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Device profile of the Coala Heart Monitor for remote monitoring of the heart rhythm: overview of its efficacy

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ABSTRACT

Introduction: Several handheld thumb ECG devices for on-demand recording of heart rhythm have become available lately. These can be used both by health-care providers and purchased by laypersons for private use.

Area covered: This profile describes the Coala Heart Monitor. This device differs from other handheld ECG monitors in three aspects: 1) it records both thumb and chest ECGs, 2) it uses both RR-dispersion and P-wave morphology for detecting atrial fibrillation, and 3) in synchronization with the chest ECG, it also records heart sounds presented as a phonocardiogram making measurement of systolic time intervals possible. The sensitivity and specificity for detecting atrial fibrillation are high. The use of systolic time interval in patients with heart failure has so far not been evaluated.

Expert opinion: The increasing use of long-term prescribed and privately owned handheld ECG devices for on-demand recording of heart rhythm will most probably cause a paradigm shift in arrhythmia diagnostics. Coala Heart Monitor´s use of both chest and thumb recordings as well as analyzing both RR-dispersion and P-wave morphology may offer an advantage in diagnosing atrial fibrillation.

1. Introduction

In patients with infrequent episodes of tachyarrhythmias, recording the arrhythmia on ECG for correct diagnosis is difficult. Standard Holter monitoring or the use of event-recording devices for shorter times are usually insufficient. This poses a particular problem in patients suffering from sporadic episodes of palpitations when paroxysmal atrial fibrillation (AF) is suspected since adequate stroke prophylaxis is of outmost importance.

During the last years, several single-lead ECG recording devices for on-demand recording of heart rhythm have become available both for health-care providers and laypersons [1–3]. In particular, the number of privately owned devices is dramatically increasing.

Several recent reports have showed that curative catheter ablation of patients with paroxysmal supraventricular tachycardia (PSVT) may be delayed many years due to difficulties documenting the tachycardia on ECG [4,5]. It is reasonable to presume that with the means of a privately owned or long-term prescribed handheld ECG device; curative ablation therapy can be offered much sooner.

The number of patients with undiagnosed (silent) AF is estimated to be substantial [6–8]. It has been suggested that a third of all individuals with AF is asymptomatic. However, these asymptomatic patients also appear to have an increased risk of stroke. Furthermore, a relation between AF and deterioration in cognitive function has been described [9,10]. Stroke prophylaxis with warfarin or newer anticoagulants is a routine procedure in AF patients at risk but may also be of importance to prevent cognitive decline [11,12].

More widespread use of thumb ECG devices could help us identify individuals with asymptomatic AF and with an increased risk for stroke and cognitive impairment but also confirm the diagnosis of AF in patients with symptomatic arrhythmias.

A review covering thumb ECG devices and their clinical use and potential use as an epidemiological tool for studying the prevalence of AF was recently published online by Peter Magnusson et al. [13].

2. Coala Heart Monitor system

2.1. Available devices

There are several thumb ECG devices available on the market today including Zenicor, AliveCor KardiaMobile, Heart Check, Apple Watch, Withing, and others. As a rule, these are used for single-lead thumb measurements, even though AliveCor easily can record chest ECGs as well, and they detect AF based on RR-dispersion.

Coala Heart Monitor differs from these devices in three main aspects.

The Coala Heart Monitor is a two-lead system that records both thumb and chest ECG with a high sampling rate. The system analyzes the recordings for multiple arrhythmias based on pattern recognition-based algorithms including detection of AF based on RR-dispersion and P-waves. The device is also provided with a stethoscope membrane making it possible to record the heart sounds, presented as a phonocardiogram

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Article highlights

- The increased availability of handheld ECG devices will most probably cause a paradigm shift in arrhythmia diagnostics.
- Coala Heart Monitor records both chest and thumb ECGs. The algorithm for automatic interpretation of heart rhythm uses both RR-dispersion and P-wave morphology in diagnosing atrial fibrillation. This may be an advantage compared with other handheld ECG devices improving diagnostic accuracy.
- The Coala Heart Monitor records both chest ECG and heart sounds synchronously making evaluation of systolic time intervals possible. However, the clinical use in heart failure patients has so for not been studied.

combined with ECG, making assessment of murmurs and systolic time intervals possible.

