TEMEO – a Novel Mobile Heart Rhythm Telemonitoring System

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Abstract

ECG telemonitoring is a relatively new advancement of medical technology which enables distant control of the health status. There is a great research progress in recording, wireless transfer and automatic analysis of ECG signals, but clinical experience with working ECG telemonitoring systems is very limited.

We evaluated 60 patients, applying simultaneously standard Holter ECG and a heart rhythm telemonitoring system – TEMEO. Data derived from both types of monitoring systems was compared. Comparison was performed also for TEMEO derived and standard ECGs.

We evaluated the level of agreement between Holter ECG derived and TEMEO derived parameters and found high and statistically significant correlation coefficients regarding average, maximal and minimal heart rate, % of time in tachycardia and single supraventricular ectopic beats. We found a very high coincidence rate of 99.3% when TEMEO derived ECGs were compared with standard ECGs.

1. Introduction

Telemedicine is a relatively new medical trend which incorporates medicine, telecommunications and information technologies, providing diagnostic work-up, treatment, consulting and training. It enables a patient to get specialized medical advice 24 hours a day independent of his/her location. Telemedicine has been acknowledged in world-leading countries and there are a large number of clinical trials and even some medical journals devoted entirely to this topic. Most of telemonitoring studies however focus on heart failure population [1, 2] – about 3500 patients included in total, with different kind of data transmission. Results from these studies have shown that telemonitoring can be effective in clinical management of patients.

Experience with ECG monitoring is still limited. Most of the results come from laboratory tests and small clinical trials [3-12], while data transmission via mobile network is rare. Another parameter often subjected to telemonitoring is blood pressure and there are at least 14 studies performed in that field [13].

ECG monitoring system was applied in different subsets of patients: high risk post STEMI patients, to detect life threatening arrhythmias [7], healthy athletes monitored during physical activity [8]. Most of the studies implied a single-channel ECG, with the exception of one study with two-channel ECG [11], and one with 12 (signal reconstruction) lead detection system [6]. As the results are promising, the investigation in this area continues.

We have evaluated the clinical applicability and patient compliance of novel telemonitoring system: Telemetric System for Collection and Distant Surveillance of Medical Information – TEMEO. We have compared the clinical information derived from that system with that of a standard 24-hour ambulatory ECG Holter monitoring and we have also compared ECGs derived from that system with standard ECGs.

2. Methods

2.1. TEMEO telemonitoring system

The system consists of elastic chest belt, handheld TEMEO device and TEMEO electronic center with GSM connection between the device and the electronic center (Figure 1).

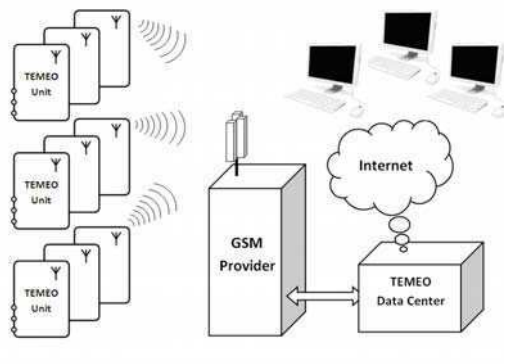

Figure 1. TEMEO telemonitoring system

TEMEO detecting and transmitting system (Figure 2) consists of two units: a mobile handheld device for recording and transmitting data (Figure 3) and an elastic belt placed on the chest, for registering precordial electrical activity of the heart and detecting R-R peak intervals.

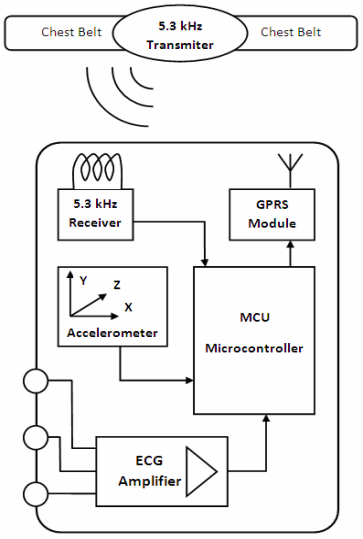

Figure 2. TEMEO detecting and transmitting system.

Figure 3. TEMEO handheld device - top and bottom view. Four pin electrodes are well seen.

