

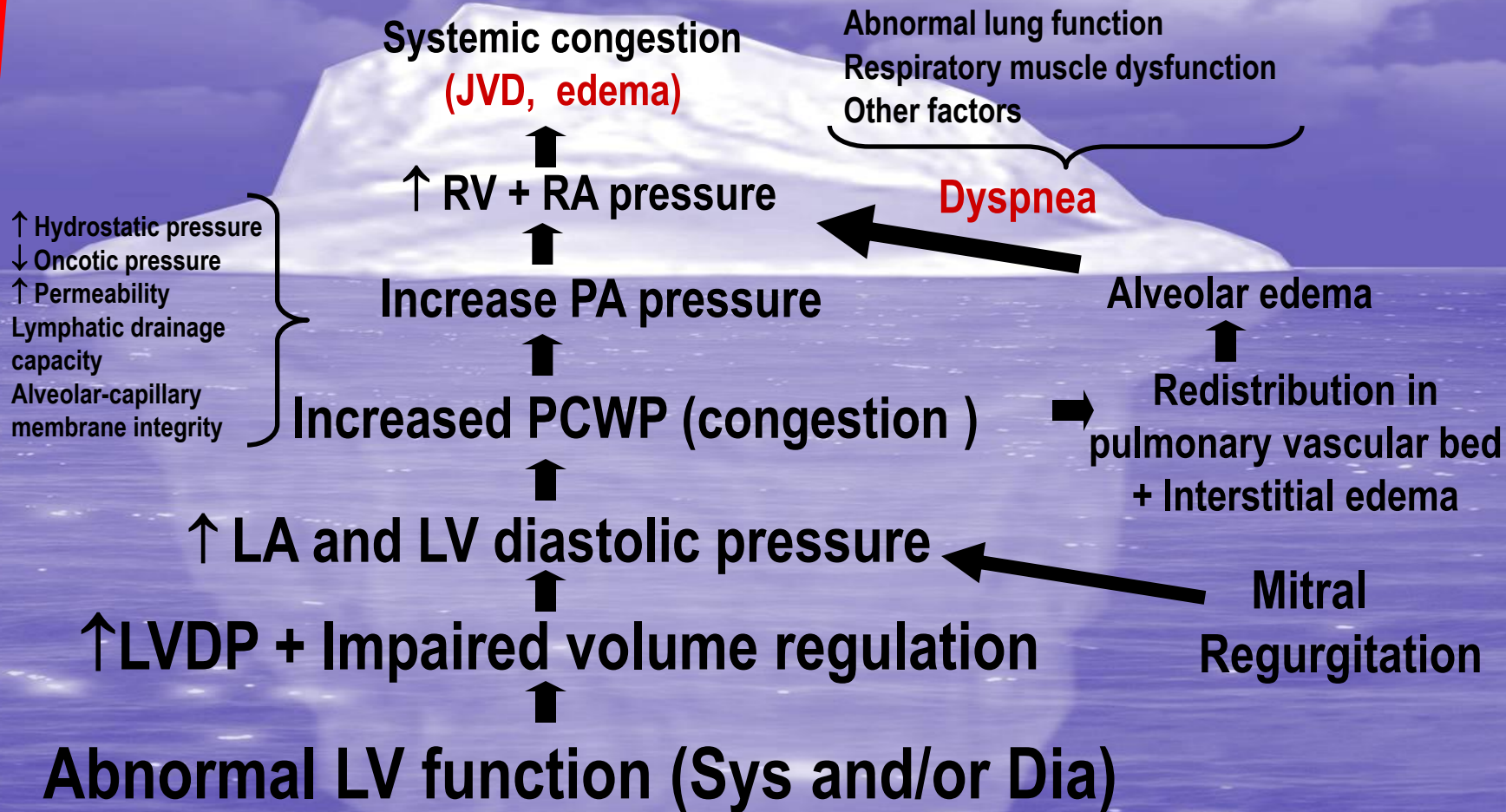


Heart Failure Management How to Monitor

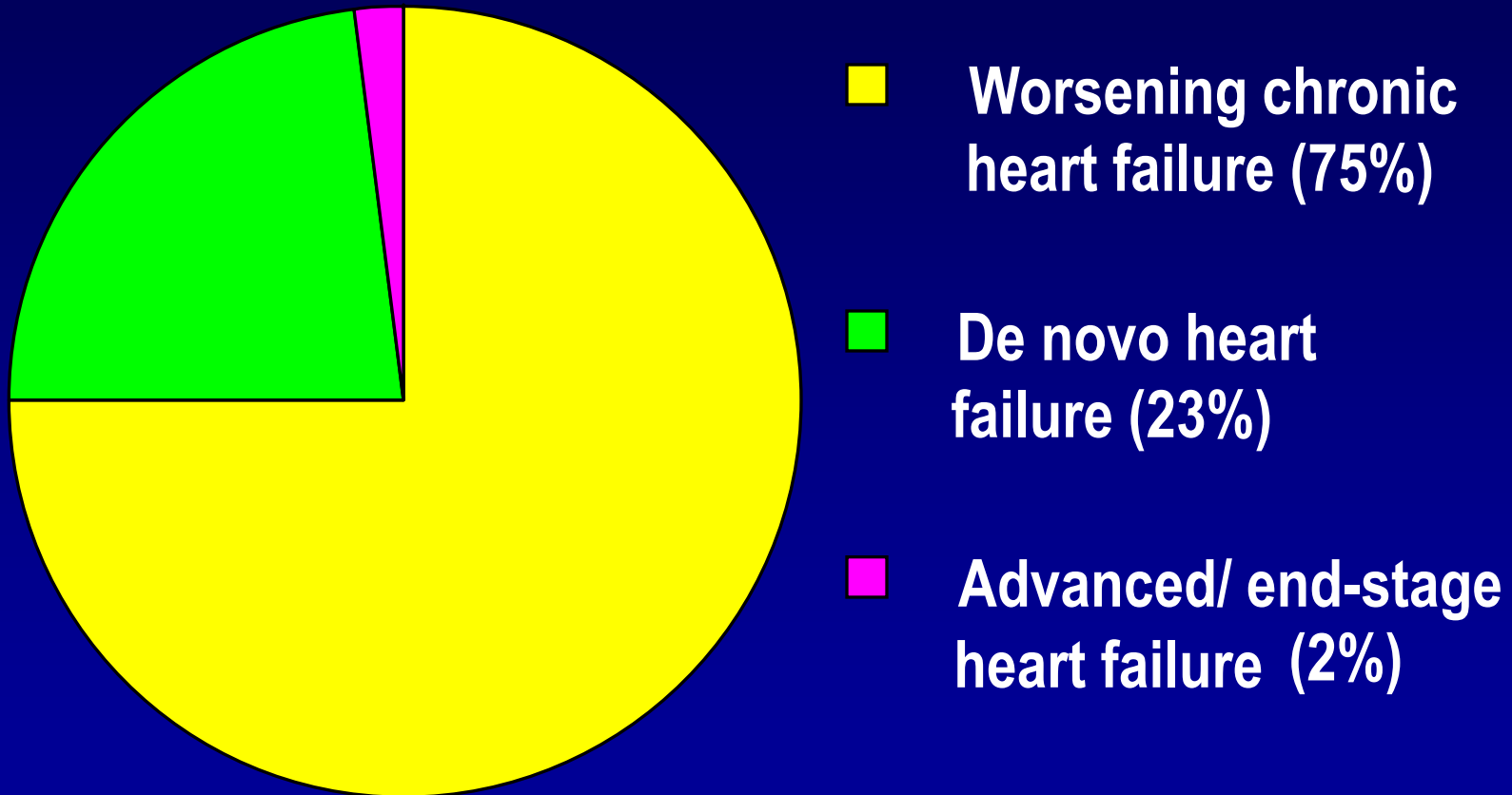
- **Prof. Mohan Nair**
- **Director**, Arrhythmia Services, Max Healthcare, India
- **President**, Indian Heart Rhythm Society

