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EHRA SURVEY

Current perspectives on wearable rhythm recordings for clinical decision-making: the wEHRAbles 2 survey

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Abstract

Novel wearable devices for heart rhythm analysis using either photoplethysmography (PPG) or electrocardiogram (ECG) are in daily clinical practice. This survey aimed to assess impact of these technologies on physicians' clinical decision-making and to define, how data from these devices should be presented and integrated into clinical practice. The online survey included 22 questions, focusing on the diagnosis of atrial fibrillation (AF) based on wearable rhythm device recordings, suitable indications for wearable rhythm devices, data presentation and processing, reimbursement, and future perspectives. A total of 539 respondents {median age 38 [interquartile range (IQR) 34–46] years, 29% female} from 51 countries world-wide completed the survey. Whilst most respondents would diagnose AF (83%), fewer would initiate oral anticoagulation therapy based on a single-lead ECG tracing. Significantly fewer still (27%) would make the diagnosis based on PPG-based tracing. Wearable ECG technology is acceptable for the majority of respondents for screening, diagnostics, monitoring, and follow-up of arrhythmia patients, while respondents were more reluctant to use PPG technology for these indications. Most respondents (74%) would advocate systematic screening for AF using wearable rhythm devices, starting at patients' median age of 60 (IQR 50–65) years. Thirty-six percent of respondents stated that there is no reimbursement for diagnostics involving wearable rhythm devices in their countries. Most respondents (56.4%) believe that costs of wearable rhythm devices should be shared between patients and insurances. Wearable single- or multiple-lead ECG technology is accepted for multiple indications in current clinical practice and triggers AF diagnosis and treatment. The unmet needs that call for action are reimbursement plans and integration of wearable rhythm device data into patient's files and hospital information systems.

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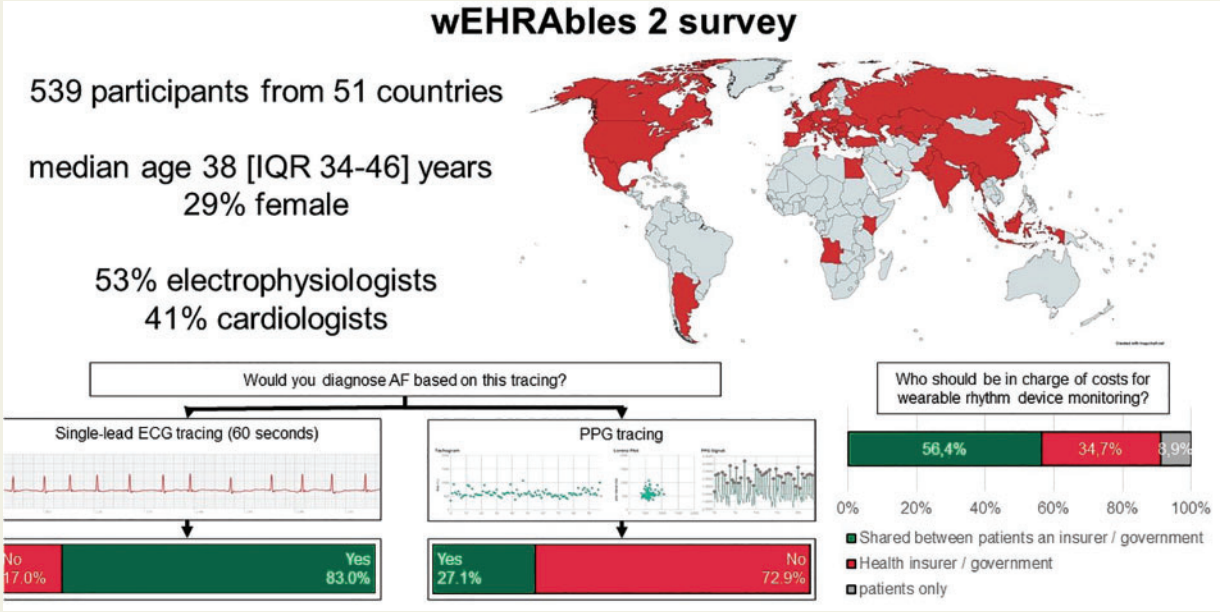
Graphical Abstract



Keywords Digital health • Digital medicine • Wearables • Arrhythmia • Atrial fibrillation • Screening • Rhythm monitoring • Telemedicine • EHRA survey

Introduction

Recently, multiple widely available wearable devices have been developed that can assess heart rate and rhythm using either photoplethysmography (PPG) or electrocardiogram (ECG).[1,2] These technologies allow detection of irregular rhythm and lead to faster diagnosis of atrial fibrillation (AF), the most common sustained arrhythmia in adults which results in increased morbidity and mortality.[3–6] However, practical guidance for clinical decision-making regarding device detected AF is sparse.

