Effectiveness of the Chest Strap Electrocardiogram to Detect Atrial Fibrillation

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Atrial fibrillation (AF) is a significant cause of cardioembolic strokes. AF is often symptomless and intermittent, making its detection challenging. The aim of this study was to assess the possibility to use a chest strap (Suunto Movesense) to detect AF both by cardiologists and automated algorithms. A single channel electrocardiogram (ECG) from a chest strap of 220 patients (107 AF and 111 sinus rhythm SR with 2 inconclusive rhythms) were analyzed by 2 cardiologists (Doc1 and Doc2) and 2 different algorithms (COSEn and AFEvidence). A 3-lead Holter served as the gold standard ECG for rhythm analysis. Both cardiologists evaluated the quality of the chest strap ECG to be superior to the quality of the Holter ECG; p <0.05/p <0.001 (Doc1/Doc 2). Accurate automated algorithm-based AF detection was achieved with sensitivity of 95.3%/96.3% and specificity of 95.5/98.2% with 2 AF detection algorithms from chest strap and 93.5%/97.2% and 98.2%/95.5% from Holter, respectively. P waves were detectable in 93.7% (Doc1) and 94.6% (Doc2) of the cases from the chest strap ECG with sinus rhythm and 98.2% (Doc1) and 95.5% (Doc2) from the Holter (p = n.s). In conclusion, the ECGs from both methods enabled AF detection by a cardiologist and by automated algorithms. Both methods studied enabled P-wave detection in sinus rhythm. **(Am J Cardiol 2019;123:1643−1648)**

Cardioembolic stroke accounts for 20% to 30% of ischemic strokes,[1,2] and atrial fibrillation (AF) is one of the most important causes of embolus of cardiac origin.[2] Furthermore, approximately 25% of strokes are classified as cryptogenic, a major portion of these being classified as embolic stroke of undetermined source.[3,4] With proper anticoagulation therapy, up to two-thirds of AF-related strokes can be prevented.[5,6] Finding the cause of stroke in order to start proper treatment remains a big clinical challenge. The gold standard for diagnosis of AF is by 12-lead electrocardiogram (ECG).[7] Current screening methods for AF include pulse palpation,[8] handheld single-lead ECG-devices,[9−11] modified blood pressure monitors,[12,13] and devices based on photoplethysmography.[14−17] Currently available consumer products have been studied in the feasibility and diagnosis accuracy of AF,[18] but there is still a need for ECG strip for the confirmation of AF diagnosis.[7] In contrast, chest strap heart rate (HR) monitors have been used for sports HR monitoring for decades, and the technique is widely available. It is unknown whether ECG acquired using a chest strap could serve as a tool for arrhythmia detection. The aim of the study was to assess the potential of an ECG aquired using a chest strap to detect AF, both by cardiologists and automated algorithms.

Methods

The study design was a prospective case-control multicenter study at 3 sites in Finland. The study data were collected in emergency departments and cardiologic wards of the participating hospitals: Kuopio University Hospital, Helsinki University Central Hospital and North Karelia Central Hospital, Joensuu. The study design was approved by the Ethical Committee of Kuopio University Hospital (Decision number 237/2017) and registered in ClinicalTrials database (NCT03721601,URL: https://clinicaltrials.gov/ct2/show/NCT03721601).

Screening of study participants was performed in the participating hospitals from admitted patients in May to September 2017. The inclusion criterion for the study was AF confirmed by a doctor-interpreted 12-lead ECG, taken for medical reasons. Exclusion criteria were body mass index (BMI) over 33 kg/m^2; implanted pacemaker device; left bundle branch block or right bundle branch block; a medical condition requiring immediate treatment that would be delayed by the study measurements, and serious infectious disease. The control group consisted of patients with normal sinus rhythm in 12-lead ECG. Study participants gave a written informed consent.

