

Prospective, multicentre validation of a simple, patient-operated electrocardiographic system for the detection of arrhythmias and electrocardiographic changes

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Aims

Electrocardiographic changes, e.g. arrhythmias causing syncope or palpitations, are often transient and therefore difficult to diagnose. Systematic and symptom-activated ECG recordings can increase diagnostic yield in such patients. We evaluated the diagnostic accuracy of a simple, leadless, patient-operated ECG device compared with a standard 12-lead ECG.

Methods and results

We recorded a standard 12-lead surface ECG and a patient-activated ECG in direct succession in 508 consecutive patients enrolled in four centres. All ECGs were analysed by a single, blinded observer. ECGs were analysable in 505 (99.4%) patients (66% male, age 61 ± 15 years, and body mass index 27 ± 4). Analysis of the patient-activated ECG adequately detected a normal ECG (sensitivity 91% and specificity 95%), atrial fibrillation (AF) (sensitivity 99% and specificity 96%), and even T-wave abnormalities (sensitivity 90% and specificity 75%). Diagnostic accuracy for atrio-ventricular nodal block was moderate (sensitivity 79% and specificity 99%). Continuous parameters correlated well: ($r^2 = 0.89$ for heart rate, 0.83 for PR interval, 0.78 for QRS duration, and 0.89 for QTc).

Conclusion

Recordings made by this patient-operated ECG device allow to detect arrhythmias and other ECG changes with high accuracy compared with a standard ECG. It may help to improve accurate diagnosis of transient ECG changes such as paroxysmal AF in palpitations or other unexplained cardiac symptoms.

Keywords

ECG • Atrial fibrillation • Palpitations • Syncope • HeartScan • Patient activated • Patient triggered
• Event recorder

Introduction

The electrocardiogram (ECG) is one of the most important diagnostic tools in cardiology. It is useful in the evaluation of most cardiac diseases and an important screening tool for cardiac arrhythmias. Unfortunately, many clinically relevant ECG changes are transient, and therefore, the search for such changes can be lengthy and cumbersome, e.g. in the evaluation of paroxysmal arrhythmias such as atrial fibrillation (AF), or in patients with palpitations or syncope. Even conventional long-term Holter ECG

recordings often miss transient ECG changes.¹ This situation is aggravated by the poor relation between intermittent arrhythmias and symptoms.^{2,3} Detection of such transient ECG changes often has therapeutic implications, e.g. when paroxysmal AF is found in patients at risk for stroke,⁴ when intermittent higher-degree atrio-ventricular (AV) nodal block is documented,⁵ or when supraventricular tachycardias (SVTs) amenable to catheter ablation are recorded.⁶ There is good evidence from clinical trials that patient-activated short-term ECG recordings increase the diagnostic yield of ECG monitoring in such patients.^{2,3,7} Most available recording

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systems require telemetric ECG transmission and a central analysis platform. A simple, patient-activated ECG recording system would allow a wider-spread use of such technologies in clinical practice. We therefore evaluated the diagnostic yield of a patient-activated, 'leadless' ECG device (Omron HeartScan HCG-801-E[®]) in comparison to a standard 12-lead surface ECG.

Methods

The leadless patient-activated electrocardiographic system

The Omron HeartScan 801[®] device is a lightweight, handheld ECG recording system with LCD display and digital storing capacity for offline, digital analysis⁸ (height 121 mm, width 67 mm, depth 24 mm, and weight 130 g). It records 30 s of a single-channel ECG. The ECG is recorded as the potential between two stainless-steel electrodes integrated into the surface of the device. The device is ready to record a few seconds after turning it on. For ECG recording, the lower surface of the device, which contains one electrode, is attached to the chest. The index finger of the right hand holds the device. This finger is in contact with the second electrode (*Figure 1*). By pressing the start button, the recording is activated for 30 s. The end of the recording is indicated by an acoustic signal. The result can be viewed on the LCD display and uploaded to a PC-based analysis station by reading out the data from the storage card for further off-line analysis. The storage card itself (standard SD-card) has to be removed from the device for data transfer, whereas the files are suitable for, for example, email forwarding due to their small size (6 kB/30 s ECG). Theoretically, the amount of ECGs fitting onto the supplied storage card is >5000. One set of batteries lasts for ~400 ECG recordings.

