NICE atrial fibrillation guideline snubs wearable technology: a missed opportunity?

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Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and a growing public health epidemic. In the UK, over 1.3 million people have a diagnosis of AF and an estimated 400,000 remain undiagnosed. AF-related strokes account for a quarter of all strokes and, as AF episodes are often asymptomatic, are still often the first manifestation of AF. Early diagnosis and initiation of oral anticoagulation, where appropriate, may prevent some of these thromboembolic strokes. Public Health England is committed to decrease the incidence of AF-related strokes and has sponsored initiatives aimed at improving AF detection by promoting the uptake of wearable technologies. However, the National Institute for Health and Care Excellence (NICE) has not recommended wearable technology in their recent AF diagnosis and management guidelines (NG196). Diagnostic accuracy of single-lead electrocardiography (ECG) generated by the latest iteration of wearable devices is excellent and, in many cases, superior to general practitioner interpretation of the 12-lead ECG. High-quality ECG from wearable devices that unequivocally shows AF can expedite AF detection. Otherwise, there is a real risk of delaying AF diagnosis with the potential of devastating consequences for patients and their families.

KEYWORDS: atrial fibrillation, stroke prevention, digital health technology, wearables, NICE

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Introduction

Atrial fibrillation (AF) is the most commonly encountered cardiac arrhythmia. In the UK, over 1.3 million people have an AF diagnosis with a further 400,000 remaining undiagnosed. AF is associated with significant morbidity and mortality. On average, there are 40 AF-related strokes in England each day which are known to be more severe and disabling than non-AF related strokes and, for many, prove fatal. Public Health England’s (PHE’s) The NHS Long Term Plan is committed to decreasing the annual stroke rate by improving AF detection and optimising its management across the UK. Oral anticoagulation (OAC) is a highly effective prevention strategy for AF-related strokes, reducing the stroke risk by two-thirds. However, up to a third of AF patients are asymptomatic and, unfortunately, an ischaemic stroke is still often the first presentation of AF. Early diagnosis and initiation of OAC, where appropriate, may prevent some of these thromboembolic strokes. To this effect, PHE together with the Academic Health Science Networks have championed the deployment of innovative digital solutions, including a 6,338 mobile electrocardiography (ECG) device roll-out programme in 2018 aimed at improving AF detection. It is therefore surprising that the National Institute for Health and Care Excellence (NICE) has not supported this technology in their recent AF diagnosis and management guidance (NG196).

Digital health revolution

Technological advancements have led to a plethora of novel non-invasive devices, many commercially available, including patches, smartphones, wearables (watches, bands and rings) and handheld devices, which can detect and monitor arrhythmias and detect possible AF (Fig 1). Initially, volumetric variations in the peripheral microcirculation detected by photoplethysmography (PPG) was used to measure heart rate variability and peak-to-peak changes to detect AF (Fig 2). PPG signals have several inherent limitations that increase the number of false-positive detections of AF, such as requiring good contact with the skin and, thus, are very susceptible to noise and artefacts from changes in pressure and motion. The latest generation of wearables incorporate ECG sensor units. These have the advantage of generating high-quality limb-lead ECGs with the patient at rest, discriminating artefact noise from actionable arrhythmias, and are easily exported and reviewed by clinicians, improving diagnostic accuracy.

Atrial fibrillation guidelines

The recently released (April 2021) NICE NG196 AF guidelines failed to incorporate wearable and handheld technology in their diagnostic pathway. Instead, NICE continues to advocate...
**Fig 1. Devices used for atrial fibrillation screening.** AF = atrial fibrillation; PPG = photoplethysmography; RCTs = randomised controlled trials.

