



UTIC | **ANMCO**
CLUB |
CRITICAL CARE COMMUNITY

“To implant, or not to implant: that is the question”.
Il ruolo del defibrillatore indossabile nella
prevenzione della morte cardiaca
improvvisa

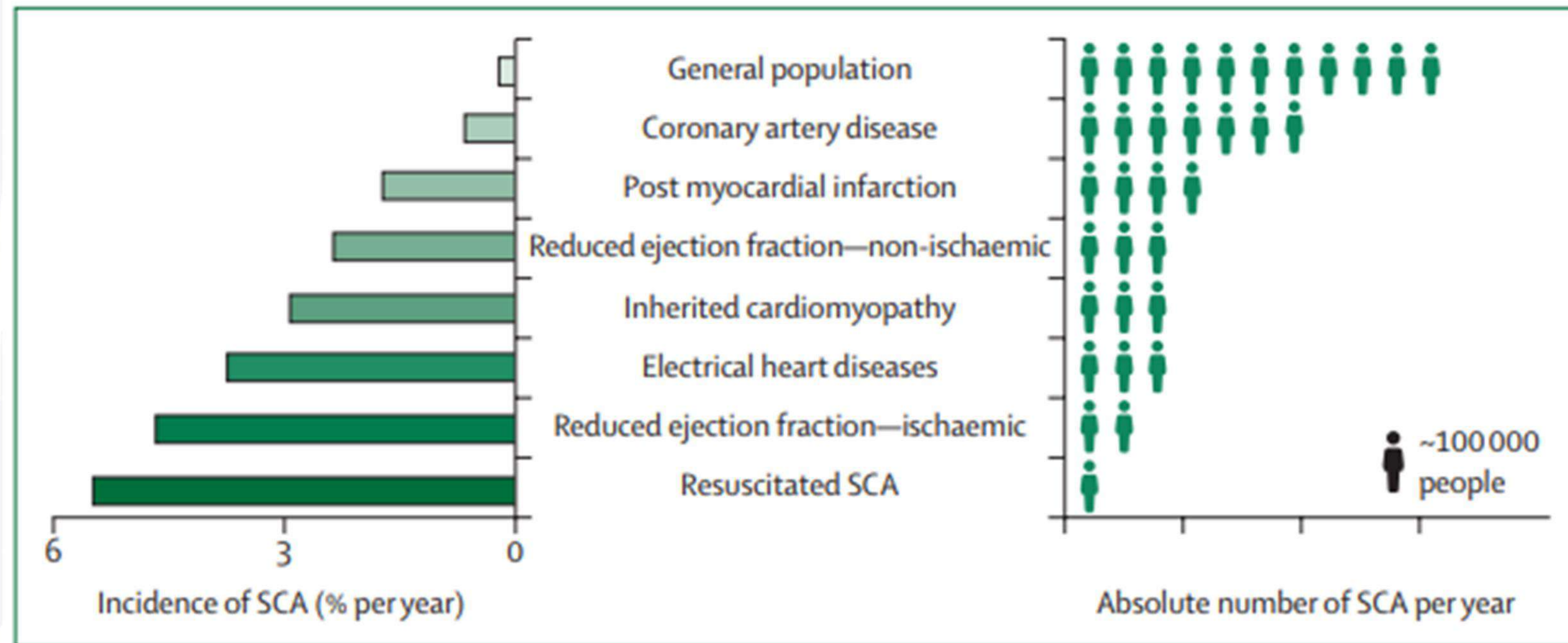
Maria Laura Canale
Cardiologia Ospedale Versilia

Fonti di finanziamento

- Nessuna

**Question #1:
Is easy to prevent SCD in the general population?**

The SCA Paradox: Risk vs. Absolute Event Numbers



“SCD prevention is also rendered difficult by the paradox in risk versus absolute event numbers. Although individuals with overt structural heart disease, especially those with history of malignant ventricular arrhythmias, constitute the highest risk subgroup for SCD, in absolute terms these cases represent a relatively small percentage of patients who have SCD in the population per year. Most SCD events occur in the general population without known heart disease.”

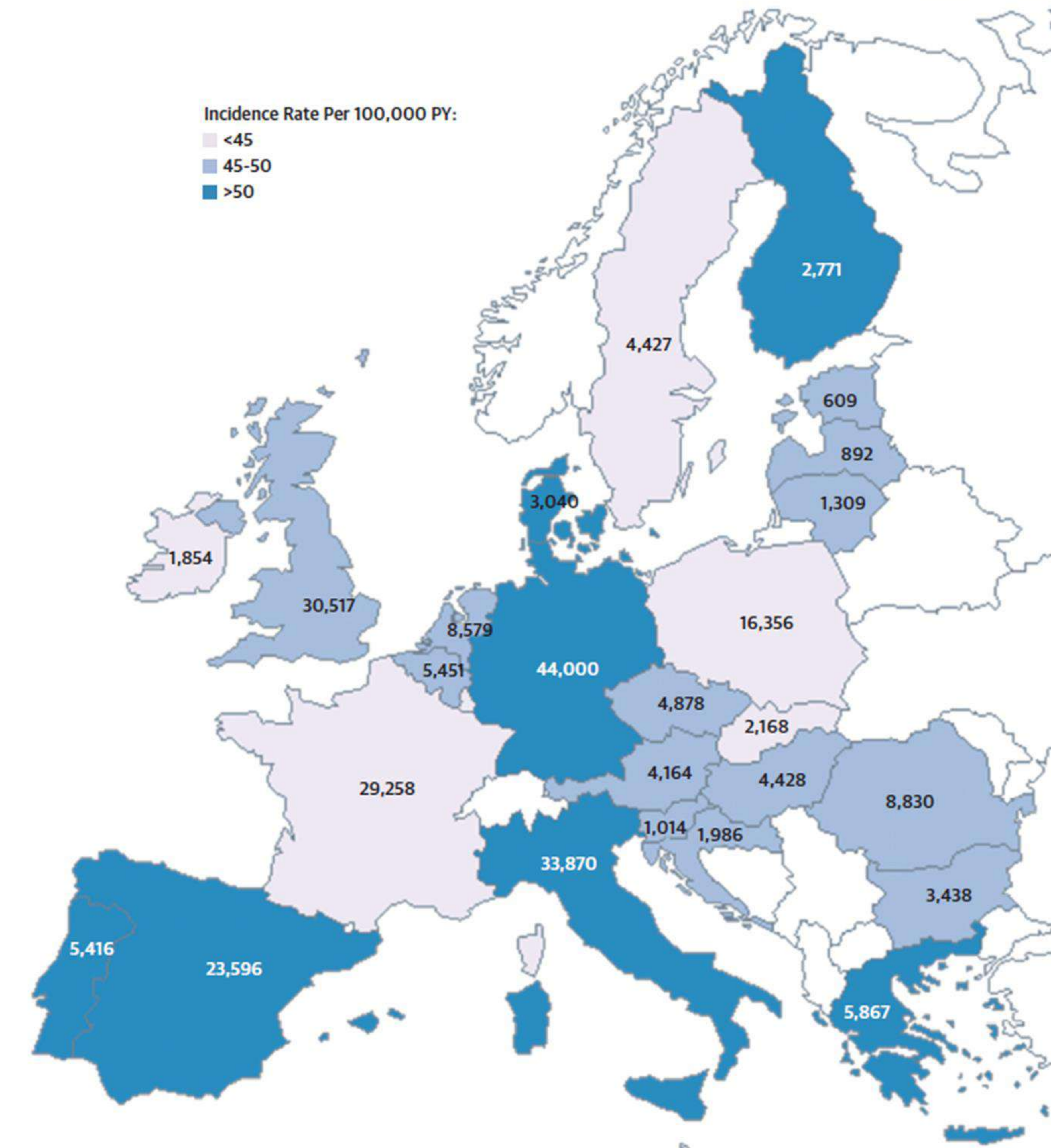
SCD: Italy in the European Context

TABLE 2 Main Clinical Characteristics and Circumstances Surrounding OHCA Across the 4 Registries

| | ARREST (n = 5,825) | SDEC (n = 14,581) | SRCR (n = 6,346) | DCAR (n = 15,238) |
|--|-----------------------|----------------------|---------------------|----------------------|
| Female | 29.2 | 35.3 | 34.3 | 36.6 |
| Age | 68.0 (59.0-78.0) | 68.5 (55.6-81.4) | 71.0 (59.0-81.0) | 72.0 (61.0-82.0) |
| OHCA in nonpublic place | 73.2 | 75.5 | 66.8 | 73.3 |
| OHCA in public place | 26.8 | 24.5 | 33.2 | 26.7 |
| Witnessed OHCA | 71.9 | 79.2 | — | 43.3 |
| Bystander CPR performed | 76.0 | 71.7 | 51.2 | 66.4 |
| Bystander AED used | 10.6 | 3.2 | 2.3 | 3.2 |
| VT-VF as first recorded rhythm | 42.2 | 26.7 | 20.5 | 20.4 |
| Median time between dispatch call and ambulance arrival, min | 8.5 (6.6-10.8) | 9.0 (7.0-12.0) | 9.0 (6.0-13.0) | — |
| ROSC | 41.8 | 40.7 | 33.2 | 29.2 |
| Transferred to hospital alive | 59.6 | 30.7 | 60.4 | 36.3 |

Values are % or median (IQR).

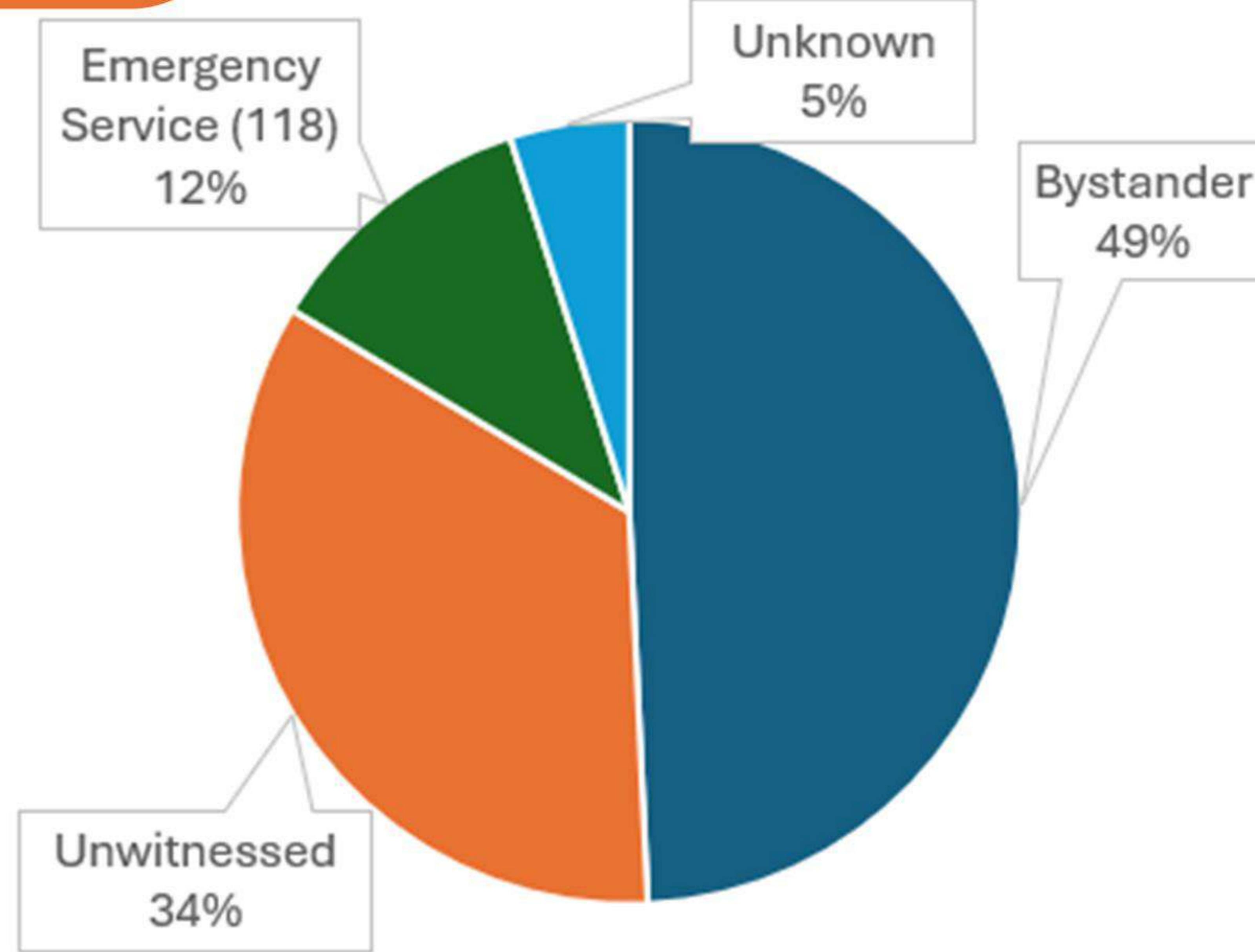
CPR = cardiopulmonary resuscitation; VF = ventricular fibrillation; VT = ventricular tachycardia; other abbreviations as in Table 1.



