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whitepaper

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THE ROLE OF NON-INVASIVE DEVICES FOR THE REMOTE TELEMONITORING OF HEART FAILURE PATIENTS

INDEX

ABSTRACT

Heart failure (HF) patients represent one of the most diffused and fragile population encountered in the clinics nowadays. They are estimated to account for around 26 million worldwide, to present a poor prognosis, a miserable quality of life and a clinical history accompanied by continuous and repeated hospital admissions caused by their chronic condition.

The frequent hospitalizations and the long hospital stays mean for the healthcare institutions an extremely high economic burden that needs to be sustained for the management of these patients. Meanwhile, the numbers of chronically diseased and elderly patients are constantly rising due to the aging of the Western population. This is all accompanied by an evident lack of specialized physicians.

To cope with this health emergency, a more efficient patients' management, better diagnostic tools, stronger preventive plans and stricter treatment regimens are of extreme need outside of the hospitals to improve patients' monitoring, quality of life and prevention of decompensation events. That is the reason why in the recent years telemonitoring has been introduced as the potential answer able to solve such needs. Different methodologies and devices have been progressively investigated as potential tools for effective home monitoring of cardiologic patients. Invasive hemodynamic devices have been demonstrated to be effective in reducing hospitalizations. However, the role of external non-invasive devices is yet to be clarified.

In this review, we will summarize the most relevant studies and clinical trials that, utilizing telemonitoring, demonstrated or not to have a beneficial effect in the management of cardiologic and HF patients. In specific, this review wants to address the role of non-invasive devices for the home monitoring of HF patients.

INTRODUCTION

Heart Failure (HF) is a clinical syndrome characterized by invalidating symptoms such as breathlessness, ankle swelling and fatigue and that may be accompanied by signs such as elevated jugular venous pressure, pulmonary crackles and peripheral edema[1,2]. The main causes are generally structural and/or functional cardiac abnormalities that may result in a reduced cardiac output and/or elevated intracardiac pressures at rest or during stress[1,2]. The current definition of HF, as stated by the recent European Society of Cardiology guidelines, restricts itself to stages at which clinical symptoms are apparent. However, patients may experience, in the asymptomatic phase, structural or functional cardiac abnormalities (systolic or diastolic left ventricular (LV) dysfunction) that can lead to overt HF[1,2]. The estimated absolute number of people suffering from HF in the world approaches 26 million and this widespread pathology can be encountered nowadays both in Developed and Developing Countries[3]. Chronic heart failure (CHF) patients represent one of the leading population at risk of frequent hospitalizations and poor life-expectancy, and indeed only the 10% of these patients is alive at 10 years from diagnosis[4,5]. Annually, 1 million patients are hospitalized with a primary diagnosis of HF, accounting for a total Medicare expenditure exceeding $17 billion in US every year[6]. Despite dramatic improvements in outcomes with medical therapy, admission rates following hospitalizations remain high, with 20-30% patients readmitted after 30 days and >50% of them readmitted within 6 months after discharge[7,8,9].

Because of the high rate of re-hospitalizations, of the high mortality, of the poor quality of life and of the heavy cost sustained by the National Healthcare System, different studies have been undertaken and different parameters or risk factors have been investigated to improve the diagnosis, the treatment and the prevention of decompensation events in the CHF population to avoid patients' hospitalizations as much as possible. Several physiological indices of HF severity anticipate higher event rates such as elevated filling pressures, jugular venous pressure, orthopnea, and echocardiographic filling patterns[10,11]. Levels of cardiac biomarkers including natriuretic peptides and cardiac troponins that may also anticipate readmission risk, particularly if they remain high at hospital discharge[12,13]. Indicators of neurohormonal activation, including higher levels of circulating catecholamines and renin-angiotensin system metabolites or lower levels of serum sodium, can also identify patients at risk[14,15]. Increasing diuretic requirements or intolerance of neurohormonal antagonists because of hypotension or renal dysfunction are likely indicators of disease progression and represent an indicator of worsening clinical outcomes[16]. Moreover, the increased burden of atrial or ventricular arrhythmias, the decrease in the heart rate variability and the development of changes in the electrocardiographic traces have been identified as predictors of decompensation events[17,18,19,20]. The main unmet need, however, is the lack of an appropriate and consistent way to predict the decompensation of patients when they are outside of the hospital.

The estimated absolute number of people suffering from HF in the world approaches 26 million and this widespread pathology can be encountered nowadays both in Developed and Developing Countries[63].