Patients

Five hundred and eight patients were consecutively enrolled in the AFNET centres at the University Hospitals Hamburg, Magdeburg, Munich, and Münster from July 2007 to February 2008. All patients had a clinical indication for 12-lead surface ECG recording. Exclusion criteria were age <18 years and the presence of a pacemaker or implantable defibrillator. We documented age, weight, and gender. All consenting patients were shortly instructed in the use of the patient-activated ECG device and recorded a short-term ECG (30 s)

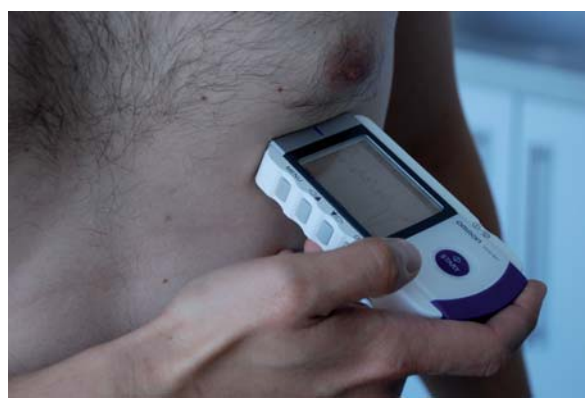


Figure 1 Photograph of the patient-operated ECG system during recording of an ECG.

immediately after the registration of a standard 12-lead ECG. The single-lead ECG recording device was positioned in proximity to the position of chest electrode C4. After the procedure, the patients reported the usability and handling using a standardized questionnaire. For external reviewing and evaluation, the ECG device produces a small data file which is stored on a standard memory card (SD-card). All ECG data files were pseudonymized, transferred to Münster (single-channel data files by Email, paper-written standard ECGs by mail), and analysed by a single, blinded observer (G.K.) for basic rhythm, intervals, amplitudes, and conduction and repolarization disturbances using the 'ECGViewer'-Software (Version 1.2.11) shipped by Omron with the device. All ECG analyses were blinded to the analysis result of the other ECG modality and to clinical information of the patient. We compared standard and patient-activated single-channel ECG by linear regression for continuous parameters (e.g. heart rate, QT, or PQ interval), and computed sensitivity and specificity for nominal parameters (e.g. detection of arrhythmias, bundle branch block, AV nodal block, and abnormalities of repolarization).

Results

Five hundred and five of the data sets (99.4%) were analysable for arrhythmias and ECG intervals. Two single-channel ECG recordings had insufficient technical quality; in one patient, insufficient clinical data were provided. Basic characteristics of the study population were: 66% male, mean age 61.4 ± 14.5 years (18–96 years), and mean body mass index 26.6 ± 4.3 . The patient-activated ECG system was simple to use for the patients. The mean rating was 1.83 (median rating 2) on a scale from 1 (very good) to 6 (unacceptable). The ECG quality was not different between old and young patients. The approval rating for the device was, however, slightly lower in patients >70 years (2.1 ± 1) than in patients <70 years (1.7 ± 0.75 , $P < 0.01$).

Arrhythmias, atrioventricular block, and other pathological findings

Three hundred and eighty of 505 12-lead ECGs (66%) were rated abnormal. Several patients had multiple abnormalities. Atrial fibrillation was present in 128 of 505 patients (28%), and other tachyarrhythmias such as atrial flutter, SVT, or other tachycardias were rarely identified. In addition, intraventricular conduction abnormalities such as complete or incomplete bundle branch block were identified in 137 patients (27%), AV block in 42 patients (8%), and abnormalities of T-wave (pre-terminal or terminal) in 223 patients (44%). Examples for a normal ECG recording, cardiac arrhythmias, and right and left bundle branch block are given in *Figure 2A–F*. Ninety-one patients (18%) had borderline findings and 78 (15%) patients had a normal ECG.

Normal sinus rhythm was almost always detected in the patient-activated ECG (sensitivity 97% and specificity 96%). The diagnosis 'normal ECG' was also detected correctly in the single-lead ECG (sensitivity 91% and specificity 95%).