In the first wEHRAbles survey, we demonstrated that tracings from wearable devices suggestive of arrhythmias are most likely to trigger further diagnostic steps.[7] For the majority of respondents, ECG-based tracings could trigger therapeutic steps, whereas therapeutic interventions were rarely based on PPG recordings. Most participants requested scientific society recommendations on the use of wearables.

Hence, we sought to define the specific data required for physicians to make clinical decisions by conducting a second survey. The aims of the wEHRAbles 2 survey were to

- define data quality required to take clinical decisions based on wearable device recordings,
- define which data coming from wearables is important for clinical decision making and how it is implemented into existing working tools,
- clarify the physicians' acceptance towards diagnostic algorithms such as artificial intelligence (AI), machine learning, and app-based follow-up,
- study clinical decisions based on case scenarios,
- describe actual handling of these technologies in the context of current guidelines and identify gaps in current evidence to delineate need for future guideline recommendations, and
- evaluate how the COVID-19 pandemic influenced the use of wearable devices and teleconsultations.

Methods

An online questionnaire consisting of 22 questions was prepared using the European Heart Rhythm Association (EHRA) infrastructure and distributed to EHRA members, members of national electrophysiology (EP) working groups, and via social media platforms (Twitter, LinkedIn, and Facebook). The questionnaire included questions on demographics, as well as possible areas of application of wearable rhythm devices, patient scenarios, use of wearable technologies for screening, future of rhythm diagnostics, reimbursement, and data management (Supplementary

material online, *Table S1*). All questions, besides questions on demographics, were classified as mandatory.

Continuous variables are presented as mean ± SD or median [interquartile range (IQR)]. Categorical variables are presented as percentages and counts. Questions of clinical decision-making were compared using Wilcoxon test for dependent and Mann–Whitney *U* test for independent variables. Correlations were calculated using Spearman's rank correlation coefficient. A two-sided *P*-value of <0.05 was considered significant. Statistical analyses were performed using R version 4.0.3 (The R Foundation, Vienna, Austria).

Results

Five hundred and thirty-nine participants completed the online survey from 1 September to 6 November 2020. Complete data are available in all respondents, since all questions were mandatory.

Median age was 38 years (IQR 34–46 years), 29% of participants were female (see *Table 1* for demographics). Median experience in EP was 6 years (IQR 3–14), 53.5% were currently working in EP. Respondents from 51 different countries from all continents participated in the survey.

Table 1 Characteristics of wEHRAbles 2 survey respondents

n	539
Median age (years)	38 (IQR 34–46)
Female respondents	29%
Occupation	
EP specialist	33%
EP team leader	13%
EP fellow	6%
Cardiologist	26%
Cardiology fellow	15%
Other	6%
Primary working environment	
University hospital	63.5%
Public cardiology centre	15.7%
District/community hospital	9.9%
Private practice	7.7%
Other	0.4%
Country (top 10, total 51)	*n*
Serbia	83
Germany	61
Italy	37
Croatia	30
Poland	27
Switzerland	25
USA	24
Romania	24
Austria	20
Spain	15

Map created with mapchart.net (CC-BY-SA 4.0).
EP, electrophysiology.

Patient scenarios for clinical decision-making

In a case example of a 58-year-old female patient with arterial hypertension and diabetes mellitus without previous history of arrhythmias and no contraindication to oral anticoagulation presenting with a 60 s single-lead ECG showing an irregular heart rhythm and absence of P waves, 83% of respondents would diagnose AF based on the tracing in the survey (*Figure 1*). Of these respondents, 72.1% would initiate oral anticoagulation. Respondents who would not diagnose AF based on the tracing would require a 12-lead ECG (83.7%), 3-lead ECG (67.4%), or tracing from an implantable loop recorder (21.6%) to diagnose AF. Respondents who would diagnose AF based on a single-lead ECG tracing were older (median 39 vs. 36 years, $P = 0.001$) and were more frequently electrophysiologists (87.2% vs. 80.1%, $P = 0.032$).

