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Monitoring Patients with Chronic Heart Failure Using a Telemedicine Platform: Contribution of the E-Care and INCADO Projects

Emmanuel Andrès[1]*, Samy Talha[2], Ahmed Benyahia A[3], Olivier Keller[1], Mohamed Hajjam[3], Jawad Hajjam[4], Sylvie Ervé[4], Justine Boehler[1], Catherine Grohens[1] and Amir Hajjam[5]

[1]Service de Médecine Interne, Diabète et Maladies métaboliques de la Clinique Médicale B, CHRU de Strasbourg, Strasbourg ; Centre de Recherche Pédagogique de la Faculté de Médecine de Strasbourg, Université de Strasbourg (UdS), Strasbourg, France

[2]Service de Physiologie et d'Explorations fonctionnelles, CHRU et Faculté de Médecine de Strasbourg, Université de Strasbourg (UdS), Strasbourg

[3]Newel, Mulhouse, France

[4]Centre d'Expertise des TIC pour l'autonomie (CenTich) et Mutualité Française Anjou-Mayenne (MFAM) – Angers, France

[5]Laboratoire IRTES-SeT, Université de Technologie de Belfort-Montbéliard (UTBM), Belfort-Montbéliard, France

***Corresponding author:** *Emmanuel Andrès, Service de Médecine Interne, Diabète et Maladies Métaboliques, Clinique Médicale B, CHRU de Strasbourg, 1 porte de l'Hôpital, 67091 Strasbourg Cedex, France, Tel: 03-88-11-50-66; Fax: 03-88-11-62-62; E-mail: emmanuel.andres@chru-strasbourg.fr*

Abstract

Introduction: Monitoring patients with heart failure by telemedicine systems is a potential means susceptible to optimize the management of these patients and avoid life-threatening emergencies. In this context, we experimented in real life an e-platform dedicated to automated, intelligent detection of situations at risk of heart failure.

Method: The e-platform based on medical sensors (TA, FC, O2, weight), communicating (Bluetooth), to go up, in real time, to an intelligent physiological information and an analysis of the ontology medical, leading ultimately to the generation of alerts. After a development phase, e-platform has been deployed and tested by health professionals and patients in an Internal Medicine unit with 20 beds, opened on emergencies to the Strasbourg University Hospitals (E-care project) and in patient home (INCADO project).

Results: 180 patients were included and 1500 measurements were taken. The patient profile included in this experiment was an elderly patient, poly-pathology in 90% of cases, with a loss of autonomy in 25%. Health professionals were using the e-platform every day to their great satisfaction. This experiment made it possible to: validate the technology choices, consolidate the system, and to test the robustness of the e-platform, l,n hospital and in patient home. The collection continuously allowed us to have the critical number of patients for more detailed analysis of the relevance of alerts related to heart impairment. A preliminary analysis showed the relevance of the generated alerts.

Conclusion: The E-care and INCADO projects have developed an "intelligent" communicative platform enabling the monitoring of patients with chronic heart failure using non-invasive sensors. As a result, this platform will assist health care professionals, especially patient nurse or doctor, by providing an automated processing of these sensors' transmitted data in order to early detect and report signs of cardiac impairment.

Keywords

Heart failure, Telemedicine, Detecting signs of cardiac impairment, Follow-up, Health care professional, Nurse

Introduction

In France, nearly 1 million people suffer from heart failure (HF), and over 120,000 new cases are diagnosed every year [1-3]. Thereby, HF is a public health problem. Managing HF is a complex, lengthy, often difficult task, with great cost to our Society, both in terms of healthcare and treatment time as well as from a financial standpoint [2,3]. HF is a chronic disease which, in addition to its significant mortality (50% at 5 years for advanced forms), has significant morbidity and induces frequent re-hospitalizations, some of which could be avoided through early action [1].

Daily monitoring of stage III and IV of the New York Heart Association (NYHA) patients, by the patient himself or by health care professionals, e.g. a nurse, prevents heart impairment and may be of interest to prevent acute HF and may of interest to preserve a good quality of life of the patients [4]. Monitoring chronic HF patients by using telemedicine systems is a potential means for optimizing the patient management process. Using telemedicine systems is also a potential means for optimizing the management of these patients.

