



Comparison of 24 h ECG Holter Monitoring with Real-time Long-term ECG Monitoring System using ECGAlert Software and Savvy Single-Lead Patch

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Abstract

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AIM: The aim of the study was to show non-inferiority of the single-channel ECGAlert system to the gold standard (ECG Holter) in the detection of arrhythmias over the total wear time of both devices.

METHODS: A prospective study enrolled a total of 165 patients hospitalized at the University Clinic of Cardiology, who underwent simultaneous single-channel ECG recording with ECGAlert system and a conventional 24 h Holter monitor on the 1st day and continued ECGAlert monitoring for few more days, under assignment of the doctor or at the wish of the patient.

RESULTS: A total of 165 patients were included in the study, 61.2% male, mean age of 58.4 ± 12.7 years. Mean duration of ECG Holter monitoring was 23.2 ± 0.5 h and mean duration of ECGAlert/Savvy monitoring was 64.6 ± 31.2 . During the first 24 h of simultaneous ECG monitoring with both methods, no statistically significant difference was found in arrhythmia detection. Over the total wear time of both devices, the ECGAlert system detected significantly more AF episodes as compared to Holter ($p < 0.000$). ECGAlert demonstrated significantly lower detection rate of false pauses (0.001). However, false detection of episodes of VT or AF was significantly higher in ECGAlert system versus Holter ($p < 0.000$ and $p < 0.000$ respectively). Patients were more satisfied with ECGAlert system, due to lesser interference in daily activities.

CONCLUSION: The ECGAlert system demonstrated superiority over traditional Holter monitoring in arrhythmia detection in the total monitoring period, but not in the first 24 h.

Introduction

Rhythm disturbances are often transient and in some patients go easily undiagnosed with conventional methods. Even further, some of the arrhythmias may be asymptomatic, which could lead to undertreatment, like inefficient stroke prevention in asymptomatic atrial fibrillation (AF). Opportunistic screening for AF has Class I recommendation, level of evidence B (by pulse taking or ECG rhythm strip) in patients >65 years of age, according to European Society of Cardiology (ESC) Guidelines for the management of AF [1]. In stroke patients, additional ECG monitoring by long-term noninvasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation (Class IIa recommendation, level of evidence B). [1].

Furthermore, the diagnosis of syncope, pre-syncope, or palpitations due to sustained arrhythmia remains a difficult task in clinical cardiology, often

leading to multiple admittances to the emergency cardiology or neurology room and repetition of different diagnostic tests.

The most frequent used three-channel Holter ECG has at least five wires, it is bulky and many patients find it uncomfortable to wear, especially if they should wear it for up to 72 h. Different patient operated devices [2], [3] and prolonged continuous ECG monitoring with skin patches [4] have been tested and validated for detection of different rhythm disturbances in different patient cohorts.

Experience with single-channel ECG monitoring patches is limited, as it is a new concept. It is definitely more comfortable for the patient, but the diagnostic ability should be tested.

The aim of the study was to show non-inferiority of the single-channel ECG monitoring to the gold standard (Holter monitoring) in the detection of arrhythmia events over the total wear time of both devices.

Methods

A prospective study enrolled a total of 165 patients hospitalized at the University Clinic of Cardiology, in Skopje, with different cardiac problems. The Institutional Ethic Board approved the protocol and all patients signed informed consent before the ECG monitoring. Inclusion criteria were hospitalization at the clinic of cardiology, the capability to understand, and signed informed consent. Patients were allowed to discontinue the ECG monitoring at any time if they feel uncomfortable by any means. Excluded patients from the study were those hospitalized in the intensive care unit, critically ill patients, and patients with implanted devices – pacemakers, or defibrillators.

Savvy device and ECGAlert system

Savvy is a small personal device with an ECG sensor for long-term ECG monitoring. It is a certified product (CE, medical device), already on market. It communicates through wireless connection (Bluetooth Low Energy) to a smartphone. The device is small, water resistant, it could be easily detached, and self-applied again by the patient. It is comfortable and does not interfere with the everyday activities of the patient. The device communicates with a smartphone through Bluetooth connection and the data are transferred from the smartphone to the internet-based web portal ECGAlert (Figure 1). Monitoring is in continuity as long as the patient wants, or as long as, the doctor has established the diagnoses. During the monitoring period, the patient could have a real-time view of the ECG signal and also could use the “mark event” option

to select the symptomatic moment for later correlation with an ECG finding.

