

Evolving Sensor Strategies & Remote Monitoring to Reduce Heart Failure Hospitalization

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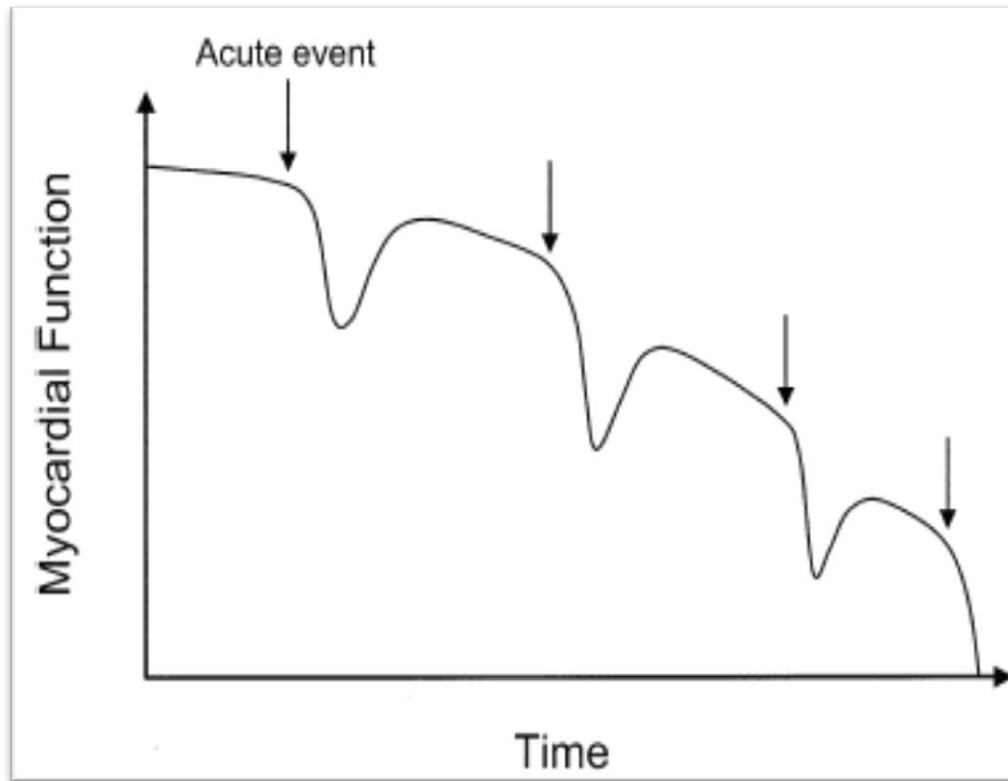
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Overview

- Background
- Sensors
 - » Simple & Sophisticated
 - » Need for Device-integrated approach
- Clinical impact of Remote Monitoring on HF
 - » Outcomes
 - » Monitoring HF progression



The Goal: Stabilize Disease Progression

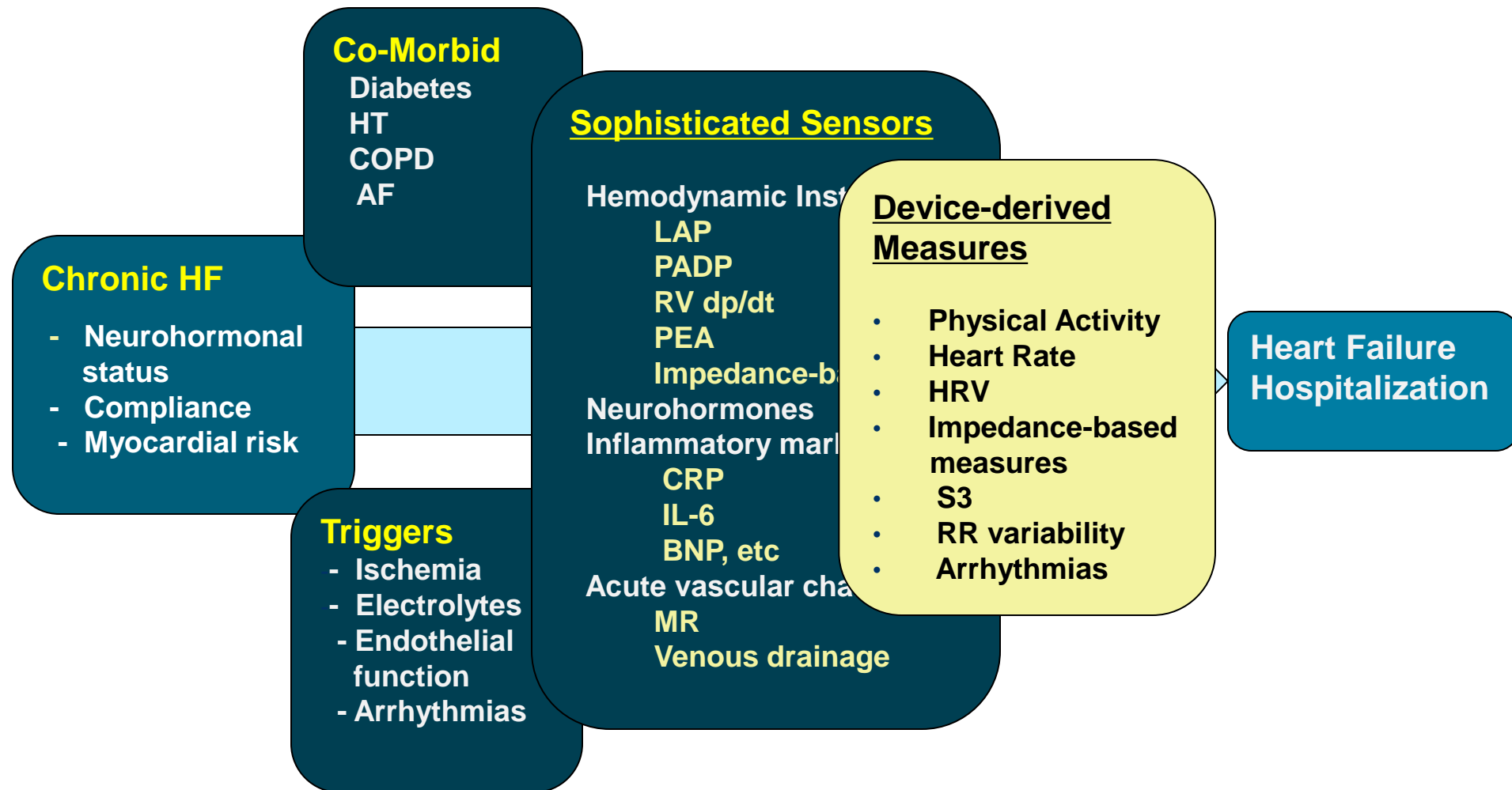


- Cumulative effect of recurrent acute heart failure events leads to progressive decline in cardiac function
- Sensor strategies and timely intervention may help

