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A new telemonitoring system intended for chronic heart failure patients using mobile telephone technology — Feasibility study

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ABSTRACT

Background: Remote monitoring is one modality of structured care in chronic heart failure. The purpose of this study was to evaluate the feasibility of a new wireless telemonitoring system via a mobile phone network.

Methods: Portable home devices for electrocardiogram, blood pressure, body weight and self-assessment measurements were connected (via Bluetooth®) to a personal digital assistant (PDA) that performs automated encrypted transmission via mobile phone. Two telemedical centres were set-up.

Results: 30 healthy volunteers were enrolled and followed for 26 days. A total of 4002 single measurements were taken, 133 ± 37 per person. No data was lost or incorrectly allocated. 880 of 937 (94%) of the ECG recordings had sufficient diagnostic quality for rhythm analysis and single beat measurements. 50 continuous ECG-streams (312 min) without disruption were performed. Total system availability was 96.6%, including that of the mobile phone network.

Conclusions: Mobile phone technology is suitable for continuous and secure medical data transmission. To evaluate the clinical use in chronic heart failure patients, a large multicentre randomized controlled trial (ClinicalTrials.gov Identifier: NCT00543881) was started.

1. Introduction

The aim of telemonitoring in chronic heart failure patients is to prevent hospitalizations by early detection of disease worsening followed by immediate intervention. It is an area-wide approach to apply structured care for this chronic condition to maintain patients in a stable condition and thus reducing the high economic burden of heart failure on health care costs [1]. Beyond structured telephone support, device assisted monitoring with transmission of symptom and physiological data has become the subject of technical development and clinical evaluation. Clinical needs determine the design of the telemonitoring system from the medical expert perspective, but technical aspects answer the feasibility and acceptance by the patient. Based on the current opinion of technology assisted monitoring, we developed a new platform for remote patient monitoring suitable for long-term use [2]. Home devices for ECG, body weight, blood pressure and self-assessment measurements were used. For data transmission, the focus was placed on utilizing existing mobile phone technologies capable of transmitting large amounts of data based on the assumption that area-wide communication to rural regions in the future will be enabled by mobile phone technology. The final phase in the development of our system was a feasibility study where healthy volunteers were included to demonstrate its technical reliability prior to evaluating the system in a large randomized controlled trial. The development and testing of the system was funded by the German Federal Ministry of Economics and Technology (Project Nr. 01MG532).

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2. Materials and methods

2.1. General information concerning the system

The telemonitoring system consists of portable home devices for ECG, body weight, blood pressure and self-assessment measurements connected to a PDA via a local Bluetooth® network. The PDA has a touch-screen option for a scaled patient self-assessment. For emergency support, a mode for continuous ECG monitoring and oxygen saturation (live stream) may be activated. The PDA transmits the data via mobile phone to central servers where the measurements are organized in a workflow-based telemedical workstation incorporating an electronic patient record which is accessible by the two telemedical centres. A home emergency call system provides direct contact to the health care professionals (Fig. 1). The need for efficient intervention upon early detection of health deterioration determined the structure of the service. For worst-case situations, a direct line to the local rescue coordination service for emergency support was established. For less critical cases, the possibility of direct communication with the general practitioner, specialist and local hospital department was provided to conduct case conferences to discuss and implement appropriate medical care.

All home devices can be easily used by patients irrespective of their age and absence of any previous technical background or use of such a device.

The ECG device is a handheld unit weighing 210 g. There are two recording modes, one for daily single 120-s measurement using integrated dry electrodes on the bottom of the device for direct skin contact that record the Einthoven I, II and III leads. The ECG data are pre-processed by an analyzer software on the central server that detects arrhythmias or critical changes and prioritizes the order of the data presentation to the physician. The second mode is for emergency support and records continuously (i.e. live streaming) via gel electrodes for the Einthoven I, II and III and the Goldberger aVR, aVL and aVF leads. In this mode, oxygen saturation is also recorded by a pulse oximeter using a separate cable.

The weighing scales operates from 2 to 200 kilogram (kg) having a resolution of 50 g between 2 and 150 kg and a resolution of 100 g between 150 and 200 kg. The blood pressure device uses the automated oscillometric method on the upper arm. It has an accuracy of ± 3 mm Hg for pressure and $\pm 5\%$ for pulse rate. A standard PDA was modified for encrypted data transmission between the local Bluetooth® network and the mobile phone network. On the touch-screen, a colour-coded scale for the patient's self-assessment (green, greenish yellow, yellow, orange and red) along with a schedule for the daily measurements is provided.