In this context, the E-care and INCADO project are developing an "intelligent" communicative platform enabling the home monitoring of patients with NYHA stages III and IV HF using non-invasive sensors. As we describe here, this e-platform is initially developed and validated in hospital and currently deployed in patient home.

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Materials, Patients and Methods

Materials

The E-care project, selected in 2011 as part of the tender: "services numériques pour la santé et l'autonomie" (grant: "Investissements d'Avenir" from the French government), was designed with the principal objective of optimizing patient monitoring, especially by detecting precursor signs of cardiac impairment or acute HF via a telemedicine system [5]. The E-care platform enables patients with NYHA Stage III HF to be monitored using non-invasive sensors [5]. This system is combined with motivational and educational tools.

After development and validation in hospital environment, the E-care platform is deployed in patients' homes, in the era of Strasbourg, as part of the project "INsuffisance CArdiaque à Domicile" (INCADO) (grant from the Agence Régionale de la Santé [ARS] d'Alsace, Strasbourg, France).

The E-care platform is developed to facilitate the job of the nurses and other health care professionals. It provides assistance to the health care professionals by automating the processing of data sent from the sensors, automatically generating alerts in order to detect and report risk situations of HF early (Figure 1) [6,7]. This platform also enables the sharing and management of heterogeneous data so as to integrate the necessary information required for monitoring any underlying pathology, such as diabetes mellitus, renal failure, respiratory insufficiency, and so on.

At the beginning of the experimentation, the e-platform is built around: 1) a console installed in the patient's room or home, for collecting vital signs; 2) non-stationary signal description tools (emitted from the sensors); 3) a central application for the reasoning and processing of physiological and medical data based on semantic web technologies [5-7].

The early detection of cardiac impairment involves processing data from multiple factors, as weight, blood pressure (BP), oxygen saturation, patient ergonomics, in addition to dietary monitoring, based on the phenotypic data of each patient (personalized medicine) [5-7]. All of these consolidated elements, combined with each patient's individual profile, facilitate not only the detection of cardiac abnormalities, but also the prevention of cardiac impairment risk factors.

Our platform uses an ontology designed to define a controlled vocabulary of diseases, medications, symptoms, and so on, as well as to model concepts related to chronic HF monitoring [5-7]. The reasoning portion is based on an inference engine in which the rules are either introduced by medical experts or generated by a data search and subsequently validated by medical experts. The E-care system fully capitalizes on its ability to consolidate different data information concerning the patient.

For each patient, E-care processes in real-time the personal data collected by the sensors, then analyzing it in conjunction with the domain ontologies describing their pathologies, medications, and symptoms [5]. This first inference constitutes its first learning process by adding new information to the patient ontology. In the second stage, E-care consolidates all the information relative to all patients in order to enhance the system. New rules are then added by searching for similar patterns describing critical events. This second step is effective as soon as there is a lot of data to process.

Patients

In a first step (E-care project), the system has been deployed in a 20-bed unit of the Department of Internal Medicine, Diabetes and Metabolic Diseases of the Medical Clinic B of the Strasbourg University Hospital (in Strasbourg, France). This unit is "open" to the emergency wards and constitutes part of the HF division implemented at the Strasbourg University Hospital (Strasbourg, France). Our experimentation of the E-care system has begun in October 2013. All

