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Home telemonitoring of respiratory activity and heart rate variability in chronic heart failure patients: the challenge of the home or hospital in heart failure project

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Home Telemonitoring of Respiratory Activity and Heart Rate Variability in Chronic Heart Failure Patients: the Challenge of the Home or Hospital in Heart Failure Project

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Abstract

Nocturnal respiratory disorders and depressed heart rate variability are known predictors of poor prognosis in chronic heart failure (CHF) patients. Intermittent monitoring of cardiorespiratory signals while the patient is at home might thus allow early identification of clinical deterioration and prompt optimization of treatment, leading to reduced hospitalizations and mortality and improved quality of life. Within the European Community multicenter trial HHH (Home or Hospital in Heart Failure), we are testing a novel low-cost system for 24-hour recording of cardiorespiratory signals, suitable to be self-managed by the patient at home, with transmission of acquired data through standard telephone lines to the medical/nursing staff. Preliminary results from 24 CHF patients enrolled so far indicate that monthly home telemonitoring is feasible and the compliance is high.

1. Introduction

Periodic breathing (PB), a respiratory disorder characterized by cyclic phases of hyperventilation separated by hypopnea or apnea, occur very frequently in patients with chronic heart failure (CHF). Recent studies on PB report a prevalence as high as 64% and 70% during respectively awake laboratory recordings and sleep studies [1]. PB is accompanied by cyclical reductions in arterial oxygen saturation and by marked fluctuations of systolic and diastolic pressure and heart rate. Periodic hypoxemia causes an increase in sympathetic activity which may contribute to the occurrence of fatal arrhythmias and cardiotoxicity. Moreover, hyperventilation and the increased work of respiratory muscles place an increased demand upon the already failing heart, thus contributing to left ventricular dysfunction. In addition, the reduced amount of sleep brought about by frequent arousals causes fatigue and excessive daytime sleepiness. It is thus not surprising that recent studies have shown that CHF patients with severe PB have a reduced life expectancy [2].

Many studies on heart rate variability (HRV) either during long-term (24-hour) or short-term (<10 min) recordings have consistently shown that HRV indexes provide independent prognostic information on mortality in CHF patients [3,4].

One of the aims of the European Community multicountry study HHH (Home or Hospital in Heart failure, QLGA-CT-2001-02424) is to evaluate in the home setting a new system for long-term non-invasive cardiorespiratory and activity monitoring (NICRAM), suitable to be self-managed by the patient, with transmission of acquired data through standard telephone lines to the medical/nursing staff. For each patient, data are being collected once per month during an entire year. We expect these data to provide important information on: i) the prevalence, pattern and natural history of breathing disorders recorded during prolonged observational periods (more than one night or one day), and their relationship with the outcome, including clinical instabilization; ii) the clinical impact of simple treatment strategies aimed at suppressing PB (O_2 + theophylline); iii) the prognostic value of abnormal (i.e., markedly reduced) HRV with particular regard to hospital readmissions.

In this paper we will be giving a general description of the recording and transmission devices used in the HHH study as well as of the analysis procedures carried out on received recordings and of cardiorespiratory parameters derived from them. Details on the overall system architecture of the project are given in another manuscript of these proceedings.

2. Methods

2.1. The NICRAM recorder

The NICRAM recorder used in the HHH study is a Holter-style portable device (Report-24, FM, Monza, Italy - fig. 1) capable of recording 24-hours of ECG (single lead), respiration (bio-impedance technique),

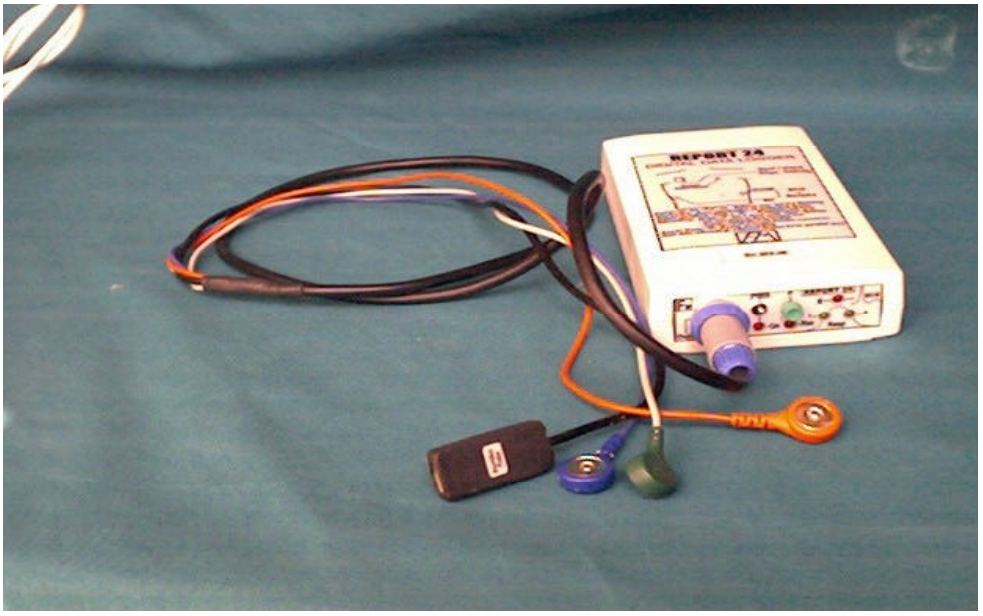

Fig.1. The NICRAM recorder used in the HHH study (Report-24, FM, Monza, Italy) with cables for monitoring ECG and respiration (those with electrode clips) and the sensor for body position and movement (small black box on the left).

