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Cardiac Status Assessment with a Multi-Signal Device for Improved Home-based Congestive Heart Failure Management

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***Abstract*— State-of-the-Art disease management for Congestive Heart Failure (CHF) patients is still based on easy-to-acquire measures such as heart rate (HR), weight and blood pressure (BP). However, these measures respond late to changes of the patient health status and provide limited information to personalize and adapt medication therapy.**

This paper describes our concept called "Cardiac Status Assessment" we have been investigating within the European project "HeartCycle" towards next-generation home-based disease management of CHF. In our concept we analyze non-invasive surrogate measures of the cardio-vascular function in particular systolic time intervals and pulse wave characteristics to estimate Cardiac Output (CO) and Systemic Vascular Resistance (SVR) both are established clinical measures. We discuss the underlying concept, a developed measurement system and first results.

I. Introduction

CONGESTIVE Heart Failure is one of the most costly chronic diseases in all developed countries [1]. Existing home-based CHF disease management systems use easy-to-acquire vital signs such as heart rate, blood pressure and weight as input variables to monitor a patient's condition. But all these parameters respond late or unspecific to CHF disease status changes. Therefore, ongoing research looks for better suited measures to improve CHF management e.g. by earlier detection of a de-compensation or to personalize treatment. Thorax impedance might be one example approach to detect a de-compensating patient earlier due to fluid accumulation in the upper thorax [2, 3].

The European-funded "HeartCycle" project investigates innovative concepts for improved medication compliance of CHF patients. One essential factor for a patient's non-compliance is suboptimal medication, since it can result in severe side effects and/or reduced treatment success. Within "HeartCycle" the concept "Hemodynamic Tailoring" has been developed to address this problem. Its basic building blocks are shown in Fig. 1.

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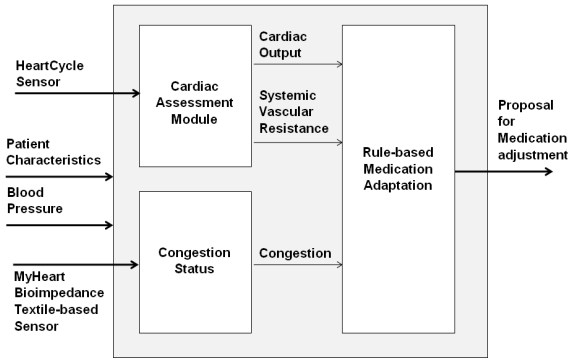

Fig. 1. "Hemodynamic Tailoring" concept being investigated in "HeartCycle" towards improved Medication Compliance.

In addition to blood pressure and patient characteristics, this concept takes into account the patient's cardio-vascular status combined with the congestion status. Congestion is estimated using the validated "MyHeart" textile-based monitoring system [3], whereas for the assessment of the cardio-vascular status a newly developed smart sensor system is foreseen. A rule-based algorithm proposes optimized medication adjustments to the treating clinician, who has to confirm or adapt a system-based proposal. The patient is asked to acquire the input signals by a daily spot check measurement of 10 min duration.

CHF essentially relates to a diminished heart pumping function, which could be easily assessed by Cardiac Output. CO is a well-known clinical established measure and plays a vital role in our concept. Still, CO cannot be reliably acquired at home so far. Echocardiography – the clinical gold standard for non-invasive CO – requires expensive, bulky equipment and well-trained operators. Impedance Cardiography (ICG) has been considered as one of the most promising techniques for home-use, but current implementations do not provide accurate CO readings for CHF patients [4]. Ongoing research analyses limitations of ICG-based CO estimation for CHF pathologies towards improved embodiments [5, 6].

This paper discusses in section II the module "Cardiac Status Assessment" and our approach to infer CO and SVR in more detail. The realized monitoring system is described in chapter III and chapter IV and V provide first results, insights and conclusion.

II. Cardiac Status Assessment

The module "Cardiac Status Assessment" has to provide as essential outputs CO and SVR derived from input signals that a) can be monitored non-invasively by a patient himself reliably at home and b) should be closely linked to the cardio-vascular status of the patient. In addition to BP and known patient characteristics, we infer the cardio-vascular status based on the analysis of the following signals: an electrocardiogram (ECG), heart sounds (HS), an impedance cardiogram (ICG) and photo-plethysmogram (PPG). These signals provide complementary as well as redundant information on the heart pumping function and the vascular status. It has been shown that ECG and thoracic impedance can be reliably measured with functional textiles [3], PPG acquisition has been already implemented in CHF disease management systems and a HS sensor needs essentially accurate placement, which could be enforced by a functional textile design as well. A complete diagram of this module with all input and output signals is shown in Fig. 2.

