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Home Care Security (HOCAS): A Telemedicine Project to Monitor Patients with Heart Failure and Atrial Fibrillation under Anticoagulation at Home

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Authors' contributions

This work was carried out in collaboration between all authors. Authors EA, ST, MH and AH designed the study, wrote the protocol, and wrote the first draft of the manuscript. Authors EA, SA, MH, JH, SE and AH managed the analyses of the study and literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Monitoring patients with heart failure, atrial fibrillation and under anticoagulant agent by using telemedicine systems is a potential means for optimizing the management of these patients. The HOCAS project is developing an "intelligent" communicative platform enabling the home monitoring

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of patients with heart failure, arrhythmias and anticoagulation drugs using non-invasive sensors, electronic pillbox to promote therapy adherence, a questionnaire to monitor patients' hygiene and diet, a questionnaire to monitor patients' therapy adherence together with additional contextual information and patients' profile. As a result, this platform will assist health care professionals by providing an automated processing of these sensors' transmitted data in order to detect and report signs of cardiac decompensation early or wrong adherence to therapy.

Keywords: Heart failure; atrial fibrillation; anticoagulant agent; telemedicine; home support; detecting signs of cardiac decompensation.

1. INTRODUCTION

In France, nearly 1 million people are affected by heart failure (HF) and 120 000 new cases emerge each year. At least 40% of these patients also have arrhythmias with a majority of atrial fibrillation (AF). HF is defined by a high level of mortality (50% of deaths occur within 5 years of early symptoms) (Fig. 1), a major disability to the daily life of sufferers (shortness of breath, fatigue, etc.) and prolonged and recurring hospitalizations [1].

Patients under anticoagulant agents (Vitamin K antagonist, oral direct anticoagulation [ODA]) also have bleeding, in relation with comorbidities (renal failure...), drugs interactions and problems of observance [2].

HF and AF, long term anticoagulation therapy consequently diminishes the quality of life of the patients and has a major economic impact on the health care costs coming primarily from the high cost of re-hospitalization (leading cause of hospitalization among people aged over 65) and from the recurrent episodes of cardiac decompensation or bleeding [2,3].

In this context, the present project framework, the *E-care* (http://www.projet-e-care.fr/) platform designed in the framework of the « Investissements d'Avenir » program (national program from the French Government to promote translational research, 2010) and University implemented at the Hospital Strasbourg (in Strasbourg, France) since October 2013 will be used to monitor patients at home: to detect cardiac decompensation; to monitor drugs intake and to promote adherence to treatment, in particular anticoagulant agents; to facilitate interaction between healthcare professionals [4]. Additional collected data through the INCADO project (grant from the Agence Régionale de la Santé d'Alsace [ARS], 2015) were also used to implement the present project

(<u>https://www.youtube.com/watch?v=3yC2IYZWm</u> <u>3Y</u>) [5].

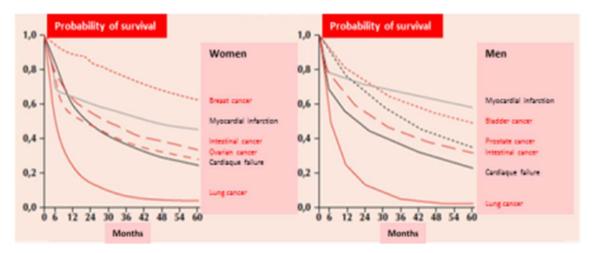


Fig. 1. Probability of survival in case of chronic heart failure related to myocardial infarction in comparison with several cancers (*adapted from* [4])

2. MEDICAL, SCIENTIFIC AND TECHNO-LOGICAL OBJECTIVES

Increased life expectancy generates changes in the leading causes of morbidity and mortality with more than 70% attributable to chronic diseases [6]. More than 15 million patients today contract such diseases and the expected figure amounts to 20 million by 2020. At least 40% of these patients also have arrhythmias with a majority of AF. AF contributes to the deterioration of the heart function mainly through a reduction in the filling of the left ventricle and through a decrease of the myocardial contractions. Such diseases generate an increase in healthcare costs within the vast majority of developed countries. Episodic care and intermittent care circuit are not suited to the needs of people suffering from chronic diseases, sometimes leading to an improper use of medications and hospital resources and hence generating significant costs supported by the health system [7].