2.2. Coala Heart Monitor

The Coala Heart Monitor consists of a small handheld ECG recording device. By holding it against the chest, a simultaneous recording of ECG and heart sounds is done through electrodes and a stethoscope membrane. The chest measurement is always followed by a thumb ECG recording. The Coala device is connected wirelessly via Bluetooth connectivity to a smartphone for use with the Coala App, see Figure 1. The Coala App installs on a compatible smartphone or portable device and is used together with the Coala Heart Monitor to record, transmit, and view measurements. The Coala App is presently compatible with smartphones running iOS (iPhone 5 or later) or Android (4.4 KitKat or later).

Measurements are transmitted from the app to the Coala Cloud server for analysis. The Coala Heart Monitor has an ECG sampling rate of 1,000 Hz, 24 bit. Data is sent uncompressed to smartphone and further on to analysis servers via Wifi or 3 G/4 G/5 G mobile transmission. The user can review the analyzed results within seconds in the Coala App, and in appropriate cases, the responsible physician or other health-care provider can review the analyzed result in the Coala Care Portal. The app features a messaging system where messages and notifications from the health-care provider can be sent to the user.

The Coala Heart Monitor is a HIPAA and GDPR compliant medical device system. From the Coala Heart Monitor device, data is sent securely via Bluetooth connectivity to an app in the user's smartphone. Data is there pre-processed and further sent via encrypted data transmission to firewall-protected Microsoft Azure servers, where data is separated into different storage servers with encrypted 128-bit keys. Providers can access recordings securely by login to web-based Coala Care portal via SSL.

The Coala Care Server provides automatic analysis of measurements, detection of cardiac rhythm deviations, storing of all recordings, and the Coala App account information for the user. The devices and system are currently used for multi-patient ambulatory cardiac diagnostics, post-procedural follow-up, long-term chronic care monitoring, and by virtual care providers. The device can also be purchased direct-to-consumer in certain regions.

2.3. Coala Heart Monitor ECG

The ECG algorithm is based on the software ECG Parser (Cardiolund, Sweden) and further developed with enhanced proprietary detection of atrial activity by the Coala Heart Monitor.

The quality of ECG recordings is generally as good as with other comparable ECG devices. Performing both a thumb and a chest recording is an advantage from an interpretation point of view. A certain percentage of thumb recordings is usually not possible to interpret or very hard to interpret due to baseline distortions or simply bad contact with device electrodes. This is also true for chest recordings, but the percentage of uninterpretable recording occasions decreases when using both thumb and chest.

A better and more distinct atrial activity may be recorded by the chest measurement compared to the thumb measurement, also improving interpretation. Examples are given in Figure 2. This is valuable in differentiating AF from high rate ectopic atrial tachycardia with low amplitude P waves and irregular AV nodal conduction or frequent premature atrial complex (PAC).

