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Sensitivity and specificity of handheld one lead ECG detecting atrial fibrillation in an outpatient clinic setting

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ABSTRACT

Aims: To validate the sensitivity and specificity of the Zenicor One handheld ECG device for detection of atrial fibrillation in an outpatient clinical setting.
Methods and results: Patients attending outpatient clinics at Danderyd Hospital ($n = 220$) were examined with one lead handheld ECG immediately after standard care 12-lead ECG recording. Twelve recordings were excluded (atrial flutter or pacing) or missing. The recordings were dichotomously categorized as "atrial fibrillation" or "not atrial fibrillation" by two senior cardiologists. In cases of diverging interpretations, a third senior cardiologist had the deciding vote. Sensitivity and specificity in diagnosing atrial fibrillation was calculated with 12-lead ECG as gold standard.
Sensitivity and specificity for diagnosis of atrial fibrillation with one lead handheld ECG and 12-lead ECG as gold standard was 98% and 99% respectively.
Conclusion: In a health-care outpatient setting, Zenicor One handheld ECG had high sensitivity and specificity for detection of atrial fibrillation when compared with 12-lead ECG.

Background

Atrial fibrillation (AF) is a major cause of morbidity and mortality worldwide. The prevalence of AF in adults is estimated to be thirty-seven million individuals globally [1]. AF has been estimated to cause 10–12% of all ischemic strokes [2]. Since many patients have unspecific or no symptoms (silent AF) [3], and as the risk of stroke can be effectively reduced by anticoagulation, screening for AF in high-risk populations and patients with suspected arrythmias should be considered according to current guidelines. [4]

For the last one or two decades, several new long-term ECG recording modalities have been developed, as options to traditional Holter long-term ECG [5]. Handheld ECG, where the ECG signal is acquired from the upper extremities of the recording individual, is one of the major novel ambulatory ECG modalities. With its relatively low cost and freedom from permanent attachment to the studied individual, handheld ECG has gained widespread use within clinical practice and clinical trials [5–7].

The handheld ECG device Zenicor I was introduced in 2004, and recorded a one-lead ECG strip of 10 s. A completely revised device (Zenicor EKG-2, recently renamed Zenicor One) was introduced in 2010 with the capability of recording a 30-s one-lead ECG using lead I. Zenicor I have been proven to have a high sensitivity (96%) and specificity (92%) for detection of atrial fibrillation [6]. Several large-scale AF screening studies have used the current Zenicor One (previously Zenicor EKG-2) handheld device [7,8]. However, its feasibility for diagnosing AF has not been proven in a controlled outpatient setting.

We report the diagnostic performance of the Zenicor One device studied in a controlled office setting and compared with 12-lead ECG recordings.

Method

The Zenicor One (Fig. 5), produced by Zenicor medical systems AB, is a CE marked (MDD class IIa) ECG device. It is a portable handheld device which register a one lead (lead I) ECG for detection of arrhythmia (Figs. 2 and 3). Patients record 30 s of ECG by placing both handhelds on the device. The ECG recording is, by a single click on the ECG device, encrypted transferred via cellular network to a cloud database. The device has a capability of storing 200 thirty-second recordings when

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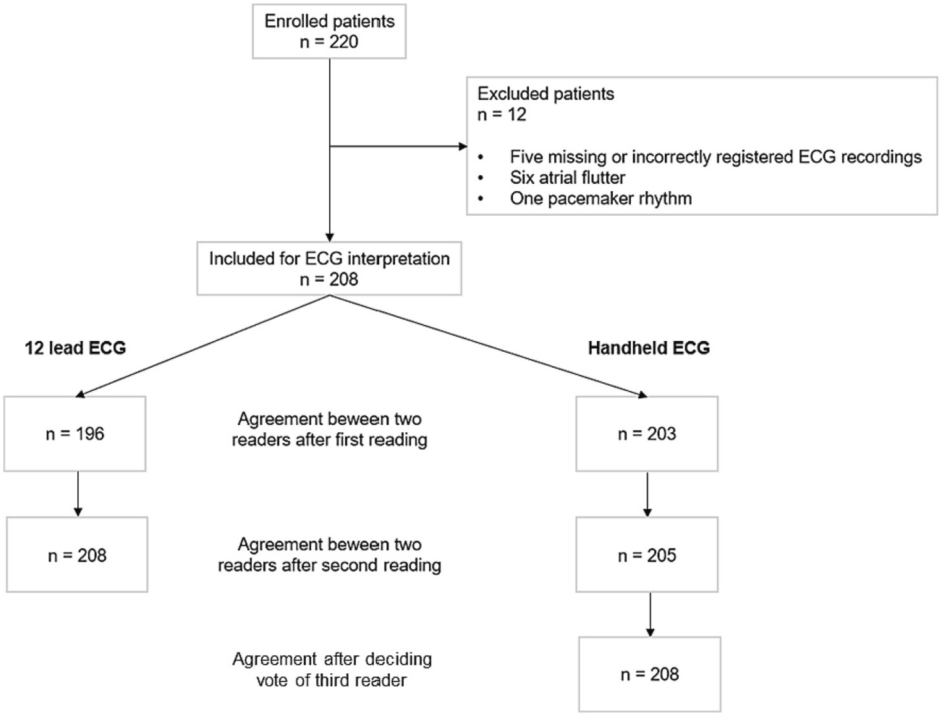