HF main symptoms (patient's signs) consist in shortness of breath associated with strain which may remain when at rest and fatigue possibly worsening with the aggravation of the disease [1,7,8]. In the event of a cardiac decompensation, fluid retention signs (weight gain, edema) occur (<u>https://www.youtube.com/watch?v=Er-</u> o3GWPXxo). Such signs may worsen and

eventually threaten patients' life (acute pulmonary edema possibly leading to asphyxiation and cardiac arrest). AF main symptoms consist of palpitations. In practice, the main causes of cardiac muscle deterioration are: high blood pressure; coronary artery disease; heart valve(s) dysfunction; tachycardia; anemia; pneumonia and the lack of adherence to lifestyle changes and therapy [3].

Current patients care aims at improving their quality of life through: alleviating symptoms (shortness of breath, fatigue, etc.); allowing for the activities of everyday life; preventing decompensation episodes and reducing hospital stays; and slowing the progression of the disease, and reducing its mortality rate [1,8].

The management of HF is currently based on 2 components: 1) a non-pharmacological based treatment related to the prescription of dietary practices and regular physical activity. Such diet and hygiene education is a key element of the therapeutic patient education; and 2) a well-

established and efficient pharmacological treatment (drugs) against HF and AF [1].

In order to improve HF care, especially in patients with AF under anticoagulation therapy, the most relevant solution consists in cardiac decompensation prevention by anticipating the symptoms via a regular monitoring of vital parameters and to promote adherence to lifestyle changes and therapy [7,8]. This adherence may have an impact of the prevention of bleeding and/or thrombosis in these frailty patients.

The current project (*HOCAS*) objective is to secure home care of these patients (Fig. 2). Early detection, prevention and treatment of long-term complications of chronic diseases and chronic therapy should contribute to limit costs, promote the emergence of new organizations, more efficient and more secure than conventional practices, and provide a better quality of life to patients.

Patients care and follow-up at their home allows monitoring their medical parameters and the storage of these so as to provide a historical record and to interpret them in order to detect at an early stage risk situations and support the caregivers' diagnosis [4]. The argument here relies on the decision-making process of the doctor which stems from the comparison between the findings of the interrogations, the clinical examination and the additional medical test results, based on the theoretical and practical knowledge and expertise gained over time through experience.

3. PATIENTS AND METHOD

The project aims at exploiting the *E-care* medical platform (<u>http://www.projet-e-care.fr/</u>) in order to monitor patients based at home [4]. It will enable us to establish a generic detection process, at the earliest possible stage, for any abnormal evolution and consequently improve the medical diagnosis for patients with one or several chronic diseases. This project will be focusing on HF, taken as a testing disease.

The adapted *E-care* platform (Fig. 2) will monitor between 50 to 100 consecutive patients with stable HF, AF and under anticoagulation drugs at home on a daily basis, using non-intrusive sensors: sphygmomanometers, oximeters, scales, thermometers and electrocardiography to monitor vital signs, electronic pillbox to promote therapy adherence, a questionnaire to monitor patients' hygiene and diet, a questionnaire to monitor patients' therapy adherence together with additional contextual information and patients' profile (e.g.: patient's age and medical history, etc.), during a period of at least 1 year. The patients fully benefit from therapeutic education through the Man – Computer interface. The *E-care* platform is described in detail in the reference [9].

Information monitoring and data collection will then be utilized to examine the combined evolution of all patients' vital signs, behavior and personal health practices (Fig. 3). This will aim at detecting the most relevant repetitive sequences (markers) allowing for the earliest and best suited medical support for a given patient. This supervision will be individualized on a very broad population.

The patients were be recruited and followed by the University Hospital of Strasbourg (Strasbourg, France), one of the major medical care and research centers in France. It hosts more than 2000 beds and employs more than 10.000 people. It is an important reference for European City University hospitals.

This study will compare the group with monitoring through the adapted E-care platform to the group without monitoring (not randomized design of the study).

4. PROJECT'S INNOVATIONS AND EXPECTATIONS

Cardiac decompensation detection, drugs intake monitoring and to adherence to treatment involves a monitoring process well suited to the various vital signs and to the hygiene and diet practices, drug intake [7-9]. Indeed, it is the whole set of these elements, together with the patient's profile, which will enable the detection of every cardiac defect and at the same time prevent risk situations.

