Original paper

"Off-label use" of the tele-ECG event recorder for the detection of ST-segment abnormalities

Fabian Knebel [a,*], Agathe Konietzko [b], Sebastian Winkler [a], Alicija Dranenkienė [c], Parwis Fotuhi [d], Karl Stangl [a], Gert Baumann [a], Friedrich Koehler [a]

[a] *Charité-Universitätsmedizin Berlin, Campus Mitte, Medizinische Klinik und Poliklinik mit Schwerpunkt Kardiologie und Angiologie, Berlin, Germany*

[b] *Herz-Zentrum Bodensee, Konstanz, Germany*

[c] *Heart Surgery Centre, Clinic of Heart and Vascular Medicine, Faculty of Medicine, Vilnius University, Vilnius, Lithuania*

[d] *HELIOS-Akademie für medizinische Fort- und Weiterbildung, Berlin, Germany*

F. Knebel and A. Konietzko have equally contributed to the manuscript

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Summary

Objective: Tele-ECG event recorders help classifying symptomatic rhythm disturbances. The ST-segment analysis was not a focus of these devices. Early diagnosis of ST-segment abnormalities in the home environment in patients at risk is important. The aim of this pilot study was to describe the potential ST-segment analysis of the tele-ECG compared to the standard 12-lead ECG.

Design and Methods: The credit-card sized tele-ECG event recorder (SM 100 / 100 IR, Vitaphone^{R}, Germany) was used in 23 patients with ST-segment abnormalities in the standard 12-lead ECG (20 males, aged 43–79 years: 13 – post-CABG, 10 – with acute coronary syndromes prior to percutaneous coronary interventions). These patients underwent 30 sec tele-ECG recordings in three chest positions to validate the diagnostic accuracy of the tele-ECG compared to the 12-lead ECG in terms of ST-segment abnormalities.

Results: During the study, 56 tele-ECGs out of 23 patients were recorded. No tele-ECG required re-transmission. Forty eight (85.7%) of the recorded tele-ECGs were of sufficient quality for diagnostic evaluation and 8 – were considered to be of poor quality because of the poor contact of the electrodes. The comparison of the tele-ECGs with the standard 12-lead ECGs showed a diagnostic sensitivity of 88% of ST-segment elevations and 77% of ST-segment depressions.

Conclusion: This is the first pilot study analysing the application of the tele-ECG compared to the 12-lead ECG in the detection of ST-segment changes. Newer devices with continuous mobile phone transmission should offer new options. Further investigations are needed to assess accurate transmission of ECG striving to improve the diagnosis and speed up adequate therapy in high-risk patients with acute myocardial infarction.

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Introduction

ST-segment abnormalities are a relevant diagnostic surrogate marker for acute cardiac diseases. The common underlying causes are myocardial ischemia and pericardial disease. In outpatient settings, acute myocardial ischemia as a life threatening disease is the major cause of ST-segment abnormalities.

Therefore, the early diagnosis and rapid transfer to a hospital with a coronary care unit is crucial [1].

Besides the symptoms, clinical examination and cardiac biomarkers, the electrocardiogram (ECG) is a mandatory basic diagnostic investigation to confirm the diagnosis of acute coronary syndromes (ACS). The time-delay between the onset of the symptoms and the diagnosis of ACS

* Corresponding address: Fabian Knebel, MD, Charité Universitätsmedizin Berlin, Campus Mitte, Medizinische Klinik und Poliklinik mit Schwerpunkt Kardiologie, Angiologie, D-10098 Berlin, Germany. Tel: +49-30-450613216 Fax: +49-30-450513905

E-mail: Fabian.knebel@charite.de (F. Knebel).

can be overcome if an ECG is recorded by the patient himself prior to admission using a tele-ECG event recorder.

Initially, tele-ECG event recorders have been developed for the measurement of the heart rate and the classification of rhythm disorders. Due to the fact, that these devices do not offer a standardized 12-lead ECG, the potential of an interpretation of the ST-segment has not been investigated yet.

Previous studies have analysed 12 lead ECGs in this setting [2,3]. The focus of this study was to apply a "smart card" small credit-card sized single-lead device.

Therefore, the aim of this pilot study was to compare ST-segment elevations recorded by the tele-ECG to the standard 12-lead ECG.