Atrial fibrillation was the most common arrhythmia in the study population. It was detected with high accuracy (*Table 1*). Other arrhythmias were also adequately detected (premature atrial beats and SVTs). There were only a few patients with atrial flutter. The differentiation of atrial flutter and AF was not always easy in the single-lead ECG (*Table 1*) due to the fact that flutter

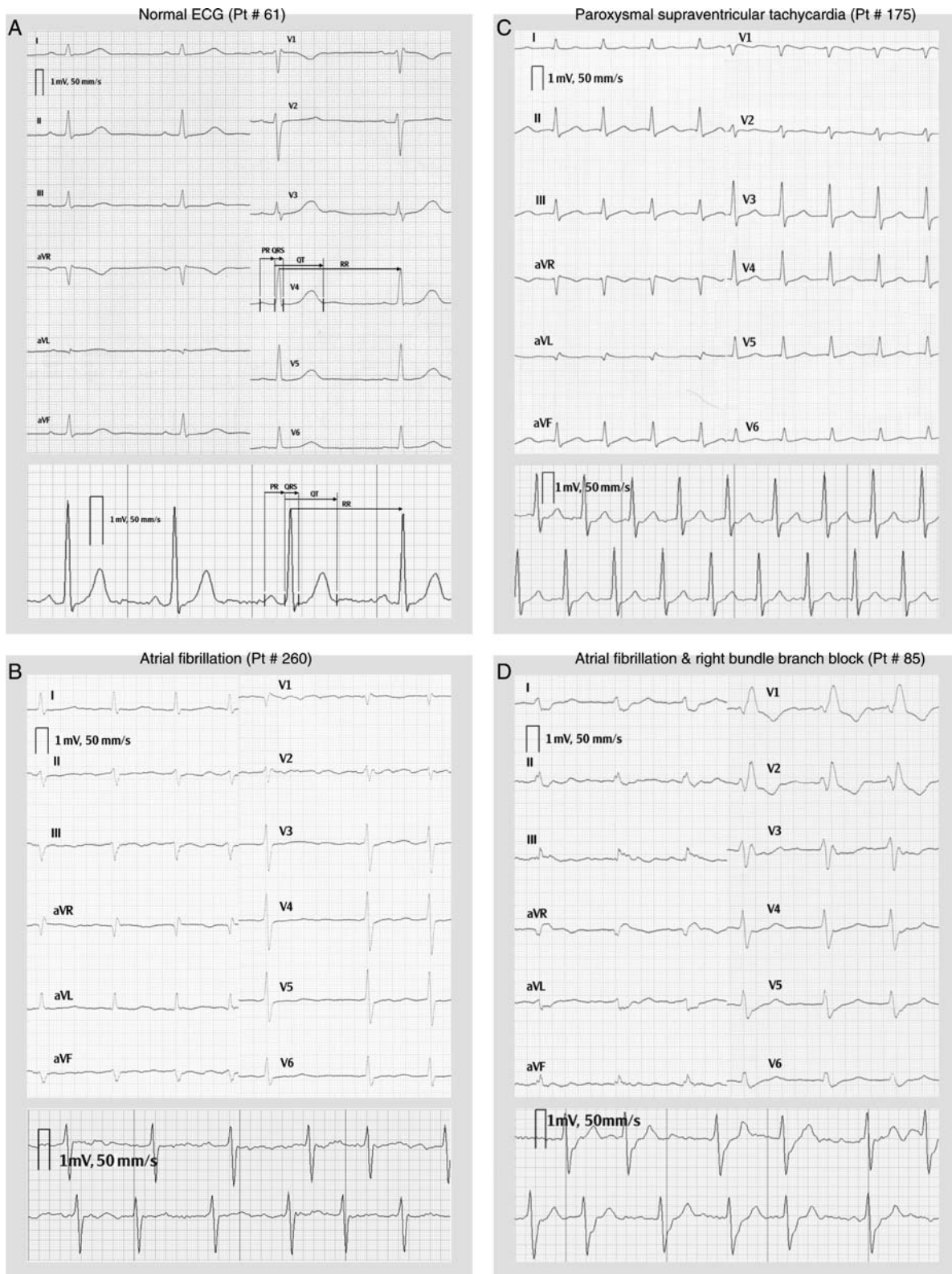


Figure 2 Six examples of patient-activated and standard six-lead ECG recorded in six patients during the study. (A) A normal ECG, (B) atrial fibrillation (AF), (C) a supraventricular tachycardia (SVT), (D) the characteristic signs of right bundle branch block in a patient who also presented with AF, (E) left bundle branch block, and (F) a non-sustained broad complex tachycardia that was only recorded in the patient-activated ECG due to the transient nature of the arrhythmia.

