

HFrEF di nuova diagnosi: esiste un rischio aritmico residuo dopo aver avviato la GDMT fino alla rivalutazione? E se sì, come lo gestiamo?

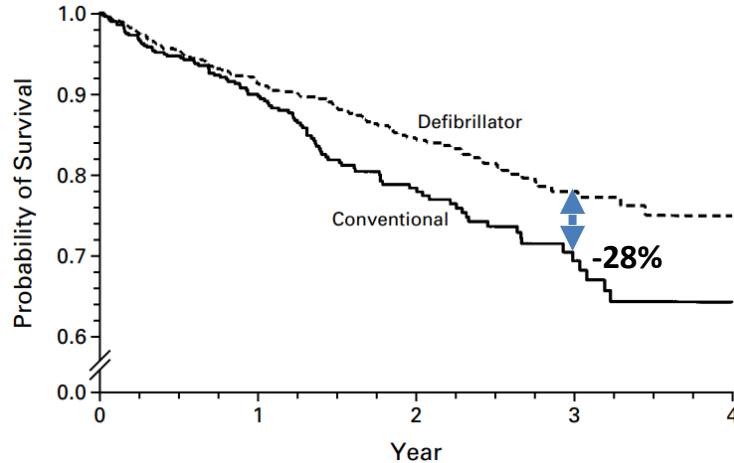
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MADIT II

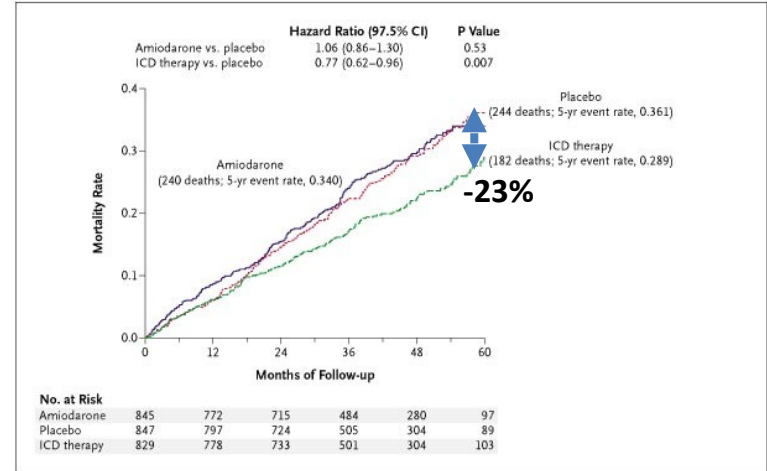
Prophylactic Implantation of a Defibrillator in Patients with Myocardial Infarction and Reduced Ejection Fraction



Moss et al. N Engl J Med 2002; 346: 877–883

SCD-HEFT

Amiodarone or an Implantable Cardioverter–Defibrillator for Congestive Heart Failure



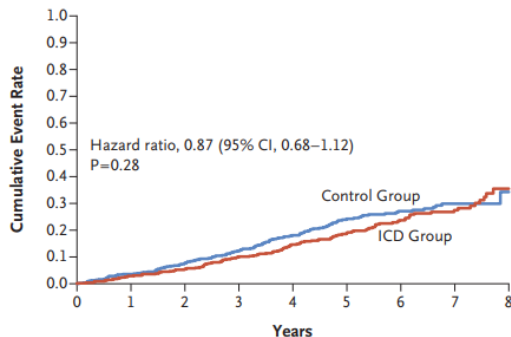
N Engl J Med 2005; 352:225–237



Nuove acquisizioni sulla valutazione del rischio di SDC in base all'eziologia dello scompenso

DANISH

A Death from Any Cause



CONCLUSIONS

In this trial, prophylactic ICD implantation in patients with symptomatic systolic heart failure not caused by coronary artery disease was not associated with a significantly lower long-term rate of death from any cause than was usual clinical care.

Køber et al. N Engl J Med 2016; 375:1221-1230

Linee guida ESC 2016

Primary prevention

An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA Class II–III), and an LVEF $\leq 35\%$ despite ≥ 3 months of OMT, provided they are expected to survive substantially longer than one year with good functional status, and they have:

- IHD (unless they have had an MI in the prior 40 days – see below).
- DCM.

I	A
I	B

Linee guida ESC 2021

Recommendations for device therapy in HFrEF

An ICD should be considered to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II–III) of a non-ischaemic aetiology, and an LVEF $\leq 35\%$ despite ≥ 3 months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status.

Ila

Nuova diagnosi di HFrEF

Il rischio acuto di SCD

FASE ACUTA



ASCEND HF¹

PROLONG II²

Pazienti ospedalizzati
per scompenso acuto

Pazienti con HFrEF
De novo (FE≤35%)

2%

SCD o RSCD

4%

Shocks

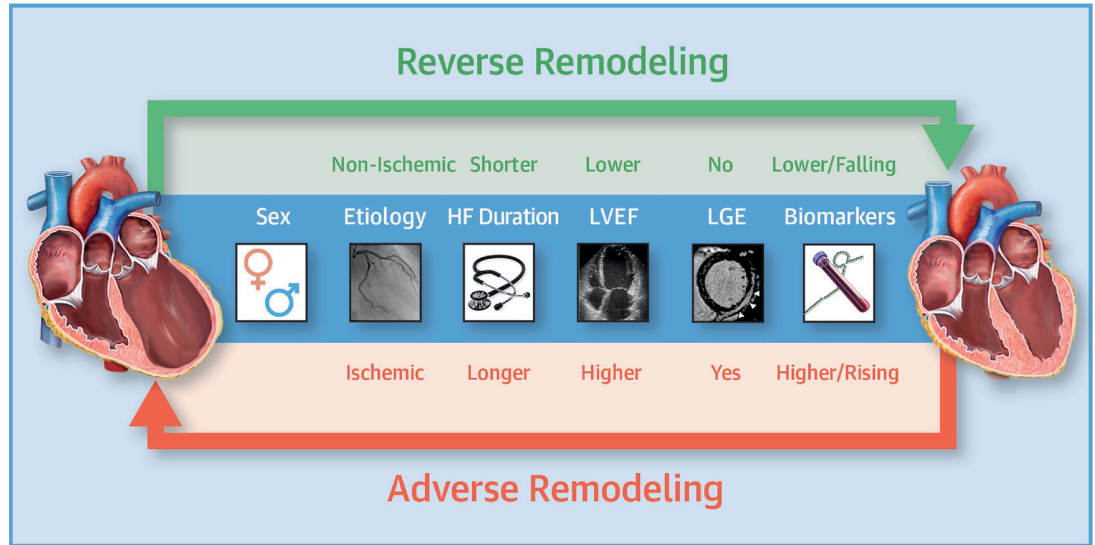
1. Pokorney SD et al.. *Eur J Heart Fail.* 2018 Mar;20(3):525-532.

