Diagnostic accuracy of an oscillometric blood pressure monitor for atrial fibrillation screening

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Objective **Atrial fibrillation is the most common arrhythmia of clinical significance and hypertension is one of its major risk factors. This study aimed to evaluate the diagnostic accuracy of an automated oscillometric blood pressure (BP) monitor with the function of atrial fibrillation detection for atrial fibrillation screening.**

Materials and methods **Patients attending outpatient cardiology clinics were recruited for atrial fibrillation screening by the BP monitor with triplicate BP measurements for atrial fibrillation detection. Furthermore, a single-lead ECG was recorded simultaneously for comparison as the reference standard. The diagnostic test's evaluation index were analyzed, including sensitivity, specificity, and receiver operator characteristic (ROC) analysis.**

Results **A total of 295 participants were analyzed including 166 males and 129 females, with an average age of 72.5 ± 5.9 years. The sensitivity and specificity for atrial fibrillation detection by the device were 1.000 and 0.904, respectively, with the area under the ROC curve of 0.952 (95% confidence interval: 0.929–0.975, $P < 0.001$). Furthermore, the device had a Kappa-value of 0.781 ($P < 0.001$) with the single-lead ECG in detecting atrial fibrillation.**

Conclusion **The automated oscillometric BP monitor (G.LAB MD41A0) with atrial fibrillation detection function has high sensitivity and specificity with good accuracy for atrial fibrillation screening, which could be used as a reliable screening tool for the early detection of atrial fibrillation with potential benefits.** ***Blood Press Monit*** **28: 144–148**

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Introduction

Atrial fibrillation is the most common sustained arrhythmia with an estimated global prevalence of 2–4% worldwide in adults and it is associated with substantial disability and mortality [1,2]. With population aging and increased detection, the prevalence of atrial fibrillation has been increasing more than two-fold for the last 10 years, especially among elderly populations which reaches 5% in subjects over 65 years and 14% for 85 years old. Consequently, it causes a rise in atrial fibrillation-related hospitalization and a burden on the healthcare system [2–4].

Atrial fibrillation screening is recommended by several guidelines, and the most common method for atrial fibrillation detection is opportunistic screening by pulse pulsation or ECG rhythm strip in patients above 65 years. Furthermore, a single-lead ECG rhythm strip is also recommended. However, the result should be read by those who are experts in ECG interpretation [5].

Hypertension and atrial fibrillation are common comorbidities, and using an automatic blood pressure (BP) monitor for atrial fibrillation detection would benefit a large number of hypertensive patients with BP measurements at home. At present, home screening for asymptomatic atrial fibrillation by self-assessment is recommended, and different handheld or wearable devices, including modified sphygmomanometers, have been used in different settings for atrial fibrillation screening with differing sensitivity and specificity [6,7]. Therefore, this study was used to evaluate the accuracy of an automated oscillometric BP monitor with the function of atrial fibrillation detection for atrial fibrillation screening.

Materials and methods

Participants and study design

Participants were recruited from cardiology outpatients in two tertiary hospitals in Xi'an of China from March to June 2022. Participants were excluded if they were with pacemakers or defibrillators, under the age of 65 years old, or with an arm circumference outside the cuff range (22–44 cm) of the sphygmomanometer. This study protocol was approved by the Ethics Committee of the Fourth Military Medical University. All participants agreed to take part in this study and gave informed consent prior to this study.

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In this study, participants' general demographic information, and risk factors for stroke due to atrial fibrillation, including hypertension, diabetes mellitus, dyslipidemia, congestive heart failure, and transient ischemic attacks were documented.

An automated oscillometric BP monitor with an atrial fibrillation detection feature, the G.LAB MD41A0 [Grandway Technology (Shenzhen) Limited, China], was used in this study. The device takes three consecutive measurements automatically at 30 s intervals to detect possible atrial fibrillation. If atrial fibrillation is present in at least two of the three automated consecutive measurements, the 'AFib' icon will appear at the end of the measurements, indicating possible atrial fibrillation. As for the algorithm for atrial fibrillation detection, the device measures and stores time for each heartbeat during measurement. It takes six heartbeats before and six heartbeats after the heartbeat with maximum amplitude, which results in a maximum of 13 heartbeats. The time difference between every two consecutive heartbeats was calculated, resulting in 12 time intervals between heartbeats. Every two consecutive time intervals are compared to get the number with the two consecutive intervals different by more than 120 ms. If the number is equal to or above two, then that measurement result is considered as an arrhythmia.