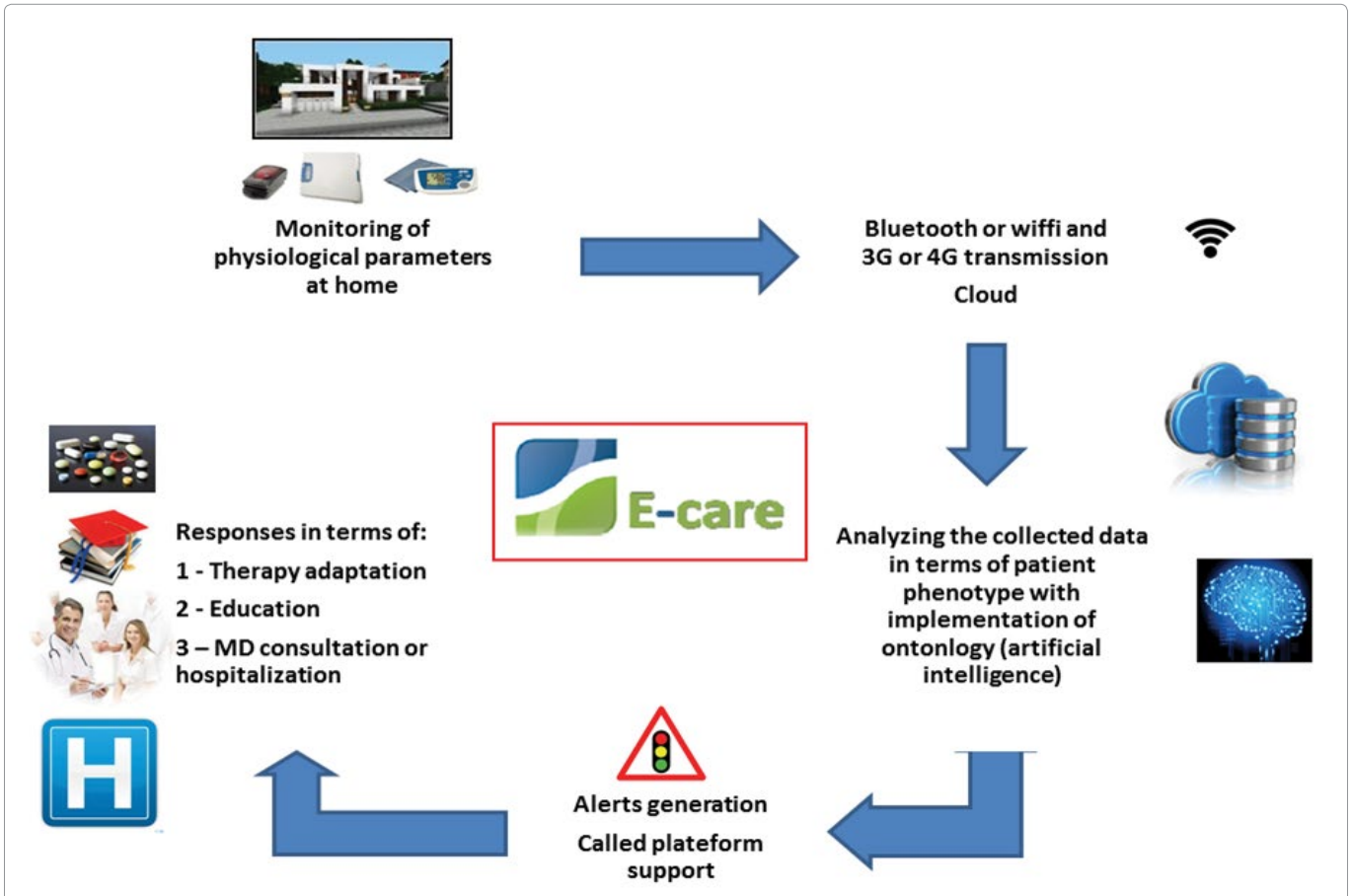

Figure 1: *E-care* platform deployed in the Department of Internal Medicine, Diabetes and Metabolic Diseases of the University Hospital of Strasbourg (in Strasbourg, France).