2. Mueller-Leisse J et al. *ESC Heart Fail.* 2021 Sep 4. doi: 10.1002/ehf2.13586.



L'importanza della fase acuta: il rimodellamento

CENTRAL ILLUSTRATION: Main Predictors of Reverse and Forward Remodeling in HF



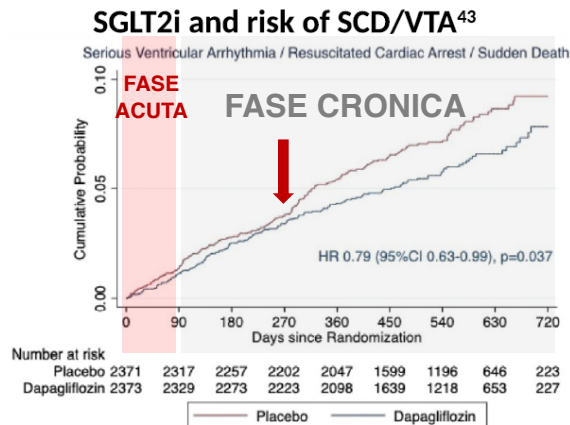
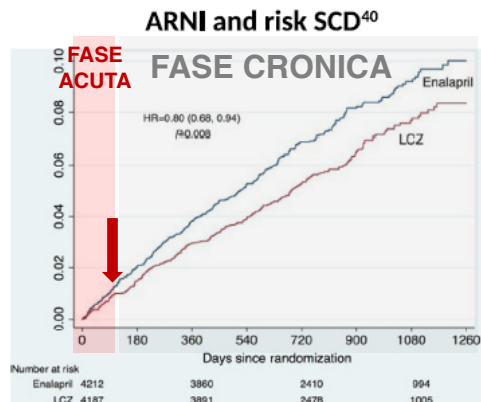
Aimo, A. et al. J Am Coll Cardiol HF. 2019;7(9):782-94.

La GDMT moderna è a tutti gli effetti una terapia antiaritmica

Farmaco	Riduzione SCD	Rimodellamento Substrato	Evidenze Chiave
Beta-bloccanti	+++	Alta (Il primo e più potente antiaritmico)	CIBIS-II, MERIT-HF, COPERNICUS
MRA	++	Media (Riduzione Fibrosi)	RALES, EMPHASIS-HF
ARNI (Sacubitril/Valsartan)	++	Rapido reverse remodeling (Riduzione burden e shock ICD)	PARADIGM-HF, De Diego, Martens
SGLT2-inibitori	+	Metabolico/Strutturale	DAPA-HF, EMPEROR-Reduced, Meta-analisi 2024

Oltre al miglioramento prognostico generale, la Quadruple Therapy modifica profondamente il substrato aritmico nel tempo.

I nuovi farmaci non riducono il rischio di SCD in acuto



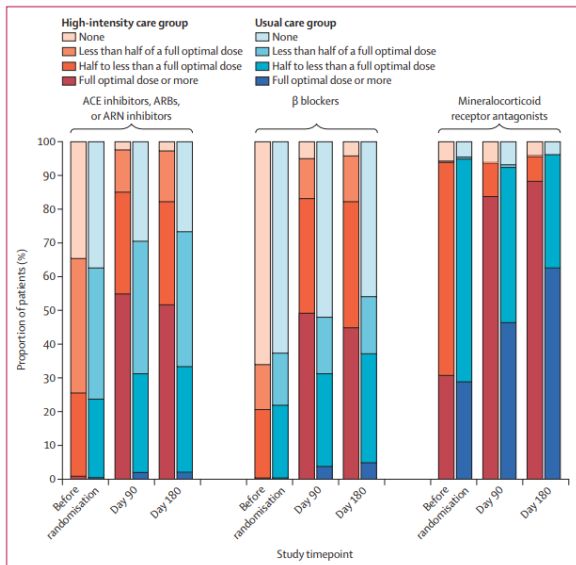
Le curve di SCD e SCD/VTA per ARNI e SGLT2i divergono solo dopo 90-270 giorni.

I nuovi farmaci non hanno effetto nel ridurre la SCD durante la fase acuta

Goldenberg I. et al. Heart Rhythm. 2025 Jan 27:S1547-5271(24)03620-8.



Nuove terapie farmacologiche e rischio cronico di SCD



Linee guida ESC 2023: aggiornamento sulla titolazione della terapia farmacologica

Recommendation	Class ^a	Level ^b
An intensive strategy of initiation and rapid up-titration of evidence-based treatment before discharge and during frequent and careful follow-up visits in the first 6 weeks following a HF hospitalization is recommended to reduce the risk of HF rehospitalization or death. ^{c,d,e 16}	I	B

McDonagh TA et al., Eur Heart J. 2023

Mebazaa A et al. Lancet. 2022; 400(10367):1938-1952



PROBLEMATICHE ALLA DIMISSIONE OSPEDALIERA DOPO RICOVERO PER HFREF

- DECONGESTIONARE
- MANTENERE EMODINAMICA
- EVITARE ECCESSIVO WRF
- INSERIRE FARMACI DISEASE MODIFY



Progetto CONNECT HF-CKD

telemonitoraggio post dimissione

Cardiologia Firenze 1 USL Toscana centro



Dimissione Ospedaliera dopo SC:

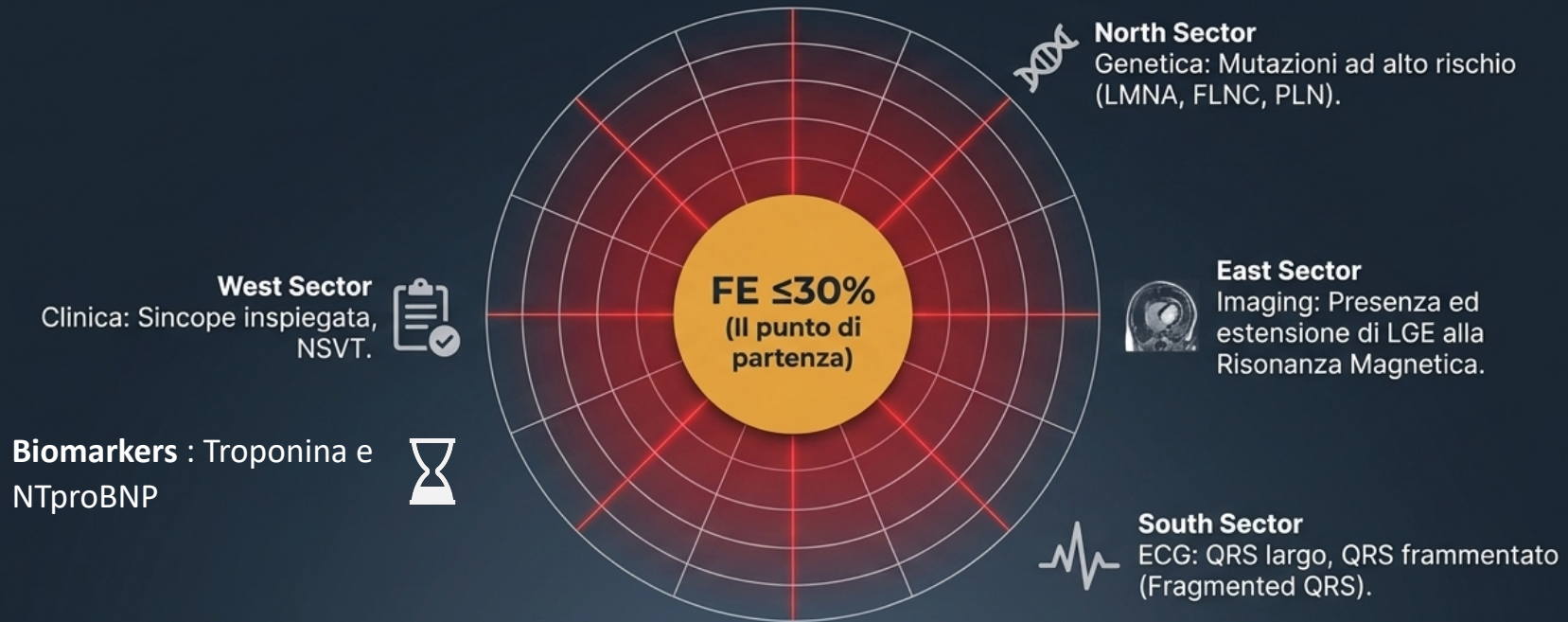
Segnalazione al MMG della dimissione del pz e trasmissione di password per accedere al portale di monitoraggio

