Heart failure and CRT: New topics and evidences in 2015

The role of remote monitoring system in CRT-D patient management: the IN-TIME study

Luca Santini, MD
Cardiology Division
Policlinico Tor Vergata - Rome
MY CONFLICTS OF INTEREST ARE

Received compensation from St. Jude Medical, Medtronic, Bayer, Boehringer and Boston Scientific for speaking.

Received compensation from St. Jude Medical, Biotronik and Boston Scientific for teaching and training courses.

Received compensation for clinical research from Biotronik, Medtronic, St. Jude Medical and Boston Scientific.
“Le telecardiogramme”.
“Archives Internationales Physiologie” 4:132; 1906
Wilhelm Einthoven

ECG transmission through the telephone line from the Hospital to the ECG lab (2 km)
REMOTE MONITORING

14 years of History

SAFE

- Early Detection
- Safe follow-up reduction

EFFECTIVE

- FDA & CE approved

APPROVED

- FDA
- CE
- Ministry of Health, Labour and Welfare

BIOTRONIK Home Monitoring®
REMOTE FOLLOW UP

All systems warrant Remote Follow Up

Results and perspectives of remote control: which clinical and organizational outcome may we expect?

- Systems for Remote control of CIEDs (PM, ICD, CRT, ILR) underwent through a terrific development in last decade.

  Devices may be completely and automatically interrogated following events daily.

- Numerous benefits have come by using these systems:
  - **Clinical advantages**
  - **Organizational advantages**

REMOTE MONITORING

More than 150 published papers

Clinical Benefits

- Proved early detection of significant clinical events (TRUST)
- Proved reduction of shocks (ECOST)
- Proved reduction of hospitalizations due to AF and of related strokes (COMPAS)
- Proved not significant reduction of mortality (TRUST)

Efficiency Benefits

- Reduction of follow up burden (TRUST, COMPAS, REFORM) compared to standard of care without RM
- High reliability of transmissions (TRUST)
- High patients’ acceptance (Ricci et al) & retention (TRUST) compared to standard of care without RM

System

- No interaction with patients

<table>
<thead>
<tr>
<th>Patient activity</th>
<th>Mean &amp; max. ven. HR during atr. burden*</th>
<th>CRT pacing*</th>
<th>Mean PVC/h*</th>
<th>Mean atrial HR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Remote follow-up and continuous remote monitoring, distinguished

Haran Burri®
Diagnostic data

In addition to providing necessary therapies for cardiac arrhythmias and heart failure, the modern implantable devices also provide useful **Patient** Diagnostic information:

**Heart Rate Variability**

Device recorded HRV has recently been shown to be lower in patients at risk of mortality and hospitalization.


**NHR**

Abrupt changes in heart rate or in the differences between day and NHR may be another clinical sign of acutely worsening HF status.


**Patient Activity**

The clinical utility of changes in the patient’s daily activity level in terms of predicting worsening HF is just now being investigated.

*Page E. et al. Europace. 2007 May 3*

**Pacing Percentage**

A high percentage of ventricular pacing is critical in order to obtain the maximal benefit of CRT therapy. However, atrial arrhythmias can lead to very high ventricular rates that result in inhibition of CRT pacing.
Modern devices are requested to give not only a therapy but even to help for clinical management of the patients.

From remote monitoring of the devices...
...to patients’ disease management.
DETECTION of CLINICAL EVENTS

Retrospective analysis of 11,626 patients

- 4,631 PM
- 6,548 ICD
- 445 CRT-D

- Mean monitoring period from 1 to 49 months
- 3,004,763 transmissions

86% of detected events are clinical events and not related to the device

Remote Control...for every type of patient

Monitoring of arrhythmic episodes and therapies delivered

Management AT/AF

Monitoring % pacing, HR

Arrhythmic patient

Clinical Impact on AF and HF

Monitoring pulmonary congestion
Activity Trend / Exercise Trend / HR distribution
Monitoring % pacing, HR

HF patient
Remote monitoring must be considered as “Gold Standard” for all CIEDs, above all for patients with AF and/or HF.

