PLACE

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA
Centro Congressi
di Confindustria
Auditorium
della Tecnica

9ª Edizione

30 Settembre
1 Ottobre
2022

HeartLogic: real world data

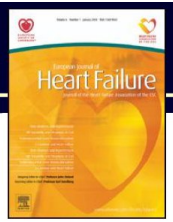
APPROCCIO MULTIPARAMETRICO CON I SENSORI FISIOLOGICI

CENTROCARDIOLOGICOUNIVERSITARIO
Azienda Ospedaliero-Universitaria di Ferrara

Matteo Bertini
M.D, PhD

Università
degli Studi
di Ferrara

Collaboration & Organization

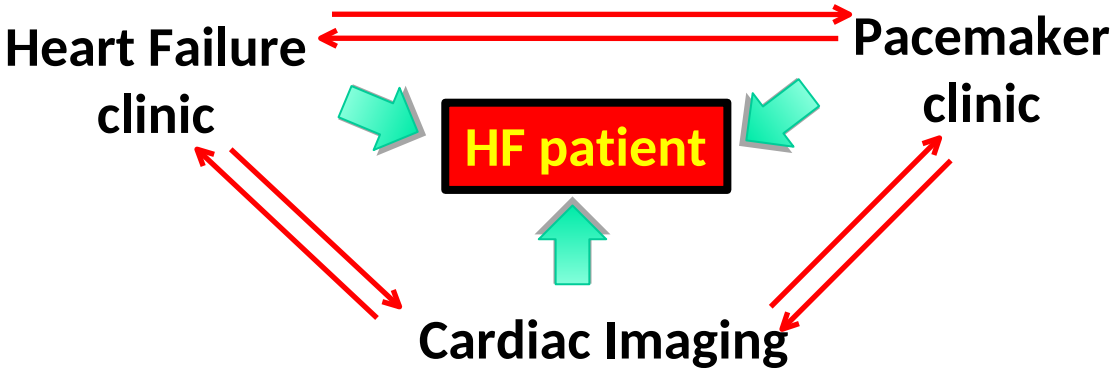


European Journal of Heart Failure 10 (2008) 1229–1235

Review

Successful treatment of heart failure with devices requires collaboration

Karl Swedberg [a,*], John Cleland [b], Martin R. Cowie [c], Markku Nieminen [d], Silvia G. Priori [e], Luigi Tavazzi [f], Dirk J. van Veldhuisen [g], Luis Alonso-Pulpon [h], John Camm [i], Kenneth Dickstein [j], Helmut Drexler [k], Gerasimos Filippatos [l], Cecilia Linde [m], José Lopez-Sendon [n], Massimo Santini [o], Faiez Zannad [p]



Multidisciplinary interventions recommended for the management of chronic heart failure

ESC GUIDELINES 2021

In order to reduce hospitalizations and mortality, earlier guidelines recommended the use of **multidisciplinary HF management programmes** (HF-MPs)

The optimal implementation of a HF-MP requires a multidisciplinary team that is active along the whole HF trajectory.

Recommendations	Class[a]	Level[b]
It is recommended that HF patients are enrolled in a multidisciplinary HF management programme to reduce the risk of HF hospitalization and mortality.[309,314,315,316]	I	A
Self-management strategies are recommended to reduce the risk of HF hospitalization and mortality.[309]	I	A
Either home-based and/or clinic-based programmes improve outcomes and are recommended to reduce the risk of HF hospitalization and mortality.[310,317]	I	A
Influenza and pneumococcal vaccinations should be considered in order to prevent HF hospitalizations.[315,316]	IIa	B

McDonagh et al., European Heart Journal (2021) 00, 1128 doi:10.1093/eurheartj/ehab368

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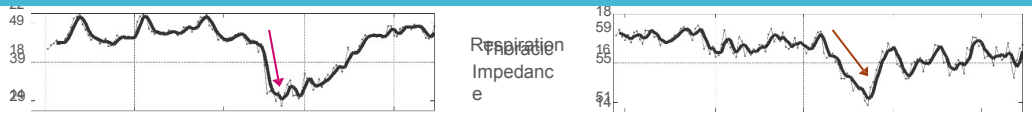
Benefit of Multiparamteric Approach

Patient A — *Two Observed Cases* — **Patient B**

Which patient had a Heart Failure Event?



