Original article

Validation of vital signs recorded via a new telecare system

Ran Kornowski*, Sharon Zlochiver†, Lior Botzer‡, Roy Tirosh*, Shimon Abboud† and Shai Misan‡

*Department of Cardiology, Rabin Medical Center, Petach Tikva, and Sackler Faculty of Medicine, Tel Aviv University; †Department of Biomedical Engineering, Tel Aviv University; ‡Medical Development Department, Medic4All, Petach Tikva, Israel

Summary

A telecare system (Medic4All) has been developed that relies on a wireless wristwatch-like sensor to measure the pulse wave from the radial artery. From this, the heart rate and respiration rate are derived. The system's performance was examined by comparing the results obtained from the pulse wave signal with those obtained from conventional electrocardiographic and spirometer devices. A total of 144 patients participated in the study; their mean (SD) age was 43 (18) years. There were 44 cardiac patients in group 1 and 100 healthy patients, who were studied in their homes, in group 2. There was a significant correlation between the heart rates measured by the two monitoring methods. A 'difference versus average' analysis showed that the error distribution had a mean (SD) value of − 0.1 (3.3) beats/min. Similarly, the respiration rates measured by the two techniques were significantly correlated. The error distribution had a mean (SD) value of 0.1 (1.9) respirations/min. The present study suggests that the wrist-worn sensor represents a promising tool for online detection and monitoring of vital signs in the home.

Introduction

Telemedicine can be used to monitor cardio-respiratory problems and allow rapid access to medical care[1–3]. We have developed a wristwatch-like sensor that transmits data wirelessly through a gateway to a medical call centre. At the call centre a computer can measure vital signs, such as heart rate and respiration rate. The medical personnel at the call centre can analyse the transmitted signals to identify heart rate irregularities, respiration rate and other vital signs. The medical history of the patient's vital signs can be retrieved from a secure server for comparison.

The wristwatch sensor is designed to monitor patients in their homes. We have therefore studied the accuracy of the sensor.

Accepted 28 May 2003

Correspondence: Dr Ran Kornowski, Rabin Medical Center, Department of Cardiology, Petach Tikva 49100, Israel (*Fax: +972 3 937 6438; Email: rkornowski@clalit.org.il*)

Telecare system

Architecture

The telecare system (Medic4All, Petach Tikva, Israel) allows wireless monitoring of physiological data. The sensor is a mobile sensing 'wristwatch' (Fig 1), which contains a piezo-ceramic transducer to detect the pulse wave from the radial artery. The signals are recorded for 30 s, amplified, digitized and transmitted via radio frequency (RF) communication to a gateway, installed at a nearby location in the patient's home (Fig 2). In addition to data transfer, the gateway can serve as a speakerphone or a videoconference unit, to allow interactive communication between the patient and

Fig 1 The wristwatch-like sensor.

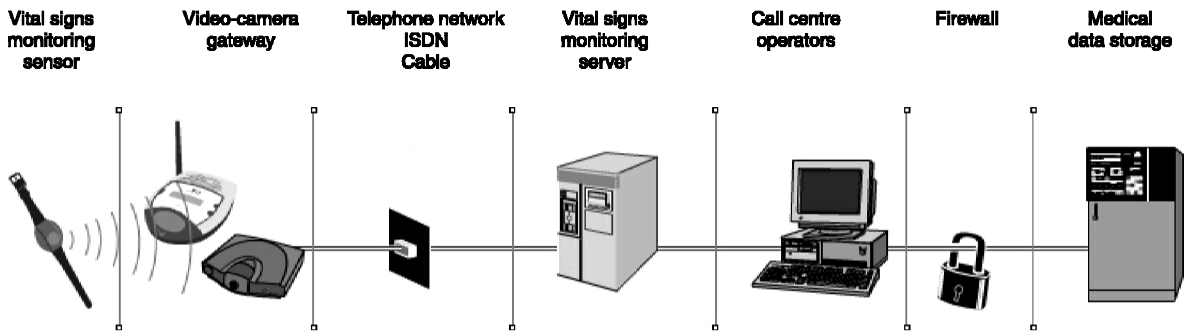

Fig 2 Telecare system architecture.

the medical staff at the call centre. Video transmission uses the H.324 standard for videoconferencing over the public switched telephone network (PSTN), at a maximum of 10 frames/s. In practice, video-pictures are transmitted at approximately 3 frames/s.