Device Based Heart Failure Management

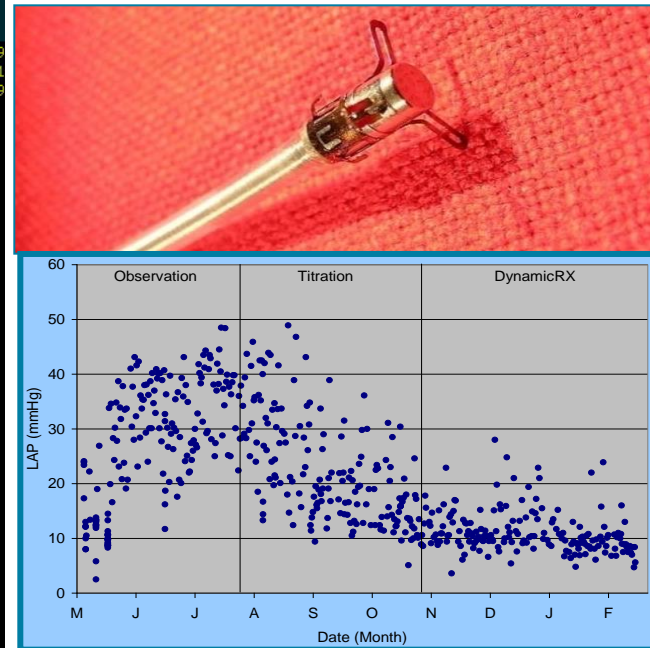
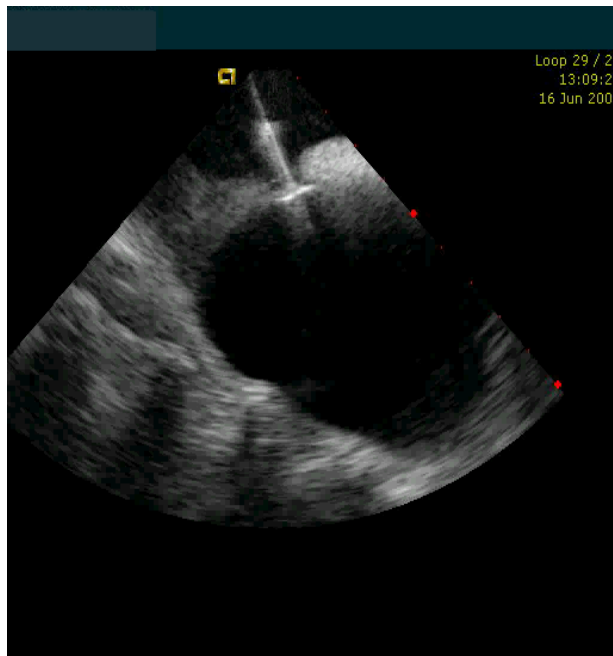
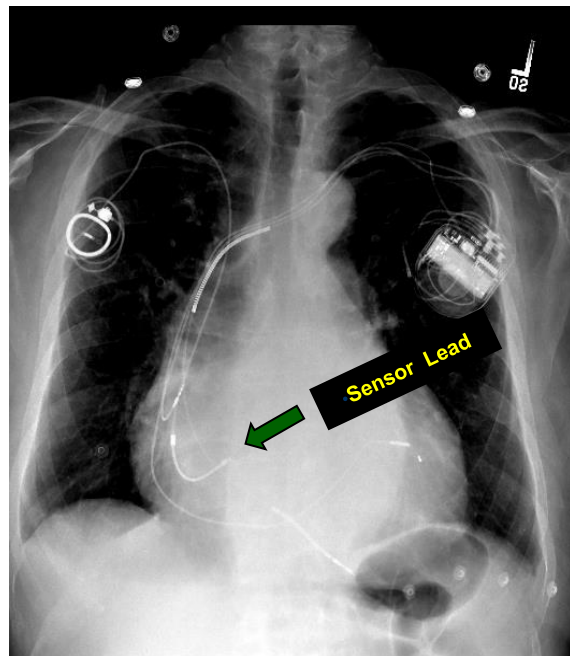
- Simple Sensors
 - Heart rate and derivatives
 - Accelerometers
 - Impedance-based
 - S3
 - Respiratory
- Sophisticated Sensors
 - Pressure: left atrial pressure, pulmonary artery pressure, RV dP/dt, etc.
 - Heart Sound: PEA
 - C Output: Doppler
 - Chemicals: PO₂, PCO₂, pH, electrolytes and glucose
 - Biomarkers: TNF, BNP, etc.

Putting it all together: Sensing & Intervening



Left Atrial Pressure Sensor Device

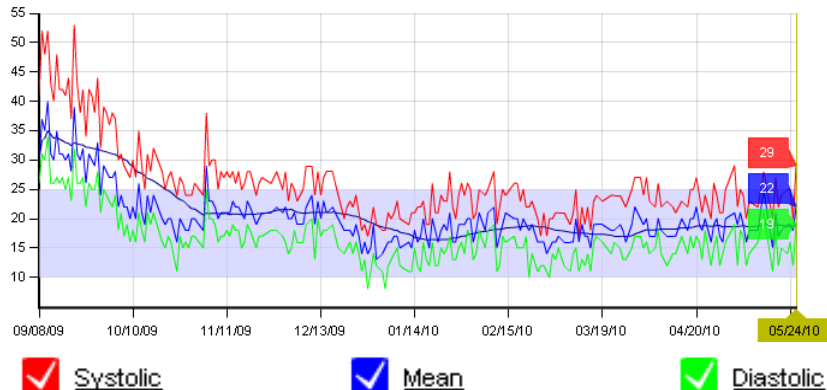
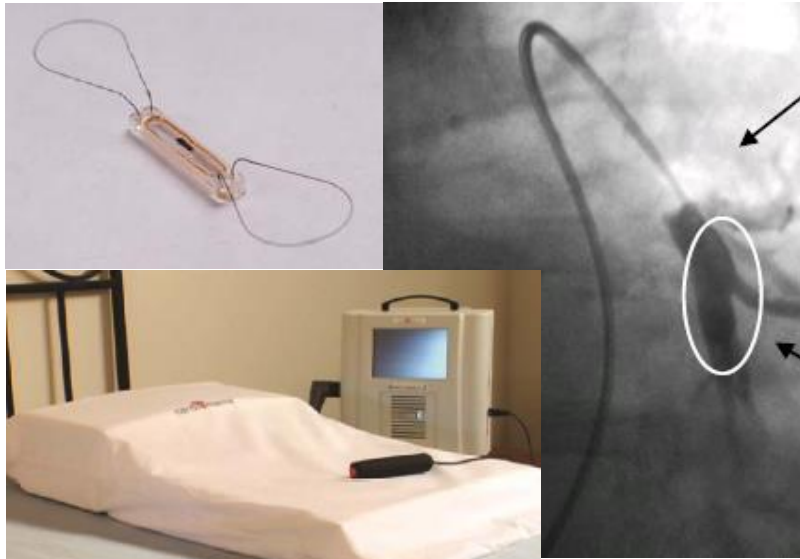
Futility leads to termination of trial



