

XI Reunión. Estado del Arte en
INSUFICIENCIA CARDIACA

PRÁCTICA CLÍNICA Y MODELOS ORGANIZATIVOS

Sede: Hotel Meliá MaríaPita, A Coruña

A CORUÑA 27-28 SEPTIEMBRE 2024



XI Meeting. State of the Art in
HEART FAILURE

CLINICAL PRACTICE AND ORGANIZATIONAL MODELS

Venue: Hotel Meliá MaríaPita, A Coruña

#ACoruñaHF2024

A CORUÑA 27-28 SEPTEMBER 2024

Usefulness of devices for remote monitoring of heart failure

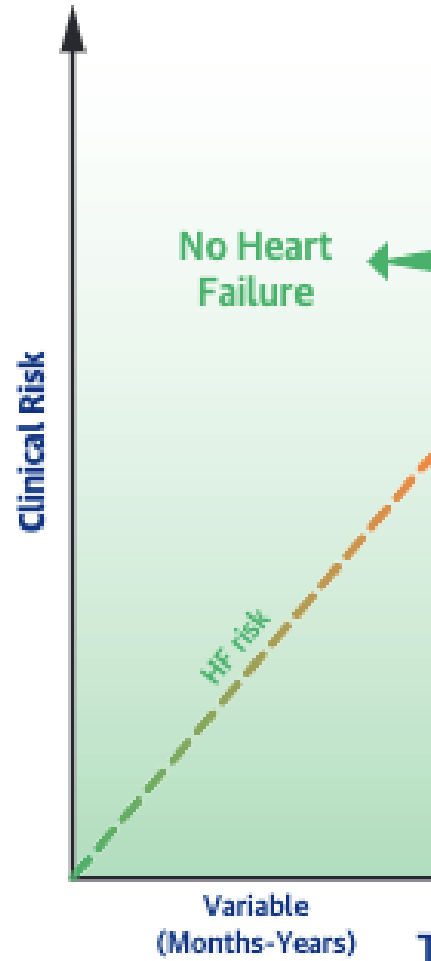
Daniel Enríquez Vázquez

*Unidad de Insuficiencia Cardíaca y Trasplante Cardíaco
Servicio de Cardiología. Complejo Hospitalario de A Coruña
CIBER-CV*

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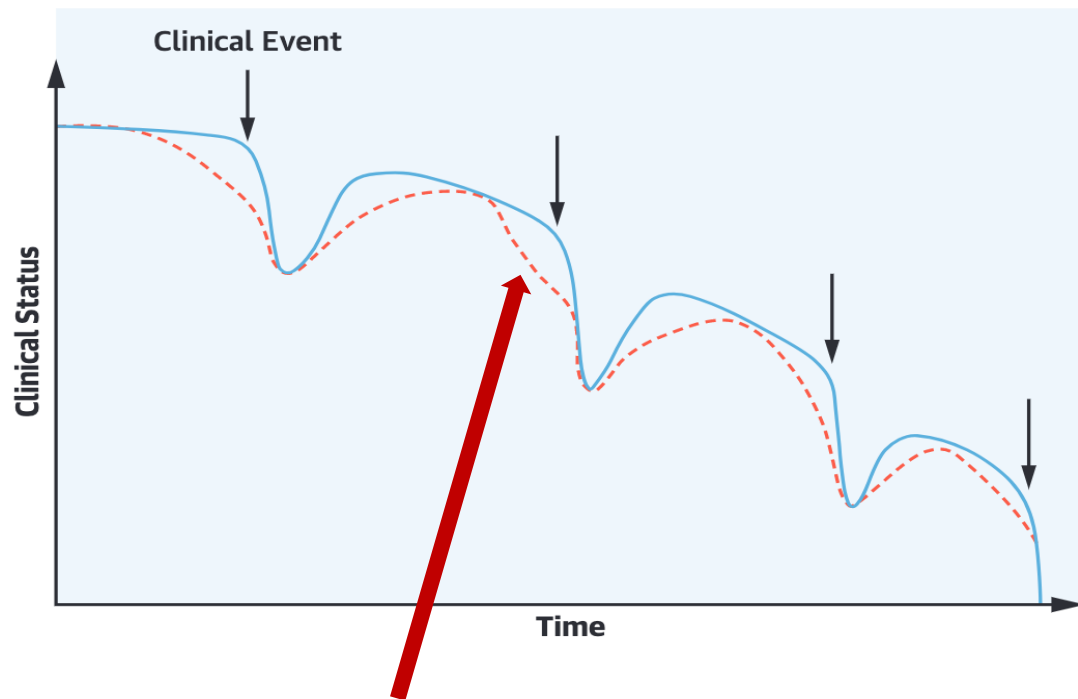
- Introduction
 - Worsening Heart Failure (WHF)
- Remote monitoring in heart failure
 - Types of monitoring
 - Devices in heart failure
- Conclusions

Worsening Heart Failure (WHF)

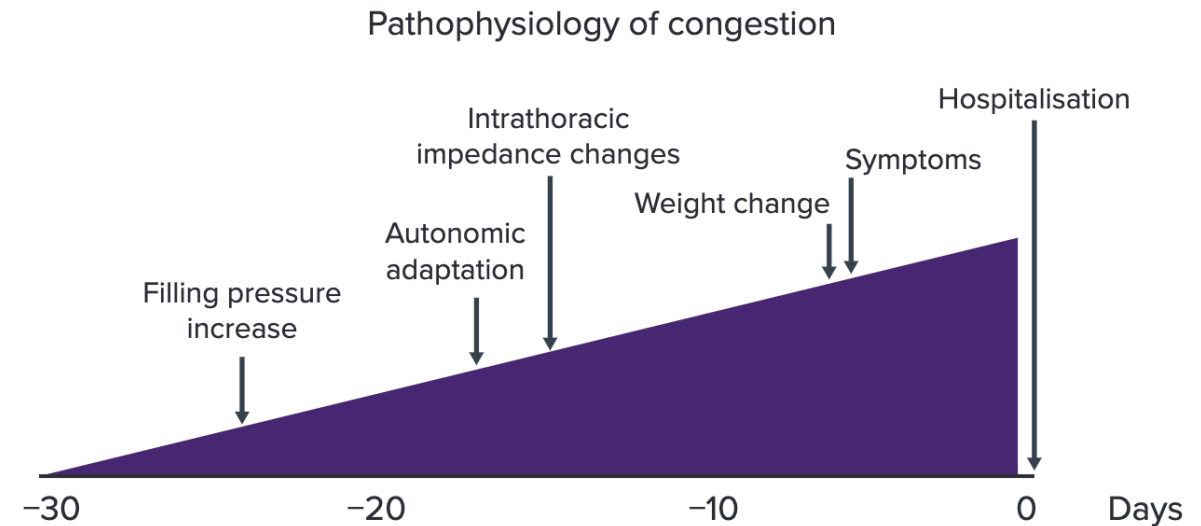


Greene SJ. JACC 2023;81(4):413–24.

Worsening Heart Failure (WHF)



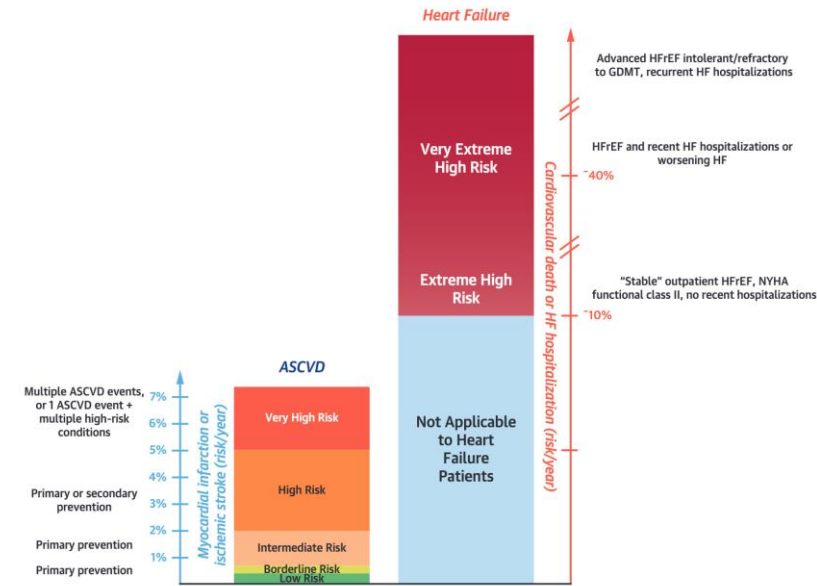
Subclinical deterioration prior to HF event



López-Azor JC. *Card Fail Rev.* 2022;8:e13. Published 2022 Apr 21
Adamson PB. *Curr Heart Fail Rep* 2009;6:287–92
Gheorghiade M. *Am J Cardiol.* 2005;96:11G-17G

Implications of WHF

- Associated with **worse prognosis** and progressive **multiorgan deterioration**.
- More than **1 million** admissions for HF in the USA and Europe per year.
- **Readmissions** up to 24% in the first month and 50% after 6 months.
- One out of every 6 patients admitted for HF **dies** within 30 days of hospitalization.



Ejection fraction	Intrahospital mortality	1 year mortality	HF readmission	Readmission for any cause
Reduced	3,4%	22 100 patients-year	29 100 patients-year	48 100 patients-year
Mildly reduced	2,1%	17 100 patients-year	19 100 patients-year	35 100 patients-year
Preserved	2,2%	17 100 patients-year	17 100 patients-year	42 100 patients-year

Kaplon-Cieslicka A. *Eur J Heart Fail.* 2022;24(2):335-50

Metra, M. *Eur J Heart Fail* 2023. Jun;25(6):776-791

Greene SJ. *JACC* 2023;81(4):413-24

Remote monitoring in HF

- Great promise in the management of HF patients, alerting to **subclinical changes** that allow **intervention before decompensation**.
- Great development during the **pandemic**. Avoids barriers to **access to the healthcare system**.
- Special interest comes from:
 - Impact of **decompensation** on prognosis.
 - Interventions that sought to **reduce readmissions** (e.g., early post-discharge reviews) proved effective.

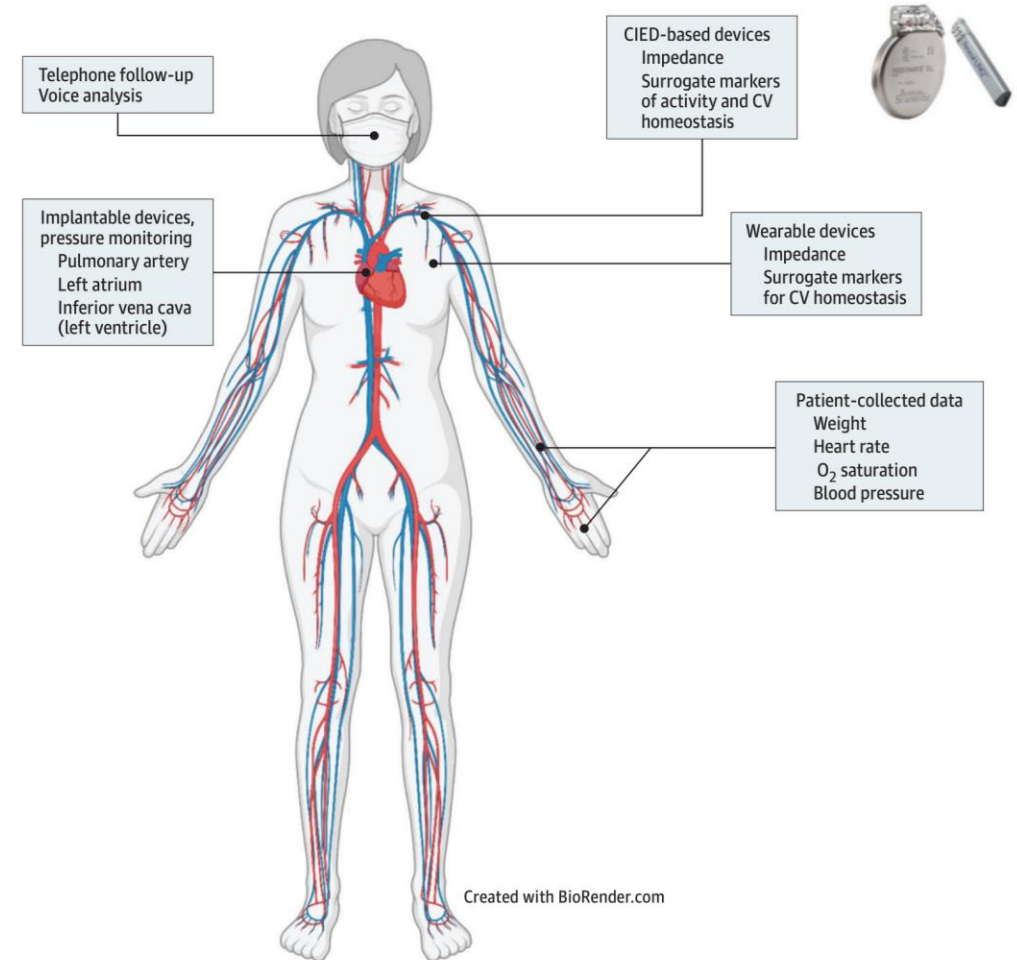
Remote monitoring in HF

Telephone

Implanted devices
(ICD, CRT)

Implantable devices
(invasive)

“Wearables”



Kennel PJ. *JAMA Cardiol.* 2022;7(5):556-564

Telephone and electronic consults

- Collects patient data via **phone** call or **digital platforms**.
- Adapted in most centers: easy, low cost, convenient for the patient.
- “Digital barrier”
- **Conflicting** evidence.
- Fundamental role of the **HF nurse**.
- **Teleconsultation** (e-consultation) has demonstrated:
 - Speed of care.
 - Ability to resolve a relevant number of consultations in a non-face-to-face manner.