<table>
<thead>
<tr>
<th>'Spot-check' photoplethysmography</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Smartphone camera and app (eg Fibrich)g</strong></td>
<td>Requires smartphone app to analyse PPG signal. Usually records for 30 seconds to 1 minute. Measures peak-to-peak variability in the PPG waveform for evidence of heart rate irregularity. Learning curve to obtain a good PPG recording. False positives due to motion artefacts, sinus arrhythmia and ectopy. Fibrich app has been used extensively for AF screening.</td>
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<table>
<thead>
<tr>
<th>Semi-continuous photoplethysmography</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Ear lobe</strong></td>
<td>Can send irregular rhythm notifications (eg Apple Watch or CART-I ring). Can combine data from accelerometers and oscillometers to identify periods of body movement to reduce false positive detection. Mechanical sensors can collect physical activity data. Deep learning algorithms can improve AF detection accuracy but require large processing power that is difficult to miniaturise and incorporate into the device; to overcome this, PPG traces can be downloaded and analysed in the cloud</td>
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<table>
<thead>
<tr>
<th>'Spot-check' single-lead electrocardiography</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>AliveCor</strong></td>
<td>Usually records a 30 seconds to 1 minute single-lead ECG; AliveCor can record six leads. Smart bands, watches and rings do not record ECG continuously. ECG is generated by touching the metal crown with a finger from the opposite hand. ECG from handheld devices (such as AliveCor, Znicor and MyDiagnosis) have been extensively validated and are being used in large AF screening RCTs. In addition to automated algorithms, ECGs for wearable and handheld devices can be easily exported in PDF format and reviewed by the physicians, which may reduce false positive detections. May be used to identify other arrhythmias or to monitor QT (AliveCor).</td>
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</tbody>
</table>

pulse palpation followed by 12-lead ECG for the detection and diagnosis of persistent AF and longer periods of monitoring (Holter or implantable cardiac monitors) for paroxysmal AF. This, of course, raises obvious concerns that delays in obtaining a 12-lead ECG in primary care (often not available at the time of a general practitioner (GP) appointment) or limited access to ambulatory monitoring will translate into fewer AF detections, leading to increased number of AF-related strokes while people await a diagnosis and are not anticoagulated. This guidance also brings about uncertainty in clinical practice: should a physician ignore single-lead ECGs from wearable devices that clearly show AF from a symptomatic patient; should OAC be withheld until subsequent monitoring confirms AF; and how should we counsel these patients and their families if they suffer an AF-related stroke while awaiting further investigations.

In stark contrast, the European Society of Cardiology (ESC) took a different stance by accepting as evidence of clinical AF an irregular rhythm without discernible P-waves on a 30-second single-lead ECG generated by a validated wearable device and interpreted by a physician. It, however, rightly advocates caution, highlighting that there is still uncertainty in this fast-moving field and calls for high-quality, large, randomised studies. This pragmatic approach relies upon physicians exercising their clinical judgement when appraising ECG waveforms from wearable devices and deciding if it represents a ‘true’ AF episode, a false-positive detection or if further investigations are required.

To establish the diagnostic accuracy of wearable devices, NICE reviewed studies that compared either automatic detection and/or clinician interpretation of both PPG and ECG waveforms to a 12-lead ECG interpreted by an expert clinician, usually a cardiologist, as the gold-standard. Although NICE acknowledged that newer devices are accurate and show promise, it did not make any recommendations as it felt a definitive test needs ‘almost perfect’ sensitivity and specificity. However, if we exclude studies that rely on automatic detection or PPG signals, and only examine those with physician interpretation of a single-lead ECG (as endorsed by the ESC), the sensitivity and specificity is high (ranging from 0.84 to 0.97 and 0.86 to 0.97, respectively; Table 1). In some cases, it was even superior to the diagnostic accuracy of GP interpretation of a 12-lead ECG (sensitivity of 0.79 and specificity of 0.92) as observed in the SAFE study, which included 2,595 primary care patients (Fig 3). Interestingly, in their current review, there was a discrepancy in the qualitative assessment of studies also included in the NICE DG35 (lead-I ECG devices for detection of symptomatic AF in primary care), having been considered previously as ‘low’ risk of bias but were now upgraded to ‘serious’ or ‘very serious’ risk of bias. The rationale for this is unclear.

