European Journal of Internal Medicine 82 (2020) 97–104

Contents lists available at ScienceDirect

European Journal of Internal Medicine

journal homepage: www.elsevier.com/locate/ejim

Original article

Consumer-led screening for atrial fibrillation using consumer-facing wearables, devices and apps: A survey of health care professionals by AF-SCREEN international collaboration

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ARTICLE INFO

Keywords:
Apps
Anticoagulants
Atrial fibrillation
Screening
Smartphones
Wearables

ABSTRACT

Aim: A variety of consumer-facing wearables, devices and apps are marketed directly to consumers to detect atrial fibrillation (AF). However, their management is not defined. Our aim was to explore their role for AF screening via a survey.

Methods and Results: An anonymous web-based survey was undertaken by 588 health care professionals (HCPs) (response rate 23.7%). Overall, 57% HCPs currently advise wearables/apps for AF detection in their patients: this was much higher for electrophysiologists and nurses/allied health professionals (74–75%) than cardiologists (57%) or other physicians (34–38%). Approximately 46% recommended handheld (portable) single-lead dedicated ECG devices, or, less frequently, wristband ECG monitors with similar differentials between HCPs . Only 10–15% HCPs advised photoplethysmographic wristband monitors or smartphone apps. In over half of the HCP consultations for AF detected by wearables/apps, the decision to screen was entirely the patient's. About 45% of HCPs perceive a potential role for AF screening in people aged >65 years or in those with risk factors. Almost 70% of HCPs believed we are not yet ready for mass consumer-initiated screening for AF using wearable devices/apps, with patient anxiety, risk of false positives and negatives, and risk of anticoagulant-related bleeding perceived as potential disadvantages, and perceived need for appropriate management pathways.

Conclusions: There is a great potential for appropriate use of consumer-facing wearables/apps for AF screening. However, it appears that there is a need to better define suitable individuals for screening and an appropriate mechanism for managing positive results before they can be recommended by HCPs.

1. Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia diagnosed in clinical practice, with an incidence that increases in the elderly [1,2] and a prevalence of diagnosed AF that is progressively increasing and is expected to further expand in the next decades in view of progressive aging of the population and exposure to risk factors and facilitating factors [3,4].

AF is associated with significant morbidity and mortality and is an important risk factor for ischemic stroke, particularly in the elderly [5]. AF is frequently asymptomatic, particularly in the elderly [6], and asymptomatic AF is associated with a worse outcome as compared to

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https://doi.org/10.1016/j.ejim.2020.09.005
Received 7 July 2020; Received in revised form 6 August 2020; Accepted 6 September 2020
Available online 12 September 2020

symptomatic AF, both in terms of risk of stroke and mortality [6,7].

Since nearly one in five AF-related ischemic strokes may occur without a diagnosis of AF prior to the stroke event [8] there is growing interest in the identification of patients with unrecognized, unknown asymptomatic AF through screening initiatives [9,10] with consequent institution of oral anticoagulants in patients at risk. It is well known that in AF, oral anticoagulation (OAC) is able to reduce the risk of stroke by more than 60% [11].

Pulse palpation has been the first and simplest method proposed for AF screening, followed by automatic blood pressure devices with dedicated algorithms for detecting AF, but more recently several new methods and tools have been proposed, with an impressive variety of technologies based on plethysmography or single-lead ECG, also implemented in wearables (smartphones, watches etc.) [12–14]. In 2017 it was reported that more than 100,000 mobile Health apps and ≥400 wearable activity monitors were available for cardiac rhythm check or monitoring and that more than 60% of owners of a smartphone use their phone for information and education about their health [15].

The wide debate focused on benefits, efficacy and limitations of screening initiatives [16–19] prompted us to propose an on-line survey to explore current views, current practice and related organizational issues on AF screening using the most advanced technologies implemented in watches, smartphones and other devices, usually named “wearables” [20].

Questions in the survey were designed to elucidate how health care professionals perceive the significance of AF screening through wearables, in what settings it may be considered as appropriate and useful, what is the current status of referral and what are the potential developments in the field.

