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Clinical Research

Screening for Atrial Fibrillation Using a Mobile, Single-Lead Electrocardiogram in Canadian Primary Care Clinics

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See editorial by Bewick, pages 799–801 of this issue.

ABSTRACT

Background: Atrial fibrillation (AF), which affects 1% to 4% of the general population, is an important risk factor for stroke. New technologies for AF screening are now available, but their real-world application in clinical settings has not yet been thoroughly investigated. The aim of this project was to describe the introduction and feasibility of a mobile electrocardiogram (ECG) device for AF screening in a large-scale, undifferentiated population.

Methods: A total of 184 Canadian primary care physicians were provided with a KardiaMobile ECG device (AliveCor) for 3 months. Physicians were asked to obtain a single 30-second ECG recording of all patients seen in their daily practice who were ≥65 years old and not previously diagnosed with AF. Evaluation of the Kardia device by physicians was measured using a Likert scale–based questionnaire.

Results: One hundred thirty-three physicians (72%) reported their findings and completed the survey. A total of 7585 patients were screened (42% of eligible patients). AF was detected in 471 patients

RÉSUMÉ

Contexte : La fibrillation auriculaire (FA), qui touche entre 1 et 4 % de la population générale, est un facteur de risque important de l'accident vasculaire cérébral. De nouvelles technologies sont aujourd'hui disponibles pour dépister la FA, mais leur mise en œuvre dans des situations réelles en milieu clinique n'a pas encore fait l'objet d'études approfondies. L'objectif de ce projet était de décrire la mise en œuvre et la faisabilité de l'utilisation d'un électrocardiographe (ECG) portable pour le dépistage de la FA dans une population importante et indifférenciée.

Méthodologie : Un moniteur ECG KardiaMobile (AliveCor) a été prêté à 184 médecins de soins primaires canadiens pendant 3 mois. Les médecins devaient réaliser un enregistrement d'ECG de 30 secondes chez tous les patients vus dans leur pratique quotidienne qui étaient âgés de 65 ans ou plus et n'avaient jamais reçu de diagnostic de FA. L'évaluation du moniteur Kardia par les médecins a été mesurée à l'aide d'un questionnaire utilisant des échelles de Likert.

Atrial fibrillation (AF), which affects 1% to 4% of the general population, is an important risk factor for stroke.[1,2] The incidence of AF is known to increase with age.[3] Given the maturing demographic of many developed countries, resource-efficient and scalable strategies for the detection of undiagnosed AF are of timely concern.[4]

An array of new technologies for AF screening is now available,[5] but the real-world application of these technologies in a clinical setting have not yet been thoroughly investigated.[6] Concerns regarding wearable technologies for arrhythmia detection include limitations in accuracy—particularly for photoplethysmography-based devices that are inherently less accurate than the conventional electrocardiogram (ECG)—and limited testing in a small number of patients in unique scenarios.[7] The KardiaMobile ECG device records, stores, and transfers a single-channel ECG; the associated software algorithm provides a "normal," "possible AF detected," or "unclassified" report with 96.6% sensitivity and 94.1% specificity for the detection of AF as compared with physician-interpreted 12-lead ECGs.[8] Even in a paediatric population, the Kardia device produces accurate single-lead ECG tracings in both healthy children and children with cardiac disease or rhythm abnormalities.[9] The aim of our study was to determine the utility and feasibility of mobile ECG testing as a means of AF screening in a large-scale, undifferentiated population.

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(6.2%). Anticoagulation therapy was initiated in 270 patients (57%). Physicians generally reported a high perceived clinical value (94%) and ease of integration (89%) of the device.

Conclusions: Previously undiagnosed AF is common in older individuals attending primary care clinics. The KardiaMobile ECG device appears to be an effective screening tool for AF with high physician acceptability. More research on the feasibility of such novel technologies is warranted for future consideration of integration in population-based screening programs.

Résultats : Cent trente-trois médecins (72 %) ont rapporté leurs conclusions et répondu au sondage. Au total, 7585 patients ont subi un dépistage (42 % des patients admissibles). La FA a été décelée chez 471 patients (6,2 %). Un traitement anticoagulant a été instauré chez 270 patients (57 %). Selon les rapports des médecins, en général, la valeur clinique perçue de l'appareil est élevée (94 %) et son intégration est facile (89 %).