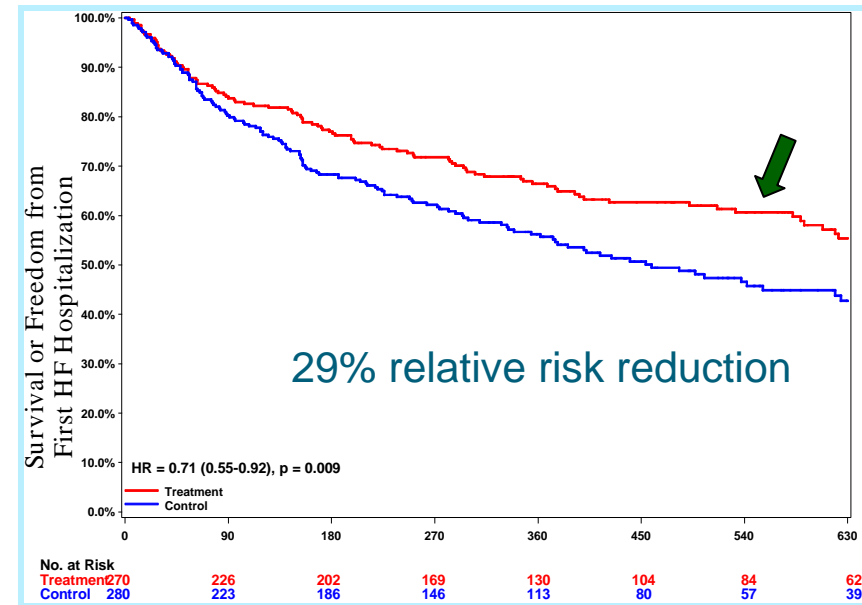
- Homeostasis Study: Safety & Efficacy
- LAPTOP-HF Study (Early termination)- Results at HFSA 2016
- Beat-to-beat hemodynamic assessment
- Engaging the patient: 3 phases
 - Observation, Titration & Dynamic Rx.

Pulmonary Artery Pressure Monitoring

Stand Alone Sensor



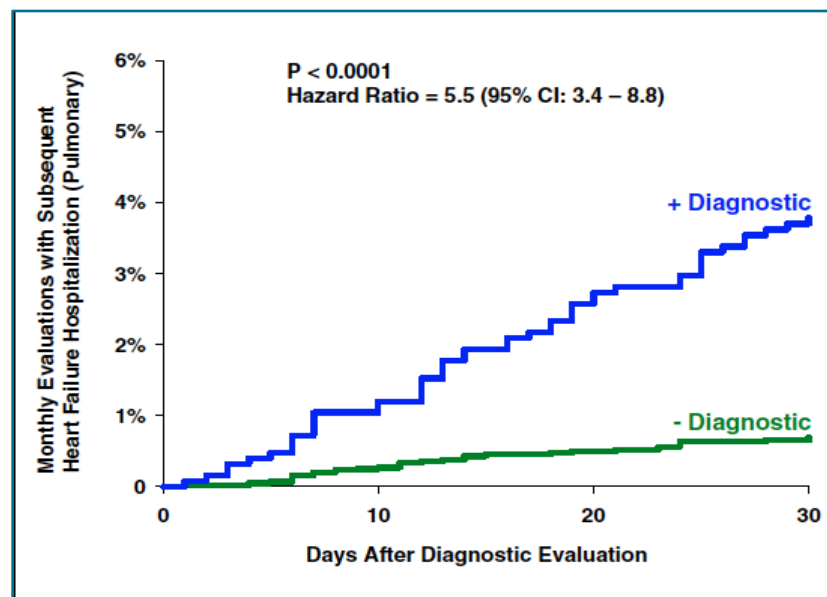
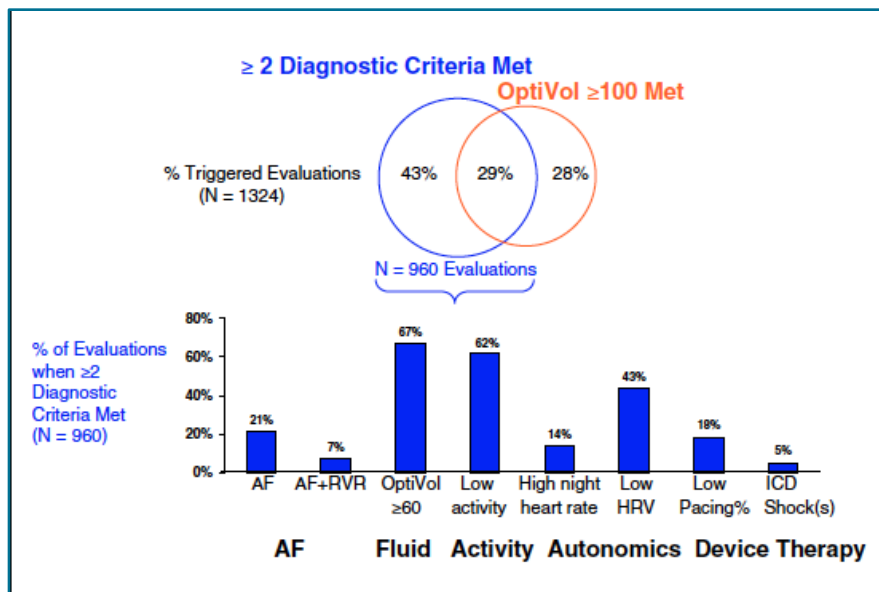
- Catheter-based delivery system
- Implanted PA branch diameter 7-15 mm
- Target range (mmHg):
 - PA systolic: 15-35
 - PA diastolic: 8-20
 - PA mean: 10-25



Champion Study, Lancet 2010

Device-integrated Sensors:

