TeleCor - Individualized monitoring for cardiac patients

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Proposal

The TeleCor project is focused on the individualized monitoring and therapy support of heart failure patients. As a result of demographic change, the early detection of dangerous symptoms of heart failure is of great importance. People with heart disease are already significantly limited in their domestic mobility mostly due to dyspnea and fatigue. A decisive goal in the care of these patients is to set up a telemedical competence center with the aim of individualized therapy for heart failure, in particular on the basis of data that is continuously obtained using a real-time heart monitoring. This should enable aging people with heart failure an autonomous life with sufficient life quality.Two additive approaches were pursued in the processing of the project. In cooperation with the project partner Thorsis Technologies GmbH a prototype for the measurement of hemodynamic parameters was developed. At the same time, in a clinical hemodynamic study, the diagnostic and prognostic algorithms are questioned to increase the efficacy of management in patients with chronic heart failure.

Technical development - multi-sensor system

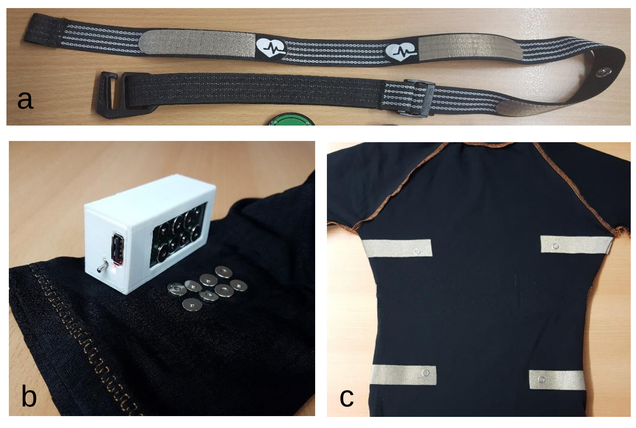

Fig. 1: a. measuring belt, b. vest, c. shirt

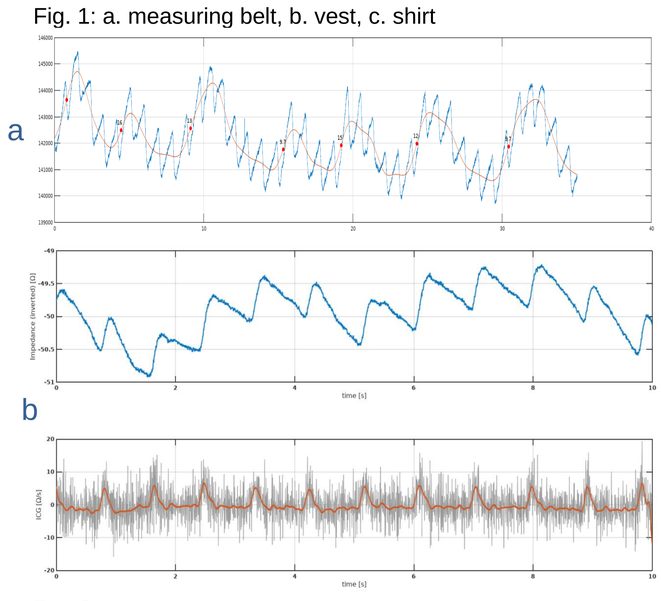

Fig. 2: a. transthoracic impedance curve sample derived from the inspiratory flank detection algorithm;
b. determination of the ICG (orange curve) from the inverted thoracic impedance (above, blue curve). Digital differentiation led to amplification of higher-frequency noise (bottom, gray). The ICG curve after filtering with a low-pass filter.

The core requirement when developing the device was to enable quick and long-term use, especially in the home environment. For this reason, the measuring system is battery-operated and can also be used as a mobile device. A tight contact of the sensors in a carrying electronics to the human body was challenging. Toward this end the textile dry electrodes with a high conductivity were made very stretchy to ensure a tight contact and compatible for different carriers. Based on this, a belt system that can be used universally as well as an individually tailored measuring shirt / vest were developed (Fig 1a, b, c). The electrode carrier of the measuring system is connected to the measuring device via magnetic buttons. The system allows recording of a 6-lead ECG, thoracic impedance, respiratory rate and locomotor activity.
The multi-sensor system was set up as a test device for carrying out test person measurements and served as the basis for the development of evaluation algorithms using real recorded data. The specified biosignals could be successfully recorded and algorithmically processed. The raw data are first recorded via a microcontroller unit (Texas Instrument MSP430) and made available via a Bluetooth module (Bluegiga BT121). The biosignals are displayed and saved using software modality. To process complex algorithms the Octave open source high-level digital analysing software with Matlab™ compatibility was used. The derived parameters include heart and respiratory rates, pre-ejection period (PEP), systolic Time Ratio (STR), thoracic fluid content (TFC). stroke volume/index (SV, SI), cardiac output/idex (CO, CI), acceleration energy of the thorax.