Remote monitoring and the twin epidemics of atrial fibrillation and chronic heart failure

Massimo Santini®
Heart Failure

- Heart failure is a common disorder associated with significant morbidity and mortality
- Despite advances in treatment, patient with HF remains at high risk for frequent hospitalizations

Heart failure has emerged as a growing health problem likely to reach ‘epidemic’ proportions in developed countries [1–3]. This has been attributed to the combination of an ageing population and more effective treatment of its major precursor, myocardial infarction [3]. Not unexpectedly, heart failure-related hospitalisation rates have been steadily increasing in

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PII: S 1 3 8 8 - 9 8 4 2 ( 0 0 ) 0 0 1 4 1 - 0
Heart Failure Progression

Every acute event has a **direct impact** on disease progression

Avoiding acute episodes should be one of the main targets of CHF treatment
Decompensated Heart Failure: the Major Contributor to Cost of Care

Episodes of decompensation
- Hospital care
- MD visits
- ED visits
- Dx testing

Surgical procedures to treat HF
- Heart transplantation
- Mechanical devices

Maintenance
- Medications
- Routine MD visits
- Nonmedical care

USA

O’Connell JB. Clin Cardiol 2000;23:III-6
Background

Pulmonary congestion is difficult to recognize in its early stages of development because of the late appearance of symptoms before hospitalization.

Days

- Euvolemia
  - Stable NYHA Class

- Proactive phase
  - > 30 days
  - -21 to -7 days

- Worsening Symptoms or Weight Change
  - -6 to -2 days

- Reactive phase
  - 0 to 5 days

- Hospitalization ER visit
- Urgent Care

1. B. Adamson, 2006 Supp Card. Medicine
Early detection of fluid overload and associated signs may:

• allow timely adjustment of therapy;

• improve patients care by avoiding hospitalization and associated costs.
Indicators for HF Decompensation (Continuous autonomic assessment)

- Heart Rate Variability (ms)
- Night Heart Rate (BPM)
- Patient Activity (minutes/day)

Days Relative to Hospital Admission

Remote monitoring via implanted devices

AIM

regard to their prospective value in predicting heart failure events.

The opinions expressed in this article are not necessarily those of the authors.

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For the use of intrathoracic impedance, we eagerly await the report of prospective randomized studies. The evidence for remote monitoring in the prevention of major cardiovascular events is scarce but is being increasingly provided. For the use of intrathoracic impedance, we eagerly await the report of prospective randomized studies. The evidence for remote monitoring in the prevention of major cardiovascular events is scarce but is being increasingly provided.

Remote monitoring of ICDs can aid in early detection of technical failures and heart failure hospitalizations. As mentioned, prospective data are few but some data on the use of remote monitoring is scarce but is being increasingly provided.

The most sensitive marker of pulmonary fluid accumulation is changes in thoracic impedance measurements, which are possibly more informative than weight gain or heart rate. It is, however, to be expected that in real life, these should aid in answering important questions such as if early detection is possible in heart failure patients with broad QRS complexes.

Cardiac resynchronization therapy can improve symptoms of heart failure but also heart failure-related parameters. Prospective data on the use of remote monitoring is scarce but is being increasingly provided.

Implantable cardioverter–defibrillators (ICDs) have become standard therapy for patients with poor systolic function and low left ventricular ejection fraction, most often due to ischaemic heart disease, and also non-ischaemic cardiomyopathy. These patients are thus protected from life-threatening arrhythmias but remain at risk of death from pump failure.

The use of parameters that can predict heart failure-related complications can be an important add-on to these remote technical functions but also heart failure-related parameters. Prospective data are thus protected from life-threatening arrhythmias but remain at risk of death from pump failure.

Remote monitoring of ICDs can aid in early detection of technical failures and heart failure hospitalizations. As mentioned, prospective data are few but some data on the use of remote monitoring is scarce but is being increasingly provided.