In the same patient scenario, when presented a PPG tracing of 60 s showing an arrhythmia with irregular intervals in a tachogram and a Lorenz plot with high scatter (*Figure 1*), only 27% of respondents would diagnose AF based on this tracing. From these respondents, 69% would also initiate oral anticoagulation. Respondents who would not diagnose AF based on a PPG tracing would ask for a 12-lead ECG (82.9%), 3-lead ECG (74.8%), single-lead ECG (50.5%), or tracing from an implantable loop recorder (47.7%) to diagnose AF. Respondents who would diagnose AF based on a PPG tracing were older (median 40 vs. 37 years, $P = 0.005$) and were more often non-electrophysiologists (32.0% vs. 23.4%, $P = 0.031$).

Areas of application of wearable rhythm devices

When asked about possible indications for the use of wearable rhythm devices, most respondents believed that single- or multiple-lead ECGs would be suitable for all stated indications (*Figure 2*). Respondents were more reluctant to use PPG devices. Respondents chose PPG for monitoring rate control in AF patients more often than all other indications (40.1%), but still significantly less often than single- or multiple-lead ECG.

Wearable rhythm devices for atrial fibrillation screening

Most respondents advocate for systematic screening of the general population for AF with the use of wearable rhythm devices (74%). These respondents would start screening at a median patients' age of 60 years (IQR 50–65 years) or at median CHA_2DS_2-VASc score of 2 (IQR 2–3) in women and 1 (IQR 1–2) in men. Most respondents (92%) believe that wearable rhythm device technology could be used for AF screening in patients with embolic stroke of unknown source. The preferred technologies used for this indication were ECG devices (55.7%), or a combination of PPG and ECG devices (38.4%), rather than PPG devices only (5.9%).

Data presentation and processing

When asked how data from single-lead ECG and PPG devices should be presented, most respondents wanted to see the tracing from single-lead ECGs (77.2%), while regarding PPG, most respondents expected heart rhythm plots (65%, see *Figure 3*). Respondents

