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Editorial

Innovative Technologies to Detect Atrial Fibrillation: "Wolf in Sheep's Clothing?"

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See article by Godin et al., pages 840–845 of this issue.

With an aging population and the growing prevalence of cardiovascular disease, atrial fibrillation (AF) has become an epidemic in contemporary clinical practice. Although AF has been shown to have a negative effect on survival and quality of life, its most dreaded complication is cardioembolic stroke, which not only takes a tragic toll on patients and their families but also imparts a significant economic burden to the health care system.

In an effort to identify patients with AF who would benefit from prophylactic anticoagulation, risk score algorithms for thromboembolic stroke in the setting of AF have been applied, including **C**ongestive Heart Failure, **H**ypertension, **A**ge, **D**iabetes, **S**troke/Transient Ischemic Attack ($CHADS_2$) and **C**ongestive Heart Failure, **H**ypertension, **A**ge ($\geq$75 years), **D**iabetes, **S**troke/Transient Ischemic Attack, **V**ascular Disease, **A**ge (65-74 years), **S**ex (Female) ($CHADS_2$-VASc). Unfortunately, a considerable proportion of patients who present with an ischemic stroke have unrecognized AF, especially among the elderly, thus prompting the need to screen undiagnosed populations of AF.

AF lends itself to a systematic "population at risk" approach because of its inherently paroxysmal nature, its typically asymptomatic presentation, and its increased prevalence with age. Traditionally, AF screening has focused on an opportunistic approach using a single time point, which has a low yield for detecting anything but permanent AF. Attempts to identify paroxysmal AF with a 12-lead electrocardiogram (ECG) or traditional 24-hour ambulatory Holter monitoring does not increase the detection rate significantly as compared with intermittent ECG recordings over a period of weeks to months. Although second-generation external ambulatory ECG recordings with a monitor patch or ambulatory telemetry monitoring may increase detection of AF, it is often cumbersome for patients with frequent electrode detachments and signal quality issues.

Hence, identifying technologies that would assist in detecting unsuspected AF in a high-risk patient has the potential for an enormous therapeutic and societal value. To this effect, there has been an explosion of mobile health devices or "wearables" for monitoring multiple biometrics. Recent innovative technologies to detect arrhythmias with various algorithms have been developed, which allow the device to inform the consumer of "possible atrial fibrillation," making it technically and economically feasible for mass population-based screening.

Over the past few years, a number of studies have assessed the utility of device-detected arrhythmias. The STROKESTOP study, a prospective population-based, systematic mass screening program including 75- to 76-year-old patients without known AF, detected new AF in 3% of their study population compared with only 0.5% on the first ECG.[1] The **Re**mote **Hea**rt **R**hythm **S**ampling Using the AliveCor Heart Monitor to Scr**ee**n for **A**trial **F**ibrillation (REHEARSE-AF) study assessed long-term intermittent ECG recordings in an AF-free, over 65 years group of patients with a mean $CHADS_2$-VASc score of 3 using the AliveCor Kardia device with twice weekly 30-second ECG tracings transmitted for 12 months.[2] AF was diagnosed in 3.8% of patients in the AliveCor group vs 1% in the routine care group at a cost per AF diagnosis of $10,780, suggesting a potential clinical benefit of using population-based screening technology. The Apple Heart Study was presented at the American College of Cardiology 2019 meeting and highlighted the potential merits of wearable technology to assess for arrhythmia detection in a large population.[3] The Apple Watch uses photoplethysmography to measure blood flow activity and detects subtle changes that could indicate an irregular heartbeat. It creates a tachogram that is then analyzed by a computer-derived algorithm. The primary end points in the study were >30 seconds of AF and simultaneous AF on ECG patch and tachogram. Not surprisingly, in a presumably healthy and young population, a notification was sent to only 0.52% of the people studied. Importantly, only 34% of those who received a notification actually had AF on the ECG patch, which could be explained in part by paroxysmal AF, highlighting the importance of validating device-detected arrhythmias.[3]