2.1.1. TEMEO belt

Two detecting electrodes are built in on the inner surface of the belt, in close contact with the skin. Data from the belt is registered continuously, and is transmitted wirelessly to the mobile handheld device. By means of GSM network, within 5 minute intervals, recorded data is transmitted (GPRS standard used) to the TEMEO electronic center for further analysis and visualization. The belt is a major component of TEMEO Holter monitoring system, which operates continuously.

2.1.2. TEMEO handheld device

This device, due to 3 active pin-electrodes (+ one inactive) placed on the back, has single lead recording capability. When placed vertical at the left sternal border it records lead vector potential similar to standard aVF. As it is seen on Figure 2a, the mobile device has an accelerometer for detection of physical activity (and therefore differentiating between rest condition and some kind of physical exertion) simultaneously with R-R interval detection.

TEMEO ECGs are recorded only on demand, after proper placement and button push.

We evaluated 60 patients (22 female, 38 male), mean age of 58 ± 8 years, applying simultaneously standard Holter ECG (Signa-Lyzer SD, Signa Cor Laboratory) and TEMEO system, for a time period ranging between 6 and 25 hours. Two different parameters were compared: **1.** TEMEO ECG and standard 12-lead ECG, where only rhythm, heart rate, supraventricular ectopic beats, ventricular ectopic beats and significant pauses are compared, and **2.** comparison between standard Holter ECG and TEMEO Holter regarding average, maximal and minimal HR, total number of analyzed complexes, percentage of time in tachycardia and single, couplets and triplets of supraventricular and ventricular extra beats.

The protocol of the study included 5 simultaneous ECG recordings - TEMEO and standard 12-lead ECG. Due to minor position/angle differences between recordings, ST-T interval changes analysis is impossible, but our data suggest that rhythm and heart rate analysis is possible and correct.

The system has a possibility to alert the patient and to the monitoring physician with a SMS in cases of extreme data parameters (e.g. heart rate less than 40 beats per minute).

The electronic center is accessible via Internet, from any PC or smart phone with previously installed TEMEO software, with security access to the system.

2.2. QRS detection

The mainstay of TEMEO continuous monitoring is detection of R waves, respectively RR intervals, and heart rate. We use algorithm for real time QRS detection using a combined adaptive threshold [14], appropriate for processing of electrocardiographic signals with high level of noise.

2.3. Arrhythmia classification

After detection of RR intervals, next important step was detection of abnormal cardiac rhythm. We used

algorithm, based on RR interval duration, and validated using the MIT-BIH database [15]. Beats were annotated as normal sinus rhythm, premature ventricular and premature supraventricular beats.

Normal and abnormal cardiac rhythm beats and episodes of atrial fibrillation are visualized in different colors in TEMEO user interface (Figure 4).

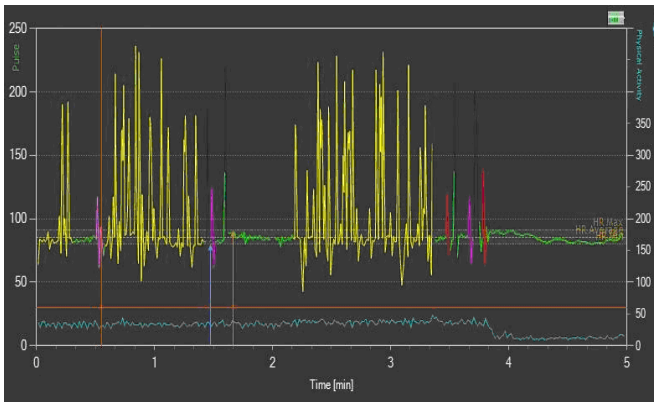

Figure 4. TEMEO Interface with detected episodes of atrial fibrillation. Yellow color displays high rate beat-to-beat variability during atrial fibrillation. Green color displays normal sinus rhythm. Purple and red colors display ventricular and supraventricular ectopic beats respectively. X-axis – time (5 minute interval), Y-axis – pulse rate.

2.4. ECG filtration

Key function of TEMEO handheld device is single lead ECG record capability. Recorded potential depends on the position of electrodes on the chest (vertical, horizontal, 30 degrees leftward). In our investigation, the handheld device was placed vertical at the left sternal border, just under the clavicle (lead vector similar to standard aVF). Noise suppression and filtration was performed, using fully automated algorithm [16]. As a result, 10 seconds long ECG was recorded (Figures 5 and 6).