Chaudry SI. *N Engl J Med* 2010; 363:2301-2309
Mazón-Ramos P. *ESC Heart Fail.* 2022;9(6):4150–9
Comín-Colet J. *J Telemed Telecare.* 2016;22(5):282-295

Telephone and electronic consults

TIM-HF2

- >2000 patients. Multicentric, randomized
- Better patient selection than TIM-HF
- Daily clinical data and questionnaire
- Multidisciplinary approach

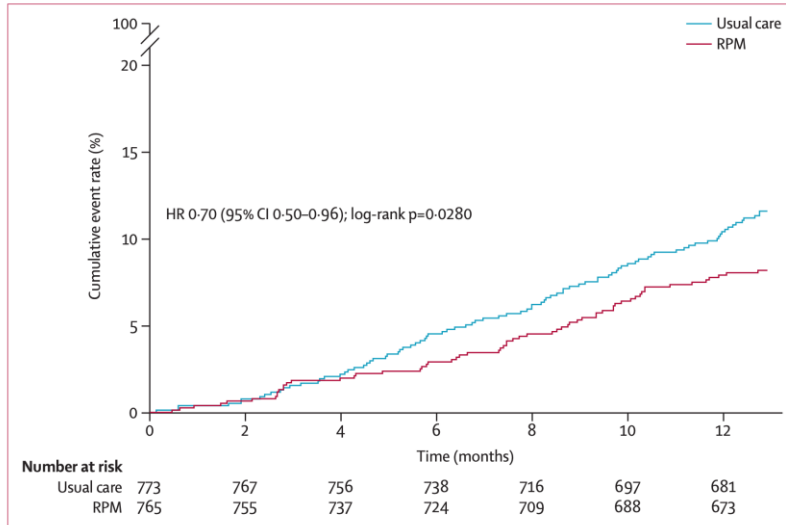
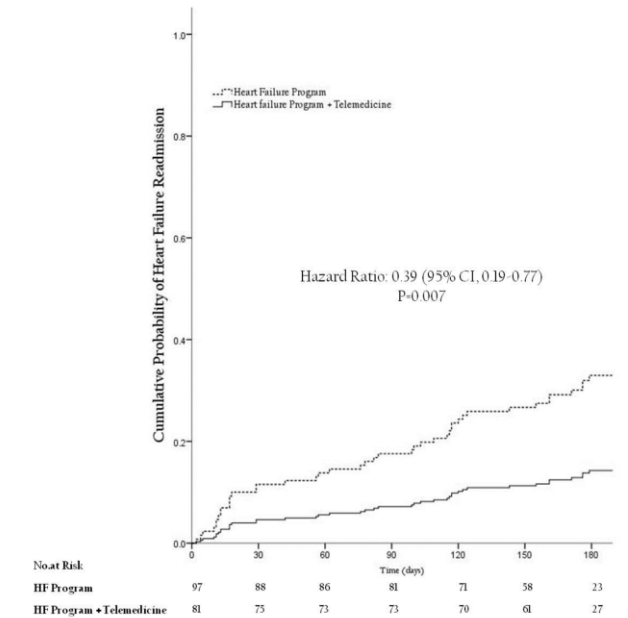
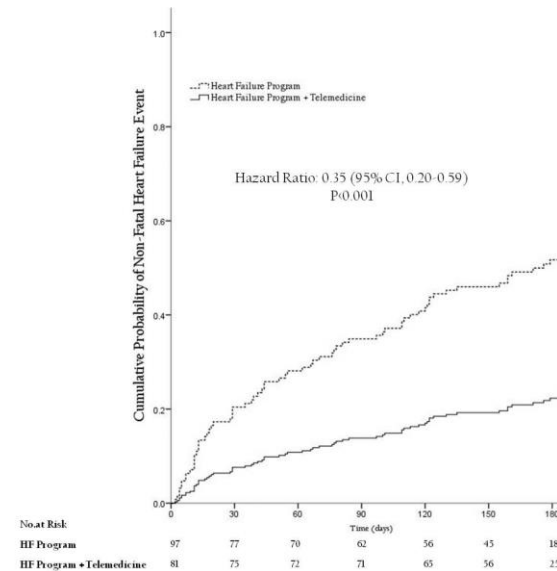


Figure 2: Kaplan-Meier cumulative event curve for all-cause death
HR=hazard ratio. RPM=remote patient management.

Reduction in admission days and all cause mortality

iCOR

- 188 patients. Unicentric and randomized
- High risk patients
- Nurse control, they could modify treatment
- Multidisciplinary approach



Koehler F. *Lancet*. 2018;392(10152):1047-1057
Comín-Colet J. *J Telemed Telecare*. 2016;22(5):282-295

Wearables

- Large number of devices under development
- Main methods used:
 - Pulmonary **congestion** measurements.
 - Integrate **vital signs** and **activity** measures
- Little scientific evidence.
- Major findings in reduction of **heart failure hospitalization**.
- No FDA approval.



Shochat MK. *J Card Fail.* 2016;22(9):713-722
Kennel PJ *JAMA Cardiol* 2022;7(5):556-564
Lala A. *ESC Heart Fail.* 2021;8(2):1047-1054

Cardiac implantable electronic devices (CIED) based monitoring

- Increasing number of intracavitary devices.
- Possibility of remote monitoring
- Modification of care and treatment based on findings.

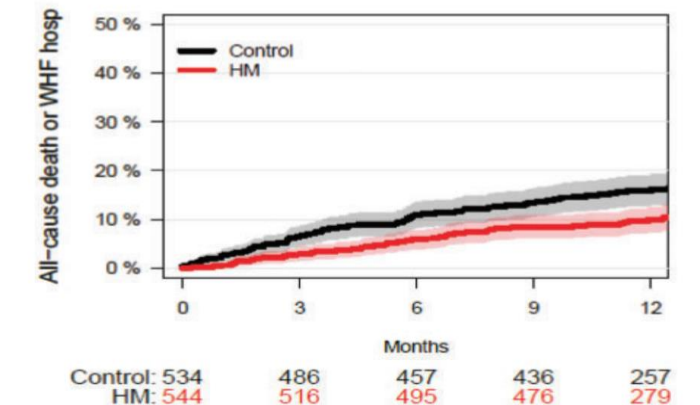
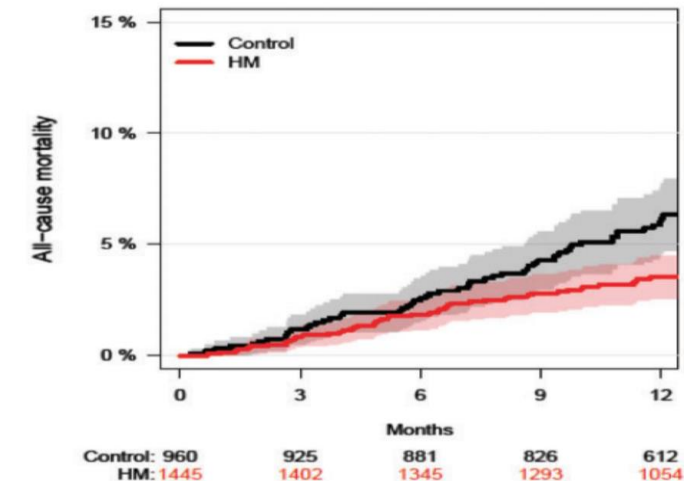
Table 1 Included trials

	TRUST ³	ECOST ⁵	IN-TIME ¹²
No. of centres	102 USA sites	43 French sites	26 German sites, 10 sites elsewhere ^a
Patient eligibility	Class 1 indication for ICD, not pacemaker dependent	Indication for ICD, not NYHA class IV	Indication for ICD or CRT-D, heart failure (≥ 3 months), NYHA class II or III, LVEF $\leq 35\%$
Primary objective	To evaluate safety and efficacy of extended IO intervals	To compare major CVAEs including all-cause death	To compare heart failure outcomes using composite ("Packer") score ^b
Follow-up schedule			
HM group	IO at 3M and 15M. HM replaced IO at 6M, 9M, and 12M	IO at 1-3M, 15M, and 27M. HM replaced IO at 9M and 21M	IO at 12M, and in-between according to hospital routine
Control group	IO every 3M	IO at 1-3M, then every 6M	Same as in the HM group
Blinded endpoint committee	No	Yes	Yes

^aDenmark (three sites), Czech Republic (two), Israel (two), Australia (one), Austria (one), Latvia (one).

^bThe score combines all-cause death, overnight hospitalization for heart failure, change in NYHA class, and change in patient global self-assessment.

CRT-D, cardiac resynchronization therapy defibrillator; CVAE, cardiovascular adverse event; ECOST, Effectiveness and cost of ICDs follow-up schedule with telecardiology; HM, Home Monitoring; ICD, implantable cardioverter-defibrillator; IN-TIME, Influence of HM on mortality and morbidity in heart failure patients with impaired left ventricular function; IO, in-office visit; LVEF, left ventricular ejection fraction; M, months; NYHA, New York Heart Association; TRUST, Lumos-T safely reduces routine office device follow-up.



Kennel PJ JAMA Cardiol 2022;7(5):556-564
Hindricks G. Lancet 2014;384:583-590
Hindricks G. Eur Heart J. 2017;38(22):1749-1755

Cardiac implantable electronic devices (CIED) based monitoring

HF

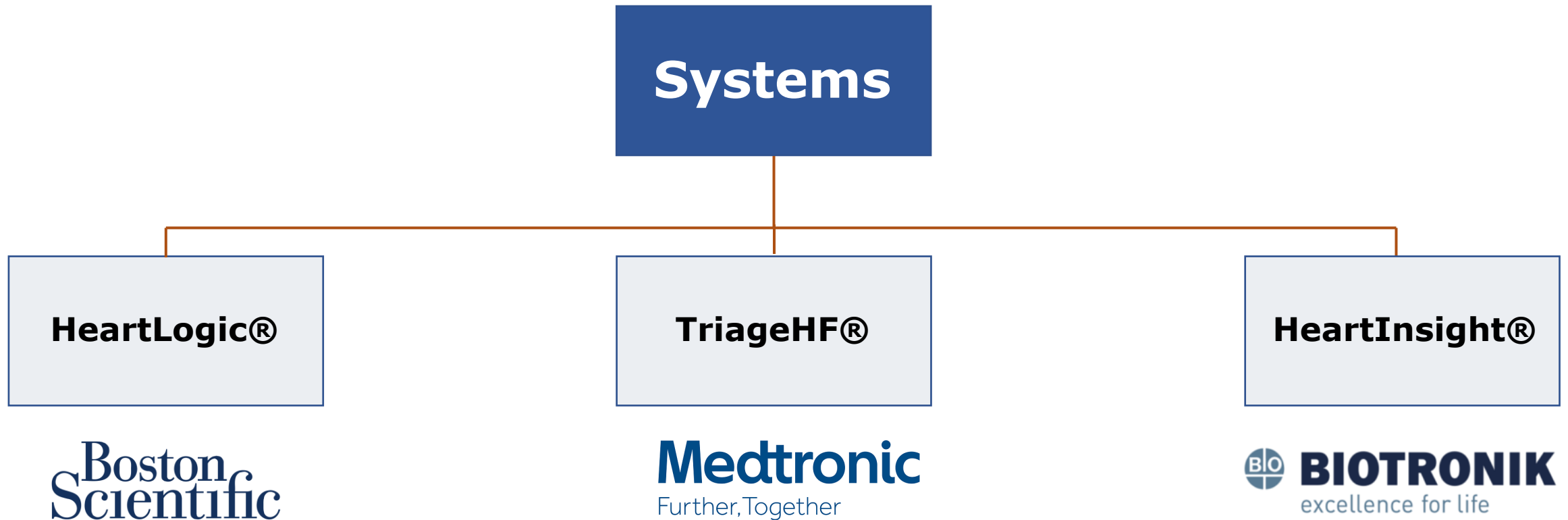
- Development of algorithms for the detection of heart failure decompensation.
- Need for ICD and/or CRT
- Each commercial company develops its own algorithms
- Evidence in favor of improved patient prognosis