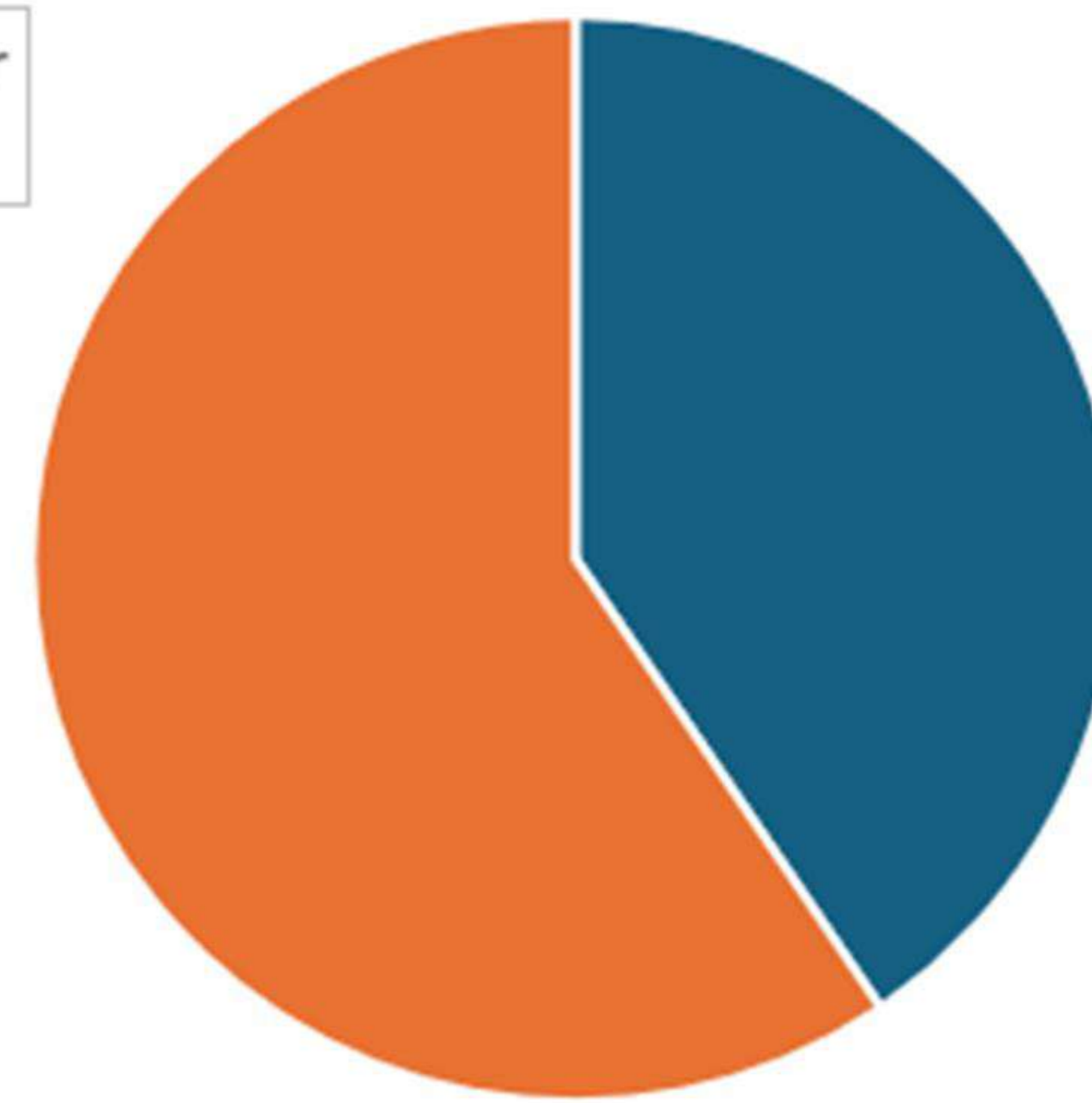
5.190 SCA confirmed in 2023 in Lombardia

