

Screening for Atrial Fibrillation Using a Single Lead ECG Monitoring Device

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Atrial fibrillation (AF) is the most common arrhythmia which needs management for stroke prevention. Therefore, it has emphasized the importance of screening for general population to detect AF earlier. We conducted screening for AF in the Chonbuk region in South Korea. Participants who were older than 50 years were enrolled. The screening test used a single lead electrocardiography (ECG) (KardiaBand, AliveCor, CA, USA). Diagnosis of AF was confirmed by electrophysiologists, if the single lead ECG demonstrated AF of more than 30 seconds. We analyzed the prevalence of AF and the characteristics of newly detected AF patients. A total of 2728 participants, 145 (5.3%) participants had already been diagnosed with AF before. The number of screening positive was 55. Among them, 40 participants were confirmed for AF. Male gender and age older than 70 years were the independent risk factors for AF among the screening positive participants. Most of newly detected AF patients were at high risk for stroke which had more than 2 points on the CHA2DS2-VASc score. We followed up with those patients and encouraged them to visit the hospital. As a result, 31 (77.5%) patients started to manage AF. The additional 1.2% of AF was detected by a screening test with a single lead ECG monitor device. Considering most participants of newly detected AF by screening were at high risk for stroke, it was thought that AF was still undertreated. Therefore, screening tests with simple mobile device might be useful for early detection of AF.

Key Words: *Mass Screening; Electrocardiography; Atrial Fibrillation*

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INTRODUCTION

Atrial fibrillation (AF) is the most common arrhythmia which needs management for stroke prevention and other morbidities such as heart failure, cognitive disorders, or impaired quality of life.¹⁻³ AF is common in old age. As Korean society is aging rapidly, the prevalence of AF is expected to be much more prevalent in the future. Indeed, the prevalence of AF has significantly increased over the past decades in Korea from 0.73% in 2006 to 1.53% in 2015. It was predicted that the prevalence of Korean AF patients would be 5.81% in 2060.² Thus, its medical cost and societal burden are also expected to rise steeply.

AF has a 4-5 fold increased risk of stroke.⁴ Conversely, at least one third of ischemic stroke has been reported that it was associated with AF.⁵ Moreover, stroke related to AF

had a worse prognosis.⁶ Therefore, AF patients who are at high risk for stroke are recommended to take oral anti-coagulants to reduce the stroke risk.¹ A previous study reported effective oral anticoagulation reduced the risk of any type of stroke by 70%.⁷ With consideration of the medical burden from AF complications like stroke, early identification and treatment of AF with subsequent initiation of oral anticoagulation would be beneficial with decreasing social costs. In this context, expanded screening for AF has been encouraged for general population to detect AF earlier.

There have been some studies about screening for AF with smart devices. These make it seem feasible and cost-effective.^{8,9} Here, we conducted systemic screening tests for AF in the Chonbuk regional community in South Korea with a mobile, single-lead electrocardiography (ECG) device (KardiaBand, AliveCor, CA, USA). We also inves-

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tigated the impact of screening tests and recommendation sby medical staff for referring patients to hospital for better care.

MATERIALS AND METHODS

1. Study populations

The study flow chart is shown in Fig. 1. A total of 2728 populations participated in the screening test from April 2019 to December 2020. The screening program was conducted with a local health promotion campaign of local public health care center in Chonbuk regional communities. All of the participants lived in the Chonbuk area and were older than 50 years. Among them, 145 of the participants who had been already diagnosed as having AF before, were excluded.

2. Ethics statement

All participants gave us written informed consent for the study protocol. The study was approved by the Institutional Review Board at Wonkwang University Hospital, Iksan, South Korea (2019043-HRE-011). The study was conducted accordance with the principles of the Declaration of Helsinki.