Fig. 1. CONSORT flow diagram illustrating inclusion of patients and the process of ECG interpretation by three senior cardiologists.

offline.

The advantage of handheld ECG compared to the gold standard 12-lead ECG is the feasibility of repeated recordings over extended periods of time to detect intermittent arrythmias. Disadvantages of handheld ECG in detecting arrythmias are information from only one ECG lead and in general less reliable quality of the recordings compared to 12-lead ECG. The p-wave is not always readily detectable in lead I.

Patients visiting Danderyd University Hospital in Stockholm were

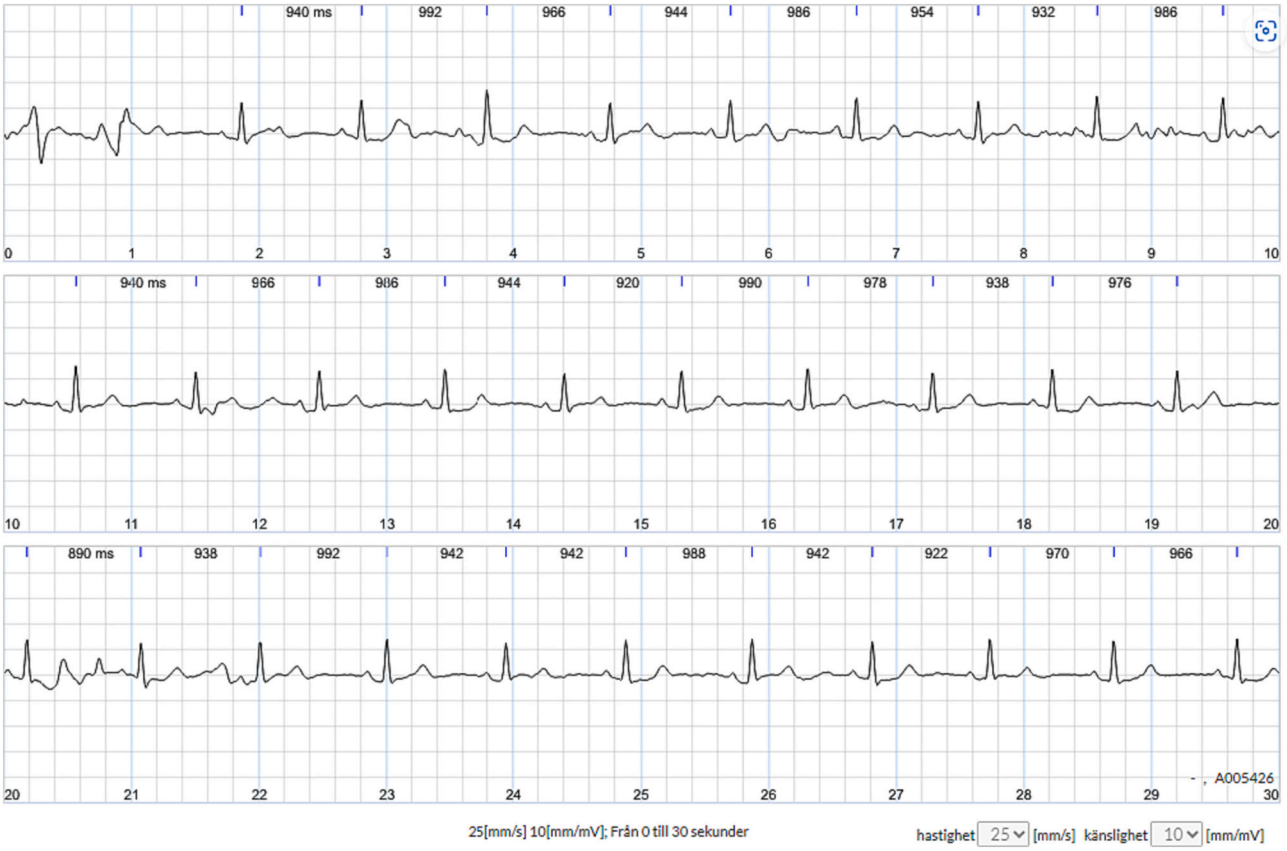

Fig. 2. Handheld ECG sinus rhythm.

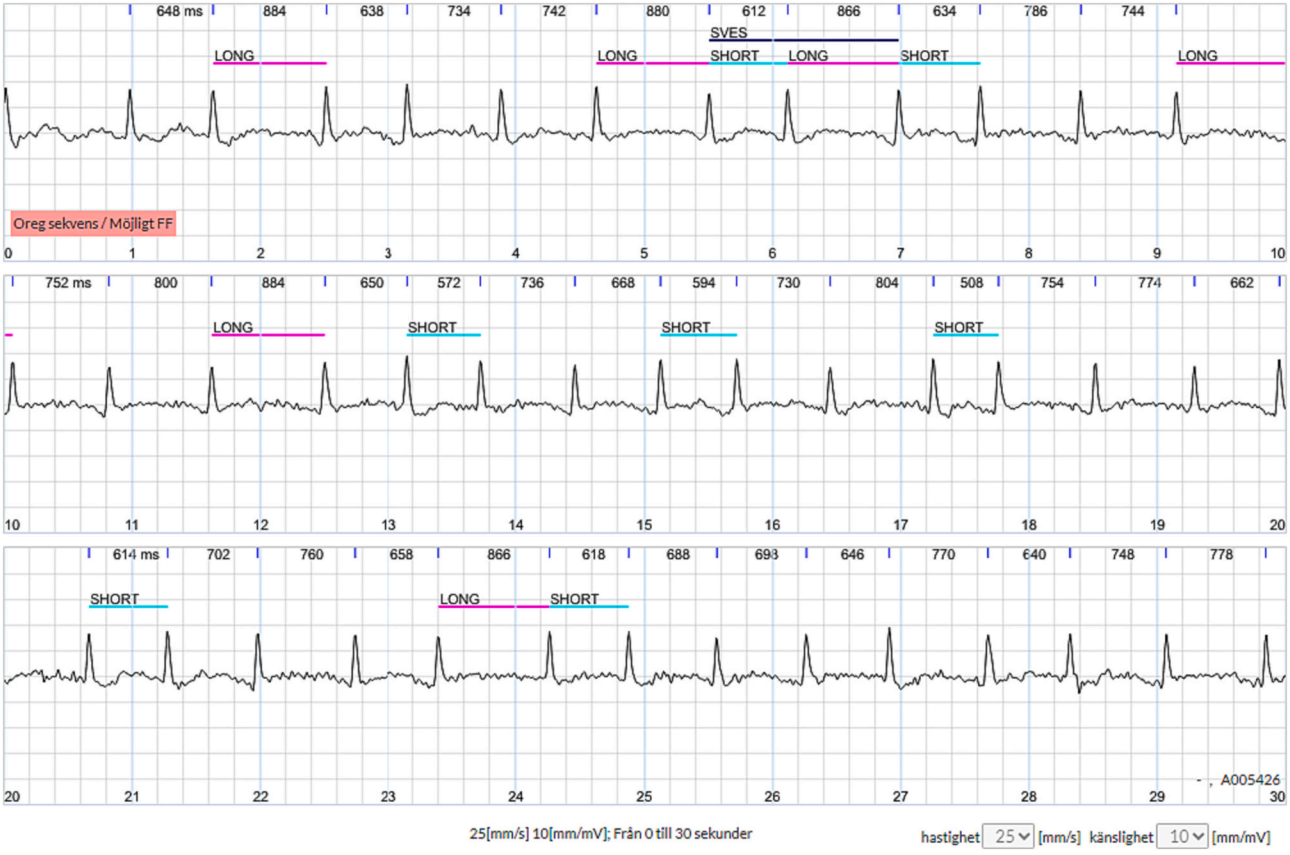

Fig. 3. Handheld ECG atrial fibrillation.