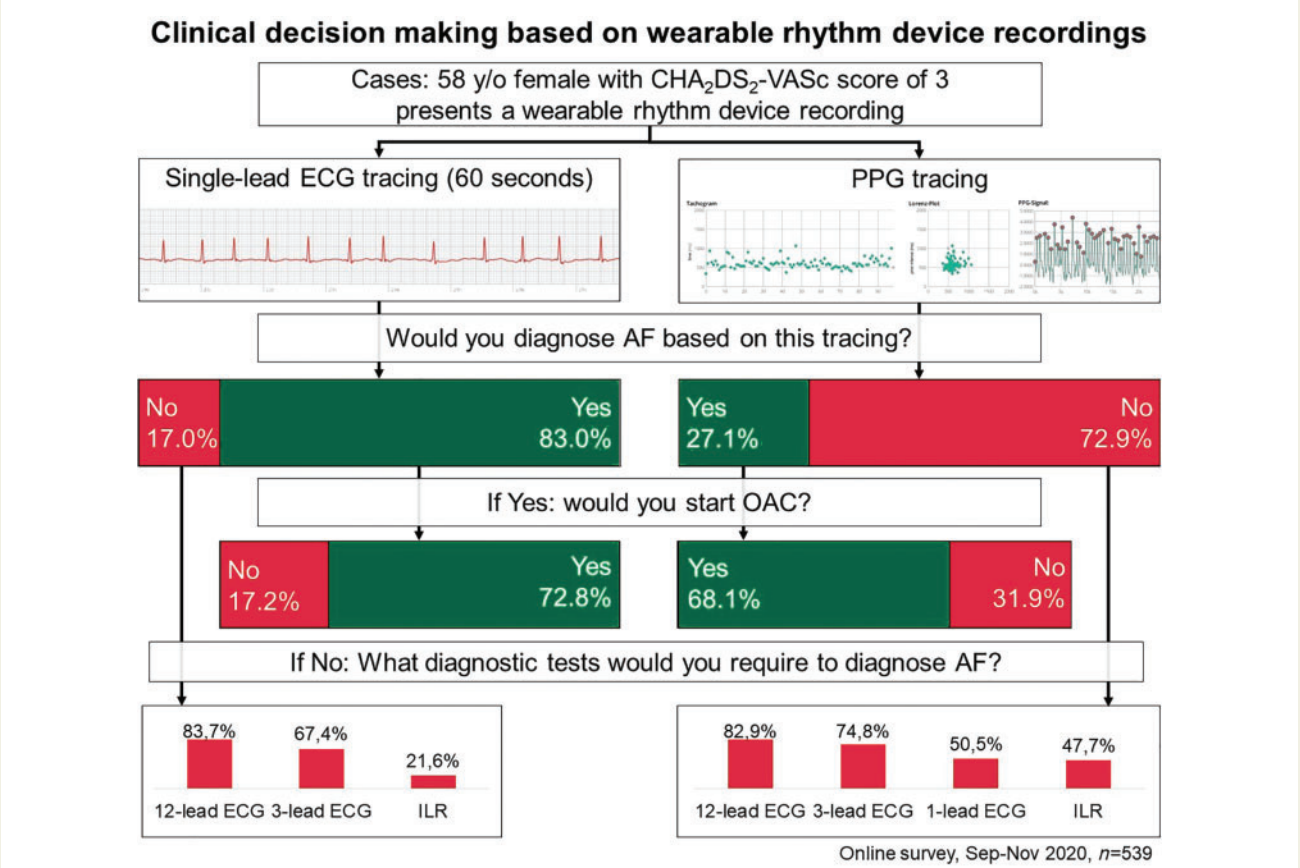


Figure 1 Decision-tree describing responses to the case scenarios. Most respondents would diagnose AF based on a single-lead ECG recording and initiate OAC therapy. AF, atrial fibrillation; ECG, electrocardiogram; OAC, oral anticoagulation.

requested heart rhythm and Lorenz plots from PPG devices, rather than from single-lead ECG devices ($P < 0.001$ each), conversely requesting tracings from single-lead ECG devices more often than from PPG devices ($P < 0.001$).

When asked how information from wearable devices is obtained in current clinical practice, most respondents stated that device tracings were presented by patients during the consultation (63%), while 49% received tracings by e-mail, 30% agreed beforehand how communication with the patient would be arranged, 20% received email notifications from device companies, and 16.7% regularly checked internet platforms from device companies.

Currently, most respondents (62.8%) either described recordings or uploaded tracings (53%) into their patient's records. Only 15.5% referenced to an external platform. In the future, respondents would prefer a manual (51.6%) or automatic (38.3%) upload to patient's records, while 30.7% would prefer an upload to an official government platform and 21.5% would prefer the tracings to be seen via a link from the medical record to an external internet platform of the device company.