Study protocol

All patients underwent simultaneous single-channel ECG recording with ECGAlert system during 24 h and a conventional 24 -h Holter monitor on the same day, under the same condition. The devices were activated consecutively. The Holter monitoring was discontinued after 24 h and Savvy device was detached at a different time under assignment of the doctor (established diagnosis) or at the wish of the patient.

The patients were furthermore questioned about any discomfort and their general satisfaction with wearing both of the systems. Their answers were classified as “Holter better,” “Savvy better,” or “same.” The satisfaction of the doctors with quality of ECG analysis, time-consuming, diagnostic help was also questioned and answers classified as “Holter better,” “Savvy better,” or “same.”

The ECG analysis was done semi-automatically, as it is usual practice in the Holter laboratory. The doctor checks significant strips pre-selected by the computer analysis and defines them as correct or false positive. Afterward, the doctor goes through the full disclosure ECG recording looking for false-negative results.

The important rhythm disturbances were pre-selected and defined as pause longer than 3 s, premature supraventricular/atrial beats (PAC), premature ventricular beats (PVC), supraventricular tachycardia (SVT), ventricular tachycardia (VT), and atrial fibrillation (AF).

The ability to pick up arrhythmia events by both devices was compared during the period of

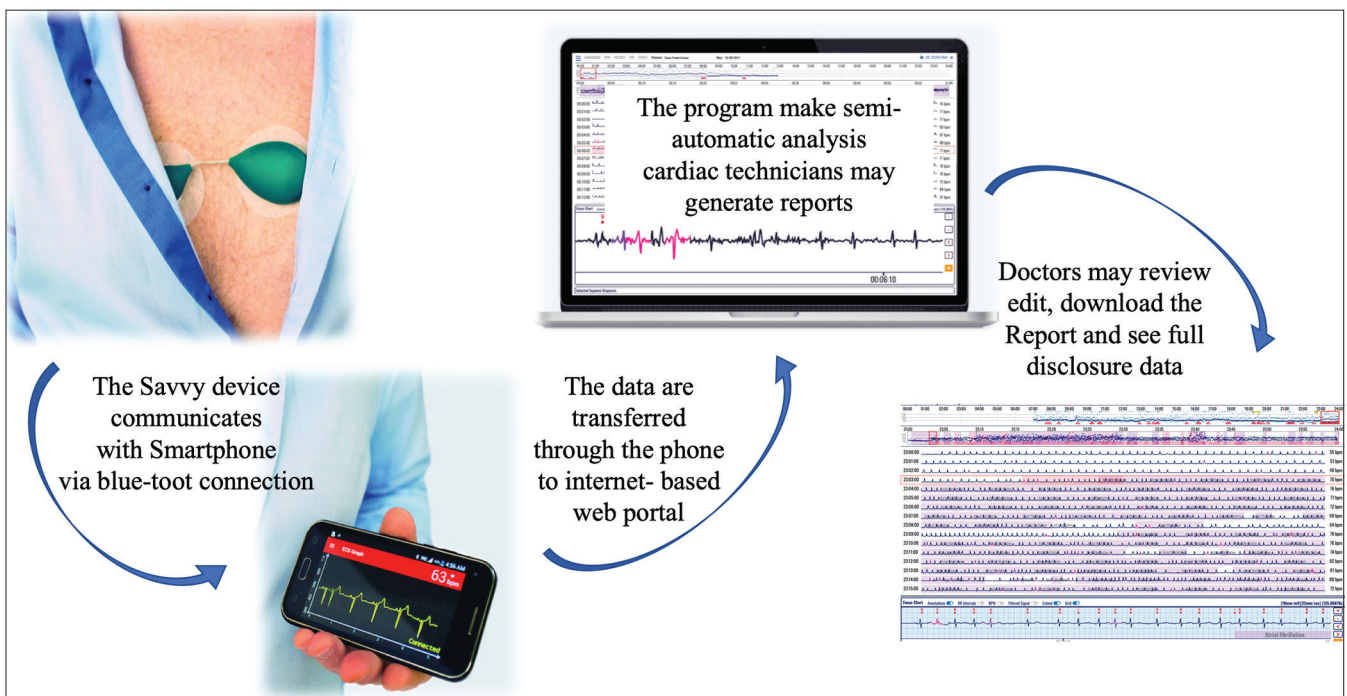


Figure 1: Chart showing data acquisition, transfer, analysis, and reporting in ECGAlert system

24 h. Afterward, the diagnostic yield of prolonged monitoring was analyzed. McNemar's tests were used to compare the matched pairs of data from the Holter ECG monitoring and ECG alert monitoring system. Descriptive statistics were used for age, total wear time, and survey results.

