Sensitivity of a Wearable Bioimpedance Monitor to Changes in the Thoracic Fluid Content of Heart Failure Patients

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Abstract

In the context of home telehealth, spectroscopic bioimpedance measurements have the potential to aid therapy guidance and health maintenance in patients at risk of abnormal fluid accumulation such as heart failure patients. To this aim, monitoring devices need to be sensitive to subtle changes in congestion and hemodynamics. In this study, we assess the sensitivity of a wearable trans-thoracic bioimpedance monitor (BIM) with textile electrodes to variations in the thoracic fluid content of heart failure patients induced by postural maneuvers and omission of medications such as diuretics. The results indicate that the BIM is able to follow these changes and that the largest effect size is accounted by the omission of heart failure medications.

1. Introduction

Telehealth for the remote management of chronic conditions requires sensitive devices to serve the purpose of health maintenance by enabling medical professionals to keep patients in an ideal range of vital signs.

In heart failure, disease progression is marked by a gradual retention of fluid in the lungs long before symptoms of disease worsening occur [1]. Fluid buildup is associated with an increase in tissue conductivity which, in turn, is reflected by a decrease in thoracic bioimpedance. Based on this principle, a wearable trans-thoracic bioimpedance monitor (BIM) was designed to detect abnormal, pulmonary fluid accumulation. A feasibility study using the BIM as part of a home telemonitoring solution for heart failure patients (the MyHeart Heart Failure Management System) has already been successfully conducted, where it was shown to be the most predictive measurement prior to hospital admissions due to worsening of heart failure [2]. The use of trans-thoracic bioimpedance measurements as part of home telemonitoring solutions could be extended, beyond the detection of crises, to health maintenance, therapy guidance, medication titration or assessment of medication compliance. A necessary prerequisite is the ability of bioimpedance measurements performed at home to follow subtle variations in congestion and hemodynamics.

This study investigates the ability of the BIM to detect subtle variations in congestion and hemodynamics induced under supervised conditions in patients with stable, chronic heart failure. Variations were induced by means of posture changes and medication omission leading to fluid redistribution and fluid retention, respectively. In this analysis, we evaluate the effect of these variations on the extracellular resistance derived from the BIM data, thus assessing the sensitivity of the device to subtle changes in thoracic fluid content.

2. Materials and methods

This section introduces the bioimpedance measurement technique and the device used in the study followed by an overview of the data acquisition protocol and data analysis.

2.1. Bioimpedance spectroscopy

Bioimpedance spectroscopy (BIS) is a technique for measuring bioimpedance over a wide frequency band and fitting the obtained data to a physical model. It can be used in assessing body composition based on the fact that the electrical characteristics of the human body vary with the contained fluid volume e.g. blood and muscle tissue have a higher conductivity than bones or fat [3], and dry, healthy lungs have lower conductivity compared to wet, lungs, affected by fluid accumulation.

The total body fluid (TBF) consists of intracellular

fluid (ICF) and extracellular fluid (ECF), which are separated by cellular membranes. Cellular membranes have a capacitive behavior causing the distribution of an alternating current injected into the body to be frequency dependent: low frequency currents flow around the cells through the ECF; high frequency currents also flow through the cell membrane and the ICF (Figure 1, left). To describe this phenomenon, the Cole theory [4] uses an equivalent electrical circuit shown in Figure 1 (right). R_E, R_I and C_M represent the resistance of the ECF, the resistance of the ICF and the membrane capacitance, respectively.

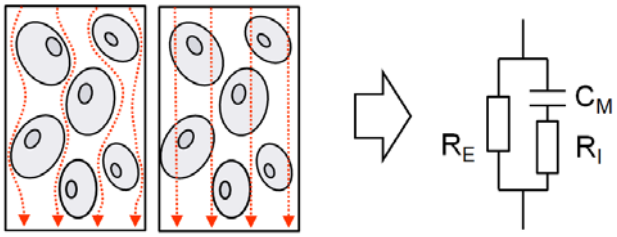

Figure 1. Left: distribution of an alternating current in biological tissue. Low frequency currents flow around the cells, only through the ECF, and high frequency currents flow through the ECF, the cell membrane and the ICF. Right: the equivalent electrical circuit diagram.

Taking into account the distribution effects due to tissue characteristics using a heuristic factor α, the measured bioimpedance can be expressed as:

$$Z = \frac{R_E}{R_E + R_I}\left(R_\mathrm{I} + \frac{R_E}{1 + \left(j\omega C_M (R_E + R_I)\right)^{\alpha}}\right) \quad \text{(Eq. 1)}$$

The parameters of the Cole model (R_E, R_I, C_M and α) can be estimated by measuring the body bioimpedance (Z) at different angular frequencies (ω) and applying curve-fitting methods to the data.