The AF Association, a UK-based charity that promotes AF awareness by educating patients and healthcare professionals, has released an ‘AF white paper’ endorsing clinically validated ECG-based wearable devices and expressed concerns that the new NICE recommendations will delay AF detection.

**Wearable devices and AF screening**

The use of wearable technology may extend the opportunity for detection to significant sections of the population with the potential for much to gain. This was illustrated in the Apple Heart Study that was conducted virtually and recruited 419,297 participants in only 8 months. The main aim was to determine AF detection accuracy of the Apple Watch; it was not designed to investigate outcomes. It included mainly a young healthy population and, unsurprisingly, only 0.5% had an irregular rhythm...
NICE AF guideline snubs wearable technology

Challenges and unanswered questions

‘Self-initiated’ rhythm monitoring with wearable technology is likely to identify short infrequent asymptomatic AF episodes in apparently healthy individuals that are of unclear clinical significance. It is important to bear in mind that net clinical benefit of thromboprophylaxis with OAC has only been demonstrated in patients with AF detected by a 12-lead ECG and a significant number of patients with consumer devices represents a healthier/younger cohort with a likely different stroke risk. Evidence from longitudinal studies of device-detected atrial high-rate episodes (also referred to as subclinical AF) suggest a significant yearly stroke risk. This is numerically smaller than patients with clinical AF and the role of OAC is not yet established. The AF burden and episode duration that merits anticoagulation is also unknown. In studies of patients with device-detected AF, the threshold for increased thromboembolic risk was met following AF episodes lasting longer than 5 minutes (MOST), 1 hour (SOS), 5.5 hours (TRENDS) and 24 hours (Botto et al, Cappuci et al and post-hoc analysis of ASSERT). Two randomised controlled trials (ARTESiA (NCT01938248) and NOAH AFNET 6 (NCT02618577)) are currently recruiting and may provide further insights regarding stroke prevention in subclinical AF. The ESC recommends considering OAC in patients with high stroke risk and subclinical AF episodes longer than 24 hours. There are also valid apprehensions that commercially available devices may not be validated to the same standard as medical-grade devices and hence generate a large number of false-positive detections leading to harm from overtreatment and unwarranted downstream investigations. Keeping abreast with the diagnostic accuracy of wearable devices with different algorithms and criteria for notification of irregular rhythms, frequent software updates and patches will also prove challenging.

Acceptance of wearable devices within the cardiology community continues to steadily increase. A survey by Maninger et al of over 500 cardiologists showed that 83% would diagnose AF based on a single-lead wearable device ECG and 72% would start oral anticoagulation. We are already experiencing an enthusiastic uptake of wearable devices from arrhythmia patients. Indeed, in TeleCheck-AF, rhythm assessment is performed by the FibriCheck app 1-week prior teleconsultation obviating the need for an ECG in primary care. This international project was set up in response to the COVID-19 pandemic and has already recruited over 4,000 patients in 41 centres.

Without acknowledgment of their clinical utility, it will be challenging to procure the necessary funding and support from all stakeholders, including regulatory bodies, for a comprehensive evaluation of current clinical services with a view of updating current infrastructure, data management systems, security and governance to facilitate the seamless integration of wearable data into electronic patient records.
Table 1. Summary of studies (sample size ≥99 patients) included in the National Institute for Health and Care Excellence Expert Review B (NG196) comparing the diagnostic accuracy of single-lead ECG interpretation by an expert physician with a 12-lead ECG (gold standard)\(^9\)