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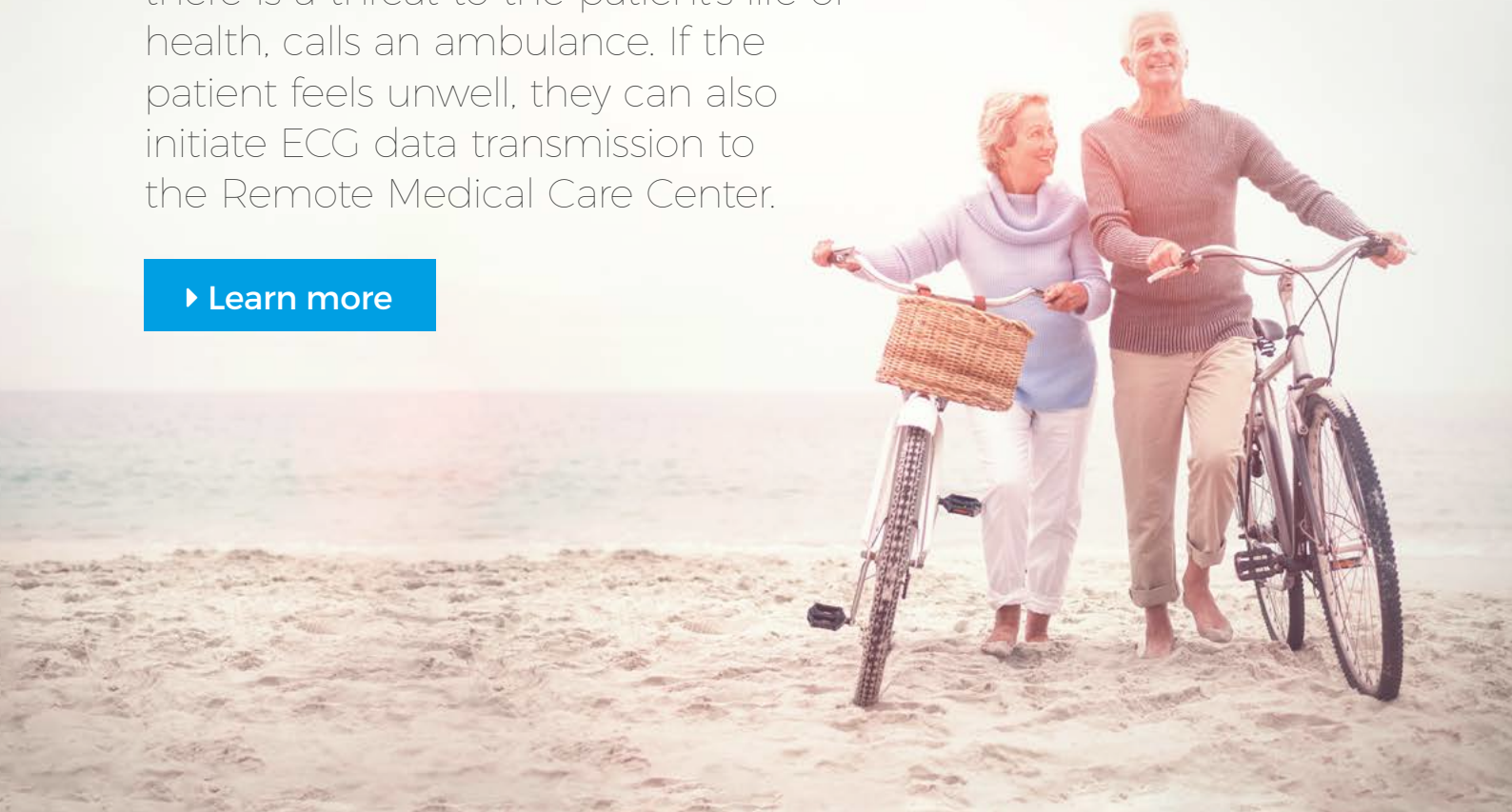
REMOTE CARDIAC CARE

MONITORING HEART ACTIVITY AT ANY PLACE AND ANY TIME

With its portable ECG signal and breathing recorder, Remote Cardiac Care enables continuous monitoring of heart activity. Using integrated detection algorithms, the recorder identifies disorders in a patient's heart rhythm. The relevant parts of the ECG record are transmitted to the Remote Medical Care Center and analyzed in detail. If any anomalies are identified, a paramedic, acting in accordance with a planned operational procedure, takes a detailed medical history and refers the patient to a remote consultation with a physician, discusses the case with an on-duty physician or, where there is a threat to the patient's life or health, calls an ambulance. If the patient feels unwell, they can also initiate ECG data transmission to the Remote Medical Care Center.