Kennel PJ JAMA Cardiol 2022;7(5):556-564

Hindricks G. Lancet 2014;384:583-590

Hindricks G. Eur Heart J. 2017;38(22):1749-1755

Cardiac implantable electronic devices (CIED) based monitoring

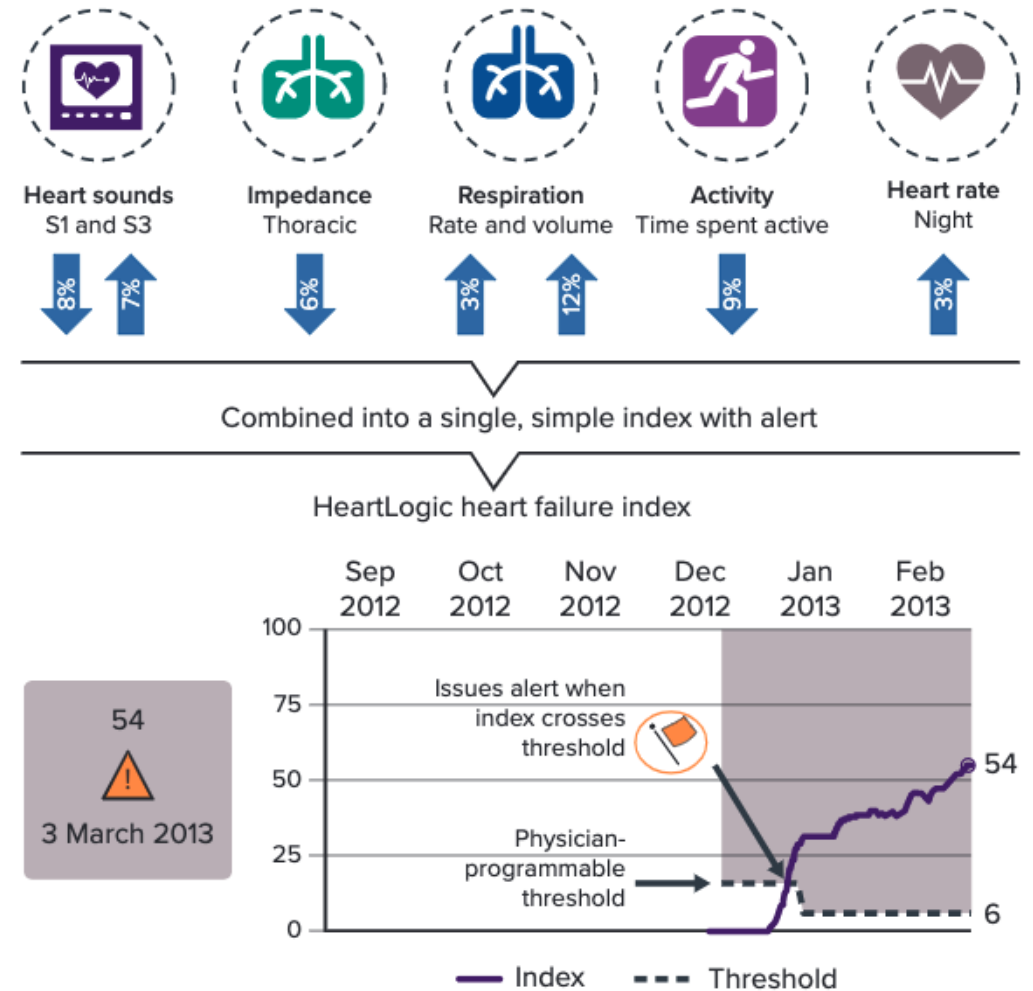


Kennel PJ JAMA Cardiol 2022;7(5):556-564

HeartLogic

- **Multiparametric** algorithm that helps stratify the risk of heart failure decompensation.
- It is a **patient-specific index**. The baseline value is calculated over 3 months.
- An **increase** in this index indicates HF decompensation.
- The usual value is **16** (can be adjusted individually).

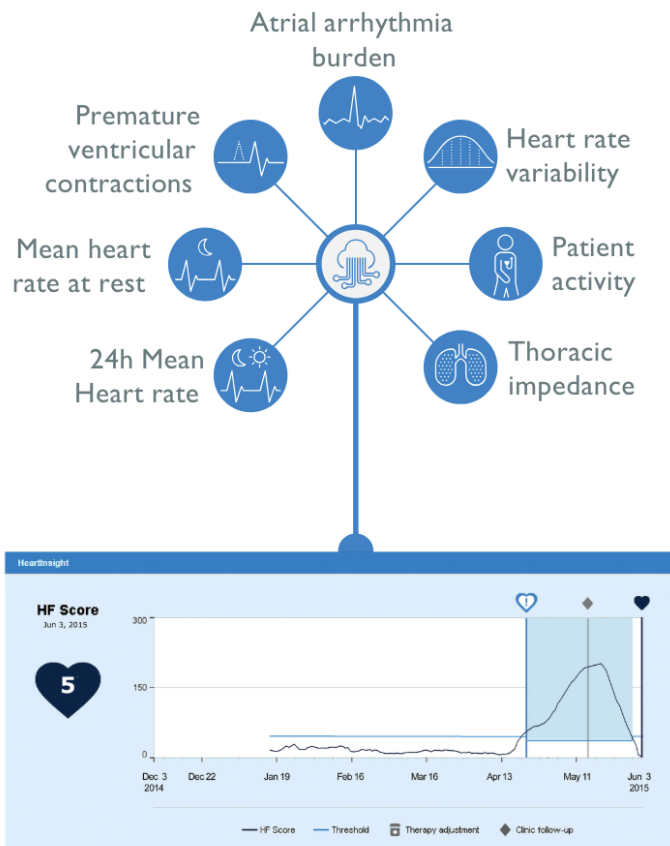
Boston
Scientific



Boehmer JP. JACC Heart Fail 2017;5:216–25
López-Azor JC. Cardiac Failure Review 2022;8

HeartInsight

HeartInsight Heart Failure (HF) Score



Meta-analysis



9 trials



369 worsening HF hospitalizations

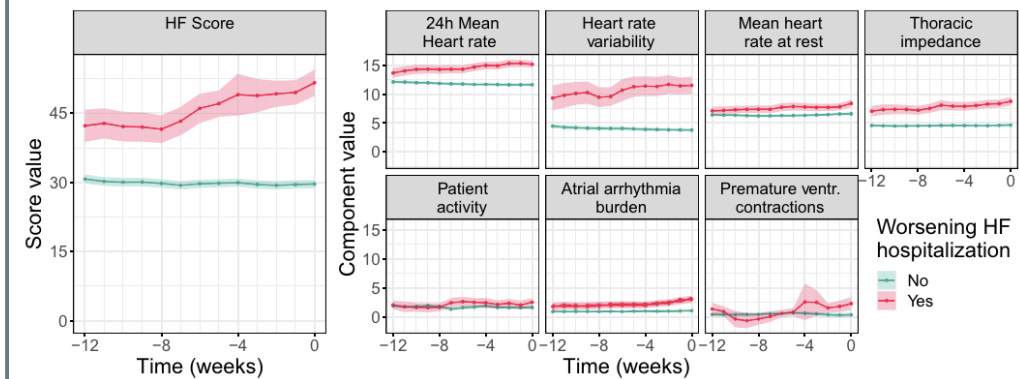


2,050 patients with ICD/CRT-D



3,939 cumulative follow up years

HF Score and components significantly increased before worsening HF hospitalizations:



The score components showed different behavior and contribution, reflecting different mechanisms or stages in the decompensation process. Trends of the HF Score may serve as a quantitative estimate of HF condition and evolution prior to worsening HF hospitalization.

Botto GL et al. *Europace*. 2024 Feb 1;26(2):euae032

TriageHF

Multiparametric algorithm

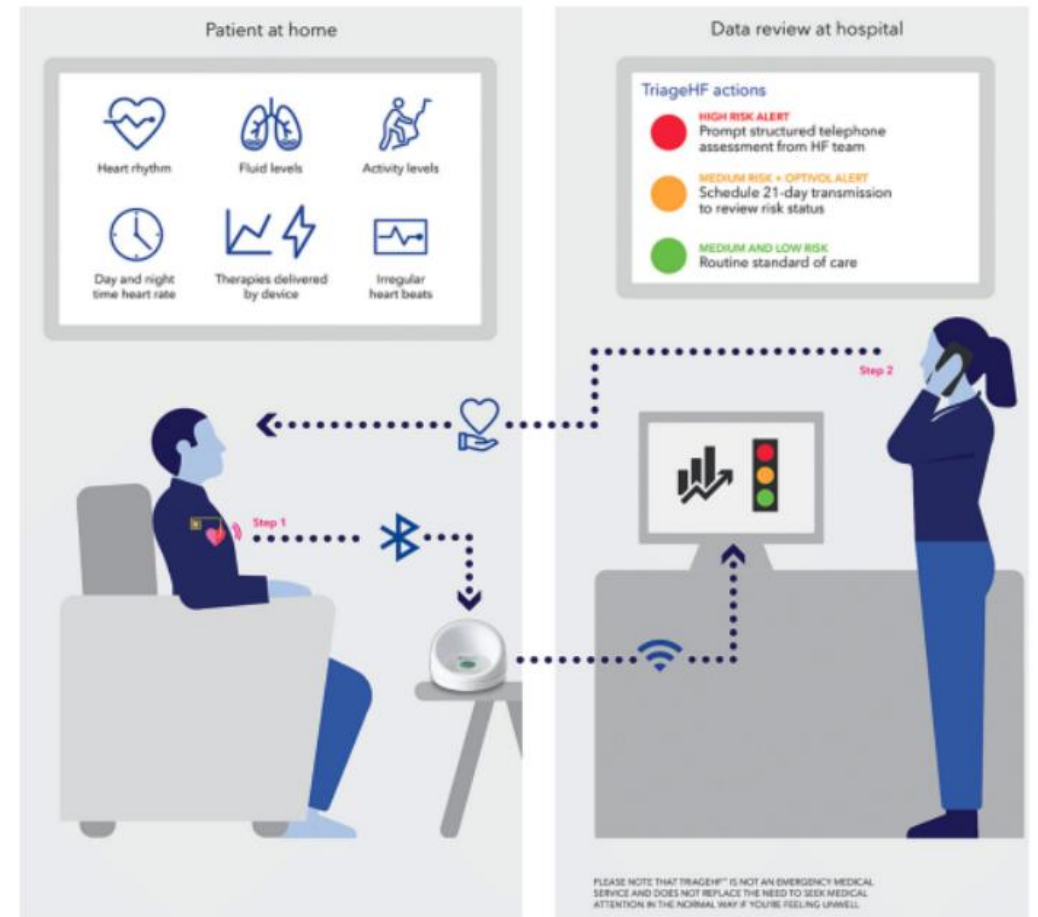
Rhythm

Arrhythmia

Device use

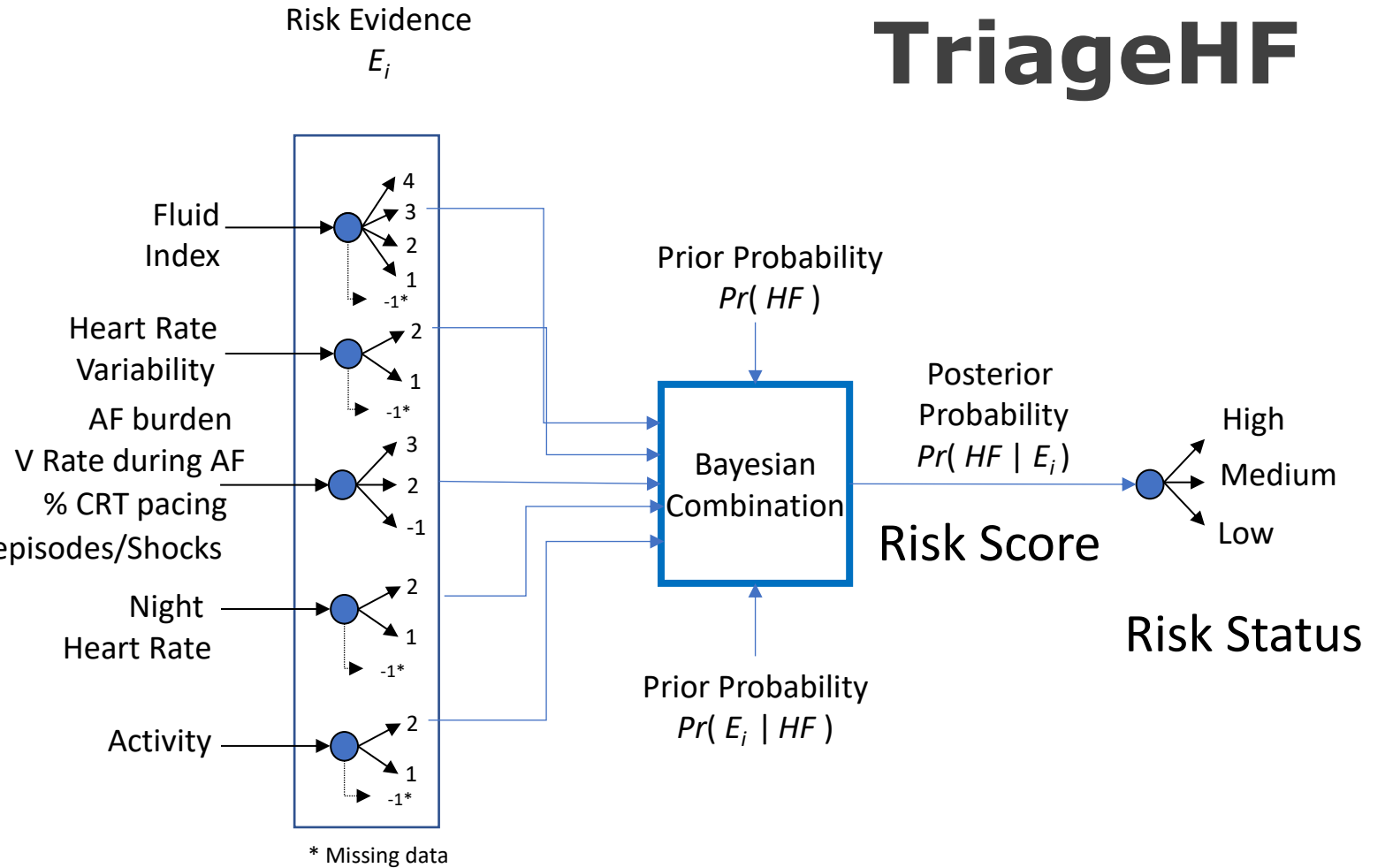
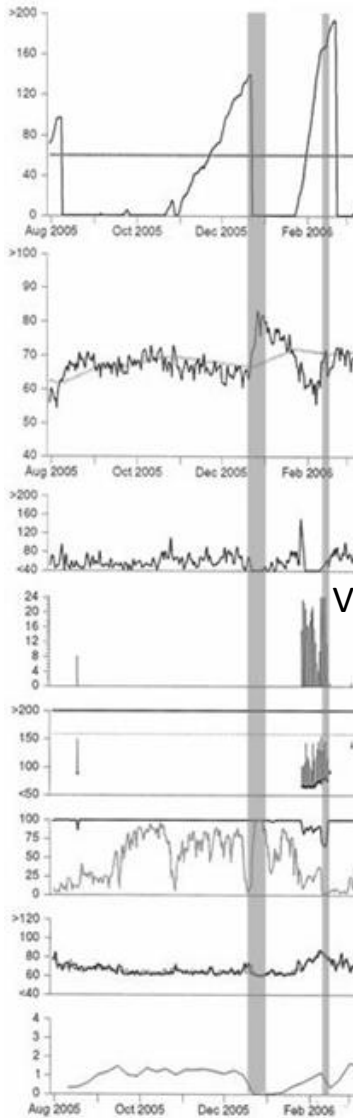
Congestion indexes