The measurement of the radial artery pulse wave is done with no intervention by the patient (i.e. transmission is passive). The operator can monitor and analyse the transmitted signals and vital signs, such as heart rate and respiratory rate, which are calculated from the radial artery pressure signal. An example screen showing the software is shown in Fig 3. The newly transmitted medical information, together with the complete measurement history of the patient, is stored on a medical data storage server.

Sensor

The wrist unit is a cordless, medical monitoring and alarm device, which measures, stores and transfers physiological data to a monitoring centre through the gateway. The device is similar to an ordinary wristwatch and has a single large button (Fig 1). Pressing quickly on this button initiates the measurement procedure.

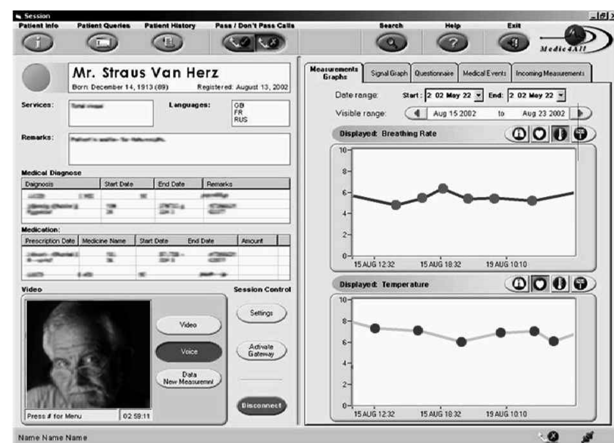

Fig 3 An example screen showing the monitoring software.

Pressing for longer triggers an alarm signal at the call centre. The unit indicates transmission success or failure, with a short confirmation tone and a green light for success, and a long tone and a red light for failure. If transmission fails, the measurement results are stored in the wrist unit, and retransmitted to the gateway the next time a measurement is performed. The unit can perform active and passive measurements. The patient initiates active measurements, and the unit can be programmed to remind the patient to perform measurements at certain times. Passive measurements are performed automatically at pre-programmed times, for example during the night, when the patient is asleep.

Measurement of heart and respiratory rates

The system measures mean heart rate on the assumption that the pulse wave intervals in the pressure signal are equivalent to the R–R intervals of an electrocardiogram. The pressure signals are first filtered to remove high frequencies related to noises such as power-line interference and low frequencies related to slow baseline drifts. The filtered signal is then autocorrelated to retrieve the dominant period, which corresponds to the mean heart rate.

The mean duration of the respiratory cycle is calculated using three methods:

(1) The baseline drift method extracts the respiratory rate from the pressure signal baseline modulation due to the relative movements between the hand and the biosensor attached to it during breathing.
(2) The amplitude modulation method evaluates the respiratory rate from the changing amplitude of the pressure wave. These changes are directly related to the different pressures applied on the heart due to the expansion and contraction of the lungs during the pulmonary cycle.
(3) In the R–R intervals modulation method, the respiratory rate is calculated from the rhythmic

Table 1 Age distribution of the study group[a]

Age group	Proportion of entire population (%)	Target number	Actual number
11–20	10	13	13
21–30	20	25	28
31–50	35	44	54
51+	35	44	49
Total	*100*	*126*	*144*

[a]No children under 11 years were included in the trial.

variations in the heart rate which are related to the respiration frequency, mostly due to the increase in neural activity in the vagal fibres during expiration[4].

For each of these methods, a quality factor is defined, which reflects the measure of certainty in the estimation produced. The final evaluation of the respiratory cycle is based on the three quality factors. A pressure signal segment is defined as noisy or non-noisy according to the values of these quality factors, and the degree of correspondence between the three respiratory rates.

Methods

The trial was approved by the local ethics committee. The accuracy of the device for measuring mean heart rate and respiration rate was assessed in comparison with conventional electrocardiography (ECG) and spirometry measurements. Subjects had to be over 10 years old, and written informed consent was obtained before inclusion in the trial.