Learn more



THE DEFINITION OF TELEMONITORING

In the recent 10 years, telemedicine, telemonitoring, mHealth and eHealth have gradually entered in the panorama of clinical medicine. The history of telemedicine has started when blood glucose-meters, Holter monitoring, event recorders and 24h blood pressure monitoring were introduced in the clinical management of patients[21,22]. It soon became clear that monitoring patients' parameters outside the hospital could be a useful way to prevent the occurrence of decompensation events, especially in a population at risk such as the one of HF patients[23]. Thanks to the advances in technology and in the devices miniaturization, a de-medicalization of the data has been achieved. This has brought a revolutionary change in what were considered the final data users, that have eventually become the patients themselves. Nowadays this is defined as telemonitoring, also known as remote patient monitoring (RPM). Telemonitoring consists in either a continuous or a sporadic monitoring that can be either dependent from the patients' action or completely independent and automated. The first non-invasive telemedical systems enabled the transfer of physiological data and parameters (e.g. body weight, heart rate, blood pressure, body temperature) collected indirectly from phone calls to patients and sent to telemedical centers for data integration[24,25]. Nowadays more advanced non-invasive systems developed devices enabled to measure and transfer electrocardiograph (ECG) tracings, oxygen saturation, blood pressure and physical activity (e.g. pedometer) data, for example[26,27]. Other systems, instead, enabled the transfer of variables measured invasively, thanks to implanted devices, that include impedance analysis and pulmonary artery or left atrial pressures[28].

Telemonitoring can also be divided in passive or automated, typical of implantable invasive devices that send either sporadically or continuously data to the receiving physician; and active, were, on the contrary, non-invasive devices involve an action (e.g. a video-call) or a self-measurement (e.g. blood pressure measurement) that a patient needs to accomplish. While the role of implantable telemonitoring devices for multi-parameters[29] or cardiac hemodynamic activity monitoring[30] has been recently established as an effective way to prevent frequent hospitalizations[31], the role of non-invasive methods for the remote monitoring of HF patients is still under debate. In this review, we will concentrate in specific, to the role of external devices and of the electrocardiography for the remote monitoring of HF patients.

Telemonitoring consists in either a continuous or a sporadic monitoring that can be either dependent from the patients' action or completely independent and automated.

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COMARCH E-CARE PLATFORM

COMARCH Healthcare

The provision of Remote Cardiac Care services is possible thanks to the Comarch e-Care platform, which enables permanent monitoring of the patient's life parameters on a remote basis. The platform allows medical data to be recived from measuring devices that record heart activity and cardiac events. It also supports medical staff in the performance of pre-determined procedures.

REMOTE MEDICAL CARE CENTER

The key element of the e-Care system is the Remote Medical Care Center, where the medical staff provide 24-hour monitoring of patients' health status and record their heart rhythm in the course of everyday activities.

- Brings together qualified medical staff: paramedics, physicians specializing in various fields of medicine: cardiologists, dietitians or physiotherapists.
- Monitors patients' health parameters around the clock, including on holidays.
- Intervenes in the case of automatically detected anomalies (exceeded norms and alarm values), the parameters of which are personalized for each patient, as well at the request of the patient (triggered by, for example. the use of the "SOS button" alarm device).
- Uses medical workflows (procedures) to enable faster and better directed interventions.

TELEPHONE SUPPORT FOR REMOTE PATIENT MONITORING

During this past decade, different studies tried to assess if telemedical interventions and telemonitoring programs would be able to affect mortality and re-hospitalizations of CHF patients. Different ways of monitoring remotely patients with CHF were studied and some methods have now become part of the clinical routine. One of the adopted methods involves regular telephone support to monitor the symptoms, the body weight measurement changes and the psychological status of the patients. One of the first studies, done by Ferrante et al demonstrated that regular phone intervention improved adherence on diet, weight control and medications[24]. Moreover, one year after the intervention ended, a 19% reduction in the incidence of all-cause mortality and all-cause hospitalizations was observed[24]. However, in 2010, a study by Chaudry et al was not able to confirm any beneficial effect of remote monitoring (defined as daily calls performed to assess the patient health status, symptoms and changes in the body weight measurement) over standard care[25]. The primary endpoint considered was readmission for any reason or death from any cause within 180 days after enrollment. Secondary endpoints included hospitalizations for HF, number of days in the hospital and number of all cause hospitalizations. This study did not include any analysis on ECG nor other vital parameters accounting only on telephone support. Of note, even if the remote monitoring of the patient's weight is considered nowadays not sensitive to detect early decompensation events, is still one of the most used method for controlling the patient's status, mainly because of the cheapness and of the large spread of standard weight scales[32]. Another study, The Interdisciplinary Network for Heart Failure (INH) trial investigated the role of telephone-based monitoring and education, addressing individual problems of the patients and pursuing networking of healthcare providers and providing training for caregivers. Even if no reduction in re-hospitalizations was achieved, mortality risk and surrogates of well-being improved significantly. This study suggested that individualized care and consideration of noncardiac problems should be integrated in the telemonitoring plans of HF patients[33].