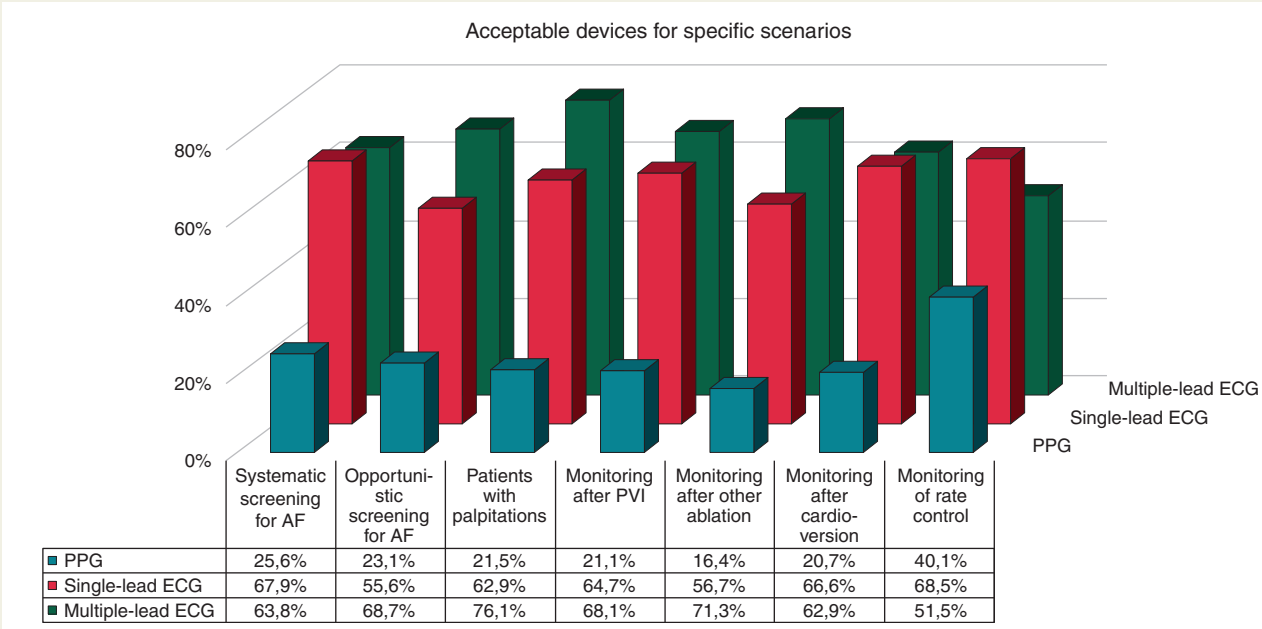
Reimbursement

Thirty-six percent of respondents claimed that there was no reimbursement for the time spent collecting and interpreting remote patient health data gathered by wearable devices, and digitally stored and transmitted to a provider in their healthcare system. Thirteen percent stated that they believed there was a reimbursement but were not sure how to claim it and only 12% knew how to claim the reimbursement. The other 39% did not know if there was reimbursement in their country. The latter reply was more common in young respondents with low EP experience ($P < 0.001$) and respondents with working positions outside of EP ($P < 0.001$). Most respondents from Northern America claimed that there was a reimbursement. Respondents from Asia, Eastern Europe, and South America stated that there was no reimbursement and respondents from Africa, Southern, and Western Europe stated that they did not know if there was reimbursement (Supplementary material online, *Figure S1* and *Table S2*).

Most respondents (56.4%) believe that the costs for wearable rhythm monitoring should be shared between patients and insurer, 34.7% believe that the health insurer or the government should be in charge of the costs, while only 8.9% believe that patients should be the only responsible side. Regarding distribution of costs, there were no differences among age groups or working positions of the respondents.

Future perspectives

Respondents believe that in 2030, AI algorithms will allow diagnosis of paroxysmal AF through sinus rhythm ECG strip (42.7%),



	Systematic screening for AF	Opportunistic screening for AF	Patients with palpitations	Monitoring after PVI	Monitoring after other ablation	Monitoring after cardio-version	Monitoring of rate control
PPG	25,6%	23,1%	21,5%	21,1%	16,4%	20,7%	40,1%
Single-lead ECG	67,9%	55,6%	62,9%	64,7%	56,7%	66,6%	68,5%
Multiple-lead ECG	63,8%	68,7%	76,1%	68,1%	71,3%	62,9%	51,5%

Figure 2 ECG-based devices are acceptable for diagnostic purposes in patients with palpitations, screening for AF, and monitoring of AF patients. Only a minority of respondents found PPG-based devices suitable for these indications. AF, atrial fibrillation; ECG, Electrocardiogram; PPG, photoplethysmography.