Results

A total of 165 were included in the study, 61.2% of male, with a mean age of 58.4 ± 12.7 years. Mean duration of ECG Holter monitoring was 23.2 ± 0.5 h and mean duration of ECGalert/Savvy monitoring was 64.6 ± 31.2 h (range from 23 h up to 246 h). The first 24 hours during simultaneous recording were used for comparison of both systems in terms of non-inferiority. As a next step, a comparison was made between 24 h Holter and total monitoring time with the ECGalert/Savvy system.

Device performance over simultaneous initial 24 h monitoring period

No statistically significant difference was found between two ECG monitoring methods during the first 24 h. There were no pauses longer than 3 s, no AV blocks, and diagnostic yield of other rhythm disturbances was almost the same (Table 1). There were only a few cases where PAC or PVC was diagnosed differently by devices.

Table 1: Ability to diagnose predefined rhythm disturbances during the first 24 h of monitoring

Test statistics ^a	Holter PAC and Savvy PAC	Holter SVT and Savvy SVT	Holter AF and Savvy AF	Holter PVC and Savvy PVC	Holter VT and Savvy VT
N	165	165	165	165	165
Exact sig. (two tailed)	1.000 ^b	1.000 ^b	1.000 ^b	1.000 ^b	1.000 ^b

a. McNemar's test
b. Binomial distribution used.

Device performance over total wear time

Longer ECG monitoring period made a difference in the diagnostic yield of the device. Three new episodes of AV block were detected with ECGalert/Savvy system after 24 h, 6 episodes of non-sustained VT, and 9 new episodes of PVC, but the difference was no statistically significant (Table 2).

Statistically, a significant difference was reached in AF detection (Tables 2 and 3). As we expected, a longer monitoring period meant more diagnosed episodes. During prolonged monitoring, 25 new episodes of AF were detected in patients previously not diagnosed as AF.

Table 2: Ability to diagnose predefined rhythm disturbances during the total time of monitoring (24 h for Holter ECG and ECGalert/Savvy system)

Test statistics ^a	Holter Pauses and ECGalert Savvy pauses	Holter PAC and ECGalert Savvy PAC	Holter SVT and ECGalert Savvy SVT	Holter AF and ECGalert Savvy AF	Holter PVC and ECGalert Savvy PVC	Holter VT and ECGalert Savvy VT	Holter AV block and ECGalert Savvy AV block
N	165	165	165	165	165	165	165
Exact sig. (two tailed)	1.000 ^b	1.000 ^b	0.625 ^b	0.000 ^b	0.064 ^b	0.125 ^b	0.250 ^b

a. McNemar's test
b. Binomial distribution used.

In our patient, Group AF episodes appeared in 35 patients (21.2%). Mean time for detection of AF was 34.4 ± 27.8 h. In the first 24 h, only 10 cases of AF were diagnosed (28.6%), which means that if the ECG monitoring was stopped after 24 h, 71.4% of the AF diagnoses would have been missed (Figure 2).

Table 3: Atrial fibrillation detection in 24 h by Holter ECG in comparison with monitoring time after 24 h with ECGalert/Savvy system

Holter AF/Savvy ECGalert AF total monitoring time	No	Yes
Yes	140	15
No	0	10

False detections of pauses, VT, or AF episodes were different between the devices and this difference was statistically significant ($p < 0.01$). False detection of pauses was more frequent with Holter ECG (33 vs. 10 cases), but false detection of VT and AF was more frequent with ECGalert/Savvy system (44 vs. 3 and 18 vs. 2, respectively) (Table 4).