The home-based emergency call system uses the analogue telephone line and can be activated directly by touching a button or by a remote control. It allows communication up to 20 m and can be initiated by the patient only.

A 120-s ECG measurement generates a 120 kByte file, ECG live streaming produces 100 kBit/s. To accommodate this data volume, a Global System for Mobile Communication (GSM) network with Enhanced Data Rates for GSM Evolutions (EDGE) was chosen. The telemedical workstation with the electronic patient record is a web application with a browser-based graphical user interface. Incoming measurements generate events according to medical prioritization rules to initiate a workflow-guided review process in the telemedical workstation and further evaluation by the medical professionals.

For the feasibility study, two telemedical centres were set-up, both situated in specialized hospitals with medical professionals experienced in treating chronic HF. The telemedical workplace consisted of an electronic patient record and a communication platform for emergency support with direct phone contact to the local rescue coordination services. The telemedical centres operated around the clock every day of the year. In the case of a technical breakdown, the complete work can be transferred to the other telemedical centre within a few minutes. Standard operating procedures and accident emergency plans were developed for patient safety.

The central database was located within the hospital complying with the state-of-the-art security standards on electronic archiving of medical data. For authentication of the individual measurements, each data transmission incorporated unique device identification information associated with the patient. Privacy of data was ensured through dynamic encryption.

To ensure patient safety, it was required that total system availability, including that of the mobile phone network, be at least 94%. Availability was defined as access to the central system internal and external to the telemonitoring system resulting in seconds of downtime. The total system availability was the product of the reachability of the single components.

For the feasibility study, 30 healthy individuals from two regions located close of the telemedical centres were asked to participate. There were no inclusion or exclusion criteria except the ability to use the home devices. Volunteers were given a 1-h training program by a nurse and were requested to take daily measurements with the home devices for 26 days.

3. Results

Thirty healthy volunteers (mean age 66 ± 10, 9 female, 21 male) were included from November 2007 to December 2007. The area of residence was randomly chosen with varying structural distinctions (mountainous area vs. non-mountainous, sparsely populated vs.