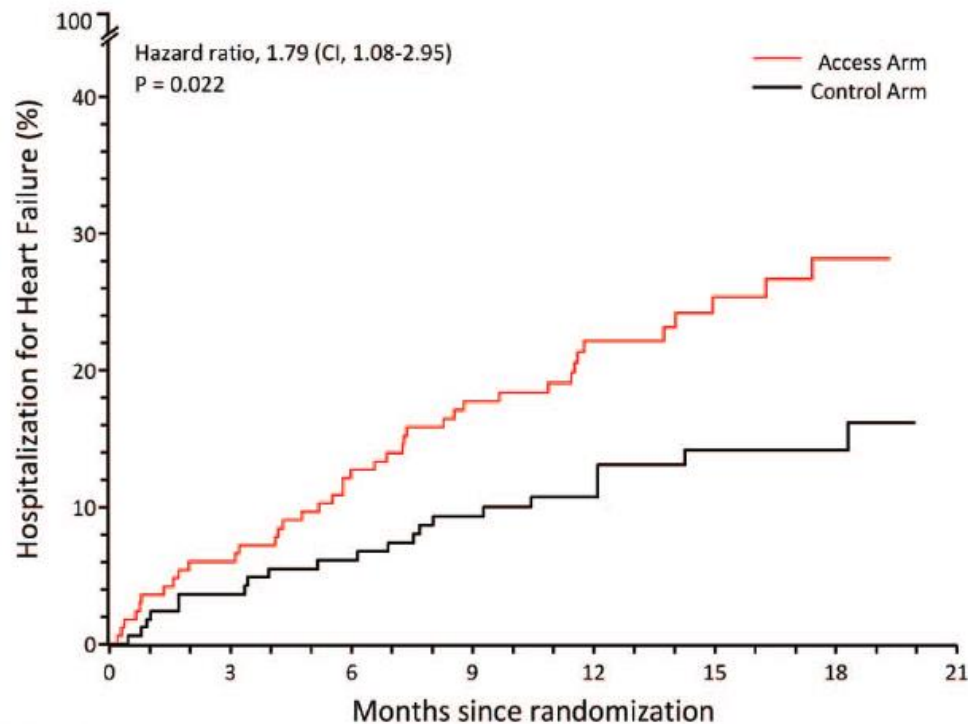
Prognosticating Failure Hospitalizations



- PARTNERS-HF
- 694 CRT patients followed up for 1 year
- 141 HF hospitalizations
- Device diagnostic criteria when positive, were associated with a 5.5 fold increased risk for HF hospitalization

We still need to learn to use the data.....

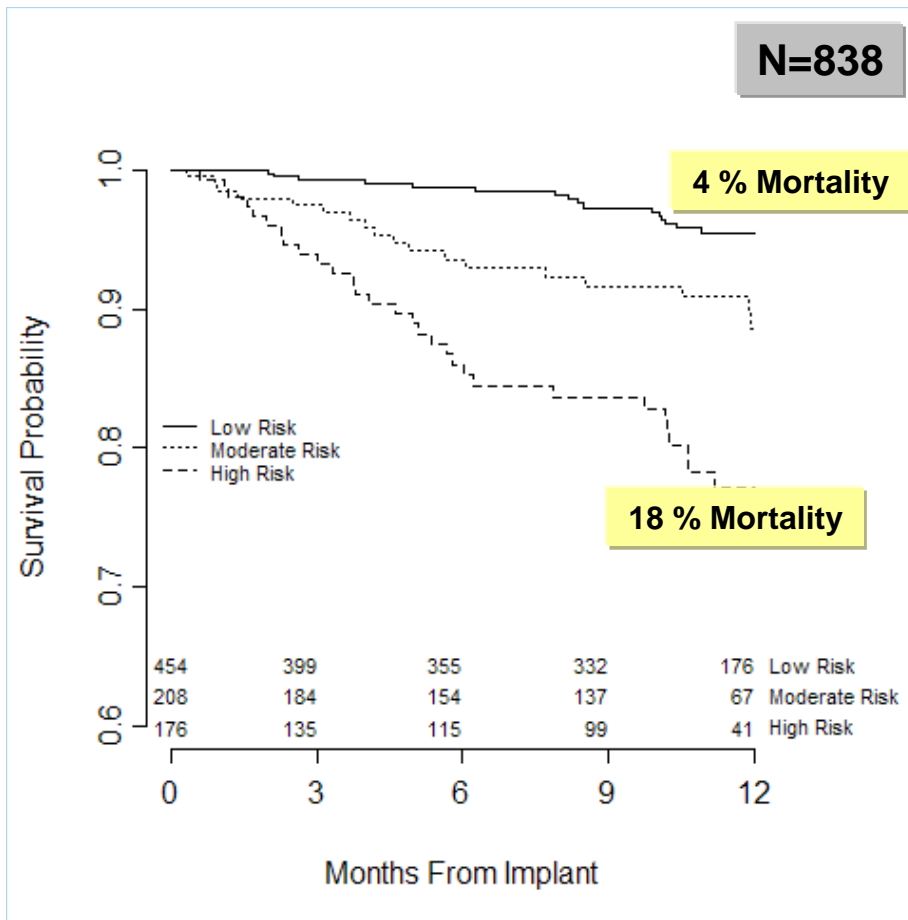
DOT-HF Study: Proactive intervention with Audible Impedance Alerts



- 335 patients randomized to OptiVol information with audible alerts
- Heart Failure hospitalizations near 2-fold higher in the Access arm versus control arm
- 3-fold increase in outpatient visits
- Role of Impedance measures questionable?

Tiered Risk Stratification

Using Device-based Simple Sensors



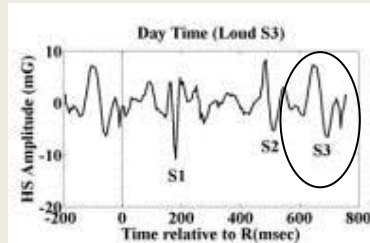
- **Clinical risk score**
 - **Contak-Renewal Study & HF-HRV Study**
 - Variables extracted from device were dichotomized with score of 1 for:
 - SDANN <43
 - mean HR >74
 - Footprint < 29
 - Physical activity % <5.
 - Total score= sum of dichotomized variables
 - Low (1)
 - Moderate: 2-3
 - High: 4

Further Refinement in Sensor Strategies

MultiSENSE Study (HeartLogic™)

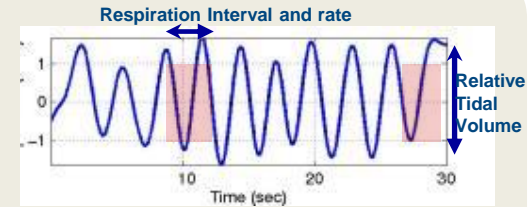
Heart Sounds

Signs of elevated filling pressure (S3)



Respiration

Rapid breathing and reduced tidal volume – shortness of breath



Thoracic Impedance

Fluid accumulation and pulmonary edema



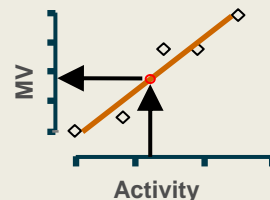
Posture

Increased night elevation angle as indicator of Orthopnea or PND



Activity Response

Physiologic changes as a result of activity – such as signs of dyspnea on exertion