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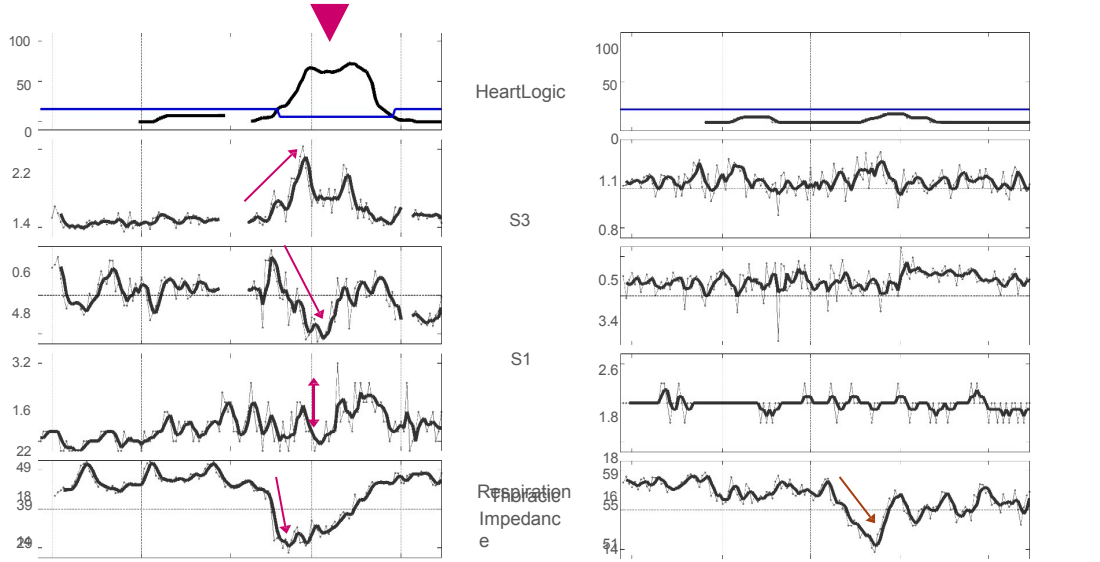
Benefit of Multiparametric Approach

Patient A — *Two Observed Cases* — Patient B

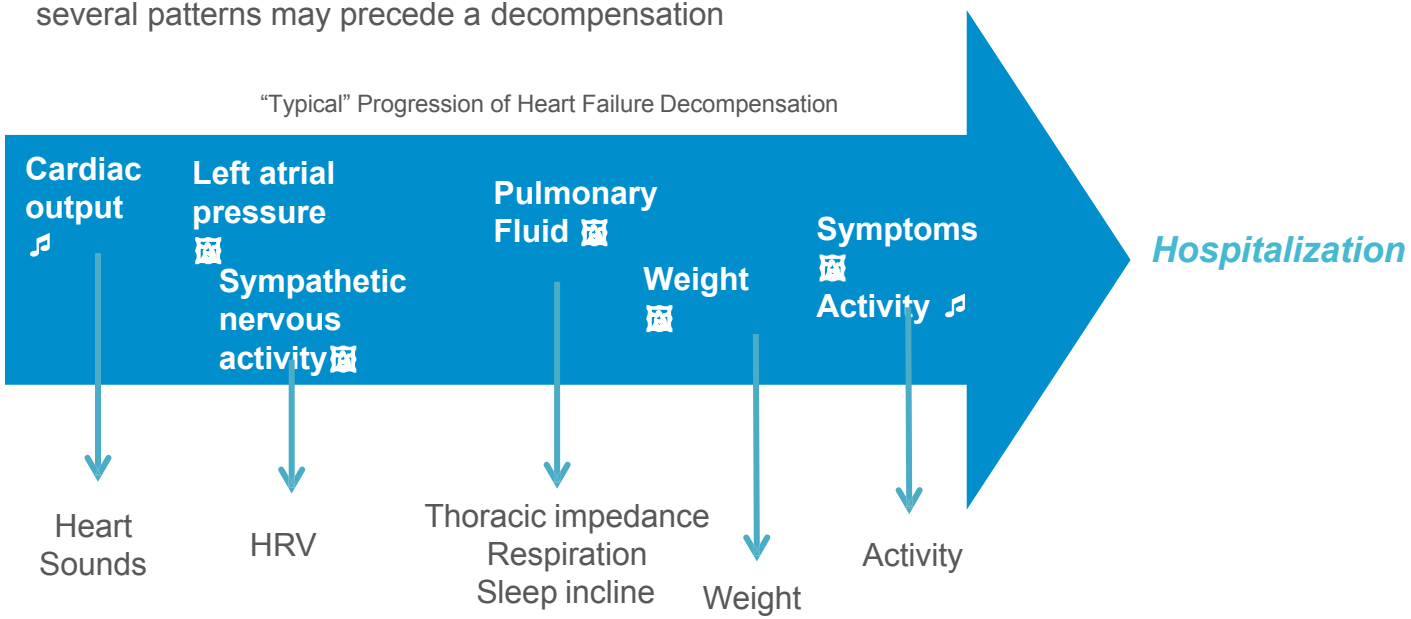
Multi-sensor Changes before a **HF Event**

Impedance-only Change with **NO** Event



Device diagnostics measure surrogates of HF symptoms

Symptoms can vary in presentation and time course, nevertheless, several patterns may precede a decompensation



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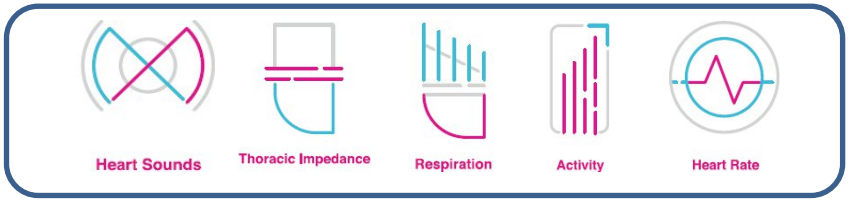
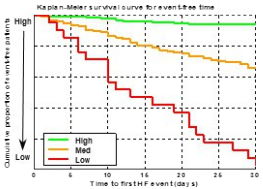
HeartLogic™

