PLACE

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA
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di Confindustria
Auditorium
della Tecnica

9ª Edizione

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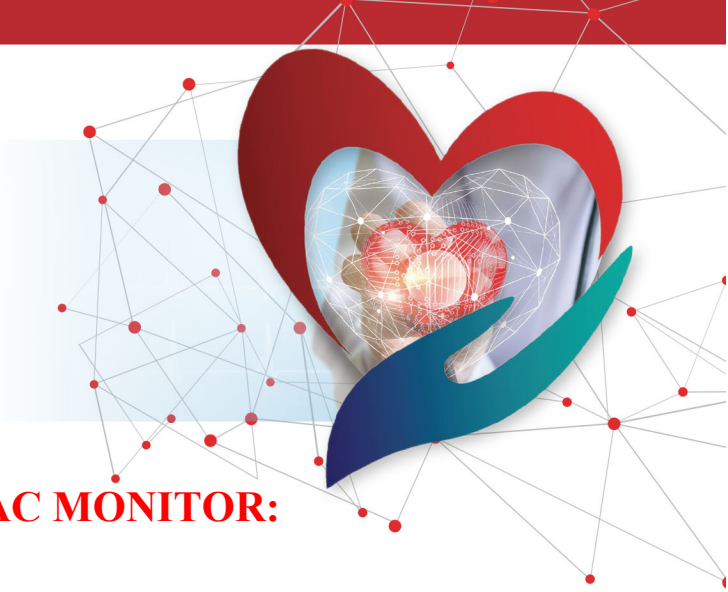
2022

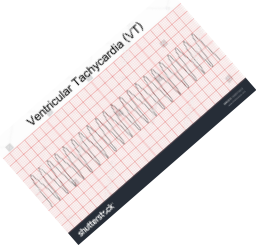


CONSENSUS CONFERENCE IMPLANTABLE CARDIAC MONITOR: LE NUOVE APPLICAZIONI

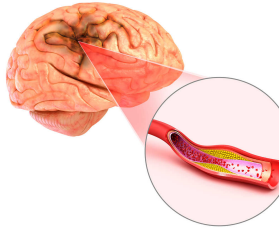
L'ICM NEL PAZIENTE SCOMPENSATO: C'È SPAZIO PER NUOVE INDICAZIONI?

Francesco Cicogna
UO CARDIOLOLGIA-UTIC POLICLINICO CASILINO

Condizioni generali affinché l'iImpianto di ICM risulti appropriato :

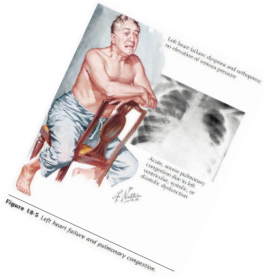


- Ci sia una ragionevole probabilità che si verifichi nei tempi di monitoraggio l'evento X che stiamo cercando



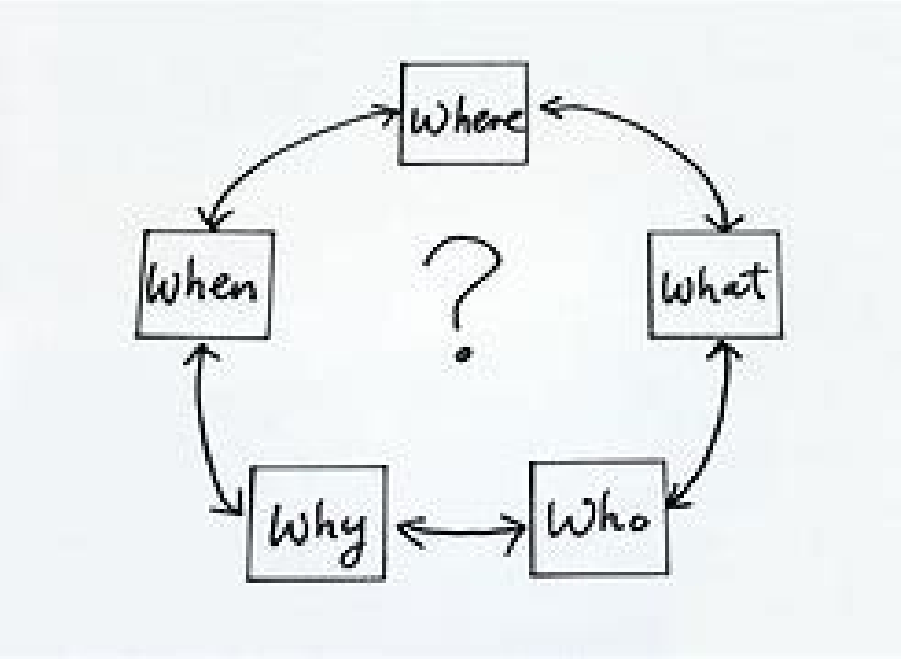
- L'identificazione precoce di tale evento consenta misure comportamentali/terapeutiche in grado di incidere sulla prognosi e/o sulla qualità di vita del paziente

- Il paziente non disponga già di altri CIED in grado di fornire le stesse informazioni



- Non vi siano modalità non invasive altrettanto efficaci nel raggiungere il nostro obiettivo

L'ICM NEL PAZIENTE SCOMPENSATO?



Perché?