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NON-INVASIVE DEVICES FOR REMOTE PATIENT MONITORING

Concerning the use of-invasive devices for telemonitoring of HF patients, the results have been contradictory, with many of the studies being small or having variable endpoints. From 2008 until 2011 a large randomized multicenter trial, the Telemedical Interventional Monitoring in Heart Failure (TIM-HF), was designed to investigate whether remote telemonitoring (RTM) would reduce mortality and hospitalizations in ambulatory chronic HF patients compared with usual care[26]. External devices for ECG, blood pressure and body weight measurements were connected via Bluetooth to the patient's home and information were sent to the Center Monitors continuously 24/7. The primary endpoint was death from any cause. The secondary endpoint was a composite of cardiovascular death and hospitalization for HF. The results of TIM-HF suggest that when RTM is applied to stable, optimally treated, ambulatory chronic HF patients, a reduction in mortality and in re-hospitalizations is not evident. However, this study confirmed that non-invasive telemonitoring improves the quality of life of HF patients[26]. Another large trial, the BEAT-HF, that enrolled 1437 participants, investigated the role of combined health coaching telephone calls and telemonitoring. Telemonitoring used electronic equipment that collected daily information about blood pressure, heart rate, symptoms and weight. The primary outcome, namely readmission for any cause within 180 days after discharge was not different between the intervention group compared to the standard of care group. In secondary analysis, there were no differences in 30-day readmission or 180-day mortality, but there was a significant difference in 180-day quality of life between the intervention and usual care groups[34]. Meta-analyses on telemonitoring and telephone support have been suggested to provide better clinical outcomes than usual care, with a reduction in mortality and hospital admissions observed[35,36,37,38]. In the Cochrane Review undertaken by Inglis et al., 25 full peer-reviewed studies on non-invasive telemonitoring were included in the analysis and incorporated 8323 patients. In addition to examining the impact on heart failure-related hospitalization and mortality, the review also considered the quality of life (QOL), acceptability of the systems, and cost efficacy. Telemonitoring reduced all-cause mortality (relative risk (RR) 0.66, 95% confidence interval (CI) 0.54–0.81, P ¼ 0.0001), whereas telephone support demonstrated a non-significant reduction (RR 0.88, 95% CI 0.76–1.01, P ¼ 0.08). Both telemonitoring and telephone support produced significant reductions in heart failure-related hospitalizations (RR 0.79, 95% CI 0.67–0.94, P ¼ 0.008 and RR 0.77, 95% CI 0.68– 0.87, P 0.0001, respectively)[35]. This hold true in a more recent analysis by Inglis et al that included the latest clinical trials, the interventions improved quality of life, reduced the costs and were acceptable to patients. Telemonitoring showed a reduction of 20% of all-cause mortality compared to standard of care[38]. For Inglis et al, improvements in drugs prescribing, patient-knowledge and self-care, and functional classes were observed. Acceptability of the technologies was uniformly high and, despite concerns that the elderly patients would have not been capable in managing the new technology, there were no differences in age ranges. Elderly people did benefit from telemonitoring as much as younger ones, with no decrease in adherence[39]. A recent pilot study on a device called MedSentry, a remotely monitored electronic pillbox that alerts people when it's time to take their medications and connects patients and caregivers when medications are not taken, showed to induce a reduction in all-causes hospitalizations and all-causes length of stay in the intervention group[40]. Other studies, instead, concentrated on the role of external devices for the measurement of bio-impedance analysis, a specific technique, already utilized invasively, for the analysis of patients' volume and hydration status and useful to detect impending HF decompensation events[41,42]. One interventional study, called MUSIC (Multi-sensor Monitoring in Congestive Heart Failure), was done to develop and validate an algorithm for prediction of impending acute heart failure decompensation with the use of different physiologic signals, among which bio-impedance, obtained from an external device adhered to the chest. Five hundred forty-three HF patients with ejection fraction less than 40% and a recent HF admission were recruited. They were remotely monitored with a multi-sensor device for 90 days. Three hundred fourteen were included in the analysis: 114 in the development cohort, and 200 in the validation cohort. A multi-parameter HF detection algorithm was developed from the data in the development cohort; this algorithm had 65% sensitivity and 90% specificity for the detection of HF events in that cohort and met the pre-specified endpoints in the validation cohort with sensitivity of 63% and specificity of 92%. However, whether this method would affect the clinical outcome of CHF patients was not studied and is still to be determined[27]. A recent study, called SENTINEL-HF, examined a transthoracic bio-impedance vest called FAV (Fluid Accumulation Vest). Participants included[42] patients hospitalized for HF. The patients were trained to autonomously make daily bio-impedance measurements and transmit them using a smartphone to the clinic of reference. This preliminary study identified that in the intervention group the use of FAV allowed to predict up to 7 days in advance the occurrence of a hospitalization, however further studies are needed to assess its role in preventing hospital admissions[43].

CARDIAC CARE SOLUTIONS

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COMARCH PMA

A digital ECG recorder enabling continuous performance of multiple-day tests with a high-quality signal

COMARCH TELEHOLTER

Easy to customise, advanced application designed to analyze cardiac data.

COMARCH CARDIODIAL

An easy-to-use portable digital event Holter monitoring device, allowing ECG tests to be performed in comfort.

COMARCH CARDIOVEST®

Long-term non-invasive ECG monitoring with sophisticated algorithms.