A single-lead ECG, LepuBrain ER2 [LEPU Medical Technology (Beijing) Co., Ltd.], was used as a comparator, which can record at least 30 s to 15 min of rhythm strip for abnormal rhythm detection. During the measurement, three automated sphygmomanometer readings and the simultaneous single-lead ECG 30 s rhythm strip was obtained on each patient by a trained physician. The measurement taken by the G.LAB MD41A0 device was performed according to the universal BP measurement protocol [8]. Furthermore, the results of the single-lead ECG were read by a cardiologist who is an expert in ECG interpretation and was blinded from the device readings. The non-atrial fibrillation ECGs were classified as sinus rhythm if no abnormal rhythm was reported based on the single-lead ECG, otherwise, the ECG was classified based on that abnormal rhythm.

Statistical analysis

The IBM SPSS Statistics 26.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Data were presented as the mean ± SD, or frequencies or percentages as suitable. The *t*-test or Chi-square test was used for comparison between the two groups. Taking the single-lead ECG detection of atrial fibrillation as the reference method, the Kappa coefficient was used for the consistency test, and the sensitivity, specificity, accuracy, and receiver operator characteristic (ROC) curve were analyzed for the atrial fibrillation detection of the tested device. A *P*-value <0.05 was considered statistically significant.

Results

A total of 295 participants were finally included in the analysis of this study. There were 166 males and 129 females, who had an average age of 72.5 ± 5.9 years and a BMI of 25.1 ± 4.2. The average heart rate (HR) of the participants was 76.4 ± 16.2 beats per minute, and the average systolic and diastolic BP were 123.3 ± 17.5 mmHg and 70.4 ± 10.5 mmHg, respectively. The most common comorbidity among the participants was hypertension with a proportion of 65.1% (192/295), followed by dyslipidemia, diabetes mellitus, congestive heart failure, etc. Furthermore, the HR and diastolic BP had significant differences between the atrial fibrillation and non-atrial fibrillation groups ($P < 0.05$) (Table 1).

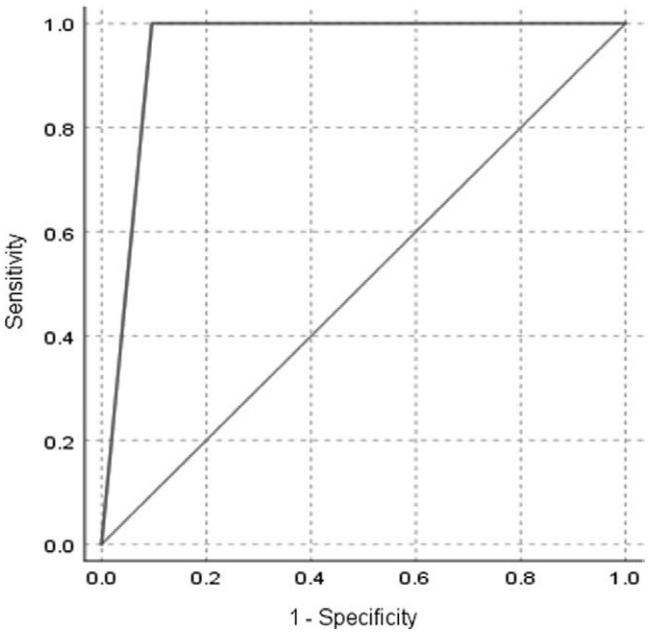
Pulse irregularity was detected in 79 patients with the device, and corresponded to atrial fibrillation in 56 patients according to the simultaneous single-lead ECG. Furthermore, the supraventricular premature beat was found in 15 patients, and frequent premature ventricular beat in 7 patients, respectively. As for atrial fibrillation screening, the Kappa-value was 0.781 ($P < 0.001$) between the device and the single-lead ECG, which showed that the device had good agreement with the single-lead ECGs in detecting atrial fibrillation (Table 2). Furthermore, there was a significant difference in the HR between the

Table 1 Characteristics of the included participants

Items	All ($n = 295$)	ECG results		t/χ^2	*P*-values
		Non-atrial fibrillation ($n = 239$)	Atrial fibrillation ($n = 56$)		
Age (years)	72.5 ± 5.9	72.5 ± 5.5	72.3 ± 7.3	0.192	0.848
Males (*n*, %)	166 (56.3%)	134 (56.1%)	32 (57.1%)	0.021	0.884
BMI	25.1 ± 4.2	24.9 ± 4.2	26.0 ± 3.8	1.812	0.071
Heart rate (beats/min)	76.4 ± 16.2	70.6 ± 9.6	101.1 ± 15.4	14.234	<0.001
SBP (mmHg)	123.3 ± 17.5	123.7 ± 17.3	121.8 ± 18.6	0.707	0.480
DBP (mmHg)	70.4 ± 10.5	69.4 ± 9.4	74.8 ± 13.5	2.861	0.006
Hypertension (*n*, %)	192 (65.1%)	159 (66.5%)	33 (58.9%)	1.153	0.283
Dyslipidemia (*n*, %)	156 (52.9%)	122 (51.0%)	34 (60.7%)	1.702	0.192
Diabetes mellitus (*n*, %)	83 (28.1%)	64 (27.1%)	19 (33.9%)	1.032	0.310
Congestive heart failure (*n*, %)	44 (14.9%)	35 (14.6%)	9 (16.1%)	0.073	0.787
TIA (*n*, %)	43 (14.6%)	32 (13.4%)	11 (19.6%)	1.425	0.233