body movement (by an accelerometer), body position and events. The device has been adapted to the specific needs of the HHH project through a strict cooperation between our group and the manufacturing company. The recorder is suitable to be easily handled by the patient at home and has the capability of being connected to a specialized modem device (see below) to transmit acquired data to the medical/nursing staff in the enrolling hospital.

Three ECG electrodes are used to pick-up both the ECG and the respiratory signal, while a small plastic box fastened on the patient's upper thorax by a piece of tape houses the body movement and position sensors (figure 2). All the wires from the electrodes and the sensor box converge to a unique cable plugged into the recording device. The signals are acquired at different sampling frequencies: 250 Hz for ECG, 10 Hz for respiration and 1 Hz for the movement and position signals. The movement signal is derived from the raw accelerometer signals. As the two pick-up electrodes are used both for the ECG and the respiratory signal (figure 2), an electrode position optimization procedure is usually required to find the best trade-off in the two signals quality. To this purpose, acquired signals can easily be inspected on a PC screen using a telemetry connection. The optimization procedure is carried out by the nurse at enrollment of the patient into the telemonitoring program and the digital picture with the optimal electrode positioning is then printed into the personalized user manual given to the patient before going home.

The recorder is also capable of performing a real-time preprocessing of the ECG signal to derive the corresponding RR time series. One lamp flashes at each detected QRS complex, while two other lamps signal the inspiration and expiration phases. Events can be recorder by pressing a button. All signals are continuously recorded on a solid state memory support (flash card, 32 MB). Since the raw ECG signal can not be transferred through the standard telephone lines in an efficient manner, only the RR time series is actually transmitted to the analysis center together with the other signals.

To reduce costs, NICRAM recorders are shared between different patients (3:1) and an express courier is used to bring them to/from the patient's home.

2.2. The Smart Modem

After completion of the 24-hour NICRAM recording, the recorder is connected by the patient to a Smart Modem (fig. 3) developed by a company member of the HHH consortium (Appel Elettronica, Torino, Italy). Data downloading (RR + respiration + movement/position) from the recorder to the Smart Modem memory buffer starts automatically after the connection. After completion of downloading, the Smart Modem carries out automatically the following tasks: i) dialing the receiving station (IVR) located in the national coordinating centre (see the paper on the HHH architecture in these proceedings), ii) setting-up a standard modem connection, iii) sending the patient ID, v) transmitting NICRAM signals, vi) managing all transmission problems, including restarting the transmission in case of communication failure. The patient has nothing to do but disconnecting the recorder after a lamp indicates the end of downloading. All received data are copied by the IVR into the study database (country database). In case of failure in data transmission, NICRAM signals are downloaded directly from the recorder when it is brought back to the hospital by the express courier.