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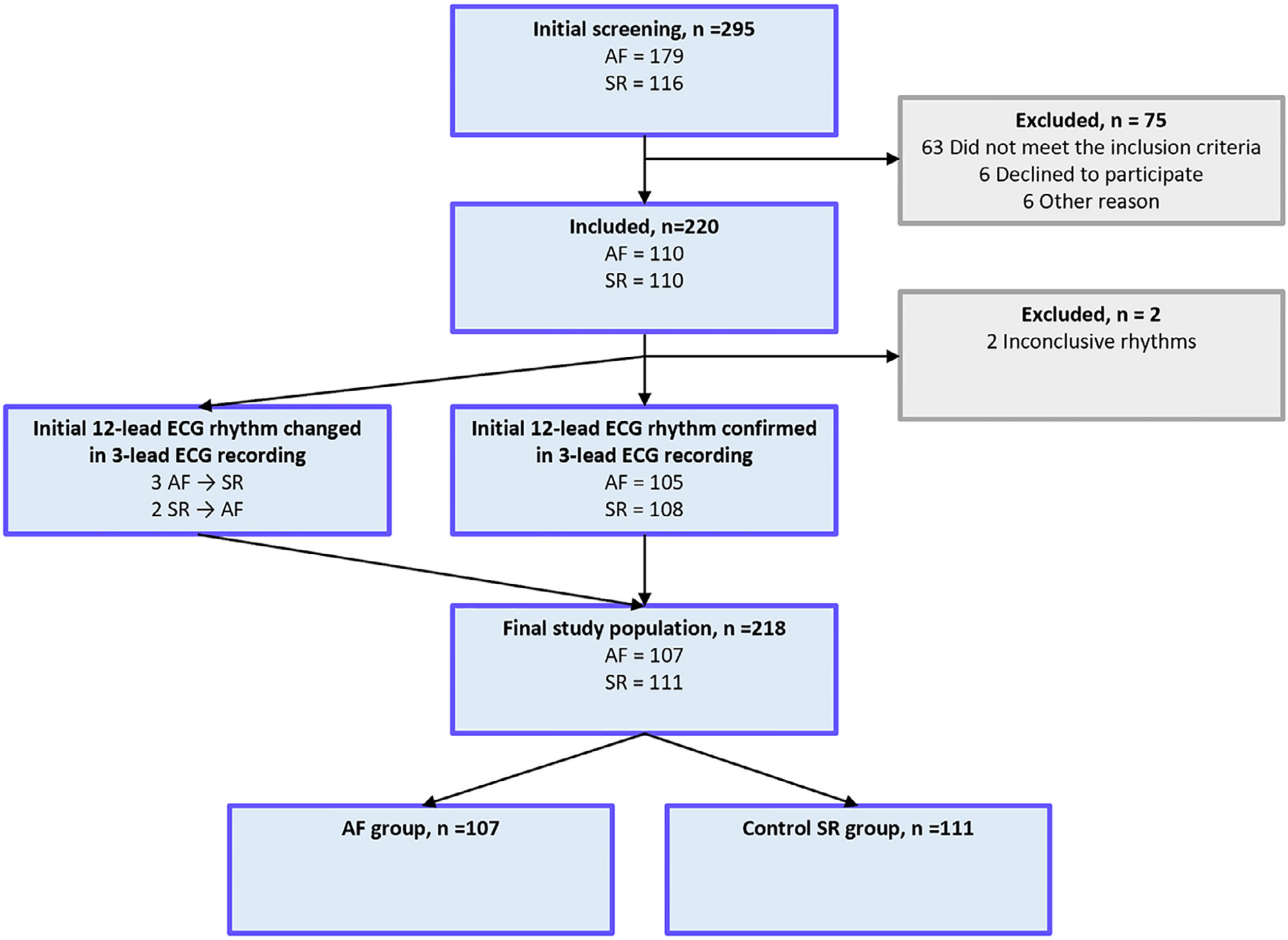

Figure 1. Flowchart. AF = atrial fibrillation; ECG = electrocardiogram; SR = sinus rhythm.

The study population consisted of 220 patients. According to the initial 12-lead ECG, a total of 110 patients with AF were collected, with the control group consisting of 110 patients with normal sinus rhythm. The initial 12-lead ECG was only used in the recruitment process of patients. The 3-lead Holter ECG rhythm analysis was conducted by 2 experienced cardiologists blinded to the initial ECG. The cardiologists' interpretation of the 3-lead Holter ECG rhythm was used as the gold standard for rhythm analysis. A flowchart is presented in Figure 1.