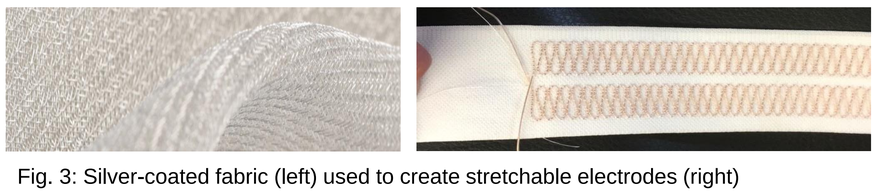

Fig. 3: Silver-coated fabric (left) used to create stretchable electrodes (right)

Clinical Study on Non-Invasive Hemodynamics

Fig. 4: Left/right cardiac catheterization (LHC/RHC), transthoracic echocardiography (TTE) and impedance cardiography (ICG)

Heart failure (HF) is one of the most common diseases in the adult population of industrialized society which occurs with increasing age. In Germany, it is the third most common cause of death. The prognosis of HF is generally poor, especially in patients who do not receive optimal therapy. In chronic HF, modern drug therapy is shown to improve the outcomes and quality of life. Nevertheless, the occurrence of acute deterioration (acute decompensation) drastically worsen the prognosis. Therefore, prevention of the impending decompensation or at least reduction of it's severity is an important health care challenge.
The aim of performed study was to identify variables for individualized monitoring to identify dangerous decompensations at an early stage in patients with heart failure. The magnitude and temporal changes of specific intracardiac measurements (impedance-based and invasively measured) were assessed duringa follow-up period of 3 and 6 month. This clinical trial used a monocentric, non-randomized clinical study design (DRKS00015635).

Results

Table 2: Baseline characteristics

	n = 50
Alter (Jahre ± SD)	74,9 ± 6,6
Geschlecht m (%)	31 (62)
KHK (%)	14 (28)
NT-ProBNP (pg/ml) [25 75]	2273 [1255 3690]
NYHA I (%)	3 (6)
NYHA II (%)	9 (18)
NYHA III (%)	35 (70)
NYHA IV (%)	3 (6)
EF (% ± SD)	50 ± 17
LVEDV Ruhe / Belastung (ml ±SD)	110 ± 52 / 105 ± 49
LVESV Ruhe / Belastung (ml ±SD)	58 ± 42 / 55 ± 38
VO_2max (ml/kg min) (CPET)	3060 (2620 – 3925)

To caught up the relative changes in cardiac performance, all datasets were collected at rest and during an exercise.
A correlation analysis between selected invasively and non-invasively measured hemodynamic parameters will be performed using an evaluation matrix given in Table 3. A comparative analysis of ICG-gained values and selected parameters of the evaluation matrix (univariate linear regression based on NYHA, cardiac index (CI), systemic vascular resistance (SVRI) and thoracic fluid content (TFC)) is exemplary presented in Table 4. Only moderate and strong correlations are shown (measure of determination R^2).

Table 3 : Evaluation matrix of the hemodynamic parameters

	ICG	TTE	L/RHC
Cardial indicies	CI	CI	CI
Contractility	IC, VI, AI, HI	EF, E/e´, RV longitudinal strain, strain rate	IC, dP/dt_{max}
Systolic Function	PEP, LVET, STR	PEP, LVET, STR	EF, dP/dt_{max}
Fluid content	TFC	LVEDV, LVESV, PAP_{sys}, 3D-RVV	RVP, L-/RVEDP, PAP, PCWP, TPG
Vascular resistance	SVRI	SVRI	SVRI, PVRI

Table 4: Comparative analysis of ICG-gained and selected parameters of the evaluation matrix

Parameter	ICG - Zusammenhang			
	CI	Delta CI	SVRI	TFC
NYHA	stark			moderat
LHC CI	moderat		moderat	
LHC ΔCI (Ruhe-Exercise)	stark	stark		moderat
LHC SVRI			Moderat	
TTE CI				
TTE ΔCI (Ruhe– Exercise)	moderat	stark		

Primary Endpoint

The reproducibility between hemodynamic real-time measurements of the hemo-dynamic parameters gained by invasive (left/right cardiac catheterization, LHC/ RHC) and non-invasive (transthoracic echo- (TTE) and impedance-cardiography ICG) methods (Table 1)

Secondary Endpoint

The crosstalk between established hemodynamic indicators and the para-meters of the clinical outcome (NYHA class, quality of life, cardiopulmonary exercise testing (CPET), values, NT-proBNP, galectin-3, peripheral edema, hospitalization rate) (Table 1)

Table 1: Clinical data acquisition

Parameter/Methods	Screening and Consent	LHC / RHC	1. Follow-up (in 3 months)	2. Follow-up (in 6 months)
Weight	X	X	X	X
Clinical exam	X	X	X	X
ECG	X	X	X	X
NYHA-Class	X	X	X	X
CPET	X[1]		X[1]	X[1]
NT-proBNP, Galectin-3	X	X	X	X
ICG	X	X	X	X
TTE	X	X	X	X
LHC / RHC		X		

[1] CPET is performed only in the absence of a contraindication

Study Criteria

Inclusion criteria were age from 60 year, HF with NYHA II-IV (NYHA IV only after recompensation), clinical indication to L/RHC, signed official consent.

Exclusion criteria were myocardial infarction or CABG-S in the last 3 months, active oncological processes, CAD requiring PTCA/surgery, pregnancy, the height of the patient (< 120 cm or > 230 cm), the patient's weight (> 155 kg and <30 kg), atrial fibrillation with HF (> 110/min), COPD > 2 GOLD, CKD on hemodialysis, other conditions preventing enrollment as assessed by a treating/study physician.

Conclusion & Further Plans

The non-invasive parameters tested in the frames of clinical study are obviously related to complex invasive hemodynamic measurements, that underscores the perspective of mobile cardiac monitoring in out-patient sector and particularly in older patients. A multidisciplinary approach of the project brought together physicians, engineers and biologists over a period of three years. A further step to question the gaps in the networking between healthcare providers (inpatient, outpatient, emergency, hospitals) to bring bridging solutions is approached in our project "KARLA - KARdiologische LandAssistenz" within the 2nd funding phase.