Heart Rate and Arrhythmias

Heart rates as indicator of cardiac status; atrial arrhythmias related to HF status



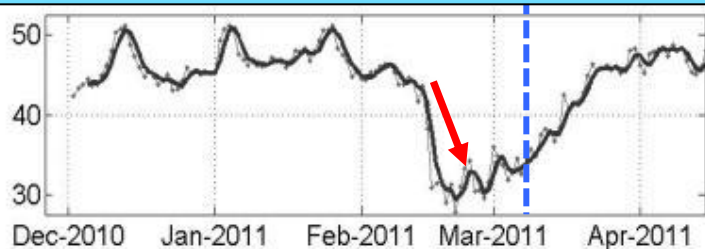
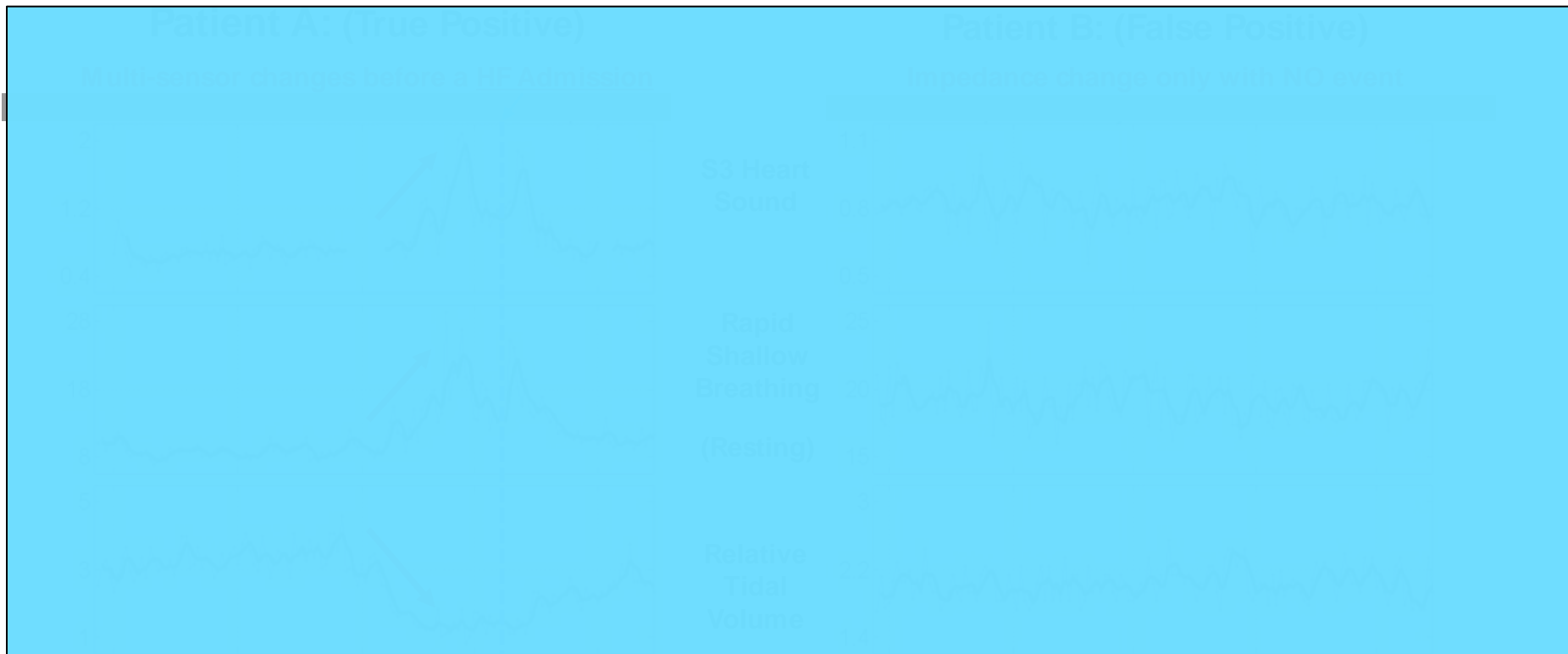
GOAL: Create a high performing composite indicator of worsening heart failure status



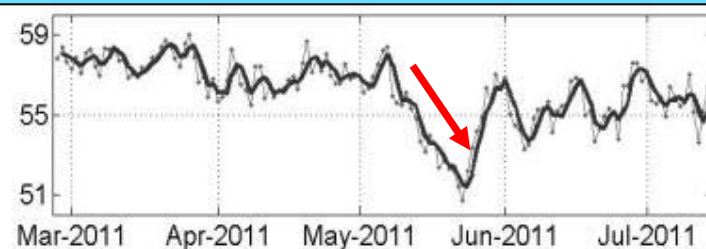
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The Multiple Sensor Approach