Design and Methods

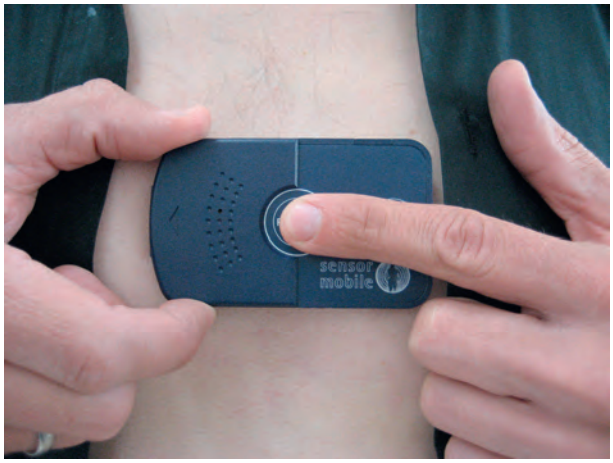
In a monocentric, prospective pilot study, 23 consecutive hospitalised patients (20 men, 3 women, aged form 43 to 79 years) in sinus rhythm with ST-segment abnormalities in the 12-lead ECG were included. The standard 12-lead ECG was recorded at a paper speed of 50 mm/s with 1 mV/cm. ST-segment abnormalities were defined as the J point depression $\geq$ 1 mm (0.1 mV) or ST-segment elevation $\geq$ 1 mm (0.1 mV). No patient had ECG deviations due to digitalis therapy or electrolyte imbalance.

Thirteen patients (56.5%) of the study population were post-operative patients who underwent coronary artery bypass grafting (CABG) and were treated in the Intensive Care Unit (ICU).

Ten patients (43.5%) suffered from acute coronary syndrome (ACS) and were included prior to the acute percutaneous coronary interventions (PCI).

The tele-ECG event recorder (SM 100 / 100 IR, Sensor Mobile, former Telemedizinische Systeme, now Vitaphone, Chemnitz, Germany) used in the study is a credit card size single-channel ECG device with four plug-on electrodes on the backside with a maximum distance of 7 cm between the electrodes. It allows 30-second tele-ECG loops. The memory unit stores up to three tele-ECG events. The tele-ECG transmission is performed by acoustic frequency modulation. The tele-ECG can be transmitted at any time through any regular phone using a toll free number without any additional equipment (Figure 1).

A complete set of tele-ECGs per patient in the ACS patients included three loops in the anterior (related to the standard ECG-leads V1-V2), the septal (related to the standard ECG leads V3-V4) and in the lateral position of the chest (related to the standard ECG leads V5-V6).



(A)

(B)

Figure 1. Recording of the tele-ECG on the patient's chest by pressing the record button (1A) and transmitting by placing the telephone mouthpiece directly over the mike of the tele-ECG device (1B).

Due to the prior thoracotomy of the post-operative CABG patients, it was not possible to record a tele-ECG in the anterior position. Therefore, the set of tele-ECGs of the CABG patients included only the septal and lateral positions.

The monitor centre is a computer based, fully automated receiving unit which handles patient calls interactively with voice control, including a voice recording of the patient's symptoms. The tele-ECG tracing and the patient's voice messages are subsequently analysed by experienced physicians. All tele-ECG measures are stored in a database.

Table 1.
Findings of the tele-ECG transmissions in patients with myocardial ischemia.

Parameter	12-lead ECG	tele-ECG anterior	tele-ECG septal	tele-ECG lateral	% detected by all three tele-ECGs
ST-segment elevation					
lead V1-V2	**2**	2	2	0	100
lead V3-V4	**2**	2	2	0	100
lead V5-V6	**5**	–	4	5	100
ST-segment depression					
lead V1-V2	**1**	1	0	0	100
lead V3-V4	**3**	–	2	0	66.6
lead V5-V6	**5**	– / 0	1/2*n*	4	100

– no recorded tele-ECGs in patients after CABG surgery,
n tele-ECGs with poor diagnostic quality.