2.2. Wearable bioimpedance monitor

The wearable bioimpedance monitor (BIM) is a device designed to assess thoracic fluid status. It includes an adjustable vest, a textile chest belt with textile electrodes and a slim electronics case connected to the belt (Figure 2, right). A wireless communication interface enables the user to control the device with e.g. a central home telemonitoring hub or a smartphone. Patients are instructed to perform self-measurements in a sitting position (Figure 2, left).

The BIM measures thoracic bioimpedance at multiple frequencies using a tetra-polar electrode arrangement. The outer pair of electrodes located on either side of the chest belt is used to apply a sinusoidal current, I, at 16 frequencies (10 kHz – 1 MHz), sequentially every 0.2 seconds. The voltage drop, U, is measured by the inner electrode pair. With known I and U, Z can be determined

Figure 2. Left: patient performing a trans-thoracic bioimpedance measurement using the BIM at home. Right: the electronics case attached to the textile electrode belt.

using Ohm's law. The Cole model parameters are estimated by fitting the model to the bioimpedance, Z, measured at each frequency [5].

2.3. Study design

The study targeted clinically-stable heart failure patients receiving guideline-directed treatment, including a loop diuretic. The patients participated under medical supervision in a sequence of physiological and pharmacological maneuvers aimed at inducing variations in thoracic fluid volume. All procedures were approved by the local Medical Ethics Committee. While multiple vital parameters were collected during the protocol, in this paper, we focus on the trans-thoracic bioimpedance measurements performed during a cohesive sub-sequence of maneuvers which included posture changes and medication omission.

At enrolment, patients gave written informed consent and performed a first measurement with the BIM in sitting position. They were then invited to return on two separate days to undergo the measurement protocol.

At the beginning of each measurement session, a measurement vest of suitable size was strapped tightly around the patient's thorax, preventing displacements of the electrodes during body movements. The vest was then worn throughout the entire session.

Posture changes: To assess the effect of fluid redistribution on trans-thoracic bioimpedance measurements, patients were measured sequentially in following body positions: semi-recumbent, supine, legs raised, standing with their hands on the abdomen, and sitting (see Figure 3). Each measurement was a three-minute snapshot taken approximately five minutes after a posture change.

Medication omission: To evaluate the effect of pulmonary fluid accumulation on bioimpedance measurements, each patient attended the measurement session twice: while following normal medication

regimen (*MedsTaken*) and after having omitted their heart failure medications, e.g. diuretics, for 48 hours (*MedsOmitted*). The order of the sessions was randomly assigned, thus preventing order bias.

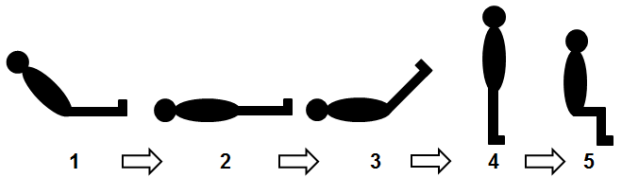

Figure 3. Measurement session overview: a session consists of snapshot measurements in semi-recumbent (1), supine (2), legs raised (3), standing (4) and sitting (5) postures.

2.4. Data analysis

Cole model parameters were estimated from the bioimpedance spectroscopy data obtained in each step of the study protocol. The fluid changes induced here through postural maneuvers and medication omission were mainly limited to the extracellular compartment. Therefore, in the current analysis, we focused on R_E as the indicator of thoracic fluid volume.

Posture changes: To enable the comparison of posture-induced variations among sessions, each R_E value was normalized to its corresponding session mean, $R_E^S = (\sum_{k=1}^{5} R_E^k)\,/5$. The effect size of a posture change was determined as the difference between normalized R_E values obtained within one session.

Medication omission: The inter-session change in R_E following medication omission was determined for each patient as the relative difference, between their measurements in sitting position from the sessions *MedsTaken* and *MedsOmitted*. The relative differences between measurements performed in sitting position at enrolment and during the session *MedsTaken* were used to indicate the normal variability of R_E values in patients following normal medication regimen.

Observed effect sizes are reported as mean value ± standard error of the mean.

3. Results

Twenty heart failure patients, predominantly over the age of sixty, participated in a total of forty measurement sessions. Absolute R_E values of both groups were scattered over a wide range (20–50Ω) with no clear thresholds to discriminate between values of the sessions *MedsTaken* and *MedsOmitted*. The data were described by a relatively large overall coefficient of variation, CV, of 22.6%. However, values measured within one session, varied within a narrow range around the session mean, R_E^S, as shown by the mean of the coefficients of variation determined per session, CV_S, of 3.6%. The large difference between the two coefficients suggests that the spread of the R_E values was primarily determined by patient characteristic such as chest circumference and fat mass, and to a lesser extent by variations induced during the protocol.