First, a 12-lead ECG was recorded over a period of 10 seconds for rhythm confirmation, after which the ECG electrodes were removed. The 12-lead ECG was mostly recorded as a part of a routine medical examination and only in a few cases for study purposes only. The time gap between the 12-lead ECG and the study recording was not limited by the study protocol and ranged from a few minutes to several hours. Because of this, in some cases the rhythm of 12-lead ECG had changed from the original recorded rhythm (4 from AF to SR; 2 from SR to AF), and this in turn affected the number of AF/SR in final rhythm analysis (Figure 1).

In the next step, 5 wet electrodes were attached to each patient to record ECG with a Faros 360 Holter device (Bittium, Oulu, Finland; *device 1, Figure 2*) used as the gold standard for rhythm monitoring. Simultaneously a HR monitoring chest strap with ECG recording capability (Suunto Movesense, Suunto, Vantaa, Finland; *device 2, Figure 2*) was applied to the chest, approximately 2 cm below the lower end of the sternum, according to the manufacturer's instructions. A total of 5-min ECG recording was made. The measurement method/study design is presented in Figure 2. Examples of ECG strips acquired are presented in Figure 3. Standard 12 lead ECG and ECG morphology produced by the chest strap is presented in Supplementary Figure 1.

The data from the HR monitor chest strap were sent via Bluetooth connection to a mobile phone, from which it was transferred via a USB cable to a PC computer. The data from the Faros Holter device were recorded to the device's internal memory card and transferred to a PC equipped with analyzing software. The data collected were anonymized and ECG data from the chest strap and the Holter device were analyzed using an in-house application developed by the authors.

The ECGs acquired by the chest strap (1-lead) and the Holter (3-lead) were analyzed in a random order by 2 experienced cardiologists blinded to the initial 12-lead ECG.

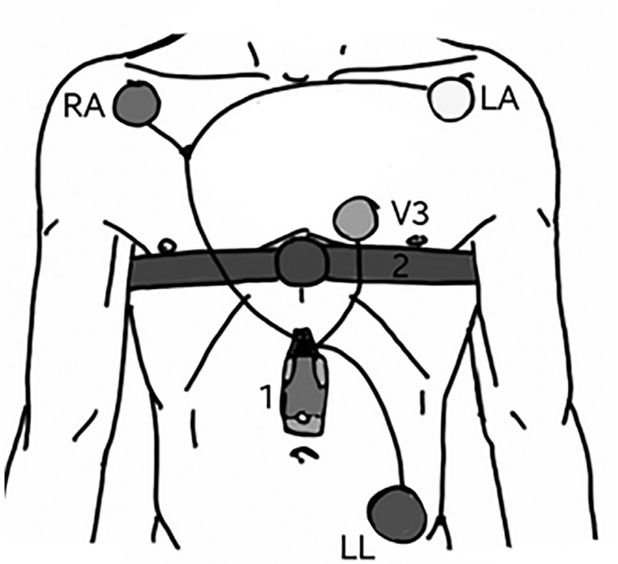

Figure 2. Measurement of ECG with Suunto Movesense chest strap with ECG acquisition (2). As control, 3-lead Faros 360 Holter device using wet electrodes were used (1). A 5-min measurement was done simultaneously using both devices with the study subject resting in supine position LA = left arm; LL = left limb; RA = right arm; V5 = electrode positioned in position corresponding electrode V5 in 12 lead ECG.

The quality of the ECG strip was defined as good (no or only minor artifacts), average (artifacts but QRS complex and/or P-wave identifiable), or poor (major artifacts, no identifiable QRS complex and/or P-wave) by the cardiologists. The rhythm of the ECG recordings was divided into 3 categories: sinus rhythm, AF, or other/inconclusive. The cardiologists also assessed the possibility of detecting P waves from the ECG strips with SR (yes/no).