Pz ad alto profilo di rischio: consegna di Kit di telemonitoraggio con rilevazione autonoma, giornaliera dei parametri da effettuare nelle prime 4 settimane dalla dimissione → Visita ambulatorio scompenso

Pz a basso profilo di rischio: attivazione dell'infermiere di famiglia (COT) che con kit di monitoraggio mobile effettua un controllo settimanale nelle prime 4 settimane dalla dimissione → Visita ambulatorio scompenso

Contatto in TELEVISITA a 10 gg dalla dimissione per controllo preordinato di:
Creatinina (GFR) e albumina/creatinina urinaria Na-K - NTproBNP

LVEF is not a sudden death biomarker



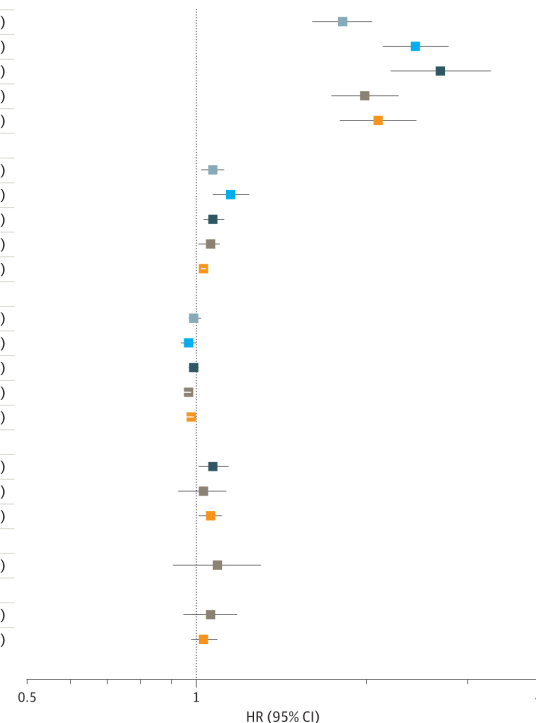
La frazione di eiezione rappresenta un indicatore di disfunzione sistolica, tuttavia per un'adeguata stratificazione del rischio aritmico è sempre da considerare un approccio multiparametrico

From: **Risk Stratification in Nonischemic Dilated Cardiomyopathy Using CMR Imaging: A Systematic Review and Meta-Analysis**

JAMA. 2024;332(18):1535-1550. doi:10.1001/jama.2024.13946

Conclusion The presence and extent of LGE were associated with various adverse clinical outcomes, whereas LVEF was not significantly associated with mortality and arrhythmic end points in NIDCM. Risk stratification using native T1 relaxation times, extracellular volume fraction, and global longitudinal strain requires further evaluation

Parameter	Studies/ patients, No.	HR (95% CI)
Late gadolinium enhancement presence (yes/no)		
All-cause mortality	23/9738	1.81 (1.60-2.04)
Cardiovascular mortality	19/5228	2.43 (2.13-2.78)
Arrhythmia	40/13791	2.69 (2.20-3.30)
Heart failure	32/9464	1.98 (1.73-2.27)
MACE	54/12040	2.09 (1.79-2.44)
Late gadolinium enhancement extent (per 1%)		
All-cause mortality	4/1852	1.07 (1.02-1.12)
Cardiovascular mortality	3/1323	1.15 (1.07-1.24)
Arrhythmia	9/2086	1.07 (1.03-1.12)
Heart failure	6/1686	1.06 (1.01-1.10)
MACE	13/3004	1.03 (1.02-1.04)
Left ventricular ejection fraction (per 1%)		
All-cause mortality	5/3220	0.99 (0.97-1.02)
Cardiovascular mortality	7/3522	0.97 (0.94-1.00)
Arrhythmia	12/5055	0.99 (0.97-1.01)
Heart failure	10/4576	0.97 (0.95-0.98)
MACE	24/5446	0.98 (0.96-0.99)
T1 relaxation time (per 10 ms)		
Arrhythmia	5/1778	1.07 (1.01-1.14)
Heart failure	3/2198	1.03 (0.93-1.13)
MACE	3/962	1.06 (1.01-1.11)
Extracellular volume (per 1%)		
Heart failure	3/1372	1.09 (0.91-1.30)
Global longitudinal strain (per 1%)		
Heart failure	3/1001	1.06 (0.95-1.18)
MACE	7/1397	1.03 (0.94-1.14)



Improved Risk Stratification for Ventricular Arrhythmias and Sudden Death in Patients With Nonischemic Dilated Cardiomyopathy