The study was performed on two groups of subjects. Group 1 comprised patients at the Rabin Medical Centre who were undergoing cardiac catheterization. The sensor was fastened to the patient's left wrist, and the measurements were taken continuously throughout the catheterization procedure via a wired connection. The output from the sensor was sampled simultaneously with an ECG signal and intra-arterial blood pressure monitoring. Both signals were stored in a file on a PC-based server for a retrospective data analysis.

Group 2 consisted of healthy patients in their own homes. The sensor was fastened to the patient's wrist. ECG and spirometer devices were connected as well.

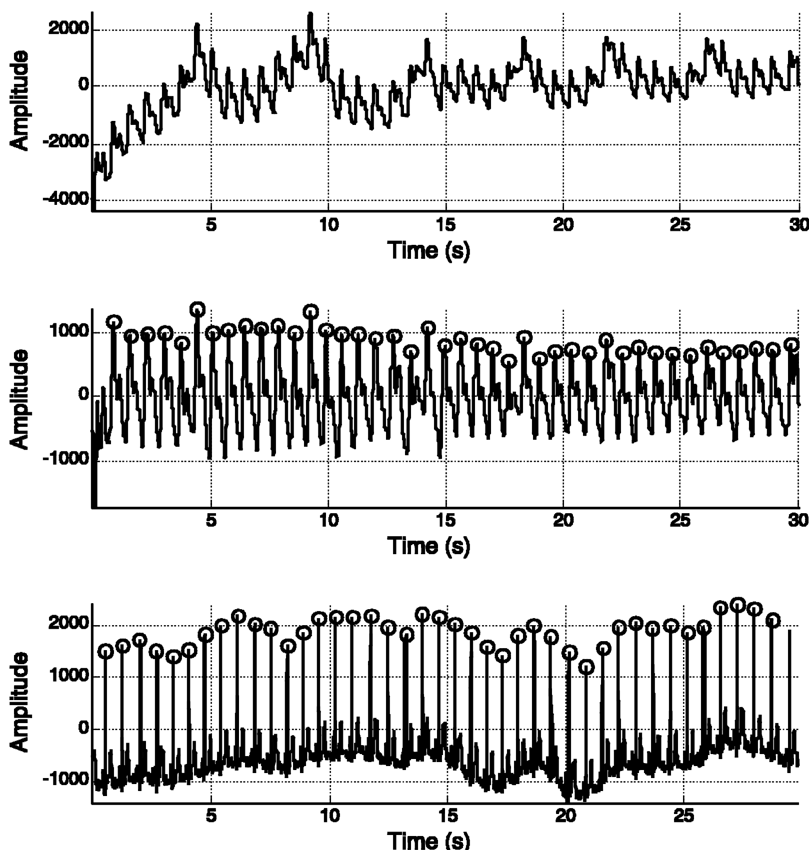

Fig 4 Example radial artery pressure signal (top panel), and the filtered signal and locations of the detected R waves (middle panel). The simultaneously recorded ECG signal and locations of the R waves are shown in the bottom panel.

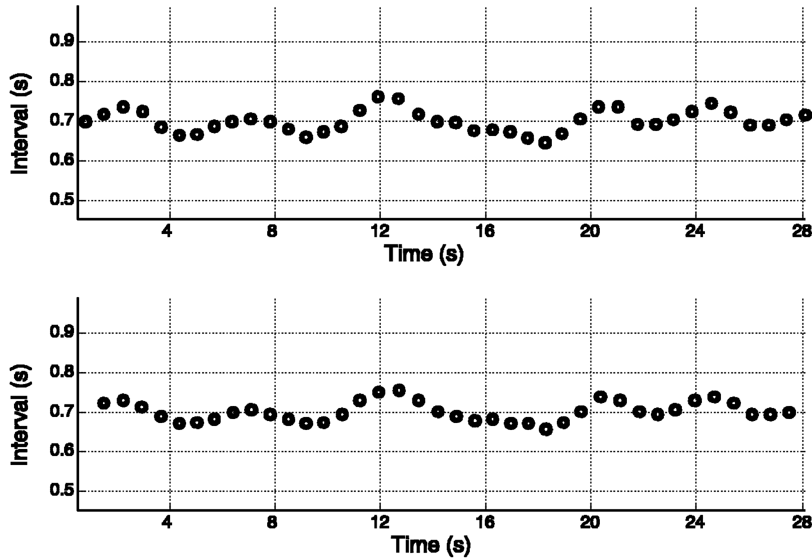

Fig 5 The R–R intervals derived from both the pressure signal recorded by the wrist-worn sensor (upper panel) and the simultaneously recorded ECG signal (lower panel).