Posture changes: Intra-session R_E variation patterns of sessions *MedsTaken* and *MedsOmitted* were similar. Therefore, in the further analysis we used the averaged variation pattern of all measurement sessions, which is depicted in Figure 4. Generally, R_E values of the upright torso, i.e. standing and sitting, were lower than those corresponding to the tilt torso, i.e. semi-recumbent, supine, legs raised.

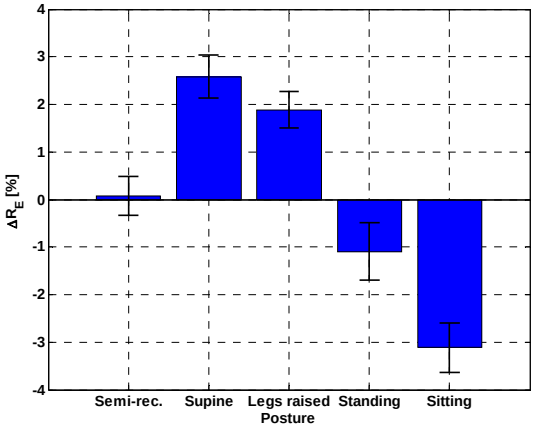

Figure 4. R_E variation pattern across postures. Values are normalized by the mean R_E of the corresponding session. The error lines represent the standard error of the means.

Based on the intra-session variation pattern, we estimated the effect size of posture changes for all sessions as depicted in Table 1.

Medication omission: Upon medication omission, we observed a large R_E change of –12.5±2.9% compared to the stable values during normal medication regimen, indicated by a relative difference, ΔR_E, of 0.0±1.8%.

Table 1. Effect size of posture changes, normal medication regimen and medication omission.

Maneuver			ΔR_E[%]
Semi-recumbent	→	Supine	+3.2±0.5
Supine	→	Legs raised	–0.9±0.2
Supine	→	Standing	–3.7±0.8
Supine	→	Sitting	–5.6±0.8
Standing	→	Sitting	–1.9±0.5
Normal medication regimen			0.0±1.8
Medication omission for 48h			–12.5±2.9

4. Discussion

Posture changes: The results show a clear variation pattern of R_E across postures which can be accounted to the combined effects of vascular fluid redistribution,

organ shifts and modifications of the thoracic contour. During posture changes, gravity alters the hydrostatic pressure balance causing a rapid fluid redistribution within the vascular compartment, followed by a gradual, local fluid redistribution between vascular and interstitial space. When the body is tilt from an erect position towards the horizontal, blood from the extremities is redistributed towards to thorax [6]. In addition, abdominal organs having a higher conductivity then the lungs advance towards the thoracic cage [3,8]. Both blood and organ shifts are, therefore, expected to lead to a lower thoracic bioimpedance in recumbent positions compared to erect body positions. However, our results reveal higher R_E values for the recumbent body positions compared to the erect thorax. This is most probably due to the third effect (modifications of the thoracic contour) being most dominant. Tilting the thorax from an erect position towards a horizontal position leads to a smaller sagittal diameter and a greater lateral diameter [8], which, in turn, results in an increased distance between the measurement electrodes of the textile vest. Since the resistance of an electrical conductor (i.e. the thorax) is proportional to its length, R_E increases after the posture change semi-recumbent to supine and decreases from supine to standing. While the further decrease from standing to sitting requires further investigation, it may be accounted to an abdominal organ shift towards the thorax that does not alter the distance between electrodes. The slight decrease in R_E observed from supine to legs raised is most likely the effect of increased thoracic conductivity due to congestion in the pulmonary venous return to the heart.

Medication omission: The stable inter-session R_E values during normal medication regimen suggest a good repeatability of the measurement in sitting position. The change of –12.5±2.9 following medication omission reflects the expected fluid retention upon omission of diuretics. Notably, the effect size of medication omission was greater than variations induced by posture changes.

While the presented results give an indication of the observed effects, future analyses should assess their statistical significance, potential confounding factors, as well as the correlation of inter-session impedance changes to the evolution of body weight, symptoms and clinical assessments of congestion.

5. Conclusions

The present study investigated the sensitivity of a wearable trans-thoracic bioimpedance monitor to variations of thoracic fluid content induced in heart failure patients. Each patient participated in a sequence of posture changes while following normal medication regimen and after medication omission for 48 hours. The diversity in patients' body characteristics did not enable the discrimination of patients on medication and after medication omission based on absolute measurement values. However, the BIM was able to detect the inter-session accumulation of fluid due to medication omission as well as intra-session fluid redistributions induced by posture changes. Moreover, medication omission led to a greater effect size compared to other maneuvers, which makes measurements of trans-thoracic bioimpedance using textile electrodes a promising way to objectively evaluate not only disease progression but also medication non-adherence.

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