The combination of chest and thumb ECG for detection of AF by an automatic P-wave-based algorithm has been shown to be superior to thumb ECG alone with the majority of
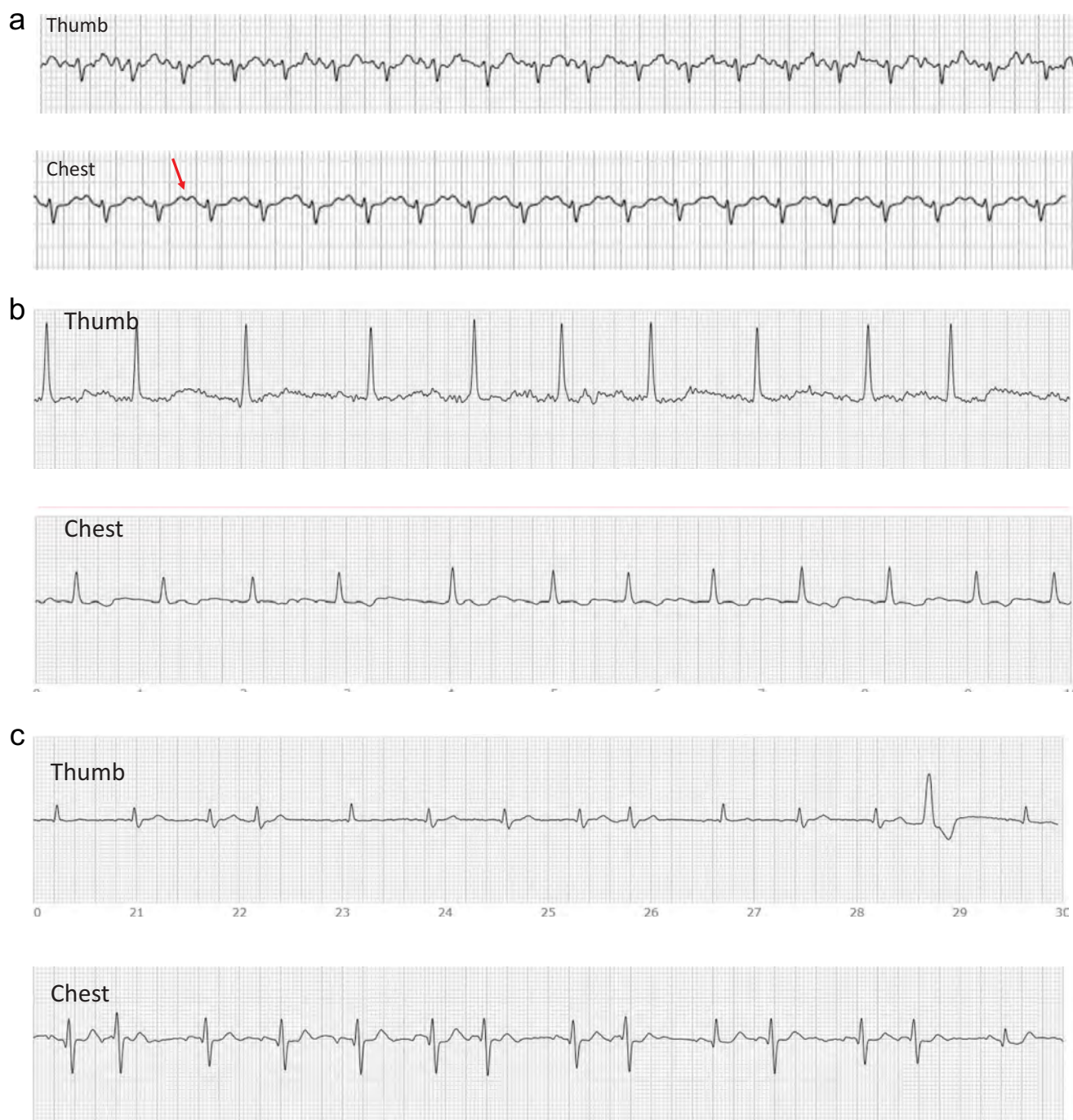

Figure 1. The Coala Heart Monitor.

Figure 2. Examples of thumb and chest ECG recordings. (a). Recordings from a patient with supraventricular tachycardia (SVT). Atrioventricular reentrant tachycardia is a common type of SVT. The P wave is usually found in the T wave. A P wave regularly distorting the T wave is easily seen in the chest recording (arrow) in contrast to thumb recording, where it is much more difficult to identify. (b). Recordings from a patient with AF. The baseline in the chest recording lacks the distortion found in the thumb recording, making a diagnosis of AF easier. (c). Patient with palpitations and irregular heart rhythm. The algorithm interprets the thumb recording as AF and the chest recording, correctly, as PAC.

automatically detected P-waves and highest assessed ECG quality in the chest recordings [14–16].