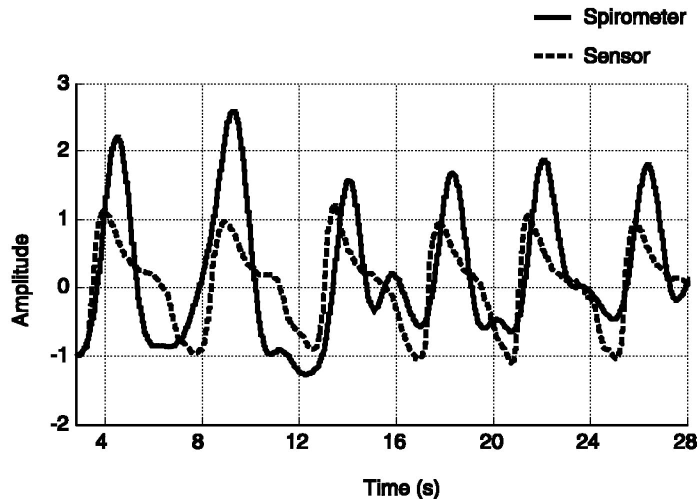

Fig 6 Respiratory amplitude signal, from the wrist-worn sensor, processed using the baseline drift method, and from a spirometer, which was measured simultaneously.

The patients were instructed to sit down on a chair and push the activation button with their other hand to start the measurement. They were instructed to stay still during the rest of the measurement procedure. The measured signals were wirelessly transmitted via a gateway, located about 10 m away, to a PC-based server and stored in a file. In addition, the ECG and spirometer signals were collected simultaneously on the server and stored in a separate file. Each patient was asked to repeat this procedure up to 10 times.

The test groups were designed to be large enough to obtain significant results with a confidence level of 95% and confidence interval (CI) of 9%. For these levels of confidence, the required target population size was 126 subjects, with the age distribution shown in Table 1. The age distribution of the actual study group is also given in Table 1 and, as can be seen, the target for each age group was reached.

Results

A total of 144 patients participated. The study group consisted of 45 females (31%) and 99 males (69%); their mean (SD) age was 43 (18) years. There were 44 cardiac patients in group 1 and 100 patients in group 2.

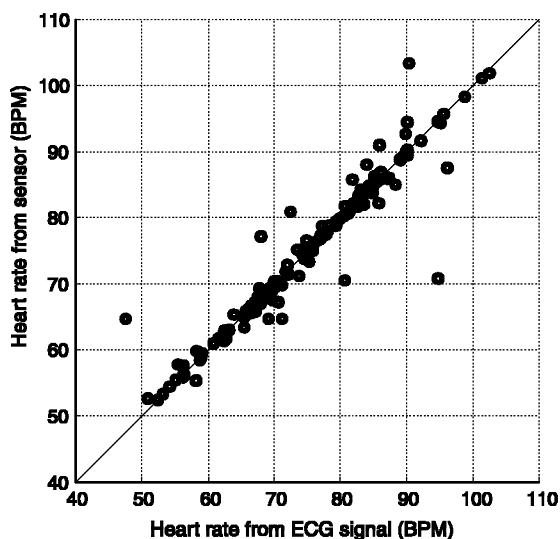

Fig 7 The mean heart rate (BPM) measured from the wrist-worn sensor's pressure signal, and that measured from the ECG signal, for all 144 patients. The correlation between the two sets of measurements is significant (r= 0.95, P<0.001).