Lombardia CARe: Overview of Regional Cardiac Arrest Registry

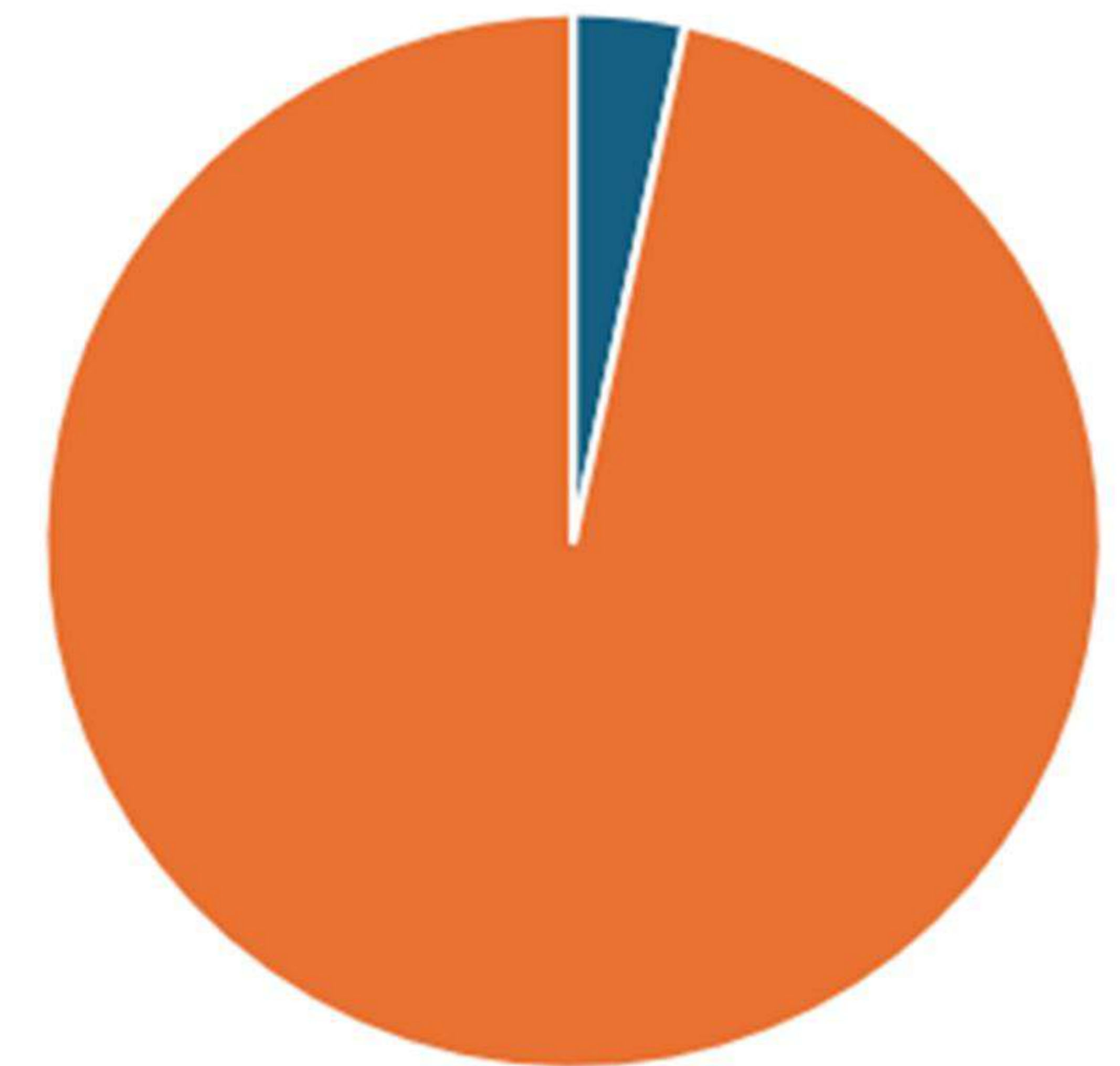
Type of witnesses



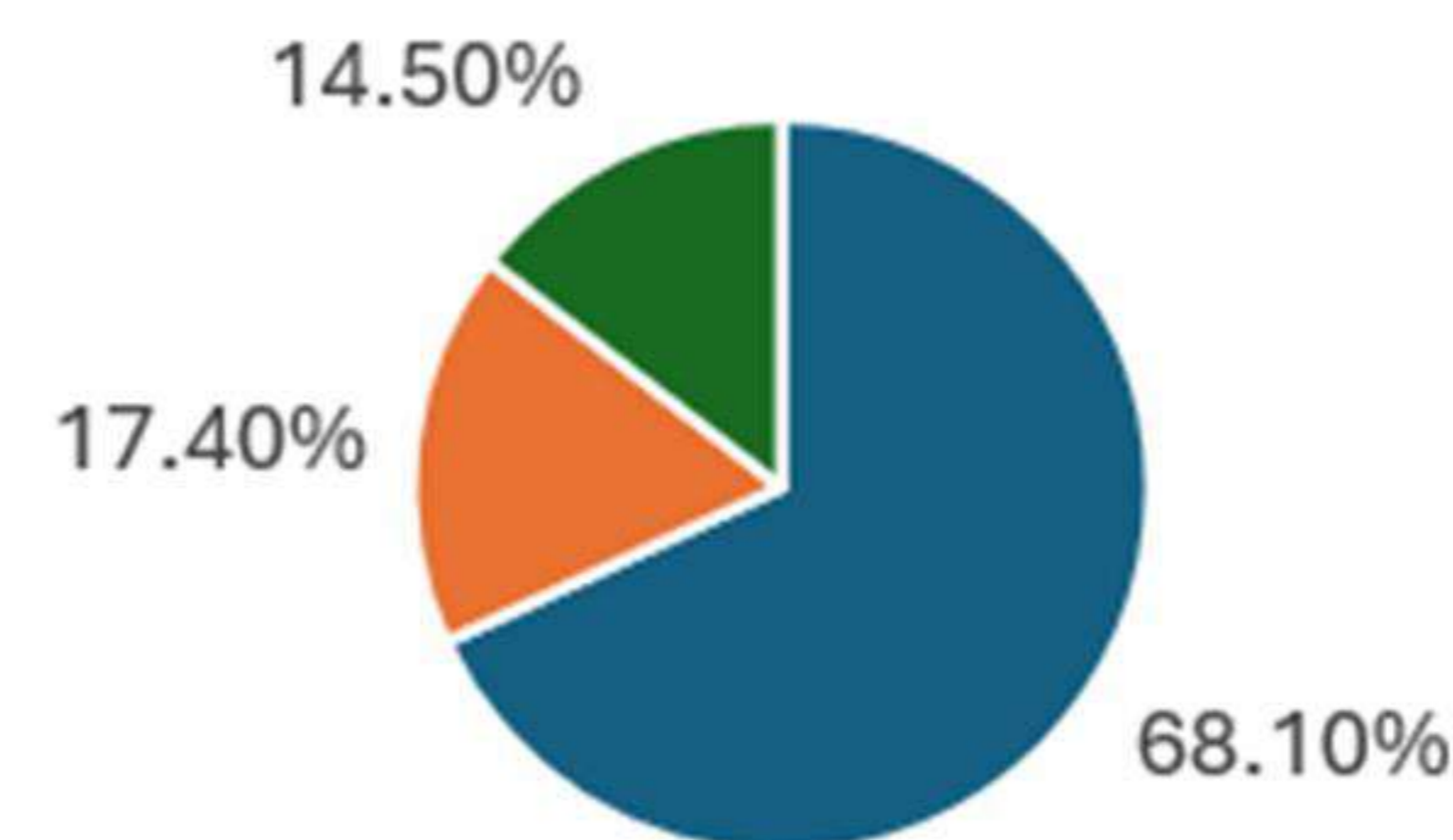
CPR before emergency arrival



AED use before emergency arrival



Outcome of the rescue

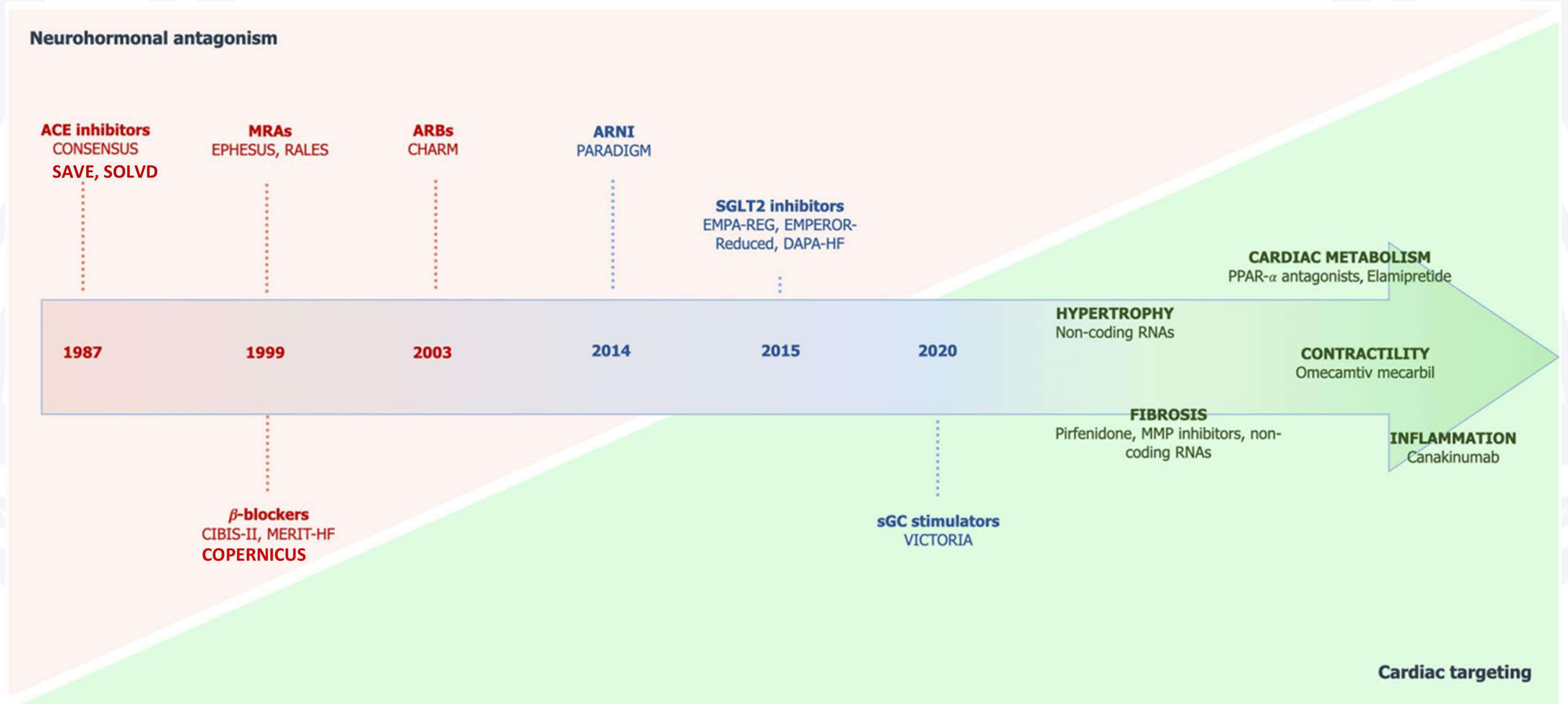


Statement 1: not at all !!!!

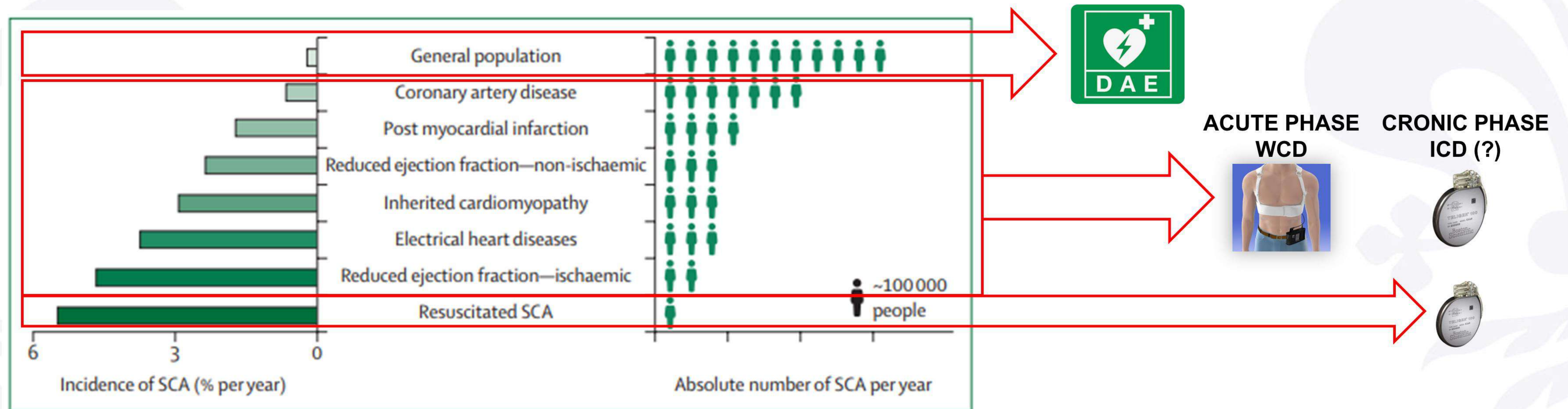


**Question #2:
How can we prevent SCD?**

HF treatment timeline: a long journey



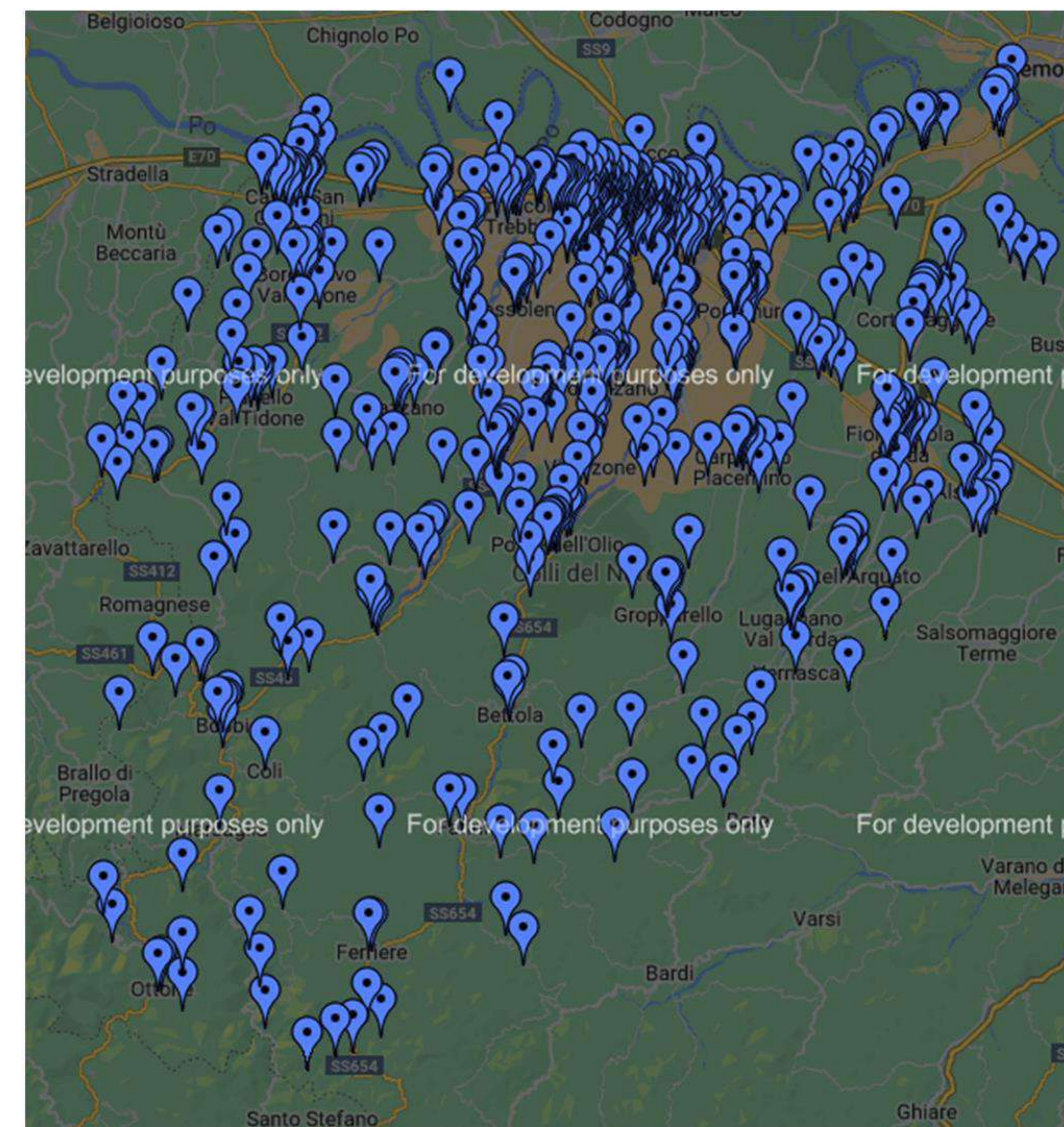
Weapons in the Battle Against SCD: Acute and Chronic Phases



Italian Experience in Protecting the General Population with AEDs



- 1.182 AED in the city of Piacenza
- 50.000 trained volunteers
- Cardio-protected condominiums
- Law enforcement patrols involved, trained, and equipped with AEDs
- School training
- Mobile App



Italian Experience in Protecting Acute High-Risk SCD Patients with WCD

European Heart Journal Supplements (2023) 25 (Supplement D), D281-D298
The Heart of the Matter
<https://doi.org/10.1093/eurheartjsupp/suad101>



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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Alessandra Chinaglia⁴, Marco Corda⁵, Daniele Nassiacos⁶, Salvatore Ivan Caico⁷,
Cristina Chimenti⁸, Marzia Giaccardi⁹, Enrico Gotti¹⁰, Stefano Maffè¹¹,
Roberta Magnano¹², Gianluca Solarino¹, Domenico Gabrielli^{13,14},
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KEYWORDS

