Noninvasive home telemonitoring for patients with heart failure: A review of medical consensuses

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Abstract. Heart Failure (HF) is the leading cause of death in Western World, producing the highest number of hospitalizations in patients over 65 years. These continuous hospitalizations generate high costs to the health system. Studies point out that multidisciplinary post-discharge treatment programs, i.e. telemonitoring or structured telephone support, can avoid a large portion of readmissions related to HF, with benefit also in mortality, length of hospital stay and quality of life. Considering the impact of telemonitoring in HF, this paper aims to identifying the different world opinions and recommendations of the participants in the management, treatment and monitoring of HF. This purpose is achieved by studying the different HF consensuses. From this study it was possible to detect a number of aspects (parameters to be monitored, health education) that should be considered when a telemonitoring system for HF patients is designed.

1. Introduction

Cardiovascular diseases (CVD) are the leading cause of death in Western World. They provoke 40% of all deceases [1]. Meanwhile, in Argentina 33% of deaths from known causes are caused by CVD, while Heart Failure (HF) is the first responsible entity, this situation has remained stable over the last 20 years. HF caused 33422 deaths in 2011 in Argentina, which represents about 35% of the deaths from diseases of the circulatory system [2, 3].

All studies indicate a substantial economic impact of this entity in the health systems of most countries. The growing concern about various aspects of this clinical syndrome is reflected in part by the numerous publications mainly from the United States and Europe. Congestive Heart Failure (CHF) is the most common medical reason for inpatient hospitalization in adults over age 65 and reducing the rate of hospital admission in this patient population has become a national priority in the U. S. [4]. This is because the high costs generated by continuous hospitalizations to the health system; projections show that by 2030, the total cost of HF will increase almost 120% to $70 billion from the 2013 estimated total cost of $32 billion [5]. In Argentina high costs are generated because of
hospitalizations, but especially by readmissions of patients for worsening HF, which constitutes 70% of all admissions for HF [6].

Common reasons for HF rehospitalizations include delays in symptom recognition, medication and dietary noncompliance, and lack of knowledge and skills for competent self management [7]. Studies point out that multidisciplinary post-discharge treatment programs, i.e. telemonitoring or structured telephone support, can avoid a large portion of readmissions related to HF, with benefit also in mortality, length of hospital stay and quality of life [8]. In addition, for many patients, frequent clinic visits may be impeded by different barriers such as transport, cost, or other diseases. That is why, in these situations, the telemonitoring systems are attractive options for closely monitoring the first signs of patients decompensation. A 2013 review showed a significant CHF-related re-admission benefit from telemonitoring and speculated this intervention may be of particular benefit for patients with physical, geographic, or socio-economic barriers to specialty care. At the same time this work indicated that recognizing the potential benefits to be realized through the expanded use of telemedicine, health insurers are developing new business models incorporating telemonitoring as a component of comprehensive chronic disease management programs [4].

Because of the impact of telemonitoring in HF, this paper aims to identifying the different world opinions and recommendations of the participants in the management, treatment and monitoring of HF. From this study a number of useful guidelines to be considered when designing a telemonitoring system emerge.

2. Theoretical background

To understand and evaluate worldwide existing opinions a series of instruments called consensuses are used. A consensus is an agreement that is reached around a theme by the consent between the members of a group or between groups. The medical consensuses are useful since they have the potential to promote the appropriate use of procedures and generally to improve efficiency in the provision of healthcare.

Most HF consensus recommendations provided by the experts were classified according to two criteria which are detailed in tables 1 and 2. A first classification is an evaluation of the degree of agreement between panelists (table 1), while the second one depends on the level of evidence (table 2).