Patient activity



TriageHF

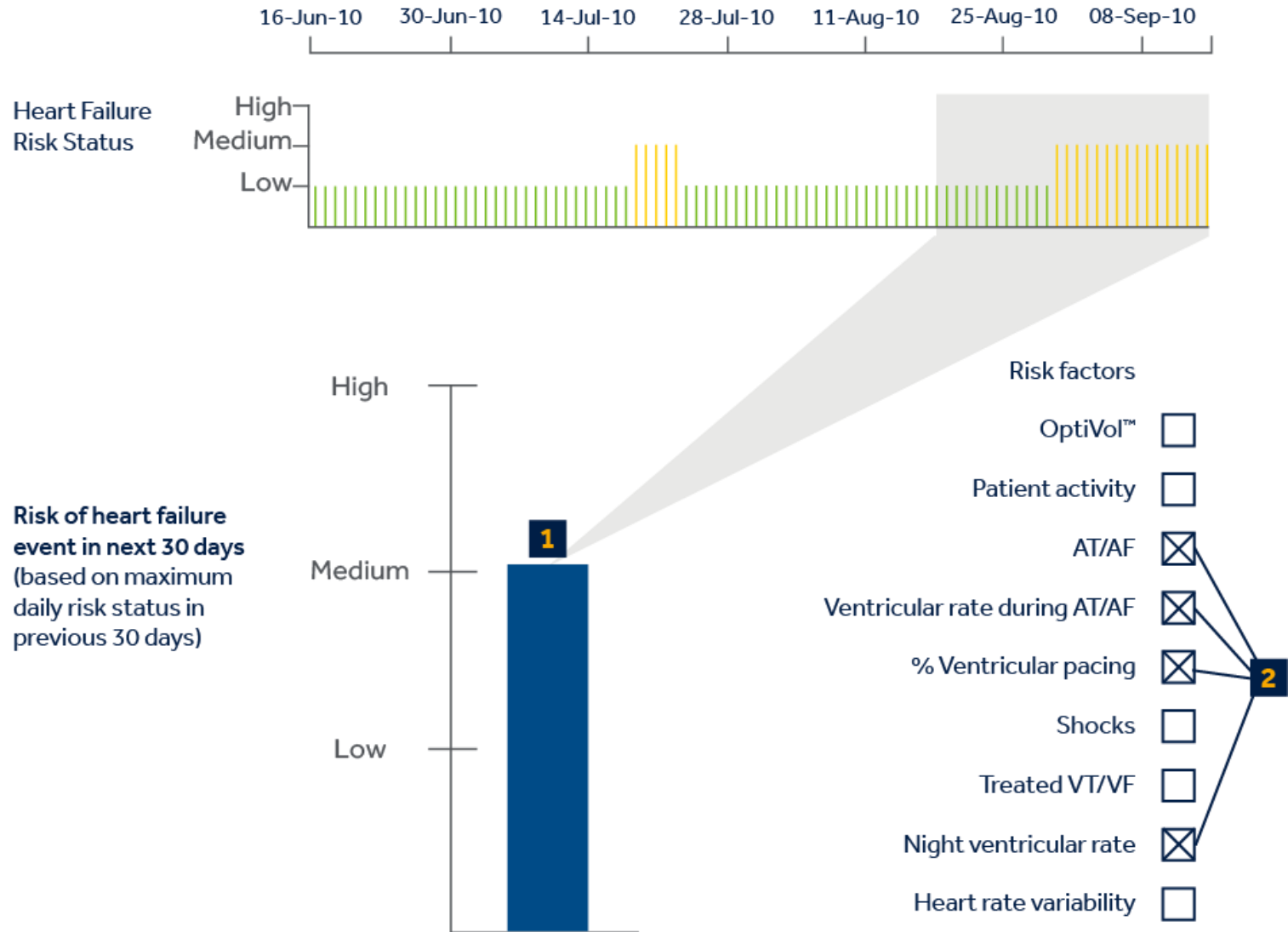
- Fluid Index
- Intra-thoracic Impedance
- Heart Rate Variability
- AF burden
- V Rate during AF
- % CRT pacing
- Night Heart Rate
- Activity



TriageHF

Calculates the risk of a HF event in the next 30 days

Based on data obtained in the previous 30 days



TriageHF

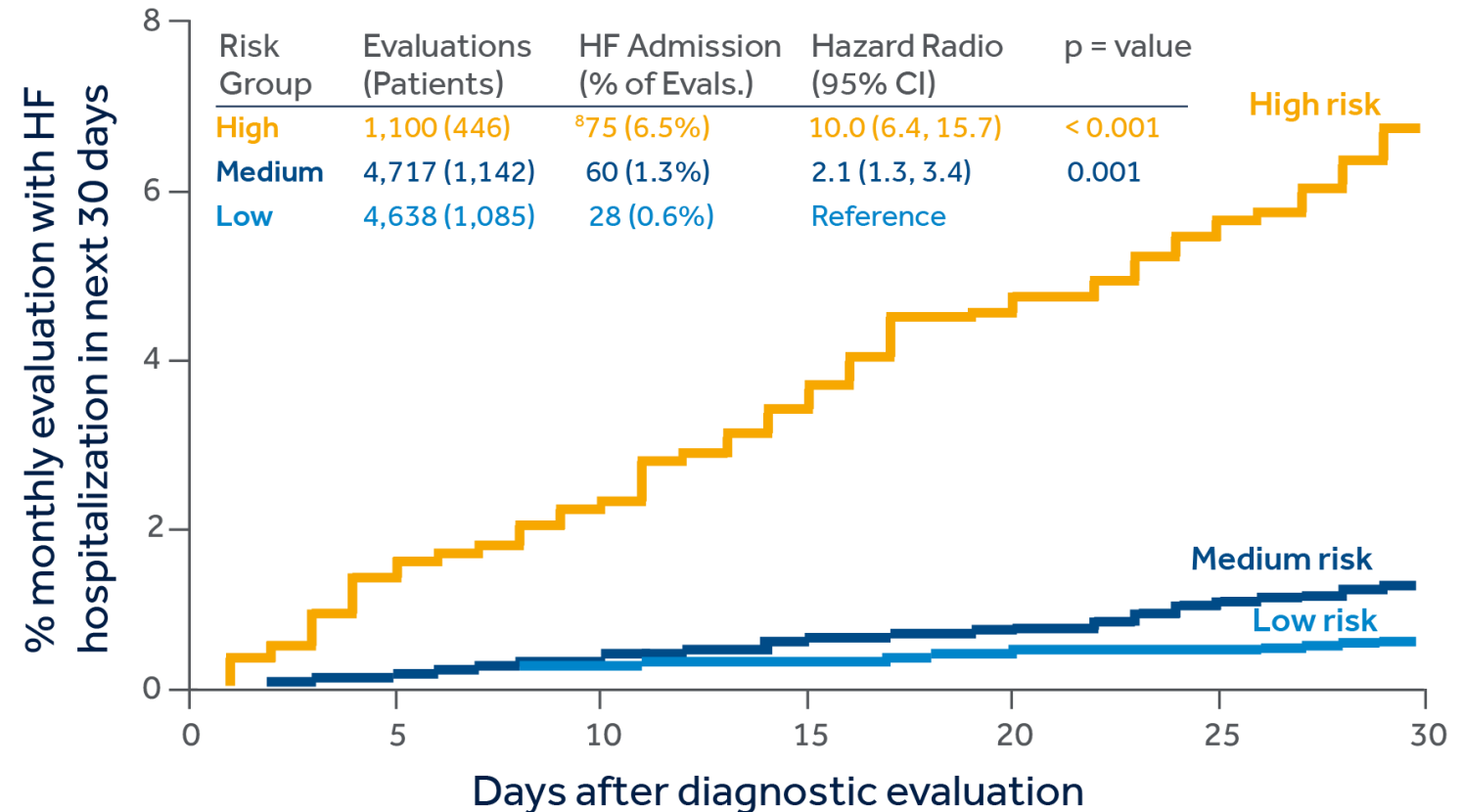
- Uses data from the previous 30 days to predict the **risk of HF decompensation** in the next 30 days.
- Calculated when data is received by the CareLink™ network (**shared management required**).
- Available from **65 days** after implantation (OptiVol™ needs 34 days to start working and TriageHF 30 more days to stratify risk)

Factors	Threshold
Optivol	$\geq 30 \Omega$; $\geq 60 \Omega$; $\geq 100 \Omega$
Activity	≤ 60 min/ día
AF/AT	≥ 1 hora/ día
Frec V durante AT/AF	≥ 90 lpm durante FA ≥ 6 horas/ día
% VP	$\leq 90\%$ (CRT)
Shocks	≥ 1
VF/VT and therapies	≥ 5
Night heart rate	≥ 85 lpm o ≤ 55 lpm
Heart rate variability	≤ 60 ms ²

TriageHF

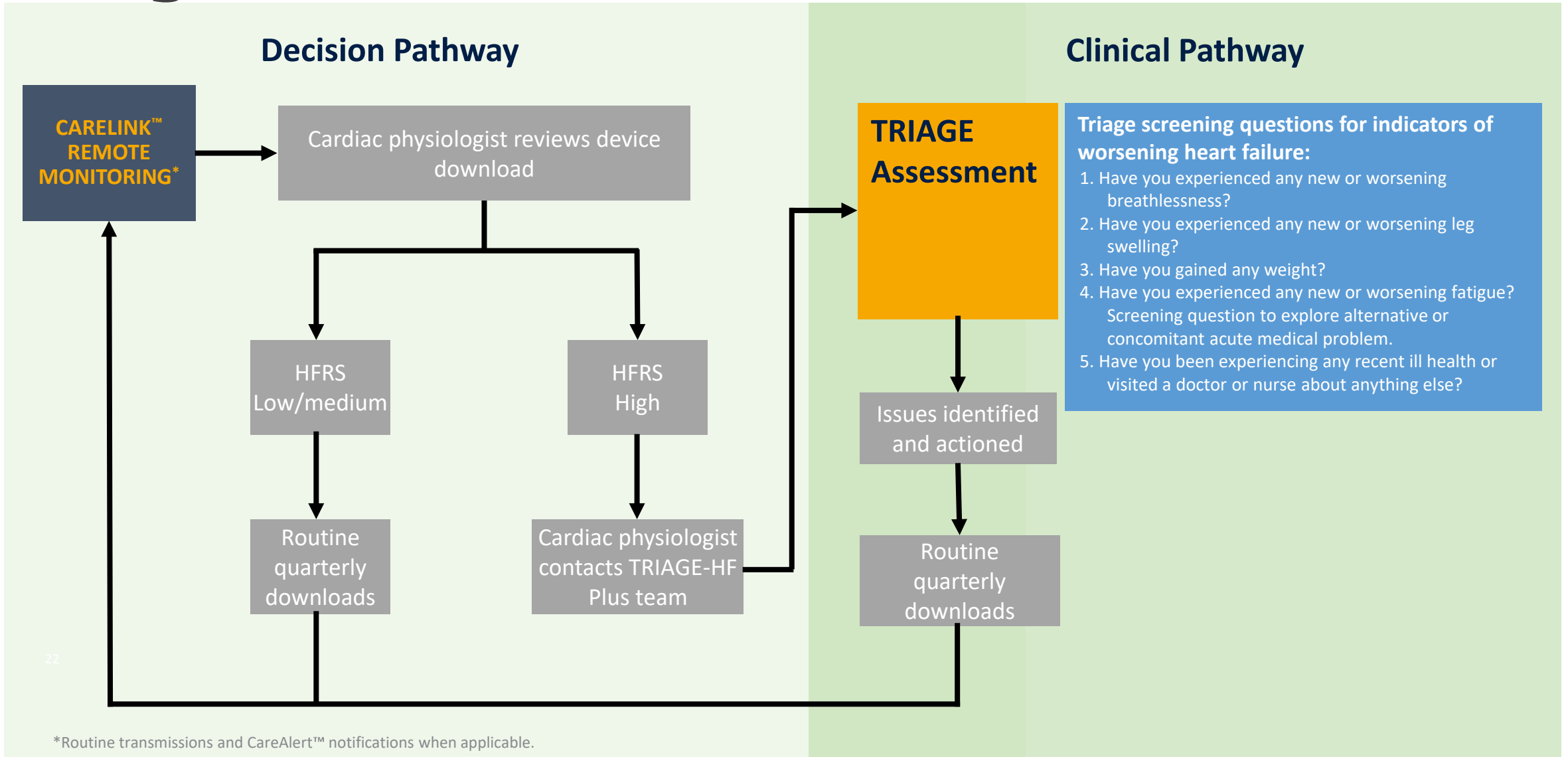
High-risk patients are **10 times** more likely to be **hospitalized** in the next **30 days** than low-risk patients.

