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NEW TECHNOLOGIES

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Prolonged ECG with a novel recorder utilizing electrode belt and mobile device in patients with recent embolic stroke of undetermined source: A pilot study

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Abstract

Background: Paroxysmal atrial fibrillation (pAF) is a major risk factor for ischemic stroke, but challenging to detect with routine short-term monitoring methods. In this pilot study, we present a novel method for prolonged ECG and screening for pAF in patients with a recent embolic stroke of unknown source (ESUS).

Methods: Fifteen patients aged ≥ 50 years with a recent ESUS were assigned to wear an external electrode belt-based 1-lead ECG device (Beat2Phone) continuously for 2 weeks (wear time). The device was operated via a mobile phone application in nonhospital conditions. The primary outcome was patient adherence to monitoring. Secondary outcomes were incidence of new pAF, quality-wise comparison to Holter, and usability of the novel ECG monitoring method with Systems Usability Scale (SUS). We also performed a 24- to 48-hr comparison between simultaneous Beat2Phone ECG and a standard Holter in 6 patients.

Results: Wear time of Beat2Phone device was over 80% in 5 (33.3%) patients, 50%–80% in 7 (46.6%) patients, and less than 50% in 3 (20%) patients. We detected pAF ≥ 30 s in 1 patient (6.7%). In the simultaneous monitoring with Beat2Phone and Holter, there were a total of 817 (out of 1979) analyzable periods of sinus rhythm or premature atrial or ventricular beats (Cohen's Kappa coefficient 0.92 ± 0.02 between Beat2Phone and Holter), and no pAF events. Beat2Phone ECG showed remarkable SUS scores in user evaluations (average score: 81.4 out of 100 on SUS).

Conclusions: Beat2Phone device was easy to use among ESUS patients and in optimal conditions provided high-quality 1-lead ECG signal for diagnosing pAF.

Clinical trial registration: The study was not registered, as it was a nonrandomized single-arm pilot study.

KEYWORDS

atrial fibrillation, electrocardiogram, embolic stroke of undetermined source, stroke

1 | INTRODUCTION

Atrial fibrillation (AF), either paroxysmal, persistent, or permanent, is the presumed etiology for at least every fifth ischemic stroke (Kolominsky-Rabas, Weber, Gefeller, Neundoerfer, & Heuschmann, 2001). Patients with a history of both AF and a previous stroke are among those with by far the highest risk of recurrent stroke (Piccini et al., 2013). Furthermore, AF-related strokes more often lead to permanent disability, compared to other causes of ischemic stroke (Benjamin et al., 2017). Once diagnosed, the stroke risk of AF can be effectively reduced with oral anticoagulation therapy (Kirchhof et al., 2016). The threshold of AF burden to cause marked risk of recurrent stroke is still to be defined, but there is clear evidence that poststroke detected AF increases the risk of recurrent stroke, leading to a need to establish AF diagnosis and initiate anticoagulation without delays (Chou et al., 2018; Noseworthy et al., 2019).

Stroke pathogenesis remains unknown (cryptogenic) in about every fourth of all ischemic strokes, resulting in untargeted and possibly insufficient secondary preventive measures. Some of these cryptogenic strokes share neuroimaging pattern similar to patients with known embolic sources, and hence, a term embolic stroke of undetermined source (ESUS) has been coined to characterize these patients. ESUS is by definition a nonlacunar stroke without a recognized major cardioembolic source, major arterial occlusions, or other causes for the stroke (Hart, Catanese, Perera, Ntaios, & Connolly, 2017). Defining a patient as ESUS is of great importance as it has been demonstrated that this patient subgroup is prone to a high risk of stroke recurrence (Putaala et al., 2015). Importantly, a large proportion of ESUS patients may have a silent paroxysmal AF (pAF; Geisler, Mengel, Ziemann, & Poli, 2018).

Standard in-hospital diagnostic methods to screen and diagnose pAF include 12-lead ECG, nonambulatory monitoring, and 24- to 48-hr Holter as well as ambulatory telemetry monitoring. These methods fall short in pAF detection mainly due to too short monitoring periods (Sposato et al., 2015). Standard 24- to 48-hr ECG monitoring unmasks hidden pAF in only 2%–4% of patients, while prolonging monitoring period to several weeks or months yields detection rates up to 30% (Sposato et al., 2015).