Two previously published AF detection algorithms were used in this study. Algorithms were used to demonstrate the possibilities of automatic screening of AF using the chest strap ECG devices with automated analysis. The first method used was AFEvidence proposed by Sarkar et al[19] AFEvidence is based on a relative population of the segments in the ΔRR 2D histogram {ΔRR(i), ΔRR(i-1)}. The threshold for AF detection is AFEvidence >50. The second algorithm used in the study was COSEn proposed by Lake et al.[20] COSEn is based on an optimized sample entropy estimate and the mean heart beat interval. The threshold for AF detection is COSEn >−1.6.

The estimated sample size was 200 observations with assumed sensitivity of the method being 95% with 3% margin of error. The data were analyzed using IBM SPSS statistics software version 23. Demographic variable data were presented as frequencies and percentages or mean and standard deviation. Group differences were tested by *t* test or chi-square test. McNemar-Bowker test was used in testing the opinion between cardiologists, and the Kappa-coefficient was calculated to measure the level of consensus. In addition, sensitivity and specificity were determined between cardiologist consensus and algorithms. All significance tests were 2-tailed with p ≤0.05 considered statistically significant.

Results

According to the flowchart, with the 3-lead Holter ECG serving as the gold standard, a total of 218 patients were included in and 2 were excluded from the analysis (Figure 1). Two of the 220 3-lead Holter ECGs could be classified neither as sinus rhythm nor AF, one in AF and one in SR group. One of them converted from atrial flutter to sinus rhythm during recording, and the quality of the other ECG was insufficient for rhythm analysis. These 2 Holter ECGs and the corresponding chest strap ECGs were excluded from the final analysis.

Demographics of study participants, including age, gender, previous medical history (as reported by patient or from patient medical records), height, weight and BMI,

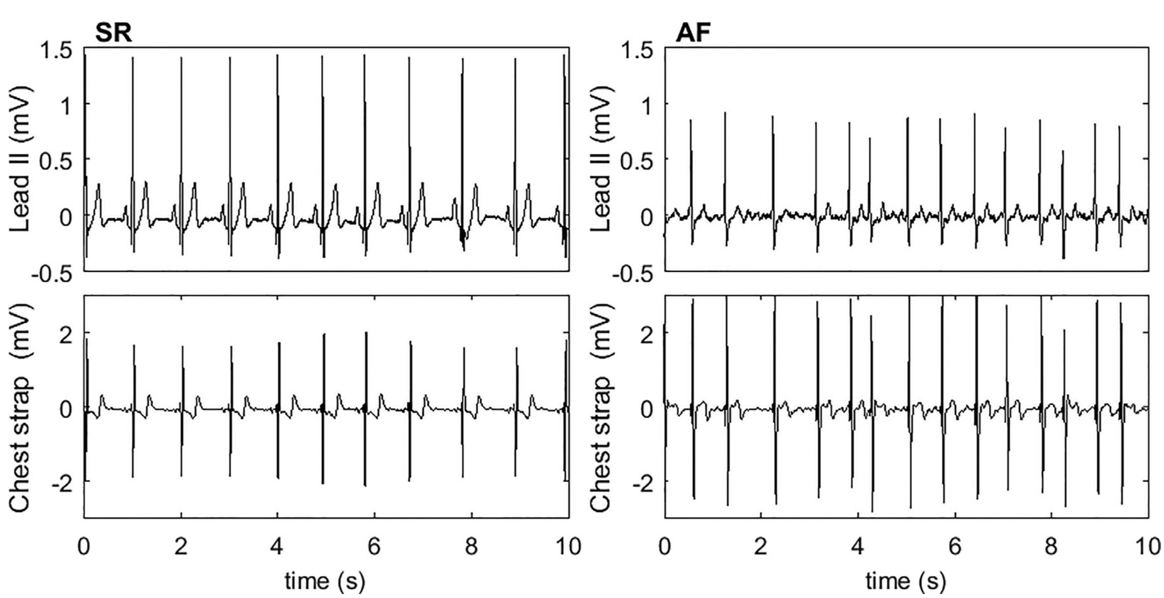

Figure 3. Typical examples of ECG recording of sinus rhythm (SR) and atrial fibrillation (AF) using Faros 360 Holter ECG and Suunto Movesense chest strap. mV = millivolt.