THE ROLE OF ECG IN IDENTIFYING EARLY DECOMPENSATION EVENTS

Much of the currently available evidence has focused more on telephone support and telemonitoring interventions with many different devices, mostly implanted, however, monitoring by ECG through external devices remains relatively understudied[36]. In a study by Cleland et al., ECG data transmission was significantly associated in reducing hospitalizations due to HF when compared with usual care[44]. In a study by Villani et al. which analyzed HF patients at high risk of relapse, the regular acquisition of simple clinical information, the possibility for the patients to contact the clinical staff and the sending of ECG data, produced better psychological status and quality of life and reduced hospitalizations for heart failure[45]. What has been found out through the IN-TIME clinical trial was that invasive detection of multiple parameters, among which ECG and arrhythmias, was effective in identifying timely atrial and ventricular arrhythmias and in reducing deaths and HF-related hospitalizations[29]. A lot of literature has been published on the utility of ECG for predicting HF worsening in chronic HF patients and the parameters which were found to predict the risk of a heart failure decompensation are the following (Table 2):

- Reduced Heart Rate Variability – defined as a reduction in time domain differences between day and night observed at Holter monitoring[18]
- Increased Heart Rate – tachycardia and increase in the basal heart rate[46]
- QRS/T Angle increase – defined as an increase in the repolarization axis angle (>60° for women and >120° for men)[47]
- Atrial and Ventricular Tachyarrhythmias – namely atrial flutter and fibrillation and ventricular non-sustained and sustained ventricular tachycardia[19,48]
- Increased ECG LV mass – more than 70 ± 9 g/m2 in men and 61 ± 8 g/m2 in women [20,49]
- QT prolongation – defined as >450 for males and >460 for females[50].
- Increased QRS duration – QRS >100 ms with or without complete and/or incomplete bundle branch blocks (left or right)[51,52]
- Left Ventricular Strain – defined as ST segment depression and T wave inversions[17,53,54]
- An old silent myocardial infarction – defined by Navacode criteria*[20,55]

What has been found out through the IN-TIME clinical trial was that invasive detection of multiple parameters, among which ECG and arrhythmias, was effective in identifying timely atrial and ventricular arrhythmias and in reducing deaths and HF-related hospitalizations[29]

EXAMPLES OF USE

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Remote Cardiac Care services are provided in accordance with the recommendations of the referring physician. Prior to each examination the medical staff take the patient's detailed cardiac history and perform a reference ECG test. This allows individual adjustment of alarm thresholds initiating an automatic response from the Remote Medical Care Center for each patient.

ECG TELEMONITORING

Recording the heart rhythm at any time interval. The patient decides when and for how long the examination will be performed, under on-going supervision of medical specialists. The examina- tion can be performed 24 hours per day, in the course of selected daily activities, or in situations when the patient feels unwell. Data is analyzed on an on-going basis by the Remote Medical Care Center. Once the examination is completed, the patient receives a telemonitoring report along with follow-up recommendations.

HOLTER ECG WITH MONITORING

24-hour recording of the heart rhythm (seven or 12 leads). Thanks to the use of replaceable battery modules, the test can be performed over a long period with uninterrupted recording. In addition to data recording, the device transmits information on automatically detected abnormalities to the Remote Medical Care Center, where the appropriate response is undertaken. Thanks to the integrated GPS and GSM modules, paramedics can call an ambulance to the place where the patient currently is.

REMOTE ECG ON REQUEST

Performing a 12-lead resting ECG at any place and at any time. The patient performs the test on their own, as recommended by the physician. The result is immediately transmitted to the Remote Medical Care Center. A test report, in the form of a textmessage, is sent directly to the ECG recording device. In emergency situations, telephone contact with the patient can be initiated. An ECG test under such a procedure can be also performed for groups of patients.

EVENT HOLTER

Multiple recording of short fragments of ECG pertaining to specified symptoms. The method allows an investigation into the reason for the symptoms (such as palpitations, fluttering sensations, fainting or pain) reported by the patient. Once the specific symptoms occur, the patient places the recorder on their chest to record the activity underlying symptoms that often do not occur in the course of routine 24-hour Holter monitoring. Each record is transmitted to and interpreted at the Remote Medical Care Center.