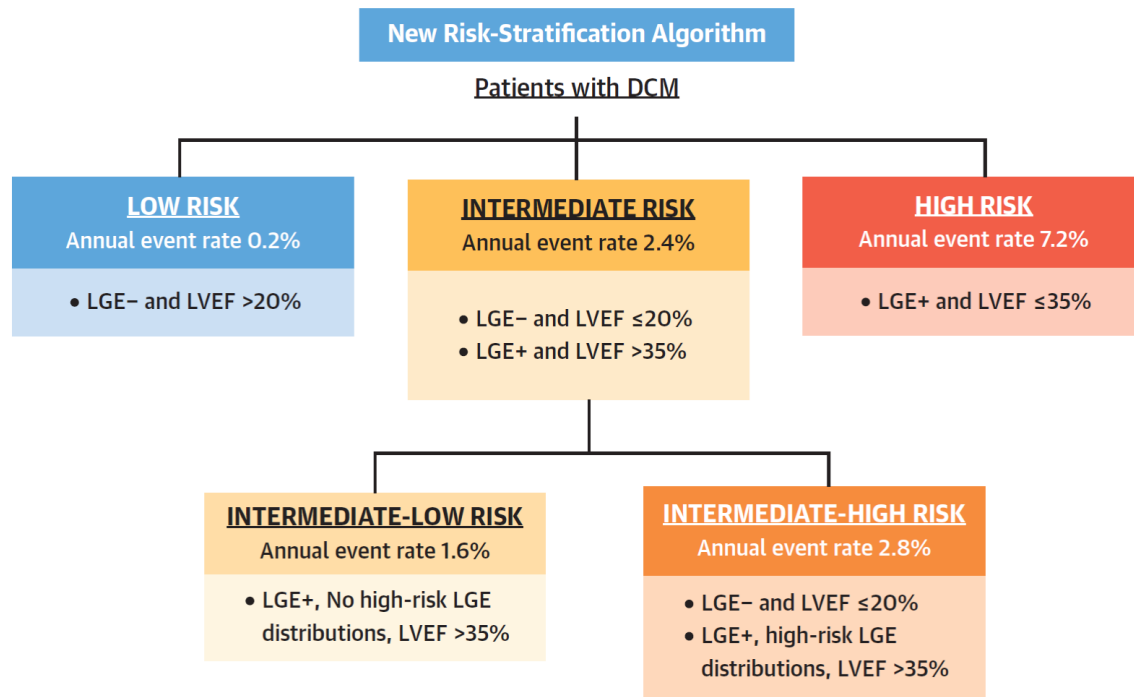


Andrea Di Marco, MD, PhD,^{a,b,c} Pamela Frances Brown, MD,^d Joshua Bradley, BSc MRSc,^d Gaetano Nucifora, MD, PhD,^d Eduard Claver, MD,^{a,b} Fernando de Frutos, MD,^{a,b} Paolo Domenico Dallaglio, MD,^{a,b} Josep Comin-Colet, MD, PhD,^{a,b} Ignasi Anguera, MD, PhD,^{a,b} Christopher A. Miller, MD, PhD,^{c,e,f} Matthias Schmitt, MD, PhD^{c,d}

Thus, the presence of at least one of the following features was identified as high-risk LGE:

Epicardial LGE, transmural LGE, or combined septal and free-wall LGE

CENTRAL ILLUSTRATION Schematic Representation of the Proposed New Algorithm



Di Marco, A. J Am Coll Cardiol. 2021;77(23):2890-905.



Prediction of sudden cardiac death using artificial intelligence: Current status and future directions

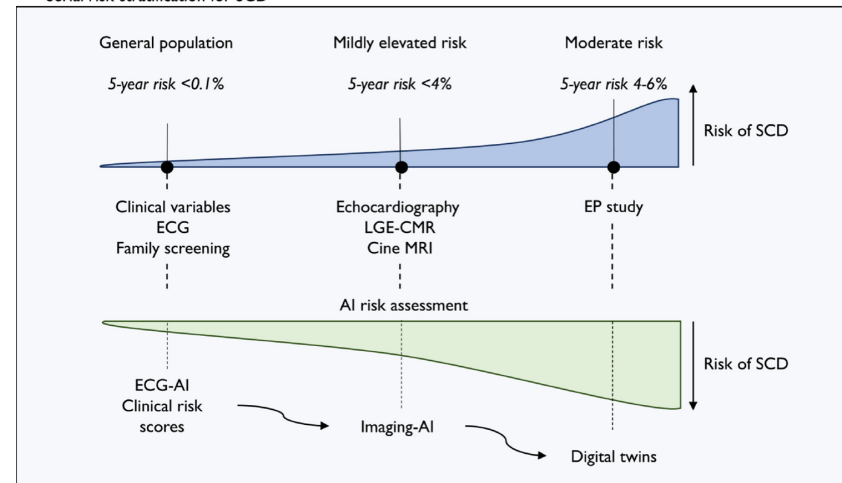
Maarten Z.H. Kolk, MD, MSc^{1,2}, Samuel Ruipérez-Campillo, MSc, MEng³, Arthur A.M. Wilde, MD, PhD^{1,2}, Reinoud E. Knops, MD, PhD^{1,2}, Sanjiv M. Narayan, MD, PhD⁴, Fleur V.Y. Tjong, MD, PhD^{1,2}