2. Methods

The survey was distributed in two steps. First the invitation to participate in this anonymous, web-based survey was sent in December 2019 by email to all 177 members of the AF-SCREEN International Collaboration, a group created in 2016 to promote discussion and research about screening for unknown or under-treated atrial fibrillation as a way to reduce stroke and death (http://www.afscreen.org/) [12,21,22]. In January and February 2020, the same invitation was distributed through e-mails, in two rounds, by AF-SCREEN members to a “convenience sample” of colleague health care professionals (HCPs), physicians, nurses or allied health professionals involved in care of patients with arrhythmias or stroke, including cardiologists, electrophysiologists, neurologists, internal medicine physicians or geriatricians, primary care physicians/general practitioners (PCP/GPs), nurses, pharmacists or other allied health professionals, as shown in Table 1. The analysis of the survey was managed in an anonymous way. Despite anonymity, the question on field of work was answered by 475 respondents: of the 113 respondents who did not answer this question, 23 were members, and 90 were non-members. In this report we will present numbers and percentages for answers to each of the survey questions.

Table 1
Survey respondent field of work (N = 475).

	Whole Group (N = 475)	AF SCREEN Members (N = 96)	Non Members (N = 379)
Category[†]	%	%	%
Electrophysiologist	37.1	38.6	36.7
General cardiologist	17.7	28.1	15.0
Neurologist/stroke physician	4.0	12.5	1.8
Primary care physician/general practitioner	24.0	10.4	27.5
Internal medicine physician/ geriatrician	2.9	5.2	2.4
Nurse/allied health professional	11.4	4.2	13.2
Other	2.9	1	3.4

Legend: Field of work category for respondents.

3. Results

Overall, 2481 invitations were sent by email and 588 HCPs completed the survey anonymously (119 AF-SCREEN members and 469 non-members, response rate 23.7%). The geographical region of respondents was reported in 482 replies, and was Europe in 373 (77.4%), Asia/Oceania in 66 (13.7%) and North or South America in 40 (8.3%), with 3 (0.6%) in other regions. Survey respondent characteristics are shown in Table 1.

The first question of the survey analysed if health care professionals ever advise use by patients of any of the available wearable devices/apps for AF-detection. The results shown in Fig. 1, panel A indicate that these devices are never suggested by 43% of respondents, while 57% of respondents at least sometimes advice their use: handheld (portable) single-lead dedicated ECG devices in 46% and wristband ECG/EKG monitors (e.g., Apple Watch 4, Kardia, Huawei, Verily, etc.) in 29%, with a lower relative percentage of suggestions addressed to wristband heart rate monitor (e.g., Apple Watch 3, Fitbit, Garmin, Biostrap, etc.) (15%) or to mobile PPG apps for smartphone camera flash downloaded from Apple or Google Play stores (10%). There were distinct differences between groups of health professionals in these responses. Between 62–67% of PCP/GPs, neurologists and other specialist physicians never advised use of these devices for AF detection compared to 43% of general cardiologists, and only 25% of electrophysiologists. The figure was 26% for allied health professionals and nurses, presumably with an interest in AF screening, and 27% for AF-SCREEN members compared to 44% for non-members. Similar differentials between HCP categories were seen for handheld ECGs, and wristband ECGs, with 45% of electrophysiologists sometimes advising wristband ECGs, compared to only 10–20% of other specialists and PCP/GPs.

The second question focused on the scenario(s) where these devices may have an important role with regard to AF detection (Fig. 1, panel B) and the answers stress the role of wearables, devices and apps to search for AF in patients with palpitations or other symptoms but no previous detected AF (supported by 75% of respondents), as well as for search of AF post stroke/TIA and post AF ablation with recurrent symptoms (supported by 48–50% of respondents). Electrophysiologists were the most likely to advise use of the devices in patients with symptoms (86%). With regard to the potential use for screening, according to 44–46% of respondents there is an important role of this technology for subjects aged > 65 years or in patients with risk factors (hypertension, diabetes, etc.). Conversely, screening in less selected subjects, with lower age, is considered to be meaningful by only a minority of respondents. Only 10% of HCPs stated there was no value of any of the potential indications for search of AF or AF screening.