Migliorare prognosi

Migliorare la qualità di vita

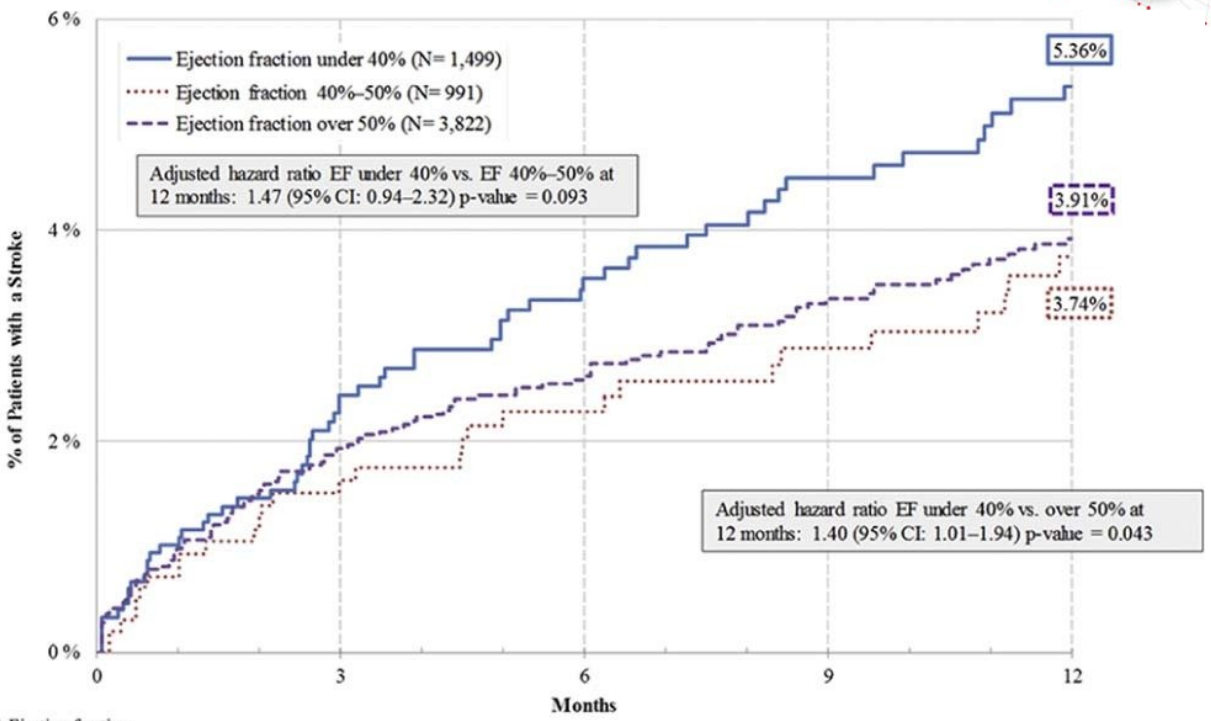
Senza dimenticare…….sostenibilità economica/Economia sanitaria

PROGNOSI

- DIAGNOSI PRECOCE DI FA ☾ PREVENZIONE EVENTI CEREBROVASCOLARI
- MIGLIOR IDENTIFICAZIONE DI PAZIENTE CON PROBLEMATICHE TACHI/BRADIARITMICHE CHE NECESSITANO DI IMPIANTO PMK/ICD ☾ PREVENZIONE MCI
- DIAGNOSI PRECOCE/PREVENZIONE RIACUTIZZAZIONE DI SCOMPENSO

DIAGNOSI PRECOCE DI FA ☾ PREVENZIONE EVENTI CEREBROVASCOLARI

- Elevato rischio



EF: Ejection fraction
* Identified as a primary diagnosis of stroke during a hospitalization.
Hazard ratio were calculated using a Cox proportional hazard model adjusting for age, gender, region, race, ethnicity, insurance type, year of index date, baseline hospitalizations, atrial fibrillation, comorbidities with a prevalence >5% (i.e. hypertension, hyperlipidemia, diabetes, depression, obesity, COPD, myocardial infarction, previous VTE), and baseline anticoagulants.

FONAROW G. HFSA 2017

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doi:10.1016/j.jacc.2006.01.060

Atrial Fibrillation and Risk of Clinical Events in Chronic Heart Failure With and Without Left Ventricular Systolic Dysfunction

Results From the Candesartan in Heart failure-Assessment of Reduction in Mortality and morbidity (CHARM) Program

Lars G. Olsson, MB,* Karl Swedberg, MD, PHD, FACC,* Anique Ducharme, MD, MSC,†
Christopher B. Granger, MD, FACC,‡ Eric L. Michelson, MD, FACC,§
John J. V. McMurray, MD, FACC,‖ Margareta Puu, PHD,¶ Salim Yusuf, MD, DPHIL, FACC,#
Marc A. Pfeffer, MD, PHD, FACC,** on behalf of the CHARM Investigators

Göteborg and Mölndal, Sweden; Montreal, Quebec, and Hamilton, Ontario, Canada; Durham, North Carolina; Wilmington, Delaware; Glasgow, Scotland; and Boston, Massachusetts

7599 pts, fu 37 months

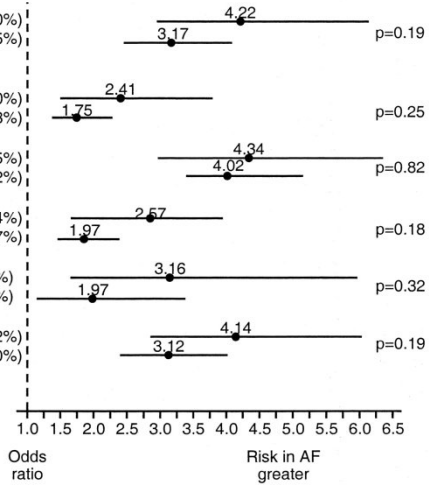
LVEF <40% VS >40%

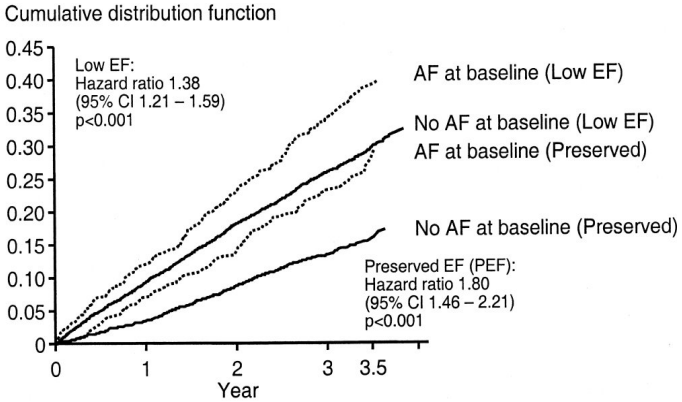
In 392 patients, AF developed during follow-up, 263 (7.8%) in the low EF group and 129 (4.9%) in the PEF group. Patients with new-onset AF experienced a higher risk of morbidity and mortality regardless of baseline EF