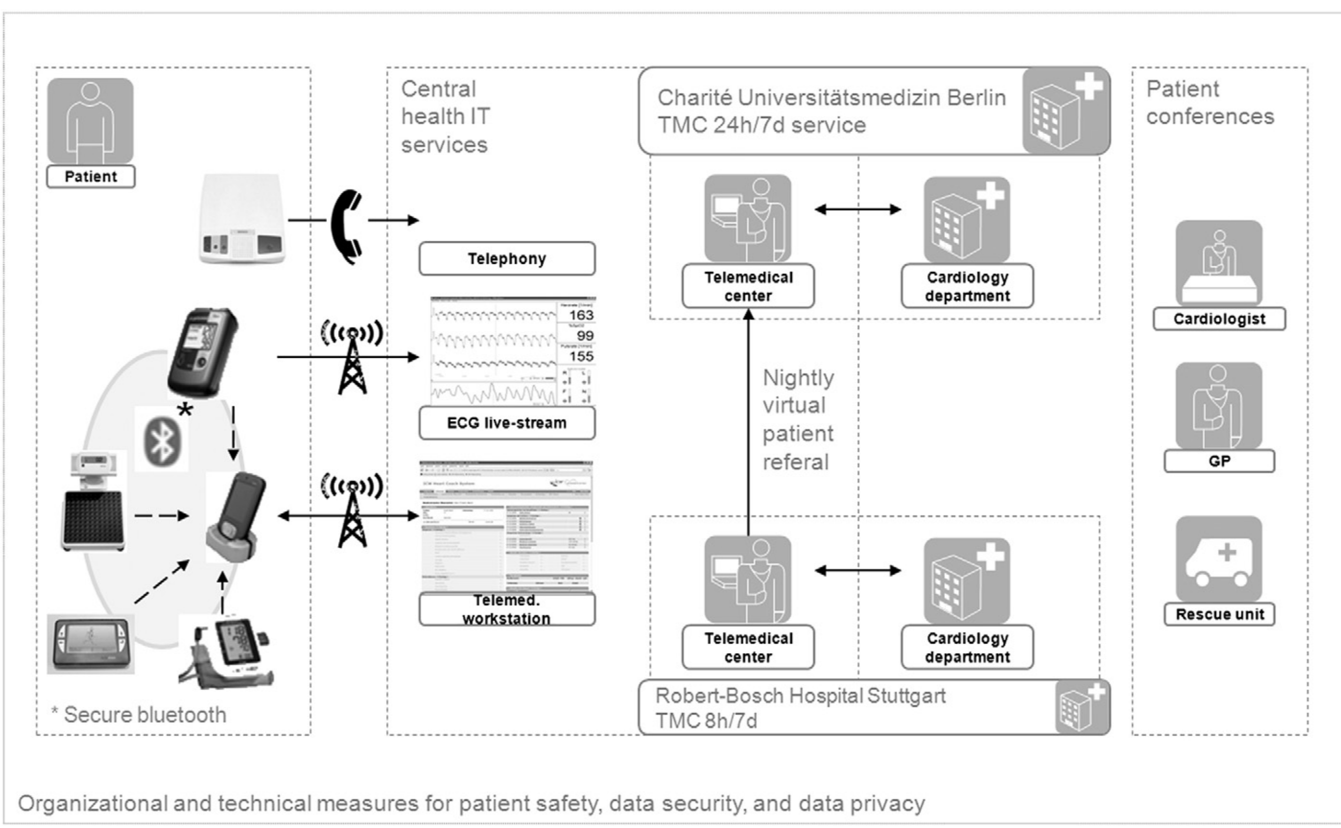

Fig. 1. Telemonitoring system and structure of service. Devices for ECG, blood pressure and weight are connected via Bluetooth® at the patient's home. A PDA transmits the data via its integrated mobile phone module to the central servers. There are two telemedical centres in hospitals for disease management communicating through an electronic patient record. A home emergency call system enables direct patient contact with the specialist.

Fig. 2. Detail of continuous ECG monitoring (live stream). ECG and plethysmograph waveforms as well as values for heart rate, arterial oxygen saturation (%SpO2) and information about electrode contact are shown in a web-based viewer.

congested urban areas). All participants were able to perform the measurements after a 60-min training program resulting in 100% complete data the following day. There was no need for repeated training. All persons completed the study period. In total 4002 measurements were taken within a 26-day period (body weight, n = 1038, blood pressure, n = 1063, ECG, n = 937, self-assessment, n = 964). Volunteers performed between 85 and 253 regular measurements (133 per person), the average period of participation was 24.3 days. A local repeater was required to boost GSM signal intensity in one location only. No data was lost or misallocated. 94% (880 of 937) of the ECG recordings had a sufficient diagnostic quality for exact rhythm analysis. 50 continuous ECG-streams (Fig. 2) totalling 312 min were taken (from 8 to 1125 s, mean 375 s). There was no disruption of transmission during live monitoring. Total system availability was 96.6%

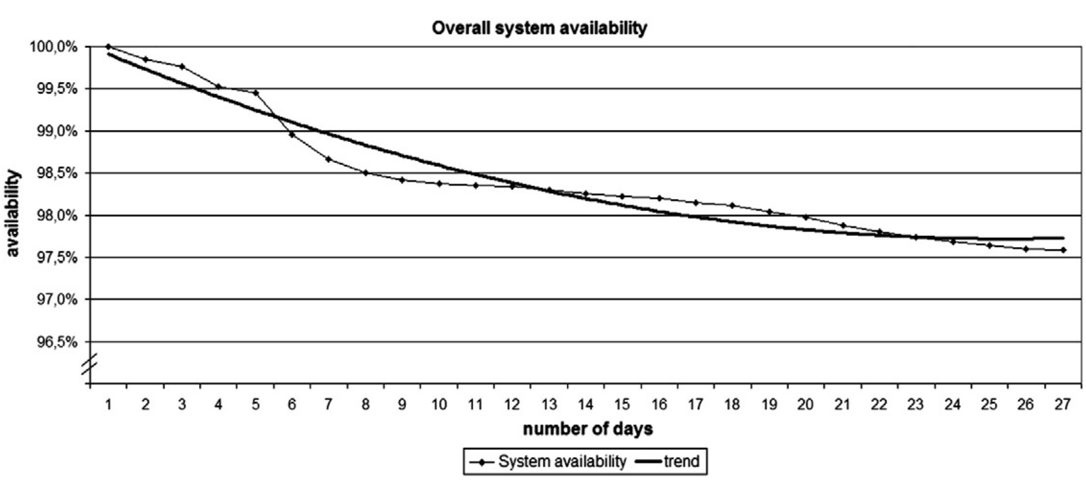

Fig. 3. Total system availability, measured as up-time of all central hardware components including mobile phone network and key software elements.

including the availability of the mobile phone network (Fig. 3). Two telemedical centres capable for around-the-clock service (24/7) and physician guided emergency support were established. It was demonstrated that in the event of an unexpected disruption in one telemedical centre the workload could be transferred to the other centre within 30 min.