Conclusions : La FA non diagnostiquée précédemment est fréquente chez les personnes âgées fréquentant des cliniques de soins primaires. Le moniteur ECG KardiaMobile semble être un outil de dépistage de la FA efficace et présenter un taux d'acceptabilité élevé chez les médecins. Des recherches plus approfondies s'imposent sur la faisabilité d'intégrer ces nouvelles technologies dans des programmes de dépistage futurs visant la population générale.

Materials and Methods

Canadian primary care physicians in Ontario and Quebec with a self-reported clinical practice heavily focused on care of the elderly were invited to participate in an AF screening program. Physicians were provided with a KardiaMobile ECG device (AliveCor, Mountain View, CA), device instructions, and journal log for a 3-month period. Physicians were asked to perform a single 30-second ECG recording using the Kardia device for all patients seen in their daily practice who were ≥ 65 years old and not previously diagnosed with AF. The results were interpreted and logged by the primary care provider. No patient-identifying information was collected or shared. Physician evaluation of the Kardia device was measured using a Likert scale–based questionnaire at the end of the 3-month period.

The primary objective was to describe the use of a mobile ECG device in Canadian primary care practice as part of a screening program for AF. Secondary objectives were to (1) estimate the rate of undiagnosed AF and (2) evaluate the perceived clinical value, satisfaction, and feasibility of routine AF screening with a mobile ECG device.

Results

From August to October 2017, 184 physicians participated in the screening program. Of these, 133 physicians, who screened a total of 7585 patients, shared the results of their screening activities and answered the poststudy questionnaire.

Physician-reported screening practices for AF are summarized in Table 1. The numbers of patients screened varied widely among the physicians (range, 0-343), with 3 physicians screening no patients. Six physicians indicated that they had 37 patients who refused to undergo mobile ECG testing. In addition to age, the most commonly cited triggers to perform an AF screening test included irregular pulse, palpitations, dizziness, and the presence of risk factors (Table 2).

The patient flow in terms of detection and initiation of anticoagulation therapy is shown in Figure 1. The device detected AF in 6.2% of patients screened. A total of 270 patients were newly initiated on anticoagulant therapy (representing 3.5% of the total cohort screened, or a 57% treatment rate of the cohort identified as having possible AF by the KardiaMobile device). Physician impressions in terms of practice, device, and patient-related parameters are shown in Figure 2.

Discussion

Widespread opportunistic screening for AF in at-risk populations has been recommended by international expert groups. The 2016 European Society of Cardiology AF guidelines advocate for opportunistic AF screening by manual pulse palpation or ECG rhythm strip in patients >65 years, as well as systematic ECG screening in patients >75 years or at high risk for stroke.[10] In addition to the human costs associated with stroke, the economic burden of undiagnosed AF is also substantial,[5] with an estimated incremental cost burden of undiagnosed nonvalvular AF of $3.1 billion.[11] A recent population-based study (n = 2100) supported the feasibility of addressing primary stroke prevention using village health workers in rural India: Kardia device readings done on 3 separate days identified AF in 1.6% of individuals (two-thirds on the first reading).[12] There have not yet been any official Canadian recommendations on mass public screening of AF, nor has there been consensus on frequency or how screening should be performed.[5,6,13,14] The current study provides support for the feasibility of implementing an AF screening program in the Canadian primary care setting.

The detection rate of 6.2% observed in this study is higher than those observed in comparable single time-point screening programs. A systematic review found that the rate of AF identification in a general ambulant adult population using electrocardiography or manual pulse palpation is 1.4%.[15] Similarly, a Canadian in-pharmacy screening project of patients ≥ 65 years found undiagnosed AF in 2.4% of participants.[16] This higher detection rate in the current study

Table 1. Physician-reported practices using the KardiaMobile electrocardiogram device for atrial fibrillation screening in a primary care population

	Physicians (n = 133)
Screening for atrial fibrillation	
Number of patients screened per physician (mean ± SD)	57 ± 59
Eligible patients screened with mobile device per physician (%)	42
Patients who would have been screened irrespective of device per physician (%)	35
Detection of atrial fibrillation	
Physicians reporting ≥ 1 positive screen (%)	90
Physicians confirming positive screens with 12-lead electrocardiogram (%)	71