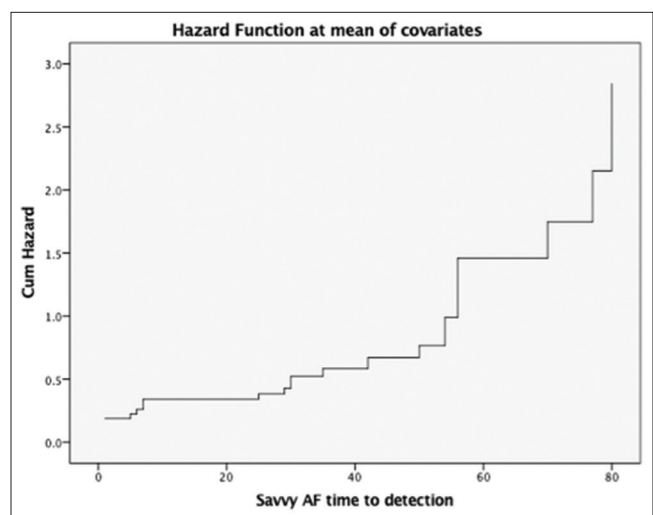


Figure 2: Time to detection of AF with ECGalert/Savvy device in hours

According to patients, ECGalert/Savvy system was better to use (58.8%) or equal to Holter (41.2%). Mean period of monitoring at patients that were more satisfied with ECGalert/Savvy system was 73.7 ± 36.1 h versus 51.6 ± 15.2 h in patients that feel the same for both monitoring systems.

Table 4: False detection of pauses, episodes of VT, and episodes of AF

Test statistics ^a	Holter false detection of pauses and ECGalert/Savvy false detection of pauses	Holter false detection of VT and ECGalert/Savvy false detection of VT	Holter false detection of AF and ECGalert/Savvy false detection of AF
N	165	165	165
Chi-Square ^b	11.256	34.043	
Asymp. sig.	0.001	0.000	
Exact sig. (two tailed)			0.000 ^c
a. McNemar's test			
b. Continuity corrected			
c. Binomial distribution used			

Regarding the preference of doctors, both systems were equal. Mean time for data analysis for Holter ECG was 20.1 ± 2.8 min (23.2 h monitoring mean value) and 27.5 ± 10.1 for ECGalert system (64.6 h monitoring mean value).

Discussion

The primary goal of long-term ECG monitoring is to establish a diagnosis in patients complaining of palpitations, syncope, or to detect asymptomatic (silent) arrhythmias. Despite the clear usefulness of ECG oIHolterHolter monitoring (24–72 h), patients finding it robust and limiting their every day activities. Single-channel Savvy device is incomparably more comfortable to wear, water-resistant, ECGalert monitoring is time unlimited, can be easily detached by the patient, and attached again. Nowadays, there is an increasing interest in telemedicine. With ECGalert system, patient sends data continuously to the web platform which the doctor can easily access.

Many single-channel ECG devices have appeared on the market in the last decade, to replace conventional 24 h Holter monitor. The Zio Patch, FDA-cleared, adhesive patch for a continuous 24 h monitoring over 2 weeks detected significantly more arrhythmia events than the Holter monitor [4]. The very important difference between Zio Patch and ECGalert system is that at the end of the 2 weeks, the patch must be sent back to the platform for a full analysis and a diagnostic report is then relayed to the patient's physician, and ECGalert system sends data continuously to the web platform that can be assessed any time. Monitoring with ECGalert may be prolonged unlimited time.

Regarding patients preference, 93.7% of patients had found the adhesive patch monitor comfortable to wear and 81% indicating that they would prefer it over the Holter monitor [4]. Furthermore, physicians thought that a definitive diagnosis was achieved more often using the adhesive patch monitor as opposed to the Holter monitor [4]. During this study, we conducted a simple survey of patients and doctors regarding both ECG monitoring systems. Our survey of patient satisfaction with the device was similar, but not so strong in favor of Savvy device versus Holter, probably because the research was conducted in

a hospital setting. For the same reason in our study, doctors have found both systems equal. However, in our previous work with ECGalert system, all of the surveyed participants answered that they would recommend ECGalert/Savvy and find it comfortable and easy to use [5].

The question if home-based self-applied wearable ECG patch can improve the diagnoses of AF was addressed and answered by the mSToPS Randomized Clinical Trial [6]. In this large trial (2659 participants), immediate monitoring using a self-applied ECG patch led to a significantly higher rate of AF diagnosis at 4 months (3.9% vs. 0.9%) in comparison with delayed ECG monitoring for 4 months [5]. In our study, monitoring was prolonged maximum to 246 h (mean monitoring time 64.6 ± 31.2 h) and that has led to the diagnosis of AF in 25 more patients (71.4% of all AF patients). Meantime for the detection of AF was 34.4 ± 27.8 h. Although Zio Patch has 14-day approved wear time, the highest diagnostic yield for arrhythmia detection was usually the first 7 days of ambulatory ECG monitoring [4], [7]. Using ECGalert system monitoring could be prolonged to the time, the diagnoses have been established and then discontinued. There is no need to unnecessarily prolongation of monitoring time.