External monitoring methods provide a more affordable option than costly implantable monitors to perform prolonged ECG screening lasting up to several weeks. The EMBRACE study demonstrated a drastic increase in pAF detection rates using a 30-day ECG monitor with belt, and multiple studies have afterward provided similar results with either plaster electrodes, wearable ECG, or implantable loop recorders (Gladstone et al., 2014; Israel et al., 2017; Sanna et al., 2014; Wachter et al., 2017). To the best of our knowledge, there are only two studies specifically focusing on ESUS patients with noninvasive monitoring methods, reporting detection rates of 22% in 21-day monitoring (Rubio Campal et al., 2020) and 12% in 28-day monitoring (Lumikari et al., 2019).

The aim of this pilot study was to assess the utility, adherence, and patient experience to a novel 1-lead ECG device with a wearable electrode belt and mobile device-assisted data transfer. Moreover, we tested whether this device could be used in screening pAF in patients with ESUS.

2 | METHODS

2.1 | Patients, clinical data, and outcomes

The study was carried out at the Helsinki University Hospital. Ethics approval was obtained from the Ethics Committee of the Hospital District of Helsinki and Uusimaa. All patients gave a written informed consent prior to participation, and the study followed principles of the Declaration of Helsinki. The researchers received no financial compensation from the device manufacturer for the study conduct. The company was not involved in planning of the study, data analysis, or reporting of the data. Patients aged ≥ 50 years with a recent ESUS (Hart et al., 2017) were assigned to wear a novel ECG monitoring device, attached to an electrode belt continuously for 2 weeks. Prior to participation, all patients underwent a diagnostic workup to reach to diagnosis of ESUS. This included brain computed tomography (CT) or magnetic resonance (MR) imaging showing findings of a nonlacunar ischemic stroke alongside CT or MR angiography to rule out relevant intracranial and extracranial artery stenosis. All patients underwent either transthoracic (TTE) or transesophageal (TEE) echocardiography to exclude major cardiac sources of embolism. All patients also underwent a standard 24- or 48-hr Holter monitoring

TABLE 1 Characteristics of the study participants ($n = 15$)

Baseline characteristics	
Age, years	59.5 ± 7.4
Male sex	10 (66.7)
Level of education[a]	
Low	1 (6.7)
Intermediate	5 (33.3)
High	8 (53.3)
Hypertension	10 (66.7)
Regular smoker	3 (20.0)
Body mass index	26.6 ± 2.8
NIH Stroke Scale score	2 (0–3)
3-month follow-up	
Modified Rankin Scale[b]	1 (0–1)
New transient ischemic attack/stroke	1 (6.7)
New atrial fibrillation	1 (6.7)
Number of patients on oral anticoagulants	
At discharge	3 (20.0)
At 3 months	4 (26.7)

Note: Data are *n* (%), mean (±*SD*), or median (interquartile range).
Abbreviation: NIH, National Institutes of Health.
[a]$n = 14$.
[b]Scale from 0 to 5 (0 = no symptoms; 5 = bedridden).

as part of routine care. Exclusion criteria included diagnosis of AF and other known etiology for the stroke or ongoing anticoagulation therapy at the time of enrollment, and contraindication to anticoagulation therapy or other diseases that would likely have prevented the patient from completing the study.

A subset of six patients underwent additional Holter recording with a GE Healthcare SEER Light 3-lead Holter device, simultaneously with the studied Beat2Phone device. After completing 24- to 48-hr monitoring with both devices, patients continued monitoring with the studied device until 2 weeks of total monitoring had been established. Results of the investigational Holter recording were available only after the end of the 2-week monitoring.

Patient characteristics, medical history, stroke diagnostic workup, and medication were recorded using standardized questionnaires and medical records. Baseline stroke severity was assessed with the National Institutes of Health Stroke Scale (NIHSS). The level of education was graded as low (primary school), middle (upper secondary school/vocational school), or high (university/polytechnic).

The primary outcome was patient adherence to Beat2Phone monitoring, measured by wear time of the desired 2-week monitoring period, and categorized as follows: over 80%, 50%–80%, and less than 50%. Secondary outcomes were incidence of newly detected pAF, quality-wise comparison to standard Holter, and user-assessed usability of the novel ECG monitoring method. We used Systems Usability Scale (SUS) with Likert rating scale to assess user experiences (Table 2; Brooke, 1996). In addition to SUS, patients were asked to provide open-ended feedback. Patients were followed up for three months for vital status, assessment of recurrent events, ongoing medication, and functional neurological status (modified Rankin Scale).