Table 2. Commonly cited triggers for atrial fibrillation screening using the KardiaMobile electrocardiogram device by physician-reported frequency

Triggers for atrial fibrillation screening	Frequency (%)
Age ≥ 65 y only	35
Signs and symptoms	
Irregular pulse	13
Palpitations	16
Dizziness	9
Other symptoms	14
Past medical history	
Diabetes	8
Hypertension	8
Cardiovascular disease	5
Risk factors (other/unspecified)	10

may be explained in part by selection bias—participating physicians only screened 42% of eligible patients and may have tended to select those with symptoms, comorbidities, and physical examination findings associated with AF. Furthermore, physicians may have underestimated the total number of patients they screened, but appropriately estimated the number of patients who screened positive, resulting in a higher ratio. The discrepancy between the number of screen-positive patients by the Kardia device and the number of patients with AF confirmed by ECG may be explained, in part, by paroxysmal AF.[6,16] Reliably establishing detection rates remains critical to appropriately determine the cost-effectiveness of any screening program.

The reported 57% of patients in the current study with positive screens and started on anticoagulation therapy are likely an underestimation of the true treatment rate, as confirmatory testing or cardiology consultation was still pending for some patients at the time of data capture. In comparison, a recent study evaluating AF screening modalities reported a 77% rate of anticoagulation therapy for patients with actionable AF.[6] It has been well documented that a substantial number of patients who would benefit from anticoagulation for stroke prevention do not receive it adequately or at all; furthermore, there is an access gap between patients who qualify for direct oral anticoagulants according to evidence-based guidelines and the subset of this cohort who are eligible based on government-funded policy.[17] Further analysis on the discrepancy between the rate of positive screens and the rate of anticoagulation is warranted in the future.

Anticoagulation therapy was initiated in 19% of patients in this study based solely on the device recording at the discretion of the primary care physician. However, the device is not currently approved for this use, and the majority of patients with positive screens received confirmatory testing by 12-lead ECG. Given the novelty of the technology, the relative value of the quality and quantity of data from a 10-second 12-lead conventional ECG vs a 30-second 1-lead mobile ECG remains to be determined.

Although adoption of the device was uneven among the physicians, physician impressions were largely favourable, with high perceived clinical value and general ease of integration into routine practice. In contrast, some physicians noted technical difficulties and were skeptical about the reliability of the results. Notably, a majority of physicians thought that their patients would be more likely to accept AF screening through the mobile ECG modality than with a 12-lead ECG. In terms of additive diagnostic yield for newly identified AF, repeated ECG recordings are the most useful for screening.[18] 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 on 1001 patients ≥ 65 years with a **C**ongestive Heart Failure, **H**ypertension, **A**ge (≥ 75 years), **D**iabetes, **S**troke/Transient Ischemic Attack, **V**ascular Disease, **A**ge (65-74 years), **S**ex (Female) (CHA_2DS_2-VASc) score ≥ 2 demonstrated that twice-weekly screening with the KardiaMobile ECG device over 12 months was