Symptoms: The Tip of the Congestion Iceberg in Heart Failure

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Worsening Chronic Heart Failure: The Major Reason for Heart Failure Hospitalizations



Clinical Need

Increased Congestion → HF progression
Increased Congestion → Increased Mortality
75 % of HF Hospitalizations → Congestion
HF Hospitalization → 1 year mortality – 33 %

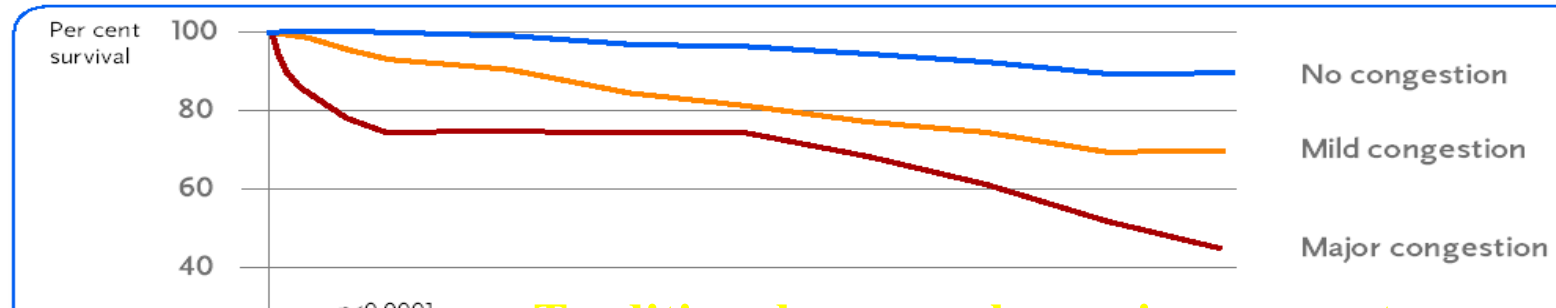
Predict Congestion Early

- Reduce hospitalizations
- Reduce mortality

Hemodynamic (high LVDP) congestion frequently develops several days or weeks before the onset of clinical symptoms and signs

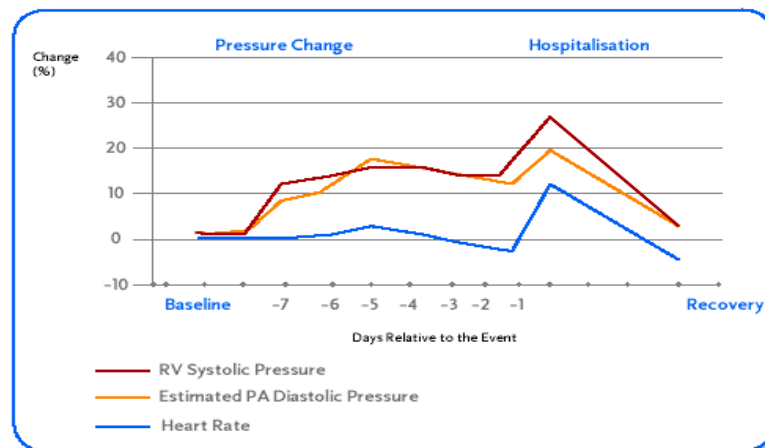
Clinical Need

Congestion significantly increases mortality¹

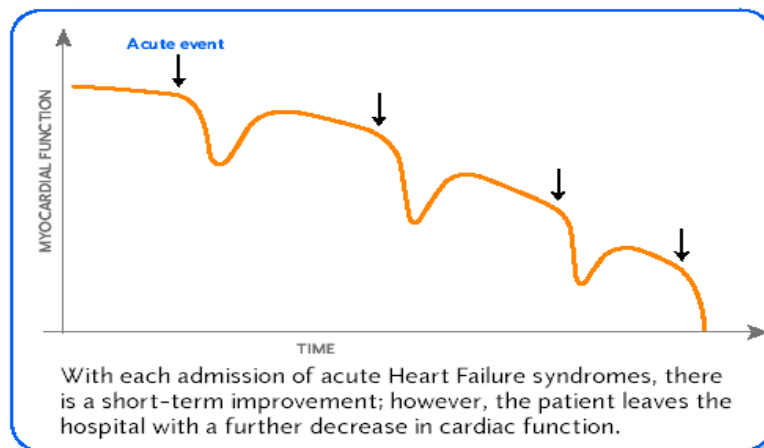


Traditional approaches – signs, symptoms, assessment of daily weights :have failed to improve hospitalization rates