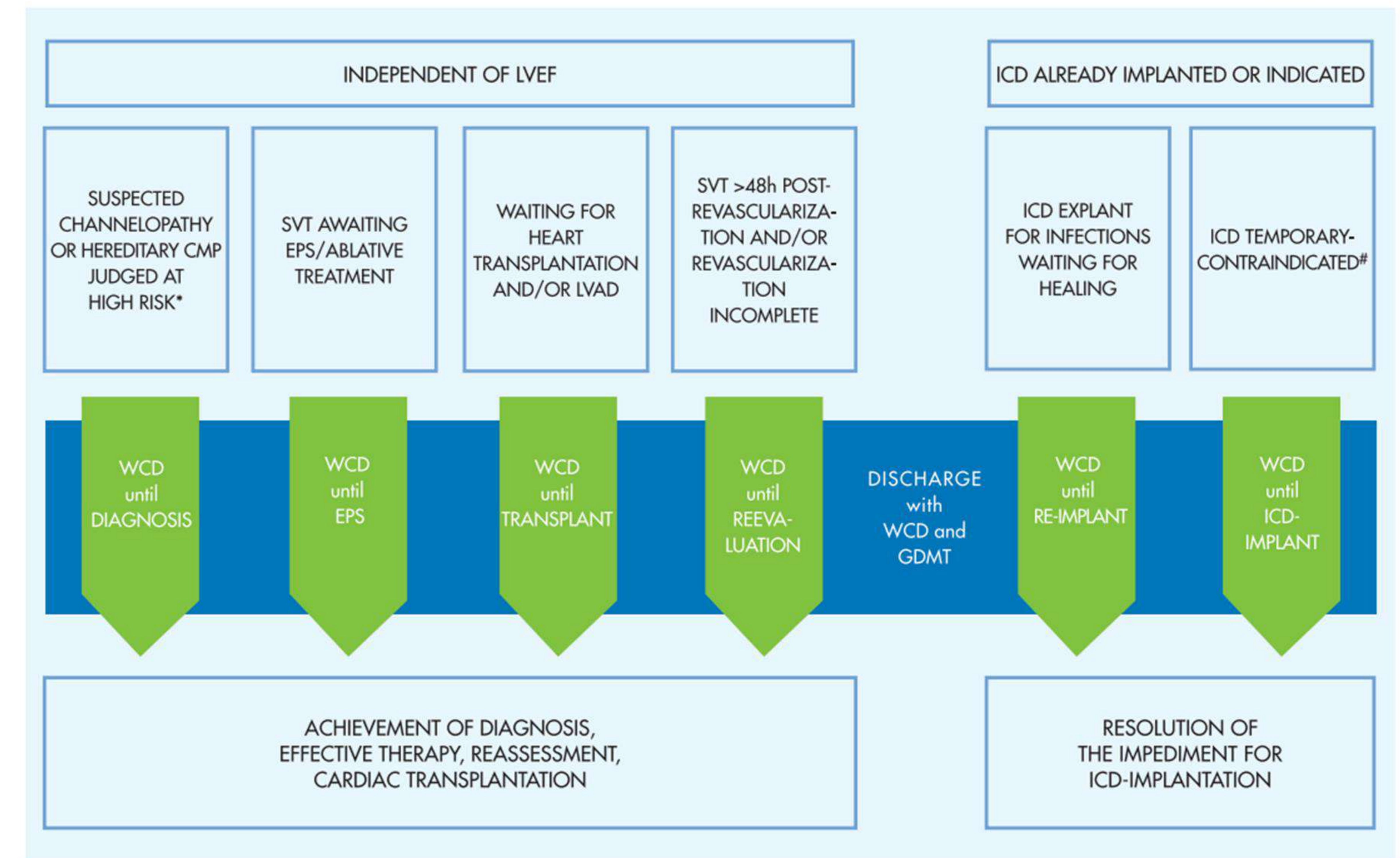
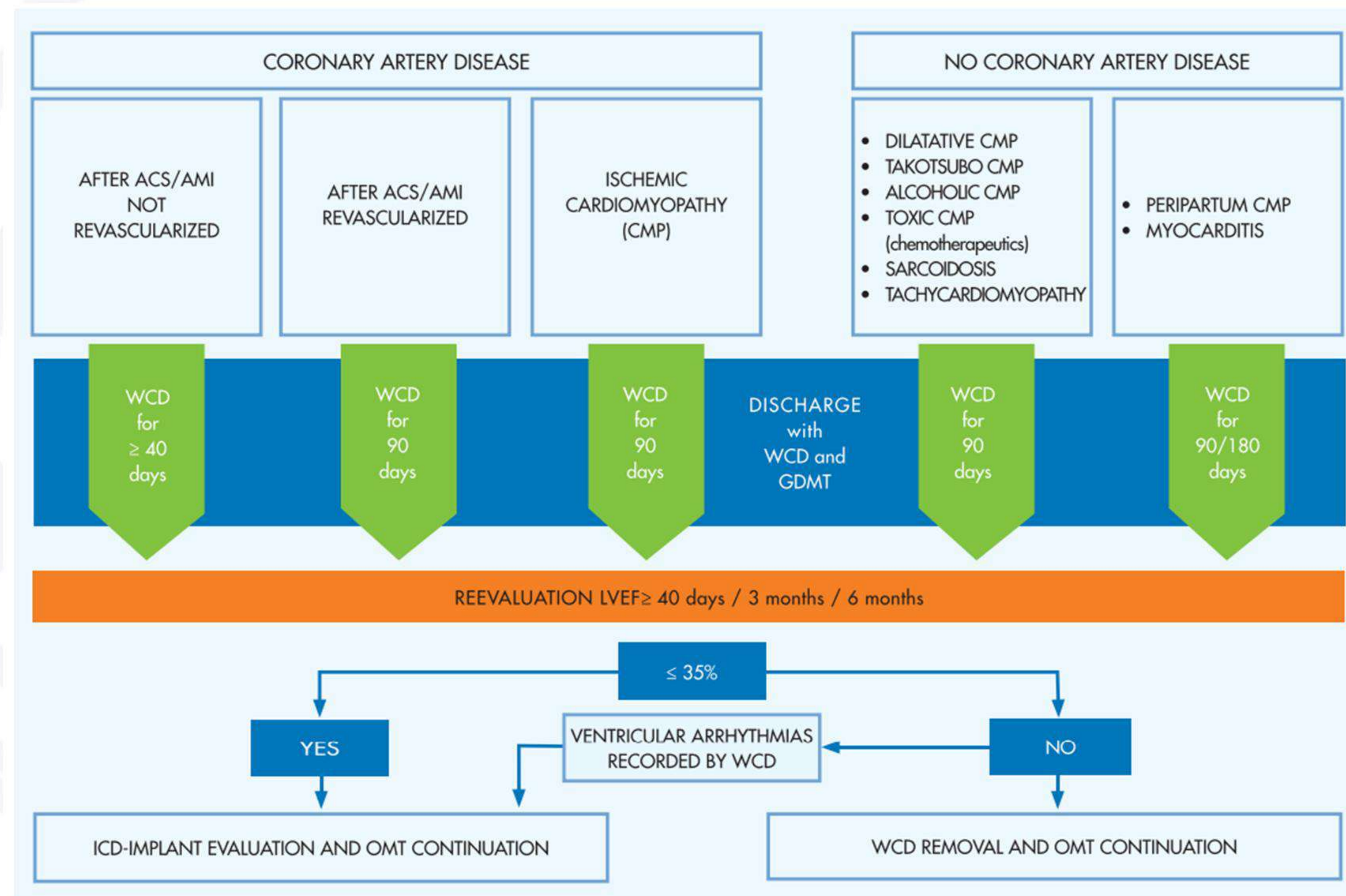
Wearable cardioverter defibrillator;
Cardiovascular disease;
Sudden cardiac death;
Patient management system

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 drugs 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 eradicating the associated infection. In all these conditions, it is important to offer



Position Paper ANMCO

Flow chart per l'identificazione dei pazienti a rischio



Expansion of WCD Use in Italy



- Rapidly growing WCD prescriptions
- Circa 1.500 patients prescribed with WCD in 2024
- Inhomogeneous patient profiles: ANMCO Position Paper needed to standardise the screening for acute risk of SCD
- Heterogeneity in economic recognition (region by region)

S/V + WCD in cardiac toxicity

Case Series: Recovery of Chemotherapy-Related Acute Heart Failure by the Combined Use of Sacubitril Valsartan and Wearable Cardioverter Defibrillator: A Novel Winning Combination in Cardio-Oncology

Maria Laura Canale^{1*}, Katia Coviello¹, Gianluca Solarino¹, Jacopo Del Meglio¹, Federico Simonetti², Elio Venturini³, Andrea Camerini⁴, Nicola Maurea⁵, Irma Bisceglia⁶, Carlo Tessa⁷ and Giancarlo Casolo¹

TABLE 1 | Summary of clinical and imaging characteristics of the presented cases.

| | Case 1 | Case 2 | Case 3 | Case 4 |
|---------------------------------|----------|-----------------------|--------------------|----------|
| Age | 57 | 65 | 83 | 65 |
| Cancer site | Desmoid | Breast | Multiple Myeloma | Breast |
| Drug | Anthra | Anthra Trastuzumab | Carfilzomib | Anthra |
| total dose (mg/m ²) | 600 | 360 na | na | 540 |
| Admission LVEF | 25% | 30% | 25% | 25% |
| LVEF after S/V | 45% | 48% | 48% | 46% |
| Recovery time | 3 months | 3 months | 2 weeks | 3 months |
| Baseline T1 msec | 1,095 | 1,040 | 1,066 | 986 |
| T1 after S/V msec | 1,051 | 1,000 | na | na |
| Baseline ECV | 40% | na | 32% | 23% |
| ECV after S/V | na | 28% | na | na |
| LGE (yes/no) | No | No | Yes (non ischemic) | No |

Anthra, anthracyclines; LVEF, left ventricular ejection fraction; S/V, sacubitril/valsartan; ECV, extracellular volume; LGE, late gadolinium enhancement; na, not applicable/not available.

SUMMARY OF CLINICAL ITEMS TO PREDICT RECOVERY

- Early diagnosis and treatment of CTR-CD
- Use of GDMT (as non-cancer patients)
- Non anthracyclines CTR-CD (reversible)
- Lower EF drop
- Reduced cumulative dose of anthracyclines

More likely to recover

- Late diagnosis and treatment of CTR-CD
- Non-optimal GDMT
- Anthracyclines CTR-CD (irreversible)
- More severely reduced EF
- High cumulative dose of anthracyclines

More likely not to recover

Statement 2: new HF drugs + AED/WCD/ICD!



**Question #3:
What about the risk of SCD in acute phase?**

Let's start with guidelines

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

Almeno 3 mesi

| | | |
|--|-----|---|
| A wearable ICD 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 |
|--|-----|---|

2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

6-12 settimane

| | | |
|--|-----|---|
| The WCD may be considered in the early phase after MI in selected patients. ^{371,372} | IIb | B |
|--|-----|---|

Novità dal congresso ESC 2025

2025 ESC Guidelines for the management of myocarditis and pericarditis

| | | |
|---|-----|---|
| WCD in myocarditis | | |
| A WCD should be considered for 3–6 months in patients with sustained ventricular arrhythmia during the acute phase of myocarditis as a bridge to recovery. ^{323,325,327–330} | IIa | C |

3-6 mesi
'As a bridge to recovery'