Development and validation of an integrated diagnostic algorithm based on device-monitored parameters to identify patients at risk of hospitalization for heart failure in an outpatient setting



Cowie MR, et al. *Eur Heart J.* 2013;34:2472-2480

TriageHF Plus



TriageHF

TRIAGE HF
PLUS

High
Risk



Triage screening questions for indicators of worsening heart failure:

1. Have you experienced any new or worsening breathlessness?
2. Have you experienced any new or worsening leg swelling?
3. Have you gained any weight?
4. Have you experienced any new or worsening fatigue? Screening question to explore alternative or concomitant acute medical problem.
5. Have you been experiencing any recent ill health or visited a doctor or nurse about anything else?

+

Last consultation and next consultation data

Recent changes in treatment

Consultations in Primary Care and other Specialties

TriageHF Plus

Triage-HF Plus: a novel device-based remote monitoring pathway to identify worsening heart failure

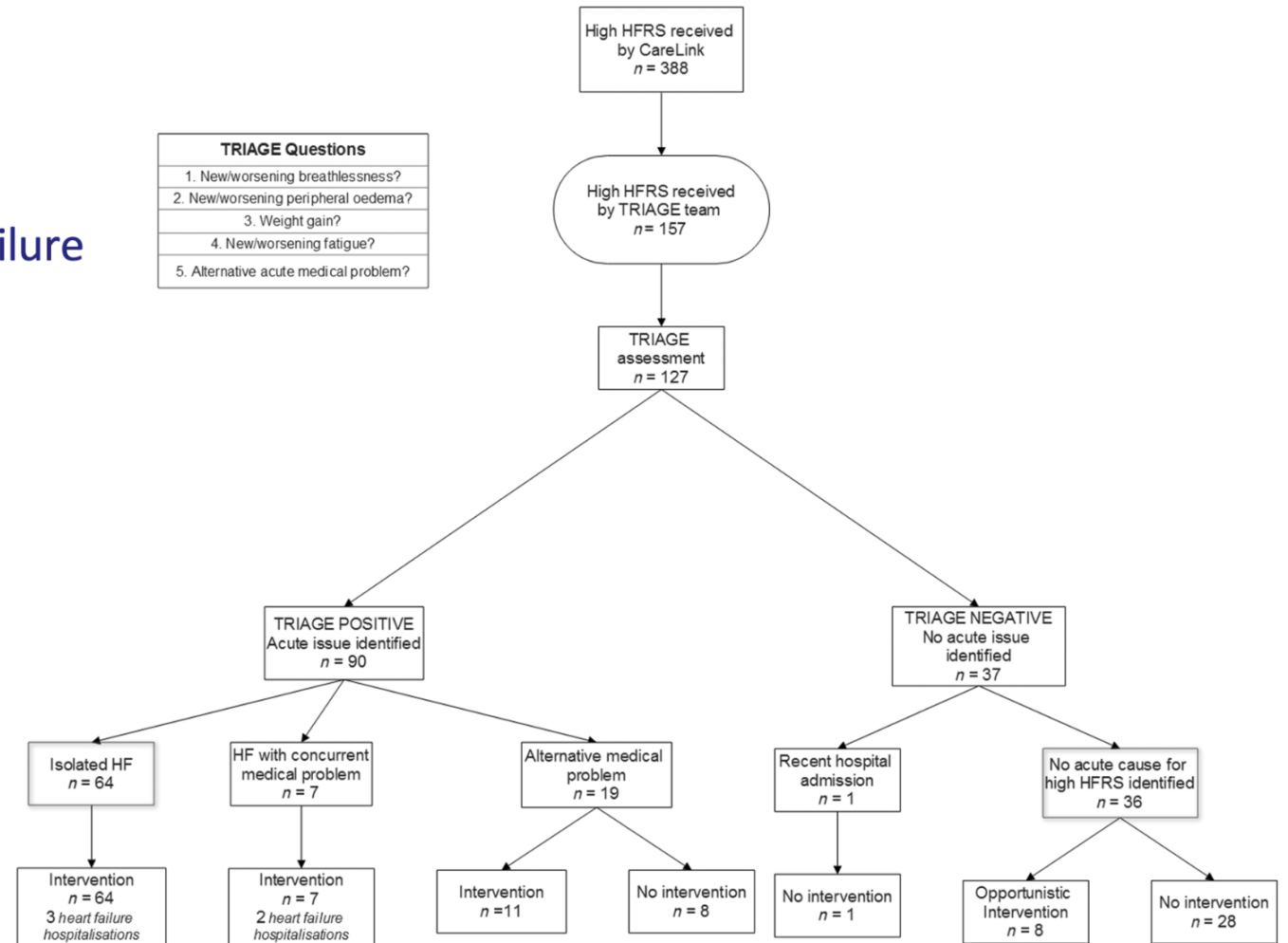
Analysis of > 2000 transmissions

388 high risk

Follow-up 27 months

55,9% had WHF
Sensitivity > 98%

TRIAGE Questions
1. New/worsening breathlessness?
2. New/worsening peripheral oedema?
3. Weight gain?
4. New/worsening fatigue?
5. Alternative acute medical problem?

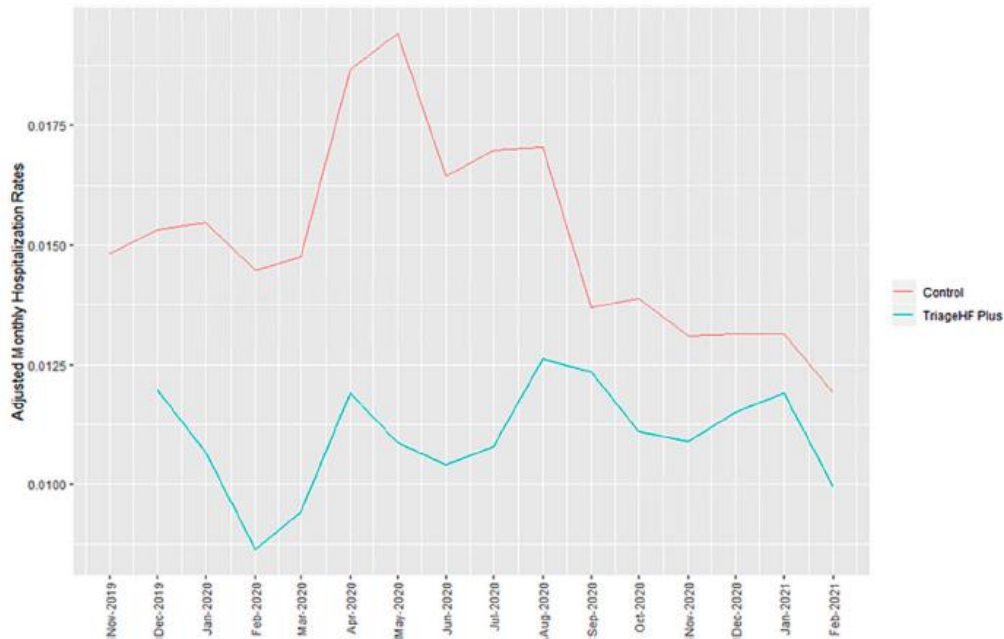


Ahmed FZ. ESC Heart Failure 2020;7(1):108–17

TriageHF Plus

Association of a device-based remote management heart failure pathway with outcomes: TriageHF Plus real-world evaluation

HF decompensation **detection**
Hospitalization **reduction**

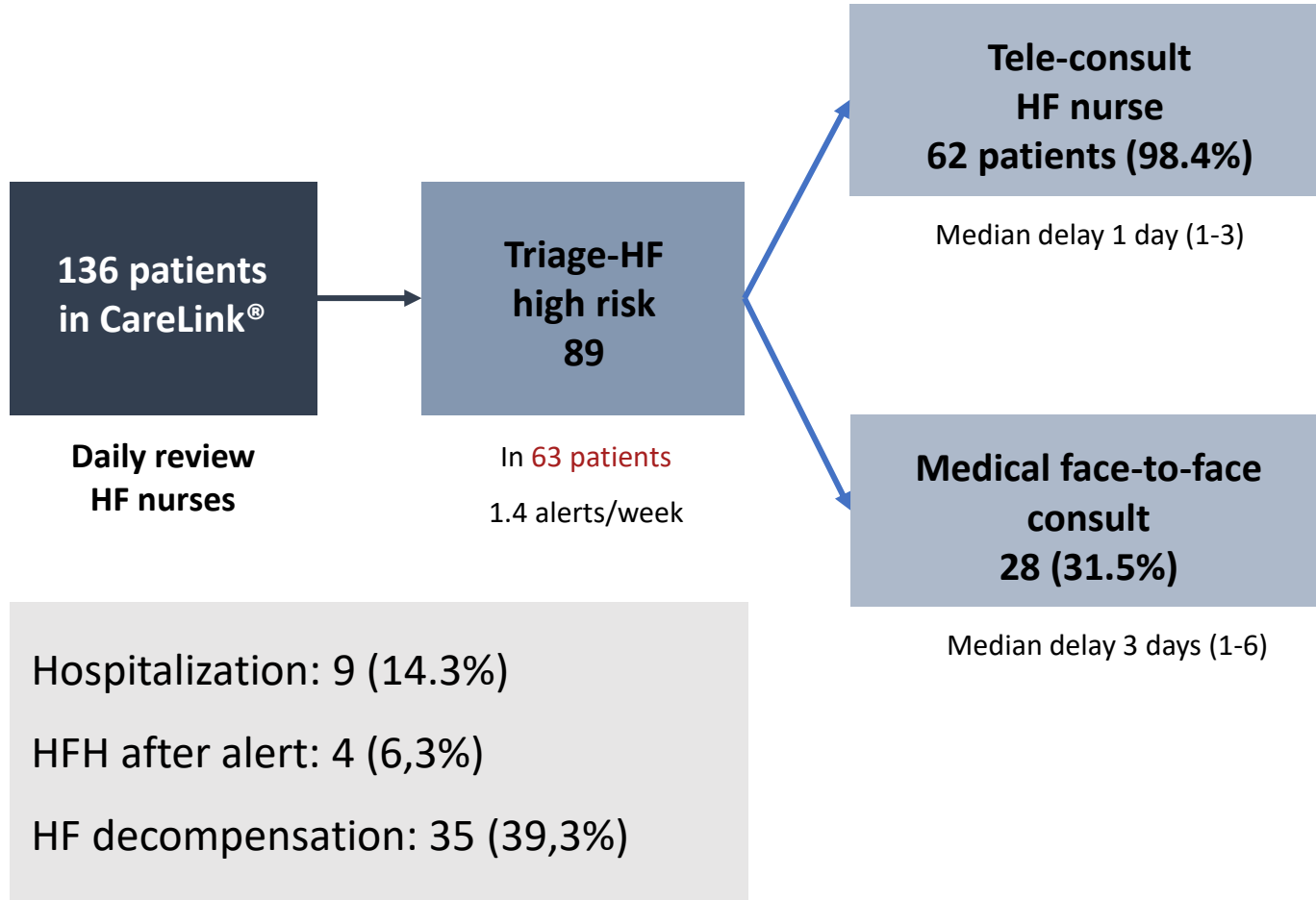


TriageHF Plus pathway	Total (N = 443) n (%) unless otherwise stated
High-risk status transmissions, <i>n</i>	196
Already hospitalized on date of transmission	9 (4.6%)
High-risk status transmission 'alerts' initial contacts	
Initial contact made	182/196 (93%)
Time to initial contact (days), median (IQR)	3 (1–4)
Acute medical issue identified	79/182 (43%)
Acute heart failure (HF)	50/79 (63%)
Clinical action taken ^a	44/79 (56%)
No acute issue identified	103/182 (57%)
Recent intervention/admission	5/103 (5%)
Actions taken at initial contact in those where acute HF was identified (<i>n</i> = 44)	
Change in cardiovascular medications ^b	33/44 (75%)
Investigations ^c	12/44 (27%)
Place of care	
Advised to attend ED/hospital attendance, <i>n</i>	<5
Existing OP follow-up escalated, <i>n</i>	<5
Treatment in day-care/in community ^d , <i>n</i>	<5
New HF outpatient follow-up arranged	9/44 (20%)
Advice: long-term care management	7/44 (16%)
Advice: daily lifestyle	11/44 (25%)
Referral to other specialist, <i>n</i>	<5
Referral to primary care team, <i>n</i>	<5