Congestion leads to hospitalisations²

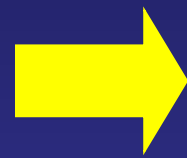


Staying out of hospital preserves cardiac function

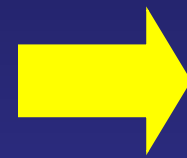




Worsening
Heart
Failure



Pulmonary
Congestion



Decreased
Intrathoracic
Electrical
Impedance



Impedance

Pulmonary Congestion

As fluid accumulates in the lungs, intrathoracic impedance decreases



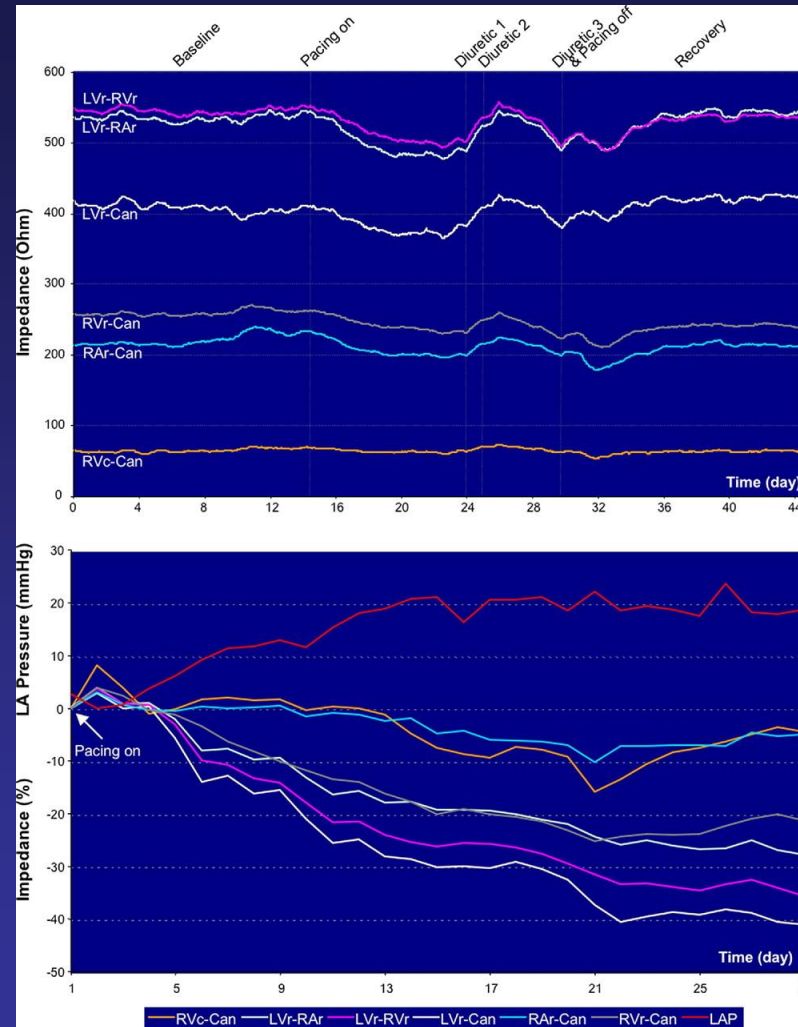
Impedance

Normal Lungs

As the lungs clear, intrathoracic impedance increases

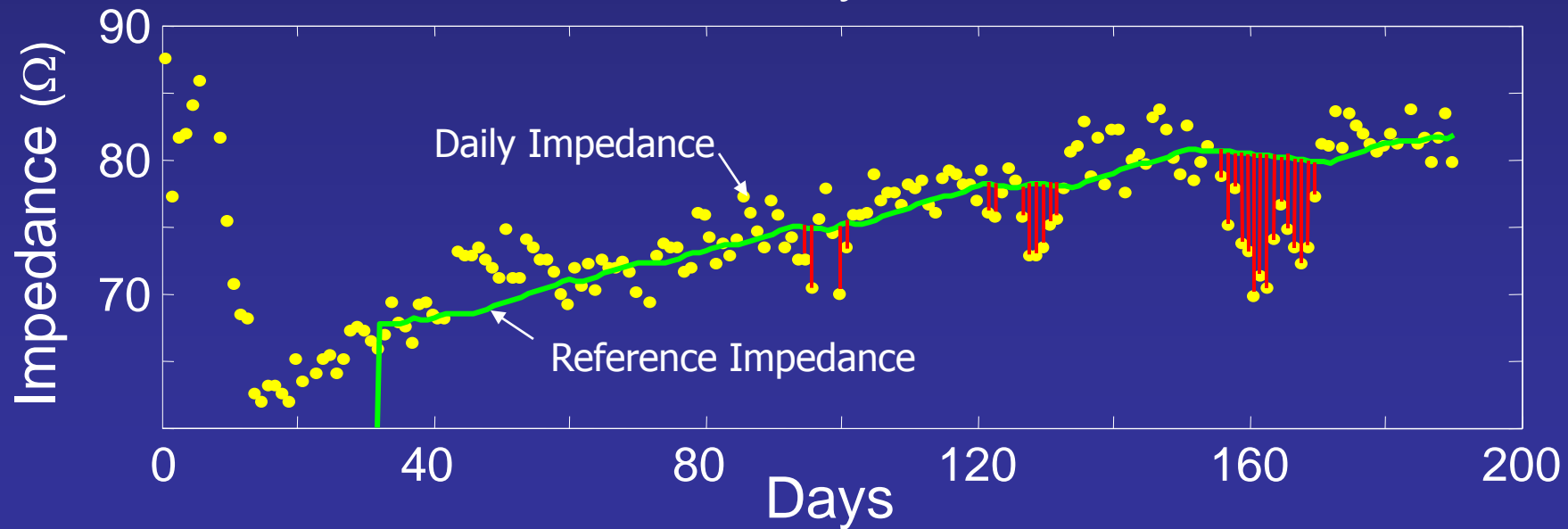
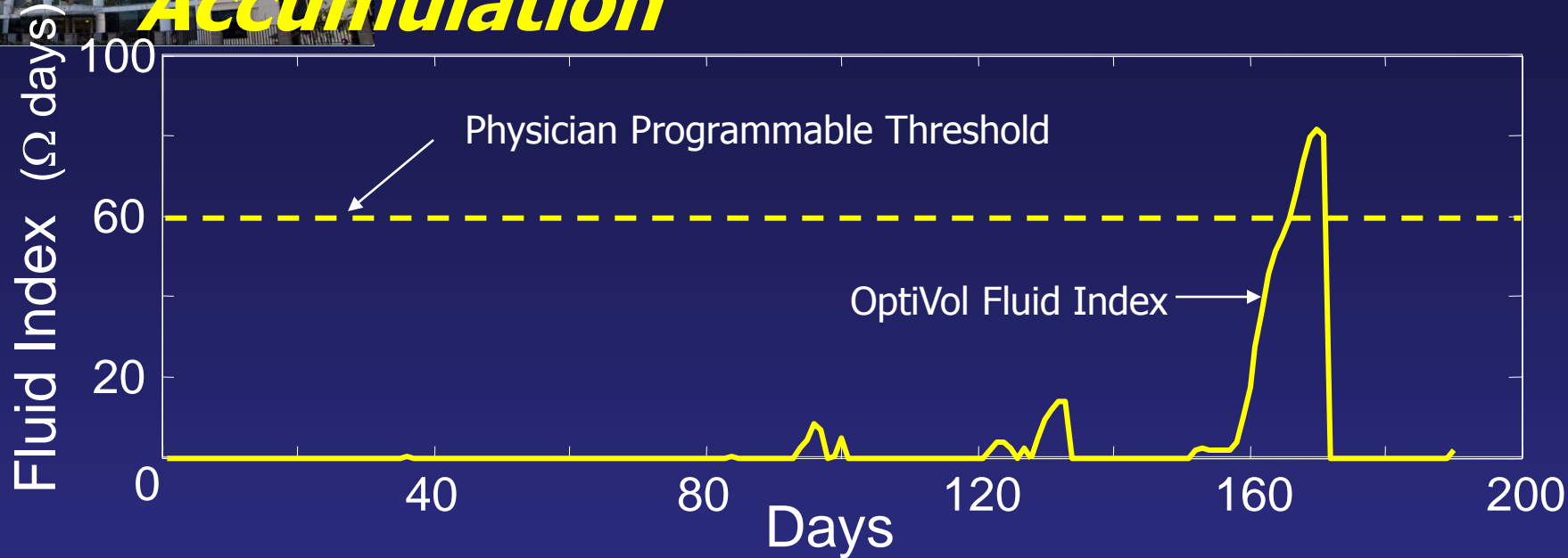