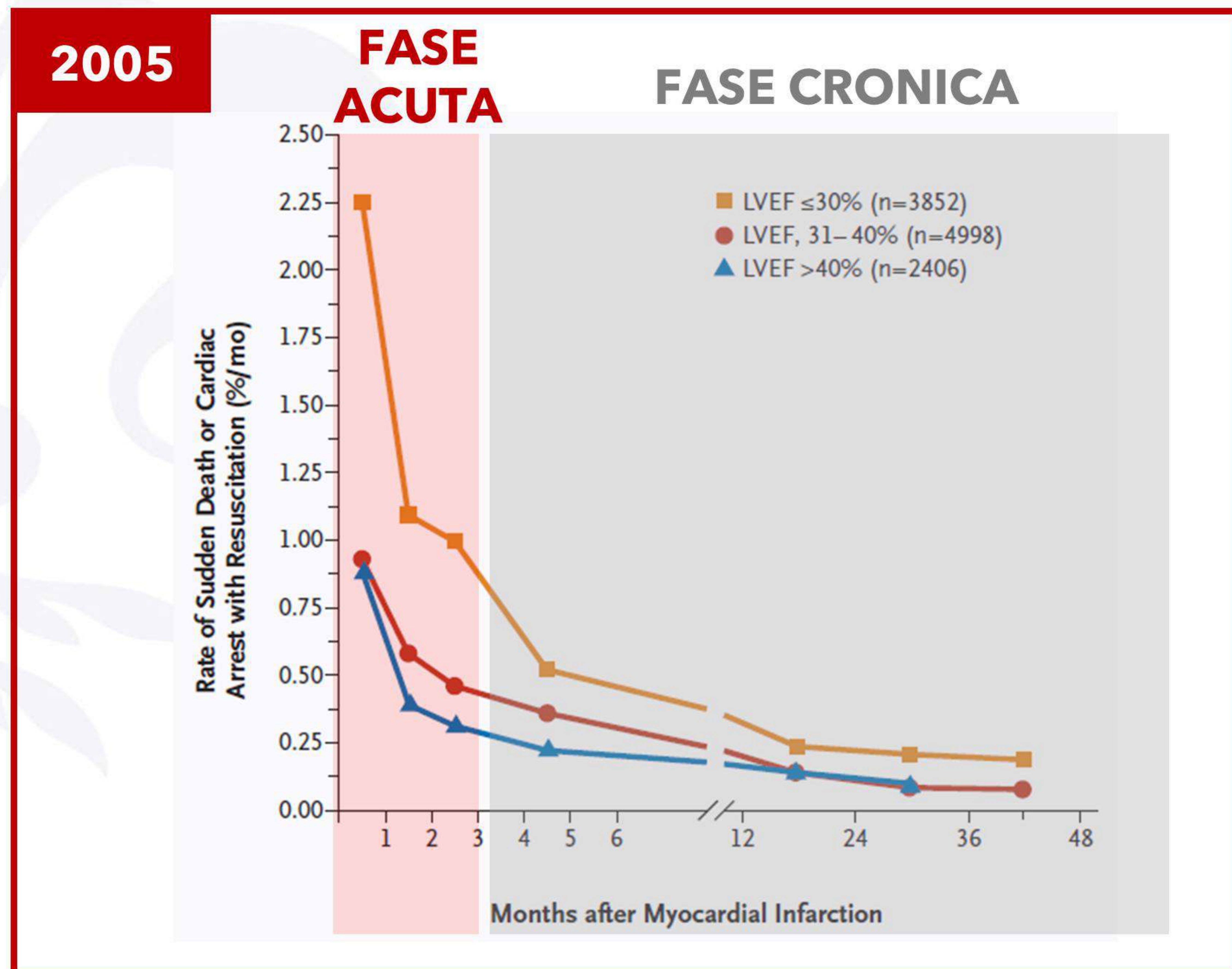
| Recommendations | Class ^a | Level ^b |
|--|--------------------|--------------------|
| The WCD should be considered for adult patients with a secondary prevention ICD indication, who are temporarily not candidates for ICD implantation. | IIa | C |

Il tempo necessario

After-MI Valiant

Studio VALIANT

ESC Guidelines 2022



The WCD may be considered in the early phase after MI in selected patients.^{371,372}

IIb **B**

È davvero cambiato qualcosa?

Pazienti POST-IMA Lo studio PARADISE-MI Cosa è cambiato dal 2005?

Meno trombolisi

Più PCI (più rapide e migliori)

Migliorata terapia farmacologica



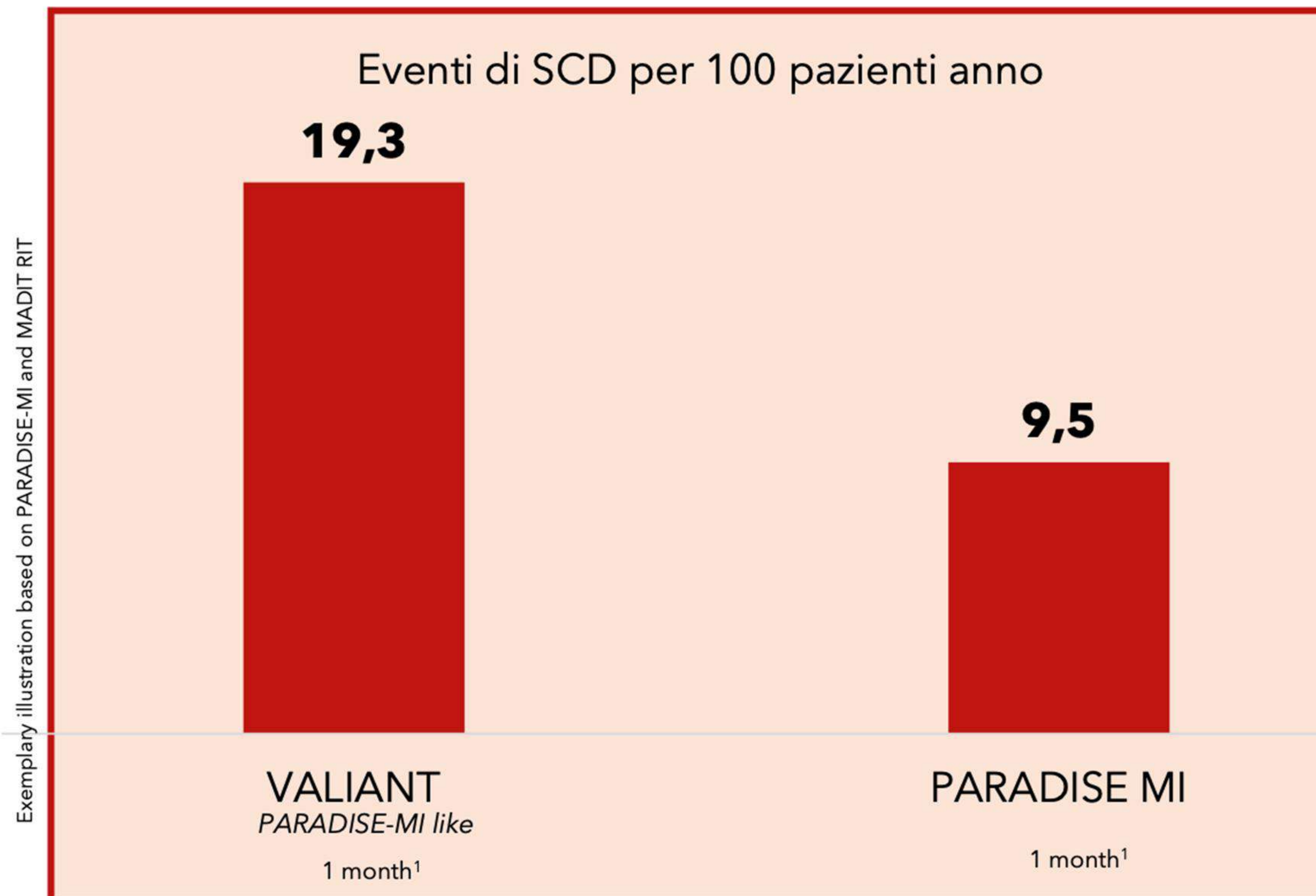
Table 1. Baseline Characteristics Comparing Patients in the PARADISE-MI Trial, VALIANT Trial With PARADISE-MI-like Characteristics,^a and the Total VALIANT Cohort

| Characteristic | PARADISE-MI (n = 5661) | VALIANT (PARADISE-MI-like) (n = 9617) | P value | VALIANT (total cohort) (n = 14 703) | P value |
|--|------------------------|---------------------------------------|---------|-------------------------------------|---------|
| Age, mean (SD), y | 63.7 (11.5) | 66.1 (11.5) | <.001 | 64.8 (11.8) | <.001 |
| Sex, No. (%) | | | | | |
| Female | 1363 (24.1) | 3113 (32.4) | <.001 | 4570 (31.1) | <.001 |
| Male | 4298 (75.9) | 6504 (67.6) | | 10 133 (68.9) | |
| Race, No. (%) | | | | | |
| Asian | 953 (16.8) | 83 (0.9) | <.001 | 141 (1.0) | <.001 |
| Black | 75 (1.3) | 255 (2.7) | | 407 (2.8) | |
| White | 4263 (75.3) | 9022 (96.4) | | 13 748 (96.2) | |
| Other | 370 (6.5) | 0 | | 0 | |
| Heart rate, mean (SD) bpm | 75.7 (11.8) | 76.7 (13.0) | <.001 | 76.2 (12.8) | .006 |
| Systolic blood pressure, mean (SD), mm Hg | 120.9 (13.3) | 122.6 (16.9) | <.001 | 122.7 (17.0) | <.001 |
| BMI, mean (SD) ^b | 28.1 (5.0) | 27.8 (5.4) | <.001 | 27.9 (5.3) | .005 |
| eGFR, mean (SD) | 71.8 (22.4) | 68.8 (20.9) | <.001 | 70.2 (21.3) | <.001 |
| Killip class (%) | | | | | |
| Class I | 2281 (41.6) | 2207 (23.0) | <.001 | 4099 (28.0) | <.001 |
| Class II | 1764 (32.2) | 4716 (49.1) | | 7076 (48.3) | |
| Class III | 1141 (20.8) | 1924 (20.0) | | 2529 (17.3) | |
| Class IV | 296 (5.4) | 757 (7.9) | | 931 (6.4) | |
| LVEF, mean (SD), % | 36.5 (9.4) | 34.6 (10.1) | <.001 | 35.3 (10.4) | <.001 |
| History of MI, No. (%) | 920 (16.3) | 2571 (26.7) | <.001 | 4104 (27.9) | <.001 |
| History of stroke, No. (%) | 263 (4.6) | 588 (6.1) | <.001 | 895 (6.1) | <.001 |
| Hypertension, No. (%) | 3676 (64.9) | 5409 (56.2) | <.001 | 8100 (55.1) | <.001 |
| Diabetes, No. (%) | 2401 (42.4) | 2513 (26.1) | <.001 | 3400 (23.1) | <.001 |
| Current smoking, No. (%) | 1196 (21.1) | 2838 (29.5) | <.001 | 4664 (31.7) | <.001 |
| Atrial fibrillation, No. (%) | 726 (12.8) | 504 (5.2) | <.001 | 960 (6.6) | <.001 |
| Prior PCI, No. (%) | 827 (14.6) | 680 (7.1) | <.001 | 1067 (7.3) | <.001 |
| Prior CABG, No. (%) | 205 (3.6) | 592 (6.2) | <.001 | 1026 (7.0) | <.001 |
| No. of days from index MI to randomization, mean (SD) | 4.3 (1.8) | 5.2 (2.6) | <.001 | 5.1 (2.6) | <.001 |
| Location of qualifying AMI, No. (%) ^c | | | | | |
| Anterior | 3853 (68.1) | 5572 (57.9) | <.001 | 8392 (57.1) | <.001 |
| Inferior | 1053 (18.6) | 3203 (33.3) | <.001 | 4805 (32.7) | <.001 |
| Other/unknown | 755 (13.3) | 842 (8.8) | <.001 | 1506 (10.2) | <.001 |
| Thrombolytic therapy, No. (%) | 253 (4.5) | 3106 (32.3) | <.001 | 5170 (35.2) | <.001 |
| PCI to treat qualifying AMI, No. (%) ^d | 4980 (88.0) | 2249 (23.4) | <.001 | 3683 (25.0) | <.001 |
| β-blocker, No. (%) | 4827 (85.3) | 6648 (69.1) | <.001 | 10 350 (70.4) | <.001 |
| ACE/ARB use before randomization, No. (%) ^e | 4436 (78.4) | 3804 (39.6) | <.001 | 5954 (40.5) | <.001 |
| Statin, No. (%) | 5370 (94.9) | 3099 (32.2) | <.001 | 5014 (34.1) | <.001 |
| Aspirin, No. (%) | 5574 (98.5) | 8777 (91.3) | <.001 | 13 418 (91.3) | <.001 |
| MRA/potassium-sparing diuretic, No. (%) ^f | 2338 (41.3) | 863 (9.0) | <.001 | 1330 (9.0) | <.001 |

Il rischio acuto di SCD è oggi trascurabile?