The answers to the question on how frequently HCPs currently have to deal with subjects with AF detected through wearable devices/apps reveals that this happens only rarely or occasionally (less than 1–2 times per month) for 25–29% of respondents (Fig. 1, Panel C). Only a small minority of respondents report to be frequently involved in this activity, while for 15% no involvement was reported. PCP/GPs were least likely to have to deal with AF detected this way at least 1–2 times per month (12%) compared to 30–44% for other physicians and general cardiologists or electrophysiologists.

The use of wearables or devices for AF search/screening may be related to a choice taken by the patient or by a physician. According to respondents to this survey, the use of these devices for AF search was the patient's personal decision in just over half of cases leading to a consultation with the HCP, while it was advised by a physician in the remainder.

The referral to physicians of patients for clinical evaluation after AF

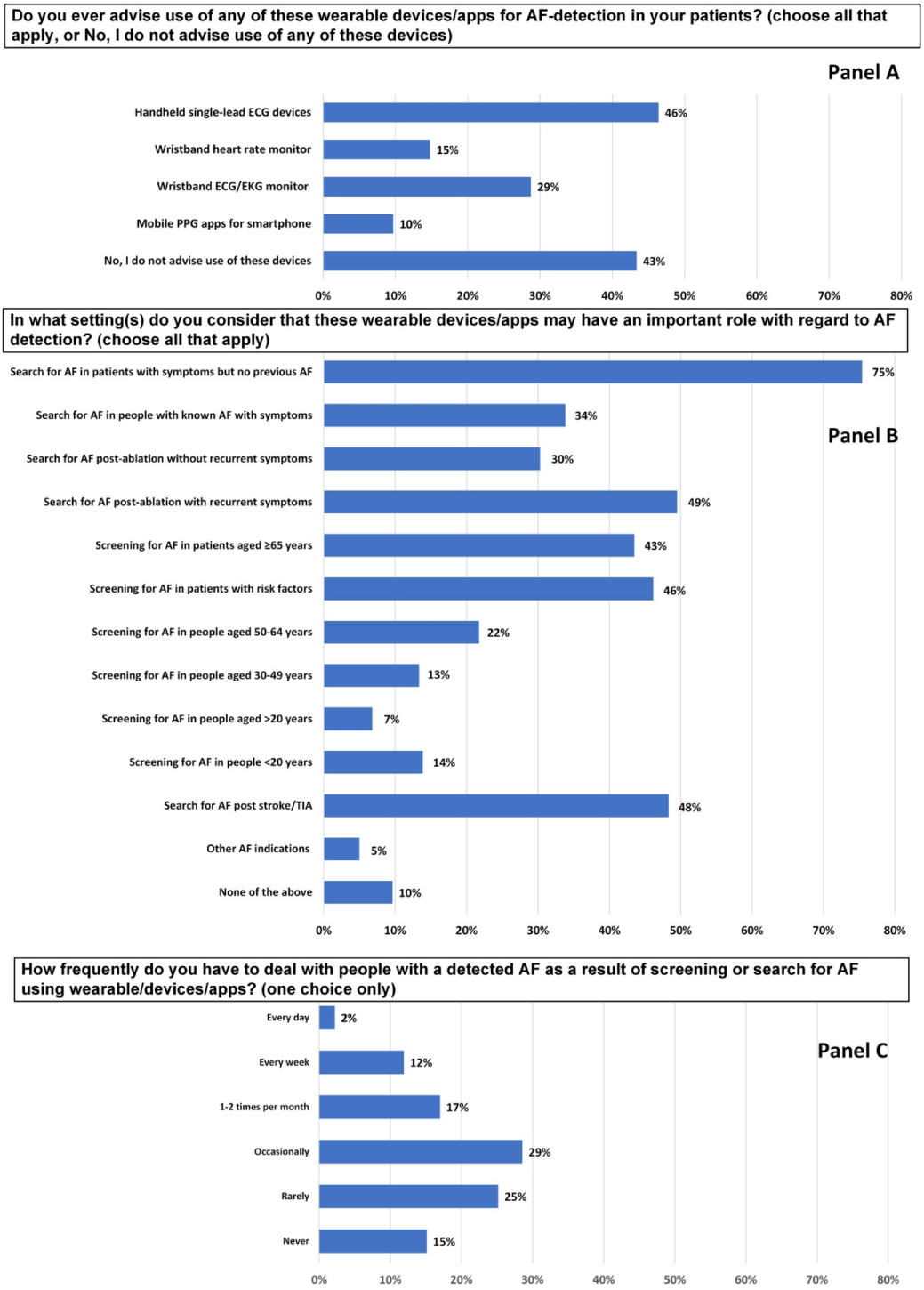

Fig. 1. Questions and answers of the survey on use of wearable devices/apps for AF detection.

detection through wearable devices/apps in more than 50% of cases was related to patient self-referral or was prompted by a primary care physicians or, less frequently by other physicians (Fig. 2, panel A). Only rarely was the referral prompted by pharmacists or patient associations/groups.

The age of subjects referred to physicians for a clinical evaluation after AF detection through wearables/apps (Fig. 2, panel B) was in the majority 65 or older although around 30% were between 55 and 65 and around 36% below 55.

The organization of referral for clinical evaluation after AF detection is an important issue and more than half of the respondents considered as appropriate a referral through general practitioners with the support of predefined pathways, or through dedicated physicians/nurses, while conventional contacts were advisable for around 29% of respondents (Fig. 2, panel C) . Referral from call centres/websites or through pharmacists had a low rate of preferences.

The potential disadvantages of mass community screening using wearable devices/apps were reported as related to anxiety in people with a positive test by around 65% of respondents, but were also related to false reassurance in case of a negative test by 41% of respondents (Fig. 3, panel A). Moreover, for 39% of respondents the risk of bleeding due to anticoagulant prescriptions after a positive test, in light of a still