Table 1. The class of recommendation.

| Class | Description |
|-------|-------------|
| Class I | Evidence or general agreement that a given procedure or treatment is beneficial, useful and effective. |
| Class II | Conflicting evidence or a divergence of opinion about the usefulness or efficacy of the procedure or treatment. |
| Class IIa | Weight of evidence is in favour of usefulness or efficacy |
| Class IIb | Usefulness or efficacy is less well established by evidence or opinion. |
| Class III | Evidence or general agreement that the procedure or treatment is not useful or effective and in some cases may be harmful. |

Table 2. The level of evidence.

| Level of Evidence | Description |
|-------------------|-------------|
| Level of Evidence A | Data derived from multiple randomized clinical trials or meta-analyses. |
| Level of Evidence B | Data derived from a single randomized clinical trial or nonrandomized studies. |
| Level of Evidence C | Consensus of opinion of experts and/or small studies. |
3. Methods
In early 2013 HF consensuses have been searched in the following databases: Annual Reviews, EBSCO, Nature.com, Ovid, Sage Journals, Science Direct, Springer Link, Wiley-Blackwell and in a general purpose search engine. Keywords used in the search were “heart failure consensus” in Spanish and in English. This search produced a series of works from major national and international societies and scientific organizations that have been published in different journals. The first selection criterion was to study only the consensuses published from the year 2000, because the previous works did not mention the telemonitoring. Another adopted criterion consisted in to exclude papers which had updates. From the analysis of the titles and abstracts of papers, several works that studied the HF from an exclusively clinical perspective (such as the incidence of certain drugs in patients or recommendations for cardiac resynchronization therapy, among others) were excluded.

After the selection and exclusion process, eleven consensuses that meet the requirements listed above were identified. These consensuses selected were classified into two groups according to the type of recommendation they provide: consensuses of general recommendations for telemonitoring and specific consensuses. Four specific consensuses were found. They deal with issues that should be considered in the telemonitoring systems design, so they will be studied with main emphasis in those topics. Between the general consensuses there is one from the Heart Failure Society of America (HFSA) from 2008 [9], three from the Canadian Cardiovascular Society (CCS) [10-12], one that studies the treatment of HF in African Americans written by Franciosa J A et al. [13] and two that belong to South American societies of cardiology, one from the Argentinian Society of Cardiology (SAC) [14] and one from the Uruguayan Society of Cardiology (SUC) [15,16]. The four remaining papers are specific consensuses that were studied only in some subjects such as health education [17-19], functional capacity [20] and patient's symptoms [18].

After defining the consensuses to study, their medical opinions and recommendations were analyzed. First, the opinions of the participants about the benefits of telemonitoring in HF patients were studied. Then, the parameters that should be monitored were studied by comparing the recommendations given by different consensuses. Finally, educational aspects that need to be taken into account in order to improve patient self-management were studied.

4. Findings
The findings were divided into three sub-sections.

4.1. Telemonitoring
The seven consensuses of general recommendations indicate that in order to improve patients quality of life and to detect patients decompensation, the telemonitoring and monitoring of certain parameters (blood pressure, body weight, symptoms, etc.) are useful. This is a consequence of that the HF signs and symptoms gradually appear along the disease and they need to be detected in time for proper medical attention, like medication readjustment or other actions. The aim pursued by these actions is to prevent possible patients decompensation that may result in hospital readmissions.

Most consensuses establish the need for a health monitoring of HF patients after discharge. The time suggested for first check-up varies according to the consensus: 72 hours in severe cases [9], first week [9, 16], second week [12] or fourth week [10], although this last consensus clarified that it is more beneficial sooner if feasible. The reason provided for check-ups after discharge, is the high probability in the emergence of various symptoms and discomforts that may lead to patient decompensation. While this corresponds to a first check-up, all consensuses recommend a frequent monitoring of patient throughout the disease, and they mention again that the management programs of HF (telemonitoring) is a means to achieve this aim. Some of the benefits mentioned by the consensuses about telemonitoring are detailed in table 3, but they also indicate a decrease in mortality [9, 13], reduced health care costs [14] and that the telemonitoring is a solution for those patients that are often unable to access the clinic [9, 13].
Table 3. Benefits of telemonitoring in HF patients.

|                     | HFSA 2008 [9] | CCS 2006 [10] | CCS 2007 [11] | CCS 2012 [12] | Franciosa J A et al. 2010 [13] | SAC 2010 [14] | SUC 2000 [15,16] |
|---------------------|---------------|---------------|---------------|---------------|-------------------------------|---------------|-------------------|
| Quality of life and clinical stability | X             | X             | X             | X             | X                             | X             | X                 |
| Early recognition of symptoms           | X             | X             | X             | X             | X                             | X             | X                 |
| Hospital readmissions reduction         | X             | X             | X             | X             | X                             | X             | X                 |
| Adherence*                             | X             | X             |               |               |                               | X             | X                 |
| Self-care                              | X             |               |               |               |                               |               | X                 |
| Assessment treatment progress           |               | X             | X             |               |                               |               | X                 |
| Patient education                      | X             | X             | X             | X             | X                             | X             | X                 |
| Communication with the physician       | X             | X             |               |               |                               |               | X                 |

* The medication is taken correctly, there are dietary compliance, etc.