Ahmed FZ. ESC Heart Fail. Published online May 7, 2024

TriageHF CHUAC

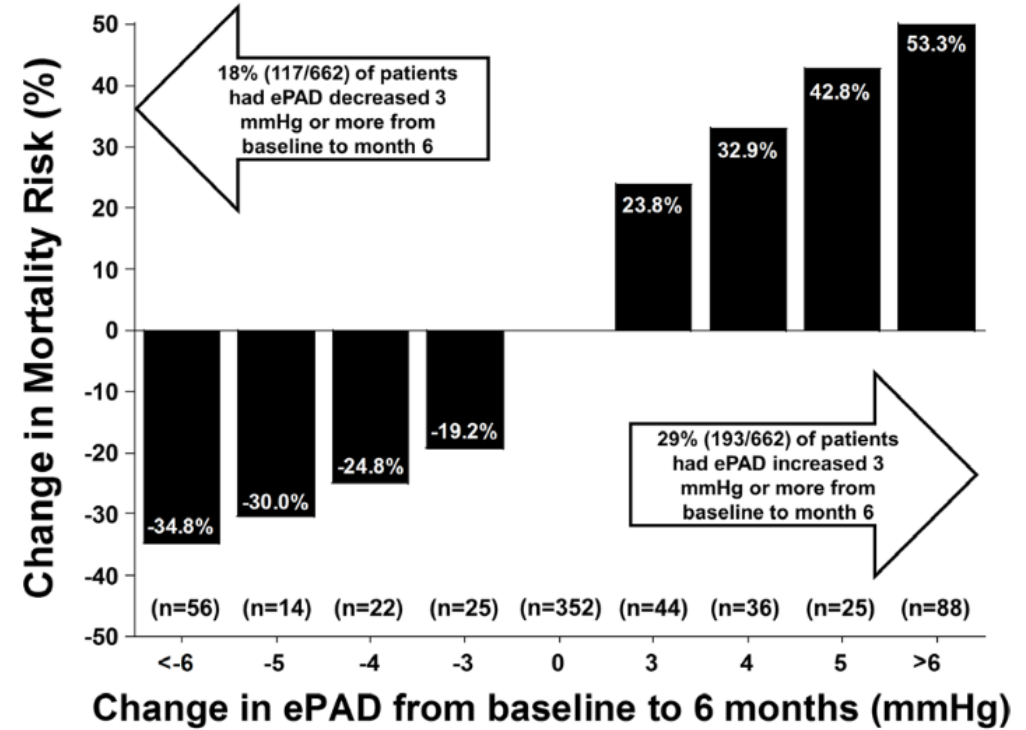
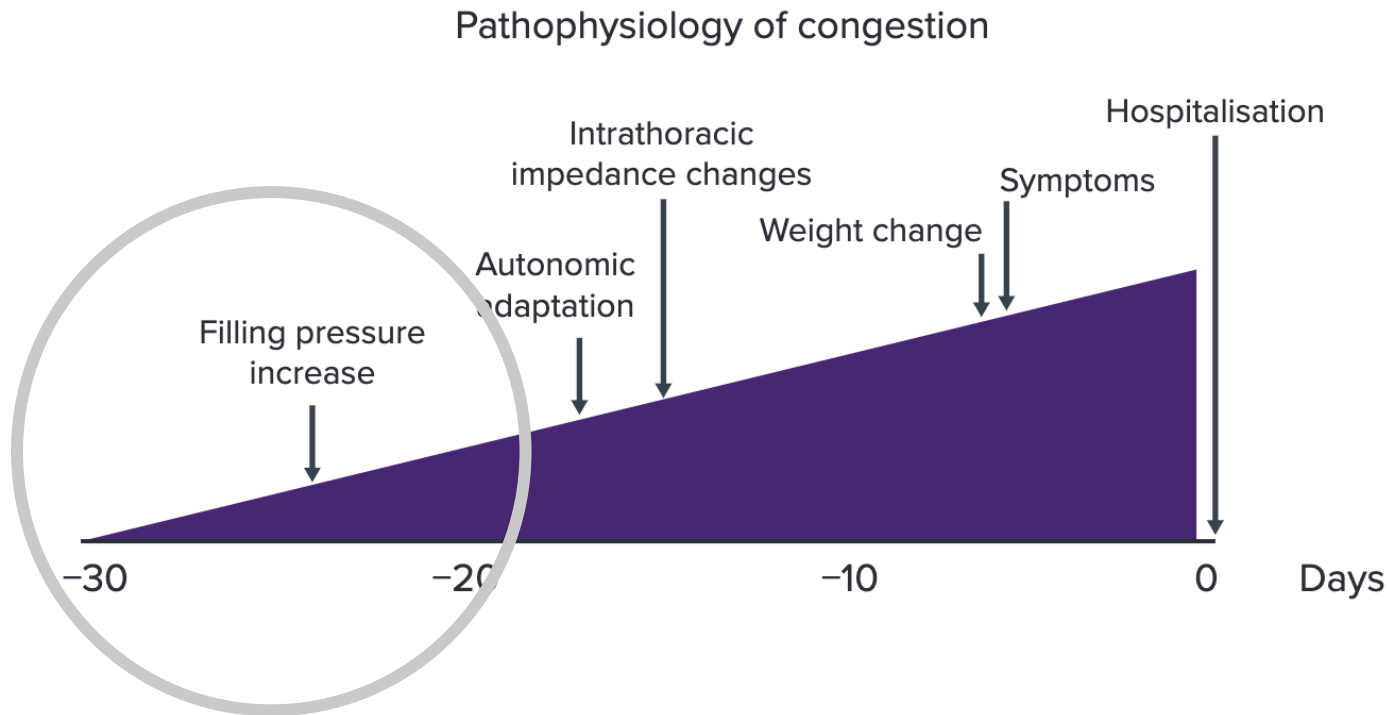
1-10-2022 to 31-12-2023



Characteristics	
N=63	
Sex female n(%)	6 (9.5)
Age median (IQR)	68 (62-75)
Hypertension n(%)	30 (47.6)
Dyslipemia n(%)	38 (60.3)
Diabetes mellitus n(%)	26 (41.2)
Obesity n(%)	20 (31.7)
Chronic Kidney Disease n(%)	35 (55.6)
Chronic Obstructive Pulmonary Disease n(%)	5 (7.9)
Ischemic cardiomyopathy n(%)	35 (55.6)
Left Ventricle Ejection Fraction median(IQR)	33 (27-38)
Atrial Fibrillation n(%)	30 (47.6)
ARNI /ACEi / ARB n(%)	47 (74.6)
Betablocker n(%)	57 (90.5)
MRA n(%)	46 (73.0)
SGLT2i n(%)	48 (76.2)
Vericiguat n(%)	6 (9.5)
Loop Diuretic n(%)	39 (61.9)
Thiazide n(%)	5 (7.9)

ESC HFA congress 2024

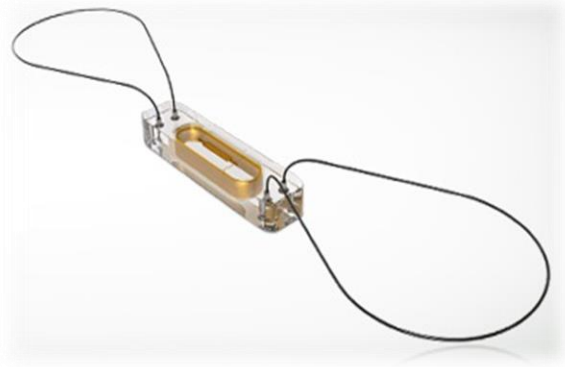
Invasive remote monitoring



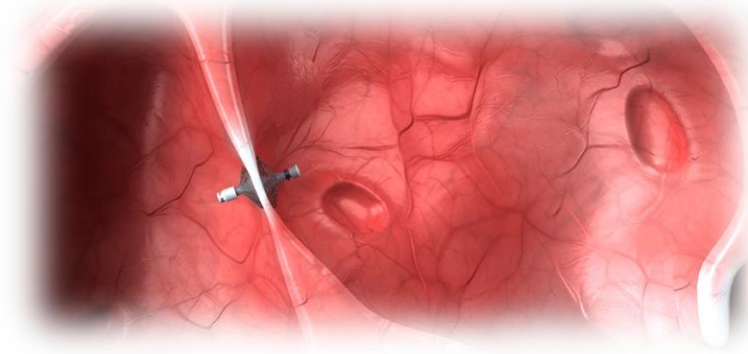
Zile MR et al. *Circ Heart Fail.* 2017;10:e003594

Invasive remote monitoring

CardioMEMS



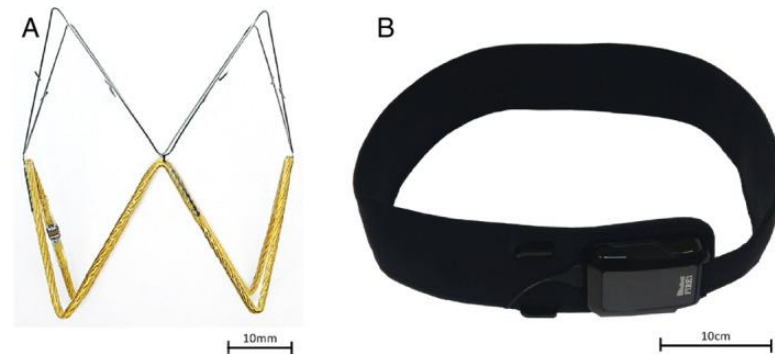
Vectorius V-LAP



Cordella (Endotronix)

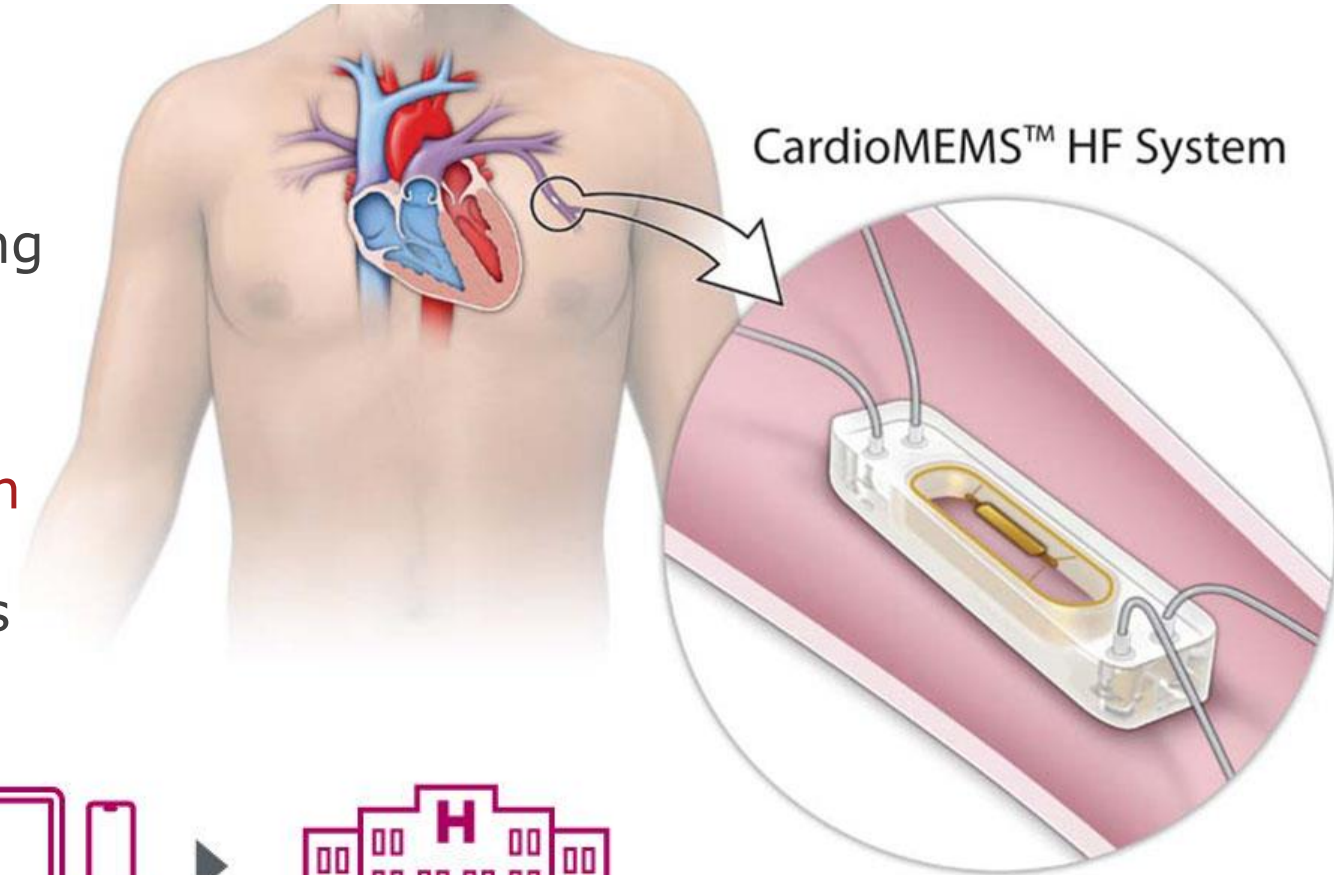


FIRE1



CardioMEMS

- Pulmonary artery pressure monitoring
- Allows daily wireless transmission
- Implantation via right catheterization
- Calibration with in-implant pressures