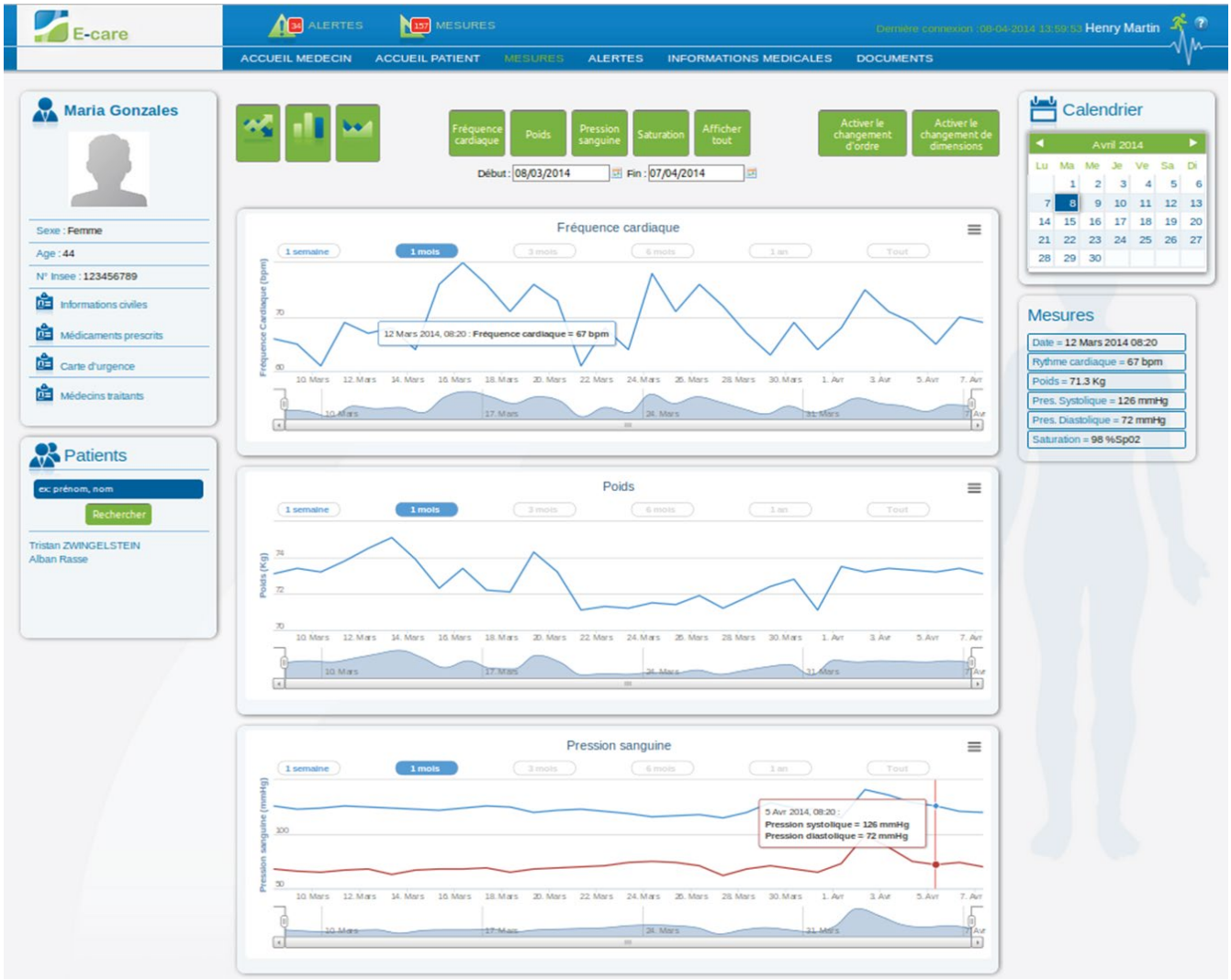

Figure 2: Man – machine interface of the system (version 2) deployed in the University Hospital of Strasbourg and in the patient home (Strasbourg, France).

consecutive adult patients of the 20-bed unit were considered to be including in the study.

In a second step (INCADO project), the system was deployed in patients' homes, in the era of Strasbourg (France). Consecutive patients with chronic HF were included and follow-up during 1 year.

Objectives

The primary objective was the validation of the e-platform and documentation of the interest of the system in the hospital world. This phase consists of the deployment of the E-care platform in real life, in the 20-bed unit of our Department. Nurses and health care professionals use the E-care measurement devices on a daily basis.

In the second phase, we tested the E-care system using (pre) determined indicators, verifying the relevance of triggered alerts, in order to assess improvements that could lead to improved patient management. At the time of writing, the second test phase was underway with the deployment of the e-platform in patient home (inclusion of patients still ongoing).

The continuous gathering of data during these two phases enables us to obtain the critical mass of patients needed to conduct a more detailed analysis of the relevance of the alerts.

Administrative authorizations

A file was submitted to the "Commission Nationale des Libertés" (CNIL). The study was presented to the local ethic committee who has given permission for the E-care system experimentation. The study was also registered in clinicaltrials.gov: "Anticipation and detection of heart failure with automatic treatment of information derived from non-intrusive sensors and devices" (no: NCT02411279).