TIA, transient ischemic attacks.

Fig. 1



The ROC curve of the device over the single-lead ECG for atrial fibrillation screening. Note: The area under the ROC curve was 0.952 [95% confidence interval (CI): 0.929–0.975, $P < 0.001$]; the sensitivity and specificity were 1.000 and 0.904, respectively. ROC, receiver operator characteristic.

Table 2 Comparison of the device to the single-lead ECG for atrial fibrillation detection

	ECG results		
Device results	Non-atrial fibrillation	Atrial fibrillation	Kappa-value
Regular	216	0	0.781
Irregular	23	56	$P < 0.001$

two groups of the 56 atrial fibrillation patients and the 23 false positive readings by the device (101.1 ± 15.4 vs. 74.8 ± 9.8, $t = 7.596$, $P < 0.001$), which indicated that HR might be a potential influence factor for the accuracy for atrial fibrillation detection by the device.

The results of the ROC curve showed that the area under the curve was 0.952 (95% confidence interval: 0.929–0.975, $P < 0.001$), and the sensitivity and specificity for atrial fibrillation detection by the device were 1.000 and 0.904, respectively. Furthermore, for the device readings compared with single-lead ECG as a reference, the positive predictive value was 70.89% and the negative predictive value was 100.00% (Fig. 1).

Discussion

This study evaluated the diagnostic accuracy of an automated oscillometric BP monitor for atrial fibrillation screening among patients in a cardiology clinic. The results of this study showed that the G.LAB MD41A0 is accurate in detecting atrial fibrillation by using single-lead ECG as a reference, and the Kappa-value was 0.781 with $P < 0.001$ between the device reading and the single-lead ECG reading. Furthermore, the device showed a sensitivity of 1.000 and a specificity of 0.904 with perfect diagnostic test results in ROC analysis. Therefore, the device has good diagnostic accuracy to detect atrial fibrillation during the regular clinical practice of BP measurements, which could be used as a potentially useful tool to improve atrial fibrillation screening without any extra effort.

The early detection of atrial fibrillation would allow patients to be treated with medication earlier, which could get effective in preventing strokes, especially for those with high risk factors or undetected atrial fibrillation [6,7]. Hypertension and atrial fibrillation are common comorbidities, especially in the elderly. In this study, as participants were above 65 years, 65.1% of participants had hypertension who might be at risk for atrial fibrillation. Self/home BP measurement by automated devices is recommended by guidelines for BP monitoring and hypertension management, which is popular for its convenience and practicality [8]. Opportunistic screening for atrial fibrillation in patients aged 65 years or above by various tools is affordable and recommended, and may be applicable for atrial fibrillation screening. The impact of premature contractions on pulse irregularity is thought to be limited in analyses by the pulse wave. On the other hand, studies had shown that the risk of cerebrovascular events was related to a high frequency of atrial premature contractions, especially in the middle-aged and older population [9]. A high frequency of pulse irregularity in hypertensive patients should undergo screening by ECG monitoring, for it may suggest a risk of cerebrovascular events. Hence, it is of clinical significance to use an automated oscillometric self/home BP monitor with the function of atrial fibrillation detection, especially in hypertensive patients, which increases the probability to detect rhythm abnormalities. Although an ECG is mandatory for the diagnosis of atrial fibrillation, the use of home BP monitors with the function of atrial fibrillation detection during routine BP measurements could prove a clinical benefit for the early detection, diagnosis, and treatment of atrial fibrillation and related consequences. Furthermore, it is more cost-effective to use this kind of device for screening and then obtaining an ECG on the small percentage with abnormal readings [6,10].