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In this issue of the *Canadian Journal of Cardiology*, Godin et al.[4] used a Kardia mobile electrocardiogram device (AliveCor) that, unlike photoplethysmography, records a single-channel ECG, and the software algorithm provides a report of "normal," "possible atrial fibrillation," or "unclassified." They studied the feasibility of using the Kardia device in an office setting to detect AF in an undifferentiated primary care population. Eligible patients older than 65 years with no known history of AF were screened with a single 30-second ECG recording. One hundred thirty-three physicians participated, and 7585 patients were screened. AF was detected in 471 patients (6.2%) with anticoagulation initiated in 270 of 471 patients (57%). The authors concluded that previously undiagnosed AF is common in patients older than 65 years attending a primary care physician's office and that the Kardia mobile ECG device appeared to be effective as a screening tool and had a high rate of acceptability by the participating physicians.

The authors are to be congratulated on this important study as it adds incremental insight into innovative technologies detecting AF. However, the study is largely observational, has limited sample size, experienced limited and perhaps selective enrolment (only 42% of eligible patients were actually enrolled in the study), and does not adequately address the real-world impact of these mobile device technologies. As such, the authors appropriately recommend the need for further research on the feasibility of integrating this point-of-care technology into population-based screening programs.

Having used the Kardia device and other similar devices in clinical practice, I offer the following assessment of mobile health device and device-detected arrhythmias and how these devices can represent a technological double-edged sword.

Merits of Mobile Health Devices

1. Although an implantable loop recorder is useful for syncope, the Kardia device allows a noninvasive option for detection of various arrhythmias including AF, supraventricular tachycardia, or ectopic beats in patients with unexplained palpitations and presyncope with negative Holter recordings.
2. Office or email transmission of rhythm strips allows for improved communication and timely changes in management strategies in patients with paroxysmal AF.
3. Diagnosing, managing, and follow-up of patients with suspected or known AF.
4. Mobile health devices allow for the correlation of an actual arrhythmia in the subset of patients with paroxysmal AF and symptoms of dyspnea, palpitations, and fatigue.

Issues With Mobile Health Devices

Smart phone–based ambulatory ECG tracings unquestionably have great clinical potential for the cardiologist. However, there are inherent concerns when the traditional model of a physician-prescribed test and interpretation becomes blurred with a patient's personal device "diagnosing" an arrhythmia or when a healthy individual subsequently becomes a "patient" due to device-detected arrhythmias. Before adopting unbridled enthusiasm for mass screening with devices for unsuspected AF, I wish to share a few personal perspectives.

Accuracy of device-detected AF

Godin et al[4] found that 471 patients had a positive AF screen with the Kardia device, but only 297 had a confirmatory 12-lead ECG. The authors correctly commented that this could be related to paroxysmal AF. However, it would have been useful for the authors to manually review all of the "positive" Kardia device tracings to determine whether the device interpretation of "probable atrial fibrillation" was actually corroborated by a cardiologist. The iREAD study found that the Kardia device had a 96.6% sensitivity and 94.1% specificity for detecting AF, but these tracings were reviewed by electrophysiologists who may have falsely increased the sensitivity and specificity of the device.[5] In my experience, I have had difficulties with clarifying the rhythm on the Kardia device due to artifact, baseline wander, and low-amplitude QRS complexes.

The Hartwacht study analyzed the Kardia device in a "real world" cohort of 277 ambulatory patients and compared the Kardia classification of the ECG with independent interpretations by the cardiology team.[6] There were 5982 Kardia ECGs reviewed during the study period with a 96% agreement between the Kardia classification and cardiologists for sinus rhythm. However, when the Kardia algorithm classified the ECG as "possible AF," the cardiology team confirmed AF in only 80% of the tracings. When the Kardia ECG algorithm deemed the tracing "unclassifiable," the cardiology team could provide a diagnosis in 81% of these tracings. Although the study noted a high negative predictive value, the positive predictive value was only 80%, leading to the conclusion that the capability of the current Kardia algorithm to independently verify ECG tracings as AF and other arrhythmias was imperfect.

