Systematic Screening for Atrial Fibrillation in Patients at Moderate-to-High Risk of Stroke

— Potential to Increase the Atrial Fibrillation Detection Rate (SCAN-AF) —

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Background: To determine the rate of undiagnosed atrial fibrillation (AF) we screened for AF using an oscillometric blood pressure (BP) monitor device followed by a single-lead handheld electrocardiogram (ECG), with confirmation by 12-lead ECG as the reference standard.

Methods and Results: From October 2017 to August 2019, 1,148 patients were enrolled without known AF, who were aged ≥ 65 years with moderate-to-high stroke risk, at 71 centers in Japan. After exclusion of 7 patients with confirmed AF at the index visit, 1,141 patients were asked to use an oscillometric BP monitor twice daily for 2 weeks (max: 4 weeks) to detect an irregular pulse. The BP monitor detected an irregular pulse in 481 patients, of which 1 patient had confirmed AF. Thereafter, 480 patients were instructed to acquire ECGs twice daily for an additional 2 weeks (max: 4 weeks) using a single-lead handheld ECG device. The handheld ECG device detected irregular rhythm in 41 patients, of which 1 patient had confirmed AF. In total, undiagnosed AF was confirmed in 9 (0.8%) patients of the overall study cohort during the 24-week follow-up period.

Conclusions: Sequential use of a BP monitor and handheld ECG for 4 weeks is a practical strategy for identifying undiagnosed AF in Japanese people at heightened risk of stroke.

Key Words: Arrhythmia; Atrial fibrillation; Diagnosis; Electrocardiography; Screening

Atrial fibrillation (AF) is a treatable risk factor for stroke, and its prevalence is increasing.^{1,2} In 2005, the number of patients with AF in Japan was 716,000; it is predicted to increase to 1.03 million, or 1.1% of the national population, by 2050.³ Because approximately one-half of patients with AF are asymptomatic or have non-specific symptoms,⁴ many are undiagnosed and may not receive an oral anticoagulant to reduce the risk of strokes. Therefore, screening for undiagnosed AF is becoming increasingly important.⁵⁻⁹ In addition to traditional methods, technologic advances have enabled a variety of approaches to facilitate AF screening.^{6,9} Newer, non-invasive devices include the oscillometric blood pressure (BP) monitor, which can detect an irregular pulse, the

photoplethysmography-based pulse monitor, long-term electrocardiogram (ECG) patches, and single-lead handheld ECG.^{6,9} Of these, handheld ECG devices are appealing for AF screening because they are easy to handle, portable, use diagnostic algorithms to perform automated analyses of heart rhythms, and record and store ECG traces that cardiologists can later analyze. Nevertheless, single-lead handheld ECG devices still require 12-lead ECG recordings for confirmation of AF diagnosis.⁹ Care must be taken when screening for asymptomatic AF because there is a possibility for misinterpretation of ECGs by general practitioners, subsequent unnecessary treatment, increased healthcare resource use, and impaired quality of life for patients beyond symptom burden or

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Table 1. Baseline Patient Characteristics

Characteristic	All patients (n=1,148)
Age, years	74.0 (69.0, 79.0)
Age ≥75 years	568 (49.5)
Sex	
Female	568 (49.5)
Male	580 (50.5)
Weight, kg	59.7 (52.1, 68.0)
BMI, kg/m ²	24.0 (21.9, 26.4)
Heart rate, beat/min	71.0 (65.0, 78.0)
SBP, mmHg	137.0 (127.0, 150.0)
DBP, mmHg	80.0 (72.0, 88.0)
CHADS ₂ score	2.0 (1.0, 2.0)
CHA ₂ DS ₂ -VASc score	4.0 (3.0, 4.0)
CHA ₂ DS ₂ -VASc score distribution	
2	178 (15.5)
3	377 (32.8)
4	349 (30.4)
5	165 (14.3)
6	68 (5.9)
7	10 (0.9)
8	1 (<0.1)
Medical history	
Hypertension	1,062 (92.5)
Congestive heart failure	51 (4.4)
Diabetes mellitus	334 (29.1)
Stroke or transient ischemic attack	25 (2.2)
Vascular disease	213 (18.6)
Chronic kidney disease	119 (10.4)
Chronic obstructive pulmonary disease	26 (2.3)
Hepatic disease	91 (7.9)
Sleep apnea syndrome	22 (1.9)
Smoker	
Current	101 (8.9)
Former	375 (32.8)
Alcohol history	
Current	517 (45.0)
Former	110 (9.6)
Patient symptom questionnaire	
History of palpitations	128 (11.1)
History of faintness or syncope	33 (2.9)
Anticoagulants	25 (2.2)