ECG-AI for SCD prediction

Imaging-AI for SCD prediction

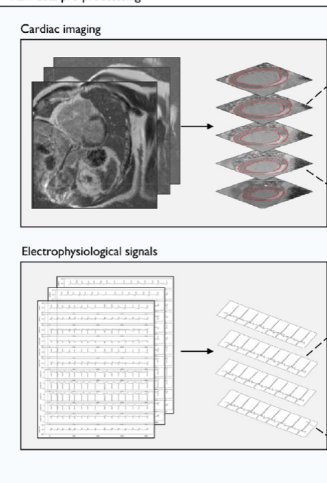
Multimodal-AI and digital twins

B Serial risk-stratification for SCD



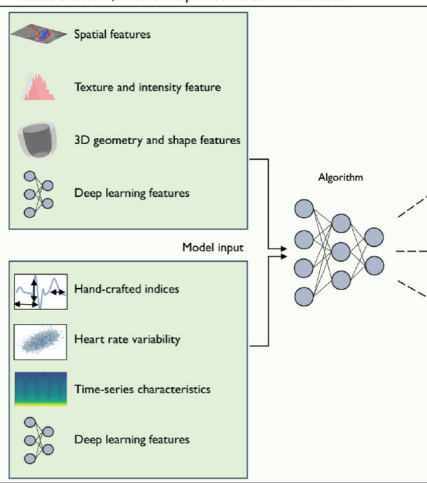
A

Raw data pre-processing



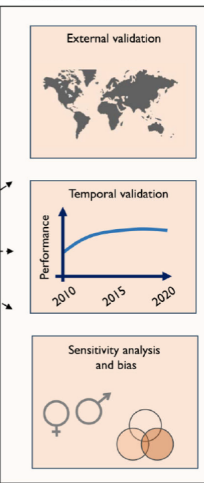
B

Feature extraction, model development and SCD risk estimation

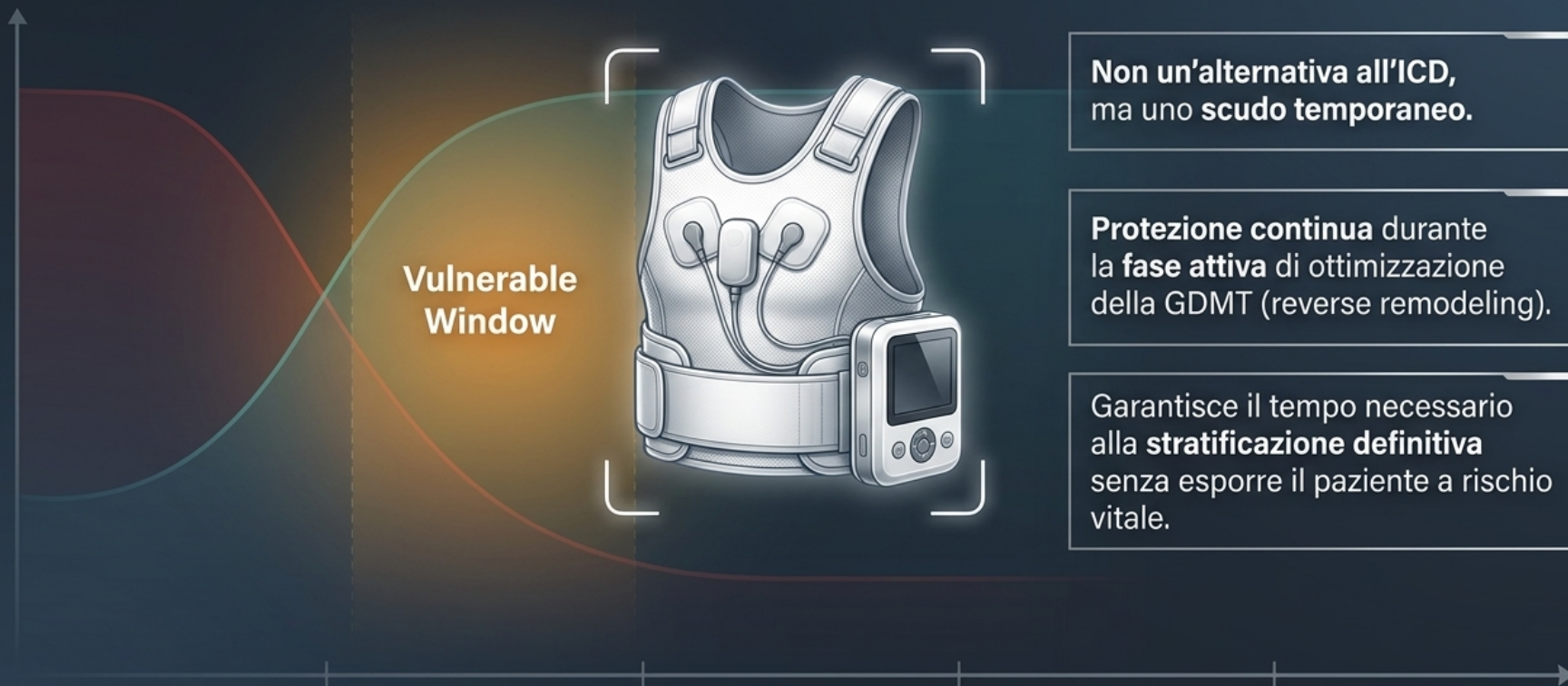


C

Evaluation and validation



Il WCD: un ponte temporale dinamico



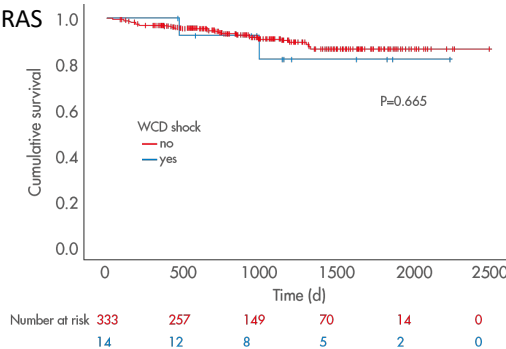
Evidenze cliniche: efficacia nell'interrompere TV/FV

Studio	Popolazione	Risultato Chiave
WEARIT / WEARIT-II	Registri prospettici ad alto volume	Elevata compliance e tassi significativi di terapie appropriate durante la transizione.
PROLONG	Pazienti HFrEF de novo	Dimostra l'utilità di estendere la protezione durante l'ottimizzazione GDMT prolungata.
VEST	Post-MI recente con FE ridotta	Riduzione della mortalità aritmica nei pazienti altamente aderenti.

Il WCD ha un'altissima efficacia nel riconoscere e interrompere tempestivamente aritmie ventricolari maligne (TV/FV) in scenari clinici real-world.

Il ruolo del defibrillatore indossabile nei pazienti con nuova diagnosi di HFrEF: lo studio PROLONG II

- 353 pazienti con WCD (69% m, 56 ± 15 anni) con nuova diagnosi di scompenso
 - 64% NICM
 - 36% ICM
- FU medio $2,8 \pm 1,5$ anni, **max. 6,8 anni**
- Eccellente tempo di indossamento: 22 ± 4 ore/giorno
- Buona terapia per HF
 - 94% Beta-bloccanti
 - 96% Inibitori del RAS
 - 88% MRA



Mueller-Leisse J et al. ESC Heart Fail 2021;8:5142-8

4% (n=14) dei pazienti con **shock appropriati** del WCD:

- 45% NICM e CMD
- 4% ICM
- 11% PPCM

Lo shock del WCD non è associato a un peggioramento della sopravvivenza

Il **53%** dei pazienti **non** aveva un'indicazione all'impianto di ICD dopo l'uso del WCD

Nessuna morte improvvisa o eventi ventricolari emodinamicamente rilevanti nei pazienti non impiantati con ICD nel FU a lungo termine

Sudden cardiac death in newly diagnosed non-ischaemic or ischaemic cardiomyopathy assessed with a wearable cardioverter-defibrillator: the German nationwide SCD-PROTECT study

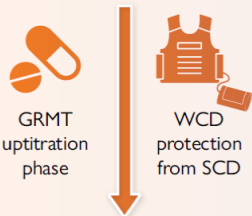
David Duncker^{1,4}, Eloi Marijon^{2,3}, Marco Metra⁴, Olivier Plot⁵,
Marat Fudim^{6,7}, Uwe Siebert^{8,9,10}, Norbert Frey¹¹,
Lars Siegfried Maier¹², and Johann Bauersachs¹

SCD-PROTECT: Sudden cardiac arrest in patients with newly diagnosed non-ischaemic cardiomyopathy or coronary artery disease

Challenge



Newly diagnosed
reduced LVEF due to
NICM or MI/CAD



Evaluate the risk of SCD
in the early phase by data
recorded by the WCD

Methods

- Epidemiological study
- Non-interventional
- Observational
- Multicenter
- Consecutive enrollment