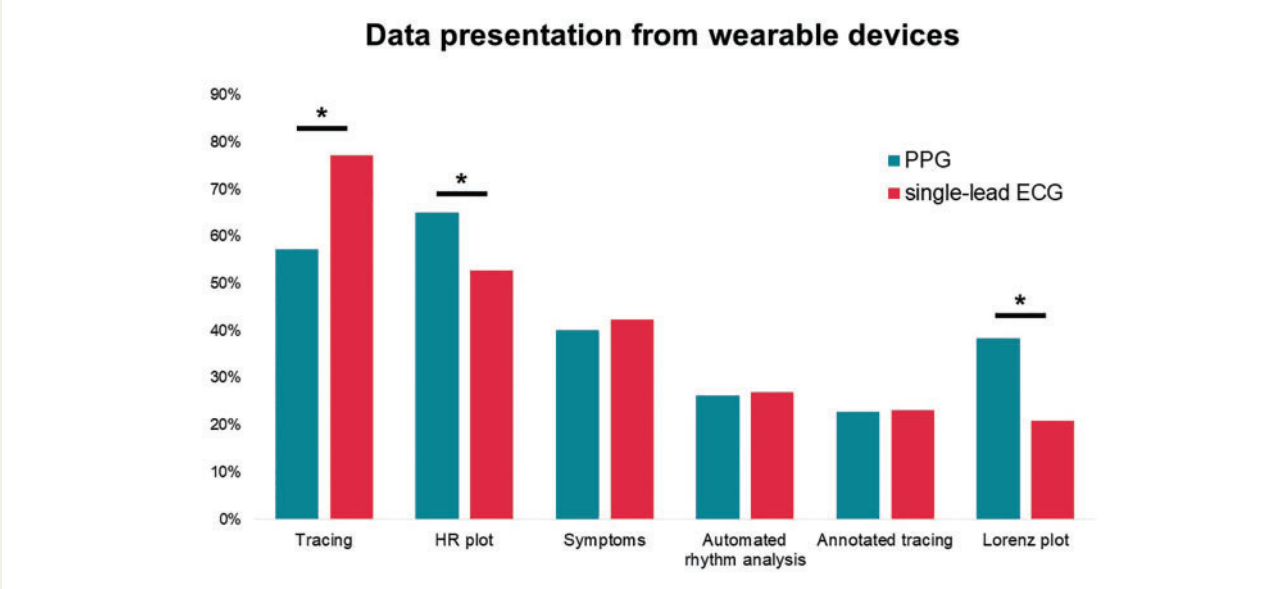


Figure 3 Physicians expect to see tracings from wearable ECG devices. Heart rate (HR) and Lorenz plots are more frequently requested from PPG-based devices. *$P < 0.05$. ECG, electrocardiogram; PPG, photoplethysmography.

automated ECG-based algorithms will be sufficient to diagnose AF in most patients (40.3%) and PPG-based algorithms, in addition to ECG-based algorithms, will be sufficient to diagnose AF for most patients (32.4%). 40.7% believe that visual ECG interpretation will still be necessary in all patients to diagnose AF.

Regarding the decision for oral anticoagulation in AF patients, most respondents believe that a combination of biomarkers, age, and clinical parameters (55.9%) or algorithms developed by AI incorporating health care details and data from wearable devices for such decisions (44.1%) would be sufficient. 41.1% of

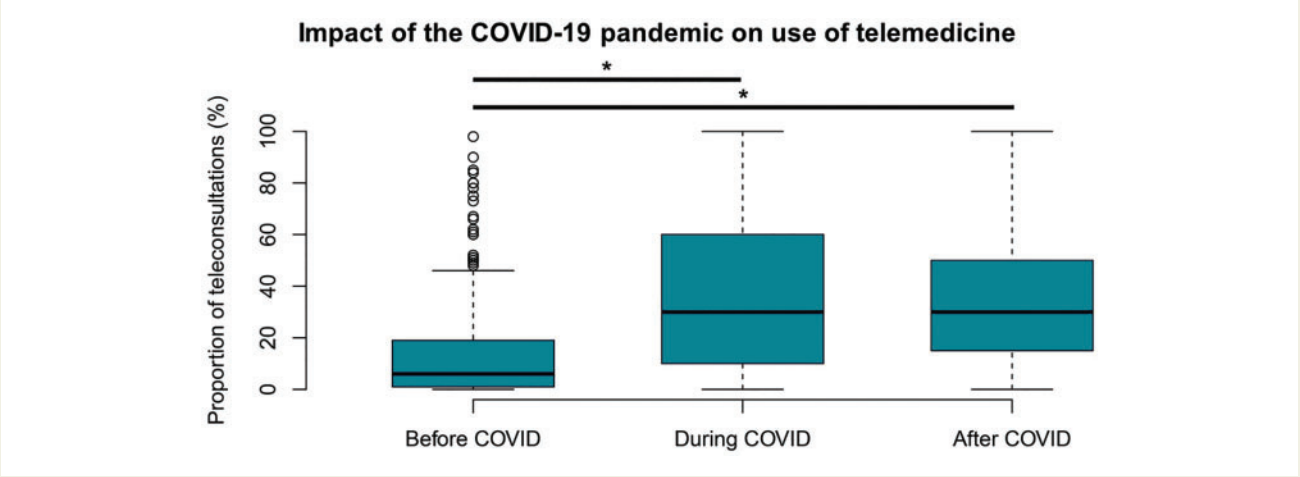


Figure 4 The proportion of teleconsultations increased during the COVID-19 pandemic and is expected to remain at the same level after the pandemic. *$P < 0.05$.

respondents believe that the CHA_2DS_2-VASc score would remain.

Use of telemedicine during the COVID-19 pandemic

Before the COVID-19 pandemic, 12 ± 17% of consultations of respondents were performed via telemedicine. The pandemic increased telemedicine consultations to 37 ± 29% ($P < 0.01$) and respondents believe that the proportion of telemedicine consultations would remain at this level (34 ± 24%, $P < 0.01$ compared to before the pandemic, see *Figure 4*). There was no correlation between number of COVID-19 cases in the respondent's country and the rate of teleconsultations (Spearman rho = 0.18, $P = 0.204$).

Discussion

Over 500 respondents from >50 countries participated in the wEHRAbles 2 survey—an initiative of members of EHRA Young EP, EHRA Scientific Initiatives Committee, and EHRA Digital Health Committee.