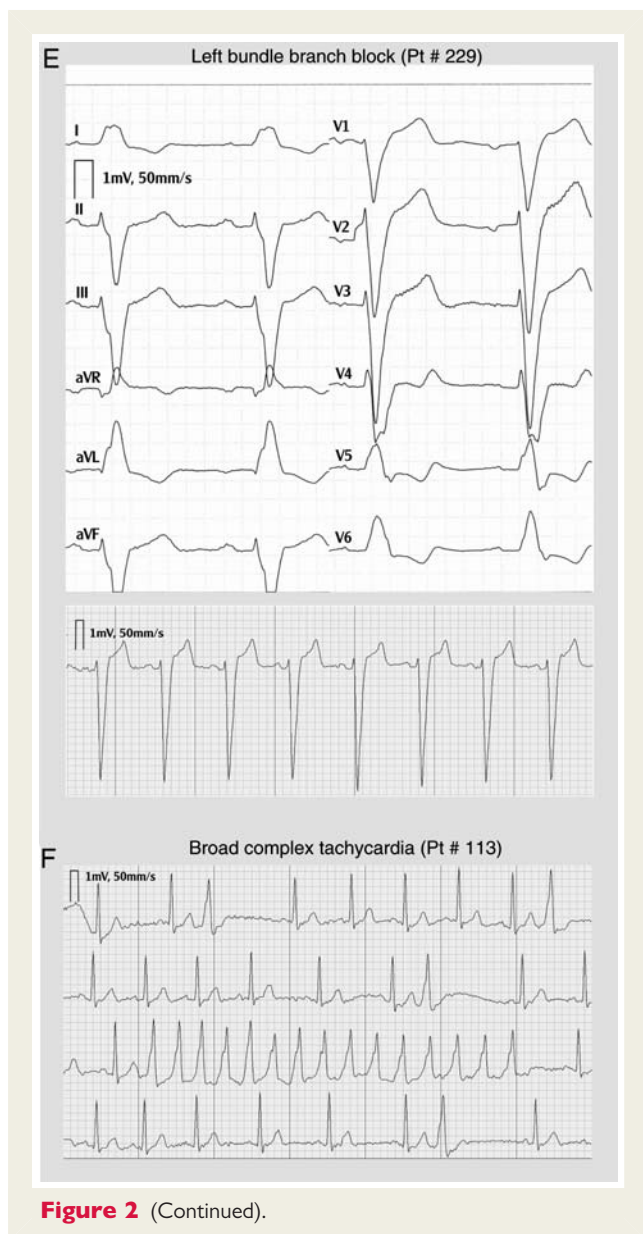


Figure 2 (Continued).

waves commonly are not present in the chest lead V4 which is approximated by the patient-operated ECG device.

Electrocardiographic intervals and bundle branch block

Electrocardiographic intervals could be adequately measured in the patient-activated ECG: heart rate showed an excellent correlation between standard and patient-activated ECG ($r^2 = 0.89$ in all ECGs), whereas PR interval, QRS width, and QT still correlated well, given the fact that a single-lead ECG recording was compared with the analysis of a 12-lead ECG. Except for T-wave amplitude ($r^2 = 0.77$), the correlation with other amplitudes (R/S), but also correlation with ST-segment, was weaker (Figure 3). Interestingly, typical right bundle branch block and left bundle branch block could be differentiated with moderate accuracy by a relatively typical QRS morphology that resembled the QRS morphology of bundle branch blocks in lead V4 in the 12-lead ECG (Figure 2E and F, correct diagnosis in 17/23 ECGs for left bundle branch block and in 22/39 for right bundle branch block). Considering the limitations of single-channel ECG, a correct diagnosis of bundle branch block with this device was primarily not expected.

Discussion

Main findings

This study demonstrates that a simple 'leadless' patient-activated ECG device can be used to detect cardiac arrhythmias, a major portion of conduction diseases, and repolarization abnormalities with high accuracy. Such a system can be helpful in the ambulatory evaluation of patients with palpitations or syncope and may help to identify asymptomatic AF.