Data are presented as number (%) or median (Q1, Q3) unless otherwise stated. BMI, body mass index; CHADS₂, congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke or transient ischemic attack; CHA₂DS₂-VASc, congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65–74 years, sex category; DBP, diastolic blood pressure; SBP, systolic blood pressure.

disease severity.⁹

To date, no trials have assessed whether treatment of screen-detected asymptomatic AF in older adults results in better health outcomes than treatment after detection via usual care or after symptoms develop.¹⁰

The purpose of the SCAN-AF study was to evaluate the detection rate of AF in patients without known AF, who were aged ≥65 years and at moderate-to-high risk of

stroke. We applied a sequential use of oscillometric BP monitoring followed by a single-lead handheld ECG monitoring device, with confirmation by 12-lead ECG as the reference standard.

Methods

Participants

The SCAN-AF study was a multicenter, prospective, single-arm study conducted in 71 hospital-affiliated specialty outpatient sites in Japan between October 2017 and August 2019. Patients were included if they did not have known AF, were aged ≥65 years and were at moderate-to-high risk of stroke: CHA₂DS₂-VASc (congestive heart failure, hypertension, age ≥75 years, diabetes, stroke, vascular disease, age 65–74 years, sex category) score ≥2 or CHADS₂ (congestive heart failure, hypertension, age ≥75 years, diabetes, stroke) score >1. The exclusion criteria included previously documented AF, use of antiarrhythmic drugs, or inability to use the monitoring devices properly and/or comply with the required procedures.

Study Procedures

Patients who met the inclusion criteria had a 12-lead ECG at the index visit. Baseline symptoms were recorded by the study investigator. Patients without AF at the index visit were instructed to monitor their BP and pulse with the home oscillometric BP monitor (HEM-9200T; OMRON Healthcare, Kyoto, Japan) twice daily for 2 weeks (up to 4 weeks). The patients in whom an irregular pulse was detected underwent 12-lead ECGs at Visit 2. If the 12-lead ECG did not confirm AF, patients were asked to use a single-lead handheld ECG device (myBeat; UNION TOOL CO. Tokyo, Japan or HCG-801; OMRON Healthcare, Kyoto, Japan) to acquire an ECG ≥30s twice daily for an additional 2 weeks (up to 4 weeks). All patients had a 12-lead ECG at Visit 3, irrespective of the irregular rhythm detected by handheld ECG. From Visit 3 until the week 24 follow-up visit, investigators were allowed to use any device to detect AF if considered appropriate. All participants were followed for up to 24 weeks to assess adverse events. Two independent electrophysiologists adjudicated ECG tracings downloaded from 12-lead ECGs and handheld ECGs. If there was no consensus, the rhythm diagnosis was decided by discussion.

Two different definitions of a positive screen for AF were used in this study. “Confirmed AF” was defined as AF diagnosed by 12-lead ECG, and “probable AF” was defined as AF detected by handheld ECGs. At each scheduled visit, study personnel assessed the new diagnosis of AF, ischemic or hemorrhagic stroke, transient ischemic attack, systemic embolism, major bleeding, vital status, and hospitalization from any cause.

Endpoints

The primary endpoint was the detection rate of all (prevalent and paroxysmal) AF confirmed by 12-lead ECG during the 24-week study period.

Ethics

This study was conducted in accordance with the International Society for Pharmacoepidemiology Guidelines for Good Pharmacoepidemiology Practices and applicable regulatory requirements, and in accordance with the ethical principles of the Declaration of Helsinki. All patients

Table 2. Detection Rate of Prevalence of All Irregular Pulse and Previously Undiagnosed AF

	Number of patients	Detection rate, % (95% CI)
Total number of patients	1,148	
Irregular pulse detected by home BP monitoring	481	41.9 (39.0–44.7)
Probable AF	41	3.57 (2.50–4.64)
Confirmed AF	9	0.78 (0.27–1.29)

The 95% CIs are based on the Wald asymptotic confidence limits. Confirmed AF indicates AF confirmed by 12-lead ECG, and probable AF indicates AF detected by handheld single-lead ECG. AF, atrial fibrillation; BP, blood pressure; CI, confidence interval; ECG, electrocardiogram.

provided written informed consent. The study was registered with the University Hospital Medical Information Network Clinical Trial Registry, number UMIN000029473. The protocol, amendments, and patient-informed consent received appropriate approval by the IRB/Independent Ethics Committee or other applicable review board as required by local law prior to initiation of study at the site. The list of site principal investigators is available in the **Supplementary Appendix**.

