New Devices to Monitor Heart Failure and Reduce Hospitalizations

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I, Michael Shochat, is The Directory of Board RSMM technology Company produced device for congestion monitoring
My *objective* today is to prove to you that we are close to achieve effective *non-invasive monitoring* of pulmonary congestion in chronic heart failure patients.

What was the basis for more than 30 years of unsuccessful attempts to design a non-invasive device for monitoring of pulmonary congestion?
The Problem: Recurrent HF hospitalizations in CHF patients that occur due to lung fluid overload (pulmonary congestion).

“**A**” period: Pulmonary congestion in progress but there are no additional specific patient’s complaints.

“**B**” period: Quick deterioration. Dyspnea complains. HF hospitalization.

Goal: to diagnose deterioration at period **A** when lung fluid accumulation is small.
The lungs which lies within the chest cavity are the target organ for monitoring. Direct measurements of pulmonary congestion is impossible.
First attempts to monitor pulmonary congestion

Technologies mainly measured changes in Total Thoracic Fluid by measuring Total Thoracic Impedance (BioZ, ZOE, NICOM – Cheetach Medical, Nimedical).

Blood in aorta is a 10-fold better conductor than lung tissue. Therefore, such technologies mainly measure aortic impedance which makes possible calculation Cardiac Output but the signal from lung tissue is weak and is not enough sensitive to diagnose an "A“ Period of pulmonary congestion.


White line: distribution electromagnetic wave though aorta
Black line: distribution electromagnetic wave though thoracic cavity and lungs

Conclusion: Individual monitoring for HF hospitalizations is impossible for significant value overlapping.
Reason: Low sensitivity of the method for detection a degree of Pulmonary Congestion.
Pacemaker based technologies (by Medtronic and Biotronic Companies).

Ypenburg C et al. Intrathoracic Impedance Monitoring to Predict Decompensated Heart Failure. Am J Cardiol 2007 15;:554-7. Results for prediction of HF hospitalizations: sensitivity of 60% and specificity of 73%.


Conclusion: Pacemaker based Impedance devices are not sensitive enough to detect changes in lung fluid content. Why? Two reasons.

1. Results of work support the hypothesis that intrathoracic impedance actually measures local tissue characteristics rather than intervening lung water (Figure A).
2. An additional problem is a parallel distribution of electromagnetic energy (Figure B).
New generation of surface devices

Outside device has to measure a fluid content inside of the chest
KYMA. Innovative Body-Penetrating RF Technology (Radar Technology)

How does it Work?

1. μCor Antenna Emits RF Signals
2. Signals Propagate through Lungs
3. Signal Reflected from Heart Back to the Device

RF electromagnetic wave (2-3 GHz) is sent into the chest wall from a generator which is putting on the chest wall. Reflecting signal is collected and analyzed. Changes in signal path delay and strength are measured to indicate changes in fluid. **Harmless - Non-ionizing radiation with very low power** - 1/100 of a cell phone
KYMA studies

Comparison to Invasive Thermodilution

7 sheep Pilot study *(Presented at ESC meeting 2014)*. Correlation between Kyma’s RF Lung Water to Extra Vascular Lung Water (EVLW): \( R = 0.96 \)

GLP study in 15 sheep *(Presented at HFSA 2014)*. Correlation between Kyma’s score to EVLW: \( R = 0.87 \). Calculated Accuracy of RFLW: \( \sigma = 50-60\text{ml} \)

Now: Trial Design (Israel: Kaplan MC)

CHF patients (Ongoing, \( n > 30 \)) admitted with pulmonary edema secondary to Acute Decompensated HF. Thoracic fluid trends followed during dehydration process. Measurements were compared to an ADHF Index (Clinical assessment, Lung auscultation, Difficulty breathing)
Sensible Medical ReDS™ Technology

See-through-wall (Radar Technology. 3 GHz RF electromagnetic wave)

Original Technology

Adapted for Clinical Application

Military see-through-wall technology

SensiVest ReDS™ Technology

CE Marked & FDA Cleared (510k)
Pre-clinical: ReDS vs. CT - 0.9 Correlation

ReDS Guided Management Reduced the Number of Heart Failure Hospitalization Over 90 Days

Pre vs. ReDS: $P = 0.01$
Post vs. ReDS: $P = 0.037$
Cardiac decompensation leads to a gradual increase in respiratory effort which is reflected in chest wall dynamics.

The respiratory dynamics were measured non-invasively by 3 miniature motion sensors that were attached to HF patient's thorax and epigastrium during their hospitalization.

The measured respiratory signals were quantified and a new parameter, excessive effort index (EEI), was defined.
EEI at discharge VS respiratory rate at discharge as predictors for re-hospitalization within the first 30 days

- All patients who had an EEI less than 0.4 were not re-hospitalized during 30 days post hospital discharge
- This non invasive, simple to use and simple to understand technology allows to quantify dyspnea and to provide physicians with a tool for a better decision making before discharge

17 patients
NYHA=3-4
EF=25.3±7.8 [%]
BNP=1566 ±1182 [pg/ml]
Parametric Electrical Impedance (pEI™): A Novel Method that Accurately Identifies Early Hemodynamic Changes, Prior to Development of Pulmonary Congestion

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MAJOR RESULTS IN A Resistivity Changed Concomitantly with LVEDP

**GR1**

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**Resistivity vs LVEDP**

- r = -0.81787, p < .0001
- r = -0.80416, p < .0001
- r = -0.86698, p < .0001
- r = -0.91947, p < .0001
- r = -0.9412, p < .001
- r = -0.9572, p < .0001

SD ±0.06

**GR2**

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**Resistivity vs LVEDP**

- r = -0.97510, p < .0001
- r = -0.97536, p < .0001
- r = -0.93179, p < .0001
- r = -0.98369, p < .0001
- r = -0.87416, p = .0004
- r = -0.95, SD ±0.05
MAJOR RESULTS
Time Relationship of % Changes in the 3 Main Parameters

- Intrathoracic Blood Volume (ITBV)
- Extravascular Lung Water (EVLW)
1. Transverse distribution of electromagnetic field A – B.

2. Transthoracic Impedance A-B ($TTI_{AB}$) = Chest Wall Impedance 1 ($CWI_1$) + Lung Impedance ($LI$) + Chest Wall Impedance 2 ($CWI_2$)
Putting additional 2 electrodes on front and back side of the chest wall enables calculation of parasitic CWI₁ and CWI₂ and operate with “net” Lung Impedance. Sensitivity for detection small changes in Lung Fluid increases more than 25 times.
Usefulness of Lung Impedance (LI)-guided pre-emptive therapy to prevent pulmonary edema during ST-elevation myocardial infarction and to improve long-term outcomes (In ICCU)*

Results:

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<td>Days in hospital</td>
<td>5.5±2.7</td>
<td>7.9±5.4</td>
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<td>Number deaths in hospital</td>
<td>0</td>
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<td>Mortality within 6 years Follow Up</td>
<td>7.0%</td>
<td>19.7%</td>
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<td>New CHF development within 6 years FU</td>
<td>18.3%</td>
<td>37.3%</td>
<td>&lt;0.01</td>
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*Shochat M et al. Usefulness of lung impedance-guided pre-emptive therapy to prevent pulmonary edema during ST-elevation myocardial infarction and to improve long-term outcomes. Am J Cardiol 2012;110:190-6
Randomized Impedance HF trial. 256 CHF out hospital patients (1:1). Mean = 48 months Follow Up. Monitoring group was treated according Lung Impedance and Control group according clinical assessment.
Thank you