This is the first world-wide survey on wearable device rhythm recordings and the first to assess such a wide range of topics. We demonstrated that physicians:

- would diagnose AF and take therapeutic steps based on a single-lead ECG,
- state that wearable rhythm device ECG technology is suitable for AF screening, arrhythmia diagnostics, and patient monitoring,
- believe in the large potential of AI for the future of AF diagnostics and clinical decision making regarding oral anticoagulation,
- point out that there is lack of reimbursement or information about reimbursement when dealing with wearable device rhythm recordings,
- believe that costs for wearable rhythm devices should be shared between patients and the health insurer or government, and
- believe that teleconsultations in the future will remain at the same level as during the COVID-19 pandemic.

Adherence to guidelines

The recent ESC guidelines for diagnosis and management of AF state that a single-lead ECG tracing showing ≥30 s of irregular rhythm without P waves is diagnostic for AF.[3] The fact that 17% of respondents would not diagnose AF based on a single-lead ECG presented in the case scenario is a call for further education on guidelines and novel rhythm monitoring devices. Younger respondents and respondents not working in EP were more likely to ignore the single-lead ECG tracing, demonstrating that adaption to these novel technologies might not be age dependent.

Sensitivity and specificity for AF detection using PPG devices are high and comparable to those of single-lead ECG devices and watches (sensitivity: 91.5–98.5% in PPG vs. 94–98% in single-lead ECG; specificity: 91.4–100% in PPG vs. 76–95% in single-lead ECG).[2,8,9] However, the use of PPG tracings for diagnosing AF needs more evidence, hence is not recommended in the recent AF guidelines.[3] This potentially explains why only 27% of respondents would diagnose AF based on a PPG tracing.

The likelihood to accept the diagnosis of AF based on ECG and PPG tracings in this survey was higher compared with the previous wEHRAbles survey (69% ECG, 14% PPG) as well as the HRS survey (72% ECG, 27% PPG) which were conducted before the recent guidelines were published.[10,11] This further demonstrates the progressive and rapid uptake of these devices in clinical practice and guidelines.

Clinical uses of wearable devices

We demonstrated that the use of novel wearable ECG devices is accepted among our respondents for screening, diagnostics in patients with symptoms suggestive of arrhythmias, monitoring of patients after AF ablation or other ablations or cardioversions, and for monitoring of rate control in AF patients. Although rhythm monitoring by

PPG applications is widely available and more cost-effective than ECG-based devices, since it uses built-in hardware of patient's smartphones, only a minority of participants find PPG applications acceptable for these purposes. This might be explained by the fact that physicians are not used to interpret PPG tracings as well as the lack of scientific data, making it difficult to choose the right application or device for the right indication in the right patient. There is a need for trials comparing the diagnostic properties of different wearable technologies to inform future formal recommendations, taking into account the required accuracy, availability, and health economic aspects in all clinical settings.

Impact on therapeutic anticoagulation and screening

Surprisingly, a diagnosis of AF based on this rhythm strip or PPG tracing would not result in initiation of oral anticoagulation by almost a third of respondents, despite a patient's CHA_2DS_2-VASc score of 3. The guidelines state the importance of stroke prevention by initiation of anticoagulation therapy after confirming AF diagnosis.[3] The paradox that AF would be diagnosed, but not treated by some respondents of the survey might be explained by the hesitation of physicians to base therapeutic actions on results of these novel technologies or the complexity of oral anticoagulation therapy in patients with other device-detected arrhythmias such as atrial high rate episodes from implantable devices.

ESC guidelines recommend opportunistic screening for AF in patients ≥65 years of age as well as systematic screening in individuals ≥75 years and those at high risk of stroke.[3] Three of the four respondents find wearable rhythm devices suitable for these indications. However, median age at which screening should be started was 60 years and screening would be recommended for those patients in whom anticoagulation would be indicated as per their CHA_2DS_2-VASc score. Current guideline recommendations are based on the scarce data from randomized controlled trials that confirm the health benefits from AF screening.[3,12,13] The lower screening threshold proposed by respondents might be explained by the new opportunities with widely available wearable rhythm devices that could be used to screen larger populations and further define populations at risk of stroke. Detecting AF in larger populations using these widely available wearable technologies might help to define further stroke risk factors that could be used in patients with intermediate risk in currently used risk scores (i.e. CHA_2DS_2-VASc score 2 in women and 1 in men). On the other side, screening in populations with low prevalence (e.g. Apple Heart Study and Huawei Heart Study) bears the risk of false-positives.[6,14]

Future directions

Most respondents believe that novel technologies will impact the way we diagnose AF in the near future. Several studies have shown that deep-learning algorithms are now capable of distinguishing between sinus rhythm and AF.[15] Surprisingly, more respondents believe that AI algorithms will allow diagnosis of AF analyzing a sinus rhythm ECG strip than those who believe that visual ECG interpretation will still be necessary in all patients to diagnose AF. This reflects an unmet need of better AF prediction and improvement of AF detection, which is often not achievable with current technology.