4.2. Parameters to be monitored

This section details the parameters that the consensuses suggest to monitor in the following of HF patients.

4.2.1. Blood pressure (BP). All consensuses put great emphasis on the BP control. On one hand, this is because one of the symptoms which often occur along the HF is orthostatic hypotension, which is a cause of syncope or fainting. While on the other hand, the consensuses say that knowledge of the BP variation during the different days, allows the doctor to make a reasonable judgment about the medication dose. The table 4 shows the levels and variations in BP that are risk indicators according each consensus.

Table 4. The levels and variations in BP.

| Consensus               | BP Control                                                                 |
|-------------------------|-----------------------------------------------------------------------------|
| HFSA (2008) [9]         | No information                                                             |
| CCS (2006) [10]         | A fall of greater than 20 mmHg in systolic BP or greater than 10 mmHg in diastolic BP on standing (Orthostatic hypotension). |
| CCS (2007) [11]         | BP should be controlled to less than 140/90 mmHg in most individuals and less than 130/80 mmHg in those with diabetes and/or kidney disease. |
| CCS (2012) [12]         | No information                                                             |
| Franciosa J A et al. (2010) [13] | They consider African Americans with hypertension a higher-risk cohort of hypertensives and, like those with diabetes, BP should be lowered to a target level of <130/80 mm Hg. |
| SAC (2010) [14]         | No information                                                             |
| SUC (2000) [15]         | BP should be controlled to less than 140/90 mmHg in hypertensive patients. In diabetic patients, BP should be less than 130/85 mmHg (Class I, Level A). |

The CCS consensuses from 2006 [10] and from 2012 [12] recommend measuring BP sitting and standing. This is because of the Orthostatic Hypotension can be detected from the knowledge of the BP variation in the different positions. This society indicates that supine BP should be measured after a patient has rested for 15 min. This consensus also indicates that standing BP should be measured within three to five minutes after the patient has been in this position, because BP may drop immediately after standing. Furthermore, only the CCS consensus from 2006 refers to the frequency of
BP measurement, indicating that repeated measurements at different times of the day are advisable because orthostatic hypotension is not consistently present in an individual. Orthostatic hypotension may be more likely to be observed in the morning.

### 4.2.2. Heart Rate (HR)

Another parameter that all consensuses except one [13] suggest to monitor is the resting HR, because it may be increased although BP is low, normal or high. Furthermore, physicians indicate that HR variability is a marker of autonomic imbalance and it has been demonstrated that its alteration is also predictive of prognosis [14]. In addition, the CCS [12] recommends that HR should be closely followed when combinations of drugs affecting the renin-angiotensin-aldosterone system are used. This follow will allow the identification of the side effects the drugs can have and of the types of drugs should be given to the patient.

In regard to the normal Heart Rate range, first the SUC [15] mention that if the HR decreases to less than 50 beats/min, the suspension or at least the reduction of the dose of the drug that cause such effect must be considered. Furthermore, the CCS [11] indicates that one of the risk factors for increased mortality includes HR of more than 84 beats/min at rest.

### 4.2.3. Weight

All consensuses recommend weight monitoring because it is an indicator of fluid retention when it increases sharply in a few days. One of the consensuses indicates that morning weight should be daily monitored in HF patients with fluid retention or congestion that is not easily controlled with diuretics, or in patients with significant renal dysfunction (Class I, Level C) [10]. In addition, two consensuses establish a daily frequency for monitoring of weight [12, 13] and only one suggests a weekly frequency [15]. The rest of the consensuses no make reference to the frequency of measurement of this parameter.

