Screening for Atrial Fibrillation using Economical and Accurate Technology (From the SAFETY study)

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The prevalence of Atrial Fibrillation (AF) is estimated at more than 3% in the adult population and there has been increased interest in screening for AF. In the SAFETY trial we chose to evaluate if inexpensive, wearable, consumer ECG sensing devices (Polar-H7 (PH7) and Firstbeat Bodyguard 2 (BG2)), could be used to detect AF accurately. We undertook a case-control study of413 participants aged > 65 (79 with AF/Flutter at the study visit and 336 without) attending 3 general practice surgeries in Hampshire, UK for a single screening visit. The PH7 and BG2 devices were tested alongside 2 established AF detection devices (AliveCor and WatchBP) in random order and the diagnosis of AF was confirmed by 12-Lead ECG interpreted by a panel of cardiologists. The sensitivity (95% CI range), specificity (95% CI range) and overall accuracy (95% CI range) of the 4 devices were: ***AliveCor*:** **87.8%** (78.7-94.0%), **98.8%** (97.0–99.7%), **96.7%** (94.4-98.2%); ***WatchBP*: 96.3%** (89.7-99.2%), **93.5%** (90.3-95.9%), **94.0%** (91.3-96.1%): ***PH7***: **96.3%** (89.7-99.2%), **98.2%** (96.2-99.3%), **97.9%** (96.0-99.0%). ***BG2:* 96.3%** (89.7 – 99.2%), **98.5%** (96.6-99.5%), **98.1%** (96.3-99.2%). The PH7 & BG2 devices were highly reliable (the devices acquired sufficient data and obtained a diagnostic result in all but 1 participant on the first attempt.) In conclusion,Inexpensive, consumer heart rate monitoring devices (PH7 and BG2) can be used to detect AF accurately with sensitivity and specificity > 95%. The consumer devices performed as well or better than WatchBP and AliveCor and have the capability to store or transmit ECG data which could be used to confirm AF.

**Keywords:** Atrial Fibrillation, ECG, Heart Rate Monitor, Medical Devices

Several factors have led to an increased interest in Atrial Fibrillation (AF) screening including the increasing incidence of AF, newer treatments to reduce the risk of AF-related stroke (which are safe, effective and simple to use in terms of monitoring) and the emergence of new devices to detect AF1. Devices such as AliveCor (a handheld, single-lead ECG device) and WatchBP (a modified sphygmomanometer) have been developed to screen for AF and shown to be accurate in meta-analysis.2 However, they are not suitable or intended for prolonged use or continuous monitoring. There has been increased interest in the use of wrist-worn pulse detection devices in medical settings3 but they have been shown to perform less well during activity4 and in participants not in sinus rhythm3 and thus may be less suitable for detecting AF. Other devices used by athletes such as the Polar H7 (PH7) sense ECG data via chest electrodes and can detect RR intervals accurately5. These devices are designed to be comfortable, compact, lightweight, unobtrusive and to perform well in suboptimal settings, such as during exercise. Electrode-based devices such as the Firstbeat Bodyguard 2 (BG2) have been used to assess heart rate variability for prolonged periods6 and can store single-lead ECG data. In the SAFETY trial we evaluated the accuracy of inexpensive consumer devices (PH7 and BG2) along with a smartphone/tablet algorithm to detect AF during a single screening visit in primary care in the UK. We directly compared the accuracy of 2 existing devices (AliveCor and Watch-BP) and evaluated participant ratings of device comfort and overall impression. One type is a wrist-worn tracker with a light-emitting diode (LED). It measures the heart rate from tiny changes in skin blood volume by using light reflected from the skin. One type is a wrist-worn tracker with a light-emitting diode (LED). It measures the heart rate from tiny changes in skin blood volume by using light reflected from the skin.

**Methods**

A case-control study design was used and has been described in a previous publication.7 Individuals from 3 general practices aged > 65 both with and without a coded diagnosis of atrial fibrillation in their medical records were invited to attend a single screening visit at their general practice. Participants were excluded if they; had a pacemaker; were deemed unsuitable by their named GP (e.g. terminally ill, bedridden); lacked capacity; had a previous moderate or severe skin reaction to electrode gel.

WatchBP detects pulse intervals (during 3 consecutive blood pressure measurement cycles) and uses an algorithm to indicate AF via an AF icon on the display. The other devices can detect AF during a single measurement period. The results for PH7 are displayed immediately after the measurement period on the screen of the tablet running the corresponding application. The results for the BG2 device were calculated off-line. AliveCor senses limb-lead ECG data when the participant’s thumbs are placed on electrodes. An accompanying application displays the corresponding ECG trace and subsequent diagnostic algorithm result. The AliveCor algorithm used in the trial (Kardia version 4.7.0) produces 4 results: suspected AF, normal, unreadable and unclassified (if the ECG was not classified in the previous categories with a normal heart rate). Normal and unclassified results were thus inferred as non-AF results and unreadable recordings as no result. The PH7 and BG2 devices and algorithm are further described in a supplementary file (Appendix 1).