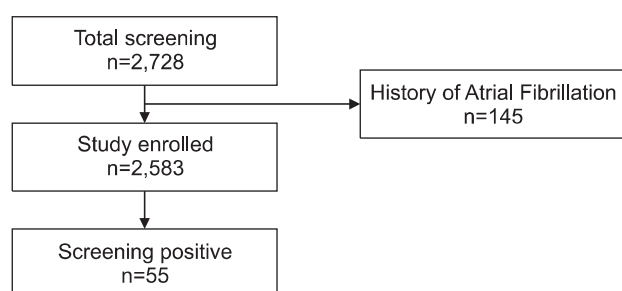


FIG. 1. Flow chart of the study.

3. Screening and confirmation AF

Participants underwent a single lead ECG recording for 30 seconds with the Kardiaband. The device recorded a similar ECG strip with lead I of a standard 12-lead ECG. The method of recording the ECG has described previously.¹⁰ The device interpreted the ECG immediately as ‘normal’, ‘possible AF’ or ‘unclassified’ on the basis of its special algorithm. The screening positive was defined as the interpretation was possible AF or unclassified. The ECG strips that were interpreted as possible AF or unclassified were reviewed and the ECG diagnosis was confirmed by electrophysiologists. The participants who were identified as having newly detected AF were encouraged to visit local hospitals for appropriate management. We followed up with them by telephone after 1 month and 6 months to check whether they had visited the hospital or not.

4. Kardiaband validation

Kardiaband and its ECG strip were introduced previously.¹¹ To further validate the accuracy of the Kardiaband, the ECG strips with screening results of negative were also assessed for the electrophysiologists’ interpretation. The electrophysiologists reanalyzed those collected ECG and confirmed whether the ECGs were interpreted accurately. Based on this data, sensitivity and positive predictive value were calculated.

5. Statistical analysis

Continuous variables were summarized as mean value±standard deviation. To compare the continuous variables, the Student’s t-test was used as appropriate. Categorical variables were presented as frequencies and percentages. They were compared using the Chi-square test or Fisher’s exact test between groups as appropriate. A logistic regression analysis was used to assess the predictors of AF in the screening of positive participants. In all stat-

TABLE 1. Baseline characteristics of participants

	Total (n=2583)	Normal (n=2528)	Screen (+) (n=55)	p value
Sex				0.165
Male (%)	1171 (45.3)	1141 (45.1)	30 (54.5)	
Female	1412 (54.7)	1387 (54.9)	25 (45.5)	
Age	66.77±9.86	60.21±15.1	74.04±11.3	<0.01
Age group				<0.01
50-60	804 (31.1)	797 (31.5)	7 (12.7)	
61-70	817 (31.6)	807 (31.9)	10 (18.2)	
>70	962 (37.2)	924 (36.6)	38 (69.1)	
Sx (palpitation)	440 (17.0)	431 (98.0)	9 (16.4)	0.893
Previous hospital visit*	180 (7.0)	174 (6.9)	6 (3.3)	0.246
Recognizing AF				<0.01
No	1919 (74.3)	1886 (74.7)	33 (60.0)	
Yes, a little	542 (21.0)	534 (21.1)	8 (14.5)	
Yes	99 (3.8)	99 (3.9)	0 (0.0)	
Recognizing AF as stroke risk factor				0.432
Yes	190 (7.4)	188 (7.4)	2 (3.6)	

*The participants who had visited hospital because symptom like palpitation had occurred. Sx: Symptom, AF: Atrial fibrillation.