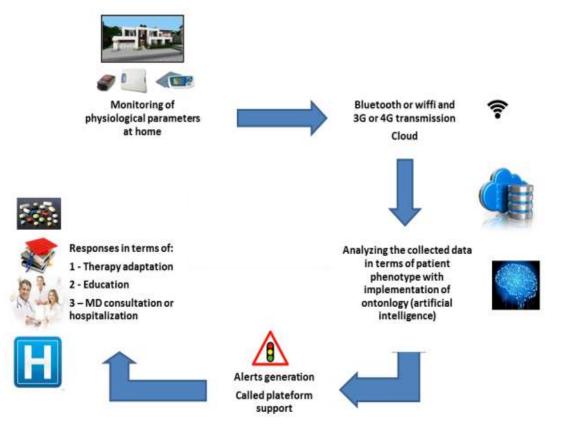


Fig. 2. Overall architecture of the HOCAS platform for monitoring heart failure, atrial fibrillation and anticoagulant therapy

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Screenshot of the man - machine interface (touch pad) From the Ecare platform

Fig. 3. Screenshot of the touch pad from the E-care system deployed in mid-term hospital stays, post care, long-term care, and in retirement homes, as well as in patient homes

Semantic Web technologies, used by E-care [10], provide us with a solid approach to the management of the associated information and processes management. They are being used increasingly for a broad spectrum of applications within which the domain expertise is modeled and formalized (ontology) in order to support widely diversified computer processing (thinking). Using effectively ontologies for reasoning purposes entails that an operational semantic be added, identifying how the modeled expertise of the ontology will be used for reasoning purposes and for the automated generation of new expertise and knowledge.

The number of daily data collected among a wide cohort of patients, together with their specifications and the information relating to their health practices is considerable. Statistical and data mining methodologies consequently play a key role in the acquisition of new knowledge. Data mining and ontological meta-data are powerfully correlated. Data mining technologies help build the *Semantic Web* and the latter helps retrieve and acquire new knowledge [11].

Our work will focus on the utilization of data mining technologies in order to enrich the ontology and to generate new knowledge. Such enrichment is defined as « adapting ontology to the need for change and the dissemination of these changes to the depending artefacts while preserving consistency ». This enrichment will generate an assessment which will take into account several quality aspects such as structure and utilization. In the defined field, we will focus on the validation of consistency and the assessment of quality. Consistency validation consists in verifying that all medical rules remain true once changes have been applied. Quality assessment allows for the changes final acceptance decision.

Such data mining technologies, used in the generation process of new knowledge, will be based on the search for markers which define the symptoms upon their first appearance. Nonsupervised learning enables the finding of markers or descriptors dependencies yet unknown, latent or concealed. This is particularly interesting when markers change slowly over time.

To this end, Kohonen self-organizing maps (*Self-Organizing Kohonen Maps*: *SOM*) and nonsupervised learning neural networks will be utilized in order to obtain a data interpretation process showing the evolution of the vital signs. Such process must be a stand-alone process, automatically self- configurable, adjustable to any change or evolution of the context and capable of building up knowledge of its own operation so as to improve during such operation [12]. Symptoms specification taking into account the evolution of each vital sign associated with hygiene and healthy lifestyle will enable us to formalize detection at the earliest possible stage thus ensuring efficient treatments. One of the main objectives will be the consolidation of all collected data in order to enrich the ontologies to which the thinking will be applied.

The *HOCAS* project naturally ties in with the development of partnerships between the university labs and Health and Autonomy technology companies. It will bring together complementary partners used to working together as demonstrated by the projects carried out (*ASAP*, grant from the French national Research Agency [*ANR Technology*], 2006; *STETAU* – "*Therapeutic innovations*" competitiveness cluster [*DGE*], 2004) in the last 5 years (communicant and intelligent stethoscope) [13,14].

Partners 'expertise, interdisciplinarity and complementarity are fully meeting the requirements expected as regard medical, scientific and structural skills that will ensure the necessary feasibility conditions for the project design, experimentation and assessment.

5. CONCLUSIONS

Monitoring patients with heart failure, atrial fibrillation and under anticoagulant agent by using telemedicine systems is a potential means for optimizing the management of these patients. The HOCAS project is developing an "intelligent" communicative platform enabling the home monitoring of patients with heart failure, arrhythmias and anticoagulation drugs using non-invasive sensors, electronic pillbox to promote therapy adherence, a questionnaire to monitor patients' hygiene and diet, а questionnaire to monitor patients' therapy adherence together with additional contextual information and patients' profile. As a result, this platform will assist health care professionals by providing an automated processing of these sensors' transmitted data in order to detect and report signs of cardiac decompensation early or wrong adherence to therapy.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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