ECG recordings are automatically analyzed. In the FDA-cleared Coala Heart Monitor, the rhythm is algorithm-interpreted as normal sinus rhythm (SR), AF, unclassified deviation from SR, or poor signal. In the CE-approved system, the unclassified categorization is further divided into tachycardia, bradycardia, number of PAC, and premature ventricular complex (PVC), and more, see Table 1.

The patients can view their ECG recordings and results from the automated analysis directly on their smartphone apps and print pdf copies of relevant ECG recordings for further analysis by their physicians.

In cases of questionable algorithm classification, the health-care provider can easily interpret the ECG online in the Coala Care Portal, and from there, if preferable, print pdf copies.
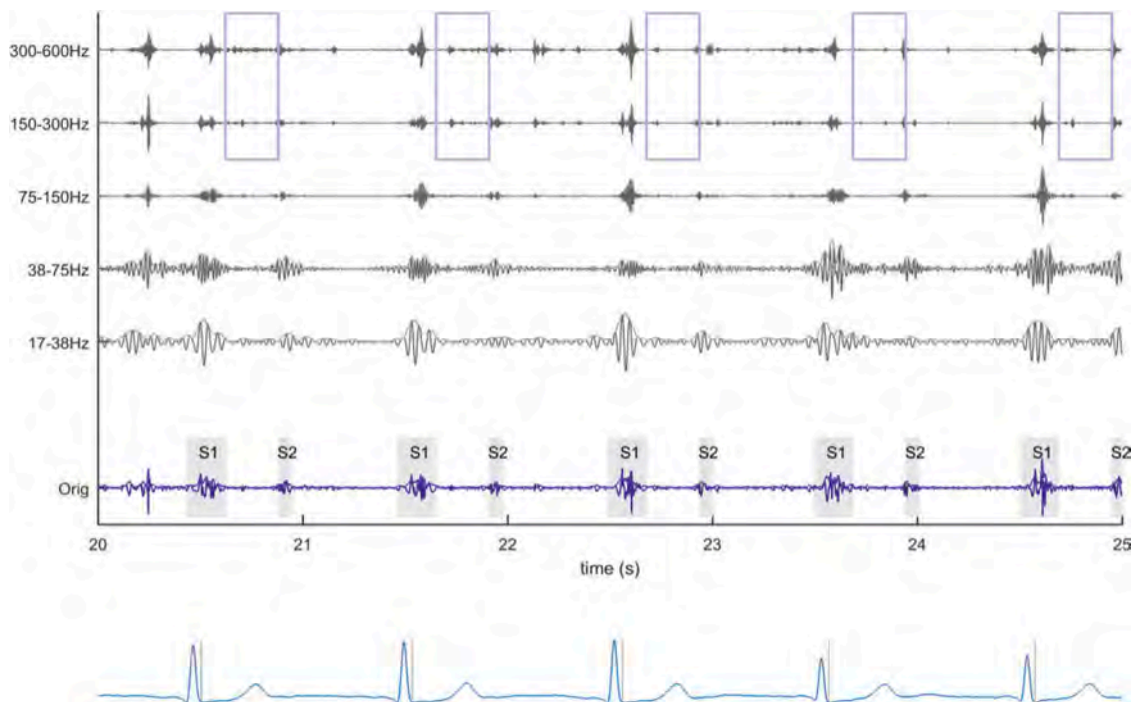
Table 1. A and B. Algorithm interpretations of recorded heart rhythms in categories. US (A) and EU (B).

A.Category description US	
0	Poor quality
1	Normal
2	Suspected atrial fibrillation. Irregular rhythm without P-waves.
3	Unclassified deviation from sinus rhythm

B.Category description EU	
0	Poor quality
1	Normal
2	Suspected atrial fibrillation. Irregular rhythm without P-waves.
3	Pause/AV block II
4	Fast, regular
5	Long-short sequences
6	Bigeminy
7	Trigeminy
8	More than 5 premature atrial complexes
9	More than 5 premature ventricular complexes
10	Irregular rhythm with P-waves

2.4. Phonocardiogram

The Coala Heart Monitor records heart sounds and ECG synchronously. The current system presents patient data in a phonocardiogram where an algorithm aids for the detection of murmurs, by identifying for noise disturbances between S1 and S2, see Figure 3. The data will in a future release also be calculated and displayed to follow systolic time intervals (STI) to get a noninvasive indicator of left ventricular systolic function.