Table 1
Patient demographics

	AF (n = 107)	SR (n = 111)	p
Male/female	58/42%	55/45%	0.68
Age (years)	72 ± 14	55 ± 19	<0.0001
Height (cm)	172 ± 10	171 ± 10	0.972
Weight (kg)	75 ± 13	74 ± 12	0.848
BMI (kg/m^2)	25.2 ± 3.0	25.3 ± 3.1	0.324
Mean HR (bpm)	94 ± 22	68 ± 13	<0.0001
Coronary heart disease	27.1%	23.4%	0.5
Diabetes mellitus	20.6%	13.3%	0.166
Hypertension	61.7%	44.1%	<0.01
Congestive heart disease	19.6%	2.7%	<0.0001
Previous heart surgery*	13.1%	4.5%	<0.05

AF = atrial fibrillation; BMI = body mass index; HR = heart rate; SR = sinus rhythm.

* Heart surgery type not specified.

were recorded (Table 1). The patients in the AF group were older, had a faster HR, and more hypertension, congestive heart disease or previous heart surgery, compared with the SR group.

The opinion of the quality of the ECGs differed significantly between cardiologists, both with the chest strap and the Holter ECGs, with a greater proportion classified as "good" with the chest strap ECG compared with the Holter ECG by both cardiologists. In patients with SR, P waves were identifiable in majority of the ECG strips of chest strap and Holter ECGs, with no significant difference between the methods studied (Table 2).

The two algorithms used detected AF from the Holter and chest strap ECG with a good specificity and sensitivity. There was no significant difference in algorithm rhythm classification between the chest strap ECG and the Holter ECG (Table 3).

Discussion

The main finding of this study was that the quality of an ECG strip recorded from the chest strap was sufficient for reliable detection of AF both by cardiologists and by automated algorithms. Detection of asymptomatic arrhythmias for prevention and searching for the cause of stroke is a big clinical challenge. As of now, there are only a few methods

Table 2
Visual quality and and P-wave visibility of Holter and chest strap recordings

Quality* (n = 218)	Holter (Doc 1/Doc 2)	Chest strap (Doc 1/Doc 2)
Good	71.6%/85.3%	83.0%/95.9%
Average	17.0%/12.4%	15.1%/4.1%
Poor	6.9%/2.3%	1.8%/0.0%
P-waves visible†		
SR (n = 111)	98.2%/95.5%	93.7%/94.6%
AF (n = 107)	0/0	0.9/0.9

AF = atrial fibrillation; ECG = electrocardiogram; SR = sinus rhythm.

* Quality of chest strap ECG is better than Holter ECG; p <0.05/p <0.001 (Doc1/Doc 2).

† P-wave visibility is better in Holter than chest strap ECG; p = n.s /p = n.s (Doc1/Doc 2).

Table 3
Sensitivity and specificity of AFEvidence and COSEn methods to detect AF from Holter and chest strap ECG recordings

		Specificity (%)	Sensitivity (%)
Holter	AFEvidence	98.2	93.5
	COSEn	95.5	97.2
Chest strap	AFEvidence	95.5	95.3
	COSEn	98.2	96.3

ECG = electrocardiogram.

available for clinical use, requiring expensive or invasive equipment and health-care professional interpretation of results. Novel methods for finding arrhythmias are needed. Currently, the use of ECG-based HR monitors is limited to HR monitoring in sports, and the already existing possibility of acquiring ECG strip is not currently used in search for arrhythmias.

Screening for AF ranges from opportunistic pulse palpation during a routine check-up to invasive, prolonged monitoring in poststroke studies. Noninvasive screening methods include pulse palpation or surface ECG and continuous hospital telemetry, ambulatory ECG (Holter), patient-triggered event recorder, and prolonged ambulatory ECG (mobile cardiovascular telemetry). Invasive screening methods include implantable loop recorders and pacemakers with atrial leads and implantable cardioverter defibrillators.[21] A recent collaboration for screening for AF (AF-SCREEN) discusses in a white paper the advantage of handheld ECG devices in providing verifiable ECG traces for diagnosis of AF according to guidelines. Furthermore, for screening to be effective in preventing strokes, it must be linked to a pathway for diagnosing AF and initiation of anticoagulation.[17] Algorithm-based devices can be used for screening purposes, but an actual ECG-strip is needed for the diagnosis of AF. Current commercial devices in detecting AF include ECG-based devices[9–11] and detection of AF by pulse irregularity using blood pressure monitors, mobile phone apps/cameras, and wearable technology.[12–16] None of them are currently able to provide an actual ECG-strip. Inexpensive consumer products have been studied for the screening of AF.[18] If these products are to be used in future for the diagnosis of AF, they need to be registered as medical devices with FDA approval (US) or CE mark (EU).

