TELEMONITORING OF HEART FAILURE PATIENTS

An integrative program of multiple SNS structures

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1. Background

People are increasingly living longer, a result of the advances in public health, medicine and economic growth over life-expectancy impacting diseases. [1] Conversely, the rise in the elderly population leads to a huge challenge: government adaptation to elderly needs, mainly in providing care to this population.[2] In a few decades, the loss in health and lives all over the world will be mostly caused by chronic or non-transmittable diseases (for example, cardiovascular diseases, neurological and cancer).[1]

Patients with chronic illnesses normally present multiple comorbidities and different levels of motor and mental disability, wherefore they require long-term care and regular, close and specialized follow-up for extended periods of time and, in many cases, for the rest of their lives. Current health care systems organized around the idea of acute episode treatment are not adequate for these patients' needs. Different experts have pointed out that the resolution consists in the decentralization of health care, making a shift to patients' household and familiar environment, empowering the patient as an active subject in his own treatment.[2,3] In this environment, apart from the continuous proximity care, efforts should be undertaken to integrate telemonitoring systems, devices, and technologies that can involve patients in the management and monitoring of their own health condition while keeping their independence and quality of life.

In Portugal, according to the European Commission, population ageing will be responsible for the increase in health-related expenses of 8.5% in the year of 2060.[4] The application of patient-centered health technologies (telemonitoring and teleconsultation), integrated in the delivery of proximity care, will not only enable patients and their health providers a better control of disease, preventing the occurrence of exacerbations, but also allow a significant reduction of related costs.

Heart failure (HF) is a complex clinical syndrome with a prevalence of 1-2% in developed countries. Despite all the advances in diagnosis and treatment, HF remains an important cause of death and re-hospitalization due to acute-on-chronic exacerbations.[5]

Telemonitoring programs in cardiovascular diseases have, as main purpose, the early detection of symptoms associated with an acute exacerbation in order to prevent hospitalizations, with a consequent reduction in

costs and improvement in the prognosis of patients. Such also applies, particularly to patients diagnosed with chronic HF.

2. Current evidence

2.1. Implantable devices

Up to now, the most compelling evidence for a telemonitoring device comes from the implantable CardioMEMS device.[6] This device is implanted in the pulmonary artery and transmits intrapulmonary pressures to a central service center. The assigned physician then receives the results and trends over time of the same results, and then is advised to take action if pulmonary artery pressures exceed an established threshold, which suggest congestion, and also when it is below normal values suggesting dehydration. The CHAMPION trial showed a significant reduction in HF hospitalization as a consequence of improved management, and effect which was maintained at long term.[7] COMPASS-HF was also designed with a similar purpose, with the implantation of a continuous hemodynamic monitor as a transvenous lead placed in the right ventricle. The primary endpoint included a reduction in the rate of HF-related events, which was reduced in 21%, but the results were not clinically significant. However, there was a lower time to first HF hospitalization, with a significant 36% reduction in the relative risk of HF-related in the intervention group.[8] Other studies were done with implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT) devices. The IN-TIME trial showed improvement in clinical outcomes with automatic and multiparameter telemonitoring from ICD devices. As compared with standard care, this approach led to an improvement of 37% in composite clinical score indicating worsening of HF.[9] Similar conclusions were drawn in the EFFECT trial, with significant reduction in death and cardiovascular hospitalisations.[10] Despite not being a randomized controlled trial, COMMIT-HF also reported a 4.9% vs. 22.3% significant reduction in mortality after 3 years of follow-up.[11] With opposite results, OptiLink HF did not show beneficial results in advanced HF by using a system of fluid status-based telemedicine alerts[12] and, in the same way, the mortality and hospitalization beneficial impact of device-based monitoring was not confirmed in a meta-analysis which included 11 randomised controlled trials with 5703 patients. However, there was a favorable reduction in the number of hospital total visits (planned, unplanned and emergency room) and also in the costs associated with implantable device telemonitoring.[13]

As a conclusion, there is no consensus on implantable device telemonitoring at present.

2.2. Non-invasive monitoring

Overall, trials of telemonitoring or telephone support did not report consistent positive results, when compared to usual care. In TELE-HF trial,