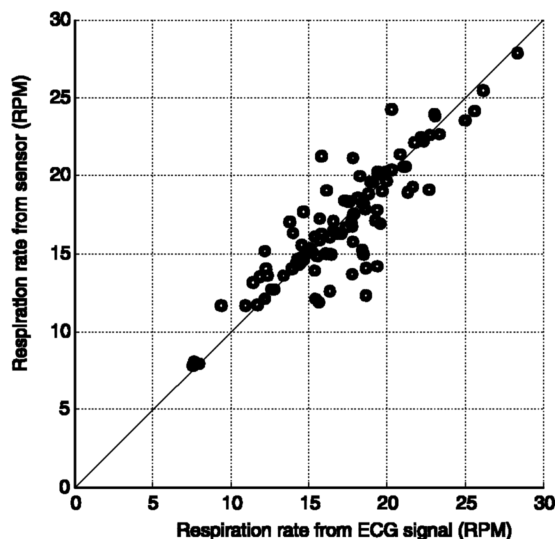

Fig 9 Respiration rate, measured from the sensor's pressure signal, is shown against the respiration rate as extracted from the ECG signal, for 99 patients' measurements. The correlation between the two sets of measurements is significant (r= 0.89, P<0.001).

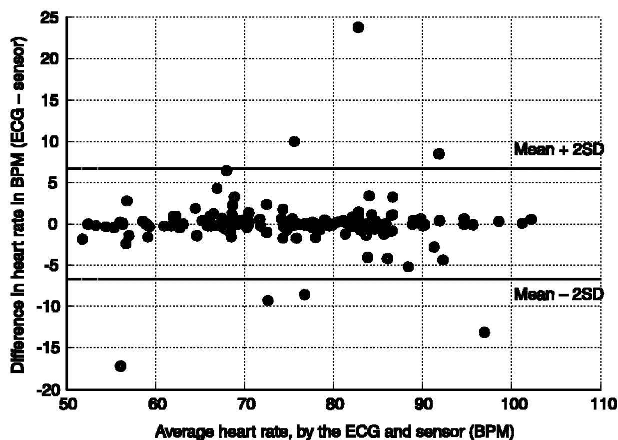

Fig 8 Agreement plot. Difference between the two heart rate measuring methods against their mean.

An example of the radial artery blood pressure signal measured by the sensor's transducer is shown in the upper panel of Fig 4. The intervals between the R waves (R–R intervals), from which the mean heart rate is calculated, are shown in the middle panel. The lower panel shows the conventionally measured ECG signal and the locations of the R waves as detected from it. The peaks in the wrist-worn sensor signal follow the peaks in the ECG signal after a small delay. The R–R intervals recorded for the sensor signal and the simultaneous ECG signal are shown in Fig 5.

An example of a respiratory airflow signal, as detected from the sensor signal, processed using the baseline drift method, is shown in Fig 6. The extracted baseline, that is proportional to the airflow during respiration, is plotted in arbitrary units against the time. The signal measured by a conventional spirometer is shown as a reference, also in arbitrary units.

The mean heart rate measured from the wrist-worn sensor's pressure signal, and that measured from the ECG signal, are plotted against each other in Fig 7 for all 144 patients. There was a significant correlation between the two monitoring methods (r= 0.95, P<0.001). A more powerful way of examining the agreement between two measurement methods is to plot the difference between the values recorded by them, against their mean[5]. Fig 8 shows the difference versus average plot for the two mean heart-rate measuring methods. The error, that is the difference between the heart rates from the two methods, was independent of the mean heart rate value, considered to be the best approximation for the 'true' heart rate. The error distribution had a mean (SD) value of − 0.1 (3.3) BPM (beats/min). Assuming that the error is normally distributed, this implies that 95% of the results lie in the interval from − 6.6 to 6.5 BPM.

A similar analysis was performed of the system's accuracy in measuring mean respiratory rate. For this study, 206 out of 1520 sensor signals (14%), belonging to 45 patients, were too noisy for the algorithm to extract a decisive mean respiratory rate. The source of this noise was the relatively long episodes of hand movements during the measurement procedure. There