Statistical Analysis

A sample of 1,200 patients allowed for the calculation of a 95% confidence interval (CI) of 2–4% for the primary endpoint, assuming a 3% rate of detection of undiagnosed AF. Frequency distribution and summary statistics (median [Q1, Q3]) are presented for baseline demographics and clinical characteristics. For the primary endpoint, descriptive statistics are provided, including the detection rate and its 95% CI based on the Wald asymptotic confidence limits. Sensitivity and specificity for AF diagnosis were calculated as simple proportions with corresponding Clopper-Pearson exact CI for the handheld ECG device for AF detection. All analyses were performed using an intention-to-screen principle of all patients, regardless of device use, adherence, or duration of participation. Statistical analyses were performed with R project software (R

foundation, Vienna, Austria).

Results

A total of 1,148 patients were included in the study. The median age at baseline was 74.0 years and 50.5% were male (**Table 1**). The median CHADS₂ score was 2.0 and the median CHA₂DS₂-VASc score was 4.0. **Figure 1** shows the study flow and results. At the index visit, 7 patients were confirmed to have AF by 12-lead ECG. The oscillometric BP monitoring device detected an irregular pulse in 481/1,141 patients (42.2%), of which only 1 had confirmed AF. Of the 480 patients who used the handheld ECGs (myBeat: n=184; HCG-801: n=299 [3 patients used both devices]), 41 patients had probable AF and AF was confirmed by 12-lead ECG in 1 patient. In total, 9 (0.8%) patients had confirmed AF and 41 patients had probable AF detected by handheld ECG (**Table 2**). The time course of probable AF detection is shown in **Figure 2**. Of the 41 patients, 28 (68.3%) were detected within the first week of monitoring and 39 (95.1%) were detected within 2 weeks. Although the protocol specified that the handheld ECG should be used for 2 weeks, due to a protocol deviation, some patients used it for up to 25 days; 1 patient had probable AF after completion of 2 weeks of follow-up. The number of patients with an irregular pulse detected by the

Figure 2. Time course of irregular rhythm detection by single-lead handheld ECG monitoring. Forty-one patients had irregular rhythm detected by single-lead handheld ECG monitoring. The bars show when irregular rhythm was first detected in days. The red line shows the cumulative incidence of first irregular rhythm. AF, atrial fibrillation; ECG, electrocardiogram.

Figure 3. Number of irregular pulse and irregular rhythm detections. (A) Number of irregular pulses detected by the home BP monitor, and (B) number of irregular rhythms detected by the single-lead handheld ECG. BP, blood pressure; ECG, electrocardiogram.

BP monitor and probable AF detected by the handheld ECG are shown in **Figure 3**. The number of times AF was detected can be taken as a rough estimate of AF burden, with more detections reflecting a higher AF burden. Irregular pulses were recorded more than 5 times in 109 (22.7%) patients, and 177 (36.8%) patients had probable AF more than 5 times. Two patients with confirmed AF had both ≥ 5 irregular pulse recordings and ≥ 5 probable AF episodes. The data logs of the handheld ECGs showed that only 5/184 (2.7%) patients using myBeat and 27/299 (9.0%) patients using HCG-801 completed the scheduled 28 recordings for 2 weeks.

Clinical Outcomes

Follow up was completed for 95.6% of the patients at 24 weeks. Eight patients experienced 8 adverse events, of which 3 were serious (1 cerebral hemorrhage; 2 extended hospital stays for subarachnoid hemorrhage and acute myocardial infarction). During the study period, no patients died.