Signal quality and validity of interpretation of the patient-activated electrocardiogram

The vast majority of single-channel ECGs (>99%) could be evaluated in terms of signal quality. In 506 of 508 patients, adequate

Table 1 Detection of arrhythmias and other abnormalities

	Sensitivity	95% CI	Specificity	95% CI	PPV	95% CI	NPV	95% CI
Normal ECG (n = 78)	0.91	0.82–0.97	0.95	0.92–0.97	0.79	0.69–0.88	0.98	0.96–0.99
Sinus rhythm (n = 343)	0.97	0.94–0.98	0.96	0.92–0.99	0.98	0.96–0.99	0.93	0.89–0.97
Atrial fibrillation (n = 143)	0.99	0.96–1.00	0.96	0.94–0.98	0.92	0.86–0.96	1.00	0.98–1.00
Atrial flutter (n = 11)	0.54	0.21–0.79	1.00	0.99–1.00	0.99	0.47–1.00	0.99	0.97–1.00
AV nodal block (n = 42)	0.79	0.63–0.90	0.99	0.97–1.00	0.85	0.70–0.94	0.98	0.96–0.99
QRS ≥ 0.12 s (n = 136)	0.62	0.53–0.70	0.97	0.95–0.99	0.88	0.80–0.94	0.87	0.84–0.90
ST deviation (n = 76)	0.63	0.44–0.79	0.95	0.91–0.97	0.53	0.36–0.69	0.96	0.94–0.98
T abnormalities (n = 223)	0.90	0.84–0.95	0.74	0.70–0.79	0.59	0.52–0.65	0.95	0.92–0.97

Correlation of the ECG-based diagnosis made in the single-channel patient-operated ECG and the standard 12-lead ECG. Sensitivity and specificity are very good for atrial fibrillation and sinus rhythm, and good (79%) for AV block. PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval.