Impedance Trends at Different Stages of the Model



Khoury, D. S. et al. J Am Coll Cardiol 2009;53:1075-1081

Algorithm Developed to Track Fluid Accumulation



Technological Solution - Optivol

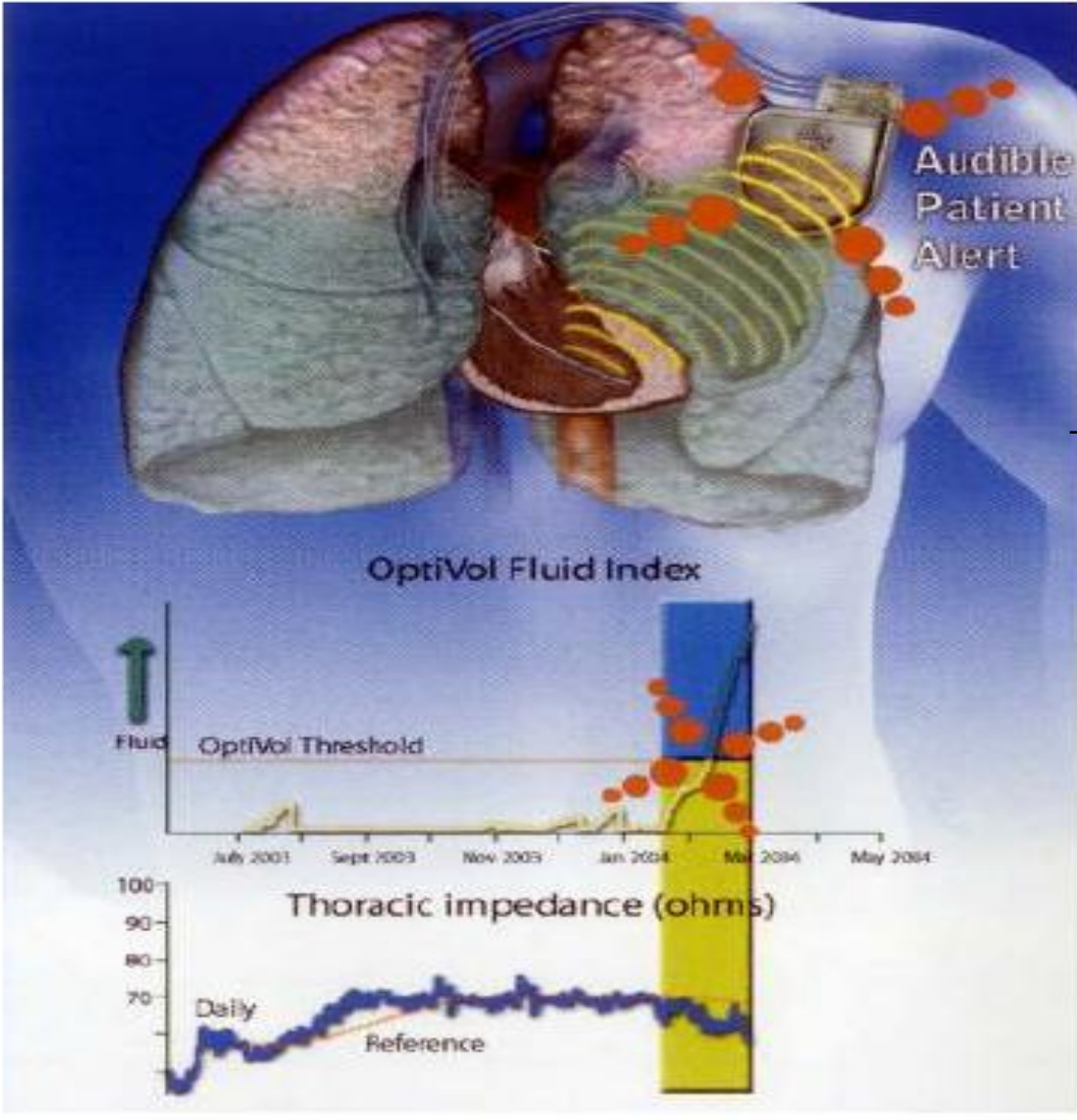


High Impedance

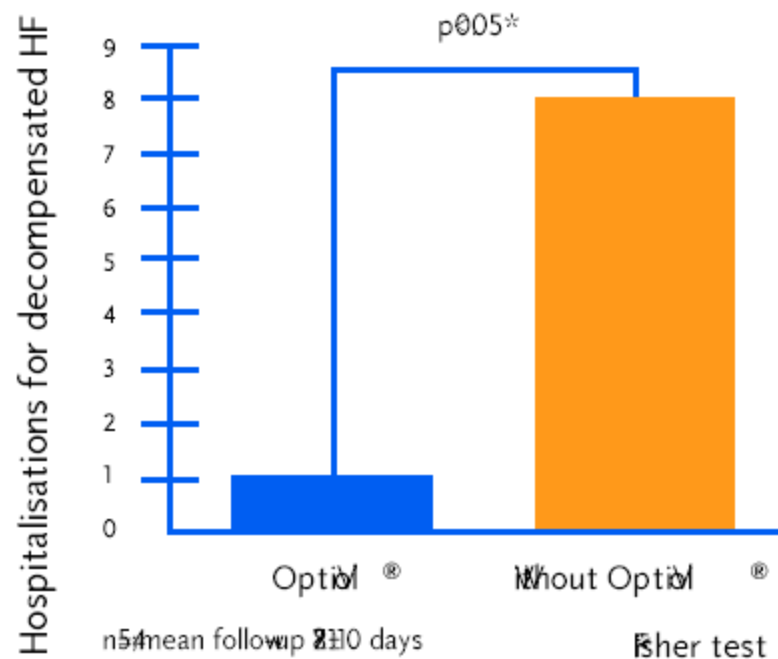
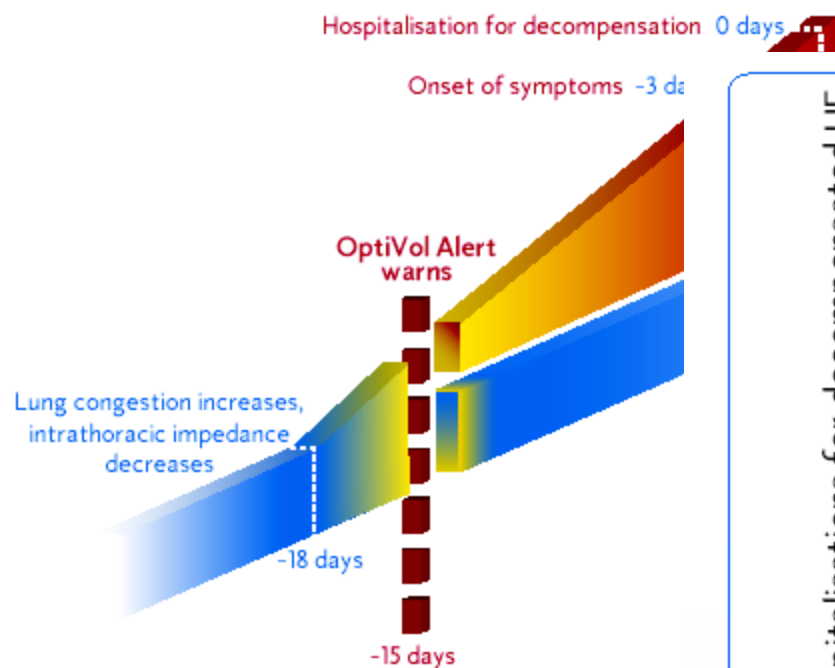
↑
Less Fluid