The interest in self-monitoring is increasing. The number of devices providing information on one's health is abundant, and they are used by a large population of consumers. The theoretical possibility of AF detection is already built in with many of the commercial chest straps used for HR monitoring in sports, since many HR monitors such as chest straps use single-channel ECG in HR measurement, detecting QRS complexes and measuring R-R intervals. The advantage of the method used in this study is the capability of some the commercially available HR monitor chest strap studied to produce and transmit ECG (Suunto Movesense), and this seems to be of a study intrerest of all the biggest HR monitor manufacturers. To the best of our knowledge, this is the first time when single-channel ECGs from a HR monitor chest strap has been used for detecting AF both by clinicians and automated algorithms, producing an ECG strip for clinician. In the SAFE study by Lown et al,[18] the screening of AF was performed by algorithm-only using 4 different devices. In our study, the diagnosis of 2 experienced cardiologists was compared with algorithm diagnosis yielding in good specificity and sensitivity for the method studied and, in addition, an ECG strip from chest strap with sufficient quality for the diagnosis of AF.

There are some limitations in this study. First, some of the patients in the original AF group were in sinus rhythm in the final analysis. The minimum number of 100 patients per group was achieved by the collection of additional patients in each group. Second, the measurement using the chest strap was made in optimal conditions with a supine, resting patient and the chest strap application being made by the researcher. The measurement period was restricted to 5 minutes. In real-life measurements, the artifacts and poor signal quality resulting from, for example, movement, inaccurate positioning of the chest strap, dryness of skin and electrodes, are sources of signal noise and decrease the accuracy for automated algorithms as well as the human eye in interpreting the ECG signal. Moreover, we did not collect patients from a specific age group. The incidence of AF increases in the elderly population, in which possible problems with cognition and ability to use new technologies can be decreased. Also, usability of the technology studied in obese patients cannot be concluded from our results, since the inclusion criterion was BMI less than 33.

After clinical validation and studies for longer measurement times and moving subjects, the chest strap with the ECG sensor could be used both in opportunistic and systematic screening for AF. For asymptomatic risk group patients, chest strap ECG screening could be implemented. Furthermore, it could be used in long-term follow-up of poststroke patients in finding AF. In both cases, chest strap ECGs would offer the ECG strip recommended by guidelines for confirmation of the diagnosis of AF. If our study technique with the use of the actual ECG acquired from the HR monitor chest strap appears to be practical and can be validated, it opens an opportunity for a low-cost screening method that is easy to implement in large populations at risk of AF and in poststroke studies.

The quality of the chest strap ECG was superior to the Holter ECG as analyzed by 2 experienced cardiologists. The ECG using the chest strap enables accurate detection of AF by using automated algorithms. P wave was detected from chest strap ECG strips in patients with sinus rhythm in 93.7%/94.6% of cases. An ECG strip from chest strap offers a possibility for confirmation of AF diagnosis as suggested in present guidelines. ECG recording using the chest strap for the detection of AF in risk groups and in poststroke screening seems promising but needs further studies in larger populations and in real-life situations in addition to encompassing longer measurement periods. In general, easy-to-use and low-cost solutions are needed in screening for arrhythmias such as AF, and the use of evolving mobile technology enables remote monitoring in the near future.

Disclosures

S. Hartikainen, J. Lipponen, T. Rissanen, M. Tarvainen, T. Martikainen, and H. Jäntti are shareholders of a company (Heart2Save) that designs ECG-based software for medical equipment. There are no other conflicts of interest to declare.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.02.028.

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