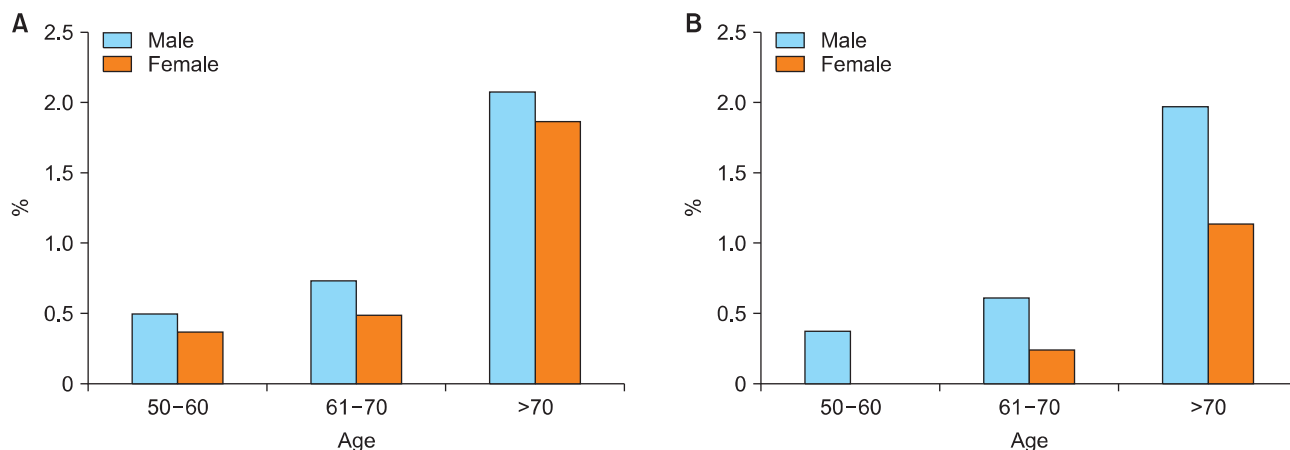


FIG. 2. (A) Rates of screening positive in each age group. (B) Rates of real atrial fibrillation in each age group which was confirmed by electrophysiologists.

istical tests, a two-sided p value<0.05 was considered statistically significant. All statistical tests were performed by IBM SPSS version 24.0 (IBM Corp., Armonk, NY, USA).

RESULTS

1. Baseline characteristics

Among the total number of 2728 participants, 145 (5.3%) participants had previously diagnosed=AF. Therefore, only the remaining 2583 participants were analyzed. Baseline characteristics are shown in Table 1. The study populations were divided by two groups - the Normal group consisting of those participants with negative screening test results and the other group made up of participants with positive screenings. The number of positive screenings was 55 (2.1%). Although female gender was predominant in the total participants, male gender was the predominant group in the screening positive group. However, it was not statistically significant. The old age participants were also more common in the screening positive group. Especially, the proportion of the participants older than 70 years old was even higher. There was no significant different in symptoms, experience of visiting hospital because of symptom, or recognizing AF as a risk factor of stroke.

2. Screening positive rates and Real AF diagnosis rates

Screening positive rates according to the age groups are shown in Fig. 2A. The prevalence rates in each age group were 0.87% (Male 0.50%) in 50-60 years and 1.22% (Male 0.73%) in 61-70 years, respectively. The screening positive rates significantly increased in more than 70 years - 3.95% (Male 2.08%). The number of true AF diagnosis was 40 (1.5%). Its prevalence rates in each age group was 0.37% (Male 0.37%) in 50-60 years, 0.86% (Male 0.61%) in 61-70 years and 3.12% (Male 1.98%) in more than 70 years (Fig. 2B).

The sensitivity of Kardiaband was 95.2% and the positive predictive value was 72.7%, respectively.

TABLE 2. Characteristics of newly detected atrial fibrillation participants

Male sex, (%)	27 (67.5)
Age	76.05±9.1
50-60	3 (7.5)
61-70	7 (17.5)
>70	30 (75.0)
Palpitation	8 (20.0)
Recognizing AF	
No	10 (25.0)
Yes, a little	24 (60.0)
Yes	6 (15.0)
Recognizing AF as stroke risk	0 (0.0)
Previous Heart disease History	3 (7.5)
Previous Cerebrovascular accidents	4 (10.0)
Hypertension	22 (55.0)
Diabetes mellitus	8 (20.0)
Dyslipidemia	10 (25.0)
Smoking	1 (2.5)
Alcohol	9 (22.5)
Medication History	
Unknown medication	2 (4.8)
Aspirin	1 (2.4)
Apixaban	1 (2.4)
Visit hospital in 6 months after screening (+)	31 (77.5)
Symptom	
Dizziness	7 (17.5)
Palpitation	6 (15.0)
Chest discomfort	8 (20.0)
Dyspnea	7 (17.5)
General edema	2 (5.0)
No symptom	21 (52.5)
Systolic Blood Pressure	131.21±14.8
Diastolic Blood Pressure	77.26±12.4
Height	164.79±8.9
Weight	59.77±22.6
Body Mass Index	15.52±2.5
CHA2DS2-VASc score	2.77±1.3

AF: Atrial fibrillation.