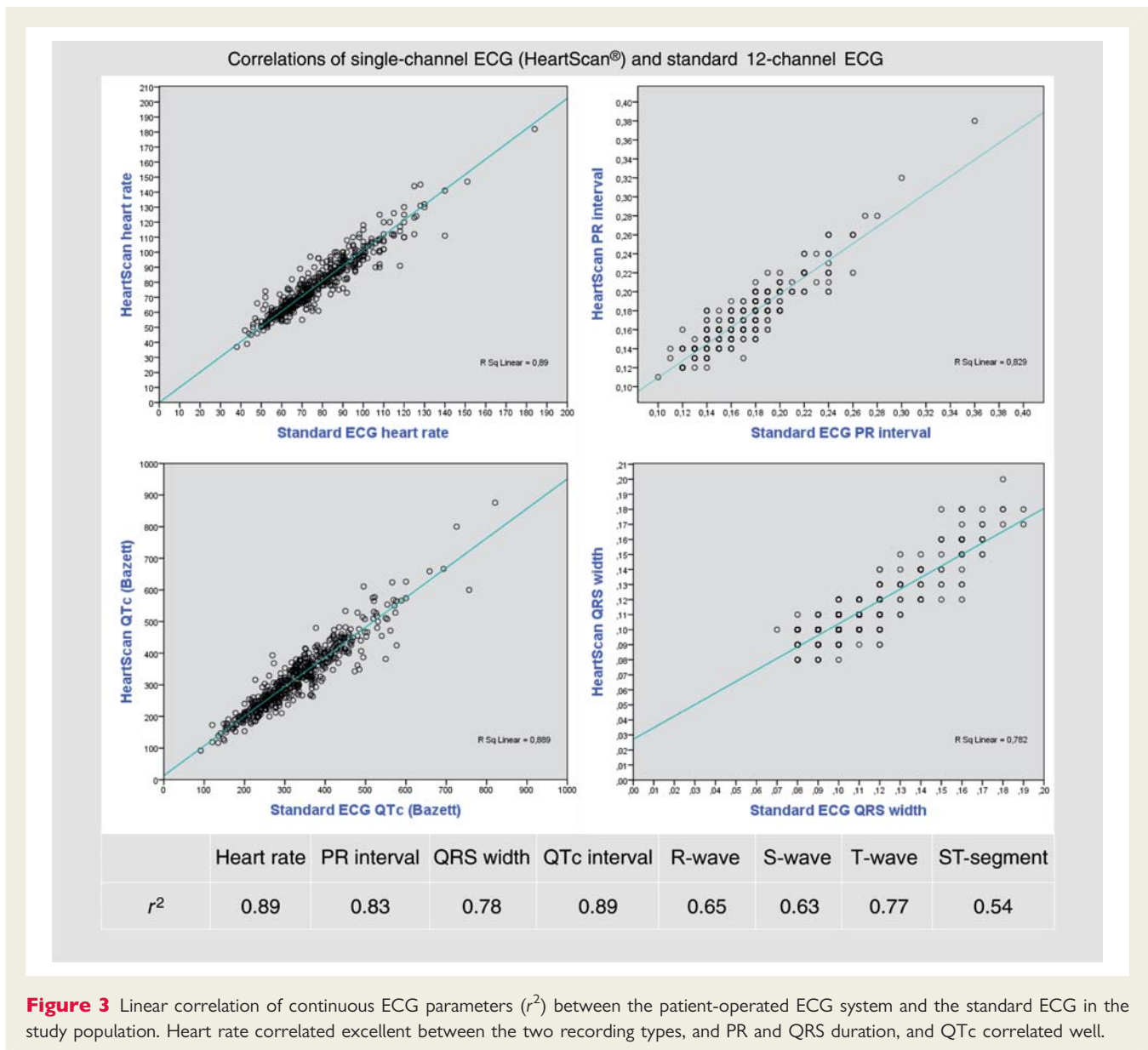


Figure 3 Linear correlation of continuous ECG parameters (r^2) between the patient-operated ECG system and the standard ECG in the study population. Heart rate correlated excellent between the two recording types, and PR and QRS duration, and QTc correlated well.

analysis of the ECG waveform was possible. In a smaller clinical evaluation study of the same device,⁸ the ECG recordings were rated as 'excellent' in 91% of the cases, only 3% were 'poor'. There was a trend towards better signal quality for the HeartScan than for the standard event recorder.⁸ The present study confirms that this simple, patient-operated, leadless ECG device provides high-quality ECG recordings. Adding more ECG leads may increase the possibilities to diagnose, e.g. bundle branch block with higher accuracy, but would probably reduce the ease of use of the system.

Comparison to other arrhythmia recorders

Patient-activated ECG event recorders are useful in the evaluation of patients with palpitations in primary care⁹ and appear to shorten the time to diagnosis when compared with conventional Holter

ECG recordings in patients with syncope and in other settings.^{10,11} Infrequent palpitations can be recorded by patient-activated monitoring systems in 75% of the patients, most often within the first 4 weeks.¹² Other symptoms (presyncope, chest pain, and dyspnoea) also showed a correlation to arrhythmias.^{8,13} On the other hand, documentation of sinus rhythm during symptoms can help to avoid costly and invasive diagnostic procedures.^{10,11,13,14} Patient-activated ECG systems are easy to use for these indications. In the evaluation of syncope, patients may not be able to activate the evaluated handheld device so that implantable loop recorders^{15,16} or event monitors with continuous skin contact may be more effective. But even in syncope patients, non-invasive tools with manual or automated trigger for ECG documentation have been proven to be useful, as well as in patients with negative workup or patients undergoing titration of antiarrhythmic drugs.¹⁷ Compared with other event recorders, this device can provide ECG documentation during unexplained

symptoms, e.g. palpitations, combined with high patient comfort due to mobility and the lack of external electrodes that have to be attached to the chest.

Potential use of patient-activated 'leadless' single-channel electrocardiographic recorders in clinical practice

Differential diagnosis of palpitations

Palpitations are a common reason to contact a physician, initially often a primary care physician. The diagnostic evaluation of palpitations usually comprises physical examination and non-invasive tests for structural heart disease (e.g. echocardiography and/or a stress test) and attempts to document the cause of palpitations by ECG.¹⁶ In this setting, the commonly used 24 h Holter ECG shows a relatively low diagnostic yield, due to the unpredictable and rare occurrence of ECG changes, especially in patients without structural heart disease.¹⁸ Electrocardiographic documentation of arrhythmias during occasional symptoms can be achieved by the device studied here. We expect that the ease of use of this system combined with the diagnostic yield of the patient-activated ECG when analysed by a physician, as demonstrated in our study, may facilitate diagnosis. This assumption requires further clinical testing.