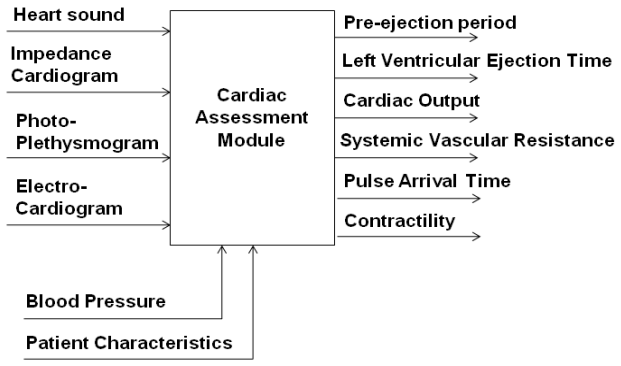

Fig. 2. Input and Output of the Cardiac Status Assessment Module being investigated in the Assessment Use Case Scenario within the project "HeartCycle"

From the input signals we estimate Systolic Time Intervals (STI), thoracic fluid status and thoracic impedance as well as vascular status parameters such as pulse transit time (PTT) and pulse arrival time (PAT).

Systolic time intervals (STI) have been shown valuable as non-invasive measures to assess left ventricular performance [7, 8]. STI reflect the duration of total electro-mechanical systole, and present two major components: the pre-ejection period (PEP) and the left ventricular ejection time (LVET). PEP is the time interval between the start of ventricular depolarization and the moment of aortic valve opening, whereas the LVET is defined as the time interval of left ventricular ejection, which occurs between the opening of the aortic valve and its subsequent closure. PEP is an index of the left ventricular function and indicates changes in myocardial contractility, pre- and after load [8]. The left ventricular ejection period (LVET) can also be related to contractility and to cardiac output.

Vascular status e.g. vessel stiffness is inferred using the pulse wave methodology. One implementation of this method analyses a synchronously measured ECG and photo-plethysmogram from which pulse propagation characteristics of the arterial tree like the PAT can be derived. PAT is defined as time interval between the peak of the R wave of the electrocardiogram and the onset of a peripheral photo-plethysmographic pulse, which has been intensively investigated as surrogate measures of blood pressure and vessel stiffness (BP) [9, 10]. Since PAT is the sum of PEP and PTT, PTT can be calculated from PAT if PEP is known. BP variability (BPV) – another potential interesting parameter - might be accessible via PAT and PTT as well, however the clinical relevance of BVP is a matter of research.

Cardiac output and Contractility index are estimated based on PEP, LVET, body surface area and age using algorithms currently under development [11]. SVR is derived from CO and the mean blood pressure (MBP) using the relation SVR = MBP/CO.

III. Realized System

A. System Design

For our current research status, we realized a system for data acquisition in clinical trials. The design already takes into account a later planned easy adaptation to home monitoring scenarios e.g. integration into functional textiles.

The system offers to measure an ECG, an ICG, near-infrared PPG, infrared PPG and a thoracic inductive plethysmogram. In addition, sound signals from two thorax locations using custom made microphones can be acquired. Up-to three 3-axis acceleration sensors at the thorax, arms or legs provide information on posture and movements. Additionally skin temperature can be measured as well. All signals but ICG are acquired with 16 bit ADC resolution, whereas the ICG is measured with 24 bit ADC resolution. ECG and ICG are picked up with standard clinical electrodes. Respiration effort is monitored with a commercial inductive respiration-belt. Custom made housings were developed for the microphones and accelerometers with a circular shape of 1.1 cm in diameter. These housings are attached by medical-grade adhesive discs on the patient's skin. Data are stored on a memory card and can be wirelessly transmitted via Bluetooth or Zigbee.

The system concept focused on an easy to use approach for the clinical staff as well as to ensure maximum comfort for the patient. The system is classified as investigational device. Since the patient is not hindered in natural movements, ambulating (mobile) patients can be continuously monitored for up-to 24 h.

A. Sensors locations

Fig. 3 shows the location of all sensors on a patient's body. The central unit is fixed to the thorax by medical grade electrodes below the nipple line. The respiration effort band measures changes of thoracic circumference at the height of the central unit. Heart sounds are picked up at two locations: a) at the left sternum border and b) at the apex position. A standard clinical SpO2 sensor is attached to the index finger to provide infrared and near-infrared photo-plethysmograms, which also allows monitoring SpO2. In the presented configuration a 3 axis acceleration sensor within the central

unit is used to detect the relative position of the thorax in the earth gravity field as well as the activity of the patient.

