

Validation of MyDiagnostick tool to identify atrial fibrillation in a multi-ethnic Asian population

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Abstract

Introduction: MyDiagnostick is an atrial fibrillation (AF) screening tool that has been validated in the Caucasian population in the primary care setting.

Methods: In our study, we compared MyDiagnostick with manual pulse check for AF screening in the community setting.

Results: In our cohort of 671 candidates from a multi-ethnic Asian population, AF prevalence was found to be 1.78%. Of 12 candidates, 6 (50.0%) had a previous history of AF and another 6 (50.0%) were newly diagnosed with AF. Candidates found to have AF during the screening were older (72.0 ± 11.7 years vs. 56.0 ± 13.0 years, $P < 0.0001$) and had a higher CHADSVASC risk score (2.9 ± 1.5 vs. 1.5 ± 1.1 , $P = 0.0001$). MyDiagnostick had a sensitivity of 100.0% and a specificity of 96.2%. In comparison, manual pulse check had a sensitivity of 83.3% and a specificity of 98.9%.

Conclusion: MyDiagnostick is a simple AF screening device that can be reliably used by non-specialist professionals in the community setting. Its sensitivity and specificity are comparable and validated across various studies performed in different population cohorts.

Keywords: AF, Asian, MyDiagnostick, pulse check, Singapore

INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia, occurring in 1%–2% of the general population, and its prevalence increases with age.^[1] AF increases the risk of stroke by up to five times.^[1] Although anticoagulation is an effective therapy for reducing the risk of stroke, documentation of AF on electrocardiography is required before initiation of therapy. Documentation of AF is made difficult by the paroxysmal nature of AF in the initial course, and up to one-third of patients are asymptomatic.^[2] Hence, the challenge lies in cost-effective screening of the general population.

Opportunistic pulse check followed by electrocardiographic (ECG) recordings is the preferred screening tool for AF detection in the general population aged 65 years and above.^[3] Other tools such as an implantable loop recorder, the Holter monitor, require specialist medical professional input. Wearable technology offers great potential. However, more research needs to be done to validate this as a screening tool in the general population. A recent publication

using the Kardia smartwatch in an Asian population showed it had 75% sensitivity.^[4]

MyDiagnostick (Applied Biomedical Systems BV, Maastricht, Netherlands) is a home screening tool for AF detection with a reported sensitivity of 94% and specificity of 93%.^[5] This is a rod with metal handles on both ends. Electrodes in both handles allow recording of a single-lead ECG when the patient holds on both ends of the tool. The device alerts the patient through an LED indicator if the rhythm is abnormal. However, there is no data for validation performed on the Asian population; hence, we sought to investigate MyDiagnostick for screening of AF in the general population.

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We performed AF screening and conducted an education programme in our healthcare institution in Singapore, which provides secondary healthcare. The primary objective was to study the utility of MyDiagnostick against manual pulse check in the lower-risk Asian population. Secondary objectives were to assess incidence of AF in this group of the Asian population.

METHODS

This was a prospective single-centre study. Members of the public were invited for AF screening over five days in a single institution in 2014. All the candidates were asked to fill up the questionnaire, which included demographics, medical history and symptoms. No patient identifiers were recorded. Candidates underwent a manual pulse check of at least 15 seconds, performed by registered nurses. Nurses would identify candidates with suspected AF if they discovered an irregularity in their radial or carotid pulse. Candidates were also screened with MyDiagnostick. The findings of the pulse check were blinded to the operators of MyDiagnostick and vice versa. Candidates who either had an abnormal pulse check or MyDiagnostick findings would then undergo a single-lead ECG rhythm strip performed by a cardiac physiologist. A cardiologist would interpret the findings. If a candidate was found to have AF, he/she would be counselled and given a referral to visit his family physician. All these were performed and completed within an hour. The process is illustrated in Figure 1. This study was approved and exempted from ethics board review.