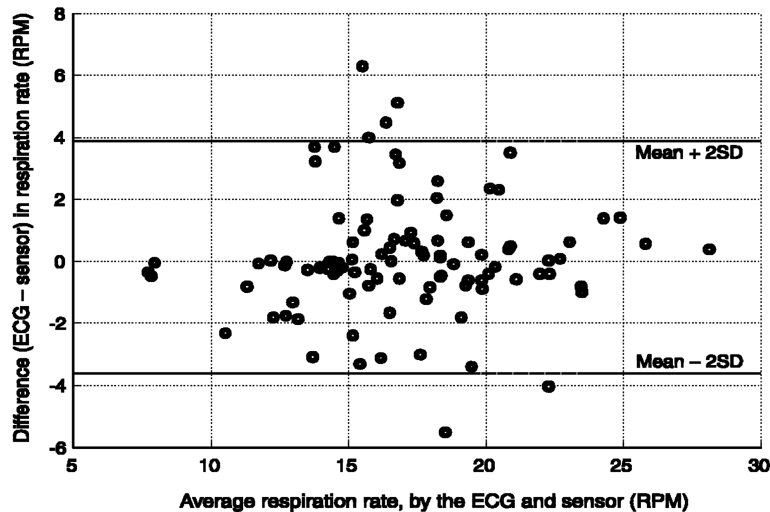

Fig 10 Agreement plot. Difference between the two mean respiratory rate measuring methods against their mean.

was a good correlation (r= 0.89, P<0.001) between the respiration rate measurements received from the wrist-worn sensor and those received from a spirometer (Fig 9). A 'difference versus average' plot between the two measuring methods is shown in Fig 10. The error distribution had a mean (SD) value of 0.1 (1.9) RPM (respirations/min). Assuming the error is normally distributed, 95% of the results lie in the interval from – 3.6 to 3.8 RPM.

Discussion

Telecare provides an opportunity to record the patient's vital signs regularly, over a long period of time, keeping track of changes and irregularities, and preventing clinical deterioration[6]. Telecare systems hold great promise in terms of a patient's quality of life. The regular measurement of vital signs, in the convenience of the patient's own home, not only reduces the need for frequent, costly hospitalization for patients being monitored following surgery, but also increases the chances of detecting and preventing morbidity[7]. Patients can remain in their familiar environment, and can initiate a session with the call centre whenever they feel the need to, most importantly when in distress. Although research shows that telecare imposes extra expenses, it may actually reduce the overall costs, without compromising quality[7–9]. Moreover, home-based surveillance before the implementation of telecare was shown to reduce morbidity and hospitalization costs among patients with severe cardiac disease[10]. With modern telecardiology facilities, such as the one described in the present study, further benefits are expected.

The feasibility of the system to measure mean heart rate and mean respiratory rate accurately was studied on 144 patients, some healthy and some undergoing cardiac catheterization. The results show that the system measurements are highly correlated to reference measurements performed with standard ECG and spirometer devices. The present study suggests that the Medic4All system represents a promising tool for online detection and monitoring of vital signs in the home.

References

1 Dorman T. Telecardiology and the intensive care unit. *Critical Care Clinics* 2001;**17**:293–301

2 Hersh W, Helfand M, Wallace J, *et al*. A systematic review of the efficacy of telemedicine for making diagnostic and management decisions. *Journal of Telemedicine and Telecare* 2002;**8**:197–209

3 Sable CA, Cummings SD, Pearson GD, *et al*. Impact of telemedicine on the practice of pediatric cardiology in community hospitals. *Pediatrics* 2002;**109**:E3

4 Berne RM, Matthew NL, eds. *Cardiovascular Physiology*. St Louis, MO: Mosby, 1997

5 Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986;**i**: 307–10

6 Scalvini S, Zanelli E, Domenighini D, *et al*. 'Boario Home-Care' Investigators. Telecardiology community: a new approach to take care of cardiac patients. *Cardiologia* 1999;**44**:921–4

7 Bruderman I, Abboud S. Telespirometry: novel system for home monitoring of asthmatic patients. *Telemedicine Journal* 1997;**3**: 127–33

8 Dansky KH, Palmer L, Shea D, Bowles KH. Cost analysis of telehomecare. *Telemedicine Journal and E-Health* 2001;**7**:225–32

9 Abboud S, Bruderman I. Assessment of a new transtelephonic portable spirometer. *Thorax* 1996;**51**:407–10

10 Kornowski R, Zeeli D, Averbuch M, *et al*. Intensive home-care surveillance prevents hospitalization and improves morbidity rates among elderly patients with severe congestive heart failure. *American Heart Journal* 1995;**129**:762–6