Frequent use of the Coala Heart Monitor offers the opportunity to track STI in patients regularly in a home environment and potentially improve management and personalize the therapy of heart failure patients.

2.5. Portal interface

In the Coala Care Portal interface, individual patients´ results of recordings are available as an overview and recordings with algorithm diagnoses deviating from normal SR can be sorted out for manual interpretation if indicated.

The physician can send messages via the portal to individual patients commenting on algorithm diagnosis if necessary or make recommendation for further evaluation or consultations depending on arrhythmia.

A summarized patient report can be retrieved for all the patient´s recordings or recordings during a specific time period. Data will be displayed as diagrams showing a timeline of normal and deviating results, detected rhythm categories and a pie chart showing the distribution of categories, representative ECG examples of recorded rhythms as well as some other data, see Figure 4.

2.6. ECG interpretation algorithm – sensitivity and specificity for AF

In an evaluation study, the Coala Heart Monitor ECG algorithm was evaluated by manual interpretation of 1,000 consecutive anonymous printouts of chest and thumb ECG, without any exclusion [14]. The anonymized printouts were blinded from algorithm analysis, apart from gender and age within a 10-year span. The recordings were derived from actual Coala Heart Monitor users in Sweden during a defined time period. The prevalence of cardiac conditions in this user population was unknown. The blinded recordings were manually interpreted by a trained cardiologist.

Figure 3. Phonocardiogram and synchronously recorded ECG for measuring systolic time interval.
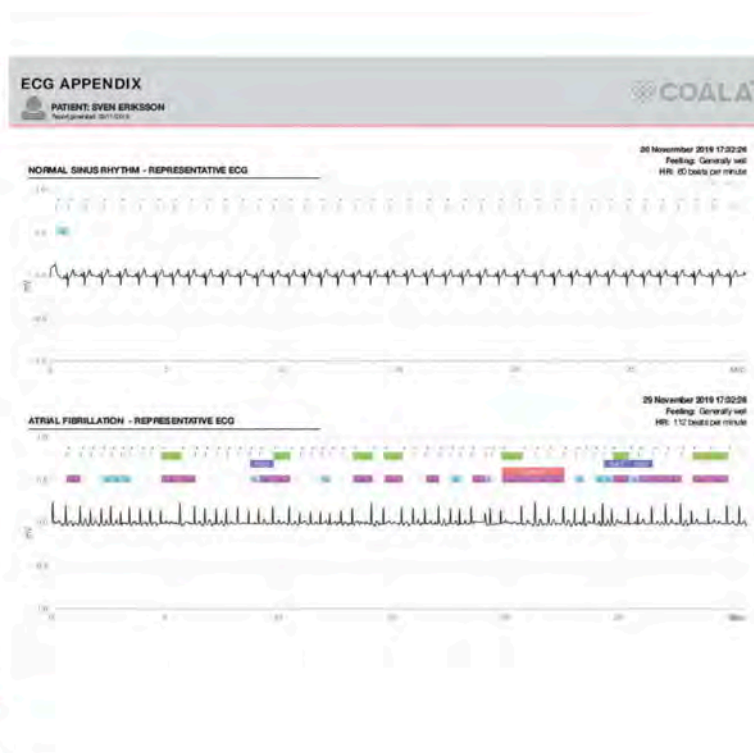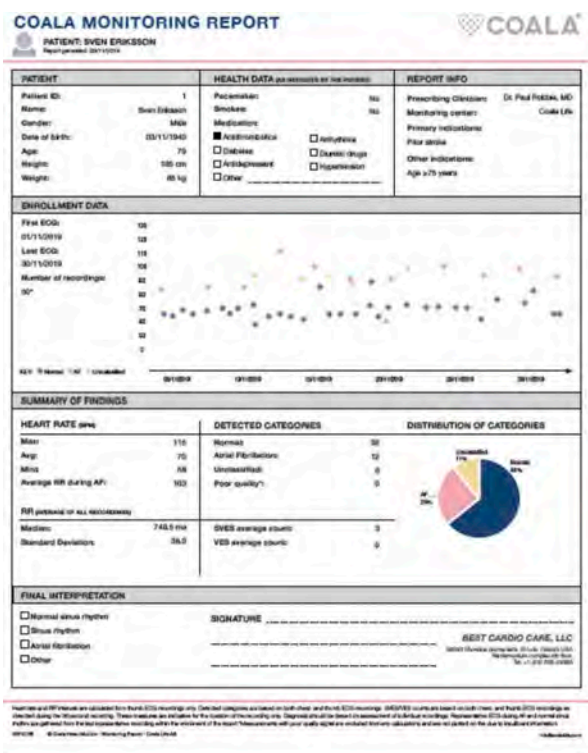
Figure 4. Coala monitoring patient report.