DIAGNOSI PRECOCE DI FA ☾ PREVENZIONE EVENTI CEREBROVASCOLARI

- Impatto prognostico

		AF	No AF	Test for interaction
CV-death or hospitalization due to CHF	Preserved EF	60/129 (47%)	478/2416 (20%)	p=0.19
	Low EF	174/263 (66%)	1288/3643 (35%)	
CV-death	Preserved EF	24/129 (19%)	233/2416 (10%)	p=0.25
	Low EF	93/263 (35%)	823/3643 (23%)	
Hospitalization due to CHF	Preserved EF	50/129 (39%)	352/2416 (15%)	p=0.82
	Low EF	147/263 (56%)	812/3643 (22%)	
All-cause mortality, new onset AF	Preserved EF	34/129 (26%)	330/2416 (14%)	p=0.18
	Low EF	112/263 (43%)	990/3643 (27%)	
Fatal or non-fatal stroke	Preserved EF	12/129 (9%)	84/2416 (3%)	p=0.32
	Low EF	16/263 (6%)	111/3643 (3%)	
CV-death or hospitalization due to CHF or non-fatal stroke	Preserved EF	63/129 (49%)	526/2416 (22%)	p=0.19
	Low EF	176/263 (67%)	1328/3643 (50%)	





Number at risk				
No AF & Low EF	3906	3542	3192	2359
No AF & PEF	2545	2455	2322	1418
AF & Low EF	670	589	514	358
AF & PEF	478	444	414	243

The absolute risk of an adverse CV outcome was highest in the low EF-new AF patient group, but the patients with PEF and new AF had a greater relative increase in risk than those with low EF and new AF

Olsson LG J Am Coll Cardiol. 2006

Impatto prognostico di una strategia di controllo del ritmo

"Our findings highlight that patients aged 65 and older with HFpEF and AF treated with rhythm control have an associated lower 1-year mortality compared with treatment with rate control, even after risk adjustment. Rhythm control is a potential treatment strategy for this population that may provide benefit"

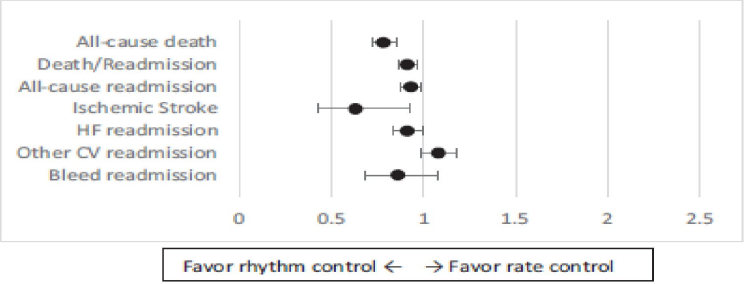
ORIGINAL RESEARCH

American Heart Association.

Rhythm Control Versus Rate Control in Patients With Atrial Fibrillation and Heart Failure With Preserved Ejection Fraction: Insights From Get With The Guidelines—Heart Failure

Jacob P. Kelly, MD, MHS; Adam D. DeVore, MD, MHS; JingJing Wu, MS; Bradley G. Hammill, DrPH; Abhinav Sharma, MD; Lauren B. Cooper, MD, MHS; G. Michael Felker, MD, MHS; Jonathan P. Piccini, MD, MHS; Larry A. Allen, MD, MHS; Paul A. Heidenreich, MD, MS; Eric D. Peterson, MD, MPH; Clyde W. Yancy, MD; Gregg C. Fonarow, MD; Adrian F. Hernandez, MD, MHS

Unadjusted Outcomes	1-year HR (CI)	p-value
All-cause death	0.78 (0.72, 0.85)	<0.01
Death/Readmission	0.91 (0.86, 0.97)	<0.01
All-cause readmission	0.93 (0.87, 0.99)	0.02
Ischemic stroke	0.63 (0.43, 0.93)	0.02
HF readmission	0.91 (0.83, 1.00)	0.05
Other CV readmission	1.08 (0.99, 1.18)	0.09
Bleed readmission	0.86 (0.68, 1.08)	0.19



Adjusted Outcomes	1-year HR (CI)	p-value
All-cause death	0.86 (0.75, 0.98)	0.02
Death/Readmission	0.95 (0.87, 1.03)	0.22
All-cause readmission	0.94 (0.86, 1.04)	0.22
Ischemic stroke	0.94 (0.43, 2.06)	0.87
HF readmission	0.95 (0.83, 1.10)	0.50
Other CV readmission	1.07 (0.95, 1.21)	0.29
Bleed readmission	0.82 (0.60, 1.12)	0.20