The same holds true for estimation of stroke risk. While the currently used CHA_2DS_2-VASc score allows fast and easy stroke risk assessment, many respondents believe that ten years from now, additional tools such as biomarkers and AI algorithms will support us in our decision.[3]

Data presentation, data processing, and reimbursement

The fact that respondents ask for tracings from ECG devices rather than annotated tracings or automated rhythm analysis point out the physician's wish to visually confirm tracings, rather than rely on algorithms of different manufacturers. However, in PPG devices, physicians find the heart rate plot more important than the actual tracing. This might again be explained that physicians are more used to interpret ECG than PPG tracings. When ECG tracings are not available (e.g. in implantable device tracings), analysis of heart rate plots seems to be the best alternative. In both cases, information about patient's symptoms is among the most requested data.

The current practice that patients present their rhythm tracings directly to their physician or through email reflects the present-day reality—patient-driven self-monitoring using widely available wearable rhythm devices.

Wearable rhythm device data are currently most presented in a patient's record. In the future, most respondents would prefer an upload of selected tracings to a patient's file, potentially reducing data overload.[7]

Most countries world-wide have implemented these novel technologies but there is still lack of reimbursement as well as lack of information regarding reimbursement. This reflects an unmet need for physician-driven monitoring and integration of novel wearable rhythm devices into health care plans requiring an active role of insurances and government.

Use of telemedicine during the COVID-19 pandemic

The COVID-19 pandemic catalyzed the use of mHealth applications in clinical practice. Among other technologies, wearable rhythm devices allow management of patients when on-site presentation is not desirable as during this pandemic.[16] The mHealth project 'TeleCheck-AF' demonstrated how quickly these infrastructures can be established using widely available technologies such as the patient's smartphone for PPG rhythm analyses.[17,18] However, survey participants believe that these processes will change our behavioural practice also beyond the pandemic.

Limitations

The present survey has limitations attributed to target respondents and questionnaire design. The survey was mainly spread through the network of EHRA and participation was completely voluntary, therefore being prone to selection bias. Since most respondents were EPs used to analyzing different forms of heart rhythm tracings, results may not be generalizable to all physicians.

Conclusion

Wearable single- or multiple-lead ECG technology is accepted for multiple indications in current clinical practice and triggers AF diagnosis and treatment. The unmet needs that call for action are reimbursement plans and integration of wearable rhythm device data into patient's files and hospital information systems. The COVID-19 pandemic has accelerated the use of novel rhythm devices and teleconsultations.

Supplementary material

Supplementary material is available at *Europace* online.

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Conflict of interest: M.M. has received speaker honoraria and/or travel grants from Biosense Webster, Abbott, Biotronik, Zoll, Boston Scientific, Daiichi Sankyo, Bayer, Pfizer, and Amomed; research grants from Biosense Webster. D.Z. has received speaker honoraria and/or travel grants from Daiichi Sankyo and research grants from Boston Scientific. J.A.B.Z. has received travel fellowships from British Heart Foundation, research grants from the UK-US Fulbright Commission, speaker honoraria and travel grants from Acutus Medical Inc., consulting fees from Tegus, Slingshot, and Physcade Inc. B.K. has received speaker honoraria from Medtronic and travel grants from Medtronic, Biotronik, Abbott, and Boston Scientific. E.S. has received speaker honoraria from Bayer, Bristol-Myers Squibb-Pfizer, Boehringer-Ingelheim, Merck-Sharp, and Dohme and Sanofi, as well as institutional research grants from Carl Bennett Ltd and Roche Diagnostics. P.V. has received speaker honoraria and/or travel grants from Abbott, Daiichi-Sankyo, Bayer, Medtronic, and Boehringer-Ingelheim. T.P. reported consultancy for Bayer and Pfizer (no fee). D.D. has received speaker honoraria and/or travel grants from Abbott, Astra Zeneca, Bayer, Biotronik, Boehringer Ingelheim, Boston Scientific, Medtronic, Pfizer, and Zoll. J.K., S.C., N.P., and R.L. have nothing to declare.

Data availability

Data available on reasonable request.

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