Appropriate Identification of the HF patient



**Thoracic
Impedance**
(RV-Can)

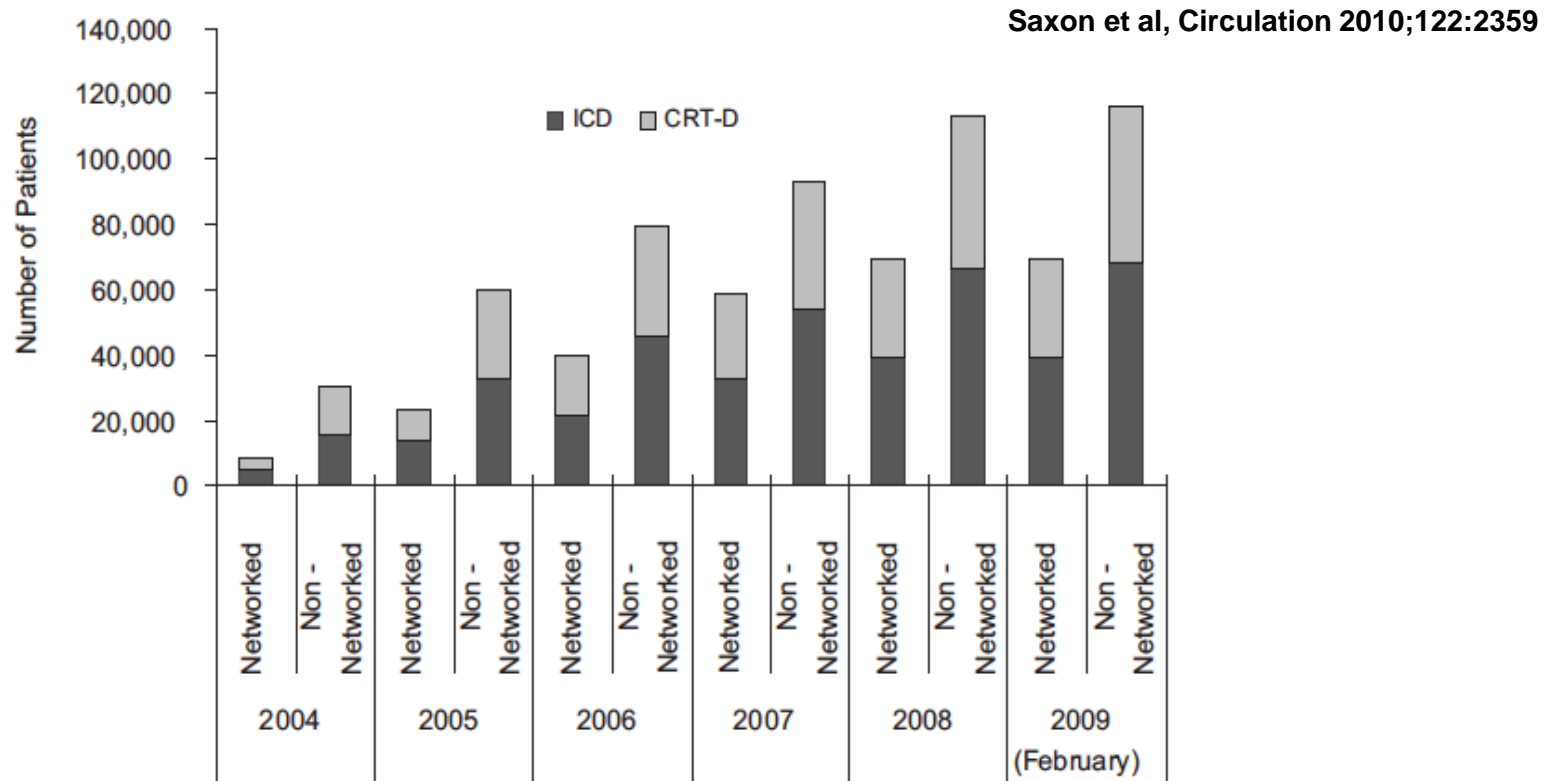


Goal for Multisensor data to be combined into a single alert
Rapid Shallow Breathing = Respiratory Rate/Tidal Volume



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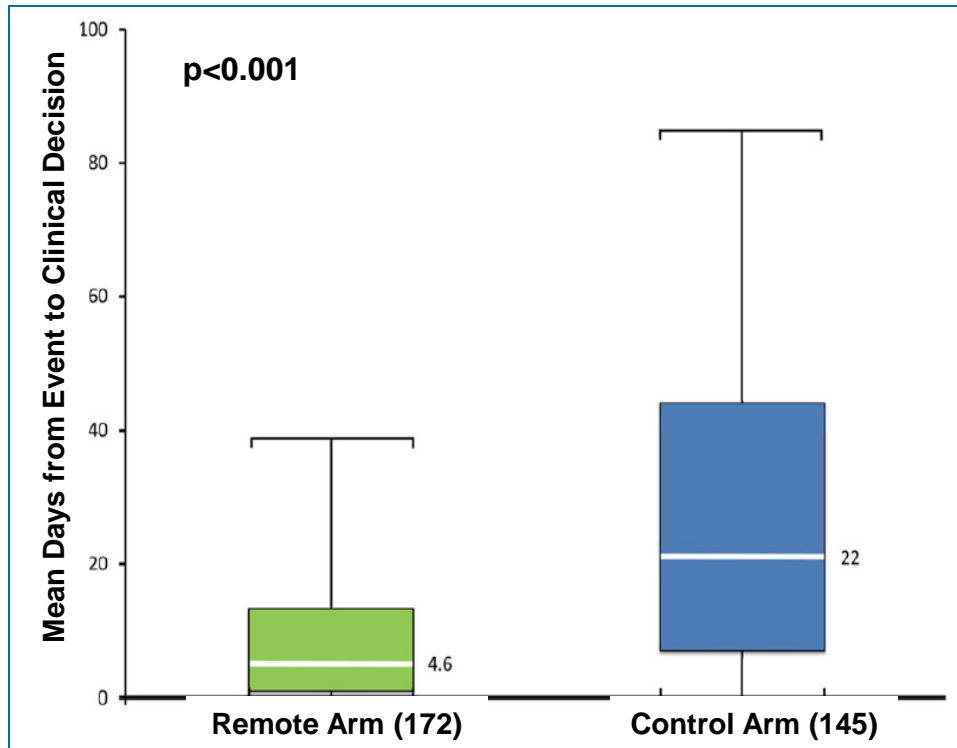
Is There a Need for Remote Monitoring?



- Implantation of cardiac electronic devices has substantially increased
- Subsequent monitoring is an integral part of device & patient care
 - Device & patient variables, disease data
- Significant clinical workload
 - Further enhanced around advisories, recalls, ERI etc.

CONNECT Trial

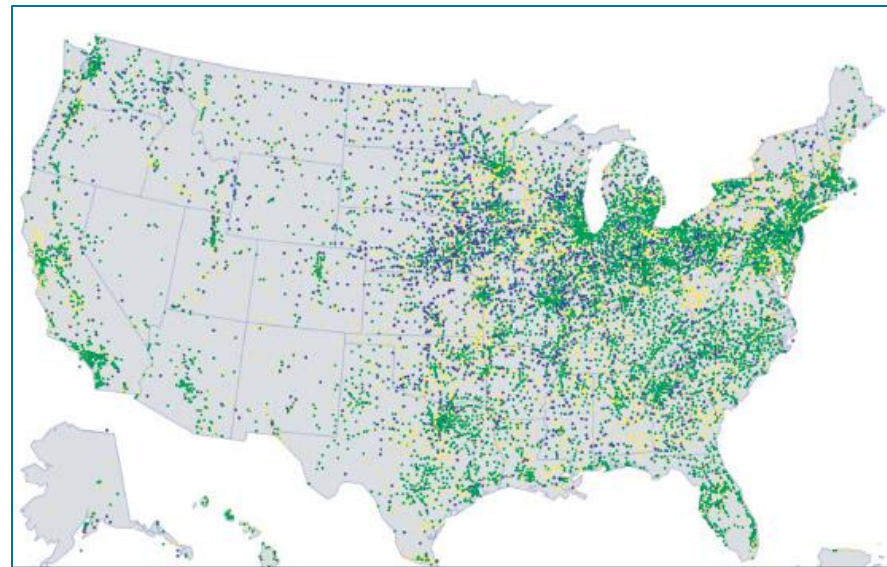
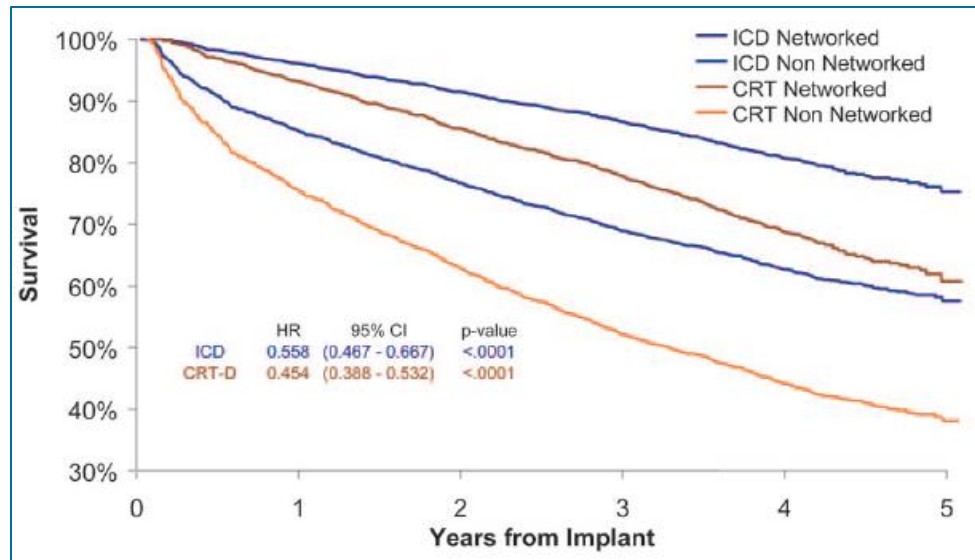
Reducing Time to Clinical Decisions & Health Care Utilization