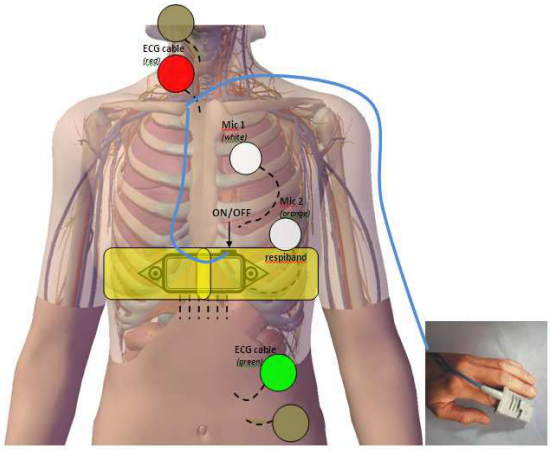

Fig. 3. Sensor locations at the patient; the central unit is located below the nipple line behind the respiration band (in yellow).

A. *System components*

The essential components of the system are shown in Fig. 4 on the left and include an external charging unit, the system cover with battery and the central electronic unit with sensor cables. A subject with an attached system is presented on the right picture in Fig. 4.

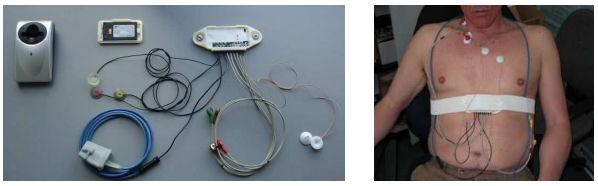

Fig. 4. left: System components with charger, system cover with battery and central unit; right: subject with attached systems

IV. Results

The following section presents preliminary results obtained in several studies within "HeartCyle".

A. *PEP and LVET estimation using Heart Sound*

The accuracy of PEP and LVET estimation using heart sounds has been investigated with healthy and CHF / Coronary Artery Disease (CAD) patients. Data were acquired in a clinical setting using an electronic stethoscope and echocardiography provided reference measurements of PEP and LVET.

TABLE I
Systolic Time Interval estimation based on Heart Sounds

Measure	Population	Absolute Error	Pearson correlation
PEP	Healthy	7.1±5.6 ms	0.53
LVET	Healthy	11.2±9.3 ms	0.87
PEP	HF&CAD	11.9±8.8 ms	0.70
LVET	HF&CAD	18.0±17.4 ms	0.83

Table I summarizes the performance of the developed algorithms in terms of absolute average error (mean and standard deviation) and Pearson correlation coefficient. The obtained results show comparable performance to the echocardiography reference measurements and confirmed to include heart sounds in our concept as essential source for reliable PEP and LVET estimation. More details can be found in [12, 13].

B. *LVET estimated from Impedance Cardiogram – Impact on CO estimation*

We tested several different existing algorithms to extract PEP and LVET using the ICG as an alternative to HS [14]. Data have been acquired from the same study group discussed before for HS. The ICG was acquired with the clinical Impedance Monitor "NICCOMO" [15]. Table II reports the measurement performance achieved using an algorithm developed inside the "HeartCycle" project for ICG segmentation [13], where in particular LVET has a higher error compared to LVET extracted from HS (Table I).

TABLE II
Systolic Time Interval estimation from Impedance Cardiogram

Measure	Population	Absolute Error	Pearson correlation
PEP	Healthy	12.4±8.7 ms	0.54
LVET	Healthy	33.4±29.4 ms	0.28

A low estimation accuracy of ICG-based LVET has been found for all investigated algorithms [13]. The underlying reason is the –ill-defined - X-point within the ICG, which is commonly used as marker of the aortic valve closure. In fact, this point did not coincide with aortic valve closure verified with synchronously measured echocardiography - signals. Similar findings were reported in [4] and ICG-based LVET estimates might be unreliable. This finding is important, since CO computed e.g. by the well-known Kubicek formula is proportional to LVET. An inaccurate LVET has therefore strong impact on CO estimation. One approach to solve this problem could be to use an LVET estimate extracted from heart sounds (Table II). First clinical evidence for this assumption under real-life condition has been acquired [13] and is currently being validated.

C. *Pulse Transit Time and Pulse Arrival Time estimation for BP inference*

We investigated using PTT and PAT as surrogate of absolute BP to potentially replace cuff-based BP measurements. We found in healthy and CHF patients a very subject-specific highly variable relation of BP vs. PAT and very weak relation of PTT vs. BP. Based on our results reliable BP estimation based on PTT or PAT is still not feasible [16] and agrees with findings of others [17]. However, PTT and PAT together with standard BP could provide information on the vessel status currently under investigation being of relevance for improved CO estimation [11].

In addition, recent research has shown that PAT in combination with standard BP provides information of

impaired short term regulation mechanisms for CHF patients as a potential useful marker of a de-compensation [18].