Detection of asymptomatic atrial fibrillation

Atrial fibrillation is likely to be asymptomatic in at least half of the episodes,^{1–3,19} and ischaemic stroke or other complications are often the first clinical manifestation of asymptomatic AF.^{20–22} A simple, patient-activated ECG monitor would allow to screen for AF in high-risk patient groups, e.g. patients who would qualify for anticoagulant therapy if AF was present.²³ The device studied here could be used for simple, easy-to-use primary screening of outpatients at risk for AF.^{1,2,19} The system can be read out on any computer, does not need disposable materials such as electrodes, and can be fully operated by the patient after a short instruction. Then the diagnosis can be found quickly by the investigating physician. As such, this device may be a reasonable screening tool for asymptomatic AF. This should be evaluated in future studies. Similarly, the system may help to identify AF recurrences or to relate symptoms to arrhythmia recurrences, in AF patients.^{2,19} Fortunately, the accuracy of this single-lead device for detection of AF is very high. Combined with its usability, the device may close a gap in systematic evaluation of this arrhythmia in routine use but also in clinical studies.

Limitations of the study

Due to the need for immediate succession of standard and patient-activated ECG recording in this validation study, the patients used the device under observation of healthcare personnel. The yield of high-quality ECG recordings may be lower when the recording is not supervised. Another small study suggested, however, that the diagnostic yield of the device was also high in a non-supervised setting.⁸ Our report clearly invites further studies on the

reproducibility and practicability of patient-operated ECG systems under daily-life conditions.

The recording of the ECGs (first standard 12-channel ECG and single-channel ECG directly afterwards) was not at the same time as the leadless ECG recording to allow full patient operation of the device. During this short period of time (estimated 5–10 s), the waveform may have changed, as evident by the broad-complex tachycardia (Figure 2F) in the single-lead ECG system that was not recorded in the 12-lead ECG. The study design did not allow to repeat the recordings in a defined time interval because patients were recruited in daily routine procedures, so information about reproducibility of the results is limited.

Conclusion

The studied patient-operated single-channel ECG device has a high accuracy for detection of AF and other ECG changes in comparison with standard ECG. The practical application in the clinical setting was reliable. It is likely that ambulatory use of the device by patients without supervision by healthcare personnel might be feasible. Considering the evidence of daily and symptom-based ECG documentation for detection of intermittent arrhythmias, this device may be helpful in the identification of AF recurrence, in the diagnosis of unknown palpitations, or in the search for suspected rhythmogenic syncope. Therefore, it may be used for the identification of AF recurrences in clinical setting or study environment.

Conflict of interest: P.K. received honoraria from Omron. G.K. received travel grants from Omron to present the results of this study.

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References

1. Page RL, Wilkinson WE, Clair WK, McCarthy EA, Pritchett EL. Asymptomatic arrhythmias in patients with symptomatic paroxysmal atrial fibrillation and paroxysmal supraventricular tachycardia. *Circulation* 1994;**89**:224–7.
2. Fetsch T, Bauer P, Engberding R, Koch HP, Luki J, Meinertz T *et al.* Prevention of atrial fibrillation after cardioversion: results of the PAFAC trial. *Eur Heart J* 2004; **25**:1385–94.
3. Kirchhof P, Auricchio A, Bax JJ, Crijns H, Camm J, Diener HC *et al.* Outcome parameters for trials in atrial fibrillation: recommendations from a consensus conference organized by the German Atrial Fibrillation Competence Network and the European Heart Rhythm Association. *Europace* 2007;**9**:1006–23.
4. Fuster V, Ryden LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA *et al.* ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation: full text: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 guidelines for the management of patients with atrial fibrillation) developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. *Europace* 2006;**8**:651–745.
5. Vardas PE, Auricchio A, Blanc JJ, Daubert JC, Drexler H, Ector H *et al.* Guidelines for cardiac pacing and cardiac resynchronization therapy. The Task Force for Cardiac Pacing and Cardiac Resynchronization Therapy of the European Society of Cardiology. Developed in collaboration with the European Heart Rhythm Association. *Europace* 2007;**9**:959–98.
6. Morady F. Radio-frequency ablation as treatment for cardiac arrhythmias. *N Engl J Med* 1999;**340**:534–44.