3. Characteristics of Newly detected AF patients

Table 2 revealed the characteristics of newly detected AF participants. They were predominantly male (N=27, 67.5%) and usually elderly participants. They did not recognize AF as a stroke risk factor at all. Over the half of them had hypertension and had no symptoms. Their mean CHA2DS2-VASc score was 2.77 ± 1.3 which was a high risk for stroke. We followed-up them in 1 month and 6 month followups and encouraged them to visit hospital and get better health management. Consequently, 31 (77.5%) participants visited hospital and managed their AF.

4. Risk factors for AF in screening positive

We investigated the risk factors for diagnosis as AF if the participants were screening positive (Table 3). In univariate analysis, the male gender was a possible risk factor for AF. In the multivariate analysis, male gender and age more than 70 years were independent risk factors for confirming AF in the screening positive participants.

DISCUSSION

The present study was conducted for AF screening in local area of South Korea. It additionally found 40 (1.5%) new AF patients of 2728 total screenings. Before screening, the participants had a 5.3% prevalence of AF. The prevalence was somewhat higher compared to whole Korean society although the populations were different. That was because the Chonbuk region is a rural area and it was assumed that the populations skewed older. Newly detected AF prevailed in the old age group more than 70 years old and the male gender group. The new AF detection rate was similar with previous research. In meta-analysis of other screening programs, new AF was found 1.4% in >65 years age group by a single lead ECG.¹² We also surveyed the extent

of recognition of AF in the screening populations. Furthermore, the participants who were detected AF were encouraged to visit hospitals by telephone follow-up. A substantial proportion of them (77.5%) visited hospitals.

Nowadays, detection of arrhythmia with smart devices or wearable ECG monitoring devices is feasible and its detection accuracy has been shown to be reliable in previous data.^{9,13} Not only for AF, but, recent data also demonstrated that smart devices could identify supraventricular tachycardia like PSVT.¹⁴ With the early detection of AF becoming more important, it is meaningful to conduct screening tests for AF using these simple smart or wearable devices. Especially, like present study, Rajakariar et al.¹⁰ verified the accuracy of Kardiaband and the authors demonstrated the moderate diagnostic accuracy of Kardiaband ECG. Its sensitivity was 94.4% and had a positive predictive value of 72.3%. Therefore, Kardiaband, as screening tool, was found to be effective. In the present study, sensitivity was 95.2% and the positive predictive value was 72.7%. The value was similar with previous studies. However, our study sample size was small so that the sensitivity and predictive value could be lower in the real world as the sample size would become larger. However, taking its simplicity and cost into consideration, the Kardiaband was thought to be an appropriate tool for screening AF.

Whether the participants' screening test results were positive or not, participants' recognition for AF was very low (Table 1). Only 7.4 % knew that the AF was a risk factor for stroke. Interestingly, screening positive participants did not know more about the AF than screening negative participants. Therefore, a large scale public campaign about AF should be carried out.

For the success of AF screening campaign, well-established referrals to the medical system would be necessary to start oral anticoagulants. One of previous studies that