19 598 patients receiving WCD in Germany
between December 2021 and May 2023

NICM 11 449 patients
MI/CAD 8149 patients

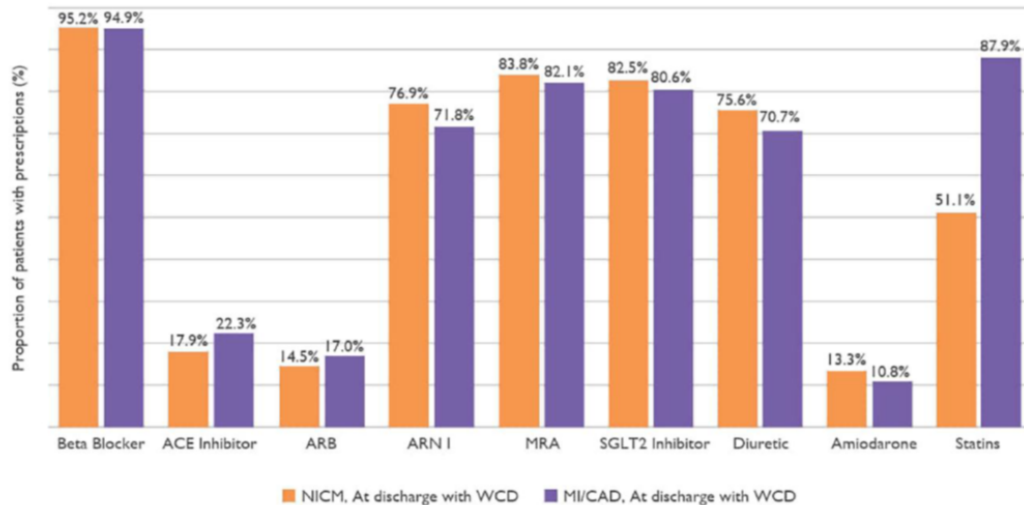
Results - Exploratory endpoints



Average LVEF

26.9% at discharge **NICM** → 38.9% WCD end of use

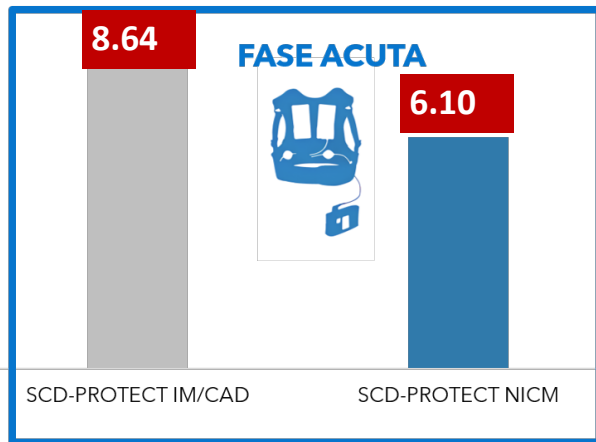
28.4% at discharge **MI/CAD** → 38.3% WCD end of use



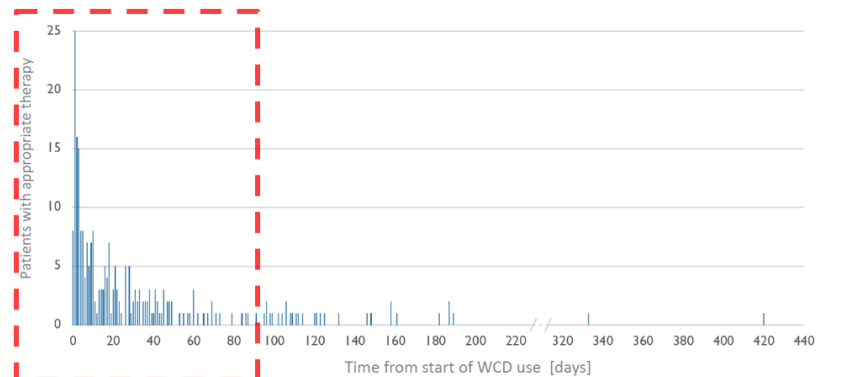
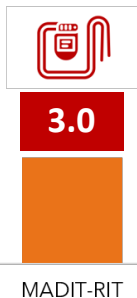
Sudden cardiac death in newly diagnosed non-ischaemic or ischaemic cardiomyopathy assessed with a wearable cardioverter-defibrillator: the German nationwide SCD-PROTECT study

David Duncker ^{1,*}, Eloi Marjon ^{2,3}, Marco Metra ⁴, Olivier Piot ⁵,
Marat Fudim ^{6,7}, Uwe Siebert ^{8,9,10}, Norbert Frey ¹¹,
Lars Siegfried Maier ¹², and Johann Bauersachs ¹³

Events per 100 patient-years



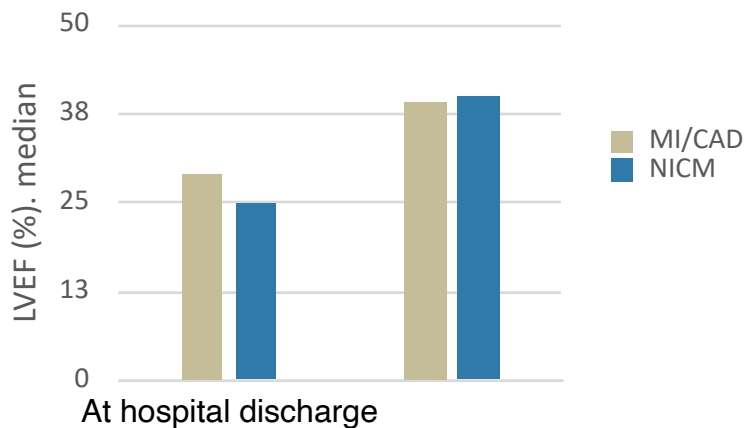
FASE CRONICA



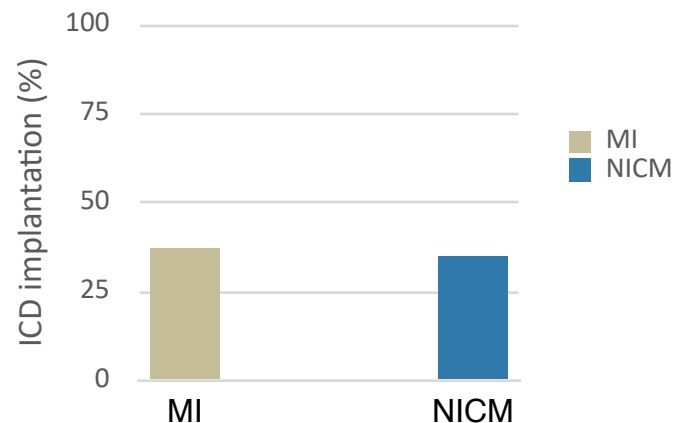
Sudden cardiac death in newly diagnosed non-ischaemic or ischaemic cardiomyopathy assessed with a wearable cardioverter-defibrillator: the German nationwide SCD-PROTECT study

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Lars Siegfried Maier ¹², and Johann Bauersachs ¹