4. Discussion

Telemedical approaches in chronic heart failure care have shown beneficial effects. Decrease in hospitalization and reduced mortality are reported both for structured nurse telephone support and for home telemonitoring with devices [3–8]. Apart from a disease related design, technology contributes substantially to the feasibility of such patient care. Most of the current telemedical systems are based on fixed cable data transmission and require time consuming training. Wireless technology preserves the patient's mobility and comfort. However, it is susceptible to faults and there is no defined standard for secure wireless transmission of medical data.

Our system is a new development intended for the remote monitoring of chronic heart failure patients using mobile phone networks. Because there is no evidence about the appropriate monitoring setting, the presented system was constructed as a robust and open platform to integrate other home devices for the monitoring of comorbidities (diabetes, chronic obstructive pulmonary disease, anticoagulants, and implantable cardiac device information). Contrary to usual clinical care in chronic heart failure management, the ECG is not part of current remote monitoring systems. Changes in heart rhythm and rate are frequent causes and indicators of disease worsening. Acute rhythm disorders can occur very suddenly at any time. Because of the hemodynamic relevance in CHF, this requires immediate diagnosis and prompt treatment, thus implicating around-the-clock (24/7) service. Our telemonitoring system offers a new device which not only acquires single measurements but can be used for continuous streaming of ECG and oxygen saturation, thus providing better support for the physicians triage and first aid management.

Monitoring of physiological data alone achieves little. It depends on the appropriate intervention. Hence the telemedical centres for the planned clinical trial were located inside hospitals and with direct contact to the rescue services to facilitate and accelerate the management of critical situations. The centres could operate around-the-clock (24/7) and full transferability enabled both sufficient and cost effective emergency support. In the feasibility study, the telemedical centres operated without technical disruptions.

In the feasibility study, all home devices used showed good usability. After structured training there was no further need for assistance in using the devices. The transmitted data had a sufficient diagnostic quality. The volunteers who participated in our feasibility were younger than the anticipated chronic heart failure population that will use our system. However, the emphasis of the study was not on usability of the home devices but on reliability of wireless data transmission.

This feasibility study demonstrated that wireless technology is suitable for continuous medical data transmission and fulfils the requirements of a secure and reliable system while maintaining patient privacy. A large multicentre randomized controlled trial to evaluate clinical use in chronic heart failure patients is currently underway. (ClinicalTrials.gov Identifier: NCT00543881). Results will be available in Q4 2010.

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The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology [9].

References

[1] European Society of Cardiology, Heart Failure Association of the ESC (HFA), European Society of Intensive Care Medicine (ESICM), et al. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2008: the Task Force for the diagnosis and treatment of acute and chronic heart failure 2008 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association of the ESC (HFA) and endorsed by the European Society of Intensive Care Medicine (ESICM). Eur J Heart Fail 2008;10:933–89.

[2] Köhler F, Schieber M, Lücke S, et al. Partnership for the Heart — Entwicklung und Erprobung eines neuen telemedizinischen Monitoring-Systems. Projekt des Innovationsprogramms “next generation media” des. BMWi DMW 2007;132: 458–60.

[3] Cleland JG, Louis AA, Rigby AS, et al. Noninvasive home telemonitoring for patients with heart failure at high risk of recurrent admission and death: the Trans-European Network-Home-Care Management System (TEN-HMS) study. J Am Coll Cardiol 2005;45:1654–64.

[4] Zhang J, Goode KM, Guddihy PE, et al. Predicting hospitalization due to worsening heart failure using daily weight measurement: analysis of the Trans-European Network-Home-Care Management System (TEN-HMS) study. Eur J Heart Fail 2009;11:420–7.

[5] Goldberg LR, Piette JD, Walsh MN, et al. Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: the Weight Monitoring in Heart Failure (WHARF) trial. Am Heart J 2003;146:705–12.

[6] Investigators GESICA. Randomised trial of telephone intervention in chronic heart failure: DIAL trial. BMJ 2005 Aug 20;331:425.

[7] Clark RA, Inglis SC, McAlister FA, Cleland JG, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. BMJ 2007 May 5;334:942.

[8] Klersy C, De Silvestri A, Gabutti G, Regoli F, Auricchio A. A meta-analysis of remote monitoring of heart failure patients. J Am Coll Cardiol 2009 Oct 27;54:1683–94.

[9] Coats AJ. Ethical authorship and publishing. Int J Cardiol 2009;131:149–50.