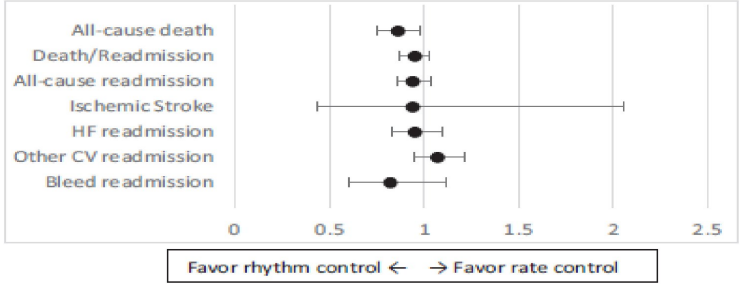
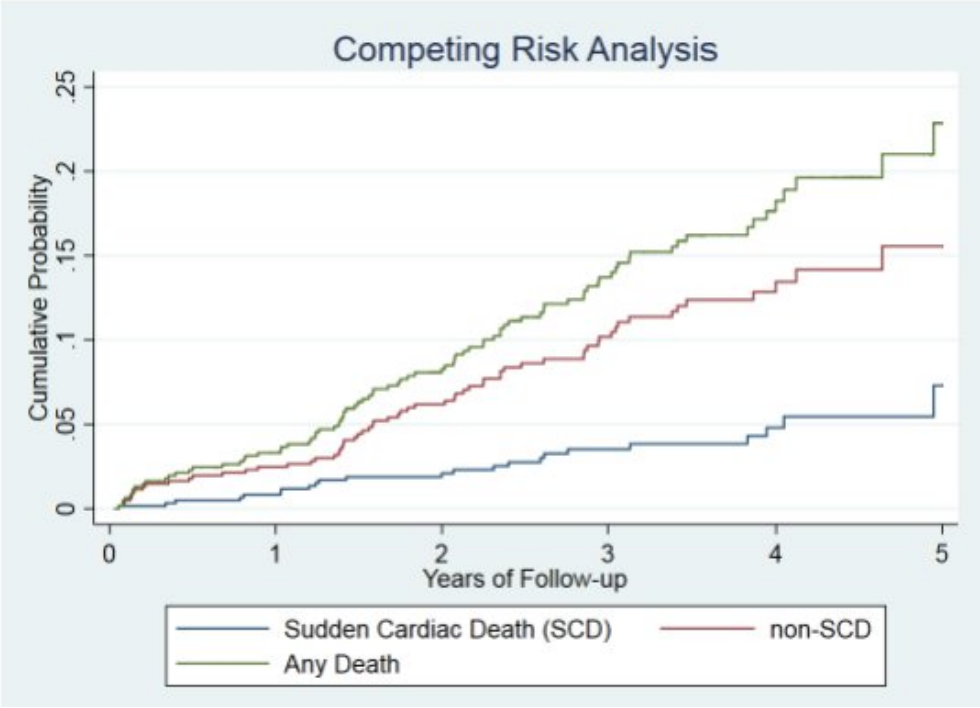


Figure 1. Unadjusted and adjusted HRs for patients with HFpEF and AF treated with rhythm control (ref=rate control). AF indicates atrial fibrillation; CV, cardiovascular; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; HR, hazard ratio.

IDENTIFICAZIONE DI PAZIENTI A RISCHIO DI MORTE CARDIACA IMPROVVISA PER PROBLEMATICHE BRADI-TACHI ARITMICHE

"Sudden cardiac death (SCD) is the most common single mode of death in HFpEF, constituting nearly 40% of cardiovascular deaths and 25% of all deaths . As the most common single mode of death in HFpEF, SCD could be a potential therapeutic target to reduce mortality"

"Sudden Cardiac Death Risk Prediction in Heart Failure with Preserved Ejection Fraction"
Selcuk Adabag, HEART RHYTHM 2019



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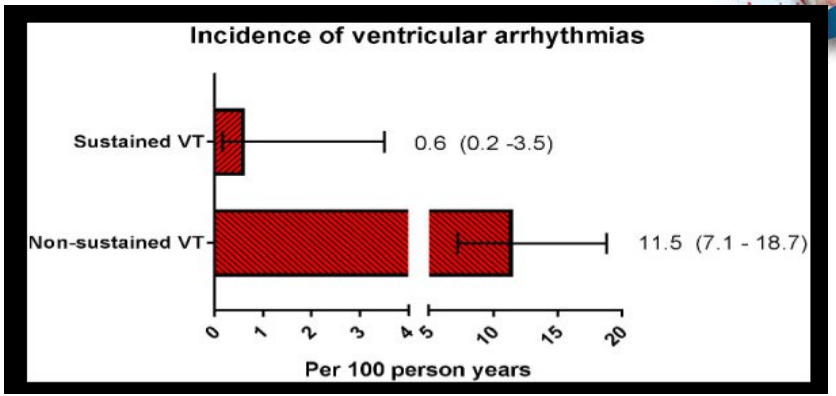
ESC European Society of Cardiology
European Journal of Heart Failure (2020)
doi:10.1002/ejhf.1970
RESEARCH ARTICL

Ventricular tachyarrhythmia detection by implantable loop recording in patients with heart failure and preserved ejection fraction: the VIP-HF study

Dirk J. van Veldhuisen[1]*, Gijs van Woerden[1], Thomas M. Gorter[1], Vanessa P.M. van Empel[2], Olivier C. Manintveld[3], Robert G. Tieleman[1,4], Alexander H. Maass[1], Kevin Vernooy[2], B. Daan Westenbrink[1], Isabelle C. van Gelder[1], and Michiel Rienstra[1]



113 pazienti arruolati (28 HFmrEF, 83 HfpEF)
657 gg monitoraggio medio
4 COMPLICANZE-->RIMOZIONE ILR

EVENTI:
16 PZ CON TVNS
1 TV SOSTENUTA (paziente con CAD)
5 BRADIARITMIE-->4 PMK
23 OSPEDALIZZAZIONI PER HF

14 DECESSI (10 PER CAUSE CV)
4 SCD (2 STORIA TVNS):
1 CASO DOCUMENTATA BRADI-ASISTOLIA
3 CASI ILR NON INTERROGATI !!!

Conclusions

Despite the lower than expected number of included patients, the incidence of sustained ventricular tachyarrhythmias in HFmrEF/HFpEF was low. Clinically relevant bradyarrhythmias were more often observed than expected.

DIAGNOSI PRECOCE/PREVENZIONE RIACUTIZZAZIONE DI SCOMPENSO

Table 1 Cardiac implantable electronic device measures used to predict worsening heart failure