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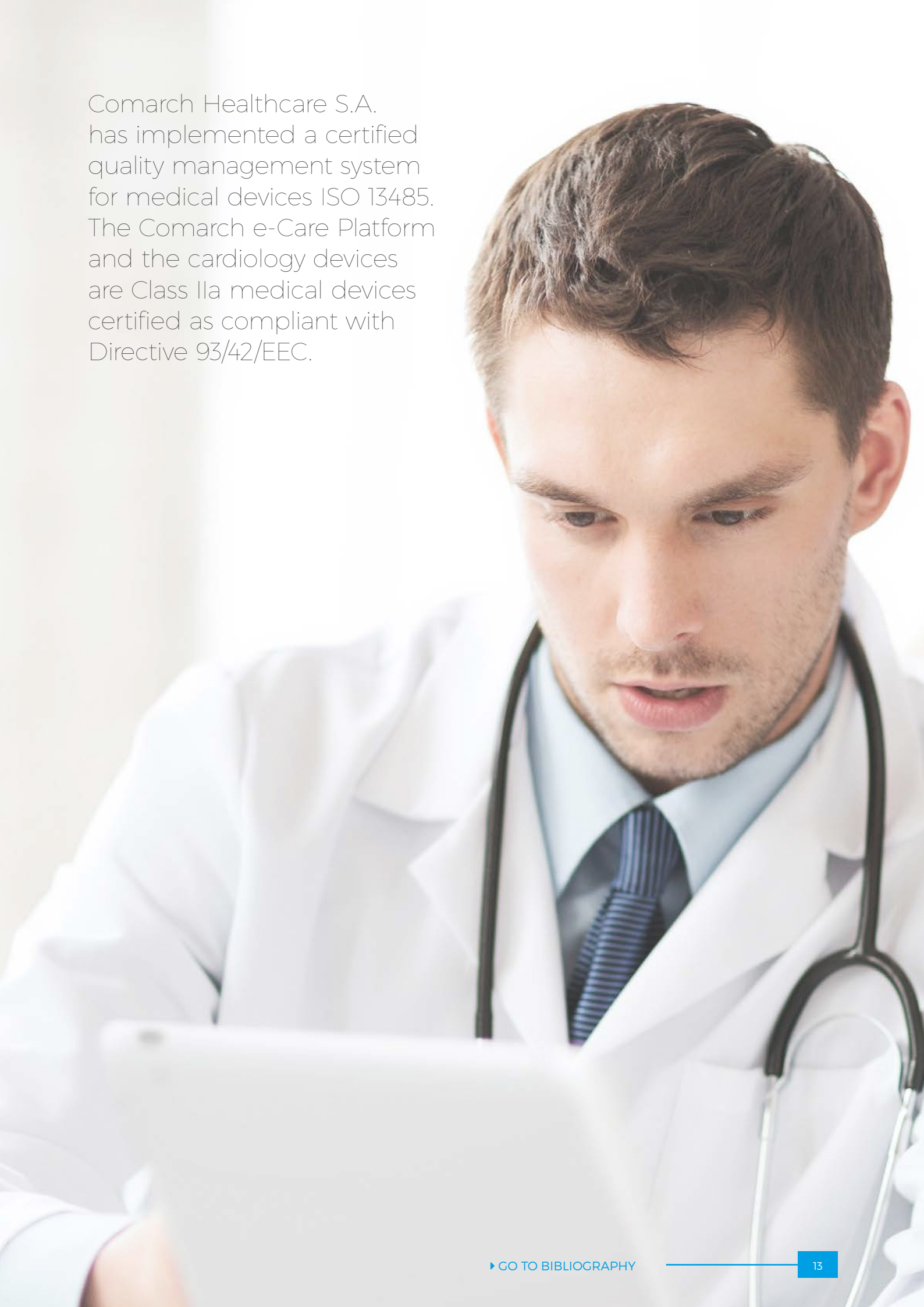
Comarch Healthcare S.A. has implemented a certified quality management system for medical devices ISO 13485. The Comarch e-Care Platform and the cardiology devices are Class IIa medical devices certified as compliant with Directive 93/42/EEC.



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ECONOMICAL ASPECTS OF TELEMONITORING

Telemonitoring has also been shown to be a powerful tool to decrease the costs of care for HF patients. This happens thanks to multiple mechanisms, however, mainly by reducing hospitalizations and hospital lengths of stay. A metanalysis by Klersy et al. demonstrated that RPM compared to usual care causes a cost-saving combined with a quality-adjusted life years (QALYs) gain of 0.06 suggesting that RPM is a "dominant" technology over existing standard care[56]. In the budget impact analysis, the adoption of an RPM strategy entailed a progressive and linear increase in costs saved. The difference in costs between RPM and usual care ranged from 300 euro to 1.000 euro per patient per year based on the Diagnosis Related Group (DRG), favoring RPM56. The higher the DRG the greater the saving. Contrasting data has been instead obtained by the group of Blum et al., where they mostly concentrated in understanding the effects of home telemonitoring on medical costs, 30-day rehospitalization, mortality, and health-related quality of life. Telemonitoring did not result in lower total costs and a decrease in 30-day readmission rates for the 1st year did not result in decreased total cost or better outcomes[57]. A more recent metanalysis, also by Klersy et al, on a more selected population, showed that compared with standard of care treatments, implantable device telemonitoring (DTM) was associated with a marked reduction in planned hospital visits[58]. In other words, DTM safely reduced healthcare utilization by reducing elective face-to-face hospital visits. Using the healthcare utilization compared with standard of care was associated with a cost saving for the healthcare structures of 15–50%[58].