Table 2. Sensitivity, specificity, and predictive values for the current Coala algorithm in detecting atrial fibrillation.

Metrics	Results with current algorithm
Prevalence of AF in the recordings	14.4% (143 of 990 recordings)
Sensitivity for detecting AF	0.951
Specificity for detecting AF	0.976
Negative predictive value (NPV) for detecting AF	0.992
Positive predictive value (PPV) for detecting AF	0.872
Accuracy	0.973

The automatic analysis performed by the algorithm in the Coala Cloud was compared with manual interpretation by a trained cardiologist [14]. AF = atrial fibrillation.

The interpretation was compared with the automatic analysis performed by the algorithm in the Coala Cloud to evaluate ECG signal performance and calculate performance metrics. The sensitivity and specificity for detecting AF were 0.95 and 0.98, respectively, see Table 2.

2.7. Available studies

After recently been approved as a medical device by EMA and FDA, studies using the Coala Heart Monitor have so far been presented as abstracts at ESC, AHA, and other meetings [14–18].

The Red Heart Study, first results reported at ESC 2019, was carried out in 913 women with palpitations causing anxiety [17,18]. The Red Heart Study was designed 1) to investigate what underlying arrhythmias could be found in women with symptomatic palpitations and 2) to explore if an instant online feed-back rhythm diagnosis during palpitation when you record ECG will decrease anxiety and improve health-related quality of life (HRQoL). Participants were between 21 and 88 years old and included from all parts of Sweden. Exclusion criteria were previously known AF, atrial flutter, or known PSVT.

The participants used a Coala Heart Monitor for 2 months and were instructed to record ECG during symptomatic palpitations but were also encouraged to regularly record ECG morning and evening regardless of symptoms for 60 days. At baseline and after 60 days of ECG monitoring, several questionnaires covering symptoms and HRQoL were answered.

During the study period, over 200 000 ECG recordings (both chest and thumbs) were performed by the participants in their home, at work, or during other common activities.

In all, 93% of the participants who concluded the study performed 50 recordings or more during the 2 months study period and 73% performed 100 recordings or more. With very few exceptions, participants had no problem handling the Coala Heart Monitor. In 94% palpitations were caused by sinus tachycardia, PAC or PVC. The results showed that instant analysis of the ECG with direct response during palpitations reduced symptoms and was associated with higher HRQOL in women.

The TEASE study investigates the incidence of newly diagnosed AF during 28 days of chest and thumb ECG in patients after a cryptogenic stroke [19]. The secondary objectives are to assess HRQoL using SF-36 and the feasibility of the Coala Heart Monitor in patients after a stroke.

The primary endpoint is 28-day cumulative incidence of atrial arrhythmia at 28 days.