The candidate was asked to grasp onto both ends of MyDiagnostick via the handles where the electrodes are located to record a single-lead ECG. After one minute, the ECG was analysed and the LED indicators gave a green or red signal, wherein green indicates absence of AF and red indicates presence. MyDiagnostick provides full disclosure to allow the physician to validate the ECG rhythm recording. It has a capacity for 140 recordings of 50–70 seconds.

AF is diagnosed via an algorithm on RR interval irregularity. It derives an overall AF score based on base rhythm, periodicity and variability. Base rhythm score is based on a sinus rhythm state machine chaining normal RR intervals, including premature intervals and short runs of tachycardia. Periodicity and variability

scores are based on the RR autocorrelation function. Overall AF score is calculated by obtaining linear combination of all scores and compared with a threshold, producing a dichotomy (AF or no AF).

Continuous variables are expressed as mean ± standard deviation unless otherwise stated. Parameters with normal distribution were compared using unpaired *t*-tests and one-way analysis of variance. Non-parametric data was compared using Mann-Whitney *U* test. Categorical variables expressed as numbers or percentages were analysed using Fisher’s exact test. Specificity and sensitivity analyses were performed for manual pulse check and the MyDiagnostick kit for detecting AF. All tests were two-tailed, and statistical significance was established at *P* < 0.05. Analyses were performed using StatView version 5.0 (Abacus Corporation, Berkeley, CA, USA) and GraphPad Prism (GraphPad Software, La Jolla, CA, USA).

RESULTS

A total of 671 candidates were recruited in this study. The baseline characteristics of the study population are presented in Table 1. A total of 12 candidates were found to have AF; hence, the prevalence of AF in this cohort was 1.78%. Of these 12 candidates,

Table 1. Demographics of screened candidates.

Characteristic	n (%)		P
	With AF (n=12)	Without AF (n=659)	
Age ^a (yr)	72.0±11.7	56.0±13	<0.0001
Male gender	6 (50.0)	228 (34.6)	0.267
Ethnic group			0.477
Chinese	11 (91.6)	517 (78.4)	
Malay	0 (0)	49 (7.4)	
Indian	1 (8.3)	75 (11.4)	
Others	0 (0)	18 (2.7)	
CHADSVASC score ^a	2.9±1.5	1.5±1.1	0.0001
Hypertension	8 (66.7)	221 (33.5)	0.016
Diabetes mellitus	2 (16.7)	98 (14.9)	0.696
Stroke	2 (16.7)	20 (3.0)	0.056
Ischaemic heart disease	1 (8.3)	22 (3.3)	0.344

^aData presented as mean ± standard deviation. AF: atrial fibrillation

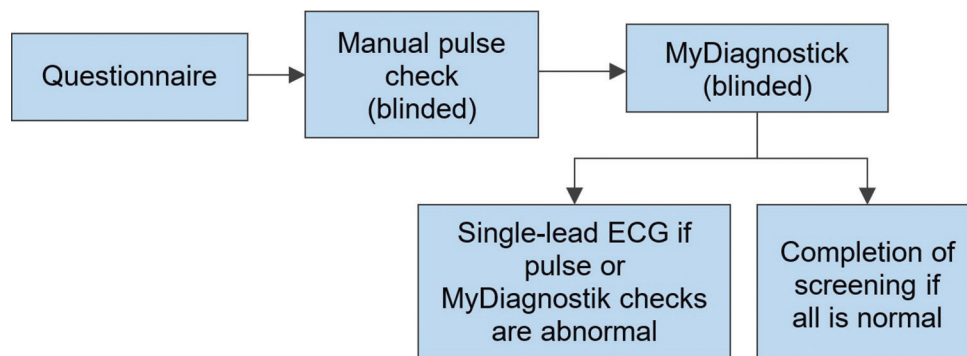


Figure 1: Flowchart shows the process of screening candidates for atrial fibrillation. ECG: electrocardiography

6 (50.0%) had a previous history of AF and another 6 (50.0%) were newly diagnosed with AF. Candidates found to have AF during the screening were older (72.0 ± 11.7 vs. 56.0 ± 13.0 , $P < 0.0001$) and had a higher CHADSVASC risk score (2.9 ± 1.5 vs. 1.5 ± 1.1 , $P = 0.0001$). The higher CHADSVASC score in the group with AF was driven by a higher prevalence of hypertension (66.0% vs. 33.0%, $P = 0.016$).