"Interventions to further protect people in the highest risk first month after infarction are needed"

FASE ACUTA POST-INFARTO



FASE CRONICA




1. Curtain JP, et al. JAMA Cardiol. 2024. 2. Veltmann C. et al. Eur Heart J, 2024: 00, 36, 1–11


SCD-PROTECT

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



GRMT up titration phase



WCD protection from SCD

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

Methods

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

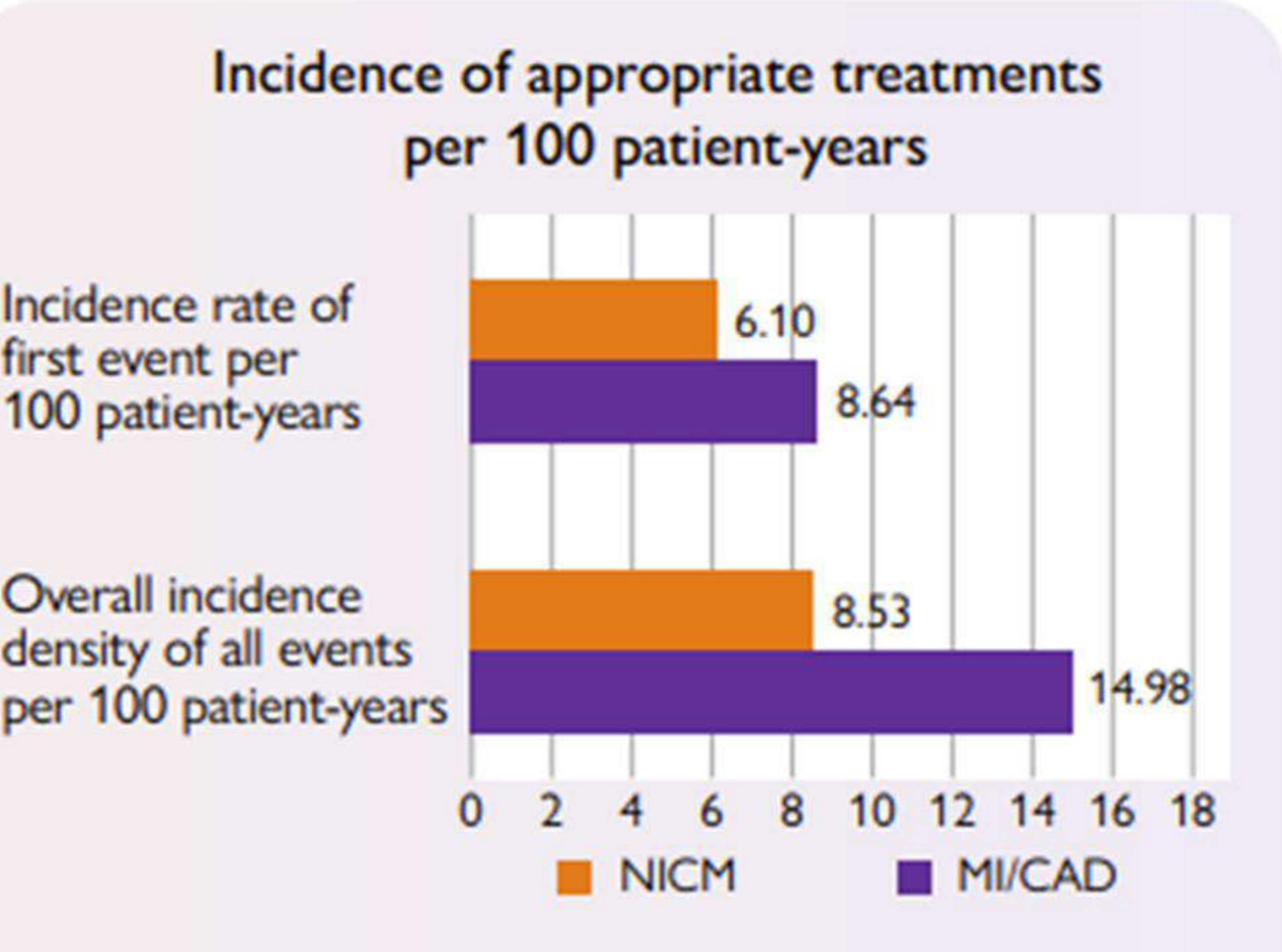


19 598 patients receiving WCD in Germany between December 2021 and May 2023


NICM 11 449 patients

MI/CAD 8149 patients

Results - Primary endpoint



Results - Exploratory endpoints



