# The Revealing timely ECG changes Decreases the likelihood of Undesirable Cardiac Events-Trial (REDUCE-Trial)

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## Background

- ECG technology is extremely useful in the diagnosis of a wide variety of cardiac diseases.
- Plenty of arrhythmic and ischemic conditions however are hard to diagnose and therefore treat because they don't appear during the physician's consultation.
- For cases with persistent or recurrent problems single-lead event recorders, holters or implantable devices have been developed to diagnose the underlying disease or symptoms.
- However due to their susceptibility to artefacts, the fact that they don't provide 12-lead ECG information data and a necessary invasive procedure, they may not lead to satisfying results in all patients(1).

## Purpose

- To investigate whether the mobile 12-lead ECG CardioSecurTM (Personal MedSystems GmbH) is offering additional value in the management of patients with cardiac preconditions.
- CardioSecur™ is a mobile 12-lead ECG device based on the validated EASI-ECG-technology and allows for a 12-lead ECG using four electrodes only.
- Once the patient has recorded a reference ECG on the device he can perform control-readings.
- An algorithm that is based on clinical guidelines, will detect ECG changes between those two ECGs and give the patient a recommendation to act (5). E. g. in the case of minor ECG changes that patient will receive a yellow-warning and the information to make an appointment with his doctor. If major ECG changes occur the patient will receive a read warning telling him to contact his physician immediately. If no ECG changes are detected, and also if minor changes are detected, the patient is informed that he should see a physicians if symptoms pertain for longer than 20 minutes.
- ECG data can be transmitted to a database that can be accessed by the physician or medical institution.

## Methods

- This is a monocentric, single-armed non-randomized trial.
- Patients were asked to undertake measurements with the device once weekly and every time they were experiencing symptoms over a maximum period of three months.
- Subsequently patients were followed up for nine months.
- At inclusion and after follow-up patients were undergoing a comprehensive diagnostic assessment consisting of standard12-lead ECG, echocardiogram and exercise-ECG.
- Inclusion criteria: 18 - 80 years of age plus CABG, PCI, AMI in the last 12 months, angina pectoris treated pharmacologically, significant rhythm disturbance for which they received either a pharmacological or electrophysiological intervention, or recurrent palpitations of unknown origin in the past. Ability to handle device, regular access to the internet, signed the informed consent form.
- The following outcomes were assessed:
- Is the device able to detect ECG-changes and give the patient a correct recommendation
- Clinical relevance.
- The local ethic's committee at the ZNA Middelheim approved the study, that was conducted in line with the guidelines for GCP and the declaration of Helsinki.

## Results

- In total 51 patients were recruited between 11/2011 and 03/2012.
- Patient characteristics and main symptoms are shown in table 1.
- Patients recorded in total 1.237 ECG-readings with 2,2% of the measurements being symptom-induced and the rest being undertaken during weekly measurements.

## Results

- In five patients (9,8%) the CardioSecur™ device showed its clinical relevance: It diagnosed a new or so far undiagnosed condition and let to a successful treatment. A full overview on the results of the readings, number of critical results, diagnosis and interventions performed is given in table 2.

**Table 1: Patient characteristics and symptoms.**

| Patient Characteristics | n (total = 51) | % |
|---|---|---|
| Female Patients | 28 | 55% |
| Age (Mean) | 59 years (+/- 10) | |
| **Symptoms** | | |
| Angina Pectoris | 7 | 13,7% |
| Palpitations | 21 | 41,2% |
| Atypical Chestpain | 17 | 33,3% |
| Tachycardia of unclear origin | 6 | 11,8% |

**Table 2: Results of clinical value.**

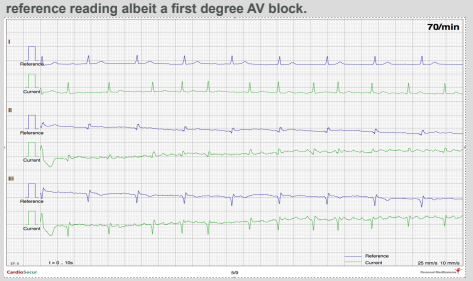
| Patient Reference ID | Result | n of Readings | Diagnosis | Intervention |
|---|---|---|---|---|
| 1 | red | 5 | 90% stenosis | Coro. Angiogramm followed by PCI |
| 2 | red | 4 | Paroxysmal AF | PVI |
| 3 | yellow | 46 | Monofocal ventricular premature beats, with bi- and trigeminia | Focal ablation |
| 4 | yellow | 18 | AV nodal re-entry tachycardia | Ablation |
| 5 | yellow | 7 | Paroxysmal AF | PVI |

- Out of those five patients,
  - One patient (ID 1) was suffering from a severe ischemia (figure 1).
  - Four patients had arrhythmias with two suffering from atrial fibrillation (ID 2 & 5), one from monofocal ventricular premature beats (ID 3), with bi- and trigemina and one from AV nodal re-entry tachycardia (ID 4).

**Figure 1: Patient 1 with ischemia in the inferior leads obvious T-wave inversion in leads II & III.**

Reference-ECG's are in blue, control-ECG's are in green.

**Figure 2: Patient 2 with paroxysmal AF in the control ECG and sinus rhythm in the reference reading albeit a first degree AV block.**




- During the study period no events were reported that the device should have been able to detect.
- Patients reported a high ease of use and 80% would recommend the device to a friend or family member.

## Conclusions

- We showed that CardioSecur™ system is an important tool for diagnosing cardiovascular disease and adds value in the management of patients with cardiac diseases such as rhythm disturbances and ischemic episodes. Further research is needed to validate this first study in larger patient cohorts and assess the long-term effects of this 12-lead mobile ECG.

**References**

(1) Barrett P et al. Comparison of 24-hour Holter Monitoring with 14-day Novel Adhesive Patch Electrocardiographic Monitoring. Am J Med. 2014 Jan;127(1):95.e11-7. (2) Drew B et al. (3) Drew et al. (4). Bonaventura. (g): Guiideline.

**Declaration of Interest**

This study has been supported by Personal MedSystems GmbH with an unconditional grant. G. van Langenhove owns a minority stake in the company the mentioned device.

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