Discussion

SCAN-AF investigated the prevalence of undiagnosed AF in Japanese patients aged ≥ 65 years with moderate-to-high risk of stroke detected with an oscillometric BP monitoring followed by a handheld single-lead ECG device with confirmation by 12-lead ECG as the reference standard. The handheld ECG device detected irregular rhythms (probable AF) in 41 (3.6%) patients, and AF was confirmed by 12-lead ECG in 9 (0.8%) patients. Although discontinuation rates for both devices were high, sequential use of a home BP monitor and single-lead handheld ECG for 4 weeks was a practical strategy for identifying undiagnosed AF.

Many studies have investigated the feasibility of population-based AF screening using a variety of screening methodologies.^{11–13} The yield of screening for identifying undiagnosed AF has ranged from approximately 0.1% to 5%.¹¹ A retrospective cohort study in Japanese patients showed that the number of new AF cases detected through screening was greater in men than women, and that 80% of new AF cases in patients aged ≥ 65 years had a sufficient stroke risk to receive a recommendation for oral anticoagulant treatment.¹⁴ A recent systematic review of 19 AF screening studies showed that the age- and sex-adjusted detection rates for undiagnosed AF were 1.44% (95% CI=1.13–1.82%) and 0.41% (95% CI=0.31–0.53%) for those aged ≥ 65 years and < 65 years, respectively.¹² The detection rate for new AF increased progressively with age.¹² AF was detected by 12-lead ECG in 9 of the 1,148 screened patients, resulting in a detection rate of 0.78%. Considering both confirmed AF (12-lead ECG) and probable AF (30s of handheld ECG device recording), the number of patients with undiagnosed AF increases to 49/1,148 (4.27%). A single 12-lead ECG might miss infrequent or short-lasting paroxysmal AF.

A unique strength of this study is that we first screened patients with a 12-lead ECG and then used a BP monitor, which is widely used in Japan, to further identify patients with undiagnosed AF. Shirasaki et al reported that 79% of the 11.2 million home electronic BP monitors sold worldwide have been sold in Japan.¹⁵ These devices can detect asymptomatic pulse irregularities consistent with atrial arrhythmias, including AF.¹⁶ An oscillometric BP monitor (OMRON 712C) has previously been shown to have high

sensitivity (100%), specificity (91%), and accuracy (92%) for the detection of AF.¹⁷ In this study, we did not calculate sensitivity or specificity of the BP monitor for detection of AF because only patients with an irregular pulse underwent 12-lead ECG. A systematic review and meta-analysis of 21 studies investigating the detection of irregular pulses caused by AF found that oscillometric BP monitors and non-12-lead ECG devices had the greatest diagnostic accuracy, and pulse palpitation had the lowest diagnostic accuracy.¹⁸

We diagnosed AF separately as either “confirmed AF” diagnosed with a 12-lead ECG or “probable AF” diagnosed with a handheld ECG. “Probable AF” describes single-lead recordings obtained with the handheld ECG that were consistent with AF based on the pattern of irregularity of the rhythm. A 12-lead ECG would be required to confirm AF with certainty.

Recent studies have reported successful identification of undiagnosed AF using smartwatches, but there are some limitations.^{19,20} A meta-analysis of 10 studies found that smartwatches had a high sensitivity and specificity, but the number of false positives in the asymptomatic population was higher than the number of true positive results.²⁰ Real-time access to ECGs, however, may allow patients to play a more active role in AF screening. In the future, not only may improved artificial intelligence algorithms reduce the number of false positives, but they may also lead to a significant increase in automated diagnostics.²¹

This study used handheld ECG devices because they are easy for elderly people to use. In addition, the user-friendly, continuous patch ECG records may be suitable for the elderly population.⁸ Evidence regarding the optimal type of screening (systematic, opportunistic, or usual care) is limited. Two studies, both in patients aged > 65 years, have shown similar rates of AF detection between opportunistic and systematic screening.^{22,23} The European Society of Cardiology (ESC) 2020 guidelines recommend opportunistic screening for AF by taking pulse or using ECG rhythm strips in patients aged ≥ 65 years (Class I), and that systematic ECG screening should be considered to detect AF in individuals aged ≥ 75 years or those at high risk of stroke (Class IIa).⁹ The National Heart Foundation of Australia and New Zealand (2018) strongly recommends opportunistic point-of-care screening in the clinic or community for individuals aged ≥ 65 years by pulse palpation followed by ECG or handheld ECG.²⁴