This tool may increase patients’ quality of life and reduce morbidity, mortality, and health economic burden, it now warrants prospective studies.

The use of parameters that can predict heart failure-related complications can be an important add-on to these remote technical functions but also heart failure-related parameters. Prospective data are thus protected from life-threatening arrhythmias but remain at risk of death from pump failure.
Monitoring of fluid status by implanted devices

Dryer lungs
Impedance increases

Wetter lungs
Impedance decreases

Physician Programmable Threshold
OptiVol Fluid Index

Daily Impedance
Reference Impedance
Clinical value of intrathoracic impedance monitoring

MID-HeFT trial
Changes in intra-thoracic impedance:
- may provide advanced warning of impending HF hospitalization
- are inversely related with PCWP and fluid status
(Yu et al., Circulation. 2005;112:841-8.)

The alert capability reduces the number of HF hospitalizations by allowing timely detection and therapeutic intervention.

Catanzariti et al. PACE 2009; 32:363–370

Remote monitoring of patients with biventricular defibrillators through the CareLink system improves clinical management of arrhythmias and heart failure episodes
Santini M. J Interv Card Electrophysiol. 2009; 24: 53–61

67 CRT-D pts. 28 OptiVol alerts:
- 20 were true positive (sensitivity 91%, PPV 71%)
- In 20 cases remote transmission, resulting in drug therapy adjustment (10), reassurance (4) and hospital visit (6)
SENSE-HF was a prospective, multicenter study that investigated the performance of OptiVol Intrathoracic impedance fluid monitoring for prediction of HF hospitalisation in patients with HF newly implanted with an ICD or CRT-D device.

SENSE-HF proved that only 38% of patients with a fluid index crossing show HF symptoms within 30 days.
CorVue™ Congestion Monitoring

J Interv Card Electrophysiol

Feasibility of using multivector impedance to monitor pulmonary congestion in heart failure patients

Philip F. Binkley • James G. Porterfield •

- 75 patients enrolled in 23 US centers
- 8.2 ± 2.6 months of follow-up

<table>
<thead>
<tr>
<th></th>
<th>CRT-D</th>
<th>ICD</th>
<th>Single vector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vector combination</td>
<td>LVr-Can and RVc-Can</td>
<td>RVr-Can and RVc-Can</td>
<td>RVc-Can</td>
</tr>
<tr>
<td>Detected clinical events</td>
<td>15 (14 cardiac)</td>
<td>13 (12 cardiac)</td>
<td>12 (11 cardiac)</td>
</tr>
<tr>
<td>Number of false positive algorithm-detected events</td>
<td>17</td>
<td>19</td>
<td>22</td>
</tr>
<tr>
<td>Total number of algorithm-detected events</td>
<td>32</td>
<td>32</td>
<td>34</td>
</tr>
<tr>
<td>FPR (false positives per patient-year)</td>
<td>0.56</td>
<td>0.63</td>
<td>0.74</td>
</tr>
<tr>
<td>Sensitivity (%)</td>
<td>71.4</td>
<td>61.9</td>
<td>57.1</td>
</tr>
<tr>
<td>Positive predictive value (%)</td>
<td>46.9</td>
<td>40.6</td>
<td>35.3</td>
</tr>
</tbody>
</table>

Published online: 12 June 2012
CorVue™ Congestion Monitoring

J Cardiovasc Med 2013, 14:726–732

Device monitoring of heart failure in cardiac resynchronization therapy device recipients: a single-center experience with a novel multivector impedance monitoring system
Giovanni B. Forleo, Germana Panattoni, Valentina Schirripa