- RCT
- 1997 patients with ICD / CRT
- In-office vs. remote follow up with automatic alerts
- 15 month follow up
- Noteworthy Results
 - Clinical time from event to clinical decision was 22 vs. 4.6 days
 - Reduction in mean length of stay per CV hospitalization (4 vs. 3.3 days)
 - Savings of \$1800 / hospitalization

ALTITUDE Study

Does Remote Follow up Influence Hard Endpoints?

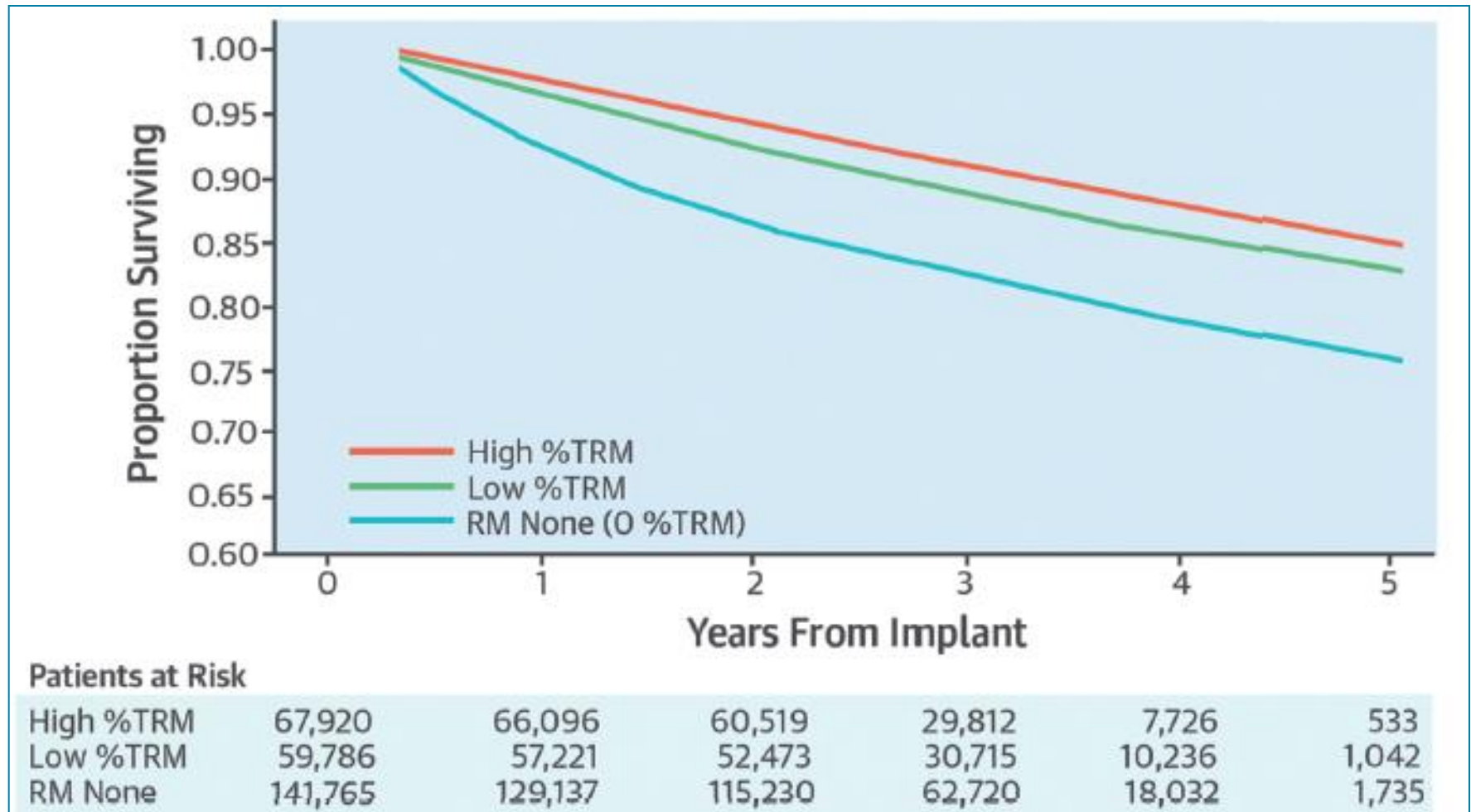


- Significantly increased survival in remotely monitored group by nearly 50%
- Reasons:
 - Earlier notification and intervention
 - Engaged and motivated patients