TABLE 2 Evaluation of the Beat2Phone device by patients with the Systems Usability Scale

Question	Likert Scale (mean)[a] $n = 9$
I think that I would like to use this system frequently	4.11
I found this system unnecessarily complex	1.33
I thought this system was easy to use	4.56
I think that I would need assistance to be able to use this system	1.33
I found the various functions in this system were well integrated	3.56
I thought there was too much inconsistency in this system	1.78
I would imagine that most people would learn to use this system very quickly	4.56
I found this system very cumbersome/awkward to use	1.89
I felt very confident using this system	4.33
I needed to learn a lot of things before I could get going with this system	2.22

[a]Scale 1 to 5 (1 = completely disagree; 5 = completely agree).

FIGURE 1 Beat2Phone device attached onto a charging dock, an electrode belt, and a mobile phone application used for the prolonged ECG monitoring

2.2 | ECG device

Beat2Phone devices (VitalSignum, Helsinki, Finland) with rubber belt built-in electrodes were used for ECG monitoring (Figure 1). The sensor has a 2 kHz ECG voltage sampling frequency, which allows precise RR interval calculation and in optimal conditions allows almost noise-free recording of the ECG PQRST sequence. The device is capable of transmitting real-time ECG data, with a 50-Hz notch filter, via a mobile phone application (VitalSignum). The mobile phone and application were provided to patients by the study personnel. All instructions were given to patients in verbal and written form. Patients were asked to wear the ECG device continuously for 2 weeks, only pausing monitoring when charging the device 2 times a day for 1 hr at a time, or when showering/bathing. Patients were asked to moisten the electrodes daily in order to increase conductivity and maintain good ECG data quality; the patients were able to review their ECG with the mobile phone application. After the 2-week monitoring period, patients returned the device and accessories to the research unit. Patients were able to contact study personnel during working hours in case of technical difficulties. Optional home visits were provided if the patient's condition required so.

2.3 | ECG analysis

Although the Beat2Phone device provided consistent data flow from the recorder to a cloud storage via mobile phone, all ECG data were analyzed retrospectively due to practical reasons. A tablet computer application "Beat2Phone" (VitalSignum) was used to analyze ECG recordings. ECG analysis was performed blinded to clinical data by a cardiologist (T.N.) and a clinical physiologist (J.Pi.) experienced in prolonged ECG interpretation. pAF was defined as ≥ 30 s of irregularly irregular R-R intervals with no detectable P waves. Beat2Phone data were pre-annotated by software. The suggested

pAF episodes were adjudicated independently by both raters, who both were blinded to clinical data. Furthermore, we compared the quality of ECG and arrhythmia detection with simultaneous 48-hr Holter monitoring.

2.4 | Statistical analysis

Data were reported as *n* (%), mean ± standard deviation (*SD*), or median (interquartile range, IQR). All the analyses were performed with SPSS version 24 (IBM Inc.).

3 | RESULTS

3.1 | Study population and patient adherence

A total of 15 patients (66.7% male; mean age: 59.5 ± 7.4 years), meeting the ESUS criteria, were enrolled. Patients presented with relatively mild stroke symptoms upon hospital admission (NIHSS score median: 2; IQR: 0–3). The most common comorbidity among patients was hypertension (66.7%), whereas only one patient (6.7%) had suffered a previous stroke before the index event (Table 1).

Median delay from hospital admission to the start of monitoring with the Beat2Phone device was 37 days. Median absolute length of continuous monitoring was 9 days (IQR 3.8–11.5), with a wear time of over 80% in 5 (33.3%) patients, 50%–80% in 7 (46.6%) patients, and less than 50% in 3 (20%) patients.

None of the patients reported ceasing the 2-week monitoring prematurely, and no serious adverse effects were reported. One of the ECG devices malfunctioned and was replaced during the monitoring period.

One patient without documented pAF during neither the ECG recording phase nor later suffered a recurrent stroke during the 3-month follow-up.

The study patients reported the ECG device and mobile phone application to be relatively easy to use (average of positive items 4.4 on the Likert scale), but reported moderate need of instruction to use the device (average of negative items 1.7 on scale 1–5; Table 2). Overall average SUS score was 81.4 out of 100. In the open-ended feedback, one patient reported challenges with device charging, and one patient reported difficulty using the mobile phone application.