Table 2  Characteristics of congestion monitoring alerts

| Patients with congestion monitoring alerts, n (%) | 29 (36.3) |
| Congestion monitoring alerts, n               | 56        |
| Congestion monitoring alerts/patient, median (range) | 2 (1–3)  |
| AT/AF alerts associated with congestion monitoring alerts, n (%) | 5 (6.3)   |
| FP congestion monitoring alerts, n (%)        | 32 (57.1) |
| TP congestion monitoring alerts, n (%)        | 24 (42.9) |
| Sensitivity for HF events, (%)a               | 61.5      |
| Sensitivity for HF hospitalization, (%)        | 53.8      |
| PPV for HF events, (%)a                       | 42.9      |
| PPV for HF hospitalization, (%)               | 17.9      |
| FP detections per patient-year               | 0.60      |

*Defined as admissions in hospital for congestive heart failure or milder manifestations of heart failure deterioration. Values are mean ± SD unless otherwise specified. AT/AF, atrial tachycardia/atrial fibrillation; FP, false positive; HF, heart failure; PPV, positive predictive value; TP, true positive.

- 80 patients enrolled at Policlinico Tor Vergata
- 8,0 ± 4,4 months of follow-up
Observing more diagnostic parameters, in a shortest time interval, allows to predict HF episodes more likely.
**PARTNERS HF Study**

**Combined Algorithm**

Positive Combined Algorithm = any 2 criteria +

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid Index</td>
<td>≥60 ohm/days</td>
</tr>
<tr>
<td>AT/AF Duration</td>
<td>≥6 hours &amp; not persistent AT/AF</td>
</tr>
<tr>
<td>V. rate during AT/AF</td>
<td>AT/AF ≥24 hrs &amp; V. ≥ 90 bpm</td>
</tr>
<tr>
<td>Patient Activity</td>
<td>Avg. &lt;1 hr over 1 week</td>
</tr>
<tr>
<td>Night Heart Rate</td>
<td>≥85 bpm for 7 consecutive days</td>
</tr>
<tr>
<td>HRV</td>
<td>&lt;60 ms for 7 consecutive days</td>
</tr>
<tr>
<td>CRT % Pacing</td>
<td>&lt; 90% for 5 of 7 days</td>
</tr>
<tr>
<td>Shock(s)</td>
<td>1 or more shocks</td>
</tr>
</tbody>
</table>

OR Fluid Index ≥100

Whellan et al. JACC Vol. 55, No. 17, April 27, 2010:1803–10
PARTNERS HF Study
Kaplan-Meier HF Hospitalization Curves

Risk of a HF hosp. for pts with + Diagnostic was 5.5 x risk of pts w/ - Diagnostic

P < 0.0001
Hazard Ratio = 5.5 (95% CI: 3.4 – 8.8)
Decreased intra-thoracic impedance detected by an implantable monitor, is associated with a 38% increased risk for HF hospitalization in a population of HF patients treated with CRT.

Some device parameters including patient activity, VT episodes, NHR and HRV are weak prognostic predictors of Acute HF events, but can be associated with intrathoracic impedance indices to better evaluate the risk of Acute HF events.

The combination of multiple device diagnostics may increase the clinical utility of alerts for monitoring HF status.
Heart Failure Remote Monitoring

Observing more diagnostic parameters, in a shortest time interval, allows to predict HF episodes more likely.
AT/AF BURDEN

V rate during AT/AF

Patient Activity

Avg. V rate

Heart rate variability

% Pacing/day

OptiVol Fluid Index

Thoracic Impedence
AF induced HF

Day and Night
HR increase

↓ Patient Activity

↓ CRT

AT/AF

Patient Activity hours/day

Heart rate variability (ms)

AF# induced #HF #
Pulmonary fluid monitoring by the CorVue algorithm

<table>
<thead>
<tr>
<th>Paziente e medico</th>
<th>Monitor. Congestione CorVue™</th>
<th>Parametri Monitor. Congestione</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nome paziente</td>
<td>T.G.</td>
<td>Monitoraggio Congestione</td>
</tr>
<tr>
<td>Data di nascita</td>
<td>6 lug 1943</td>
<td>Trigger Congestione Superata</td>
</tr>
<tr>
<td>Data di implanto</td>
<td>8 giu 2010</td>
<td>Avviso Monitoraggio Congestione</td>
</tr>
<tr>
<td>Medico /Implanto</td>
<td></td>
<td>On</td>
</tr>
<tr>
<td>Medico /Follow-up</td>
<td></td>
<td>Trigger Congestione</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Avviso Monitoraggio Congestione</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Avviso Paziente</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Off</td>
</tr>
</tbody>
</table>