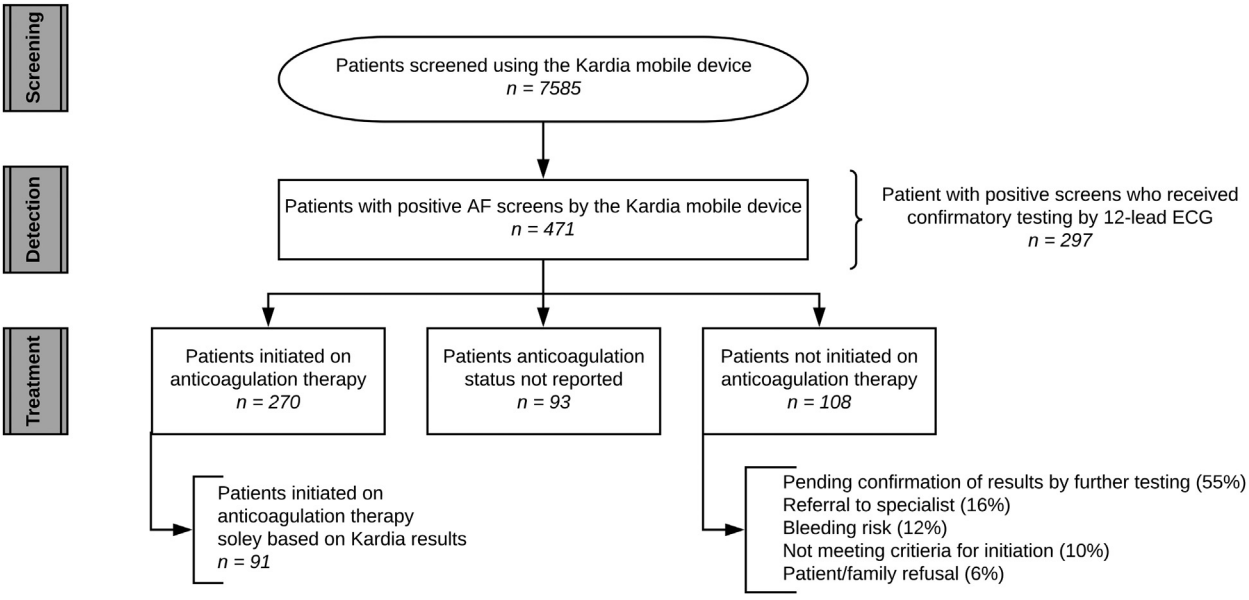

Figure 1. Screening, detection, and initiation of anticoagulation therapy for AF in a primary care population using the KardiaMobile ECG device. AF, atrial fibrillation; ECG, electrocardiogram.