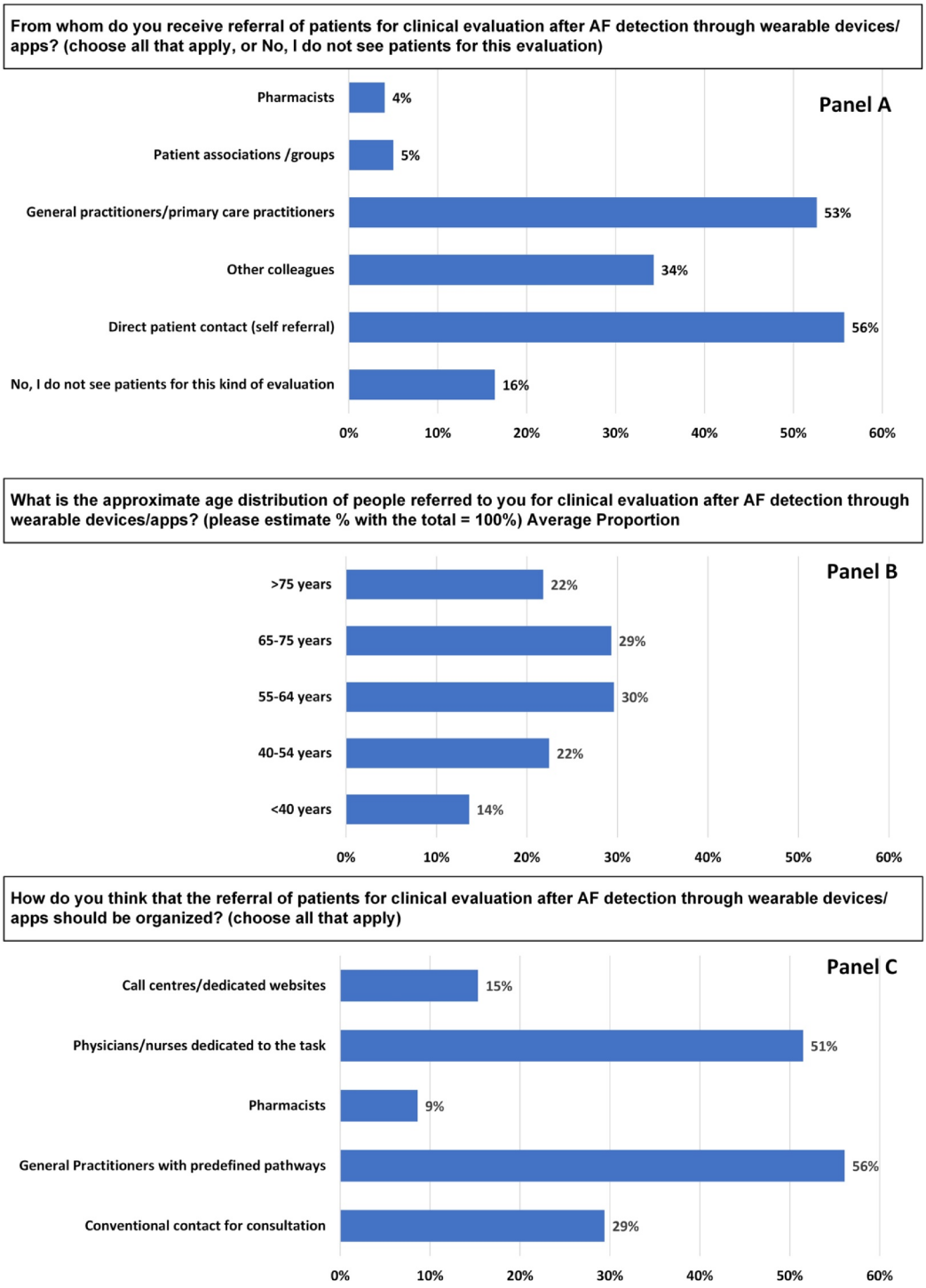

Fig. 2. Questions and answers of the survey on referral of patients after AF detection through wearable devices/apps.

unproven benefit for AF detected this way, actually represents a disadvantage of screening. Conversely, for around 20% of respondents no important disadvantages for mass community screening are currently perceived at the level of individual people.

As there are now many Apps currently available for download from Apple or Google Play stores, between 30 and 45% of respondent considered in order to appropriately guide the consumers it would be important to obtain validation through randomized controlled trials, reports based on scientific data, or recommendations from Scientific Associations. About 25% believed there should be more rigorous regulation from Health Authorities and/or valid comparisons between devices or apps (Fig. 3, panel B).

The final question of the survey explored respondents' thoughts on whether we are actually ready to commence mass community screening for AF using wearable devices/apps now: the answer was no for almost 70% of respondents. There were no important differences amongst the different HCPs.

4. Discussion

Wearables now allow non-invasive monitoring of a range of human body vital signs and could facilitate user-initiated disclosure of many