Low Impedance

↓
More Fluid



OptiVol Clinical Results



77 % sensitivity

75% alerts related to clinical events

1 Yu et al. Circulation 2005; 112:841-848

2 Maines et al. Heart Rhythm Society. 2006 Scientific Sessions; May 19, 2006; Boston, MA. Abstract AB48-4

3 Vollmann et al. Eur Heart J 2007; epub



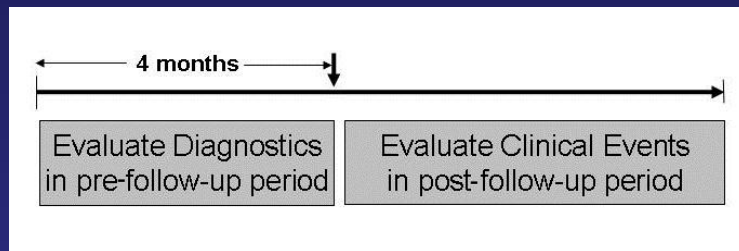
Journal of Cardiac Failure Vol. ■ No. ■ 2009

Changes in Intrathoracic Impedance are Associated with Subsequent Risk of Hospitalizations for Acute Decompensated Heart Failure: **Clinical Utility of Implanted Device Monitoring without a Patient Alert**

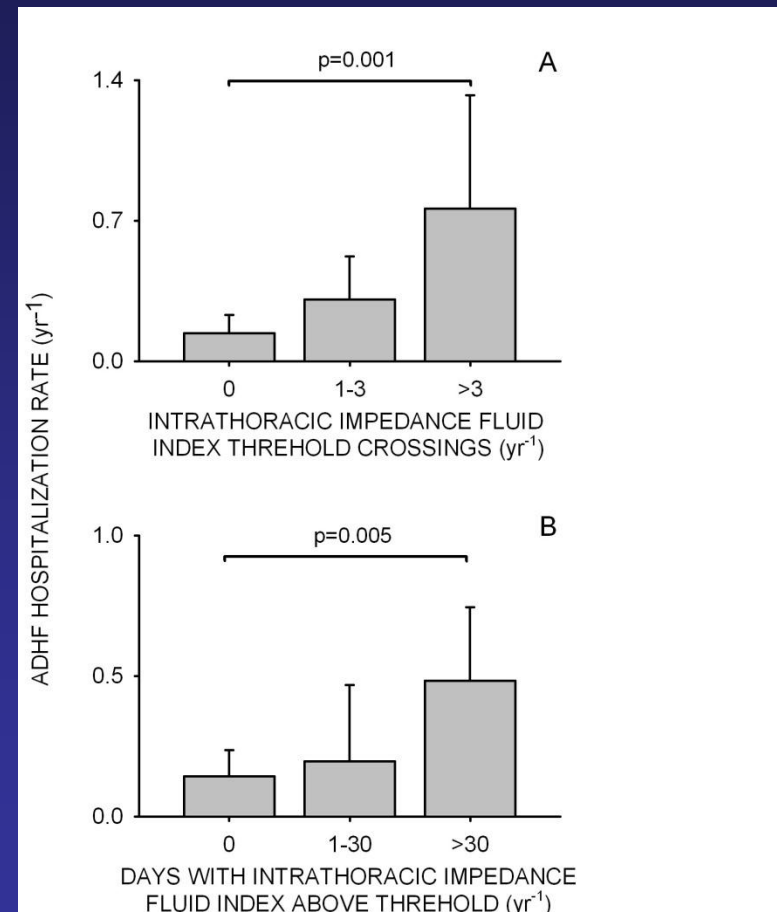
ROY S. SMALL, MD,¹ WILLIAM WICKEMEYER, MD,² ROBIN GERMANY, MD,³ BOBBI HOPPE, MD,⁴ JOHN ANDRULLI, DO,⁵
PETER A. BRADY, MD,⁶ MELODY LABEAU,⁷ JODI KOEHLER, MS,⁷ SHANTANU SARKAR, PhD,⁷
DOUGLAS A HETTRICK, PhD,⁷ AND W. H. WILSON TANG, MD, FAHA⁸

*Lancaster, Pennsylvania; Des Moines, Iowa; Oklahoma City, Oklahoma; St Paul, Minnesota; Camden, New Jersey; Rochester, Minnesota;
Minneapolis, Minnesota; Cleveland, Ohio*

Frequent or sustained OptiVol threshold crossings predicted significantly higher risk of HF hospitalizations. (OFISSER)