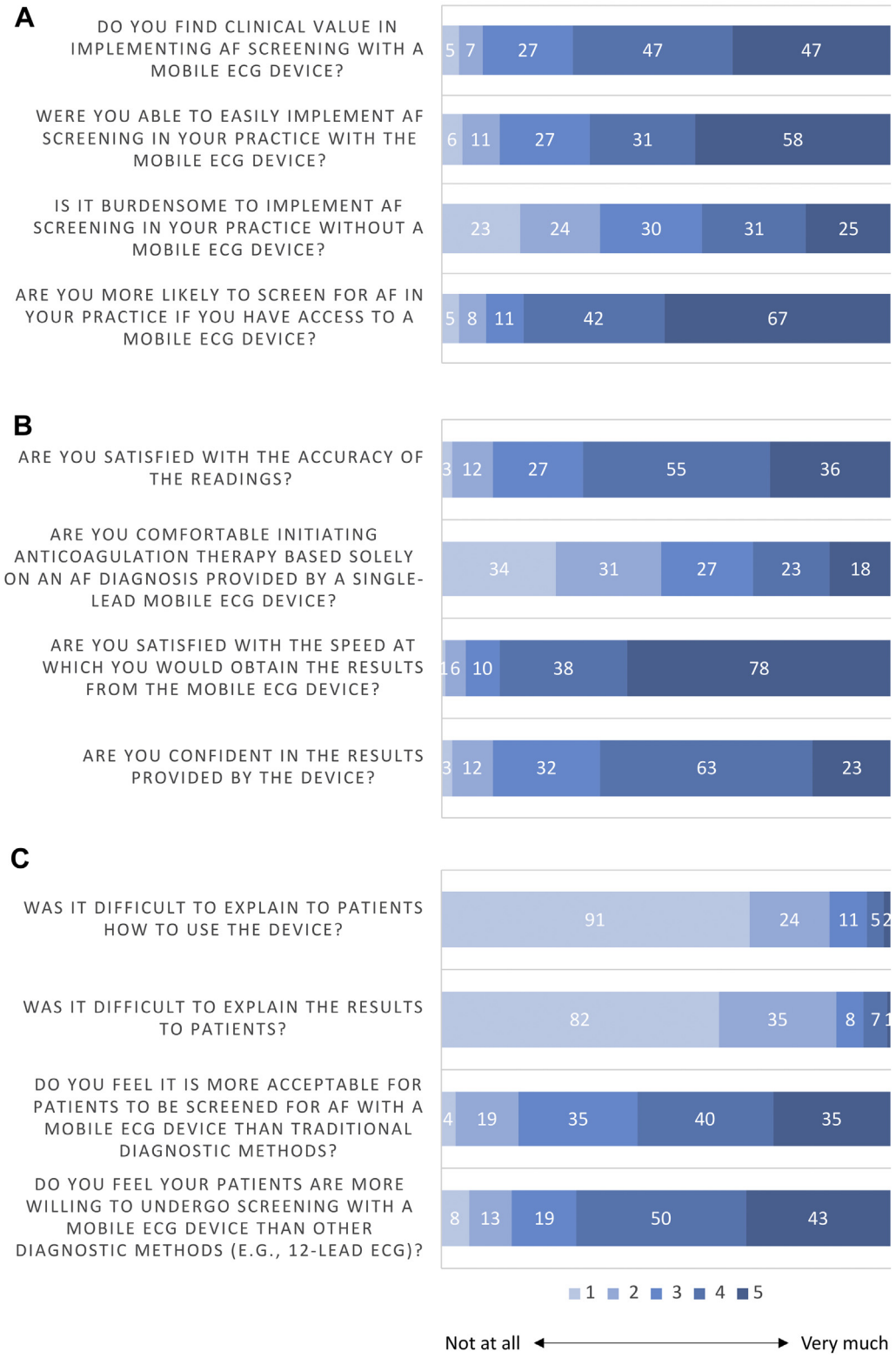

Figure 2. Physician's impressions of mobile screening for atrial fibrillation on a Likert scale from 1 (not at all) to 5 (very much): (**A**) practice-related parameters; (**B**) device-related parameters; and (**C**) patient-related parameters. AF, atrial fibrillation; ECG, electrocardiogram.

significantly more likely to identify AF than routine care.[19] Patient-centred devices, such as the KardiaMobile ECG device, may improve accessibility to screening strategies involving multiple readings. Recent Canadian guidelines for the management of AF suggest that it may be reasonable to prescribe anticoagulation therapy for subclinical AF in patients $\geq$ 65 years

with a $CHADS_2$ score ≥ 1, depending on burden, duration, and other risk factors for stroke.[20] Integration of cardiac monitoring with the Kardia device may be useful in the detection of subclinical AF and help guide stroke prevention strategies.

However, the additional physician workload and economic impact of implementing such a technology into an AF screening program—in terms of time required for analysis and consultation, especially for artefact findings or inaccurate device interpretations—remains largely unstudied.[21] The Hartwacht Arrhythmia program, a symptom-driven remove arrhythmia monitoring program that evaluated 5982 Kardia device recordings from 233 patients, concluded that the current performance of the arrhythmia detection algorithm makes the device inadequate as a stand-alone application, supporting the need for manual ECG analysis. Refinement of custom-tailored algorithms for the detection of arrhythmias such that manual assessment is less frequently necessary will reduce the associated workload.[22] Costs associated with this technology are estimated up to CAD$13,000 per AF diagnosis when used in population screening.[7,19] Given that the current study was designed with an opportunistic screening paradigm, which allows targeting of high-risk patient populations, the results may not be fully applicable to a systematic screening program.[23] Besides population-level screening, this technology may have a niche in (1) symptom-rhythm correlation in patients with paroxysmal arrhythmias and (2) screening for asymptomatic arrhythmias in patients at high risk.[7,24] Ongoing trials seeking to answer these questions include The **M**obile Phones in Cryptogenic Str**o**ke Patients **B**ringing **S**ingle **L**ead **E**cgs for **A**trial **F**ibrillation Detection (MOBILE-AF) study, a randomized clinical trial in which patients with cryptogenic stroke or transient ischemic attack will be randomized to record their ECG twice daily for 1 year with the Kardia device, compared with a 7-day Holter monitor, with the primary outcome of AF detection.[25] More research comparing the cost-effectiveness of such novel patient-centred technologies for arrhythmia detection will be crucial to determining their role, if any, in future AF screening programs.

Limitations

Given the study design, it was not possible to determine the rate of false detections or missed AF readings by the mobile device, or the physicians' clinical decisions after such events. The survey data collected in this observational study were among physicians selected by the sponsor. Therefore, typical limitations of observational data apply, including selection bias (for both physicians and patients) and potential for reporting bias and recall errors. The results are based on physician reports, and there was no adjudication or confirmation of their findings. Instructions for inclusion criteria (patients ≥ 65 years) were broad, but only a portion of these patients were screened, possibly further indicating an element of selection bias. Lastly, no patient-level data were collected (such as demographics or baseline characteristics).