Sensor inserted via
right heart
catheterization



Patients take daily sensor
reading from the comfort
of their home

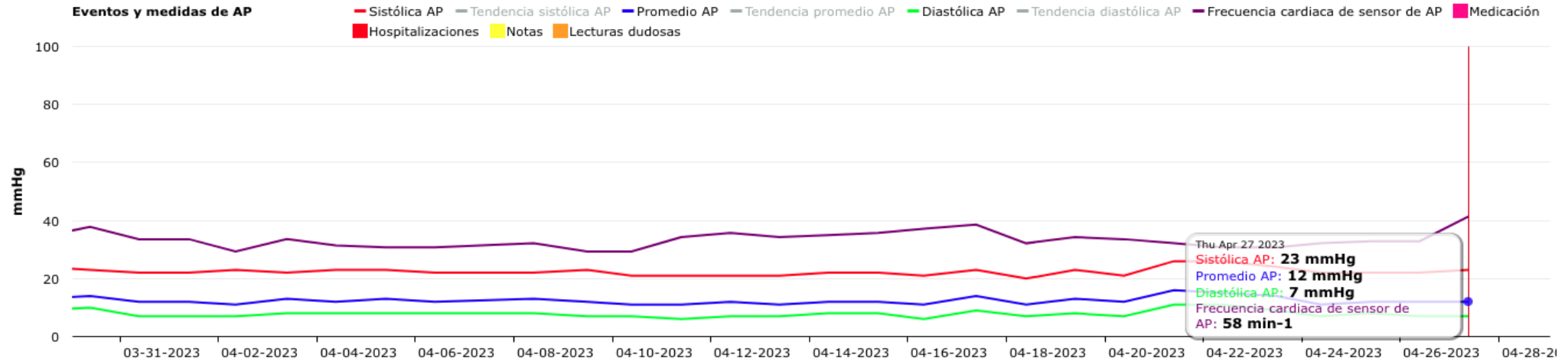


Data wirelessly
transmitted to clinician's
secure website



Clinician reviews data
and contacts patient
as necessary

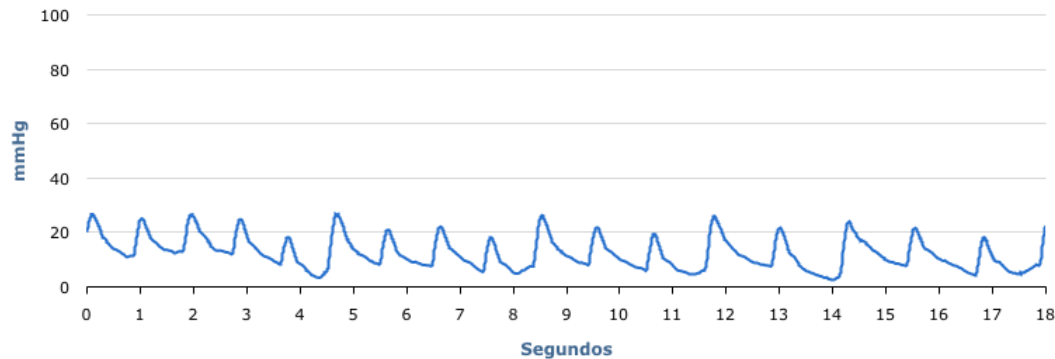
CardioMEMS



Tipo : Lectura del sensor del paciente

Realizada el : 04-27-2023, 09:33 AM

	Sistólica AP	Promedio AP	Diastólica AP	Frecuencia cardiaca
Sensor:	23 mmHg	12 mmHg	7 mmHg	58 min-1

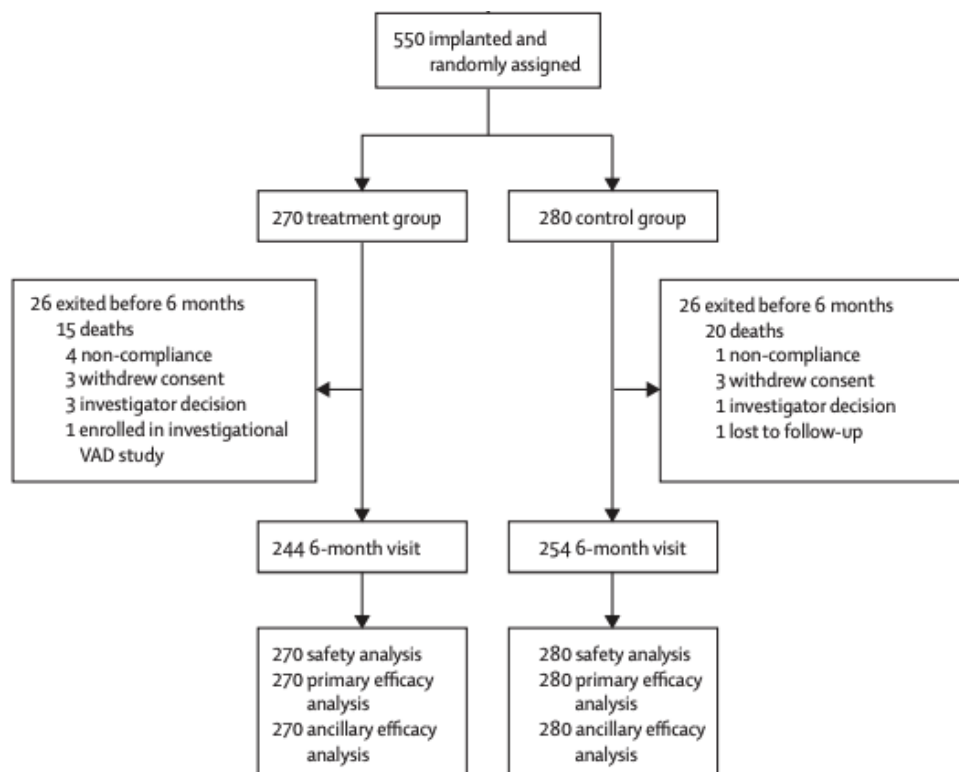


Daily measurements
 Allows to see the **trend**
 Evaluate **pressure curve**
 Clinical notes

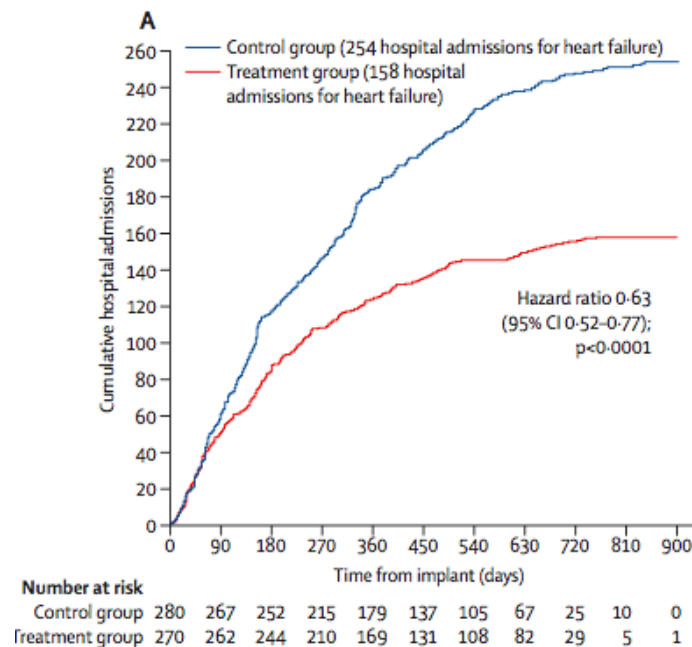
CardioMEMS: CHAMPION Trial

Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial

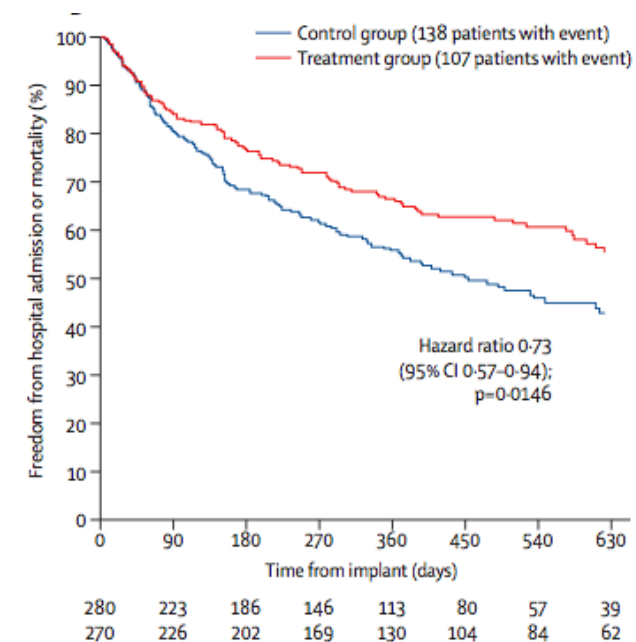
William T Abraham, Philip B Adamson, Robert C Bourge, Mark F Aaron, Maria Rosa Costanzo, Lynne W Stevenson, Warren Strickland, Suresh Neelagaru, Nirav Raval, Steven Krueger, Stanislav Weiner, David Shavelle, Bradley Jeffries, Jay S Yadav, for the CHAMPION Trial Study Group*



HFH



HFH + mortality



Abraham WT et al. Lancet 2011; 377: 658-66

CardioMEMS: MONITOR HF Trial

N=348

Any Ejection Fraction

NYHA III with WHF episode (12 months)

Primary outcome: quality of life

Efficacy outcomes: HFH

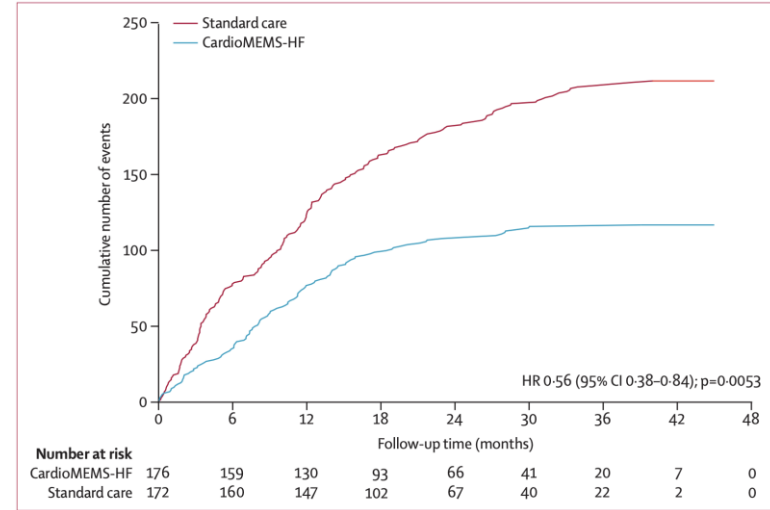
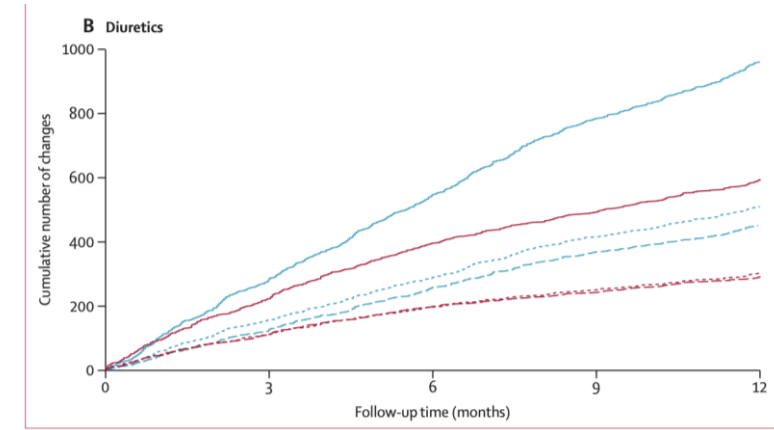
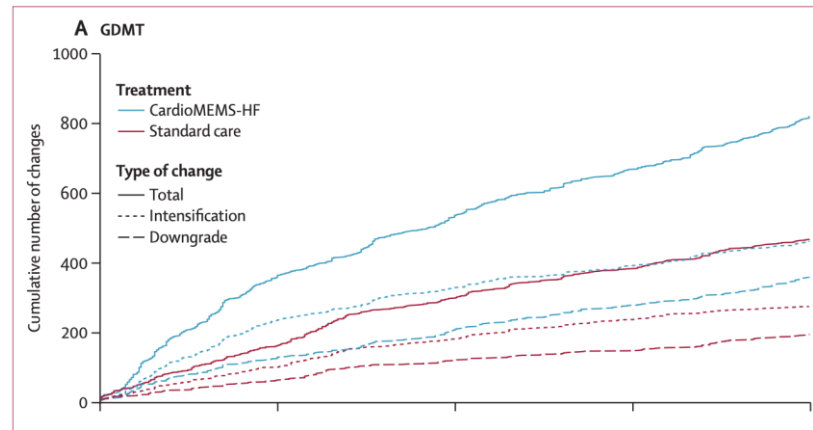


Figure 4: Cumulative number of total heart failure hospitalisations (heart failure hospitalisations and urgent visits with necessity of iv diuretics) during entire follow-up

Treatment changes



CardioMEMS

1898 patients in a pooled analysis of pulmonary pressure-guided therapy from CHAMPION, GUIDE-HF and MONITOR-HF trials

Characteristics

- EF \leq 40% 66%
- Men 68%
- Ischaemic aetiology 48%

Mean follow-up periods

- CHAMPION 17.6 M
- GUIDE-HF 10.8 M
- MONITOR-HF 21.4 M

PA sensor and delivery system

4.5 cm
120 cm

Key inclusion criteria

CHAMPION

- Chronic HF
- Independent of EF
- NYHA class III
- Previous HFH (12M)

GUIDE-HF

- Chronic HF
- Independent of EF
- NYHA class II-IV
- Previous HFH and/or Elevated NT-proBNP