Regarding to weight fluctuations, the SAC [14] considers that patients with a weight gain of 2 Kg or more in 3 days should be instructed to increase the dose of diuretics (Class I, Level C). While the SUC [15] indicates that if the weight gain is 2 Kg or more, the patient should consult a doctor promptly.

### 4.2.4. Electrocardiogram (ECG)

In reference to the ECG the SAC recommended continuous ambulatory electrocardiographic monitoring (Holter) for the detection of paroxysmal tachycardia or the presence of intermittent bradycardias which cause or aggravate HF symptoms [14]. Another consensus recommends ECG monitoring as a necessary measure for the initial diagnosis of HF and to identify rhythm abnormalities (atrial fibrillation, flutter or bradycardia and ventricular tachycardias), acute coronary syndromes, RV, LV or atrial hypertrophy or strain, as well as myopericarditis. Moreover, if there are cardiac arrhythmias it should be evaluated by a 12-lead ECG and continuous ECG monitoring [11]. In no case, the rest of the consensuses mention continuous ECG monitoring.

### 4.2.5. Symptoms

Another aspect analyzed by the seven general consensuses and the specific consensus of Goodlin S J et al. [18] is the detection of symptoms (subjective elements perceived only by the patient), because they are an indicator of health status or patients quality of life. Some consensuses recommend using questionnaires to assess symptoms. These questionnaires have been validated and are effective especially in those patients suffering from HF. The HFSA [9] recommends using the following questionnaires: The MOS 36-item short-form health survey (SF-36), el SF-12, The EuroQol-5D, The Chronic Heart Failure Questionnaire, The Minnesota Living with Heart Failure Questionnaire and The Kansas City Cardiomyopathy Questionnaire. While, the SAC [14] suggests using the questionnaires that are listed below: The Chronic Heart Failure Questionnaire, The Yale Scale and The Minnesota Living with Heart Failure Questionnaire. The other consensuses not specify any particular questionnaire to assess symptoms.

### 4.2.6. Functional status

Another parameter that most of the consensuses suggest to monitor is patient functional status. While not all consensuses directly recommend perform the known functional
classification the New York Heart Association (NYHA), absolutely all of them use it to provide their recommendations about exercise, medication, etc. This is because the functional classification has an important prognostic value and is used as the decisive criterion in the choice of certain therapeutic interventions, both medical and surgical. With the periodic evaluation of the patient functional class, doctors can know the patients progress and their response to treatment. Besides this classification, there are other tools used and/or recommended by the consensuses to assess functional status as shown in table 5.

Table 5. Tools used and/or recommended by the consensuses to assess functional status.

| NYHA | Ergometry | 6MWT\textsuperscript{a} | CPX\textsuperscript{b} | IPAQ\textsuperscript{c} | Duke Activity\textsuperscript{d} | VO\textsubscript{2} Max\textsuperscript{e} | Pedometers\textsuperscript{f} |
|------|-----------|----------------|----------------|----------------|----------------|----------------|----------------|
| HFSA (2008) [9] | X | X | X | X | X | X | X |
| CCS (2006) [10] | X | X | X |
| CCS (2007) [11] | X |
| CCS (2012) [12] | X |
| Franciosa J A et al. (2010) [13] | X | X |
| SAC (2010) [14] | X | X | X | X |
| SUC (2000) [15] | X | X | X | X |
| Piepoli M F et al. [20] | X | X | X | X |

\textsuperscript{a} Six-minute walk test  
\textsuperscript{b} Cardiopulmonary exercise testing  
\textsuperscript{c} The International Physical Activity Questionnaire  
\textsuperscript{d} Duke Activity Index scale  
\textsuperscript{e} Maximal oxygen consumption  
\textsuperscript{f} Physical activity detectors

4.3. Health education

All consensuses underline the importance of proper health education to patient, family and caregivers. This is necessary in order to achieve the correct self-care and thereby avoid diverse problems which are generated because of ignorance of caregivers on how to deal with common situations of this kind of illness.