	Definition and comments	Association with heart failure hospitalization	Predictive accuracy for worsening heart failure
Intrathoracic impedance[3,32,36]	Reducing impedance correlates with increasing fluid volume.[7] Threshold 60 ohm-days.[36,37]	OR 1.36 (1.08–1.70) $P = 0.008$.[32]	Sn 60%, Sp 73%, clinical HF[35] Sn 60%, PPV 60%, clinical HF[34] Sn 76%, worsening HF[37] Sn 21%, PPV 5%, HFH[38] Sn 70%.[39]
Heart rate variability	SD of 5 min median atrial–atrial intervals in 1 day (SDAAM).[24,39] Abnormal <60 ms[23] or 80 ms.[32,36]	HR 3.20 (no CI) all-cause mortality low SDAAM <50 ms vs. SDAAM <100 ms.[39] No association in larger study.[24] OR 1.004 (1.000–1.007) $P = 0.047$[32]	Median time threshold crossing to hospitalization 16 days.
Night heart rate[32,39]	Mean ventricular rate between midnight and 4 am, excluding atrial high rate episodes.[39] Abnormal >85 b.p.m.[23] or 90 b.p.m.[32,36]	OR 1.003 (0.999–1.006) $P = 0.125$[32] Increased from 75 to 78 b.p.m. at hospitalization.[39]	Low accuracy.[39]
Patient activity[32,36,39]	Number of minutes active per day defined by accelerometer counts exceeding 70 steps/min.[39] Low activity <30 min.[32,36]	Decline from 188 to 164 min/day at hospitalization.[39] OR 1.006 (1.000–1.011) $P = 0.032$[32]	Low accuracy.[39]
AF burden	Duration in 24 h period. ≥6 h on ≥1 day.[29]	Any AF HR 2.0 (1.4–2.9). AF ≥1 day NVR HR 3.4 (1.8–6.2).	Unknown.
AF ventricular rate	Mean ventricular rate during AF over specified time period.[29] Abnormal 1 day ≥90 b.p.m.[23]	AF ≥1 day RVR HR 5.9 (3.5–10.0).	Unknown.
CRT pacing[57]	Ventricular pacing <90%.	Pacing >92% vs. ≤92% HR 0.56, $P < 0.00001$ for death or HFH.[57]	Unknown.
ICD shocks[58]	≥1 shock.	Unknown.	Unknown.

HF, heart failure; HFH, heart failure hospitalization; HR, hazard ratio; ICD, implantable cardioverter defibrillator; NVR, normal ventricular rate; OR, odds ratio; PPV, positive predictive value; RVR, rapid ventricular rate; SDAAM, standard deviation of 5 min median atrial–atrial intervals; Sn, sensitivity; Sp, specificity.

Predicting heart failure decompensation using cardiac implantable electronic devices: a review of practices and challenges. ***Hawkins NM*** Eur J Heart Fail. 2016

Prevenire il decadimento cognitivo

Table 6 Meta-analyses relating atrial fibrillation to dementia and cognitive impairment

Author	Study design	Outcome	Inclusions/exclusions	Risk
Kwok *et al.*[24]	Meta-analysis cross-sectional and prospective studies	Dementia	Patients with H/o stroke, 7 studies; $n = 2425$	OR 2.43; 95% CI 1.70–3.46; $P < 0.001$; $I^2 = 10\%$
Kalantarian *et al.*[25]	Meta-analysis cross-sectional and prospective studies	Cognitive impairment and dementia	Patients with H/o stroke, 7 studies; $n = 2409$	RR 2.70; 95% CI 1.82–4.00; $I^2 = 32.3\%$; $P = 0.18$
			Excluding patients with or adjusting for H/o stroke 10 studies	RR 1.34; 95% CI 1.13–1.5

H/o, history of; OR, odds ratio; RR, relative risk.

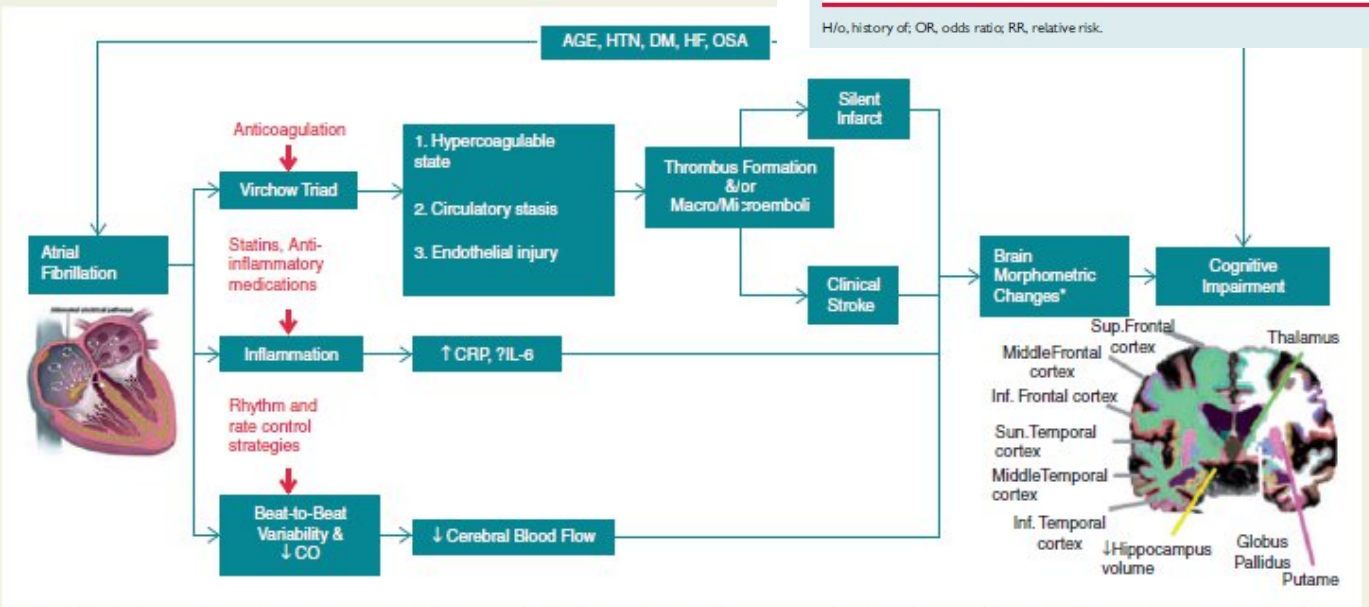


Figure 1 Different mechanisms through which atrial fibrillation may contribute to cognitive impairment. Potential interventions are shown in red. [a]Some of the reported brain morphometric changes include: hippocampus atrophy, white matter hyperintensities, and frontal medial lobe atrophy. Reproduced with modification after permission from Ref.[64] CO, cardiac output; CRP, C-reactive protein; DM, diabetes mellitus; HF, heart failure; HTN, hypertension; IL, interleukin; OSA, obstructive sleep apnoea.