Secondary endpoints are the prevalence of previously known atrial arrhythmia before the inclusion in the study and the number of these patients who had anticoagulant therapy compliance with chest and thumb ECG at week 4 (number of recorded scheduled ECG tracings), patient-reported experience with chest and thumb ECG measured at week 6, HRQoL (SF-36) at week 6 and at 12 months and the association with AF and compliance with chest and thumb ECG, cumulative incidence of stroke after 3 years in patients with AF versus without AF, all-cause mortality after 3 years in patients with AF versus no AF. The results have recently been submitted for publication.

In a further study submitted, a novel RR- and P-wave-based automatic detection algorithm implemented in the Coala Heart Monitor was evaluated for detection accuracy by the comparison to blinded manual ECG interpretation based on real-world data. An evaluation was conducted on 100 consecutive anonymous printouts of the chest- and thumb-ECG waveforms, where the algorithm had detected both irregular RR-rhythms and strong P-waves in either chest or thumb recording (non-AF episodes classified by algorithm as an irregular rhythm with P-waves). This novel, P-wave-based automatic ECG algorithm, showed a 0% false negative error rate for AF detection in ECG recordings with RR-variability but the presence of P-waves, as compared to manual interpretation by a cardiologist.

3. Expert opinion

During the last years, small ECG recording devices connected to smartphones have become available to affordable costs for patients. It is reasonable to believe that the number will increase dramatically in the future in parallel with privately owned blood pressure monitors.

We are convinced this will cause a paradigm shift in diagnosing arrhythmias. Instead of consulting a health-care giver due to palpitations and start evaluation with Holter monitoring or the use of other devices, patients will consult their physicians for palpitations but at the same time bring with them ECG recordings printed from pdfs with documented arrhythmias.

It is reasonable to presume that patients with paroxysmal AF or supraventricular tachycardias will get correct diagnoses and adequate treatments much sooner as privately owned handheld ECG devices increase in number. Furthermore, these devices should be excellent tools to better evaluate treatment strategies for AF by monitoring patients long-term following drug therapy, ablation, or other procedures.

Another group of individuals that may benefit from these devices are those suffering from stress, nervousness, or anxiety caused by palpitations, which in most cases are due to benign sinus tachycardia or PAC/PVC [18]. Documenting the benign nature of their palpitation should have the potential to improve their symptoms [17].

The incidence and prevalence of AF may be vastly underestimated because until recently no reliable and accurate way existed to monitor patients who were not at specific risk for AF.

Handheld ECG devices offer excellent opportunities to gather real-world data on AF from both general and specific populations and receive better data regarding the actual incidence and prevalence of AF in the general population [13].

3.1. Five-year review

According to information received from the company, Coala Life is running several development projects to further enhance the algorithms for accurately detecting AF, expand the indications, and enable predictive detection of AF but also in enabling early detection of deterioration in heart failure patients. The Coala Heart Monitor records the heart sounds synchronously with the ECG, enabling the ability to follow systolic time intervals and by use of a personalized heart model powered by AI to learn and track the progression of STIs. This may provide abilities for early detection and warning well before the user experience any symptoms. The integrated digital stethoscope also offers additional abilities to record and analyze other organ sounds such as pulmonary sounds.

The Coala algorithms are currently in AI-training, and with the help of personalized neural networks, the Coala may have the potential to predict the new onset of AF. As the database of cardiac data continues to exponentially grow, this opens the abilities to further analyze the ECG with precision and accuracy that will reduce the false positive tracings.

The Red Heart Study proved the first insights that patient-centric ECG monitoring with instant response has benefits on symptoms and quality of life. A vision for Coala Life is to develop the Coala Heart Monitor to a digital therapeutic solution, ultimately classed as a prescription-based digital medicine for people troubled by arrhythmias.

4. Limitations

Results and conclusion regarding the efficacy of the Coala Heart Monitor are solely based on presented abstracts and ongoing studies and should consequently be read with some caution.

Declaration of Interest

The authors have no relevant affiliation or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript.