Following informed consent, participants were screened for AF by study nurses using 4 devices (AliveCor, WatchBP, PH7, BG2) in a random sequence. They had a 12-Lead ECG which was subsequently read by a panel of 2 cardiologists to interpret the rhythm, with a 3rd cardiologist adjudicating disagreements. The research nurses recorded the algorithm results for Alivecor, WatchBP and the PH7. The study nurses recorded the number of attempts required (to obtain a diagnostic output for AliveCor, WatchBP and the PH7 and to record a sufficient number of RR intervals (>=60) for the BG2). They also asked the participants to rate each device in terms of comfort and overall impression (regarding unsupervised use for screening) on a 1 (very unsatisfied) -10 (very satisfied) scale. Research nurses performing the screening and the cardiologists interpreting the ECGs were blinded as to whether the participant had an AF diagnosis. The participants were asked not to convey a pre-existing diagnosis of AF at the study visit. The devices used in the trial are depicted in Figure 1.

Continuous variables are reported as mean±SD with 95% confidence intervals ("exact" Clopper-Pearson confidence intervals). These analyses were performed with IBM SPSS statistics version 24 software (IBM SPSS Statistics, IBM Corp, Somers, NY). The study complies with the declaration of Helsinki, and the protocol was approved by the London - City & East Research Ethics Committee in June 2016 (ref 16/LO/1173). Informed consent was obtained from all participants (trial registration ISRCTN: 17495003).

**Results**

A trial flow diagram is depicted in Figure 2. 418 attended screening visits in Hampshire, UK between 8th December 2016 and 1st November 2017 with a mean age (SD) of 73.9 (6.1). A total of 3, 12-Lead ECGs were adjudicated by the third cardiologist. 79 participants had AF and 336 did not have AF (or atrial flutter) diagnosed on the 12-lead ECG. 3 participants were found to have atrial flutter and these were included with the AF cases making a combined total of 82. There was 1 new case of AF and a new case of atrial flutter detected during the trial. No adverse events were reported during or after the trial. There were no missing diagnostic results in the data. As there were only a small number of missing usability metrics; 18 for the number of attempts required by each device (WatchBP 13; AliveCor 1; Polar H7 4) and a total of 10 missing data entries for the comfort and overall impression scores, a complete case analysis was performed. A trial flow diagram is depicted in Figure 2.

The sensitivity, specificity of the devices are shown in Table 1 along with participant ratings (0-10) of device comfort of use (mean, SD) and of overall impression of each device (mean, SD). The median number of attempts needed to obtain a diagnostic output was: AliveCor 1 (range 1-6); WatchBP 3 (range 3-4); PH7 1 (range 1-1); BG2 1 (range 1-2). 65/419 (15.5%) participants required > 1 attempt to obtain a diagnostic reading with AliveCor, 0/419 with the PH7 and 1/419 (0.2%) with the BG2 device. In 17/419 (4.1%) the WatchBP device required an additional BP measurement (4 in total) to yield a diagnostic result. Table 2 details the participant IDs, 12-Lead ECG rhythm and other device results for the incorrectly classified results by device.

**Discussion**

In this case-control study in a typical screening population we have demonstrated that inexpensive consumer devices used in conjunction with an optimised algorithm can detect atrial fibrillation accurately with sensitivity and specificity > 95%. Importantly, the BG2 and PH7 devices measure ECG data which could be used to confirm AF. The PH7 and BG2 devices were more specific than WatchBP with similar sensitivity and yielded similar specificity to AliveCor with higher sensitivity although the difference in sensitivity was not statistically significant. The performance of the algorithm was similar to the results in the literature detailing the algorithm (sensitivity = 97.4%, specificity = 98.4% – MIT-BIH AF paroxysmal AF database). 8

Importantly, the results have been benchmarked against 2 existing devices in the same trial. The AliveCor device has been shown to have both sensitivity and specificity > 90% in other studies and in particular in a large pharmacy based study of 1000 participants (sensitivity 98.5%, specificity 91.4%).9 Similar results have been obtained using a blood pressure device using the same algorithm as the WatchBP device (sensitivity of 100% and a specificity of 91%.10) In a systematic review of methods for detecting AF, blood pressure monitors were found to have similar results (sensitivity 98%, specificity 92%).2 We were able to store single lead ECG data using the BG2 device and although it is not currently implemented commercially, a variant of the PH7 device can transmit single lead ECG data which could be used to confirm the AF diagnosis.