Conclusions

There is a high prevalence of undiagnosed AF in Canadian primary care clinics. The KardiaMobile ECG device appears to be an acceptable modality for AF screening to the majority of both physicians and patients and may have a role in routine clinical care. More research on the feasibility of such novel technologies is warranted for future consideration of integration in population-based screening programs.

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Disclosures

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References

1. Rahman F, Kwan GF, Benjamin EJ. Global epidemiology of atrial fibrillation. Nat Rev Cardiol 2016;13:501.
2. D'Souza A, Butcher KS, Buck BH. The multiple causes of stroke in atrial fibrillation: thinking broadly. Can J Cardiol 2018;34:1503-11.
3. Lloyd-Jones DM, Wang TJ, Leip EP, et al. Lifetime risk for development of atrial fibrillation: the Framingham Heart Study. Circulation 2004;110:1042-6.
4. Turakhia MP, Shafrin J, Bognar K, et al. Estimated prevalence of undiagnosed atrial fibrillation in the United States. PLOS One 2018;13:e0195088.
5. Sandhu RK, Healey JS. Screening for undiagnosed atrial fibrillation. Expert Rev Cardiovasc Ther 2018;16:591-8.
6. Quinn FR, Gladstone DJ, Ivers NM, et al. Diagnostic accuracy and yield of screening tests for atrial fibrillation in the family practice setting: a multicentre cohort study. CMAJ Open 2018;6:E308-15.
7. Cheung CC, Krahn AD, Andrade JG. The emerging role of wearable technologies in detection of arrhythmia. Can J Cardiol 2018;34:1083-7.
8. 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.
9. Gropler MRF, Dalal AS, Van Hare GF, Silva JNA. Can smartphone wireless ECGs be used to accurately assess ECG intervals in pediatrics? A comparison of mobile health monitoring to standard 12-lead ECG. PLOS One 2018;13:e0204403.
10. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Eur Heart J 2016;37:2893-962.

11. Turakhia MP, Shafrin J, Bognar K, et al. Economic burden of undiagnosed nonvalvular atrial fibrillation in the United States. Am J Cardiol 2015;116:733-9.

12. Soni A, Karna S, Fahey N, et al. Age-and-sex stratified prevalence of atrial fibrillation in rural western India: results of SMART-India, a population-based screening study. Int J Cardiol 2019;280:84-8.

13. Tarride JE, Dolovich L, Blackhouse G, et al. Screening for atrial fibrillation in Canadian pharmacies: an economic evaluation. CMAJ Open 2017;5:E653-61.

14. Tarride JE, Quinn FR, Blackhouse G, et al. Is screening for atrial fibrillation in Canadian family practices cost-effective in patients 65 years and older? Can J Cardiol 2018;34:1522-5.

15. Lowres N, Neubeck L, Redfern J, Freedman SB. Screening to identify unknown atrial fibrillation. A systematic review. Thromb Haemost 2013;110:213-22.

16. Sandhu RK, Dolovich L, Deif B, et al. High prevalence of modifiable stroke risk factors identified in a pharmacy-based screening programme. Open Heart 2016;3:e000515.

17. Wan D, Healey JS, Simpson CS. The guideline-policy gap in direct-acting oral anticoagulants usage in atrial fibrillation: evidence, practice, and public policy considerations. Can J Cardiol 2018;34:1412-25.

18. Svennberg E, Engdahl J, Al-Khalili F, Friberg L, Frykman V, Rosenqvist M. Mass screening for untreated atrial fibrillation: the STROKESTOP study. Circulation 2015;131:2176-84.

19. 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.

20. 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.

21. Bumgarner JM, Lambert CT, Hussein AA, et al. Smartwatch algorithm for automated detection of atrial fibrillation. J Am Coll Cardiol 2018;71:2381-8.

22. 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.

23. Shin SY, Lip GYH. The importance and future of population screening for atrial fibrillation. Can J Cardiol 2018;34:1407-11.

24. Steinberg JS, Varma N, Cygankiewicz I, et al. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. Ann Noninvasive Electrocardiol 2017;22:e12447.

25. Treskes RW, Gielen W, Wermer MJ, et al. Mobile phones in cryptogenic strOke patients Bringing sIngle Lead ECGs for Atrial Fibrillation detection (MOBILE-AF): study protocol for a randomised controlled trial. Trials 2017;18:402.