EHRA/HRS/APHRS /LAHRS expert consensus on arrhythmias and cognitive function: what is the best practice? Europace 2018

I Costi dello scompenso:

Con una degenza ospedaliera che in media supera i dieci giorni il Ssn spende complessivamente 550 milioni di euro l'anno

la spesa annuale per paziente è di 11.800 euro, di cui l'85% rappresentato dai costi di ospedalizzazione.

costo delle riospedalizzazioni è quasi il doppio di uello del primo ricovero (oltre 7.000 euro contro rca 4.500 per il primo ricovero)

THE REAL WORLD EVIDENCE OF CHRONIC HEART FAILURE: FINDINGS FROM 41,413 PATIENTS OF THE ARNO DATABASE

ALDO P. MAGGIONI, ELISA ROSSI, ELISA CINCONZE, MIHAELA NICA, DELIA COLOMBO, MARISA DE ROSA, FRANCESCO ORSO, NELLO MARTINI ON BEHALF OF ARNO-CORE CARDIOVASCULAR OBSERVATORY

BACKGROUND

AIMS

METHODS

RESULTS

SUMMARY

CONCLUSIONS

ACKNOWLEDGEMENTS

PLACE 9ª Edizione

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

Alternative non invasive?

eBRAVE-AF trial

#ESCCongress

Smartphone-based AF screening

Conclusion

Atrial fibrillation (AF) screening using conventional smartphones more than doubles the detection and treatment rate in older people compared to routine screening.

Impact on clinical practice

App-based pre-screening was only one part of the programme, which also included electrocardiogram (ECG) validation and assessment of the findings by an independent physician.

Study objectives

The eBRAVE-AF trial was a site-less randomised study in older adults at risk for stroke who owned a smartphone. Smartphone screening was compared with usual screening for the ability to detect AF that was then treated with oral anticoagulation.

Who and what?

5,551

Adults (median age 65 years; 31% women)

randomised

6 months

Smartphone AF screening

Conventional AF screening

Measurements
- 2x a day for 14 days
- then 2x a week

Abnormal results

ECG patch

ECG results

Consult independent local physician for treatment decision

Primary efficacy endpoint

Newly diagnosed AF within 6 months leading to initiation of oral anticoagulation by an independent physician.

Rate%

1.33%

0.63%

Odds ratio 2.12
95% CI 1.19–3.76; p=0.010

Second 6-month study phase

Participants who did not reach the primary endpoint in the first 6 months were invited to crossover to the other arm

4,752 Participants 6 months

Smartphone AF screening → Conventional AF screening

Conventional AF screening → Smartphone AF screening

Again, digital screening was superior to conventional screening in detecting AF that was then treated with oral anticoagulation:
Odds ratio 2.95
95% CI 1.52–5.72; p=0.001

ESC

REMOTE MANAGEMENT OF HEART FAILURE WITH PRESERVED EJECTION FRACTION: A SINGLE CENTER EXPERIENCE

Ciccarra F[1,2], Martino A[2], Palozzi G[2], Mennuni S[2], Tota C[2], Jacomelli I[2], Ferraiuolo F[2], Casalese A[2], Turriè V[2], Federici F[1], De Ruvo E[2], Calò L[2]

1) Scuola di specializzazione in Malattie dell'Apparato Cardiovascolare Sapienza Università di Roma; 2) Unità Operativa Cardiologia UTIC Policlinico Casilino Roma; 3) Dipartimento Management e Diritto Università Roma Tor Vergata

INTRODUCTION

Experience of remote monitoring (RM) management of Heart failure with preserved ejection fractio (HFpEF) are still scarce and n standardized. The aim of our stud was to evaluate the clinical ar economic impact of remo management of HfpEF with Doctu plus system (DPS) named VreeHeal

23 PATIENTS

>68. 000 TRASMISSIONS in 7.3 ± 3.6 MONTHS OF FU

METHODS

The DPS was used for RM of Hfp This system is based on a kit t allows the measurement a transmission of EKG, arterial blo pressure, O2 saturation, weight a body fluid accumulation data that subsequently processed and ma available for consultation through dedicated platform. The platfo presents pathological measu values as "alarms" coded in red (h priority), yellow (medium priority) depending on their severity (on the basis of predefined ranges) and green (absence of measurements).

RESULTS

Overall 26 HFpEF patients were prospectively enrolled for remote management with DPS, in the Cardiology Unit of Casilino Polyclinic, from 12/02/2018 to 30/04/2019 (average monitoring time: 7.3 ± 3.6 months). During this time, the system reported > 68.000 transmissions containing 945 alarms including 327 green, 129 red and 486 yellow. The subsequent clinical alarms analysis, performed by the operators, revealed 51 true red and 61 true yellow alarms. Alarms management requests on average 816 and 150 minutes pat/year, respectively for Technicians' and Cardiologists' activities.

Based on the data provided by the system, 36 therapeutic actions were undertaken, 6 physical or instrumental medical assessments were prescribed and 1 patient was hospitalized.

We estimated that 8 hospitalizations for heart failure were avoided during this period of RM.

With regard to financial implication, the total management of the 26 patients including further examinations accounts to 27.075 €/year. The financial benefit for avoiding 8 hospitalizations is about 47.900 €.