Only the HFSA focuses specifically on health education [17]. This consensus defines health literacy as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. This health education includes the ability to: comprehend complex vocabulary, share personal information with health care providers, make decisions about healthy lifestyle habits, and participate in self care and chronic disease management while navigating a complex health care system. Furthermore, this consensus mentions a number of studies that conclude that “low literacy is associated with several adverse health outcomes”, including increased risk of hospitalization and lack of knowledge about health services. In summary, the HFSA indicates that limited health literacy is associated with decreased knowledge of one’s medical condition, poor medication recall, nonadherence to treatment plans, poor self-care behaviours, poorer physical and mental health, increased hospitalizations, and increased mortality. This society also state that instruct patients about good health practices can help them to improve self-care and achieve positive health benefits.
SAC consensus [14] mentions that the literature suggests that only 20-60% of HF patients adhere to treatment, therefore the patients and their family should be informed about the disease, its symptoms and signs of decompensation and should be encouraged to self-care and early consultation. Moreover, this society emphasizes that health education is a continuous process and not of a single medical check-up (Class I, Level C).

Table 6 was made for summarizing the reasons why each of the consensuses recommend and continuously mention the need to educate patients, their families and caregivers.

### Table 6. Benefits of health education to patients and their caregivers.

|                        | Quality of life | Self-care | Decrease hospitalizations | Recognition of symptoms | Adherence | Medication recall |
|------------------------|----------------|-----------|----------------------------|-------------------------|-----------|------------------|
| HFSA (2008) [9]        |                |           |                            |                         |           |                  |
| CCS (2006) [10]        | X              | X         |                            |                         |           |                  |
| CCS (2007) [11]        | X              | X         |                            |                         |           |                  |
| CCS (2012) [12]        | X              | X         |                            |                         |           |                  |
| Franciosa J A et al. (2010) [13] |                |           |                            |                         |           |                  |
| SAC (2010) [14]        |                |           |                            |                         |           |                  |
| SUC (2000) [16]        | X              | X         |                            | X                       |           |                  |
| HFSA (2010) [17]       | X              | X         | X                          | X                       |           | X                |
| Goodlin S J et al. (2004) [18] | X             |           |                            |                         |           |                  |
| Barisani J L et al. (2010) [19] | X             | X         |                            |                         |           |                  |

The consensuses name different subjects on which the HF patients should be educated. Some recommendations are directed to the understanding of the disease and of the symptoms that could appear, whereas other recommendations of the consensuses are specific topics about to lead a healthy life according to possibilities, such as physical activity, smoking, alcohol, nutrition, among others.

### 5. Discussion

Knowing that HF is a disease that causes a progressive deterioration in the patients, and considering that the studied consensuses recommend to follow the patients after discharge, the need to continuously monitoring HF patients is established. Moreover, the study of the consensuses indicate that the telemonitoring can have many benefits including quality of life, medication recall, adherence to treatment, self-care behaviours, decrease in hospitalizations, decrease in mortality [9,13], reduced healthcare costs [14] and it can be a solution for those patients that are often unable to access the clinic [9,13]. For these reasons the telemonitoring proves to be a correct tool for continuous HF patients monitoring.

Taking into consideration consensuses recommendation about the care of HF patients, it can be deduced that an adequate telemonitoring system should be capable of allow early detection of symptoms and of physiological parameters variations that indicate a possible decompensation of the patients. These indicators should be properly communicated to the medical team for enabling them to act against dangerous situations and to avoid hospital readmissions. Besides, the decrease of hospitalizations would also decrease healthcare costs and with the appropriate preventive actions would reduce the mortality of HF patients. Moreover, it the telemonitoring system provides adequate
health education for patients and their caregivers, it would contribute to improve their quality of life. This can be said because it has been shown that with the health literacy leads to improvement of patient self-care behaviour and to greater adherence [17].

Based on the similarities found from the study of consensuses, a serie of parameters of interest that should be monitored with the telemonitoring systems can be defined. These parameters are the BP, HR, body weight, symptoms and functional capacity. As far as the ECG is concerned, is recommended that it should be continuously monitored only in patients with arrhythmias so it is not included within the parameters of interest.

Finally it could be argued that telemonitoring system designers should take into account at least two aspects which arise from the recommendations of the consensuses. For one hand the system should be able to monitor the parameters of interest mentioned above. On the other hand, these telemonitoring systems should provide an adequate means of health education for patients and their caregivers. If the telemonitoring systems meet these characteristics, according to the studies mentioned in the consensuses, the patients, their family, their caregivers and even the health system will benefit.

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