Heart Failure Diagnostic

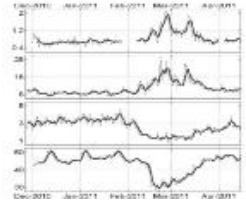


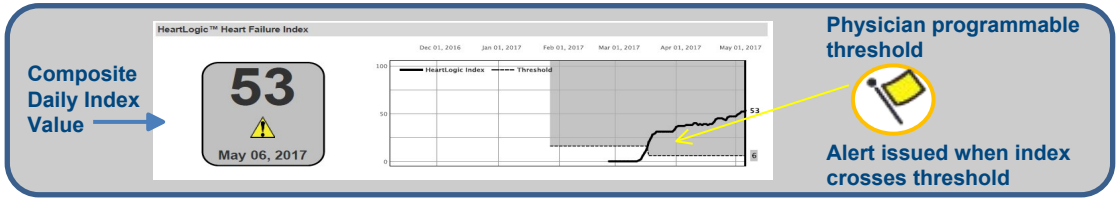
Assess patient risk for worsening HF

Evaluate changes from patient baseline



Combined into a single, simple index with alert to detect signs of worsening HF





Emulate Clinical Assessments

Multiple Sensors

Objective Measurements Relevant to HF

Intelligent **Personalized** Algorithm

Developed and **Validated** in 900 Patients

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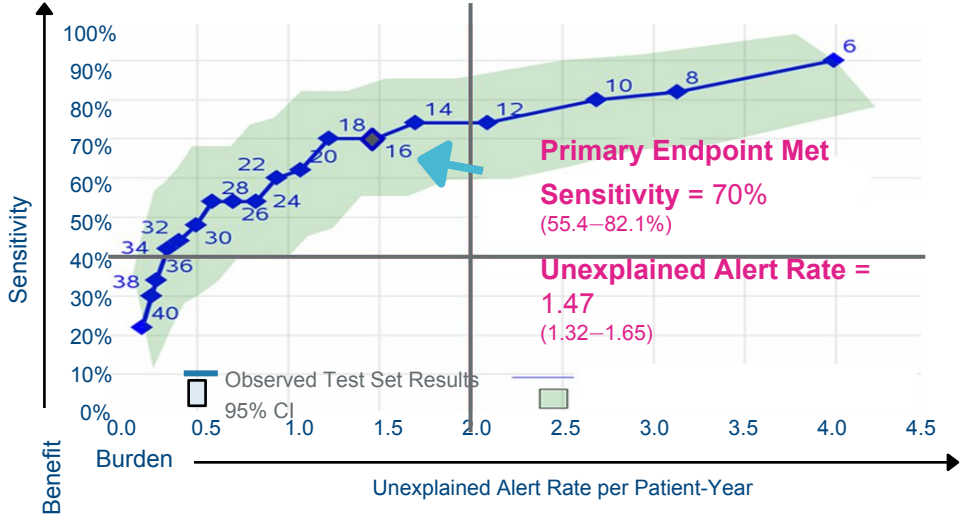
A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices

Results From the MultiSENSE Study

The MultiSENSE Study validated that HeartLogic:

- Had **high sensitivity** of 70% in detecting heart failure events[1]
- Had a **very low alert burden** of less than 2 alerts per patient per year[1]
- Provided *a* **median of 34 days of advance notice** of a potential heart failure event[1]



Boehmer JP et al., JACC Heart Fail. 2017 Mar;5(3):216-225. doi: 10.1016/j.jchf.2016.12.011..

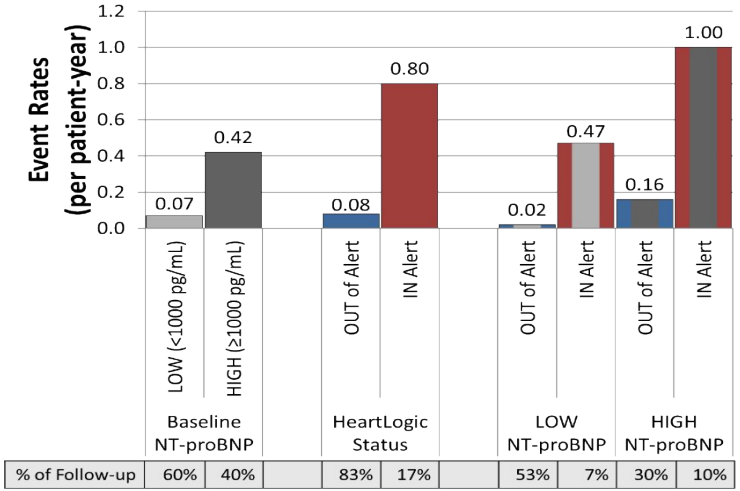
MultiSENSE analysis

The MultiSENSE Study demonstrated **HeartLogic's ability to identify high risk patients:**

10 times higher heart failure event rate when IN alert than OUT of alert

50 times higher heart failure event rate when IN alert and high NT-proBNP

Very low non-alert event rate of 0.08 per patient year



Gardner, R et al. Circ Heart Fail, 2018; 11(7):e004669 DOI: 10.1161/CIRCHEARTFAILURE.117.004669

ESC HEART FAILURE ORIGINAL RESEARCH ARTICLE
ESC Heart Failure 2019; **6**: 308–318
Published online 11 January 2019 in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/ehf2.12394

Preliminary experience with the multisensor HeartLogic algorithm for heart failure monitoring: a retrospective case series report

24 HeartLogic™ threshold crossings in 16 patients (**0.99 alerts/pt-yr**).

Time in alert state: **12%** total observation time

The results from the **blinded phase** of this experience over 58 patients

- ***Sensitivity: 100%***
- ***Rate of unexplained alerts: 0.41 per pt-year#***
- ***Positive predictive value: 58% (14/24)***
- The median ***early-warning time was 38 days*** in the case of hospitalizations and 12 days in that of minor events reflecting clinical deterioration of HF.