Whether widespread AF screening is both cost-effective and provides a net clinical benefit in people with undiagnosed AF is not established. A cluster randomized controlled trial found that both systematic screening and opportunistic screening in people aged > 65 years identified more cases of AF than routine practice;²² however, the cost of systematic screening was significantly greater than that of opportunistic screening from the perspective of the health service provider. This is supported by 2 other studies that have also shown systematic screening is associated with higher costs.^{22,25} In addition, the 2018 European Heart Rhythm Association, the Heart Rhythm Society, the Asian Pacific Heart Rhythm Society and the Sociedad Latino Americana de Estimulación Cardíaca y Electrofisiología (EHRA/HRS/APHR/SOLAECE) guidelines state that systematic screening for AF is associated with higher costs than opportunistic screening.²⁵ If opportunistic screening for AF became as commonplace among primary care providers as screening for hypertension, it might increase the

rate of AF detection and subsequent treatment, thereby reducing the rate and costs of stroke in the older at-risk population.

Most previous AF screening studies in asymptomatic individuals have been observational studies that lack a control group, and therefore it is not possible to assess the balance of benefits and harms of AF screening. Several recent randomized trials provide evidence to support AF screening in asymptomatic older people.^{7,8,26} Of these, the SCREEN-AF trial, conducted in individuals aged ≥ 75 years with hypertension but without known AF, showed that the use of a wearable continuous ECG monitor increased AF detection 10-fold compared with standard care (5.3% vs. 0.5%).⁸ Anticoagulation was initiated in 75% of patients who had AF detected in the screening group.⁸ The results of this study suggest the need for future research to determine the effect that screening will have on clinical outcomes like stroke, bleeding and death rates. One screening study for AF, STROKESTOP, has reported clinical outcomes in elderly patients in Sweden (5-year data for STROKESTOP II are expected in 2024).²⁷ The primary outcome was the combined endpoint of ischemic stroke, systemic embolism, death, and major bleeding; patients who were screened had significantly fewer events than those in the overall population.²⁷

Care should be taken when initiating screening programs, as abnormal results may cause anxiety for patients, ECG misinterpretation may lead to overdiagnosis and overtreatment, and ECGs may detect other abnormalities (true or false positives) that may lead to invasive tests and treatments that have the potential for serious harm.¹⁰ Further study is needed to determine which patients would benefit most from AF screening and the best type of screening to be used.

Study Limitations

The screening methods used in this study have some intrinsic limitations, in that they rely on intermittent detection of the pattern of irregular pulses or rhythms recorded for only 30 s by a single-lead ECG, a technique that is consistent with, but not necessarily diagnostic for, AF. To confirm the diagnosis, a 12-lead ECG or a longer continuous recording with a wearable device is required. This study did not have a control arm to assess the rate of detection of undiagnosed AF in clinical practice. The rate of clinical events was low during the 24-week follow-up period, so the potential benefits and harms of screening for AF could not be assessed. The rate of AF detection may have been underestimated due to suboptimal sensitivity, improper use of the mobile devices, obtaining recordings only twice daily, and/or non-compliance. AF could have been under-detected by intermittent handheld ECG recordings if they were not taken overnight or at dawn. In addition, this study was designed to determine the incidence of undiagnosed AF, so we did not obtain the data needed to assess factors associated with development of AF, including sick sinus syndrome.

Conclusions

The sequential use of the home oscillometric BP monitor followed by a handheld single-lead ECG device for monitoring is a practical strategy for the identification of undiagnosed AF in Japanese people with moderate-to-high risk of stroke. Detection of underdiagnosed AF provides physi-

cians with an option to consider anticoagulation therapy to reduce the risk of stroke in patients who would otherwise not have been offered this remarkably effective preventative therapy.

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Disclosures

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IRB Information

The Teikyo University Ethics Committee (Number: Teirin 17-198), Fujita Health University Bantane Hospital (approval number: HM18-233), and Oita University Hospital (approval number: 1318) approved this study.

Data Availability

All relevant data have been included in this manuscript. The Bristol Myers Squibb policy on data sharing may be found at: <https://www.bms.com/researchers-and-partners/independent-research/data-sharing-request-process.html>.

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Supplementary Files

Please find supplementary file(s);
<http://dx.doi.org/10.1253/circj.CJ-21-0813>