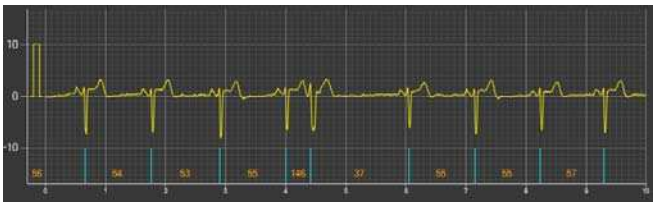

Figure 5. TEMEO ECG record of sinus rhythm with ventricular ectopic beat. x – axis: 10 seconds time interval; y – axis: milivolts.

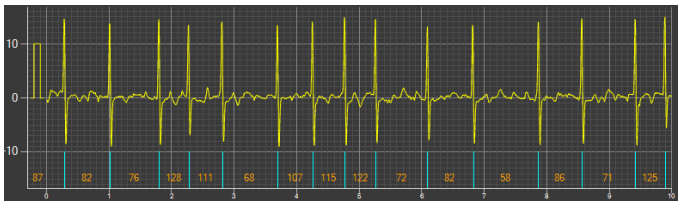

Figure 6. TEMEO ECG record of atrial fibrillation.x – axis: 10 seconds time interval; y – axis: milivolts.

3. Results

Data analysis was performed, with SPSS ver. 13. A two-tailed p value < 0.05 was considered statistically significant. The distribution of continuous variables was tested using the Kolmogorov-Smirnov test.

3.1. ECG capability comparison

We analyzed ECG recordings considering the above mentioned 5 parameters. For these parameters the percentage of coincidence between TEMEO and standard ECG was 99.3%. Most of the differences regarded heart rate (in 8 cases) – a disparity of 3-6 beats per min, all in ECGs of patients with atrial fibrillation. Cases of sinus rhythm were correctly interpreted in every TEMEO ECG recording. Half of the standard ECG's with atrial flutter (12 recordings) were interpreted in corresponding TEMEO as atrial flutter, 5 – as atrial tachycardia and one recording – as atrial fibrillation. In all standard ECGs with atrial fibrillation (8.7% of the recordings), the rhythm was correctly interpreted in the corresponding TEMEO ECG recordings. In all cases, quality of TEMEO recording was good enough for proper determination of all examined parameters.

3.2. ECG Holter capability comparison

Regarding the monitoring period we have evaluated the following parameters: average, maximal and minimal HR during the recorded period, total number of analyzed complexes, percentage of time in tachycardia and single, couplets and triplets of supraventricular and ventricular ectopic beats. These parameters were then compared using correlation analysis and calculating the intraclass correlation coefficients. (Table 1)

4. Discussion and conclusion

There are two widely applicable methods for ECG data recording and analysis: a simultaneous ECG capture during patient examination and a 24-hour ECG recording with a post analysis – Holter monitoring. The disadvantage of the 1st method is that it is not possible to have the complete diagnosis, which often requires more

than a single ECG recording. The shortcoming of the 2nd method is that it is not possible to intervene immediately, which sometimes can have serious consequences. TEMEO system has a potential to combine these two methods of examination in one functional monitoring system with its options for very continuous monitoring with multiple event ECG recording.

TEMEO patient monitoring provides results that are similar to those derived from a standard Holter ECG, regarding average, maximal and minimal heart rate, % of time in tachycardia and single SVEB.

Due to noise reduction and filtering algorithms, TEMEO derived ECGs have a very high coincidence rate with standard ECGs. The system is good enough to register episodes of atrial fibrillation, even short standing and "silent". At that moment, this is the most promising application of this telemonitoring system, and is under further investigation.

TEMEO Telemonitoring system is not supposed to eliminate the need from ECG and Holter ECG, but may give further information for exact diagnosis.

Table 1 Correlations between different parameters measured with standard Holter ECG and TEMEO monitoring system. HR – heart rate; VEB – ventricular ectopic beats; SVEB – supraventricular ectopic beats.

Parameter	ECG Holter	TEMEO system	p value
Time of monitoring	72 778 minutes	61 389 minutes	
Registered QRS complexes	83 505 ± 14806	78 912 ± 14736	0.8
Average heart rate	73 ± 14 bpm	74 ± 16 bpm	0.16
Maximal heart rate	133 ± 33 bpm	121 ± 19 bpm	0.007
Minimal heart rate	54 ± 14 bpm	47 ± 12 bpm	<0.001
% time in tachycardia	11.4 ± 18.3%	9 ± 15.1%	0.24
Single VEB	2897 ± 8388	363 ± 722	0.02
Single SVEB	1040 ± 2148	315 ± 678	<0.001

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