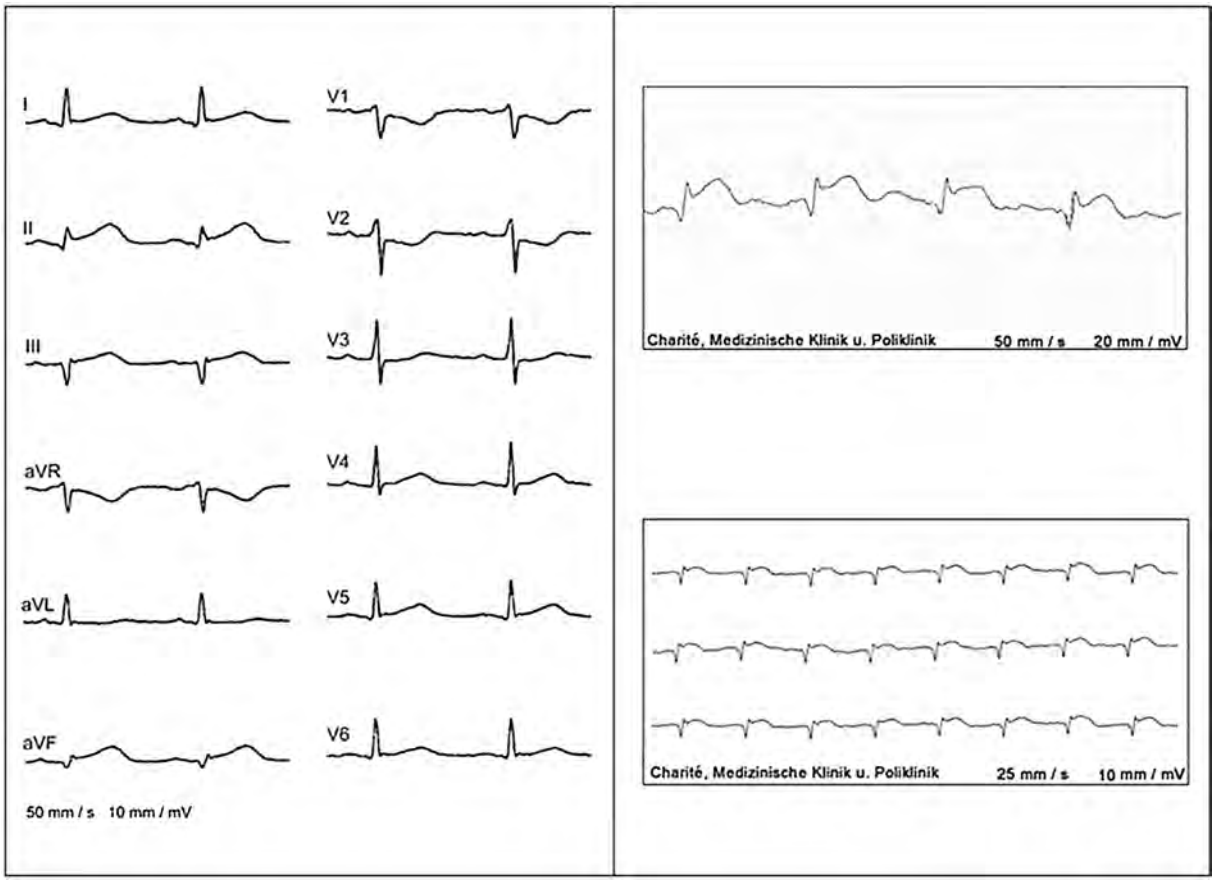


Figure 2. Ischemic ST-segment elevation in the standard 12-lead ECG (lead II, III) (left) and in the tele-ECG recorded in the lateral position of the thorax (right).

Results

A total number of 56 tele-ECGs of the 23 patients were transmitted. Information, including the number of the recorder, the date, duration and the start time of the tele-ECG was automatically recognised in all cases. No patient was harmed by the study. No tele-ECG required retransmission. Forty eight (86%) of all tele-ECGs sent for the diagnostic evaluation were of sufficient quality. Eight tele-ECGs were considered to be of reduced quality because of the poor skin contact of the electrodes.

There was no difference in the diagnostic quality between the CABG group patients (22 out of 26; 85%) and the group of patients prior to acute PCI (26 out of 30; 87%).

There is a good diagnostic accuracy (>75%) of every single loop of the tele-ECGs compared to the corresponding position of the gold standard (12 lead ECG); single tele-ECGs showed 88% of

ST-segment elevations and 77% of ST-segment depressions.

The diagnostic accuracy of the tele-ECG to detect the ST-segment abnormality in any position of the standard 12 lead ECG increases to 100% if all three loops (anterior, septal, lateral) were recorded.

Numeric results are summarised in Table 1. An example of a pathological tele-ECG is shown in Figure 2.

Discussion

The gold standard of tele-cardiology in the pre-hospital diagnostics of ST-segment abnormalities is the 12-lead tele-ECG [2–4]. The diagnostics of ST abnormalities with a single-lead tele-ECG, which has been initially made for the measurement of the heart rate and the detection of rhythm disturbances, is an "off-label" use.

Due to the fact that 12-lead tele-ECGs demand extensive patient education and a complex algorithm for data transmission there is a need for simplification and miniaturization of ECG devices in primary prevention in coronary artery disease ("ECG-in-the-pocket"). The miniaturized devices allow mobility for coronary patients at risk. There are two basic technological developments: a) the credit-card size event recorder with analogous ECG data transmission of max. three 30 sec loops and b) the Physiomem® (Getemed AG, Teltow, Germany) tele-ECG recorder that allows 120 sec tele-ECG recording using four plug-on electrodes or a continuous ECG streaming using adhesive electrodes including oxygen saturation (SpO2) via a mobile phone (Figure 3). An ECG streaming via a mobile phone requires an adequate mobile phone data transmission protocol, at least EDGE (Enhanced Data Rates for GSM Evolution) with a data upload 200 kbit/s (Figure 4).