included in the study. Half of the included patients attended the Department of Cardiology for a scheduled electrical cardioversion and the remaining 110 patients visited the Department of Clinical Physiology, predominantly for acquisition of preoperative ECGs. Most ECGs obtained prior to electrical cardioversion were expected to show atrial fibrillation while most of the ECGs from the Department of Clinical Physiology were expected to show sinus rhythm, why a prevalence of atrial fibrillation in the study population was assumed to become approximately 50%. Patients with implantable cardiac devices were excluded from participation in the study. The study cohort size was estimated from a previously published nomogram [9].

The study has been approved by the Swedish Ethical Review Authority (Dnr 2022–02121-01). Written consent was collected from all participants. Instructions for use of the device was given by JM to all participants. A 30-s one lead ECG was recorded immediately after the standard care 12-lead ECG recording (Cardiolex EC Sense). Both 12-lead ECGs and one-lead ECGs were pseudonymized and stored digitally in pdf format.

Table 1
Sensitivity and specificity of one lead handheld ECG with 12 lead ECG as gold standard.

12 lead ECG \ 1 lead handheld ECG	AF	SR
AF	98% (n = 106)	2% (n = 2)
SR	1% (n = 1)	99% (n = 99)

12-lead ECG and handheld ECG recordings were interpreted independently by two senior cardiologists (JE and PD) with extensive experience in one-lead ECG reading. Recordings were dichotomously categorized as “atrial fibrillation” or “not atrial fibrillation”. If the two cardiologists disagreed on rhythm diagnosis, they were allowed to review the recordings independently of each other once more. If the interpretations still diverged after this second reading a third senior cardiologist (GS) had the deciding vote. Patients with atrial flutter were excluded from the analysis. Sensitivity and specificity in diagnosing atrial fibrillation with the Zenicor one lead ECG was calculated with 12-lead ECG as gold standard.

The Zenicor One device has an optional feature of recording a second lead ECG tracing (lead II) which may in some cases improve the diagnostic quality. Recording of a lead II tracing does however require application of an extra electrode, which makes the recording more complex and is not used in clinical at our hospital. We therefore choose to only evaluate the standard one lead handheld ECG.

Continuous variables were reported as mean + − SD. Binary variables were reported as percentage. Diagnostic performance was calculated using 2 × 2 table and standard definitions of sensitivity and specificity.

Results

Patients were included between June 14, 2022 and May 31, 2023. Out of 220 patients initially enrolled in the study, 12 were excluded

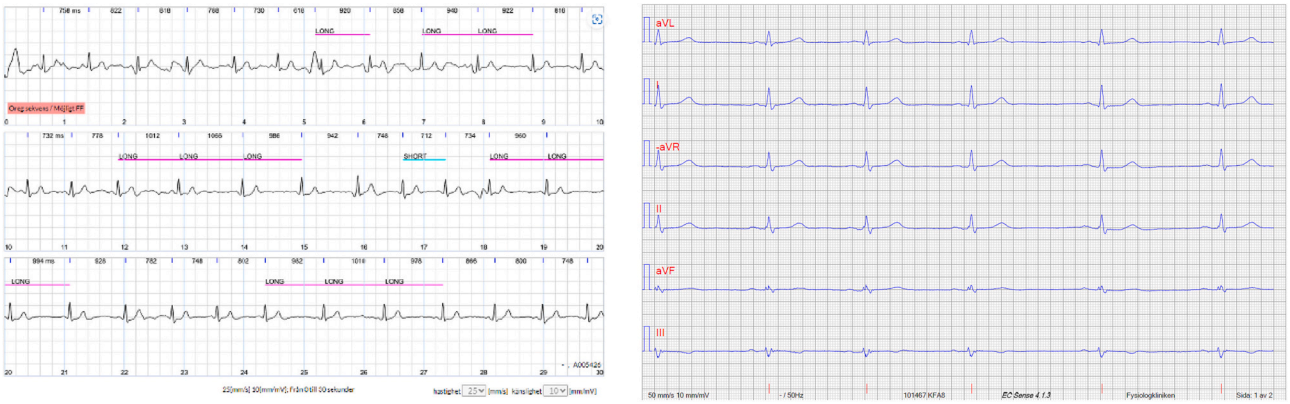

Fig. 4. The only false positive handheld ECG in a patient with sinus arrhythmia.