7. Patten M, Maas R, Bauer P, Luderitz B, Sonntag F, Dluzniewski M et al. Suppression of paroxysmal atrial tachyarrhythmias—results of the SOPAT trial. *Eur Heart J* 2004;**25**:1395–404.
8. Scherr D, Dalal D, Henrikson CA, Spragg DD, Berger RD, Calkins H et al. Prospective comparison of the diagnostic utility of a standard event monitor versus a 'leadless' portable ECG monitor in the evaluation of patients with palpitations. *J Interv Card Electrophysiol* 2008;**22**:39–44.
9. Hoefman E, van Weert HC, Reitsma JB, Koster RW, Bindels PJ. Diagnostic yield of patient-activated loop recorders for detecting heart rhythm abnormalities in general practice: a randomised clinical trial. *Fam Pract* 2005;**22**:478–84.
10. Fogel RI, Evans JJ, Prystowsky EN. Utility and cost of event recorders in the diagnosis of palpitations, presyncope, and syncope. *Am J Cardiol* 1997;**79**:207–8.
11. Kinlay S, Leitch JW, Neil A, Chapman BL, Hardy DB, Fletcher PJ. Cardiac event recorders yield more diagnoses and are more cost-effective than 48-hour Holter monitoring in patients with palpitations. A controlled clinical trial. *Ann Intern Med* 1996;**124**:16–20.
12. Schuchert A, Behrens G, Meinertz T. Evaluation of infrequent episodes of palpitations with a patient-activated hand-held electrocardiograph. *Z Kardiol* 2002;**91**:62–7.
13. Wu CC, Hsieh MH, Tai CT, Chiang CE, Yu WC, Lin YK et al. Utility of patient-activated cardiac event recorders in the detection of cardiac arrhythmias. *J Interv Card Electrophysiol* 2003;**8**:117–20.
14. Zimetbaum PJ, Josephson ME. The evolving role of ambulatory arrhythmia monitoring in general clinical practice. *Ann Intern Med* 1999;**130**:848–56.
15. Ashby DT, Cehic DA, Disney PJ, Mahar LJ, Young GD. A retrospective case study to assess the value of the implantable loop recorder for the investigation of undiagnosed syncope. *Pacing Clin Electrophysiol* 2002;**25**:1200–5.
16. Brignole M, Alboni P, Benditt DG, Bergfeldt L, Blanc JJ, Bloch Thomsen PE et al. Guidelines on management (diagnosis and treatment) of syncope—update 2004. *Europace* 2004;**6**:467–537.
17. Olson JA, Fouts AM, Padanilam BJ, Prystowsky EN. Utility of mobile cardiac outpatient telemetry for the diagnosis of palpitations, presyncope, syncope, and the assessment of therapy efficacy. *J Cardiovasc Electrophysiol* 2007;**18**:473–7.
18. Kuhne M, Schaer B, Moulay N, Sticherling C, Osswald S. Holter monitoring for syncope: diagnostic yield in different patient groups and impact on device implantation. *QJM* 2007;**100**:771–7.
19. Patten M, Maas R, Karim A, Muller HW, Simonovsky R, Meinertz T. Event-recorder monitoring in the diagnosis of atrial fibrillation in symptomatic patients: subanalysis of the SOPAT trial. *J Cardiovasc Electrophysiol* 2006;**17**:1216–20.
20. Flaker GC, Belew K, Beckman K, Vidaillet H, Kron J, Safford R et al. Asymptomatic atrial fibrillation: demographic features and prognostic information from the Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) study. *Am Heart J* 2005;**149**:657–63.
21. Paciaroni M, Agnelli G, Caso V, Venti M, Milia P, Silvestrelli G et al. Atrial fibrillation in patients with first-ever stroke: frequency, antithrombotic treatment before the event and effect on clinical outcome. *J Thromb Haemost* 2005;**3**:1218–23.
22. Appelros P, Nydevik I, Viitanen M. Poor outcome after first-ever stroke: predictors for death, dependency, and recurrent stroke within the first year. *Stroke* 2003;**34**:122–6.
23. Hobbs FD, Fitzmaurice DA, Mant J, Murray E, Jowett S, Bryan S et al. A randomised controlled trial and cost-effectiveness study of systematic screening (targeted and total population screening) versus routine practice for the detection of atrial fibrillation in people aged 65 and over. The SAFE study. *Health Technol Assess* 2005;**9**:iii–iv, ix–x, 1–74.