A total of 25 candidates were found to have abnormal results on MyDiagnostick but had normal manual pulse checks. A total of three candidates had abnormal pulse checks but normal findings with MyDiagnostick. A total of 14 candidates were found to have abnormal results on both MyDiagnostick and manual pulse check. MyDiagnostick had a sensitivity of 100.0% (95% confidence interval [CI] 73.5%–100.0%) and specificity of 96.2% (95% CI 94.6%–97.6%). Its positive predictive value (PPV) was 32.4% (95% CI 24.6%–41.3%) and negative predictive value was 100%. In comparison, manual pulse check had a sensitivity of 83.3% (95% CI 51.5%–97.9%) and specificity of 98.9% (95% CI 97.8%–99.5%), and its PPV was 58.8% (95% CI 39.5%–75.6%) and negative predictive value was 99.7% (95% CI 98.9%–99.9%). The types of arrhythmia that were detected as abnormal by MyDiagnostick as compared to manual pulse check and subsequently adjudicated on ECG rhythm strip are shown in Figure 2. However, owing to the small number of abnormal findings by either MyDiagnostick or manual pulse check, the differences were not statistically significant [Table 2].

Patients who were newly diagnosed with AF were given referral to their family physician with a copy of the ECG rhythm strip tracing of AF. Patients who were already known to have AF were reminded to continue their follow-up with their physicians.

DISCUSSION

Various portable devices to screen AF continue to be favoured

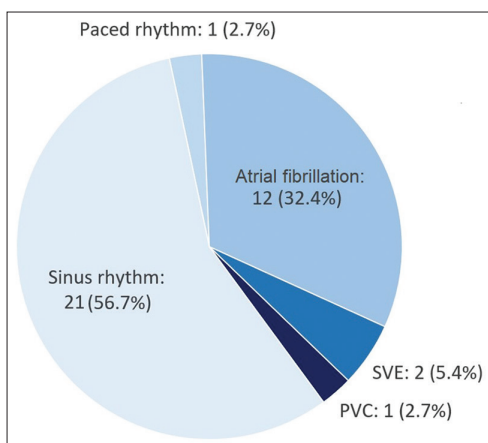


Figure 2: Pie chart shows 37 patients who were identified as abnormal by MyDiagnostick and underwent confirmatory single-lead rhythm strip for rhythm diagnosis. PVC: premature ventricular contraction, SVE: supraventricular ectopy

over manual pulse check for AF screening in clinical practice. AliveCor Heart Monitor and, more recently, the Apple Watch Series 4 are the latest wearable technologies that show promise for AF screening in the primary setting. Sensitivities and specificities of the AliveCor vary across different studies partially because of its sampled population and with updates on its AF detection algorithms. The AliveCor sensitivity was as low as 66.7% in a cohort of 2,052 patients in Hong Kong compared with 94.4% in a smaller cohort of 381 patients in the United States.^[6,7] The recently published Apple Heart Study showed that when the device triggered an irregular pulse notification after confirmation of multiple irregular tachograms, its PPV was 0.84 (95% CI 0.76–0.92).^[8] In comparison, the PPV of the device based on an individual tachogram was 0.71 (95% CI 0.69–0.74). Machine learning with a deep neural network is another promising aspect of AF screening through passive detection in smartwatches.^[9] However, we will need to await prospective data to assess its application in the clinical context.