Monitoraggio Congestione™ CorVue (Vista 3 mesi)

![Graph showing changes in impedance over time with marked periods of congestion and alerts.](image-url)
Intrathoracic Impedance Monitoring

Home Monitoring (Biotronik)

Intrathoracic impedance raise after 1 month

HF drug therapy adjustment
MANAGING PA PRESSURE:
ADDRESSING THE UNDERLYING PATHOPHYSIOLOGY

Traditionally, heart failure management has relied on patient-reported symptoms, impedance, blood pressure and/or weight gain changes that often manifest only after decompensation has begun. Clinicians need an objective, direct marker that enables more proactive care. The answer is the CardiMEMS™ HF System.

PATHOPHYSIOLOGY OF CONGESTION

- Filling Pressure Increase
- Autonomic Adaptation
- Intrathoracic Impedance Changes
- Symptoms
- Weight Change
- Decompensation

Time Proceeding Hospitalization (Days)
When used by clinicians to manage HF, the CardioMEMS™ HF System is the first and only FDA-approved HF monitor proven to significantly reduce HF hospital admissions and improve quality of life in NYHA class III patients.¹⁴

**CARDIOMEMS™ HF SYSTEM**

**37%**  
**REDUCTION IN HEART FAILURE HOSPITAL ADMISSIONS**

**0**  
**SENSOR FAILURES**

**98.6%**  
**COMPLICATION-FREE**

**2.4 DAYS**  
**FEWER DAYS IN HOSPITAL AT 6 MONTHS OF FOLLOW-UP**

**ACROSS OVER 1,167 PATIENT-YEARS OF EXPERIENCE**

**References**  
2. Adamson et al., Impact of Wireless Pulmonary Artery Pressure Monitoring on Heart Failure Hospitalizations and 30-Day Readmissions in Medicare-Eligible Patients with NYHA Class III Heart Failure: Results from the CHAMPION Trial AHA 2014, Chicago. Abstract 16744.
Conclusions: The model suggests that PAP guided management of HF using the CardioMEMS HF System is cost-effective. This ICER of $30,167 was below the conventional US acceptability threshold of $50,000.

Conclusions: Heart failure hospitalization rates were most effectively reduced by a management strategy based on pulmonary artery pressures without reliance upon clinical changes. This supports the strategy of early intervention prior to clinical signs to avert clinical decompensation and heart failure readmissions.

Conclusions: On top of optimal medical therapy including CRT or ICD devices, PAP management still resulted in additional benefit to decrease all-cause hospitalizations and mortality.
Do HF patients benefit of Remote Monitoring?
Results from ALTITUDE database

Large US database with 185,778 patients (ICD and CRT-D)
First analysis investigating the impact of RM on mortality in ICD/CRT-D

RM associated with a 50% relative reduction in the risk of death
Hazard ratios
ICD = 0.56; CRT-D = 0.45; P<0.0001.

Saxon LA et al. Circulation 2010
Conclusions

RPM confers a significant protective clinical effect in patients with chronic HF compared with usual care. (J Am Coll Cardiol 2009;54:1683-94) © 2009 by the American College of Cardiology Foundation
Early Detection of Adverse Events with Daily Remote Monitoring versus Quarterly Standard Follow-Up Program in Patients with CRT-D

ERMENEGILDO DE RUVO, M.D.,* ALESSIO GARGARO, Ph.D., M.D.,† LUIGI SCIARRA,

CRT-D patients without HM had a 86% rate of clinical adverse events due to the late diagnosis of critical events, during a mean follow-up of 7 months.