MultiSENSE results confirmed

considering therapy discontinuations as «unexplained alerts»

Capucci A. et al., ESC Heart Fail. 2019 Apr;6(2):308-318. doi: 10.1002/ehf2.12394.

First prospective experience in clinical practice

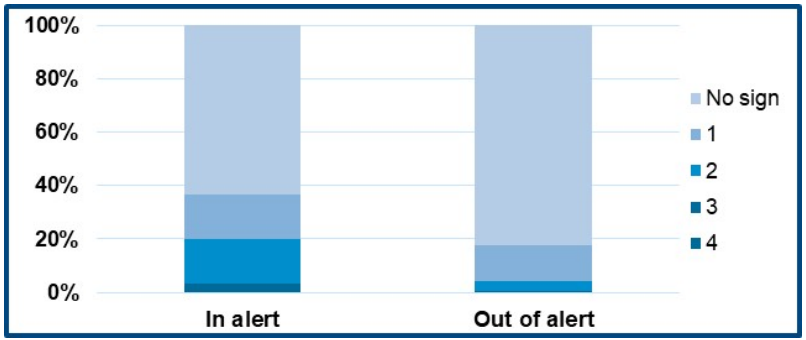
(104 patients)

Received: 19 February 2020 | Revised: 23 March 2020 | Accepted: 24 March 2020
DOI: 10.1002/clc.23366

CLINICAL INVESTIGATIONS

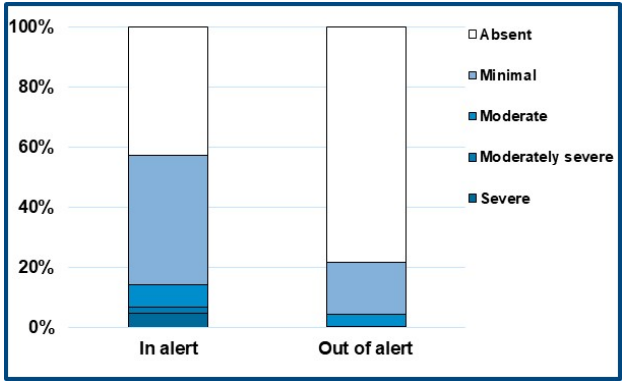
CLINICAL CARDIOLOGY WILEY

Prospective evaluation of the multisensor HeartLogic algorithm for heart failure monitoring



Any HF **sign** (i.e. S3 gallop, rales, jugular venous distension, edema) was detected during

- ✓ 18% of in-office visits performed OUT of HL alert condition
- ✓ 34% of in-office visits performed in HL alert condition (p=0.002).



Moderately severe and severe symptoms of HF were reported during

- ✓ 0.1% of examinations out of the HL alert condition
- ✓ 4.8% of examinations in the HL alert condition (P < .001)

Santini L. et al., Clin Cardiol. 2020 Jul;43(7):691-697. doi: 10.1002/clc.23366

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HeartLogic Spanish Registry

Original article

Remote heart failure management using the HeartLogic algorithm. RE-HEART registry

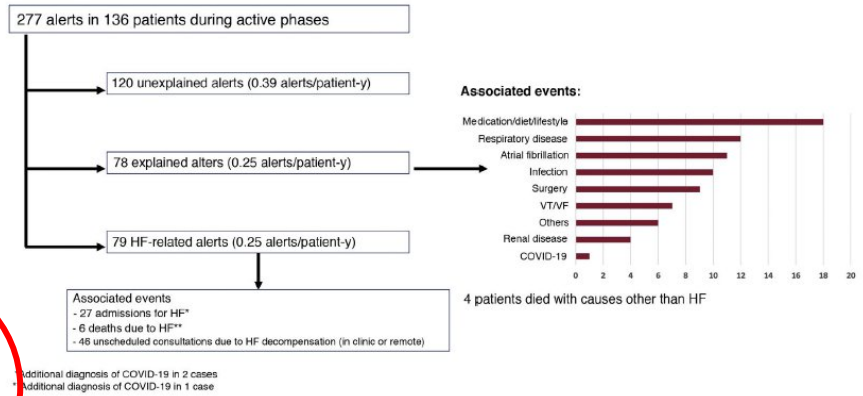
15 HeartLogic centers in Spain and included a total of **288 patients** followed in **an active phase** for a median observation period of 16 [95% CI: 15 – 22] months

The design of the study included three different phases:

1. Blinded phase
2. Prospective phase in clinical practice per local practice
3. Prospective phase in clinical practice following a standardized protocol

	Phase 1 (blind)	Phases 2 and 3 (active)
Sensitivity	100%	98%
Specificity[a]	93%	90%
Positive predictive value[b]	18%	29%
Positive predictive value[c]	27%	57%
Negative predictive value[d]	100%	99.9%
Rate of unexplained alerts	0.52 alerts/patient-y	0.39 alerts/patient-y
Rate of false-positive alerts[e]	0.59 alerts/patient-y	0.64 alerts/patient-y