MyDiagnostick was found to have a sensitivity and specificity of 94% (95% CI 87%–98%) and 93% (95% CI 85%–97%) in a primary care setting with most patients known to have AF (161 of 191 patients were known to have AF).^[5] When MyDiagnostick was used to screen in another primary care cohort of patients with a lower prevalence of AF (53 of 192 patients were found to have AF), it showed a sensitivity of 95% (95% CI 93%–100%) and specificity of 95.9% (95% CI 91.3%–98.1%).^[10] In comparison, our population had a much lower prevalence of AF (1.78%), which was a more representative prevalence of a general population. In our cohort, MyDiagnostick had a sensitivity of 100% and specificity of 96.2%, which compares well with the other studies.

As an AF screening tool, it would be difficult to justify MyDiagnostick as a cost-effective tool (PPV 32.4%; GBP 500) compared with manual pulse check (PPV 58.8%; free). However, a manual pulse check is less likely to be available in the general community without first training patients or the screeners to differentiate a regular from an irregular pulse. In our study, the manual pulse check was performed by nurses and MyDiagnostick was administered by non-medical personnel.

In the United Kingdom, Microlife WatchBP Office AFIB (Microlife AG, Clearwater, FL, USA) was recommended

Table 2. Results of MyDiagnostick against manual pulse check.

Rhythm strip	n		P
	MyDiagnostick	Manual pulse check	
Atrial fibrillation	12	10	–
Sinus rhythm	17	3	0.118
Sinus arrhythmia	4	1	–
Paced rhythm	1	1	–
Supraventricular ectopy	2	1	0.2
Ventricular ectopy	1	1	–

by the National Institute for Health and Care Excellence to screen for AF during office blood-pressure measurement in patients aged above 65 years. In a cohort of 2,052 primary care patients in Hong Kong, it had a sensitivity of 83.3% and specificity of more than 98%.^[7]

There is a dearth of information on the prevalence of AF in Singapore in the general population, which is a multi-ethnic Asian population. The incidence of 1.78% in our cohort suggests a similar prevalence of AF in the general population as previously reported in an overseas predominant Caucasian population.^[11,12] In comparison, AF screening in the Chinese population in Hong Kong revealed a prevalence of 2.3% (95% CI 2%–2.6%). The most recent study performed in Singapore Chinese revealed a similar prevalence AF rate of 1.5%.^[13]

The strength of our study is that we included all comers from the community with a good size of sample cohort. The screening process with MyDiagnostick was performed while blinded to the results of the pulse check. This confirms that a similar screening can be done by non-specialist professionals in the primary care setting either in a clinic or in the community setting.

Limitations of the study include a possible biased population. Being a health screening exercise, this could inevitably attract candidates who are more health-conscious and more compliant in the treatment of their AF risk factors. Not all the participants were screened with a gold-standard rhythm strip, thus potentially missing patients who had AF but were not picked up by MyDiagnostick or by manual pulse check. However, this is less likely, as MyDiagnostick was designed to be a screening tool and hence errs on the side of being more sensitive. This approach of validating only the results of patients who were identified by a screening tool rather than every patient is similarly practised in other similar studies.^[4,8] Being a single-centre study, the sample population may not be representative of the population. Nevertheless, the racial representation of our cohort is similar to the racial proportions in our national population. A similar study can be performed with AF screening in the community at various geographical locations to help improve population representation. Finally, the medical histories of the candidates might not have been entirely accurate, as they were voluntarily offered by the candidates and not verified.

In conclusion, MyDiagnostick is a simple AF screening device that can be reliably used by non-specialist professionals in the community setting. Its sensitivity and specificity are comparable and validated across various studies performed in

different cohorts of population. AF prevalence in this low-risk Asian cohort is similar to that seen in other countries.

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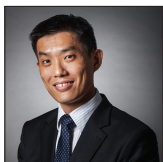
Conflicts of interest

There are no conflicts of interest.

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