From Cox analyses it’s overt that the only two independent predictors of AEC within the 18 months of f.u. are the method used to make f.u. and EF (De Ruvo, PACE 2010)
The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts.
Crossley GH et al. CONNECT Investigators J Am Coll Cardiol. 2011 Mar 8;57(10):1181-9

Multicenter, prospective, randomized study involving 1,997 patients underwent insertion of ICD and CRT-D; Medtronic Carelink system. F.u.: 15 months

Crossley et al. (2011) showed that remote monitoring leads to earlier identification of device/disease-related problems, enabling timely, potentially life-saving intervention to improve clinical outcomes-

Overall time to the physician's clinical decision was **22 days** for those monitored in-clinic, versus **4.6 days** for patients in the RM group (p<0.001)
Secondary objective: to compare the rates of CV health care utilization between patients in the remote and in-office arms.

Remote monitoring reduces length of stay for cardiovascular hospitalization.

Mean reduction 18% (p = 0.002)

Estimated savings per hospitalization $1,659*
Italy: EVOLVO STUDY

EVOLVO: Italian study powered by Medtronic and Region Lombardia

Remote control reduces HF visits, hospitalizations and costs
Comparison between remote patient management (CareLink) and regular follow-up

Enrollment
n=1,000
80 EU centers

Randomisation

- CRT-D indication according to current guidelines

Follow-up

Primary end point:
1. Time between event onset and clinical decision
2. Death from any cause, CV and device-related hospitalization

Follow up visits every 4 months
The primary endpoint of Phase 1 was the delay between an alert event and clinical decisions related to the event in the first 154 enrolled patients followed for 1 year.

Overall, taking into account both scheduled and unscheduled visits (in a referral clinic) plus emergency department visits (with or without subsequent hospitalization) a 37.5% reduced burden was observed in the Remote group.

Conclusion
The Phase 1 results of the MORE-CARE randomized study indicate that RM allows a significant reduction in delay from event onset to clinical decisions. The impact of RM on clinical aspects of disease management in heart failure patients needs to be assessed in the second phase of the trial.
AIM of the study
The MULTItarameTric EvalUation of Heart Failure in DEvice-implanted patients (MULTITUDE-HF) trial has been designed to assess the respiratory trends correlation with clinically relevant heart failure events.
Methods: 124 patients with a history of HF and implanted with ICD endowed with the RR Trend diagnostic feature (Boston Scientific Inc., Natick, MA, USA) were prospectively enrolled. Patients were followed-up for 12 months.

Results:

- The weekly variation of RR was significantly higher prior hospitalization (33 events) \((p<0.05)\).
- A weekly variation >3 breaths/min of maximum RR predicted an impending event of hospital admission for HF with sensitivity of 73% and specificity of 57%.

Conclusion: In our study, elevated values of ICD-monitored RR allowed to identify patients with worse functional status and lower systolic function. The weekly variation of RR increased before events of HF decompensation.
Impact of BIOTRONIK Home Monitoring® on the clinical status of Heart Failure patients

Results of the IN-TIME Study
Inclusion and Exclusion Criteria

716 HF patients, 36 investigational sites

Major Inclusion Criteria

- Dual-chamber ICD or CRT-D indication
- Chronic heart failure with NYHA Class II or III
- LVEF $\leq 35\%$ within 3 months prior to screening
- Indication for therapy with diuretics before randomization:
  - Stable optimal drug therapy
  - Transmission performance of Home Monitoring $\geq 80\%$

Major Exclusion Criteria

- Permanent atrial fibrillation

Clinical Trial Design

716 Enrolled

Run-in Phase (1 month)

664 Randomized analysis population

52 excluded before randomization
- 18 consent withdrawal
- 11 inclusion criteria violated
- 7 missing 1-month FU
- 4 death
- 12 other reasons