published in 2010, telemonitoring did not lead to improved outcomes, using a telephone-based interactive voice-response system that collected daily information about symptoms and weight, reviewed by the patient's clinicians.[14] However, there was no direct contact between healthcare providers, which can possibly explain the very low adherence of 14% enrolled patients never using the system and only 55% of the patients using the system at least 3 times a week by the final week of the trial period. In WISH trial, 344 patients were randomized to either receive an electronic scale that would send an automatic sign to a central internet-based data server system or contacting the HF clinic in case of weight gain of > 2 kg in 3 days. Both groups would weigh themselves daily. After 12 months of follow-up, there was no significant difference in endpoints between groups, despite having a mean of 75% of compliance.[15] In the MCCD trial, a randomized controlled trial where 204 subjects were randomized to usual care or daily weight, blood pressure, heart rate and heart rhythm monitoring by an experienced heart failure nurse, telemonitoring did not result in lower total costs, decreased hospitalizations, improved symptoms or improved mortality. However, 30-day readmission rates and emergency department visits decreased for the first year, despite not resulting in decreased costs or improvement outcomes.[16] TIM-HF trial also failed to demonstrate a positive effect on the primary endpoint of all-cause mortality in ambulatory patients with chronic heart failure, when randomized to receive either remote telemedical management or usual care.[17] However, the large TIM-HF2 trial, published very recently, has suggested that a structured, remote intervention in selected patients versus usual care can not only reduce the percentage of lost days due to unplanned cardiovascular hospitalizations but also global mortality.[18] Recently published meta-analyses and systematic reviews have also suggested that telemonitoring may improve clinical outcomes.[19-22]

As a consequence of the abovementioned trials, with different methods, patients, heart failure severity, responsible health care practitioner, performed interventions and lack of drug-titration protocols, there were mixed findings. Following these results, the recommendation of HF telemonitoring by European Society of Cardiology is still limited (class of recommendation IIb, level of evidence B).[23]

3. Heart failure telemonitoring pilot program in Portugal

In Portugal, there is an ongoing pilot telemonitoring program for patients with HF, whose inclusion and exclusion criteria can be found in tables 1 and 2, respectively.

Table 1. Inclusion criteria
1. Heart failure diagnosis based on ESC criteria; 2. NYHA II-III functional class; 3. Any left ventricular ejection fraction (evaluated in the last 6 months) 4. Age > 18 years 5. Patients with past heart failure hospitalisation, emergency room observation or external consultation/day hospital less than 1 year; 6. Patient or caregiver with the capacity to understand or follow telemonitoring system instructions in Portuguese; 7. Patient availability to daily use telemonitoring system; 8. Patient residing in the telemonitoring center geographic zone in order to be able to receive additional treatment if deemed necessary, as well as easy access to consultation, day hospital and/or hospitalisation; 9. Signed informed consent; 10. Optimized medical treatment.

Table 2. Exclusion criteria
1. Acute myocardial infarction (AMI) in the last 4 weeks; 2. Orthopedic, neurological, psychiatric or cognitive impairment that could impair understanding and usage of telemonitoring equipment; 3. Primary significant valvular heart disease with programmed surgery; 4. Patient in dialysis program.

Note that while those were the criteria of inclusion/exclusion for the pilot study, it still is necessary to identify new criteria more adjusted to the real world and the most recent evidence. Due to the great disparity in results observed in many studies (and based on TIM-HF2 results)[18] there is a need to cautiously

select patients with a higher risk of hospitalization for these programs. This tool cannot be of universal implementation in HF patients, but only in highly selected ones.

Required equipment consists of blood pressure monitor, pulse oximeter, bioimpedance (in patients who can do it) to evaluate water body content, pedometer, 3 classical lead electrocardiogram (DI, DII, DIII) and body weight.

It is important to mention that telemonitoring of vital signs is comparable with what patients have in the hospital environment. We know that prompt detection of exacerbations can prevent hospitalizations with a consecutive decrease in costs and a better prognosis. But, over and above, in particular, other results are expected of this project, namely:

a) Quality upgrade in community health service, making patients feel continuously followed in their disease;
b) Reduction in at least 2 yearly hospitalizations due to patient's health deterioration;
c) Reduce 3 exacerbation episodes with emergency service visit per patient in the program;
d) Reduce 2 external consultations and/or day hospital visits, per year, which will consequently allow a reduction in costs linked to special medicalized transports (transporting the patient from home to responsible health unit;
e) Continuously and proactively follow the fluctuations in patient condition, allowing prompt reaction and postponing as long as possible disease worsening.

Our telemonitoring experience was started in May of 2018. From the beginning the project was divided in 2 different arms: i) HF arm, with 21 patients enrolled; and ii) acute myocardial infarction arm, with 15 patients enrolled so far. From all the patients enrolled in the project, a total of 1094 clinical alerts were generated, with only 1% confirmed (10 alarms). Heart rate and diastolic blood pressure were the most frequent parameters that triggered the alarm. On the other side, body weight and heart rate were the most frequent alarm triggers in the confirmed clinical alerts.

4. What have we learned from our experience

Telemonitoring programs should be designed with HF patients always at their center. Obtained data will be monitored and analyzed by competent healthcare professionals, who will identify previously established alarm signs. Relevant cases will be reported to the responsible hospital health care professional, who will determine the need for clinical action in order to modify patient therapy conduct, always in close proximity with the patient's community health center. This early response intends to avoid clinical exacerbations that justify a visit to emergency departments or hospital care. In this way, this technology comes to strengthen communication and relationship between hospitals, primary healthcare, patients and their families/caregivers.

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