A significant number of the false positive results detected by WatchBP were found to have sinus bradycardia on the 12-Lead ECG. Rate limiting therapy for AF may lead to increased parasympathetic activity and an increase in heart rate variability causing more false positive results. However, only 6/22 (27.2%) of the false positives had a prior diagnosis of AF and the specificity of WatchBP was > 90% in keeping with other studies and it is therefore unlikely that medical treatments for known AF significantly impacted on the specificity results. Similarly, as the sensitivities of WatchBP and AliveCor were relatively high and in keeping with other studies, it is unlikely that rate limiting therapies significantly reduced heart rate variability and impacted on the sensitivity results. In 2 of the 3 cases of atrial flutter, AliveCor classified the recordings as normal and although there is disclaimer for ECGs categorised as normal, physicians and patients should be wary of the need for physician oversight for the diagnosis of Atrial Flutter. 42/418 (10.0%) of the AliveCor recordings yielded unclassified algorithm results which would pose a considerable workload if all abnormal recordings were to have physician oversight.A further explanation of the false positive and negative results is given in a supplementary file (Appendix 2).

The accuracy of the consumer devices was comparable to a cardiologists interpretation of single-lead ECGs. In a study of 1000 ambulatory patients aged > 75, a meta-analysis of 4 cardiologists interpretations of single-lead ECG data gave a sensitivity of 94.4% and a specificity of 94.6%11 using the 12-L ECG as the reference and in another study of 100 participants at a cardiology clinic the accuracy was sensitivity 92%; specificity 96%).12 In the Strokestop study, 3.5% of participants were referred for further monitoring due to difficulties in diagnosing AF from multiple single-lead ECG recordings (average 26.4 recordings per subject).13 In the SAFE trial of 2595 participants aged > 65, GP diagnostic accuracy of a single-lead limb lead ECG yielded sensitivity of 82.5% and specificity of 88.5%.14

6 participants had unreadable recordings with the hand-held single-lead ECG device AliveCor (there was an average (SD) of 3.3 (1.9) attempts to obtain a diagnostic result and the average age (SD) of these participants was 78.3 (5.1). Inability to hold the device due to motor impairment is a potential problem particularly in more elderly and frail populations.15 In a trial involving hospitalised elderly participants, over 20% of those recruited were unable to hold the device. 16 2/6 participants with unreadable recordings had low-voltage QRS (reported by the 12-L interpretive software in the limb leads) which is a potential limitation of single-lead hand-help devices in terms of signal to noise ratio and thus signal quality. Although uncommon, low-voltage QRS in the ECG is likely present in > 1% of the population.17 In order to circumvent this, manufacturers could consider multiple device configurations such as electrode based use in addition to hand-held operation which could also enable prolonged monitoring options. In addition, various algorithm setting could be useful; more sensitive for single-screening and more specific for prolonged screening18. Although we only tested the PH7 device using the chest strap in the trial, we were able to use the detached connector in hand-held operation and also using gel electrodes applied to the chest for prolonged periods.

Importantly, in a supervised nurse-led clinic, no additional attempts to obtain a diagnostic result were required with the PH7 and only 1 additional attempt was required with the BG2 device. 65/418 (15.6%) participants required more than 1 attempt to record a 30s ECG trace. In 17/418 (4.1%) participants, the WatchBP device performed 1 additional BP reading (a total of 4 to obtain a diagnostic result). Thus, the commercial devices appeared to have good usability and reliability although the performance of all the devices would likely decline in unsupervised use. Importantly the devices were well accepted in terms of comfort and overall impression with regard to home use for screening. It should be noted that the primary function of WatchBP is to measure blood pressure.

The algorithm we used in conjunction with the commercial devices in this study employed a single descriptive statistic (entropy) and it is likely that other more complex algorithms could yield improvements in performance. Such advancements could pave the way for reliable, acceptable, accurate, non-obtrusive and cost effective alternatives to Holter monitors or implantable recorders which could potentially be used for prolonged monitoring and estimation of AF burden. Accurate algorithms could be used to provide short summaries with segments of ECG data that could be used to confirm diagnosis requiring minimal clinician oversight / time. Such claims have been made regarding smart-watches using ECG technology.19 The same claims have been made for single-lead ‘patch’ monitor devices such as the Zio Patch20 (iRhythm technologies Inc) although cost is currently a consideration (cost £800 for the device including data analysis and a clinical report for a 14-day monitoring period for a single patient21) Collaboration with industrial partners could realise cost effective, reliable, acceptable and accurate alternative to existing monitor technology with devices such as the PH7 (cost price £26) which are reusable. Other clinical uses could include existing indications for Holter monitoring such as syncope and palpitations. Further clinical evidence would be required however to validate our findings and support the use of consumer devices for the detection of AF.

In conclusion, inexpensive consumer heart rate monitoring devices (PH7 and BG2) can be used to detect AF accurately. The consumer devices performed as well or better than WatchBP and AliveCor and have the capability to store or transmit ECG data which could be used to confirm AF.

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**Figure 1 – The AF detection devices used in the SAFETY trial (top left – Polar-H7, top right - AliveCor, bottom left – Firstbeat Bodyguard 2, bottom right WatchBP)**

**Figure 2 – Trial Flow Diagram**