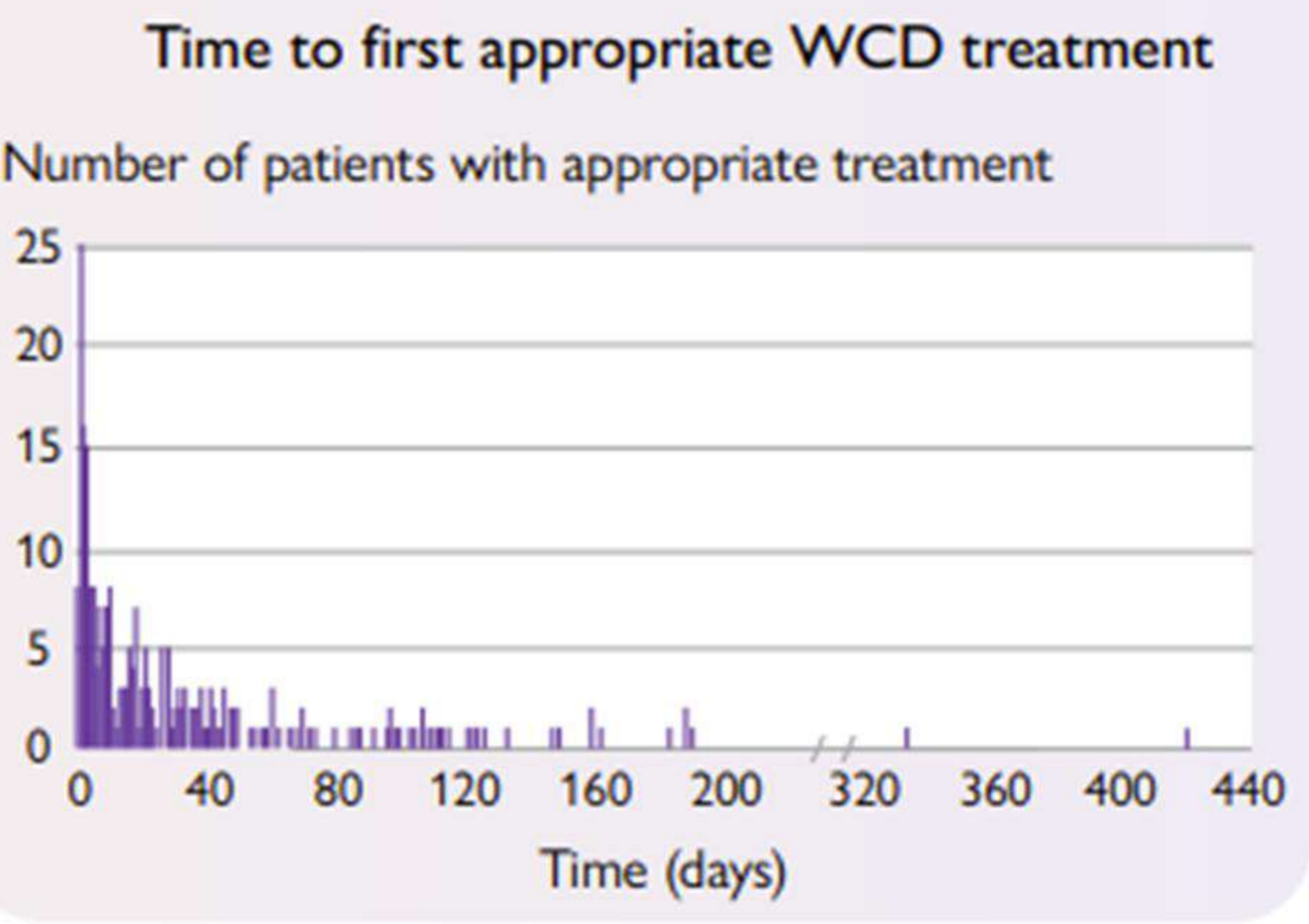
Average LVEF

NICM

26.9% at discharge → 38.9% WCD end of use

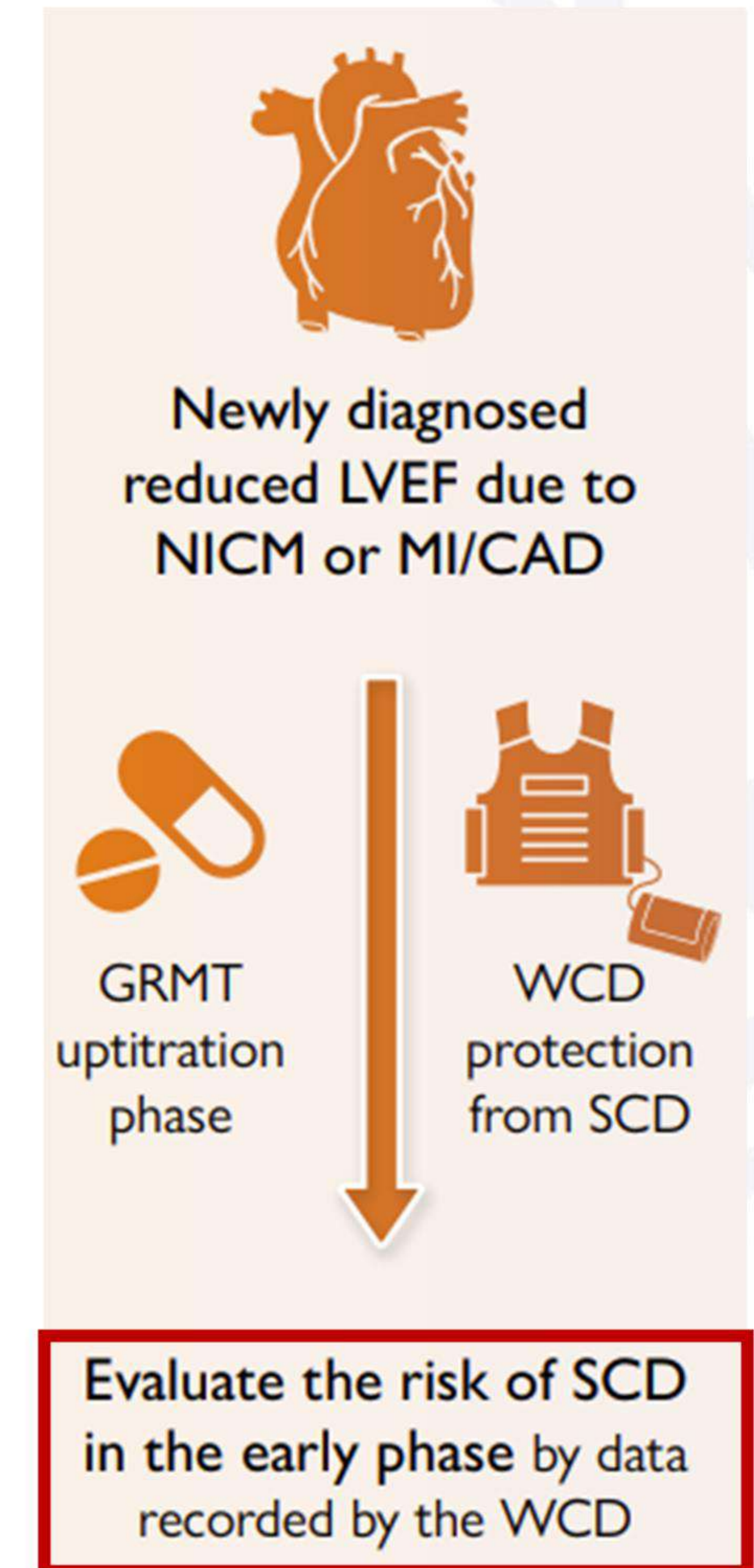
MI/CAD

28.4% at discharge → 38.3% WCD end of use



SCD-PROTECT

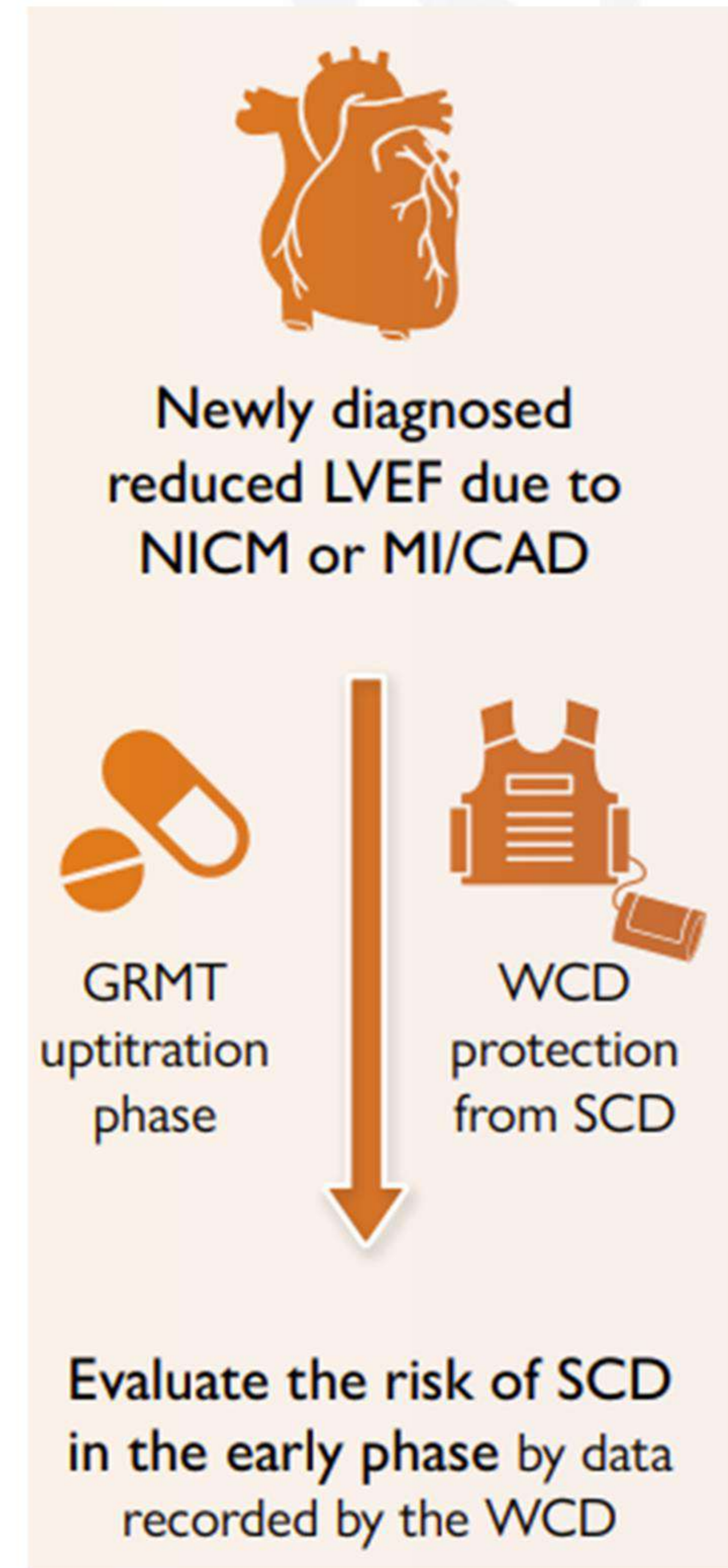
- Studio epidemiologico, osservazionale,
- 946 ospedali in Germania
- **19.598** pazienti consecutivi hanno ricevuto un WCD tra dicembre 2021 e Maggio 2023



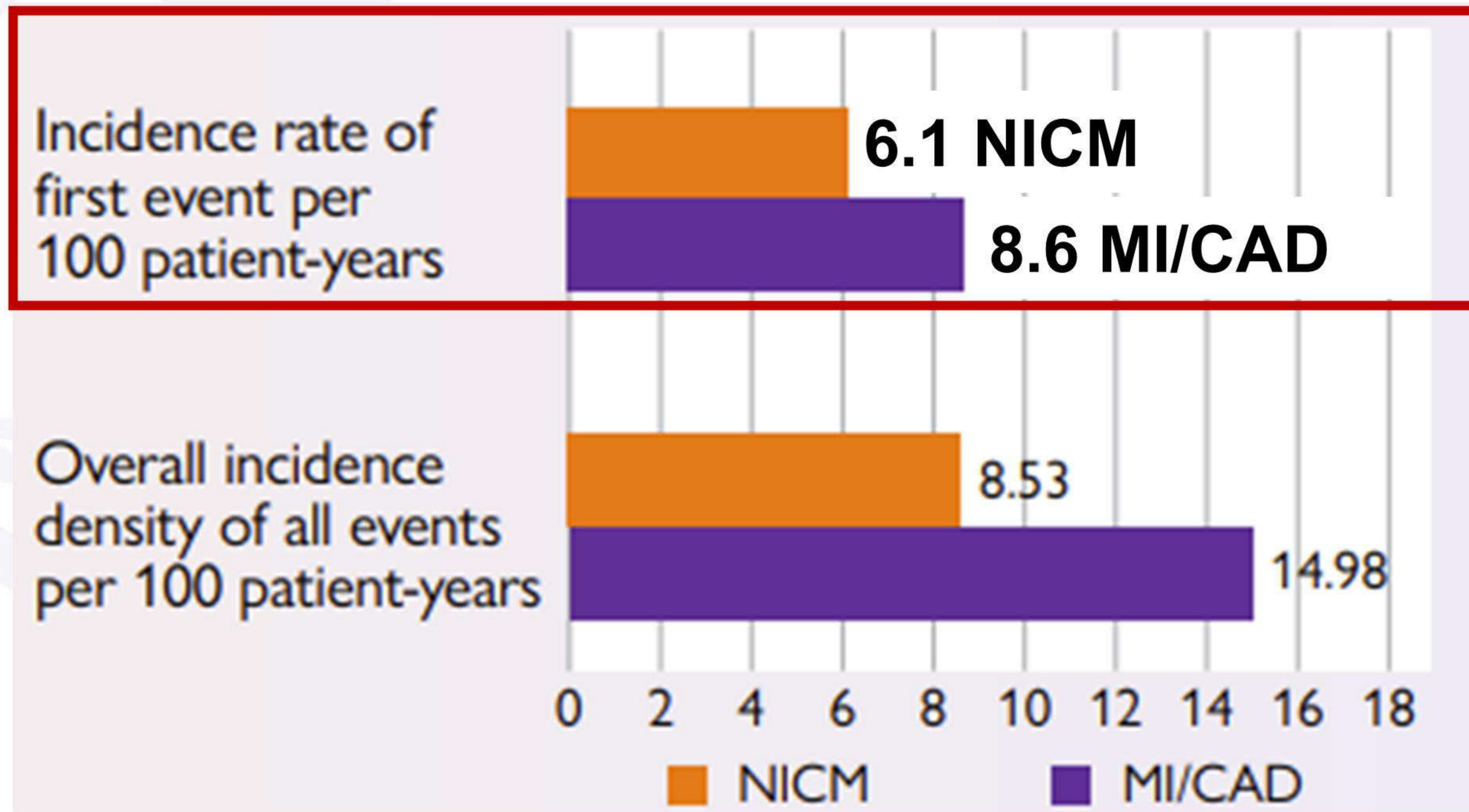
| | |
|--------|-----------------|
| NICM | 11 449 patients |
| MI/CAD | 8149 patients |

SCD-PROTECT

NICM 11 449 patients
MI/CAD 8149 patients



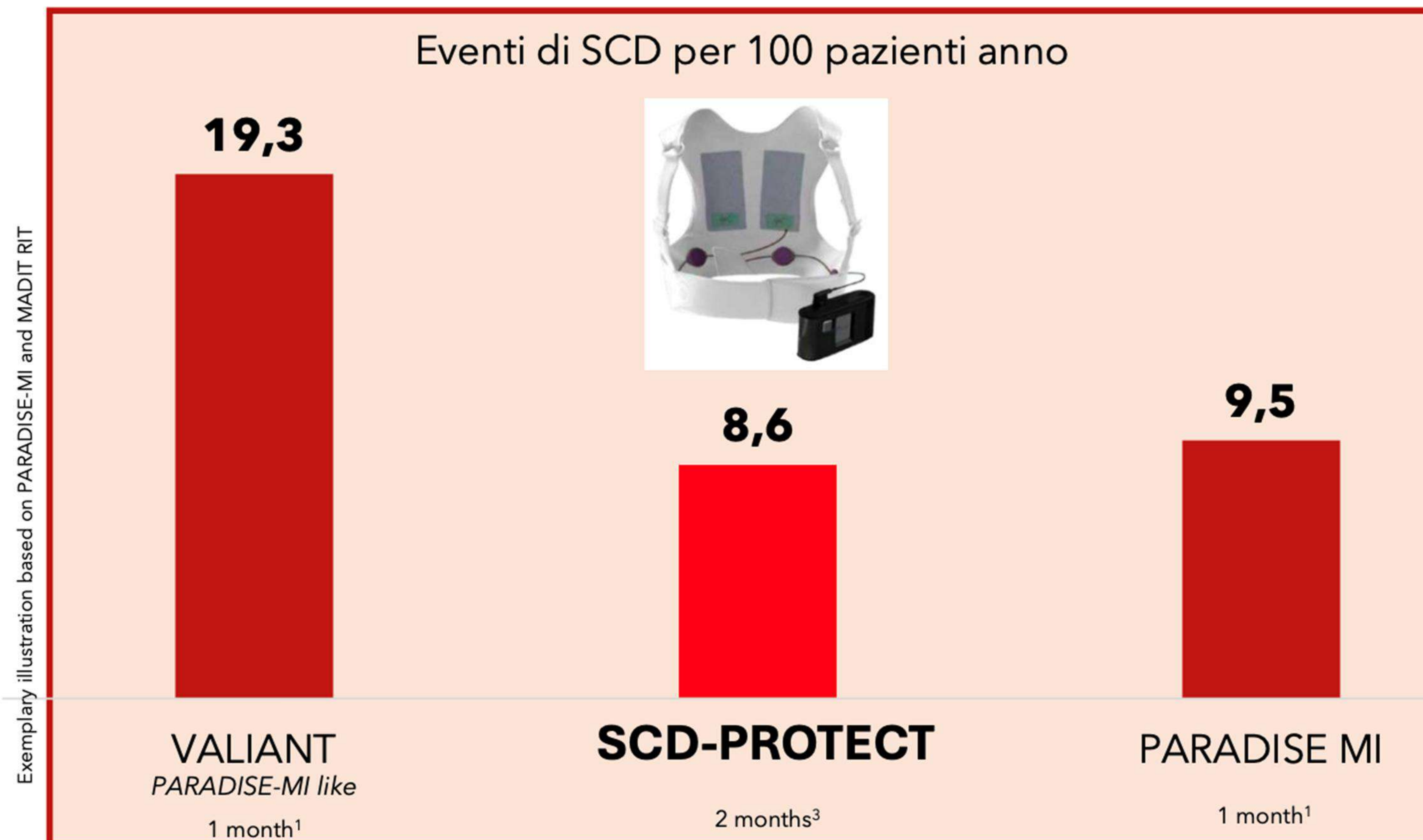
SCA incidence



Il rischio acuto di SCD quindi è ancora oggi trascurabile?