The G.LAB MD41A0 used in this study had been validated for BP measurement accuracy [11,12], which has an algorithm for detecting atrial fibrillation using the three sequential measurements. This study showed it has good accuracy with high sensitivity and specificity in detecting atrial fibrillation among outpatients of cardiology clinics. A systematic review showed that the sensitivity and specificity of atrial fibrillation detection by BP monitors with three readings for assessment were 92–97% and 89–97%, respectively [10]. In our study, the accuracy of atrial

fibrillation diagnosis was 100% for sensitivity and 90.4% for specificity, which showed superior atrial fibrillation detection sensitivity with comparable specificity. Thus, all atrial fibrillation patients were identified, and it showed that the device represents a useful tool for the identification of atrial fibrillation with sufficiently low to give rise to false negative atrial fibrillation diagnoses. As preview, studies assessed the accuracy of several modified BP monitors for detecting atrial fibrillation and showed that sensitivity and specificity values differed slightly among the studies, and were mainly dependent upon the number of atrial fibrillation-positive readings used for classifying a patient as atrial fibrillation-positive [10]. To address what would be the best algorithm for atrial fibrillation screening, it indicated that three measurements should be preferred for a higher sensitivity would be more useful than a higher specificity to increase the chance of diagnosing atrial fibrillation-positive patients on occasion. Although for home BP devices with multiple self-measurements, a relatively low specificity for atrial fibrillation detection would lead to relatively high false positive results, mainly among those who have no symptoms. In this study, there were 23 patients with false atrial fibrillation alarm, and, in most cases, this was due to frequent supraventricular or ventricular extrasystoles. This study participants were recruited from the cardiology outpatient clinic; these participants can be expected to have a higher prevalence of underlying heart disease than the general population and are more likely to have abnormal heart rhythms. In addition, long-term studies following patients using this device at home need to be conducted to determine the number of new episodes of atrial fibrillation detected and the cost of the false positive readings.

Although the device showed good accuracy with high sensitivity and specificity for atrial fibrillation screening, there were still misjudged readings for atrial fibrillation in patients without atrial fibrillation. The algorithm of the device for atrial fibrillation detection depends on the difference among time intervals for each heartbeat during measurement, and the results might be influenced by HR, which needs to be further studied. In this study, most false positive cases were with a supraventricular premature beat or ventricular premature beat, which showed the algorithm of the device might misjudge supraventricular or ventricular premature beat for atrial fibrillation in some cases, and consecutive positive readings of each measurement would be important to identify the true atrial fibrillation. Furthermore, the patients with false positives reading indicated that atrial fibrillation diagnosis needs to be confirmed by a physician, which may be inconvenient and add some cost, however, it does not result in any harm to the patient. The apparently very high sensitivity level is important to examine because this tool is expected to be used for screening, and atrial fibrillation has a relatively low prevalence in the population. Furthermore, it could benefit from obtaining an early medical consultation and ECG for possible clinically relevant non-atrial fibrillation rhythm abnormalities.

This study also had several limitations. First, the participants were recruited from cardiology clinics with ages above 65 years who were more likely to have abnormal heart rhythms and had relatively higher atrial fibrillation prevalence, and were different from the community population, which would also influence the ability to detect atrial fibrillation. As the device is used for monitoring the BP and potential users are hypertensive patients or populations at high risk, they might also have higher atrial fibrillation than the normal population. Second, the measurement was performed in the clinic office which was different from the self/home measurement condition and it might potentially influence the results. The device is a fully automated BP monitor and the atrial fibrillation detection function with three sequential measurements is carried out automatically without manual intervention, which makes it easy to operate at home for self-measurement and atrial fibrillation screening. Third, this study used single-lead ECG as a reference tool for atrial fibrillation detection instead of a 12-lead ECG or other tools, which might slightly lower the diagnostic accuracy as the reference method. This study used the single-lead ECG as a control for its tiny volume and ease to use with convenience. Furthermore, a single-lead ECG rhythm strip is also recommended as an opportunistic screening tool in patients above 65 years by several guidelines [5]. In addition, in this study, the results of the single-lead ECG rhythm strip were read by a cardiologist who is an expert in ECG interpretation which ensured the diagnostic accuracy and the reliability of the results. Finally, real world and long-term studies using the device are warranted to determine the number of new episodes of atrial fibrillation detected and the effect of early therapy on cardiovascular outcomes. Furthermore, the use of different tools for atrial fibrillation screening should be individualized for diversity in disease epidemiology, socioeconomic status, access to technology, and healthcare setting.

Conclusion

The automated oscillometric self/home BP monitor with the function of detecting atrial fibrillation is investigated in this study; the G.LAB MD41A0 has good accuracy with high sensitivity and specificity for atrial fibrillation screening. The use of this kind of device in hypertensive patients or for self/home measurements would be taken as a reliable opportunistic screening tool for the early detection of atrial fibrillation with potential benefits.

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The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

Conflicts of interest

There are no conflicts of interest.

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