MultiSENSE results confirmed



de Juan Bagudá Jet al., Rev Esp Cardiol (Engl Ed). 2022 Sep;75(9):709-716. English, Spanish. doi: 10.1016/j.rec.2021.09.015

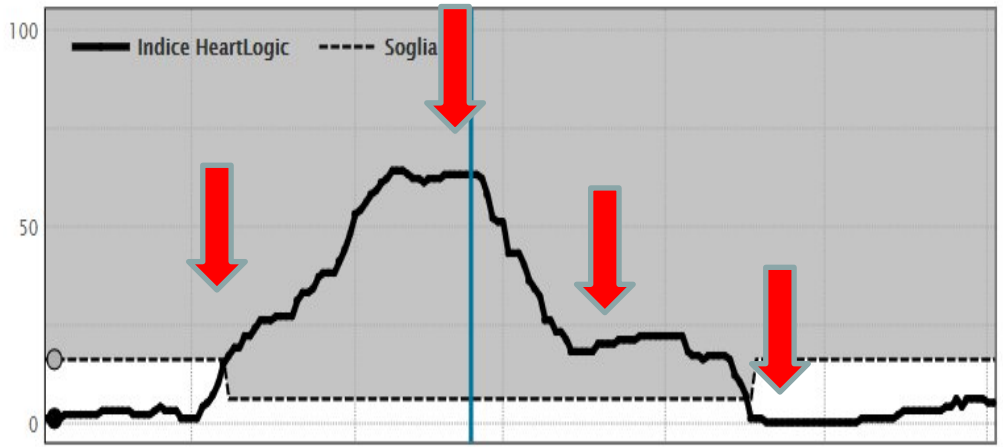
Vedi: 1 m 3 m 6 m 1 a

01 gen 2021 01 feb 2021 01 mar 2021 01 apr 2021 01 mag 2021 01 giu 2021

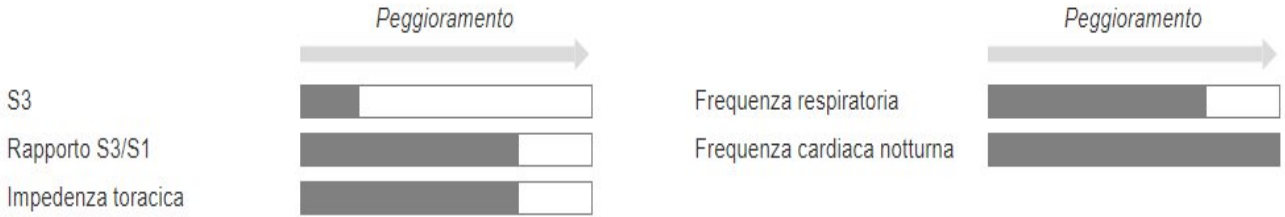
Indice insufficienza cardiaca HeartLogic™

63

23 feb 2021

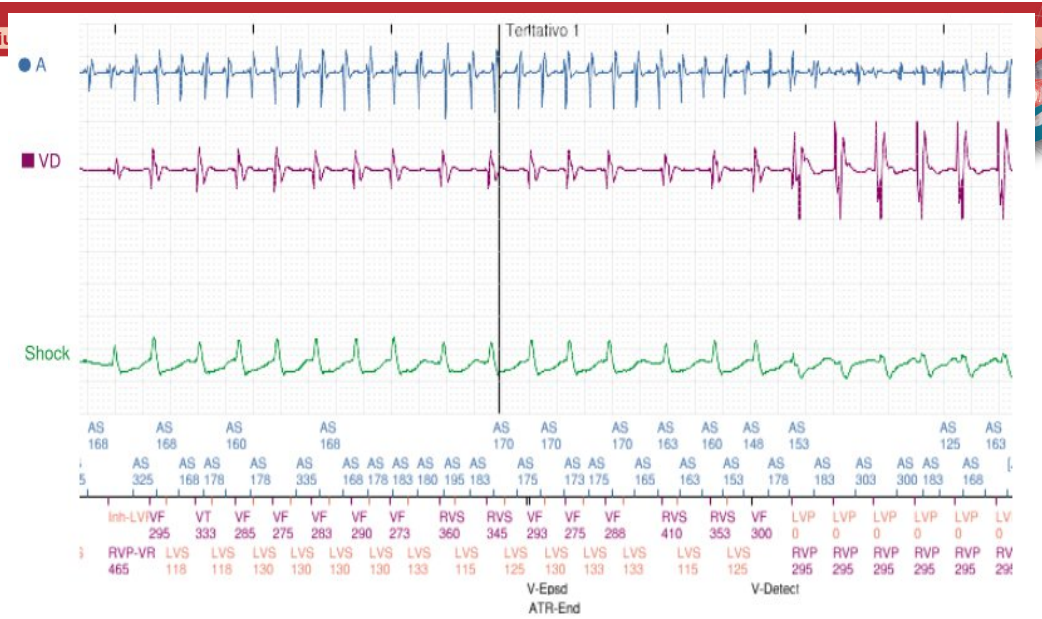


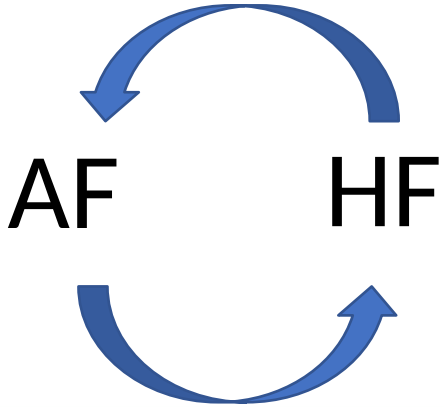
Tendenze contribut.



