitors in a high-risk population: the REVEAL AF study. *JAMA Cardiol* 2017;**2**:1120–1127.
28. Klaveback S, Svennberg E, Nyman C, Braunschweig F, Lidin M. Management of modifiable risk factors and comorbidities in atrial fibrillation: suggestions for improvement from a patient perspective. *Eur J Cardiovasc Nurs* 2024;**23**:169–175.