<table>
<thead>
<tr>
<th>Index test</th>
<th>Study</th>
<th>n</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AliveCor (lead-I ECG)</td>
<td>Desteghe, 2017(^{12})</td>
<td>445</td>
<td>1.00 (0.83–1.00)</td>
<td>0.98 (0.95–0.99)</td>
</tr>
<tr>
<td></td>
<td>Haberman, 2015(^{17})</td>
<td>130</td>
<td>0.94 (0.73–1.00)</td>
<td>0.99 (0.95–1.00)</td>
</tr>
<tr>
<td></td>
<td>Williams, 2015(^{13})</td>
<td>99</td>
<td>0.93 (0.77–0.99)</td>
<td>0.76 (0.64–0.85)</td>
</tr>
<tr>
<td></td>
<td>Koltowski, 2019(^{20})</td>
<td>100</td>
<td>0.928</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>Himmelreich, 2019(^{18})</td>
<td>219</td>
<td>1.00 (0.85–1.00)</td>
<td>1 (0.98–1.00)</td>
</tr>
<tr>
<td></td>
<td>Total: 993</td>
<td></td>
<td>Pooled: 0.95 (0.88–0.99)</td>
<td>Pooled: 0.96 (0.81–0.99)</td>
</tr>
<tr>
<td>KardiaBand (equivalent to lead-I ECG)</td>
<td>Bumgamer, 2018(^{14})</td>
<td>100</td>
<td>0.88 (0.79–0.94)</td>
<td>0.86 (0.76–0.93)</td>
</tr>
<tr>
<td>Merlin ECG event recorder (single-lead ECG)</td>
<td>Kearley, 2014(^{19})</td>
<td>1,000</td>
<td>0.939</td>
<td>0.901</td>
</tr>
<tr>
<td>Omron HeartScan HCG (single-lead ECG)</td>
<td>Kearley, 2014(^{19})</td>
<td>1,000</td>
<td>0.964</td>
<td>0.946</td>
</tr>
<tr>
<td></td>
<td>Kaleschke, 2019(^{22})</td>
<td>568</td>
<td>0.99 (0.96–1.00)</td>
<td>0.96 (0.94–0.98)</td>
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<tr>
<td></td>
<td>Total: 1,568</td>
<td></td>
<td>Pooled: 0.97 (0.93–1.00)</td>
<td>Pooled: 0.95 (0.93–0.97)</td>
</tr>
<tr>
<td>MyDiagnostick (single-lead ECG; one measure over 60 seconds)</td>
<td>Desteghe, 2017(^{12})</td>
<td>445</td>
<td>0.85 (0.62–0.97)</td>
<td>0.95 (0.92–0.98)</td>
</tr>
<tr>
<td>Zenicor (bipolar lead I; one measure of 10 seconds)</td>
<td>Doliwa, 2009(^{16})</td>
<td>100</td>
<td>0.96 (0.86–1.00)</td>
<td>0.92 (0.81–0.98)</td>
</tr>
<tr>
<td>Beurer ME90 (single-lead ECG; one measure of 30 seconds)</td>
<td>Brito, 2018(^{23})</td>
<td>126</td>
<td>0.84 (0.60–0.97)</td>
<td>1.00 (0.97–1.00)</td>
</tr>
<tr>
<td>ECG-Bone (single-lead ECG; unclear duration)</td>
<td>Proesman, 2019(^{26})</td>
<td>223</td>
<td>0.90 (0.83–0.95)</td>
<td>0.97 (0.92–0.99)</td>
</tr>
<tr>
<td></td>
<td>Total: 1,568</td>
<td></td>
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CI = confidence interval; ECG = electrocardiography.

Conclusion

AF is a growing public health epidemic with an estimated 400,000 patients remaining undiagnosed in the UK. AF-related strokes account for a quarter of all strokes and oral anticoagulation reduces the stroke risk by two-thirds. Undoubtedly, there are many challenges and hurdles prior to widespread adoption of digital health technologies and rigorous studies are warranted. However,
rather than not integrating any wearable technology, a more nuanced approach is desirable: incorporating high-quality single-lead ECG data from the latest generation of wearable devices that unequivocally show AF may expedite AF detection. Otherwise, there is a real risk of delaying AF diagnosis with the potential for devastating consequences for patients and their families. ■

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**References**


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