TRAIETTORIA FE



IMPIANTI DI ICD ALLA FINE DELL'USO DEL WCD



Pazienti con nuova diagnosi di HFrEF

Linee guida HF ESC 2021

Primary prevention		
An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II–III) of an ischaemic aetiology (unless they have had a MI in the prior 40 days—see below), and an LVEF $\leq 35\%$ despite ≥ 3 months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status. ^{161,165}	I	A
An ICD should be considered to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II–III) of a non-ischaemic aetiology, and an LVEF $\leq 35\%$ despite ≥ 3 months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status. ^{161,166,167}	IIa	A
<u>A wearable ICD</u> may be considered for patients with HF who are at risk of sudden cardiac death for a limited period or as a bridge to an implanted device. ^{173–176}	IIb	B

Pazienti post IM

Linee guida SCD e VA ESC 2022

Recommendations	Class ^a	Level ^b
Risk stratification		
In patients with pre-discharge LVEF $\leq 40\%$, re-evaluation of LVEF 6–12 weeks after MI is recommended to assess the potential need for primary prevention ICD implantation. ^{568,573,574}	I	C

Zeppenfeld K et al. Eur Heart J 2022;43:3997-4126

ICD implantation is not recommended within 40 days of a MI as implantation at this time does not improve prognosis. ^{177,178}	III	A
<u>The WCD may be considered in the early phase after MI in selected patients.</u> ^{371,372}	IIb	B

Role of the wearable cardioverter defibrillator in the initial period of sudden cardiac death risk stratification: results of a European Heart Rhythm Association survey

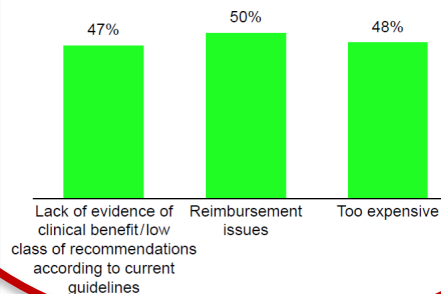
Federico Migliore ¹*, Laura Perrotta ², Mark T. Mills ³, Ante Anic ⁴,
Arian Sultan ⁵, Piotr Futyma ⁶, Michał Mazurek ⁷, Martina Nesti ⁸,
Gabor Z. Duray ^{9,10}, Raimondo Pittorru ¹, and Julian K. R. Chun ¹¹

Role of the wearable cardioverter defibrillator in the early risk stratification period for the sudden cardiac death: results of an EHRA survey



- ✓ 182 respondents
- ✓ 68% EP specialist
- ✓ 31% 40–49 years
- ✓ 74% male
- ✓ 77% routinely use WCD in their clinical practice

Main barriers for implementation of WCD



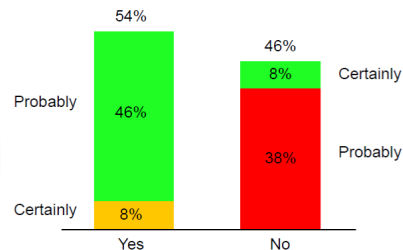
Currently most frequently indications for WCD

- ✓ After ICD explantation when reimplantation is not possible
- ✓ Secondary prevention ICD indication — patients temporarily ineligible for device implantation

Possible emerging indications for WCD

- ✓ Temporary protection in patients with newly diagnosed HF with LVEF $\leq 35\%$ until LVEF re-evaluation after ≥ 3 months of OMT

Will the use of the big 4 heart failure medications in the near future increase the need for WCD?



Cost-utility analysis of the use of a wearable cardioverter defibrillator (LifeVest®) versus standard of care in the prevention of sudden cardiac death in patients after myocardial infarction

Przemysław Mitkowski^{1*}, Maciej Sterliński^{2*}, Marcin Czech^{3,4}, Andrzej Przybylski^{5,6}, Jerzy K Wranicz⁷, Maciej Kempa⁸, Jarosław Kaźmierczak⁹, Marcin Michalak¹⁰, Paweł Ptaszyński⁷, Adam Sokal^{11,12}, Marek Gierlotka¹³, Robert J Gil¹⁴, Michał M Farkowski^{14,15}, Oskar Kowalski¹⁶, Agnieszka Pawlak^{14,17}, Łukasz Szumowski², Mateusz Tajstra¹⁸, Adam Witkowski¹⁹, Adam Wojtaszczyk⁷, Andrzej Ząbek^{20,21}, Iwona Dobrowolska²², Katarzyna Młyńczak²², Maciej Niewada^{22,23}, Dominik Golicki^{22,23}

Cost-utility analysis of the use of WCD (LifeVest®) in Post-MI patients in Poland

 Context

- **350,000** sudden cardiac arrests/year in Europe
- **Post-MI patients** at high risk of **SCD**
- **WCD (LifeVest®)** validated by **VEST trial** & Polish registry

 Methods

- **Markov model**
- **Perspective:** Polish NHF (public payer)
- **Horizon:** Lifetime
- **Input:** VEST trial, Polish registry, Polish costs

 Conclusion

- WCD is a **cost-effective** and **clinically beneficial** strategy for **SCD prevention** in **Polish post-MI** patients.

 Objective

Compare cost-effectiveness of

 **WCD (LifeVest®)** vs.  **Standard of Care (SoC)**
in **post-MI** patients

 Key Results

- **+0.49 life years**
- **+0.39 QALYs**
- **Incremental cost:** PLN **51.3K** (€ **12.1K**)
- **ICUR:** PLN **132.4K/QALY** (€ **31.1K/QALY**)
 **~40% below** Polish cost-effectiveness threshold



European Heart Journal Supplements (2023) 25 (Supplement D), D201-D206
The Heart of the Author
<https://doi.org/10.1093/eurheartj/ehad070>



ANMCO position paper: guide to the appropriate use of the wearable cardioverter defibrillator in clinical practice for patients at high transient risk of sudden cardiac death

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KEYWORDS

Wearable cardioverter defibrillator
Cardiovascular disease
Sudden cardiac death
Patient management system

Extended risk stratification and optimal management of patients with a permanently increased risk of sudden cardiac death (SCD) are becoming increasingly important. There are several clinical conditions where the risk of arrhythmic death is present albeit only transient. As an example, patients with depressed left ventricular function have a high risk of SCD that may be only transient if there will be a significant recovery of function. It is important to protect the patients while receiving and titrating to the optimal dose the recommended drug that may lead to an improved left ventricular function. In several other conditions, a transient risk of SCD can be observed even if the left ventricular function is not compromised. Examples are patients with acute myocarditis, during the diagnostic work-up of some arrhythmic conditions or after extraction of infected catheters while radiating the associated infection. In all these conditions, it is important to offer