Nota: La parte ombreggiata indica il grado di peggioramento su 23 feb 2021

- **AF is a common comorbidity in HF**
- **Whatever AF triggers or is triggered by worsening HF is debated**

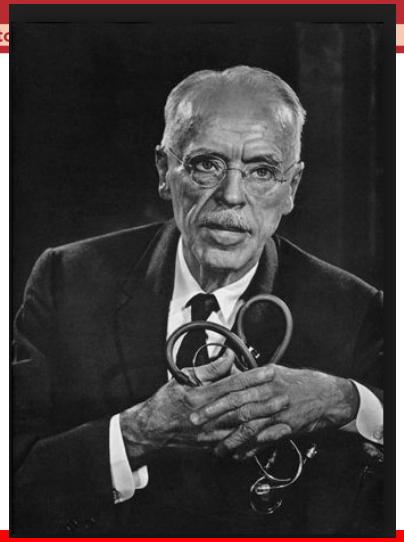




What we know…

Patients with AF and concomitant HF suffer from a worse prognosis

- **INCREASED MORTALITY**

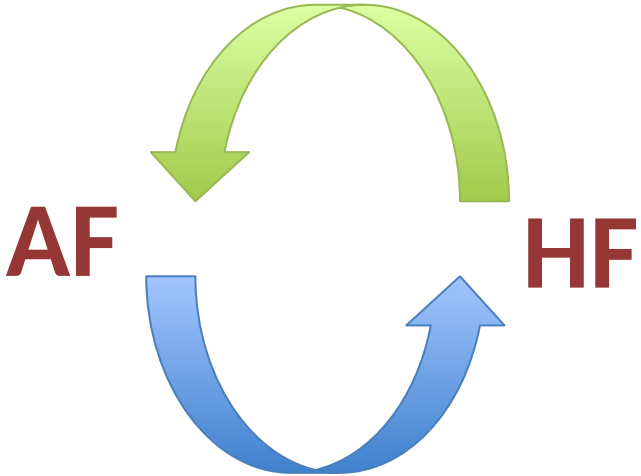


1914 Paul Dudley White:

*"Since auricular fibrillation so often complicates very serious heart failure or even death, unless successful therapy is **quickly** instituted"*

Heart Failure and Atrial Fibrillation

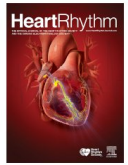
- AF is a common comorbidity in HF patient
- Whatever AF triggers or is triggered by worsening HF is debated
- Multiple sensors provides detailed information about HF status, concurrent with AF progression on a daily basis



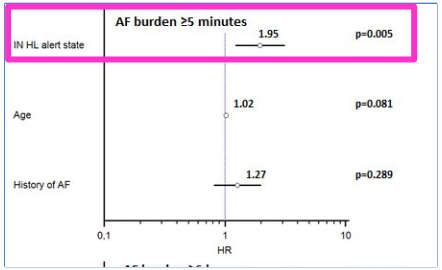
Implantable defibrillator-detected heart failure status predicts atrial fibrillation occurrence

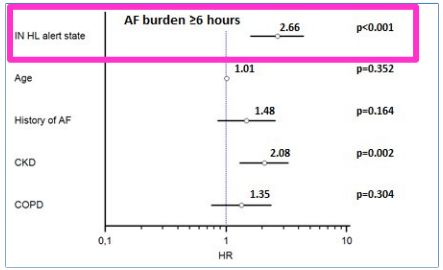
Check for updates

Matteo Bertini, MD, PhD,* Francesco Vitali, MD,* Luca Santini, MD,† Vincenzo Tavoletta, MD,‡ Angelo Giano, MD,§ Gianluca Savarese, MD,¶ Antonio Dello Russo, MD,‖ Vincenzo Ezio Santobuono, MD,** Agostino Mattera, MD,†† Carlo Lavalle, MD,‡‡ Claudia Amellone, MD,§§ Domenico Pecora, MD,¶¶ Raimondo Calvanese, MD,‖‖ Antonio Rapacciuolo, MD,*** Monica Campari, MS,††† Sergio Valsecchi, PhD,††† Leonardo Calò, MD‡‡‡

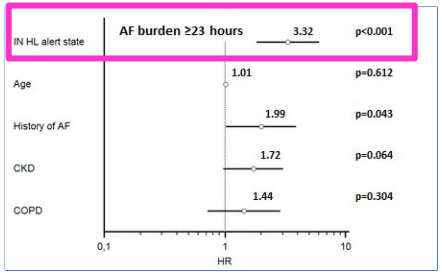


From December 2017 to June 2021, HeartLogic was activated in **568 patients, fup 25 mths**