3.2 | ECG analysis

Two new pAF episodes lasting approximately one minute each were detected in one (6.7%) patient (Figure 2). Oral anticoagulation was commenced in this patient.

In the 24- to 48-hr comparison between Beat2Phone and standard 3-channel Holter in 6 patients, 60% of the Beat2Phone monitoring consisted of too noisy ECG for the comparison (Figure 2).

In the comparison of ECG events between the monitoring methods, there were a total of 1979 events detected by the Beat2Phone® software, out of which 817 were labeled to be adequate for analysis. An event was defined as a beat or rhythm with distinct beginning and ending. These events were analyzed by a clinical physiologist in both Beat2Phone and Holter ECG. Among the analyzable events, there were variable periods of sinus rhythm or premature atrial or ventricular beats (Cohen's Kappa coefficient of 0.92 ± 0.02 between ECG events seen in Holter, compared to events detected in Beat2Phone). There were no pAF events among these monitoring periods.

4 | DISCUSSION

The main objective of our pilot study was to evaluate the feasibility of the Beat2Phone ECG device for prolonged cardiac monitoring in ESUS patients. We found that these stroke patients had moderate adherence to continuous use of the Beat2Phone ECG device. User feedback on the SUS revealed that ESUS patients found the monitoring device and attached mobile application easy to approach and use.

Our secondary objective was to compare the Beat2Phone device to standard Holter. The interpretation of data was challenged by the high rate of noisy 1-lead ECG signal. Nevertheless, during optimal conditions with good signal quality, the device performed well compared to standard Holter and was able to reveal new pAF in one patient.

In our previous study, we detected pAF in 12% of the patients in a 4-week monitoring (Lumikari et al., 2019), which was in accordance with prior studies of 1- to 4-week monitoring periods (Sposato et al., 2015). The low pAF detection rate in the present patients (6.7%) was most probably caused by the relatively low age of our patients and limited sample size. An additional factor may be the relatively long delay from hospital admission to the start of monitoring (37 days), as compared to previous studies with delays less than a week (Silverman, 2016). The optimal monitoring pattern for external ECG devices in ESUS patients is yet to be proven and is also dependent on patients' own preferences.

Regarding the poor ECG quality, dry skin and dry electrodes may be the sources to lead loss, as patients were not allowed to shower while wearing standard Holter.

Extensive continuous periods wearing monitoring equipment are likely to lead to lower patient adherence and data loss due to a limited number of electrodes used. In the EMBRACE study, out of 572 stroke patients, 61.7% completed 4 weeks of the desired 4-week monitoring period (Gladstone et al., 2014). Another study reported a drop out rate of 24 out of 75 (32%) patients using 1-lead plaster Ziopatch electrode with patients of known AF but no known stroke.

There are a growing number of wearable devices that utilize photoplethysmography (PPG) to assess volumetric variations of arteries in order to depict phases of the heart cycle. This indirect information is used to measure variations in beat-to-beat intervals, which is the basis for determining the heart rhythm without ECG. The two