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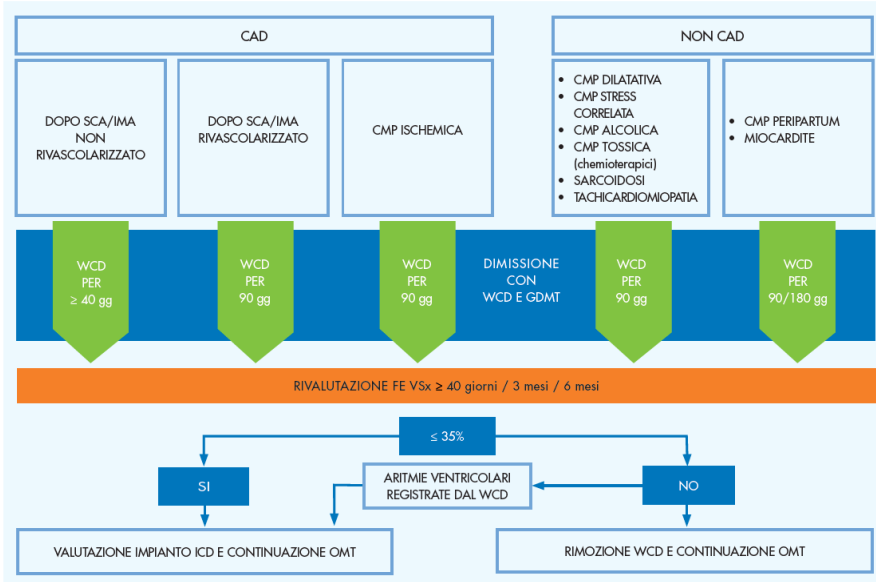
Position Paper ANMCO: guida all'uso appropriato del WCD nella pratica clinica per i pazienti a rischio transitorio di morte improvvisa

Obiettivi:

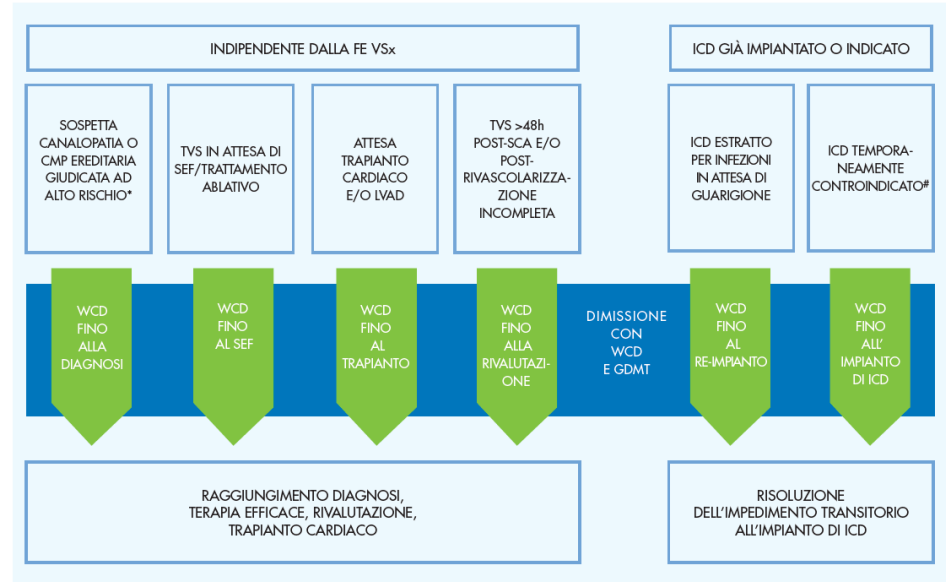
- Fornire una sintesi delle più recenti raccomandazioni all'utilizzo del WCD
- Come effettuare lo screening/selezione dei pazienti
- Suggestire una guida al processo decisionale e alla gestione del paziente durante il periodo di utilizzo del WCD

WCD: position paper ANMCO

FLOW CHART PAZIENTI CON NUOVO RISCONTRO DI FE VSx $\leq 35\%$

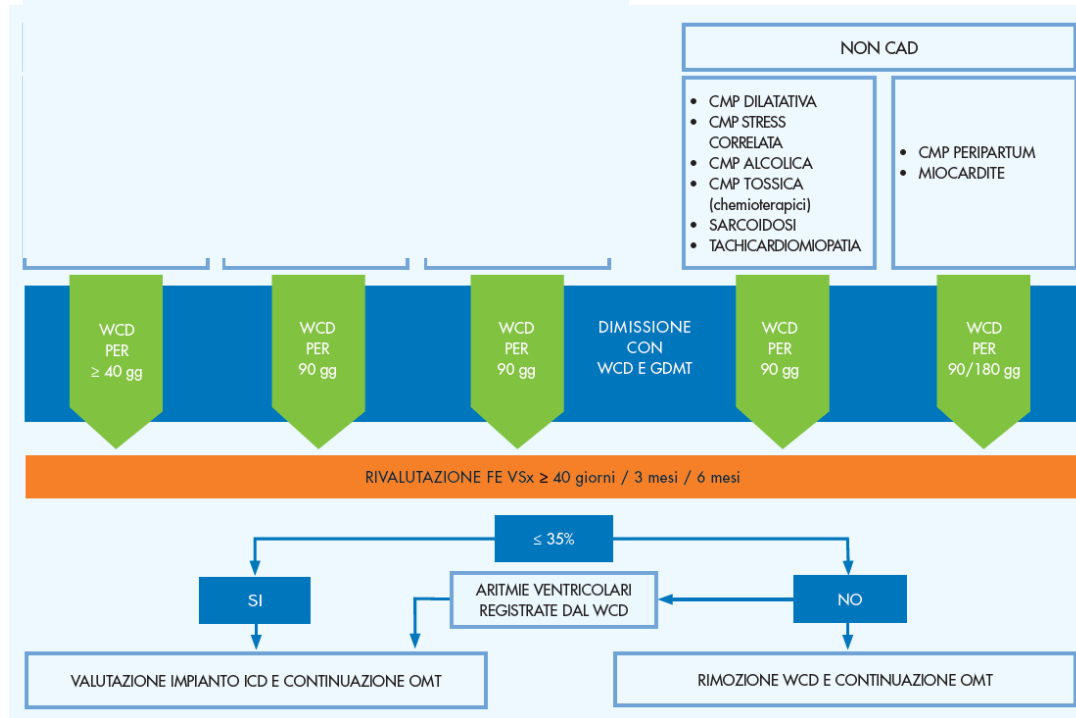


FLOW CHART PER ALTRI CASI DI PAZIENTI A RISCHIO DI MORTE CARDIACA IMPROVVISA



WCD nel HFrEF

FLOW CHART PAZIENTI CON NUOVO RISCONTRO DI FE VSx $\leq 35\%$



Take-Home Messages: La Visione 2026

1

L'HF_rEF de novo presenta un picco di rischio aritmico significativo ed immediato già alla diagnosi.

2

La Quadruple Therapy (GD_{MT}) è una potente terapia antiaritmica, ma richiede tempo per il reverse remodeling.

3

Il 30-50% dei pazienti recupererà la FE, rendendo l'impianto immediato di ICD inappropriato.

4

LVEF is not a biomarker: serve una stratificazione multiparametrica (genetica, imaging, clinica) per svelare il rischio residuo.

5

Il WCD rappresenta la soluzione moderna al paradosso clinico, offrendo un ponte sicuro verso una decisione definitiva basata sui dati.

GRAZIE PER L'ATTENZIONE