Results

Characteristics of the patients

The system has been deployed since October 2013 in a 20-bed unit of the Department of Internal Medicine, Diabetes and Metabolic Diseases of the Medical Clinic B of the Strasbourg University Hospital (in Strasbourg, France). This unit is "open" to the emergency wards. Around 800 patients are hospitalized in this unit per year. To date, more than 180 patients have been included in the 2 phases of the study (inclusion of patients still ongoing).

The patient profile included in this experiment was: elderly patient, with several chronic diseases as: chronic HF > 60%; anemia > 40%; arrhythmia due to atrial fibrillation (AAF) > 30%; type 2 diabetes > 30%; chronic obstructive pulmonary disease > 30%; cancer 20%; chronic renal failure > 15%; and dementia > 15%. In 25% of cases, patients present a total loss of autonomy.

Results of the two phases of the experimentation

The first test phase was underway in the Department, commenced in February 2014. To date, over 180 patients have been enrolled and over 1,500 measurements performed. Nurses use the E-care measurement devices on a daily basis when carrying out their patient rounds. This phase relies notably on the establishment of a new human-machine interface and new inference engine (Version 2 of E-care platform) (Figure 2). This phase includes a satisfaction and practical use survey of the system's ergonomics, filled out by

caregivers and patients. The E-care system operated perfectly and the experimental phase enabled us to validate the technological choices. A qualitative survey of the health care professionals and patients helped to positively assess the system's ergonomics. A preliminary analysis of the relevance of alerts, admittedly on a limited number of patients with acute HF during hospitalization (n = 12), with our first inference engine design resulted in no malfunctions.

At the time of writing, the second test phase (INCADO project) was underway with the deployment of the e-platform in patient home (inclusion of patients still ongoing). The continuous gathering of data during this second phase enables us to obtain the critical mass of patients needed to conduct a more detailed analysis of the relevance of the alerts. Several patients with chronic HF are included with a daily use of the system by the personnel patient health care professionals (n = 10). Preliminary analysis shows that using telemedicine systems is a potential means for optimizing the management of patients with chronic HF and to facilitate the job of the nurse and the health care professionals.

Discussion

As we have demonstrated, the E-care and INCADO projects are developing an "intelligent" communicative platform enabling the monitoring of patients with chronic HF using non-invasive sensors (Figure 1). As a result, this platform will assist health care professionals by providing an automated processing to early detect signs of cardiac impairment. Our telemonitoring e-platform uses advanced technology in order to ensure the home telemonitoring of vital signs [5-7]. The E-care platform uses an ontology designed to define a controlled vocabulary (diseases, medications, symptoms, etc.) and to model concepts related to the monitoring of HF.

The monitoring of chronic disease patients using telemedicine systems is theoretically a promising means for optimizing patient management in these cases, as already demonstrated in certain diseases, such as diabetes or chronic HF [2,4]. Meta-analyses have suggested that telemedicine can reduce morbidity and mortality in patients with these types of disorder [4].

Nevertheless, the results of telemonitoring studies and meta-analyses have been controversial. In reviews assessing these methods, telemedicine approaches range from computer-based support systems to ones founded on structured telephone support, or even to programs led by nurses and physicians [2,8,9]. Thereby, it is difficult to have a definitive opinion based on what we know now on whether or not telemedicine has a significant role to play in HF management.

Meta-analyses have suggested that telemedicine, with heath care monitoring (patients himself or health care professionals), can reduce morbidity and mortality in patients with these types of disorder. In the exhaustive meta-analysis from Anker et al., 11 studies were analyzed in the setting of a comparison between the effects of telemonitoring versus usual care (noninvasive telemedicine) [4]. Telemonitoring was found to reduce the following rates: all-cause mortality (10.4% vs. 15.4%; $p < 0.0001$); all-cause hospital admission (47.2% vs. 52.1%; $p = 0.02$); hospital admission related to chronic HF (22.4% vs. 28.5%; $p = 0.008$).