Fig. 5. Zenicor One handheld ECG device.

before analysis (5 with missing or incorrectly registered handheld ECG recordings, 6 with atrial flutter and one with pacemaker rhythm). The average age of enrolled patients was 70 years (range 29–93 years), 44% were female and 52% of 12-lead ECGs showed atrial fibrillation.

The two cardiologists' interpretations of the 208 12-lead ECGs initially diverged in 5/208 (2%) cases, after independent re-review of these five ECGs all the interpretations matched. Interpretation of handheld ECGs initially diverged in 12/208 (6%) cases and after re-review three unmatching recordings remained which were evaluated by the third cardiologist. (Fig. 1).

There were two false negative and one false positive (Fig. 4) handheld ECG. Sensitivity and specificity for diagnosis of atrial fibrillation with one lead handheld ECG and 12-lead ECG as gold standard was 98% (95% CI 93,5%-99,8%) and 99% (95% CI 94,6%-99,97%) respectively. (See Table 1.)

Discussion

We report high diagnostic performance of the Zenicor One handheld one-lead ECG device as compared to 12-lead ECG in an outpatient setting. The arrhythmia analysed against sinus rhythm was atrial fibrillation, the arrhythmia most relevant for large-scale arrhythmia screening.

As handheld and wearable ECG devices are gaining popularity and availability for atrial fibrillation screening, it is important to assess the diagnostic quality of such devices. Consistent with previous validation studies of similar devices [6,10–13], the current study shows excellent sensitivity and specificity of the current handheld ECG device in an outpatient clinical setting.

The diagnostic performance of the Zenicor One device reported here is in line with the levels reported in the meta-analysis by Wong et al. [14]. In this meta-analysis, studies performed in the community showed lower diagnostic performance in general. However, this meta-analysis studied the performance of the automated ECG reading algorithms, our study used manual reading.

The current study did not evaluate the device's automatic diagnostic algorithm. Previous studies of various such automatic algorithms have in general shown less diagnostic accuracy compared to manual readings. [5,14–16]

It is important to note that all three cardiologists involved in ECG interpretation are heart rhythm specialists and possess extensive experience in reading handheld ECGs. A significant number of both 12-lead ECGs and handheld ECGs were initially interpreted different by the readers. This could be considered to highlight the value of team assessment in diagnostic procedures in general, which may not always be done in real-life clinical practice. [17] Further, the skills and experience of the reader should always be taken into account when using ambulatory ECG devices, in particular one-lead ECG settings which has been appreciated to be challenging. A review of usefulness, pitfalls and interpretation of handheld single lead electrocardiograms has previously been published. [18]

Limitations

Handheld ECGs were recorded in a controlled setting immediately after instructions which may not fully generalize to recordings in a home environment. In a meta-analysis Wong et al. [14] found significant variation of diagnostic accuracy of handheld one lead ECG devices in community versus hospital settings.

This study could by design be seen as a case control study and the positive and negative predictive value of handheld ECG for detection of atrial fibrillation cannot be calculated without the knowledge of atrial

fibrillation prevalence in any given clinical context.

Conclusion

In a health-care outpatient setting, Zenicor One handheld ECG had high sensitivity and specificity for detection of atrial fibrillation when compared with 12-lead ECG.

CRediT authorship contribution statement

Johan Malmqvist: Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Johan Engdahl:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Gunnar Sjölund:** Investigation. **Piotr Doliwa:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation.

Declaration of competing interest

Johan Engdahl has received consultant or lecture fees from Roche Diagnostics, Pfizer, Bristol Myers Squibb, Organon, Piotrode and Philips. Research grants from the Swedish Research Council, The Swedish Heart&Lung Foundation, The Swedish Innovation Agency and The Stockholm Region.

Other authors have nothing to declare.

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