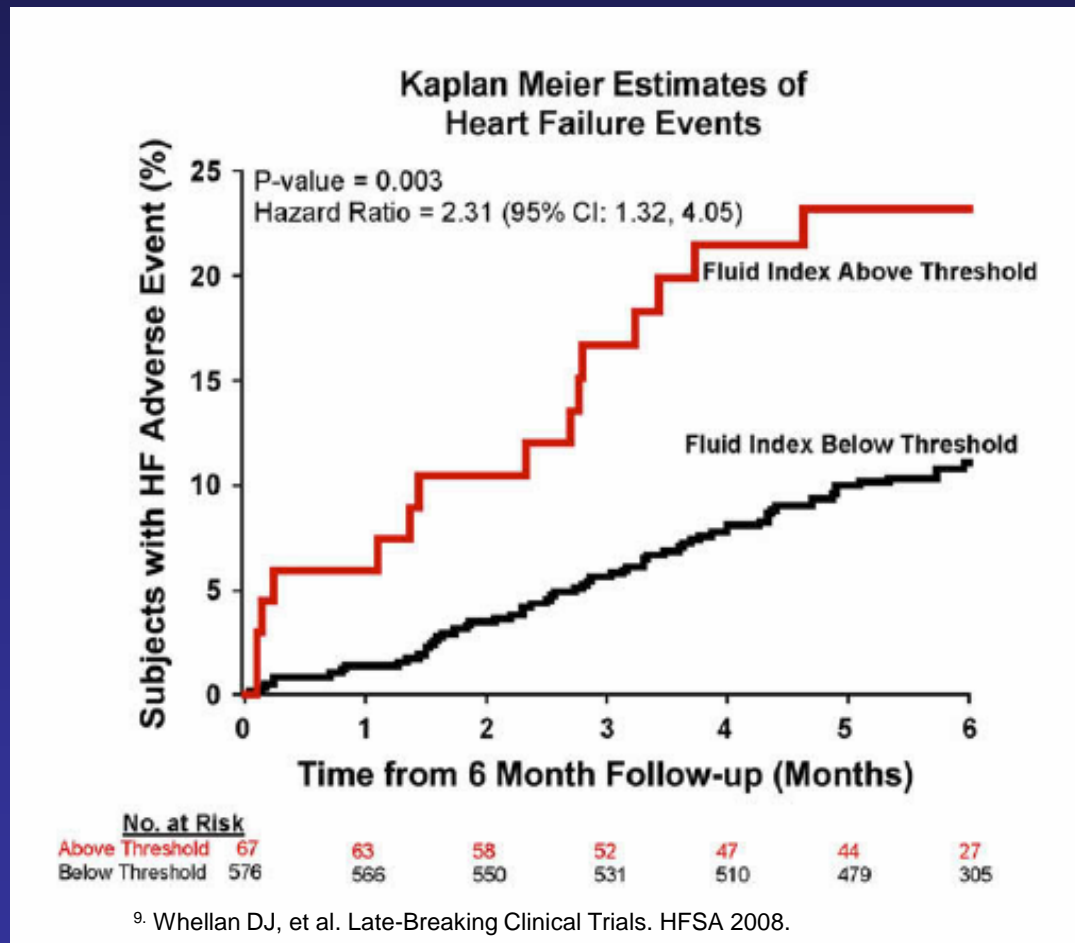


- Retrospective multicenter study
- 326 patients tracked over 1 year, pooled among seven clinics



⁸. Small R, et al. *J Card Fail*. In press.

Patients with an OptiVol Fluid Index above threshold were at significantly higher risk of an HF event. (PARTNERS-HF)



⁹. Whellan DJ, et al. Late-Breaking Clinical Trials. HFSA 2008.

Unadjusted Kaplan-Meier estimates



***Weights alone are good
enough***

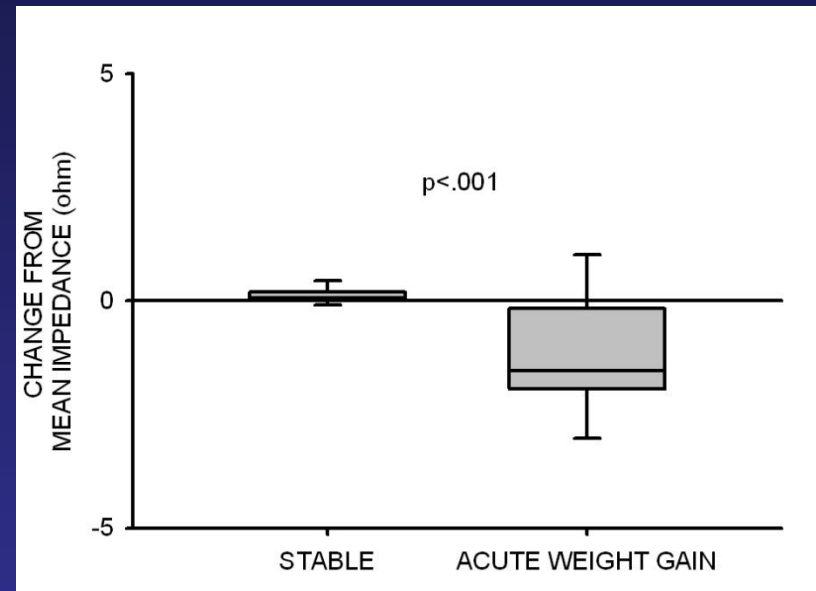
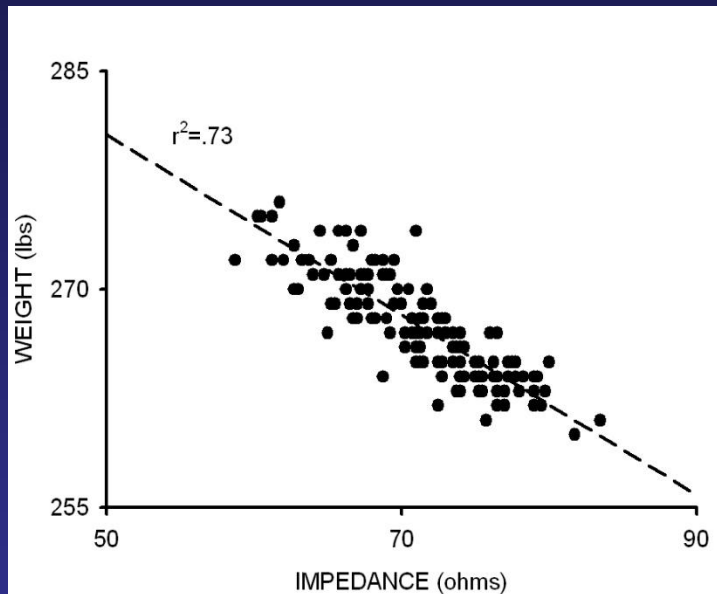