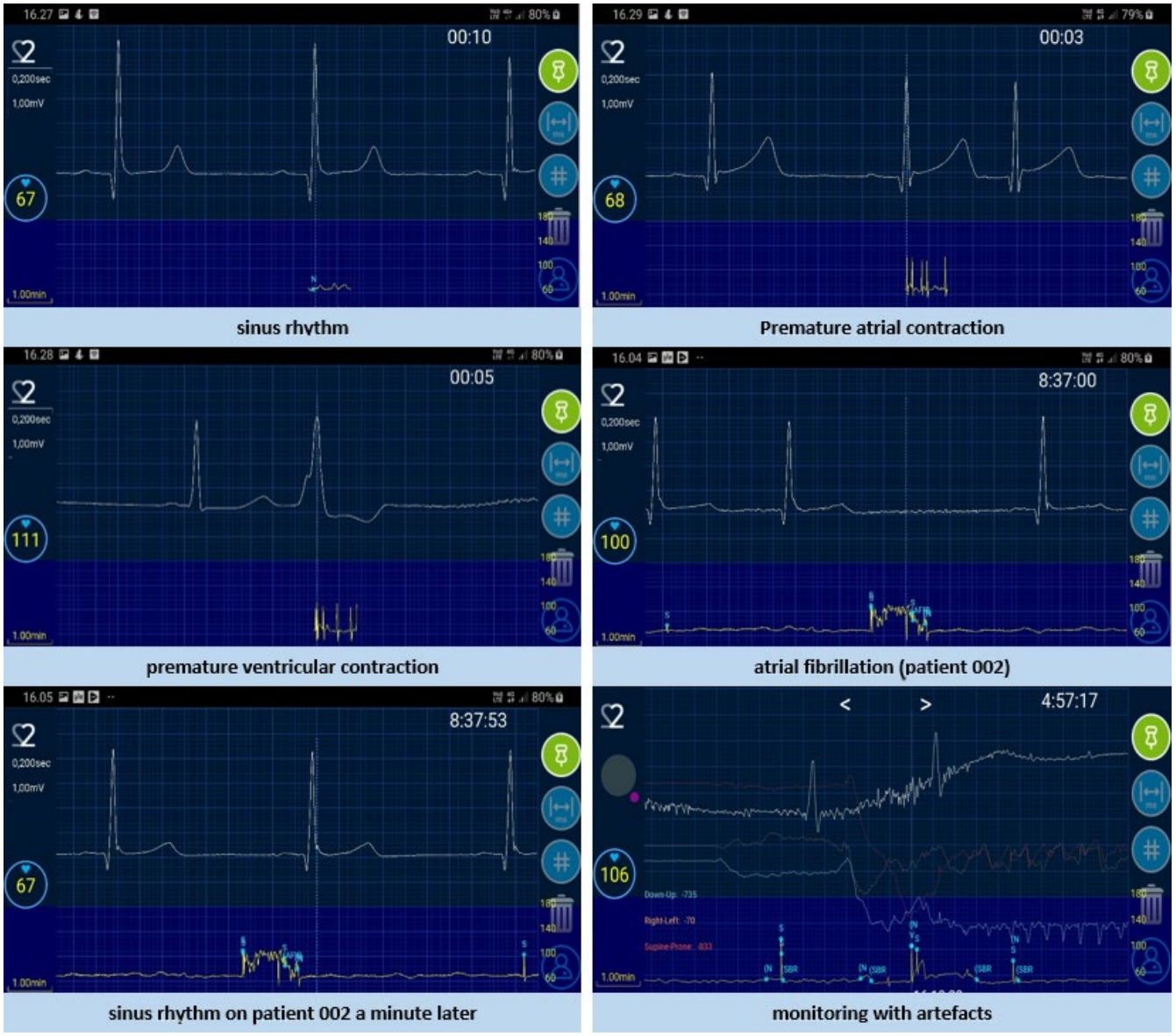

FIGURE 2 Examples of ECG recordings with Beat2Phone device in the study patients. An example of noisy recording in bottom right corner. This type of noise origins commonly from motion artifacts from upper body movements or due to insufficient electrode contact

major studies in AF detection from PPG data, Apple Heart study and Huawei Heart study, reported high sensitivity and specificity for AF detection (Guo, 2019; Perez et al., 2019).

Atrial fibrillation is still an electrical phenomenon, and all the AF treatment trials have been based on different types of ECG documented AF. Extrapolating the results to nonelectrical method, that is, PPG, is a paradigm shift still necessitating widespread research before general acceptance.

Our study has limitations, such as the small sample size. Our patients were younger, and their recovery from stroke was relatively good. Thus, the selected group of ESUS patients may not fully reflect usability of the Beat2Phone device in all ESUS patients or in patients with more severe stroke or major cognitive deficits.

In conclusion, this pilot study demonstrated that Beat2Phone can be used in prolonged ECG monitoring in ESUS patients with a moderate patient adherence and highly rated user feedback. Despite the high rate of noisy ECG, at best, Beat2Phone device has the potential to provide a high-quality 1-lead ECG signal that could guide clinical diagnosis of pAF. Further research is needed to optimize patterns of usage and electrode contacts for prolonged monitoring periods.

CONFLICT OF INTEREST

The researchers received no financial compensation from the device manufacturer for the study conduct. The company was not involved in planning of the study, data analysis, or reporting of the data.

ETHICAL APPROVAL

Ethics approval was obtained from the Ethics Committee of the Hospital District of Helsinki and Uusimaa. All patients gave a written

informed consent prior to participation, and study followed principles of the Declaration of Helsinki.

DATA AVAILABILITY STATEMENT

Data openly available in a public repository that issues datasets with DOIs.

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