DISCUSSION: PRESENT AND FUTURE PERSPECTIVES OF TELEMONITORING

Despite all the new advances in therapy, the management of CHF patients remains a massive burden for the healthcare system. This is only worsened by the increasing lack of physicians with expertise in HF and cardiology. This problem is particularly relevant in rural areas and in industrial countries, such as Germany or the UK. Therefore, telemedical care has been recently proposed as a potentially efficient and cost-effective way to provide care and improve the outcome of HF patients[59]. Many studies have been undertaken, providing both invasive and non-invasive solutions for HF patients. While for invasive remote monitoring a large consensus has been obtained especially after the CHAMPION[60] and IN-TIME trials[29], a certain disagreement is still present about the effectiveness of non-invasive methods in reducing patients' hospitalizations (Table 1). Telemonitoring as an intervention has been shown to reduce symptoms and improve quality of care through frequent monitoring of patients at home. This needs to be coherent with an easy utilization of these devices, that need to be portable and usable by everyone. Of extreme relevance is the consideration that most of the population with CHF are patients older than 65 years. The metanalysis by Inglis tackled this subject and revealed that no differences in age ranges affected the outcome and the adherence to telemonitoring in the studies analyzed[39].

Concerning the economic aspects of telemonitoring, many studies showed a reduction in costs by utilizing telemonitoring, encouraging its further utilization. This has been suggested for both non-invasive and invasive devices[56,58]. However, a consensus needs to be reached on the most appropriate endpoints to use and to establish the gold standard outcome to allow fair comparisons, especially from an economic perspective[61]. Remote patient monitoring allows a more frequent assessment of the patient status and an earlier recognition of decompensation events. This method provides the patients with a structured disease management process and can be self-empowering, meaning that the patient is actively involved in controlling his health status and lifestyle. This is consequent to the role of the patient, that has changed completely in the recent years, switching from a passive to an active one given by the spread of medical knowledge through internet. What is to be considered is the fact that patients at really high risk, who are already provided with an implanted device, may have a smaller evidence for the need of non-invasive devices. Nonetheless, an active monitoring can probably turn out to be beneficial also for them in the long term, affecting their everyday lifestyle.

Moreover, an interesting aspect is that, when telemedical solutions incorporate human interaction, such as between the patient and the physician, or the nurse, for example via telephone, this contact can also detect depression, which is a known risk factor of poor outcome in HF[62].

Eventually, another aspect that merits consideration is that telemonitoring should be applied and tailored to specific categories of patients. When talking about HF patients, the presence of comorbidities, such as chronic obstructive pulmonary disease, chronic kidney disease or anemia, for example, can negatively affect their outcome. The assessment and the measurement of these comorbidities will need new sensory techniques and new specific devices that need to be addressed to the specific patients' characteristics. Currently, the profile of patients who can potentially benefit from telemedicine is still partially unknown and should be investigated in adequately powered randomized clinical trials[61]. Since nowadays the spread of portable and affordable external devices is increasing, many of which connected to smartphones, clinical trials on the usefulness of these devices would be useful to assess the real clinical utility. A lot of literature has been published on the role of ECG for predicting HF worsening in chronic HF patients, however, these parameters are rarely utilized to predict remotely the patients' decompensation events. For this reason, either new devices and new algorithms are needed to improve the diagnosis and the risk stratification workflow of HF patients.

[...]the role of the patient, [...] has changed completely in the recent years, switching from a passive to an active one given by the spread of medical knowledge through internet.

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Comarch e-Care telemedicine platform is not only an information technology product. It is primarily a certified medical product, meeting all strict requirements and standards applicable to medical care tools and devices. The main concept of the solution is the creation of an additional channel for providing care within the framework of existing relations between the patient and their doctor.

Bartosz Pampuch,
Vice-President of the Board,
Comarch Healthcare

CONCLUSIONS

Modern advances in technologies have created new opportunities to provide telemedical care as an adjunct to medical management of patients with HF. Meta-analyses suggest that telemedicine can reduce morbidity and mortality in such patients; however, some prospective clinical trials do not support these findings. The debate on the utility of non-invasive devices for home telemonitoring is still open and future devices should concentrate on obtaining specific parameters based on the patients' profiles.

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TABLES

Table 1. A sample of clinical trials and metanalysis that investigated the effects of non-invasive telemonitoring in HF patients.