TABLE 3. Risk factors for atrial fibrillation in screening positive participants

	Univariate analysis			Multivariate analysis		
	OR	Confidence interval	p value	OR	Confidence interval	p value
Sex	8.31	1.99-34.64	0.004	24.62	2.69-225.71	0.005
Age group						
50-60			0.172			
61-70	3.11	0.41-23.39	0.270	8.53	0.43-171.02	0.055
>70	5.00	0.93-27.04	0.062	5.00	1.74-453.51	0.019
Palpitation	3.50	0.39-30.71	0.258			
Hx of visiting hospital	2.00	0.21-18.69	0.543			
Heart disease history	1.14	0.11-11.85	0.916			
Previous CVA	0.72	0.12-4.42	0.725			
Diabetes mellitus	NA	0.23-4.41	1.000			
Hypertension	0.61	0.18-2.11	0.437			
Dyslipidemia	0.68	0.18-2.42	0.538			
Smoking	NA		1.000			
Alcohol	NA		1.000			
CHA2DS2-VASc score	0.96	0.63-1.45	0.848			

OR: odds ratio, CVA: Cerebrovascular accident.

conducted massive AF screening and their study populations who were newly diagnosed AF accepted to start oral anticoagulant.¹⁵ The authors referred the new AF patients directly to cardiologists. Therefore, they could follow-up whether the study participants started anticoagulants or not. We also checked the participants' visits to hospital. Unfortunately, we could not access each patient's medical information, therefore, we did not know the status of beginning of anticoagulation.

The study population who were newly diagnosed as having AF had more than 2 points on the CHA₂DS₂-VASc score on the average. It meant that stroke risk would be high. Considering the large portion of old age more than 70 years and over the half of newly detected AF patients had hypertension, a high risk for stroke was inevitable and they should take oral anticoagulants to prevent stroke. From this point of view, the present study pointed out that a large portion of undetected AF might have been under-treated. In addition, as the societal burden of stroke increases, it would be better to find undetected-AF and to take oral anticoagulants earlier to reduce the risk of stroke. In this context, AF screening test for early detection of AF would be worthwhile.

This study had several limitations. First, the sample size was relatively small compared to previous studies because it was conducted in single center and local area. It requires larger scale research to generalize the results. Second, we could not review all the screening negative ECGs because this study was conducted as a part of health promotion campaign of local health care center and many of the screening negative patients left without detailed information. Therefore, the validation of this ECG device might be limited. Third, we did not check all the 12 lead ECGs in the screening positive participants. Current guidelines commented that single-lead ECG strips of more than 30 seconds can be diagnostic for AF. However, a comparison with 12-lead ECG would complement the diagnostic accuracy. Lastly, even though we followed up by phone call, we do not know whether the newly detected AF patients got appropriate management including oral anticoagulants.

The present study highlighted some important points. It was not only investigator-led, but also conducted with the cooperation of local public health care centers. As a result, we found the additional 40 AF patients and 77.5% of them went to hospital by the medical staff's recommendation. Further, we analyzed the risk factors for confirming AF in the screening positive participants. Older than 70 years and male gender were found to be risk factors. Therefore, the present study offers a guide for physicians in the screening tests which patients should be evaluated further in detail. Especially, in the Chonbuk area, which is one of the regions in South Korea where a large portion of the elderly population lives. Considering how common AF is in old age, it was expected that screening positive rates for AF would be high in this area. In that point, AF screening in Chonbuk area might be meaningful to reduce the social and medical cost by early detection of AF. Indeed,

the prevalence of AF including previously detected AF in those older than 50 years was 5.3% in the present study. It was the similar value that expected in the future of 2060 in Korea. Therefore, the screening test with a simple device would be useful in this area of aging society as found in the present study.¹⁶ Of course, the screening AF could easily be justified in whole Korea, where an aging is rapidly progressing.

In conclusion, we conducted this AF screening in the Chonbuk area. It demonstrated that AF's prevalence was 5.3% which was increased by 1.5% by the screening. Old age and male gender were independent risk factors for AF diagnosis in screening positive populations. Screening positive populations were encouraged to visit hospital and 77.5% of them reported visiting the hospital for AF management. Most of general population has no concept of AF and its potential risk of stroke. Considering most newly detected AF cases by this screening were at high risk for stroke by means of more than 2 points on the CHA₂DS₂-VAS score, AF is still undertreated. Therefore, simple screening devices might be useful for early detection of AF with health care promotion campaign.

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CONFLICT OF INTEREST STATEMENT

None declared.

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