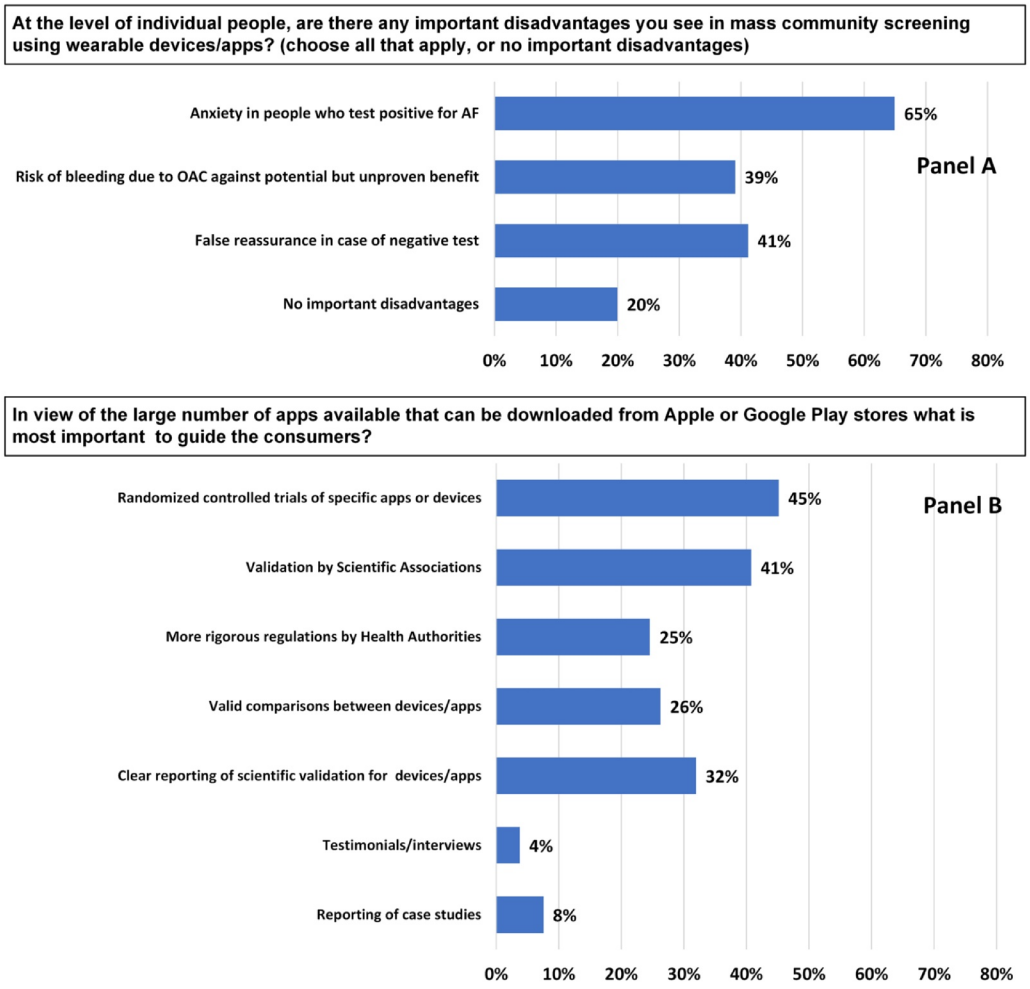

Fig. 3. Questions and answers of the survey on AF screening using wearable devices/apps.

diseases [23]. The field of mobile technology has in recent years been characterized by an impressive growth which has the potential for changing clinical practice as a disruptive transformation. Moreover, the use of wearables to diagnose AF is being promoted widely to the general public by manufacturers as a health benefit of their products. However, apart from the need for specific regulations, also taking into account the legal implications of mode and time of physician's reaction to detection of a suspected AF [24,25], our survey respondents did convey a number of caveats on the use of wearables and Apps. Finally, the majority indicated that these devices were not yet ready for commencing mass screening for AF.

In general, screening for an arrhythmia like AF using devices and apps marketed to the general community should be well organized, with a specific and appropriate design of screening initiatives, as well as defined pathways involving health care professionals and individuals engaged in the screening process with effective feedback loops [26]. For AF, the wide diffusion of devices that can provide information on cardiac rhythm carries the risk that the coordination, in terms of appropriate targeting and management of screening activities, may no longer be in the hands of clinicians and HCPs, but will by default become an uncontrolled activity, with unknown risks and consequences [20,27,28].

Our survey focused on wearables and apps [25] in the setting of screening and search for AF, and highlights that in a sample of almost 600 HCPs, involving mostly electrophysiologists, cardiologists and general practitioners, the use of these devices is currently advised by around half of them. Unsurprisingly, electrophysiologists and to a lesser degree general cardiologists, were more likely to advise their use that other specialist physicians and PCP/GPs. The nurses and allied health professionals who took our survey were also high users of this technology, as might be expected for groups of these HCPs with an interest in AF screening who were recruited to this survey. Overall, there was a preference for handheld (portable) single-lead dedicated ECG devices and to a slightly lesser degree for wristband ECG monitors, but a much lower degree of preference for apps based on photo-plethysmography using a wristband or the camera flash of smartphones. This may be interpreted as a higher degree of confidence, from the perspective of physicians, on tools detecting AF by direct recording of an electrocardiographic signal.