V. DISCUSSION

Current CHF disease management lacks access to hemodynamic parameters to tailor medication therapy to a patient disease status. The concept "Hemodynamic Tailoring" assumes access to CO and SVR both being clinically established measures with guideline-enforced therapy consequences. Our approach to infer CO and SVR at home combines well-known measurement principles to assess the cardiac and vascular status using surrogate measures derived from heart sounds, thoracic impedance and pulse wave characteristics. All signals can be reliably acquired simultaneously with our developed system. The concept design enables an easy transfer of our approach to the envisioned home scenario, where a patient checks his disease status by a daily measurement. This has been enabled due to progress in sensor integration and in functional textiles.

Preliminary results obtained in several clinical studies within the project already show the benefit of a combined analysis of complementary and redundant signal sources e.g. to improve the accuracy of LVET estimation using HS or PPG signals instead of ICG. Still, more clinical evidence has to be provided, which is one focus of our ongoing research. Algorithms for improved CO estimations using the accessible input signals have already shown promising results [13].

VI. CONCLUSION

The "HeartCycle" project investigates new sensors and algorithm concepts towards personalized medication adaptation for home-based CHF disease management. Access to the patient's hemodynamic status at home could optimize CHF management by personalized medication to avoid hospitalization and reduce treatment side effects to a minimum. This can help to improve patient compliance in CHF management, which is a essential objective of the "HeartCycle" project.

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REFERENCES

[1] T. Thom et.al., Heart Disease and stroke statistics – 2006 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation 2006; 113e85-e151

[2] F. Garcia et.al., Automated Daily Transmission of Implant-based Impedance Data to Detect Intrathoracic Fluid Accumulation, DOI 10.1515/BMT.2010.191

[3] J. Habetha et.al., TeleHealth improves chronic disease management of heart failure, Medica Mundi vol.52, no.3, pp. 22-30, 2008.

[4] David J. Wang et.al. Impedance cardiography: More questions than answers, Current Cardiology Reports vol. 8, no. 3, pp.180-186, 2006

[5] P. Carvalho et.al., Robust Characteristic Points for ICG: Definition and Comparative Analysis, Biosignals, Int. Conf. on Bio-Inspired Systems and Signal Processing, 2011

[6] M. Ulbrich et.al., Simulation of Continuous Spectroscopic Bioimpedance Measurements for Impedance Cardiography, Int. Workshop on Bioimpedance Spectroscopy, Chemnitz 2010

[7] J. Oh et.al., The return of cardiac time intervals. The Phonix is rising., J. of the Am. Col. of Cardiology, vol. 42, no. 8, pp. 1471-1474, 2003

[8] T. Gillebert et.al. Time intervals and global function. Use and limitations, Eur. Heart J., vol. 25, pp. 2185-2186, 2004

[9] A. Steptoe et.al. "Pulse Wave Velocity and Blood Pressure Change: Calibration and Applications", Psychophysiology, vol.13, no.5, pp. 488-493, 1976.

[10] D. B. Newlin, "Relationships of Pulse Transmission Times to Pre-Ejection Period and Blood Pressure", Psychophysiology, vol.18, pp.316-321, 1981.

[11] R. Couceiro et.al., Cardiac Output from Heart Sound, EMBC-2011, 33rd Annual Int. Conf. of the IEEE Engineering in Medicine and Biology Society, 2011 (submitted)

[12] R. P. Paiva et.al., Assessing PEP and LVET from Heart Sounds: Algorithms and Evaluation, EMBC-2009, 31st Annual Int. Conf. of the IEEE Engineering in Medicine and Biology Society, 3129-33, 2009

[13] P. Carvalho et. al. Comparison of Systolic Time Interval Measurement Modalities for Portable Devices, EMBC-2010, 32nd Annual Int. Conf. of the IEEE Engineering in Medicine and Biology Society, 606-609, 2010

[14] Shyu L.Y. et.al., The detection of impedance cardiogram characteristic points using wavelets, Computers in Biology and Medicine, vol.34, pp. 165-175, 2004

[15] NICCOMO cardiovascular monitor: www.niccomo.com

[16] J. Proença, et al., Is Pulse Transit Time a good indicator of Blood Pressure changes during short physical exercise in a young population? EMBC 2010, 32nd Annual Int. Conf. Of the IEEE Engineering in Medicine and Biology Society, 598-601, 2010

[17] R. A. Payne et.al., Pulse transit time measured from the ECG: an unreliable marker of beat-to-beat blood pressure, J. Appl. Physiol, vol.100, no.1, pp. 136-141, 2006

[18] D. R. Wagner et.al., Relationship between pulse transit time and blood pressure is impaired in patients with chronic heart failure, Clin Res Card. vol.99, no.10, pp. 657-64, 2010