8 HF HOSPITALIZATIONS AVOIDED

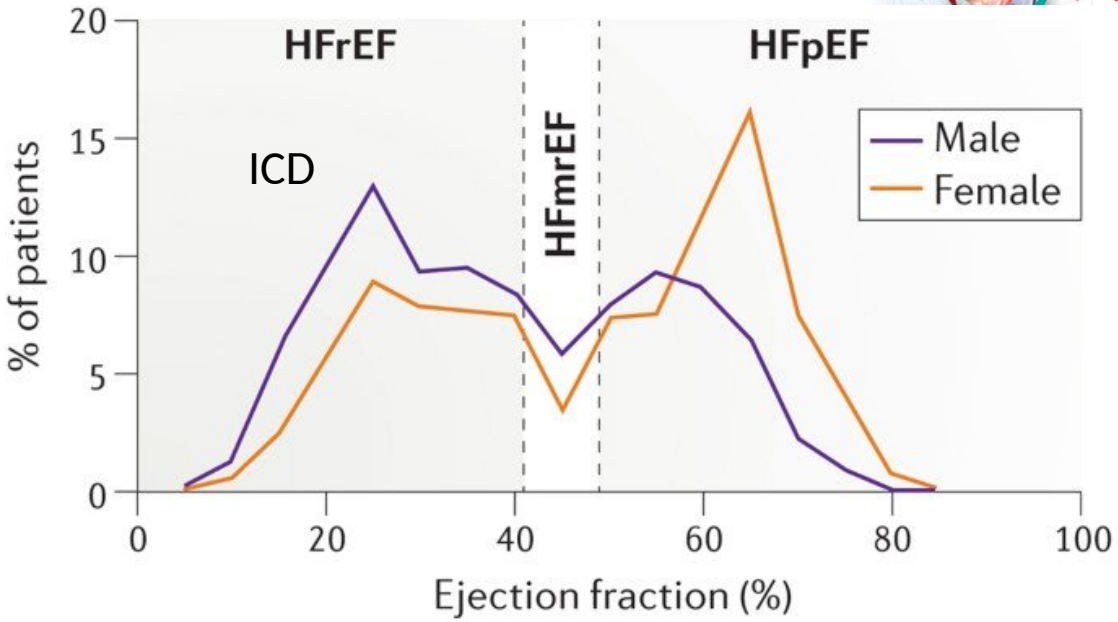
OVER 20.000 € SAVED

CONCLUSIONS

The RM of HfpEF with the DPS has showed a great power in reducing HF hospitalizations. It has been considered a self-coverage and cost-effective service eligible to provide a better service at a lower cost. We observed that erroneous measurements performed by the patients, and the consequent false alarms, represented the greatest weakness point of this system, suggesting the need for adequate patients's selection and training.

A chi?

Tutti i pazienti con HF che non hanno indicazione ad altri tipi di device?



Nature Reviews | Cardiology

Solo pazienti non scoagulati?

Solo pazienti con elevato rischio?

Solo pazienti giovani?

Solo pazienti con sintomi dubbi?

Cosa?

Fondamentale Home monitoring

Possibilità di affiancare al monitoraggio eventi aritmici
strumenti utili alla gestione paziente scompensato

Come ?

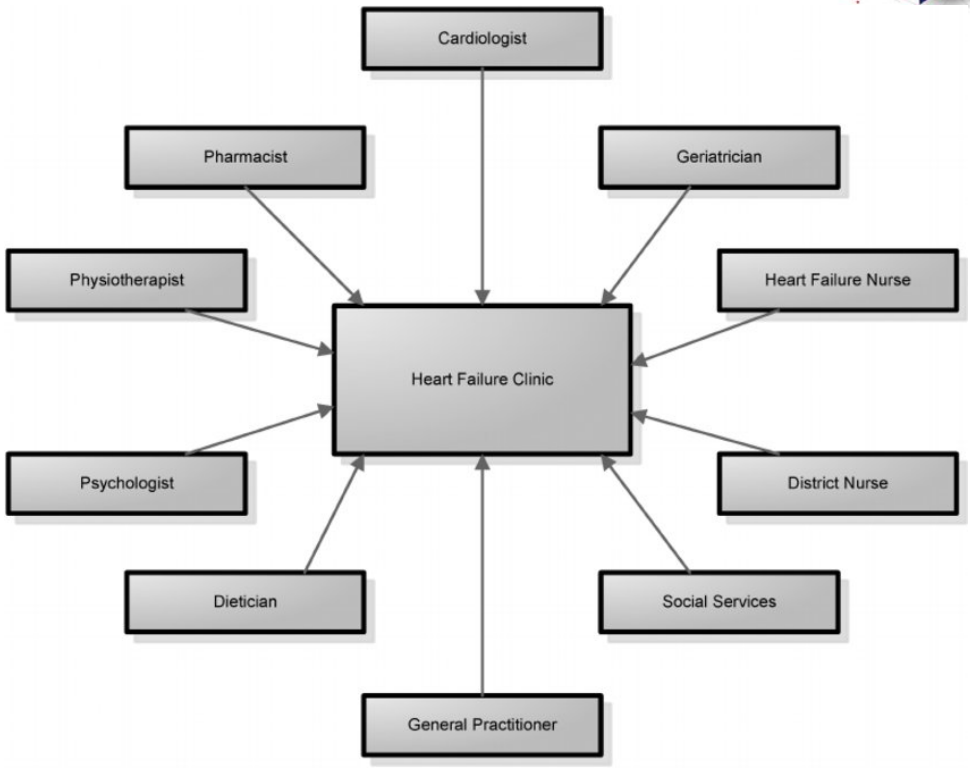
Programmazione individualizzata

Tempi ragionevoli di rivalutazione delle trasmissioni da remoto

Integrazione dei dati con altre informazioni cliniche

Quando?

Dove?


Cardiologist
Pharmacist
Geriatrician
Physiotherapist
Heart Failure Nurse
Heart Failure Clinic
Psychologist
District Nurse
Dietician
Social Services
General Practitioner

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Prime esperienze

Neth Heart J (2019) 27:46–51
https://doi.org/10.1007/s12471-018-1198-x

CrossMark

Telemonitoring with an implantable loop recorder in outpatient heart failure care

One year follow-up report from a prospective observational Dutch multicentre study

R. S. S. Kort · Y. S. Tuininga · H. A. Bosker · M. Janssen · R. Tukkie

Published online: 3 December 2018

Inclusion and exclusion criteria

Patients with stable systolic heart failure (ejection fraction 35–45%) or diastolic heart failure (ejection fraction > 45% and echocardiographic signs of impaired diastology or NT-proBNP >250 ng/l) were included. Stable was defined as a New York Heart Association (NYHA) Class II or III, without hospitalisation in the last 3 months or a scheduled intervention in the coming 3 months. Patients with a pacemaker/ICD or an indication for such a device were excluded. Since we sought possible therapeutic implications from continuous monitoring, patients with known AF, a virtual CHA_2DS_2-VASc of 1 or less or already on an OAC were excluded.