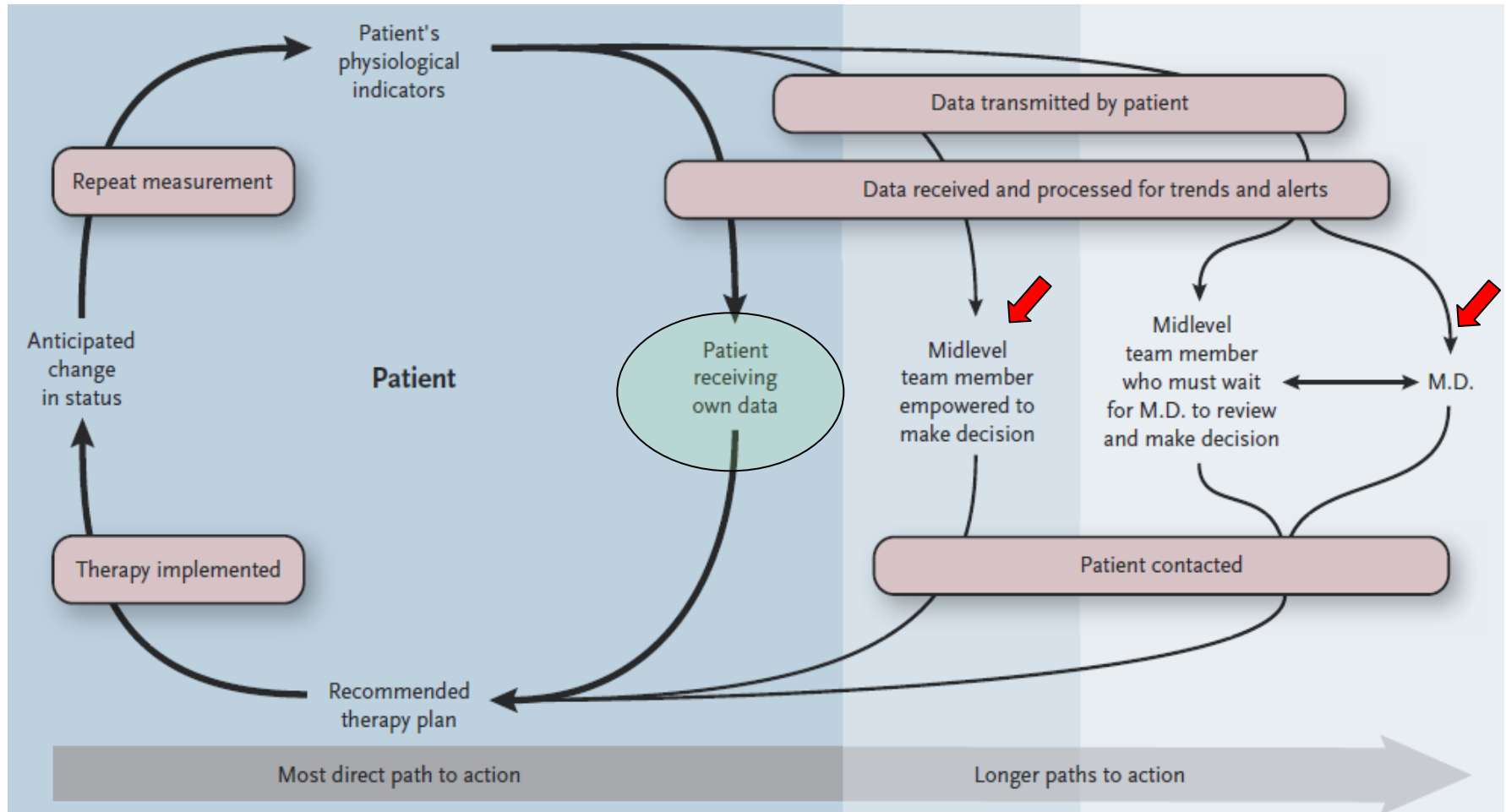
- 194,000 patients on Boston Scientific Latitude system
- 69,556 on network versus 124,450 with conventional clinic follow up, non-randomized
- Remote transmissions
 - 3-4 times / month
 - Additional clinic visits 2/year

Extent of Remote Monitoring & Survival

Graded Impact on Outcome (n= 269,471)



Changing Paradigm within Remote Monitoring



Adapted from AS Desai and LW Stevenson, NEJM 2010; 363: 2364-2367



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Summary

- Where are we now?
 - Paradigm shift in management of Implantable devices
 - Continuous monitoring permits enhanced care
 - But still no concrete uniform strategy
- Widespread adoption is inevitable
 - Evolution in device-derived sensor strategies will enable patient-centric care
 - Clinical outcomes studies underway
- Where do we need to be?
 - Uniformity in practice
 - Sensors coupled with remote monitoring integrated into clinical practice, will facilitate personalized medicine
 - Additional creation of self-management strategies for patients



Thank you!



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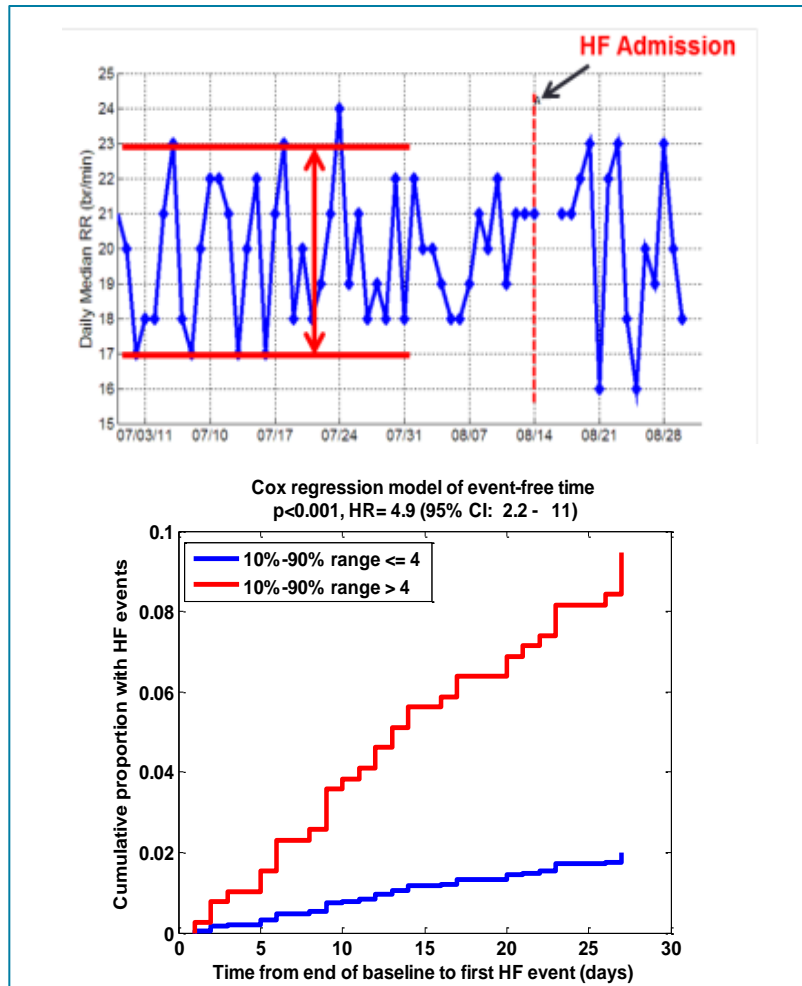


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New Device Derived Sensor Measures

Some Data

Variability in Respiratory Rate



Audible + Sub audible S3

