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

van Langenhove G[1], Schwagten B[1]

1 ZNA Middelheim, Antwerpen, Belgium

Background

- ECG technology is extremely useful in the diagnosis of a wide variety of cardiac diseases.
- Many arrhythmias and ischemic conditions are difficult to diagnose and treat because they do not present in a clinical setting or a consultation.
- For cases with persistent or recurrent problems, single-lead event recorders, holters and 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 data and may necessitate an invasive procedure, they may not lead to satisfying results in or be suitable for all patients (1).

Purpose

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

Methods

- This is a single-centre, single-arm 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 with a follow-up of nine months.
- At inclusion and after follow-up patients were undergoing a comprehensive diagnostic assessment consisting of standard 12-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 were also inclusion criteria.
- The following outcomes were assessed:
  - Ability of the device to detect ECG-changes and give the patient a correct recommendation
  - Clinical relevance of mobile ECG
- The local ethic's committee at the ZNA Middelheim Hospital 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 of which 2.2% were symptom-induced and the others during routine weekly measurements.

Results

- In five patients (9.8%) the CardioSecur™ device showed its clinical relevance by diagnosing a new or 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.
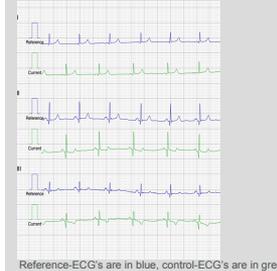
Table 1: Patient characteristics

Patient Characteristics	# (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	# 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 and T-wave inversion in leads II & III.

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

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

- 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 others.

Conclusions

- The 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. Am J Med. 2014 Jan;127(1):95.e11-7. (2) Drew B et al. J Electrocardiol. 1994; 27 Suppl: 249. (3) Drew B et al. J Electrocardiol. 1995; 28 Suppl: 211. (4) Bonaventura K et al. Touch Points 2012. (5) The Taskforce on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology (ESC) EHJ (2012) 33, 2569.