For silent AF detection innovative iPhone ECG technology has been engaged [8]. SEARCH-AF, a cross-sectional study was aimed to determine the feasibility, impact, and cost-effectiveness of community pharmacy-based screening, using innovative iPhone ECG technology to identify previously undiagnosed AF [9]. An automated AF algorithm provided high accuracy for diagnoses of AF when used in a community setting and is a feasible and cost-effective strategy that could potentially reduce the high cost and societal burden of stroke and systemic thromboembolism associated with AF [8], [9]. Automated algorithm in ECGalert also has high accuracy for diagnoses of AF, VT, and other predefined rhythm disturbances (Figure 3).

We want to emphasize that the information provided by the ECG Holter monitors (three or 12 channel) is an obvious advantage for the analysis of electrical axes, aberrant QRS complexes, and ST-segment changes. However, evidence from our and some other studies indicate that no episode of SVT or AF detected by three-channel Holter ECG was undetected by the ECGalert system [4], [10].

Advantage of ECGalert system over different external loop-recording techniques [11], [12] is the

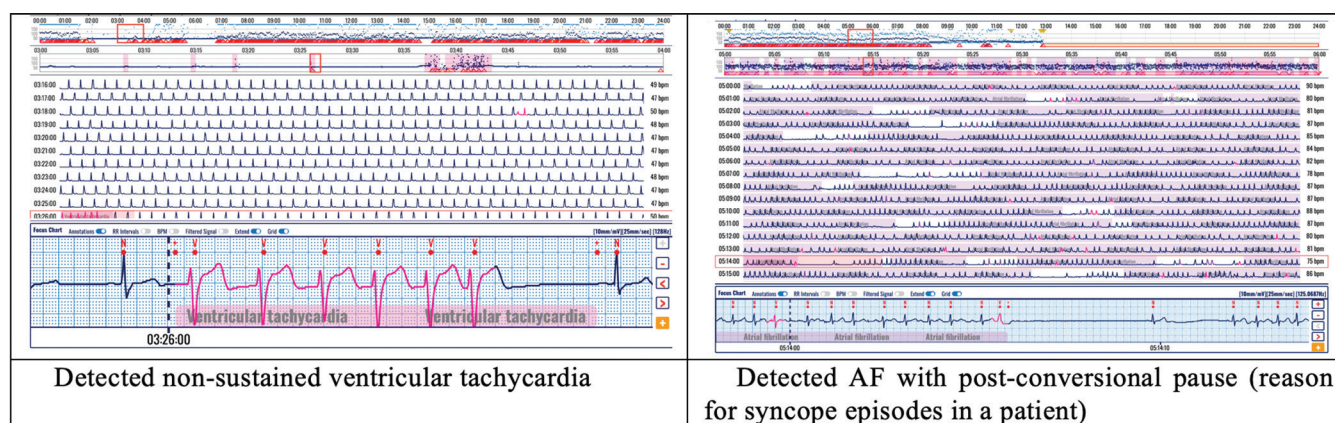


Figure 3: Detection of predefined rhythm – disturbances by ECGAlert system

availability of full-disclosure ECG record for analysis, not only predefined diagnosis strips or patient selected events.

Study limitations

The patients enrolled in this study were hospitalized patients with previously diagnosed heart diseases. This was not an ambulatory ECG monitoring by definition, while participants were in the ward hospital conditions, not much physically active. Although the majority had no previously documented arrhythmia, several had pre-existing arrhythmias and were referred for reasons other than symptomatic arrhythmia. In future practice, ECGAlert system should be used as ambulatory ECG monitoring for a longer time period.

Conclusion

During the first 24 h of simultaneous ECG monitoring with both methods, no statistically significant difference was found in arrhythmia detection. Over the total wear time of both devices, the ECGAlert system detected significantly more AF episodes than the Holter monitor. The difference was found in detection of AV blocks and NSVTs, but not statistically significant.

On the basis of these findings, single-channel, prolonged duration, ECG monitoring with ECGAlert system may soon replace conventional Holter monitoring platforms for the detection of arrhythmia events in patients referred for ambulatory ECG monitoring.

In the future, this monitoring platform with very comfortable devices may develop new diagnostic algorithms for heart rate variability analysis, interplay with other chronic disease, and correlation with exercise or drug regiments.

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