Anticoagulation for device-detected AF

Godin et al[4] found the Kardia device–detected AF in 471 patients with 270 patients started on anticoagulation by family physicians. Importantly, 91 were anticoagulated solely based on the diagnosis of "probable AF." Andrade et al.[7] in the recent Canadian guidelines recommended that anticoagulation can be considered in subclinical AF with a $CHADS_2$ >1 with episodes >24 continuous hours in duration. Currently, we do not know whether brief episodes of AF are clinically important. This raises several concerns when incorporating a management strategy on the basis of a device-detected arrhythmia. What if the device interpretation were wrong and the rhythm were sinus tachycardia with premature atrial contractions or sinus arrhythmia? Where is the robust evidence of initiating long-term anticoagulation to reduce stroke risk in a device-detected brief episode of subclinical AF? What is the potential risk of bleeding in this hitherto device-detected AF population?

Socioclinical implications of device-detected AF

Godin et al[4] reported that 71% of the patients with Kardia device–detected AF were not anticoagulated, pending the confirmation of further testing or specialist referral.

Device-detected arrhythmias can lead to diagnostic ambiguity culminating in a cascade of further investigations adding to increased health care costs. Furthermore, patients adapt quickly to this technology and can easily transmit large volumes of data impacting office workflow and leading to "information overload." This consequently leaves the onus on the physician to interpret multiple tracings and recommend a management strategy to the patient and family physician. As newer devices come onto the market, the ability of these devices to detect brief arrhythmias over longer durations of time and the uncertainty around their clinical significance will place the physician in a difficult position, particularly as it relates to initiating anticoagulation. Finally, there is the "emotional toll" device-detected arrhythmias can have on patients and families, especially without the benefit of a physician-patient conversation to provide clinical context.

In summary, we are in the age of digital transformation with the future promise of more efficient health care and enhanced patient-physician engagement. The combination of easy accessibility of devices and an aging population will undoubtedly increase the detection rate of AF and the use of anticoagulation for stroke prevention.

However, before embarking on widespread adoption of such technologies, the balance between benefits and harms of screening for asymptomatic AF must be clarified.

I would suggest we proceed with cautious optimism until rigorous, scientifically driven, and population-based clinical trials address the clinically important matter in question of whether placebo vs anticoagulation for device-detected AF unequivocally demonstrates improved outcomes, both in diagnosis and treatment strategies. A number of ongoing clinical trials using cardiac implantable electronic devices addressing subclinical AF will undoubtedly elucidate more decisive decision making in this germane issue.

The era of mobile device—detected arrhythmias have proliferated, are here to stay, and are part of a broader spectrum of "digital health," and although there is an immense clinical potential, physicians have to be absolutely reassured that these innovative technologies are able to deliver high-quality data and provide irrefutable value to the patient and clinician.

Disclosures

The author have no conflicts of interest to disclose.

References

1. Svennberg E, Engdahl J, Al-Khalili F, et al. Mass screening for untreated atrial fibrillation: the STROKESTOP study. Circulation 2015;131:2176-84.

2. Halcox JPJ, Wareham K, Cardew A, et al. Assessment of remote heart rhythm sampling using the AliveCor heart monitor to screen for atrial fibrillation: the REHEARSE-AF study. Circulation 2017;136:1784-94.

3. Turakhia M, Perez M; on behalf of the APPLE HEART STUDY Investigators. Apple Heart Study. Paper presented at: American College of Cardiology 2019 Meeting. March 16, 2019; New Orleans, LA.

4. Godin R, Yeung C, Baranchuk A, Guerra P, Healey JS. Screening for atrial fibrillation using a mobile, single-lead electrocardiogram in Canadian primary care clinics. Can J Cardiol 2019;35:840-5.

5. William AD, Kanbour M, Callahan T, et al. Assessing the accuracy of an automated atrial fibrillation detection algorithm using smartphone technology: the iREAD study. Heart Rhythm 2018;15:1561-5.

6. Selder JL, Breukel L, Blok S, et al. A mobile one-lead ECG device incorporated in a symptom-driven remote arrhythmia monitoring program. The first 5,982 Hartwacht ECGs. Neth Heart J 2019;27:38-45.

7. Andrade JG, Verma A, Mitchell LB, et al. 2018 Focused update of the Canadian Cardiovascular Society guidelines for the management of atrial fibrillation. Can J Cardiol 2018;34:1371-92.