Weights alone are good enough

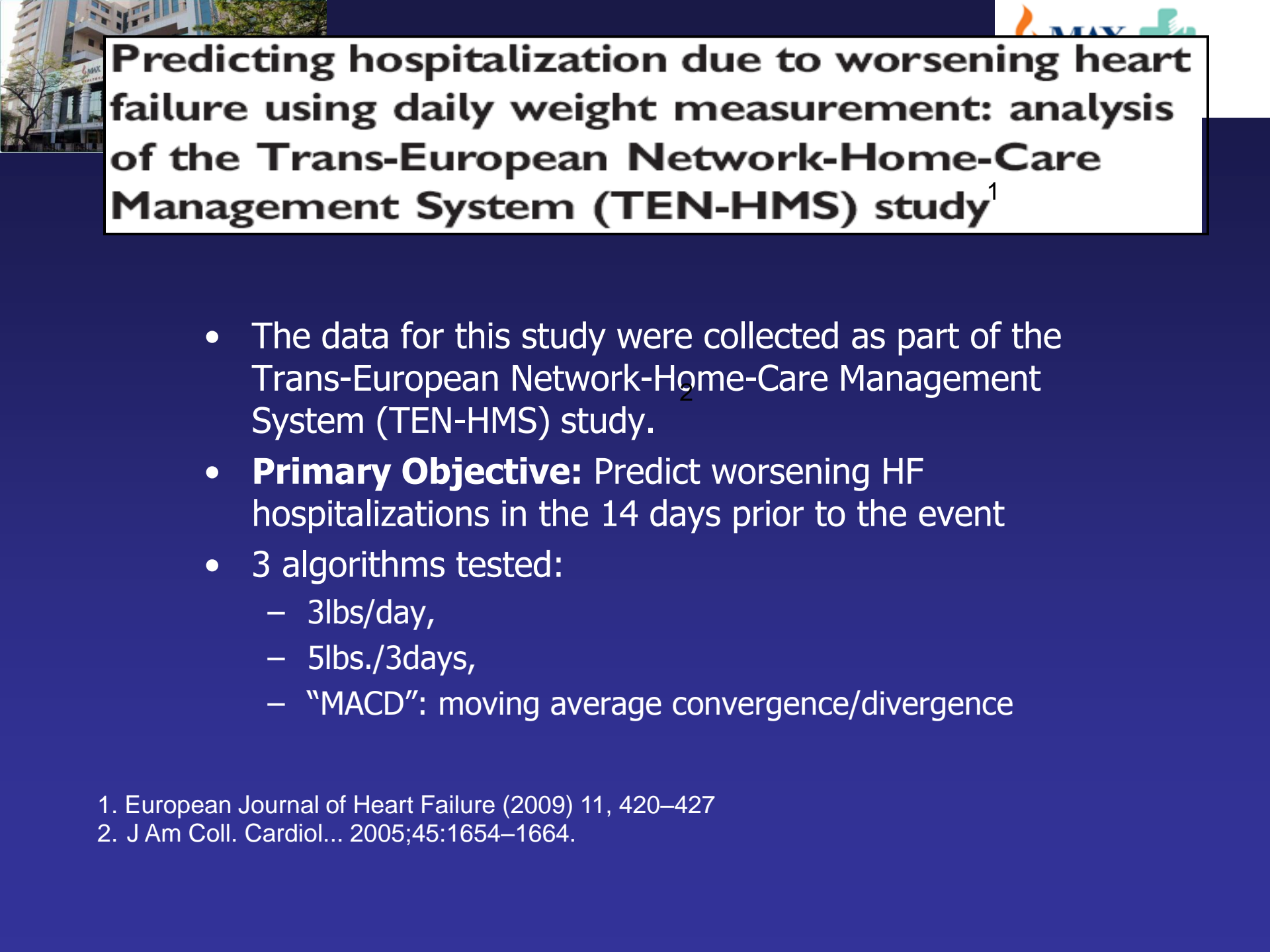
- Don't discount weight changes
- Its not about which is better; OptiVol and weights are **both** signs of worsening HF **and** compliment each other.

Weights alone are good enough

OptiVol and Weight: IMPEDE HF Study



- Weight and Impedance are inversely correlated
- Acute weight gains of 3 lbs are more w/in a week were associated with a significant drop in impedance.



Predicting hospitalization due to worsening heart failure using daily weight measurement: analysis of the Trans-European Network-Home-Care Management System (TEN-HMS) study¹

- The data for this study were collected as part of the Trans-European Network-Home-Care Management System (TEN-HMS) study.²
- **Primary Objective:** Predict worsening HF hospitalizations in the 14 days prior to the event
- 3 algorithms tested:
 - 3lbs/day,
 - 5lbs./3days,
 - “MACD”: moving average convergence/divergence

1. European Journal of Heart Failure (2009) 11, 420–427

2. J Am Coll. Cardiol... 2005;45:1654–1664.

Myth #5: **Weights alone are good enough**



**IF YOU TAKE ISSUE WITH OPTIVOL,
DON'T TELL US WEIGHTS ALONE
ARE BETTER!!**

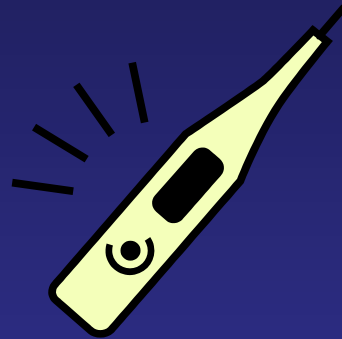


Figure 1 Example of a patient's weight measurement, symptom changes, and alerts produced by the moving average convergence divergence (MACD) and rule-of-thumb (RoT) algorithms prior to a hospitalization due to worsening heart failure (H).

- Only 20% of patients have weight gain in the period prior before a WHF hospitalization or episode of worsening HF.
- “Acute pulmonary edema can occur in the absence of weight gain”
- “Lack of weight gain does not exclude the presence of worsening HF”
- “It may be that weight alone is not sensitive or specific enough to detect episodes of worsening HF

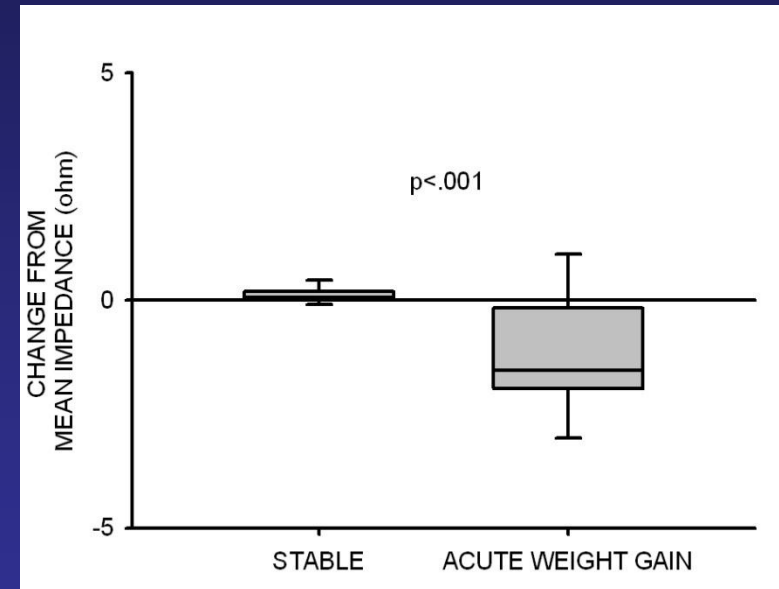
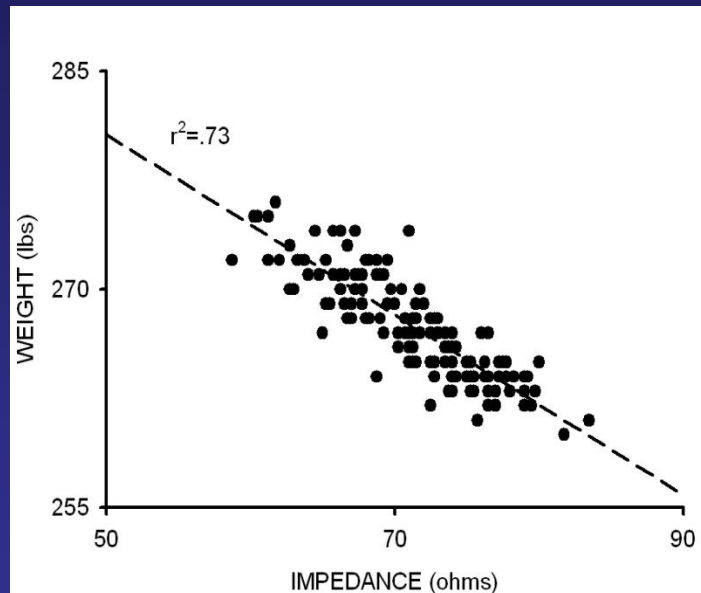