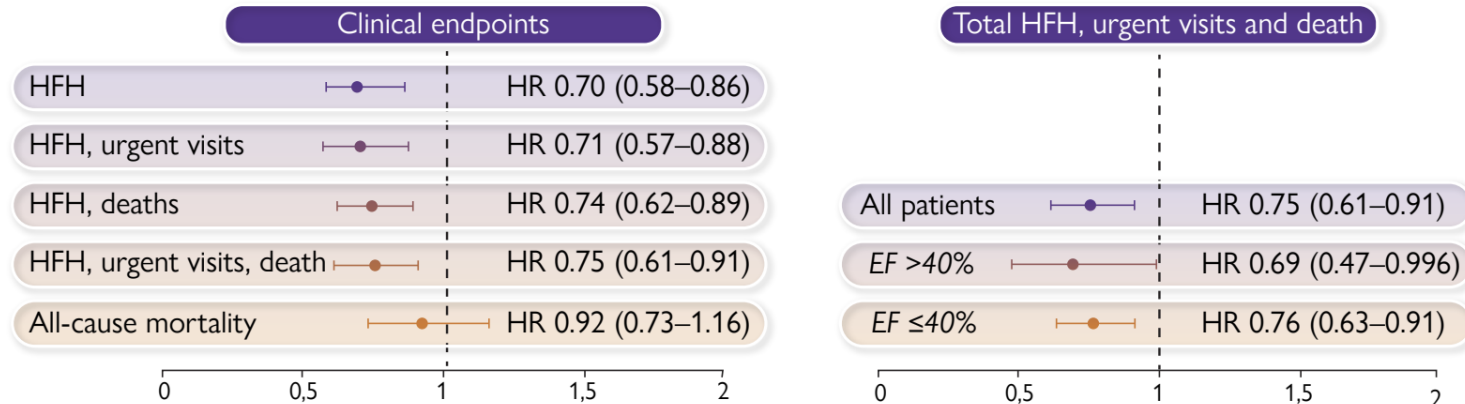
MONITOR-HF

- Chronic HF
- Independent of EF
- NYHA class III
- Previous HFH (12M)

Patient electronic system

PA pressure database

Physician access via secure website



Clephas PRD. *Eur Heart J.* 2023;44(37):3658-3668

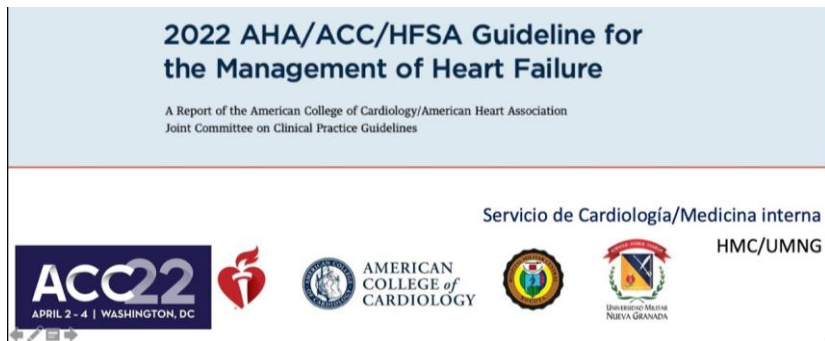
Invasive PAP monitoring



Monitoring of pulmonary artery pressure using a wireless haemodynamic monitoring system may be considered in symptomatic patients with HF in order to improve clinical outcomes.³⁷²

IIb

B



COR	LOE	Recommendation
2b	B-R	1. In selected adult patients with NYHA class III HF and history of a HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated stable doses of GDMT with optimal device therapy, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain. ¹⁻⁴

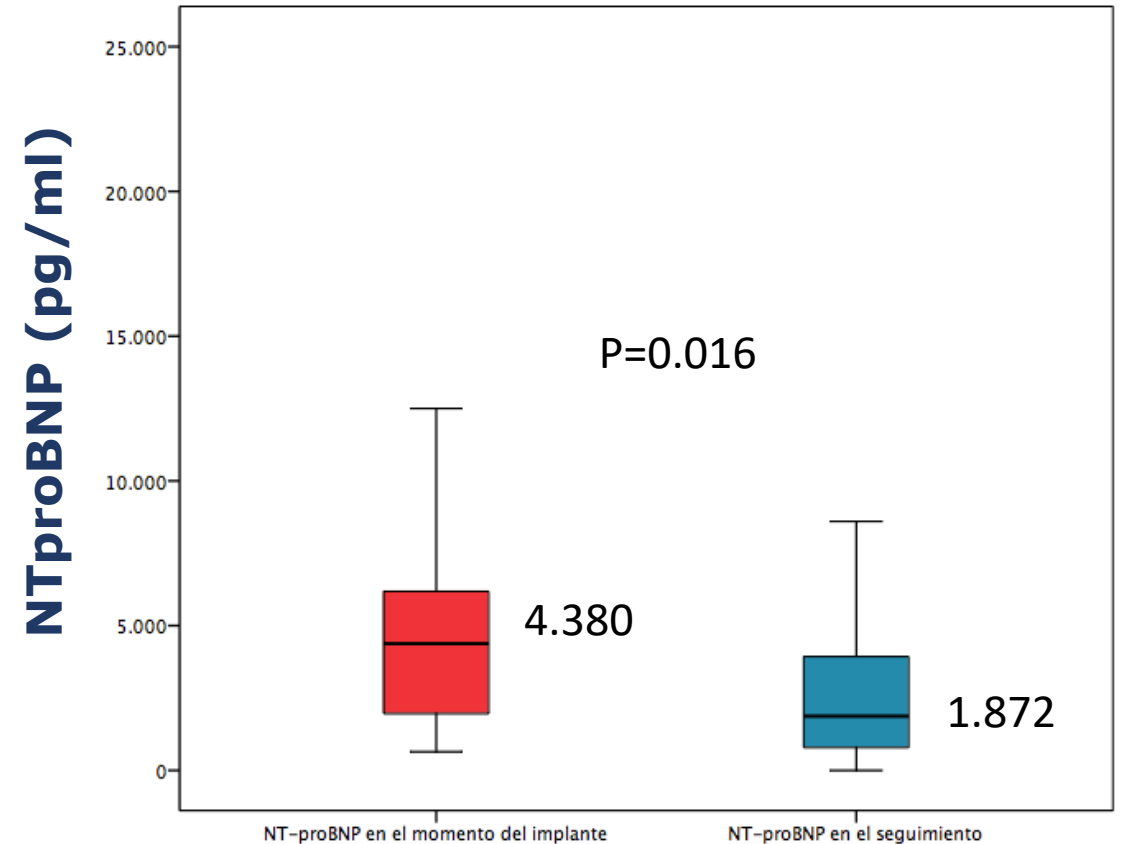
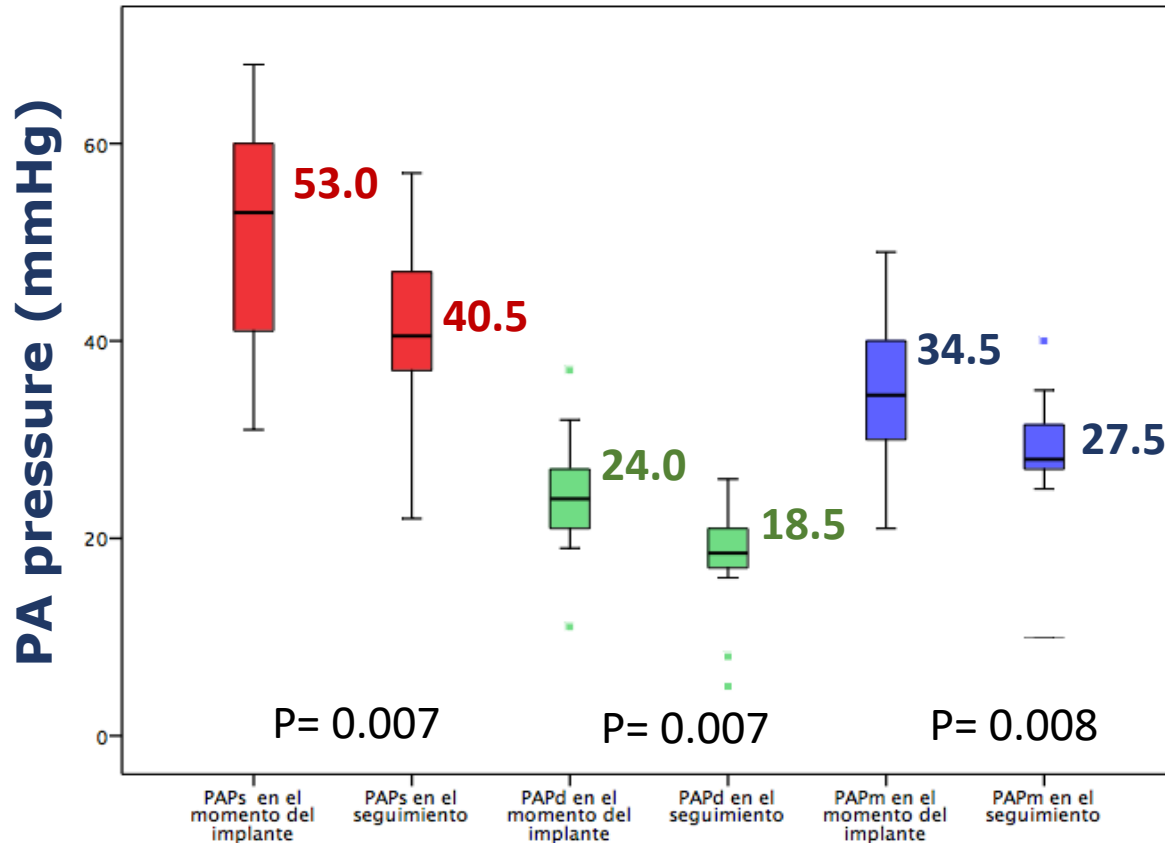
McDonagh TA et al. *Eur Heart J* 2021;42(36):3599-3726
Heidenreich PA et al *Circulation*. 2022;145:e895–e1032

CardioMEMS: CHUAC experience

HFH previous year (excluding HT list)
1.85 admissions/patient



HFH after implantation (excluding HT list)
0.23 admissions/patient/year

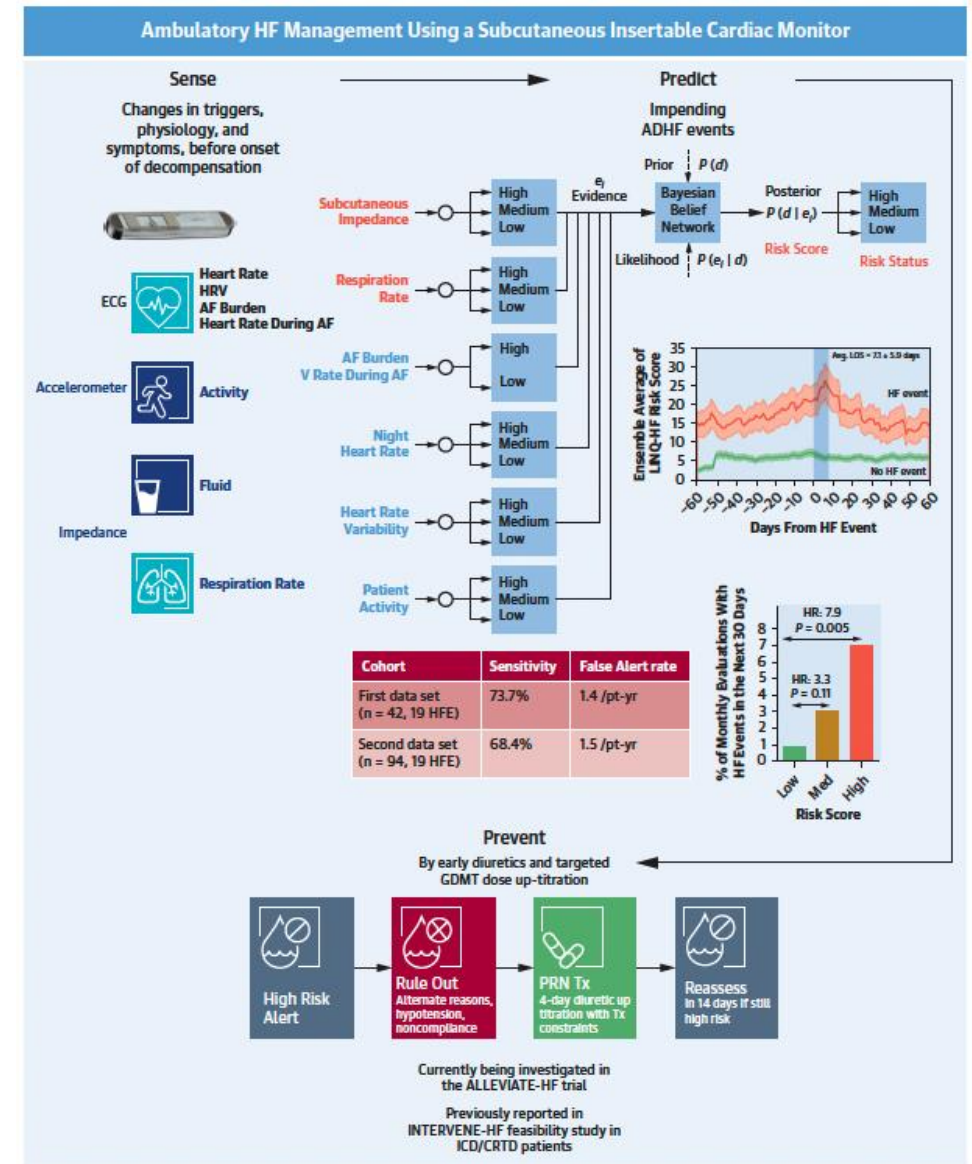


Future perspectives

A Novel Heart Failure Diagnostic Risk Score Using a Minimally Invasive Subcutaneous Insertable Cardiac Monitor



ALLEVIATE HF
Ongoing



Zile MR et al. JACC Heart Fail. 2024 Jan;12(1):182-196

Conclusions

- **HF decompensations**: very important **prognostic impact** on patients.
- **Remote monitoring** systems represent a technological advance to detect **HF decompensations**.
- **Patient selection** for each monitoring system is important.
- Systems using **implanted devices** (ICD / CRT) can **detect HF decompensation** and the possibility of early treatment.
- **PA Pressure** invasive monitoring can reduce HFH in selected patients.
- Importance of skilled **nursing**, and **trained professionals**.
- **Promising future** in the field of telemonitoring.

Thank you!