Prospective, randomized, multi-center design

Home Monitoring 333

Conventional 331

143 ICD 131 ICD (total = 274 ICD; 41%)

200 CRT-D (total = 390 CRT-D; 59%)

Hindricks G et al. The Influence of Implant-Based Home Monitoring on the Clinical Status of Heart Failure Patients with an Impaired Left Ventricular Function
ESC 2013
Endpoints

**Primary endpoint:** modified Packer score
At study end, a patient is classified "worsened" in case of
- death
- overnight hospitalization for worsening heart failure
- worsening in NYHA class
- deterioration in the patient’s global self-assessment

**Major secondary endpoint:** all-cause mortality, number of hospitalizations due to HF and length of hospital stay

Primary Endpoint
Reduction of worsening of clinical status

Impact on Modified Packer Score of heart failure patients with ICD and CRT-D devices

Secondary Endpoint

> 50% reduction in all-cause mortality

Impact on all-cause mortality of heart failure patients with ICD and CRT-D devices

Hazard ratio: 0.356 (95% confidence interval: 0.172–0.735)

10 deaths (3.4%)

27 deaths (8.7%)

IN-TIME Conclusion

IN-TIME is the first randomized clinical trial to show a mortality benefit for heart failure patients with device-based remote monitoring.

Early detection of arrythmias & suboptimal therapy, and closer patient monitoring lead to >50% reduction in all-cause mortality.

Monitoring IN-TIME requires a clinically relevant set of parameters, a highly reliable technical platform, and a workflow that supports a quick response.
**Summarizing:**

The value of continuous remote monitoring in providing better care

<table>
<thead>
<tr>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduces the burden of in-clinic follow-up on healthcare systems, physicians and patients</td>
</tr>
<tr>
<td>Reduces overall cost of follow-up</td>
</tr>
<tr>
<td>Allowing any device problems to be detected immediately</td>
</tr>
<tr>
<td>Anticipating clinical actionable events and reducing time from event to clinical decisions</td>
</tr>
<tr>
<td>Diagnosing asymptomatic conditions</td>
</tr>
<tr>
<td>Allowing individual tailoring of patient treatment and continuous updating of therapeutical strategy</td>
</tr>
<tr>
<td>Reducing length of stay for cardiovascular hospitalization</td>
</tr>
</tbody>
</table>
## What is cost-effectiveness?

Costs of therapy

<table>
<thead>
<tr>
<th>Costs of therapy</th>
<th>Consequences (Effects) of therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>- Less effective, less expensive</td>
</tr>
<tr>
<td>+</td>
<td>+ More effective, more expensive</td>
</tr>
<tr>
<td>+</td>
<td>+ More effective, more expensive</td>
</tr>
<tr>
<td>-</td>
<td>- Less effective, less expensive</td>
</tr>
</tbody>
</table>

The most cost-effective and effective option is the bottom right cell, where the therapy is more effective and less expensive.
Summarizing:

The value of continuous remote monitoring in providing better care

- Reduces the burden of in-clinic follow-up on healthcare systems, physicians and patients
- Reduces overall cost of follow-up
- Allowing any device problems to be detected immediately
- Anticipating clinical actionable events and reducing time from event to clinical decisions
- Diagnosing asymptomatic conditions
- Allowing individual tailoring of patient treatment and continuous updating of therapeutical strategy
- Reducing length of stay for cardiovascular hospitalization

Cost-effectiveness
Conclusions

- Remote monitoring is an efficient method to manage HF patients with CIEDs.
- Several indexes may be used to identify early changes in hemodynamic status to prevent acute events and hospitalizations.
- Hemodynamic sensors may increase diagnostic sensitivity and specificity.
- To integrate all available diagnostics into an algorithm capable of predicting impending heart failure with a low rate of false alerts represents the challenge for the near future.
CONCLUSION

“The future in cardiology is remote monitoring, potentially of all types of cardiac patients, which will come to be regarded as so important as to be on a level with, for example, dual-chamber pacing, lithium batteries, active can defibrillation, and cardiac resynchronization therapy in the evolution of the technology of implantable devices.”

(Richard Sutton)
Thank you for your attention