OptiVol versus Weight versus BNP



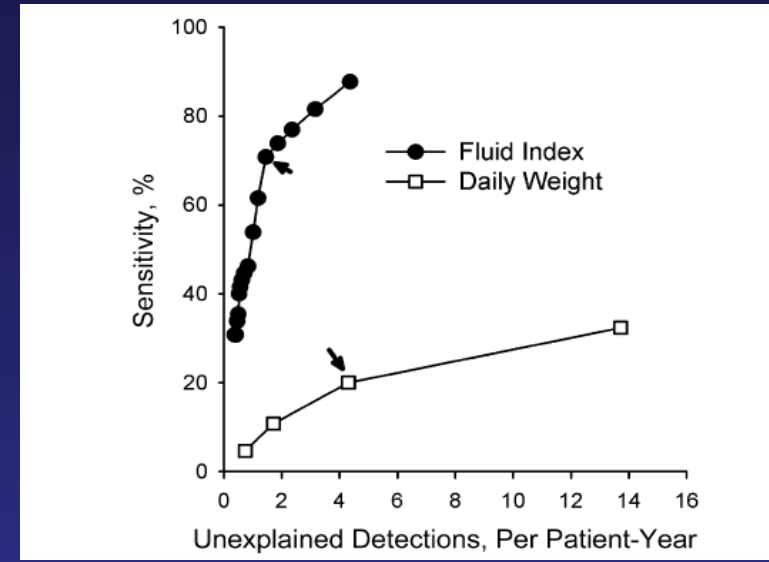
OptiVol and Weight:

IMPEDE HF Study





Accuracy of Fluid Index vs. Daily Weight measurement

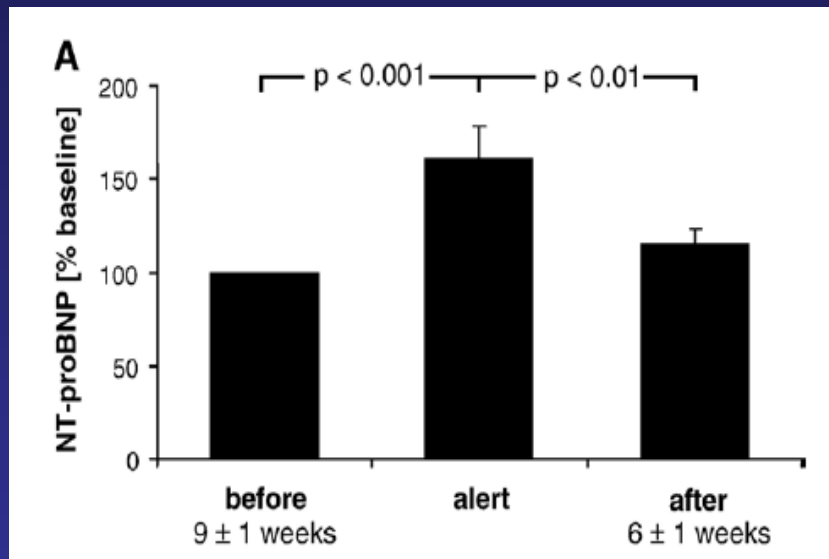


	FLUID INDEX ^a	WEIGHT ^b	P VALUE
Sensitivity, %	76.4 (60.8-87.1)	22.5 (12.5-37.1)	<.0001
Unexplained detection rate, per patient-year	1.9 (1.7-2.1)	4.3 (3.2-5.8)	<.0001

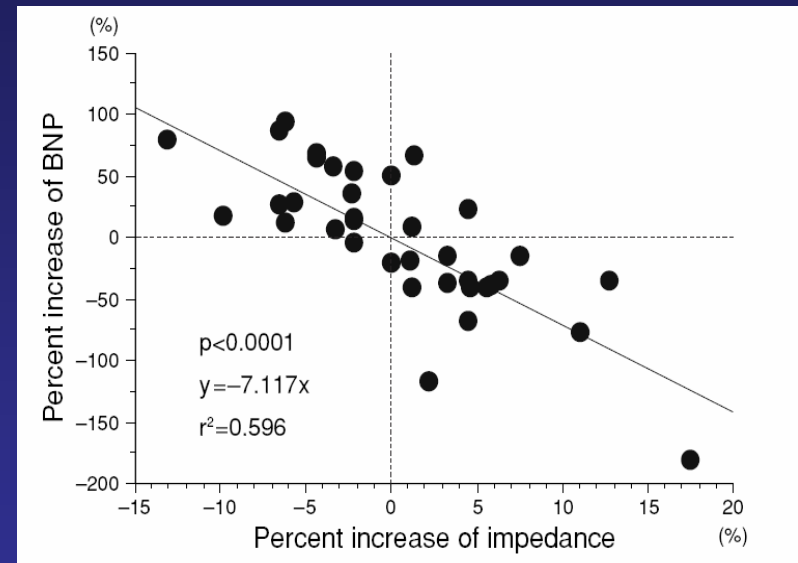


OptiVol and BNP

Association between Impedance and BNP



¹⁵. Lüthje L, et al. *Eur J Heart Fail.* 2007;9:716-722..

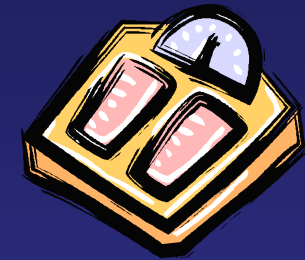


¹⁶. Matsushita K, et al. *Circ J.* 2006;70:1462-1465.



OptiVol versus Weight versus BNP

- It's NOT a contest



- BNP is a useful clinical tool
- **OptiVol is a useful clinical tool**
- Weight is a useful clinical tool