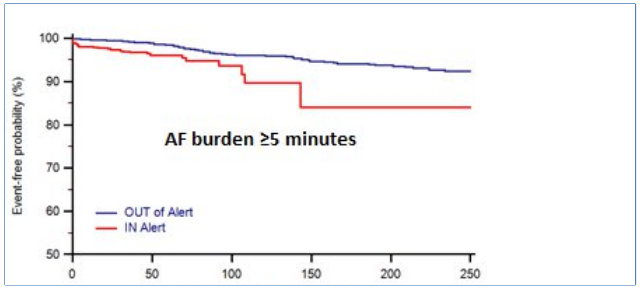


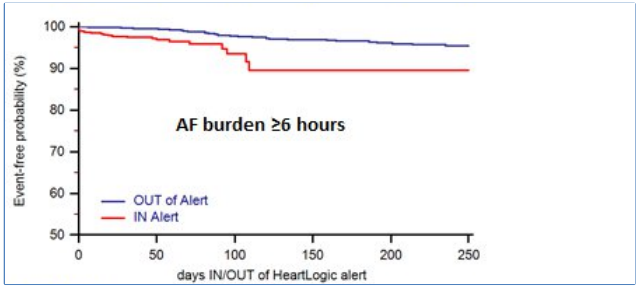
The HeartLogic alert state was independently associated with
- AF burden of ≥5 minutes/day (HR: 1.95),
- AF burden ≥6 hours/day (HR: 2.66),
- AF burden ≥23 hours/day (HR: 3.32);

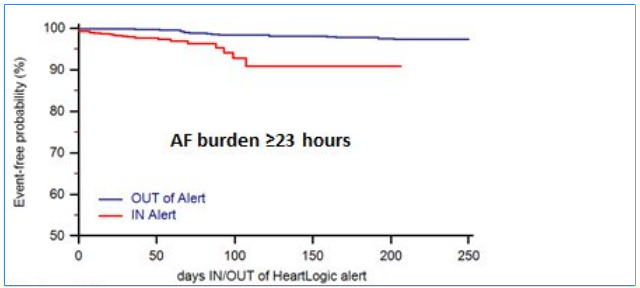


Bertini M. et al., Heart Rhythm. 2022 May;19(5):790-797. doi: 10.1016/j.hrthm.2022.01.020

The intervals of time defined by the algorithm as **periods of increased risk of HF** also **allow risk stratification of AF** according to various thresholds of daily burden (≥5 minutes/day, ≥6 hours/day and ≥23 hours/day).

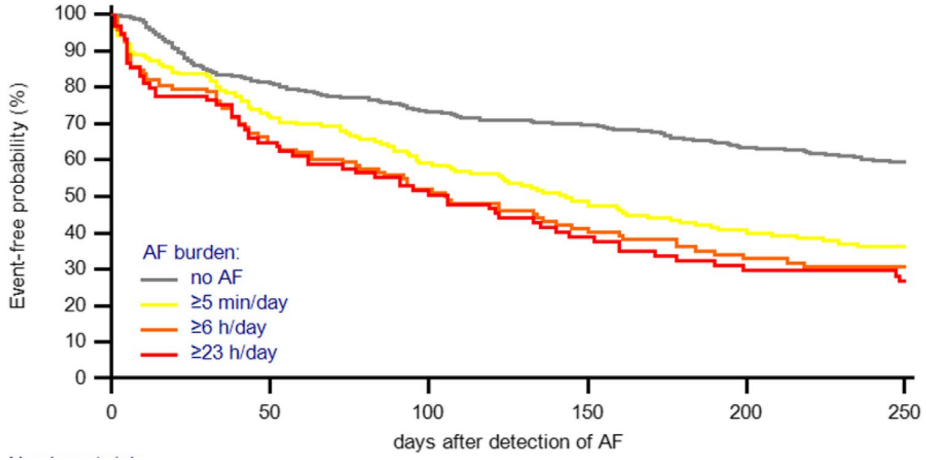






Bertini M. et al., Heart Rhythm. 2022 May;19(5):790-797. doi: 10.1016/j.hrthm.2022.01.020

- The time to AF onset is shorter when a patient enters an IN-alert state period.
- Moreover, AHRE are associated with subsequent HeartLogic alerts, i.e. a surrogate of HF decompensation.