30 pazienti arruolati…

sex	age	heart failure	event	action
female	81	HFREF	bradycardia/NSVT	none
female	68	HFREF	asystole	dose beta blocker changed
male	65	HFREF	atrial fibrillation	dose beta blocker changed/OAC started
male	78	HFREF	asystole	none
male	86	HFPEF	bradycardia/Atrial fibrillation	OAC started
male	71	HFREF	atrial fibrillation	OAC started
female	77	HFREF	SVT	dose beta blocker changed
female	74	HFREF	atrial fibrillation	OAC started
male	59	HFREF	atrial fibrillation	OAC started
female	74	HFREF	asystole	dose beta blocker changed
female	65	HFREF	atrial fibrillation	dose beta blocker changed/OAC started
male	62	HFREF	atrial fibrillation	OAC started
male	71	HFREF	atrial fibrillation	OAC started
female	71	HFPEF	bradycardia	beta blocker stopped
female	80	HFPEF	AV block	pacemaker implanted

HFPEF heart failure with preserved ejection fraction, *HFREF* heart failure with reduced ejection fraction, *NSVT* non-sustained ventricular tachycardia, *OAC* oral anticoagulant, *SVT* supraventricular tachycardia.

"We conclude that continuous monitoring of heart failure patients with an ILR detects more arrhythmic events and leads to a relevant number of therapeutic changes compared with standard care."

«È ben difficile, in geografia come in morale, capire il mondo senza uscire di casa propria.» (Voltaire)

Evaluation of a proactive clinical management and early diagnosis of arrhythmias in patients with heart failure and non severely reduced left ventricular function through a telemonitoring system: a prospective randomized clinical trial VASCO STUDY

Promoter: Italian Association for Cardiovascular Prevention, Rehabilitation and Epidemiology (IACPR)

Principal Investigator: Prof.Leonardo Calò

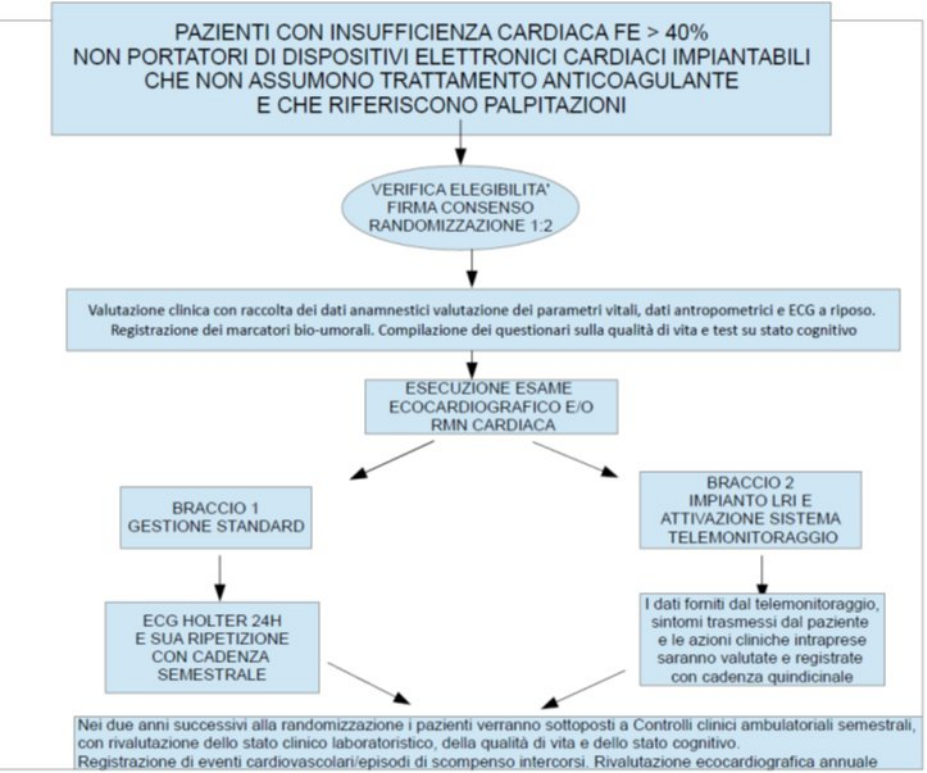
Study aim: Evaluate the clinical benefits of a remote monitoring management based on ILR vs standard practice in patients with high risk of cardiac arrhythmias, heart failure and left ventricle ejection fraction (LVEF)> 40% .

The study will enroll about 331 patients (221 in the ILR group and 110 in the conventional management group) with heart failure, LVEF> 40% and meeting the selection criteria

Enrollment in the study is expected to take approximately 18 months.

The total duration of the clinical investigation is expected to be approximately 42 months.

The study will be conducted in some centers in Europe with competitive enrollment.



Primary Endpoint:
Detection rate of arrhythmias that require treatment (medical or interventional)

Secondary Endpoints:

- Endpoint composed by atrial fibrillation (AF), longer than 6 minutes, sustained ventricular tachycardia or fibrillation (VT/VF), and high-risk bradyarrhythmias (high degree AV block or sinus pause > 6 seconds)
- Recurrent CV endpoint, consisting of unscheduled CV hospitalizations (including stroke) and CV emergency visits, with death as competing endpoint when compared to conventional management.
- -Major adverse cardiac events (MACE) :death, TIA, Stroke , MI
- The endpoint composed by unscheduled cardiovascular (CV) hospitalizations (including stroke), CV emergency visit, or death
- Hospitalizations for HF
- Pharmacological Therapy
- Hospitalizations for all causes
- Emergency Room Accesses
- Quality of life, assessed using:EQ-5D, KCCQ, Mini mental test
- time from the events to diagnosis
- Unscheduled visits
- Clinical resources required for patient management
- Patient economic burden: Patient Productivity loss/ Direct costs