Most of the consumer-facing devices and apps are registered as a medical device [29–34]. Many studies have validated the novel devices and tools, with variable sensitivity and specificity. However, the same rigorous validation does not necessarily apply to many apps proposed to consumers without availability of valid scientific data [15], nor to the outcome of screen-detected AF in the mostly younger people who choose to buy and use wearable devices and apps in this way. In the literature, a great debate has developed in recent years on the significance and effectiveness of initiatives targeting AF search/screening in specific target populations. Moreover, many wearable products are marketed as direct-to consumer so it is probable that they will be largely used by subjects with healthier profiles and lifestyle [35], as seen in both the Apple Heart Study and Huawei Heart Study where the mean age was 41 and 35, respectively [33,34]. These individuals have a low pre-test probability of AF with a questionable significance of screening for AF [12]. In fact, the “possible AF” notification rate in the 52% of participants aged <40 in the Apple Heart Study was only 0.16% [34].

As a matter of fact, age- and literacy-related disparities in the use of mobile technologies were reported both in Germany [36] and the United States [37], with a discrepancy between the epidemiology of AF, more common and more dangerous among older people with multiple chronic diseases, and the low penetration in this population of wearable devices [38].

Our survey suggests that there is a consensus on recommending wearables/apps for searching for AF in symptomatic patients or post stroke/TIA, two settings where wearables may constitute an alternative to Holter monitoring (24-h or longer durations), external continuous or loop recorders or, even to implantable loop recorders. The place of AF screening itself, whether this is case finding, or opportunistic or systematic screening is still a debated topic [12,16,17,39–44]. Thus, it is not surprising that the use of wearables/Apps for this purpose remains even more controversial. What emerges from the current referral of subjects following AF detection by wearables and apps marketed directly to consumers is a true asymmetry between the current buyers and users of wearables, and the appropriate target. Buyers and wearers are mostly people younger than 50 years, and not those who would represent the most appropriate age group to target with AF screening programmes according to detection rates and number needed to screen to detect one person requiring thromboprophylaxis for stroke [10], as recommended in guidelines and consensus documents (i.e. subjects above 65–75 years) [12–14,45–47].

At present, despite the availability of many wearables for monitoring cardiac rhythm and detecting AF, it is apparent from our survey, that the evaluation by physicians of patients with AF detected through a wearable device is not common, and that there are no specifically-defined care pathways for referral, despite general recommendations [12–14,45,46].

According to around 65% of the respondents, the potential anxiety of people who tested positive at AF screening constitutes a major limitation to the use of wearables, and this concern, including also the risks of false positives, and of prescribing anticoagulation to those who may not benefit but are exposed only to the risks, similar to any disease screening initiative, is in line with the comments by US Preventive Services Task Force and other experts in the field [16,17,40]. However, appropriate targeting with screening addressed to subjects at a higher risk of stroke if AF is detected, coupled with detailed information to screening candidates on the significance and the implications (in terms of anticoagulant treatment) of undergoing screening, could help to minimize anxiety, as in any screening program. Importantly, perceived disadvantages also included the risks of falsely reassuring those with AF that may be missed by the various wearable systems that rely on intermittent-monitoring PPG algorithms to initiate a warning. The heterogeneous opinions on the current value and significance of AF screening through wearables is highlighted by the opposite position of 20% of respondents, who actually indicated that nowadays there are no important disadvantages at the individual level for promoting mass community screening activities.

Ongoing randomized studies, already started or in a planning phase [12,14,41] will be an important step for defining the net benefit of AF screening in specific populations, with regard to stroke prevention and long-term survival, against adverse bleeding events related to OAC [48,49]. As compared to other screening initiatives, AF screening through wearables certainly has potential, provided there is appropriate population targeting, for a favourable cost-effectiveness profile, a key element in evaluation of health care interventions [50]. The collection of data on population screening, in specific target populations, can help to estimate the benefits of screening interventions, as done in Sweden where the 5-year follow up of a systematic screening performed in patients aged 75 showed a lower incidence of ischemic stroke in the intervention region, as compared with a control region, in parallel with an 88% rate of screening-detected AF treatment with oral anticoagulants and excellent long term adherence to therapy [51].