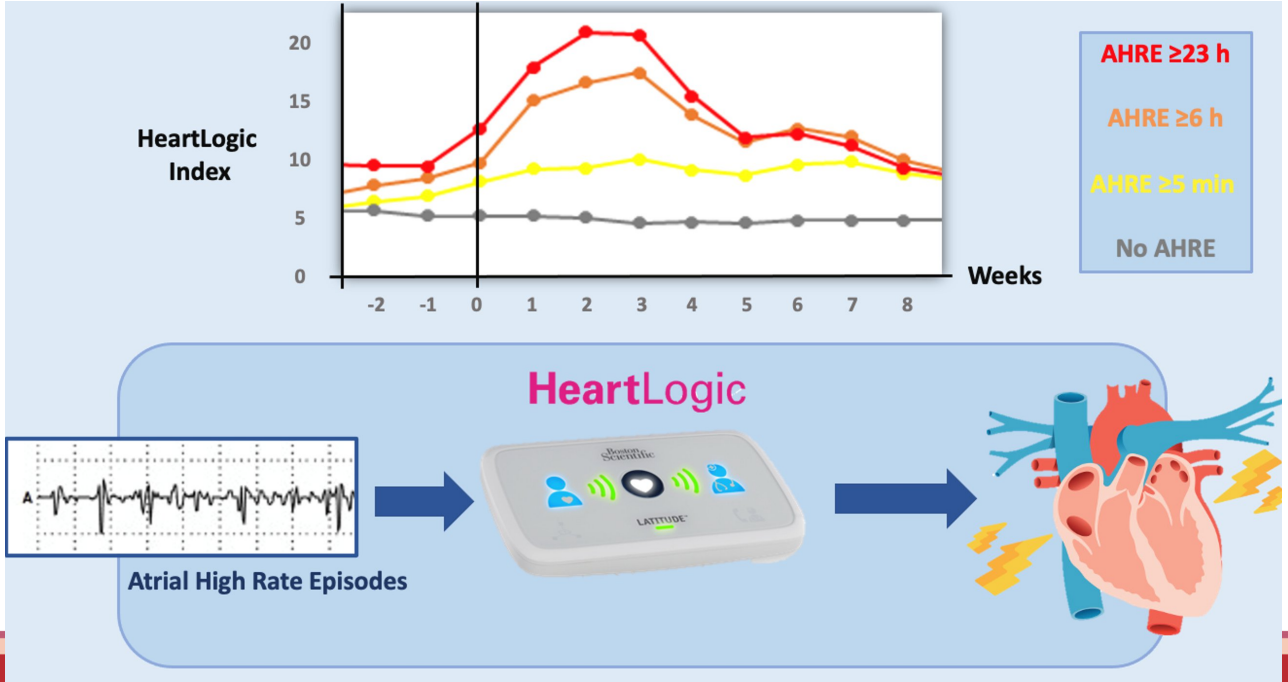
In conclusion, patients who experience ICD-diagnosed HF events are at greatest risk of AF occurrence and viceversa.

Bertini M. et al., Heart Rhythm. 2022 May;19(5):790-797. doi: 10.1016/j.hrthm.2022.01.020

1.The onset of AF occurs earlier when a patient enters an IN-alert state period

2.AF and HF has robust association

3. These findings could lead to the construction of management flowcharts that include decongestive treatments, antiarrhythmic therapies and stroke prevention strategies, in response to the automatic sensors of implanted devices.



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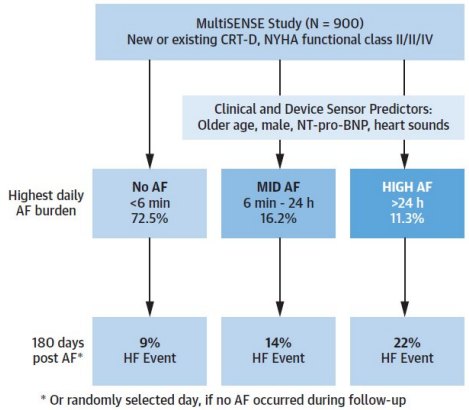
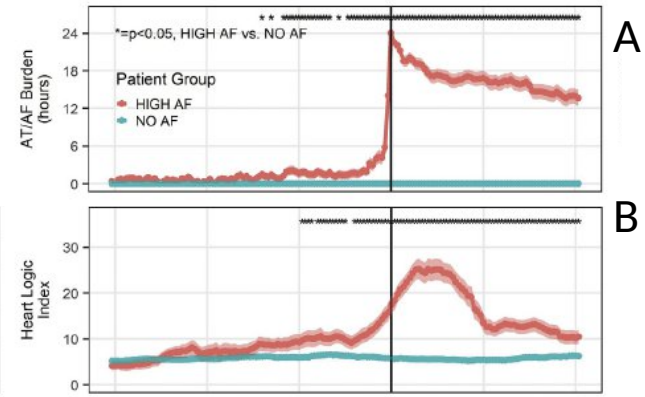
MultiSENSE analysis

Temporal Association of Atrial Fibrillation With Cardiac Implanted Electronic Device Detected Heart Failure Status

Alessandro Capucci, MD,[a] Jorge A. Wong, MD, MPH,[b] Michael R. Gold, MD, PhD,[c] John Boehmer, MD,[d] Rezwan Ahmed, PhD,[e] Brian Kwan, MS,[e] Pramodsingh H. Thakur, PhD,[e] Yi Zhang, PhD,[e] Paul W. Jones, MS,[e] Jeffrey S. Healey, MD, MSc[b]



869 had device-measured AF data available during the median follow-up of 393 days



The **temporal evolution of HeartLogic** (B) index in the HIGH AF PATIENTS aligned with respect to the first day of 24-hour AF, and IN patients in the NO AF group aligned with respect to a randomly selected day (A).

The analysis of device measured sensors changes indicated:

- **a significant worsening of HF status preceding new incidence of AF**
- **AF onset significantly changed multiple physiologic sensors**, including the HeartLogic index

Capucci A. et al., JACC Clin Electrophysiol. 2022 Feb;8(2):182-193. doi: 10.1016/j.jacep.2021.09.015.

Final Considerations

HF management

- Characterized by hospitalization and re-hospitalization
- Timely treatment is crucial but challenging
- Symptoms are difficult to assess
- Patients compliance….
- Heartlogic has been proven to be a validated and reliable tool for early prediction of heart failure events.

Device diagnostics definitely provide additional insight!!!

Thanks for your attention!

The combination of multiple diagnostic sensors provides for increased sensitivity to heart failure events.

Heartlogic has been proven to be a validated and reliable tool for early prediction of heart failure events.

Could we implement an HeartLogic alert-based strategy to optimize a safe and efficacy HF patients management?