The advantage of the SM 100 / 100 IR device is its credit-card size and the possibility to be carried by a patient anywhere. However, the disadvantage of the SM-100 is that a patient has to stay still for 3 × 30 seconds for data transmission. Furthermore, there is a limited memory with only three loops of 30 sec. This is a potential source of data loss.

The advantage of the new 3-lead devices is that they offer online transmission of a 3-lead ECG using mobile phone technology (EDGE-Protocol). EDGE technology offers continuous, ubiquitous and safe data transmission at least in all parts of Germany and Austria. Therefore, this technology is available especially in rural areas with poor

Figure 3. The Physiomem® (Getemed AG, Teltow, Germany) tele-ECG recorder allows 120 sec tele-ECG recording via a mobile phone.

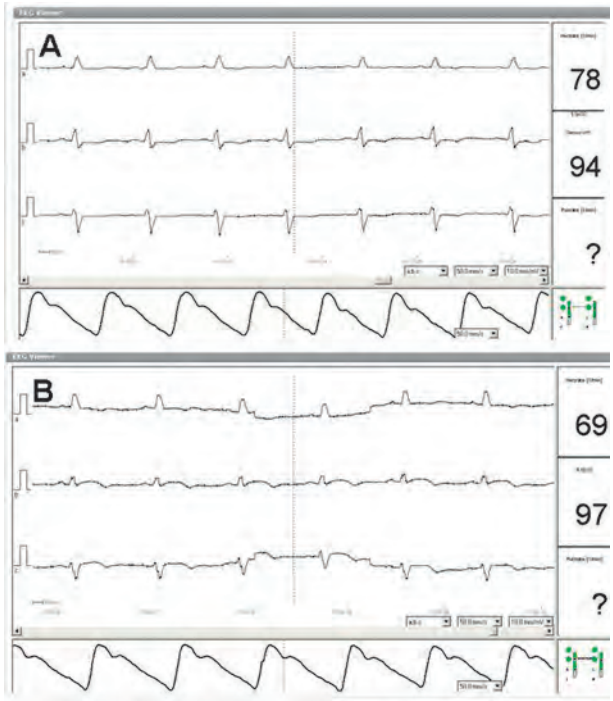


Figure 4. An example of the streaming ECG of a 77-year-old patient (ischemic cardiomyopathy, LVEF 30%, NYHA III) in comparison with a normal streaming-ECG at a baseline examination (A). The patient had severe chest pain and sent the streaming ECG 20 minutes after pain onset (B). The ECG showed ST-segment elevations. 70 minutes later, the patient underwent emergency coronary angiography. A stent in the LAD was implanted.

UMTS network. The size of the devices is still large and the electrodes are adhesive, but future developments will generate ECG devices with integrated SIM cards. There is no time-delay between recording and transmission of an ECG which is an important aspect in patients with acute myocardial ischemia.

This study is the first pilot study to investigate ST-segment abnormalities by a single-lead tele-ECG. There is evidence that three loops of the tele-ECG in different positions can reliably detect ST-segment abnormalities in 100% regardless of the depression or elevation of the ST segment. Therefore, these technologies are a safe option for the "ECG-in-the-pocket" concept.

The quality of the signal transmission is good and could be improved by the education and training of a patient, the poor skin contact being the main obstacle to obtain perfect diagnostic quality. The education of a patient includes instruction and the training session in a stable situation. Being familiar with the tele-ECG transmission procedures, the patient with severe chest pain will be able to record and transmit his ECG for the comparison with the baseline recordings.

Certainly, these devices cannot be distributed unselectively to the patients with CAD. But for high-risk patients (with diabetes, multi-vessel disease, left main stem stenosis, status after high risk PCIs, renal failure and other relevant comorbidities) this new technology offers a safety aspect.

Limitations

This was a small pilot study, which had an in-hospital setting for the proof of a principle. Tele-ECGs were performed by the study personnel, not the patients themselves. Due to the inclusion criterion of pre-existing ST-segment abnormalities, this allows the analysis of ST-segment abnormalities by tele-ECGs that are not present in standard 12-lead ECGs. The total number of patients was low. Further larger studies are needed to evaluate these devices in daily practice.

Conclusion

This is the first study analysing the application of the single-lead tele-ECG in the detection of ST-segment abnormalities. We conclude that the devices with a fast, reliable and accurate transmission of the ECG can improve the pre-hospital diagnosis and speed up an adequate therapy.

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