Still, 2 prospective clinical trials have produced results that do not support these findings [10,11]. The Tele-HF trial randomly assigned patients hospitalized for HF to either telemonitoring (n = 826) or standard care (n = 827) [10]. In this trial, no significant difference was noted between the telemonitoring and control groups in terms of rate of any readmission or death from any cause within 180 days of inclusion (HR: 1.04; 95% CI: 0.91–1.19).

The TIM-HF trial in Germany randomly assigned stable chronic HF patients to either telemonitoring (n = 354) or usual care (n = 356) [11]. In this trial, the total mortality rate for the primary outcome of death for any cause was 8.4 per 100 patient-years of follow-up in the telemedical group, compared to 8.7 per 100 patient-years of follow-up in the usual-care group (HR: 0.97; 95% CI: 0.67–1.41; $p = 0.87$).

Advances in telecommunication technologies have created new opportunities to provide telemedical care as complementary treatment to the medical management of HF patients. In recent years, there has appeared to be renewed interest in France in the field of telemedicine and its applications for chronic HF, with the development of several projects, such as: SCAD (Suivi Cardiologique A Distance, remote cardiological monitoring); PIMP's (Plateforme Interactive Médecins Patients santé, doctor-patient interactive healthcare platform); OSICAT (Optimisation de la Surveillance Ambulatoire des Insuffisants CArdiaques par Télécardiologie, optimization of ambulatory HF monitoring with telecardiology), and MEDICA (Monitorage Electronique à Domicile de l'Insuffisance CArdiaque chronique, home electronic monitoring of chronic HF) [12-15].

At the time of writing, no published results were available from these projects. All these projects are non-invasive and designed to enable patient management at home or in nursing homes.

They are mostly based on standard tools for monitoring HF, namely blood pressure monitors, weighing scales, and so on, at times integrating tools enabling the feedback and transmission of collected information (Bluetooth, 3G, 4G, etc.) as well as patient-healthcare professional interaction (call center, digital tablet, website, etc.) [12-15]. Several projects have also integrated motivational and educational tools. One of these project: the "Plateforme Interactive Médecins Patients santé" (PIMP's) project also includes biological telemonitoring, with brain natriuretic peptide (BNP) telemonitoring [15].

These projects are based on prospective or cohort studies of HF patients, with widely varying sample sizes of 100 to 1000 patients, and different follow-up periods ranging from 3 months to 2 years, for the most part stemming from evidence-based medicine [12-15]. It is important to emphasize that the objectives or indicators of these various projects vary from modest to the more ambitious, defined as anything from improved morbidity and mortality to reduced readmissions, enhanced quality of life, and improved health economic costs.

Compared to other telemedicine projects, our projects thus envisage an "intelligent" and communicative platform to carry out home monitoring, using non-invasive sensors, of patients with chronic HF [5]. As such, this platform assists the medical team by automating the processing of information transmitted by these sensors in order to detect and report risk situations of cardiac impairment early (Figure 2).

Once the system will be consolidated, the third phase will consist in implementing E-care in mid-term hospital stays, post-care, long-term care, and in retirement homes. This last phase will enable us to conduct a comprehensive study, notably in order to work on improving medical diagnosis by promoting the self-learning capacity of the system, therefore improving the detection of any anomaly at an even earlier stage.

The expected future development of this platform in providing a coherent solution in the field of medical monitoring will involve taking into account various diseases and equipment limitations. E-Care is an open and scalable platform enabling the sharing and management of heterogeneous data relating to different diseases.

Conclusions

The E-care and INCADO projects are developing an "intelligent" communicative platform enabling the home monitoring of patients with chronic HF using non-invasive sensors. Our telemonitoring e-platform uses advanced technology and ontology process. Our system assists the health care professionals (nurse or Doctor) by automating the processing of information transmitted by the sensors, automatically generating alerts in order to early detect and report risk situations of HF impairment. In our experience, monitoring patients with HF by using telemedicine systems is a potential means for optimizing the management of these patients and to facilitate the job of the nurse and the health care professionals.

Author contributions

This work was carried out in collaboration between all authors. E. Andrès and S. Talha designed the study, wrote the protocol, and wrote the first draft of the manuscript. E. Andrès, S. Talha, A. Hajjam managed the literature searches, analyses of the results of the study. All authors read and approved the final manuscript.

Conflict of interest

none

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