AUTHOR	YEAR	TYPE OF THE STUDY	ENDPOINTS	METHOD STUDIED	ECG MONITORING	RESULTS
Cleland - TEN-HMS	2005	Interventional Study	All-cause mortality or re-hospitalizations for any cause	Structured telephone support or non-invasive home telemonitoring	YES	BENEFICIAL EFFECTS Lower rate of all-cause mortality
Klersy	2009	Metanalysis	All-cause mortality, hospitalization for any cause or hospitalization for HF	Remote Patient Monitoring (Nurse Telephone Support and Technology-Assisted Monitoring)	YES	BENEFICIAL EFFECTS Lower rate of all-cause mortality, hospitalizations and hospitalizations for HF
Chaudry	2010	Interventional Study	All-cause mortality or re-hospitalizations for any cause	Nurse Telephone Support	NO	NO BENEFICIAL EFFECTS No differences between the interventional group and the usual care one
Ferrante – DIAL HF	2010	Interventional Study	All-cause mortality or hospital admissions 1 year after randomization	Nurse Telephone Support	NO	BENEFICIAL EFFECTS Lower rate of all-cause mortality and hospitalizations for HF
Kohler - TIM-HF	2011	Interventional Study	All-cause mortality or re-hospitalizations for HF	Remote Telemonitoring with external devices	YES	NO BENEFICIAL EFFECTS No differences between the interventional group and the usual care one
Angermann – INH study	2012	Interventional Study	Time to death or re-hospitalization, HF symptoms and quality of life	Nurse/MedicalDoctors Telephone Support and Education	NO	BENEFICIAL EFFECTS Decreased mortality risk and increased quality of life
Kotb	2015	Metanalysis	All-cause mortality, hospitalization for any cause or hospitalization for HF	Structured telephone support or non-invasive home telemonitoring	Not applicable to all the studies	BENEFICIAL EFFECTS Lower rate of all-cause mortality and hospitalizations for HF. Improvement in patients' quality of life
Ong - BEAT-HF	2016	Interventional Study	Readmission from any cause within 180 days after discharge	Structured telephone support and non-invasive home telemonitoring	YES	NO BENEFICIAL EFFECTS. No differences between the interventional group and the usual care one.
Inglis	2017	Metanalysis	All-cause mortality or hospital admissions for HF	Structured telephone support or non-invasive home telemonitoring	YES	BENEFICIAL EFFECTS. Lower rate of all-cause mortality and hospitalizations for HF. Improvement in patients' quality of life

Table 2. A synopsis of the electrocardiographic parameters that have been identified to predict the onset or the worsening of heart failure.

PARAMETERS	DEFINITION	STUDIES
Reduced Heart Rate variability	Reduction in time domain differences between day and night observed at Holter monitoring	Aronson - Am J Cardiol 2004
Increased Heart Rate	Tachycardia and increase in the basal heart rate	McKelvie - BMJ 1999
QRS/T Angle Increase	Increase in the repolarization axis angle (>60° for women and >120° for men)	Gotsman - Am J Cardiol 2013
Atrial and Ventricular Tachyarrhythmias	Atrial flutter and fibrillation and ventricular non-sustained and sustained ventricular tachycardia	De Sousa - Eur J Heart Fail 2008 Potpara - Eur J Heart Fail 2013
Increased ECG LV mass	More than 70 ± 9 g/m2 in men and 61 ± 8 g/m2 in women	Rautaharju - Hypertension 1999 Rautaharju - Am J Cardiol 2007
QT Prolongation	QTc >450 ms (males) QTc >460 ms (females)	Rautaharju - Journal of Card Electrophysiology 2002
Increased QRS duration	QRS >100 ms with or without complete and/or incomplete bundle branch blocks (left or right)	Dhingra - Hypertension 2006
LV strain	ST segment depression and T wave inversions	Kannel - Am J Med 1983 Levy - JAMA 1996 Okin - Hypertension 2004
An old silent myocardial infarction	Navacode Criteria*	Rautaharju - Journal of Electrocard 1998 Rautaharju - Am J Cardiol 2007

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SUPPLEMENTAL MATERIAL

*NAVACODE CRITERIA FOR DEFINING AN OLD SILENT MYOCARDIAL INFARCTION) ECG CATEGORIES ASSOCIATED WITH PREVALENT MYOCARDIAL INFARCTION/ISCHEMIA (MI LIKELIHOOD)[55]

No significant Q waves and no significant ST-T abnormalities

- Q score < 15 and STD and TN scores < 10

Q WAVE MI

Q wave MI: Major Q waves with or without ST-T abnormalities

- Q score >= 35 in any lead

Q wave MI: Moderate Q waves with ST-T abnormalities

- Q score >= 25 in any lead and STD or TN score >= 20 in any lead group

Possible Q wave MI: Moderate Q waves without ST-T abnormalities

- Q score >= 25 in any lead and STD and TN score < 20 in all lead groups

Possible Q wave MI: Minor Q waves with ST-T abnormalities

- Q score >= 15 in any lead and STD or TN score >= 20 in any lead group

ISOLATED ISCHEMIC ABNORMALITIES

ST abnormalities without Q waves

- TD score >= 20 in any lead and Q score < 15 in all leads and Code 6.0 (No LVH)

T wave abnormalities without Q waves

- TN score >= 20 in any lead and Q score < 15 in all leads and Code 6.0 (No LVH)

ISOLATED MINOR Q AND ST-T ABNORMALITIES

Minor Q waves without ST-T abnormalities

- Q score >= 15 in any lead and STD and TN score < 20 in any lead groups

Minor ST-T abnormalities

- STD or TN score >= 10 in any lead group

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