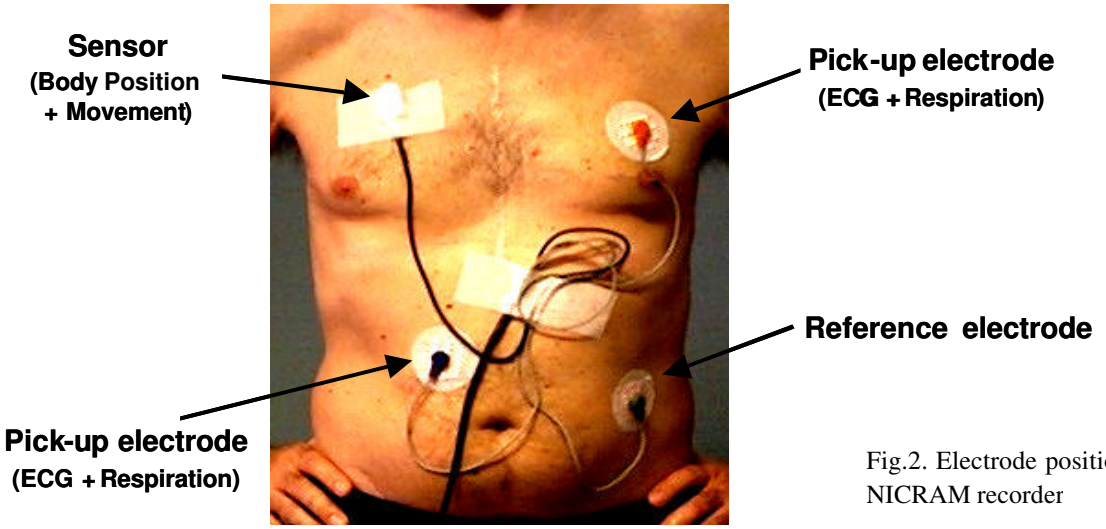

Fig.2. Electrode positioning of the NICRAM recorder

2.3. Signal quality check and analysis

Each newly received NICRAM recording is first checked by the signal analyst in order to assess signal quality. A NICRAM recording is judged as not acceptable by the SA when i) the respiratory signal or the R-R signal are absent (due for instance to electrode misconnection) or ii) when either of them does not satisfy the quality criteria defined in the guidelines of the study. A respiratory signal is defined as being of good quality when the signal-to-noise ratio is high enough to allow the signal analyst to reliably classify breathing activity (phasic, periodic or artifact) and detect abnormal respiratory events (hypopneas and apneas).
The RR signal is defined as being of good quality if its trend is compatible both in value and pattern with known human physiology and pathophysiology and there is a low rate of false detections and missing beats. Should the quality be poor, the patient will be asked to repeat the recording (for a maximum of 2 times).

The analysis of respiratory recordings provides a set of standard and non standard quantitative indexes of breathing disorders developed by the patient during the day, the night and the overall 24 hour period. They include: i) the duration of PB, ii) the total number of recognized apneas, iii) the apnea prevalence, iv) the apnea index and the apnea/hypopnea index.

The analysis of RR time series is carried out interactively on consecutive 5 min segments and provides a set of standard quantitative indexes of heart rate variability, in the time and frequency domain, for the overall 24 hour period as well as for daytime and night-time epochs. Final indexes are average measurements across all analyzable segments.

A report containing cardiorespiratory indexes as well as an uncalibrated physical activity score is i) sent to the patient's enrolling center and ii) saved permanently into the country database.

3. Ad interim results

The HHH study is currently in progress in the three European countries involved in the project (Italy, UK and Poland). Ad interim results on the feasibility and patient's compliance of home telemonitoring of NICRAM signals are now available for Italy, where 24 patients have been enrolled so far. Out of 130 scheduled recordings, 123 (95%) were actually feasible, being the patient alive and at home. Among them, 122 (99%) were actually carried out by the patients. Transmission of these recordings by means of the Smart Modem failed in 22 (18%) cases, due to patient error (46%), technical problems (18%) or organizational reasons (36%). Yet, most (91%) of non transmitted recordings were recovered by direct downloading of signals from the recorder. The final number of recordings available for analysis was 120 (98% of feasible recordings). One hundred and three respiratory recordings (84% of feasible recordings) were considered eligible for the study (> 2.5 hours of good quality data during the night), while 67 (56%) recordings satisfied the eligibility criteria for HRV (> 5 hours and > 2 hours of analyzable data during the day and night respectively). This eligibility rate for HRV is only slightly lower than the one we have observed (67%) in large sample (510) of edited and annotated RR time series from a commercial Holter system.

4. Conclusion

These preliminary results indicate that monthly 24-hour home telemonitoring of cardiorespiratory signals based on self-management of recording and transmitting devices is feasible in CHF patients and the compliance is high.

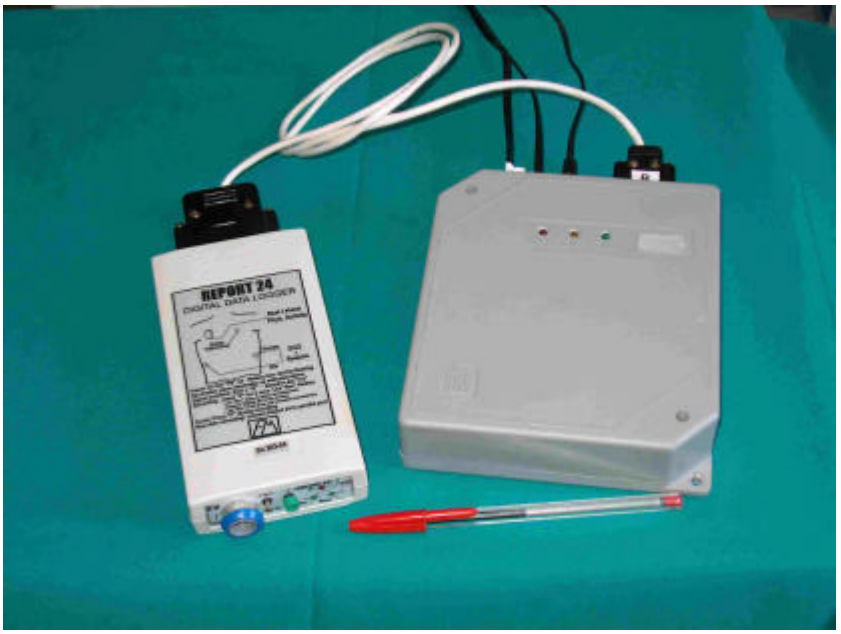

Fig.3. The NICRAM recorder Report-24 (left side) connected to the Smart Modem (right side) through the connection cable

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