For some wearables, the diagnostic value of the specific technology has been tested in terms of sensitivity and specificity (Huawei, Apple watch, Kardia, etc.) in specific settings, with some limitations given the ultimately small numbers used in the direct comparisons. However, as highlighted by respondents, there is absolute need to make clear to consumers what devices or Apps are validated. In the rapidly growing market of mobile health technology (more than 100,000 mobile Health apps and $\geq$400 wearable activity monitors available) [15], no clinical validation is available for many of these devices and therefore caution is needed in their use for clinical reasons. Given this perspective, scientific associations, patient associations and regulatory agencies should provide some guidance on how to organize initiatives on AF screening and in whom it is reasonable to address a search for AF, as well as propose pathways for appropriate evaluation of subjects who test positive, independently of commercial interests. Even if there is a general tendency in the market to directly approach consumers and to promote use of wearables and Apps without the traditional control of physicians, the need for appropriate targeting, provision of information, and evaluation of individuals tested positive, indicate that physicians should be involved in these activities. This is required to magnify the potential value of these new diagnostic resources that may actually change the process of care, and minimize the harms of inappropriate use. Despite general recognition of the potential, it is noteworthy that according to around 70% of HCPs we surveyed, we are actually not ready to apply the technology of wearable devices/apps for mass community AF screening.

In our society the media share important responsibilities in addressing the general use of wearables in a proper and rational way, with need for a clear distinction with regard to lifestyle and wellness, the fields where wearables are widely promoted [27]. Scientific Associations, patient groups and associations, general practitioners, specialist physicians, and researchers in the field, as well as the industry, other health care providers and regulators should have a greater dialog and collaboration in the field of AF screening to increase the value for the health care process through appropriate use of these new diagnostic resources, in a context where physicians responsibilities still need to be well defined.

Our survey has some limitations, first of all related to a response rate of 24% . Response rates to physician surveys have declined over the past several decades, and paradoxically web surveys were found to result in lower response rates compared to other more traditional data collection modalities [52,53]. As reported in the literature, conducting surveys among physicians and medical personnel is more difficult than in other fields, and response rates are actually lower than response rates of surveys conducted within the general population [52-54].

Moreover, as for any anonymous survey based on voluntary participation, we can presume that willingness to participate may per se identify health care professionals with a specific interest on the topic of AF screening and with specific knowledge on most recent technologies for cardiac rhythm monitoring. On the one hand this may limit the possibility to extrapolate the findings to other health care professionals with a lower degree of knowledge or confidence with wearables, but on the other hand it increases the relevance of the caution in promoting mass screening for AF using wearables that this survey highlights.

5. Conclusions

There is a great potential for appropriate use of consumer-facing wearables/apps for AF screening, but the current consumer-led use following direct marketing suggests the need for identification of appropriate targets, organization of referral and appropriate patient information on the purpose and implications of AF detection. Greater dialog between stakeholders is required to ensure there is value for the health care process through appropriate use of these new diagnostic resources. The final gestalt of the majority of the 588 respondents to our survey was that these apps and devices which are directly marketed to consumers are not yet ready for mass screening for AF.

Funding

R.B.S. has received funding from the European Research Council (ERC) under the European Union's Horizon 2020 research and innovation program (grant agreement No 648,131), from the European Union's Horizon 2020 research and innovation program under the grant agreement No 847,770 (AFFECT-EU) and German Center for Cardiovascular Research (DZHK e.V.) (81Z1710103); German Ministry of Research and Education (BMBF 01ZX1408A).

Declaration of Competing Interest

GB reported speaker's fees of small amount from Bayer, Boehringer, Boston, Biotronik and Medtronic.

RBS has received lecture fees and advisory board fees from BMS/Pfizer outside this work.

RDL: Research support from Bristol-Myers Squibb, GlaxoSmithKline, Medtronic, Pfizer; Consulting fees from Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi-Sankyo, GlaxoSmithKline, Medtronic, Merck, Pfizer, Portola.

BF reported grants to the institution, personal fees and non-financial support from BMS/Pfizer; grants to the institution, personal fees and non-financial support from Bayer; personal fees and non-financial support from Daiichi Sankyo; non-financial support from Alivecor; personal fees and non-financial support from Omron; all outside the submitted work.

The other authors did not report conflicts to disclose.

Acknowledgments

The authors thank Roberta Napoleoni, from Population Health Research Institute, Hamilton, Canada for help in data collection and analysis.

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