Reviewer Disclosures

One peer reviewer has participated in a research project using the Coala Monitor. Peer reviewers on this manuscript have no other relevant financial relationships or otherwise to disclose.

References

1. Mittal S. Smartphone-based electrocardiographic and cardiac implantable electronic device monitoring. Cardiol Rev. 2017 Jan-Feb;25(1):12–16.
2. Garabelli P, Stavrakis S, Po S. Smartphone-based Arrhythmia monitoring. Curr Opin Cardiol. 2017 Jan;32(1):53–57.
3. Guzik P, Malik M. ECG by mobile technologies. J Electrocardiol. 2016 Nov–Dec;49(6):894–901.

4. Musa T, Darrat Y, Etaee F, et al. Gender differences in management of patients undergoing catheter ablation of atrioventricular nodal reentry tachycardia. Pacing Clin Electrophysiol. 2019;42:937–941.

5. Carnlöf C, Iwarzon M, Jensen-Urstad M, et al. Women with PSVT are often misdiagnosed, referred later than men, and have more symptoms after ablation. Scand Cardiovasc J. 2017;51:299–307.

6. Dilaveris PE, Kennedy HL. Silent atrial fibrillation: epidemiology, diagnosis, and clinical impact. Clin Cardiol. 2017;40(6):413–418.

7. Healey JS, Alings M, Ha A, et al. Subclinical atrial fibrillation in older patients. Circulation. 2017;136(14):1276–1283.

8. Sandgren E, Rorsman C, Edvardsson N, et al. Stroke incidence and anticoagulation treatment in patients with pacemaker-detected silent atrial fibrillation. PLoS One. 2018;13(9):e0203661.

9. Ding M, Qiu C. Atrial fibrillation, cognitive decline, and dementia: an epidemiologic review. Curr Epidemiol Rep. 2018;5(3):252–261.

10. Dietzel J, Haeusler KG, Endres M. Does atrial fibrillation cause cognitive decline and dementia? Europace. 2018;20(3):408–419.

11. Cheng W, Liu W, Li B, et al. Relations of anticoagulant therapy with cognitive impairment among patients with atrial fibrillation: a meta-analysis and systematic review. J Cardiovasc Pharmacol. 2018;71:380–387.

12. Friberg L, Rosenqvist M. Less dementia with oral anticoagulation in atrial fibrillation. Eur Heart J. 2018;39:453–460.

13. Magnusson P, Samuelsson M, Pergolizzi JV Jr, et al. Atrial fibrillation and the role of thumb ECGs. Intechopen. 2019 Feb 28. DOI:10.5772/intechopen.83660.

14. Olson A. Symptom-ruled real-world arrhythmic recordings with an internet-based system. Abstract 12893. Circulation. 2018;138(Suppl 1). Available from: www.ahajournals.org/action/doSearch?AllField=olson+a

15. Olsson A, Samuelsson M Performance evaluation of dual vs. single lead automatic, real-world arrhythmic ECG recordings. Presented at the European society of cardiology ESC congress; Paris, France; 2019.

16. Olsson A, Samuelsson M Evaluation of an enhanced, cloud-based AF-detection algorithm based on real-world arrhythmic. Presented at the European society of cardiology ESC congress; Paris, France; 2019.

17. Carnlöf C, Insulander P, Jensen-Urstad M, et al. Instant analysis of the ECG with a new digital technique during palpitations reduces symptoms, anxiety, depression, and increases HRQOL in women. Presented at the European society of cardiology ESC congress; Paris, France; 2019.

18. Insulander P, Carnlöf C Jensen-Urstad, et al. Symptomatic palpitations causing anxiety in women, what are the underlying arrhythmias? Presented at the European society of cardiology ESC congress; Paris, France; 2019.

19. Magnusson P, Koyi H, Mattsson G. A protocol for a prospective observational study using chest and thumb ECG: transient ECG assessment in stroke evaluation (TEASE) in Sweden. BMJ Open. 2018;8(4):e019933.