FASE ACUTA POST-INFARTO

Eventi di SCD per 100 pazienti anno

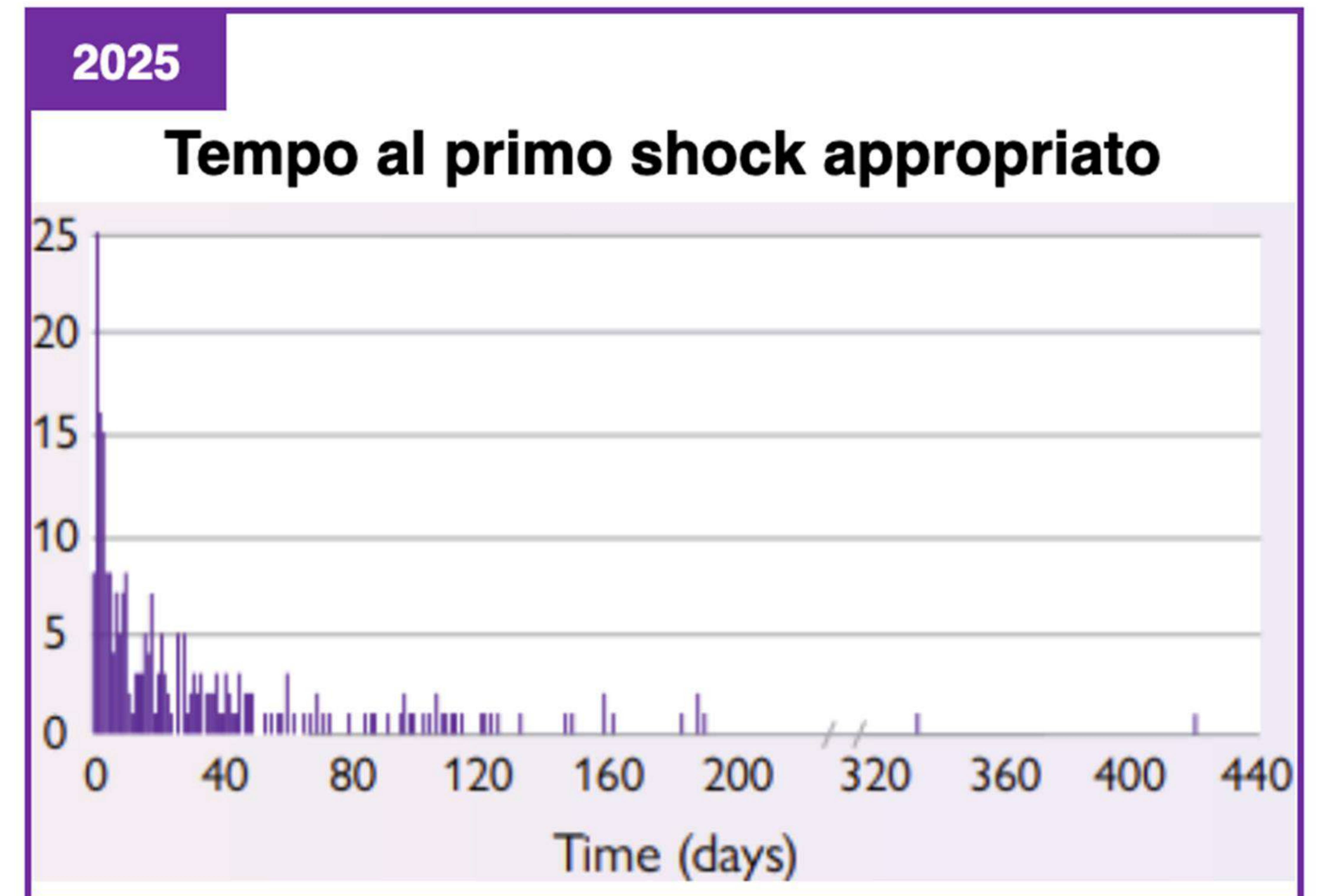
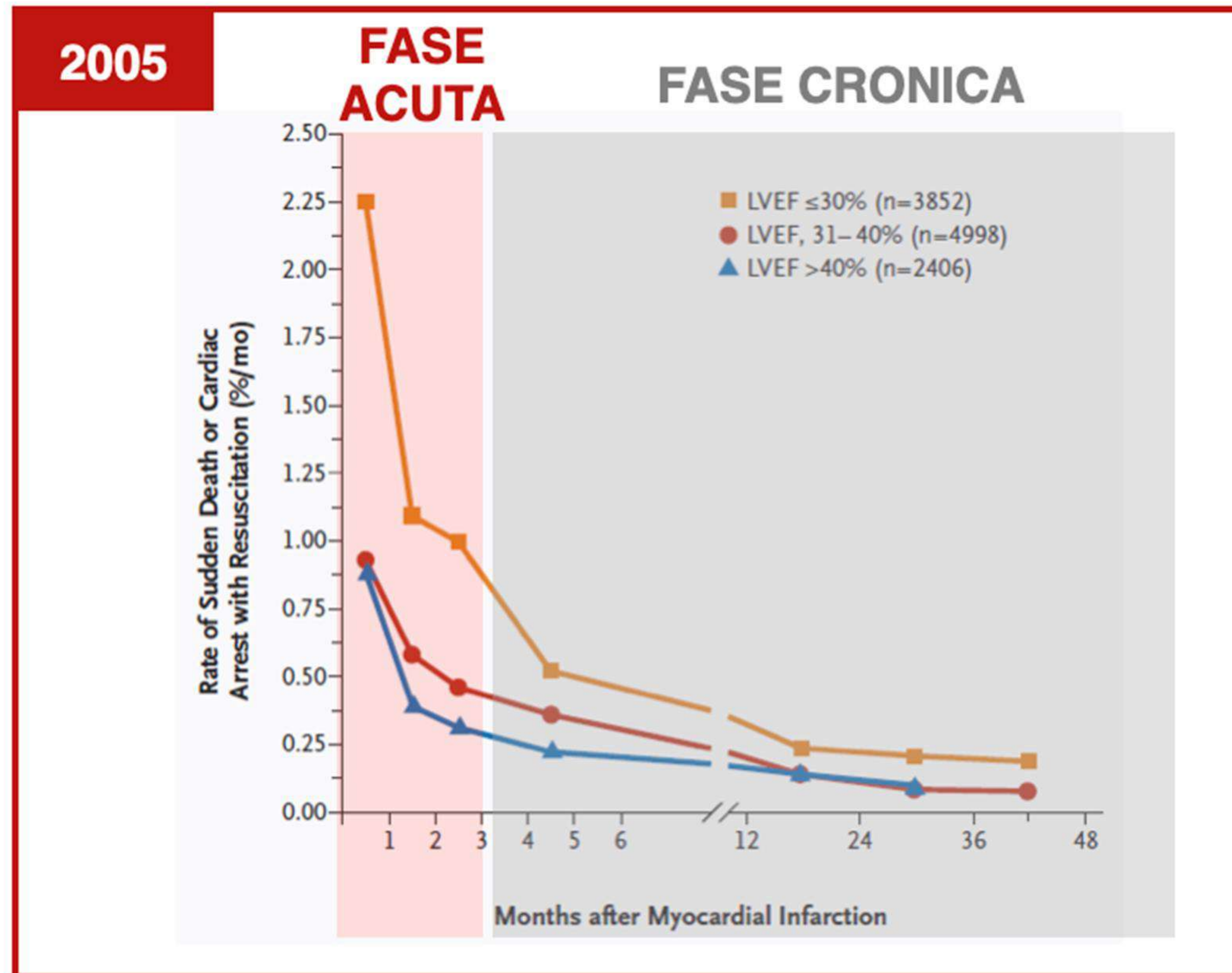


FASE CRONICA

Eventi di shock per 100 pazienti anno



Il rischio di SCD nella fase acuta SCD-Protect



Statement 3: it's reducing..... but still significant!



**Question #4:
What about the risk of SCD in HFrEF?**

WCD in HFrEF

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

| 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 |
| A wearable ICD 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 |

2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

| Recommendations | Class ^a | Level ^b |
|---|--------------------|--------------------|
| Risk stratification | | |
| Early (before discharge) assessment of LVEF is recommended in all patients with acute MI. ^{567,568} | I | B |
| 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 |
| 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 |

Pazienti con nuova diagnosi di HFrEF

I nuovi farmaci hanno cambiato il rischio di SCD o è solo una percezione?

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

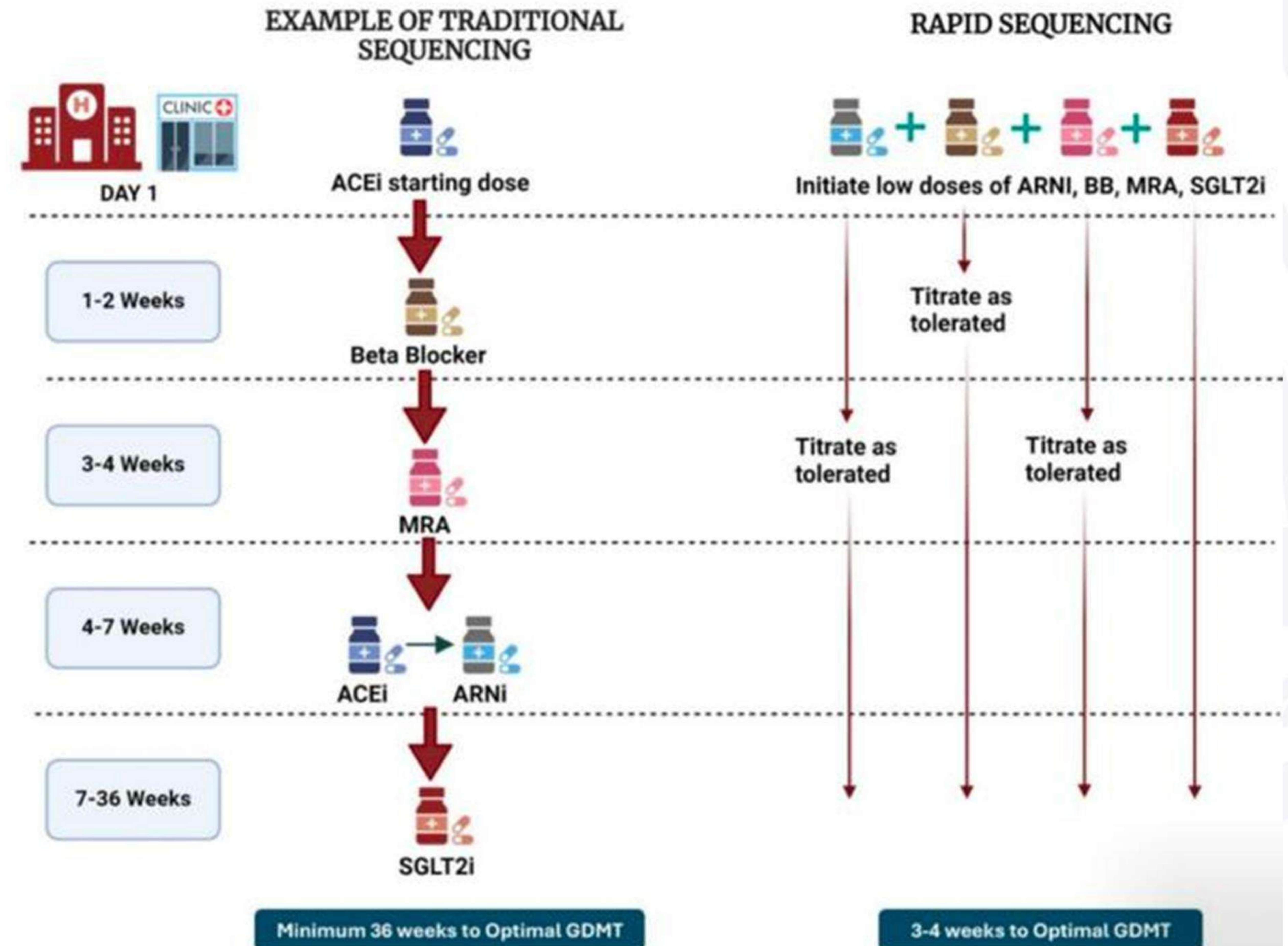
A wearable ICD may be considered for patients with HF who are at risk of sudden cardiac death for a limited period or as a bridge to an implanted device.^{173–176}

IIb

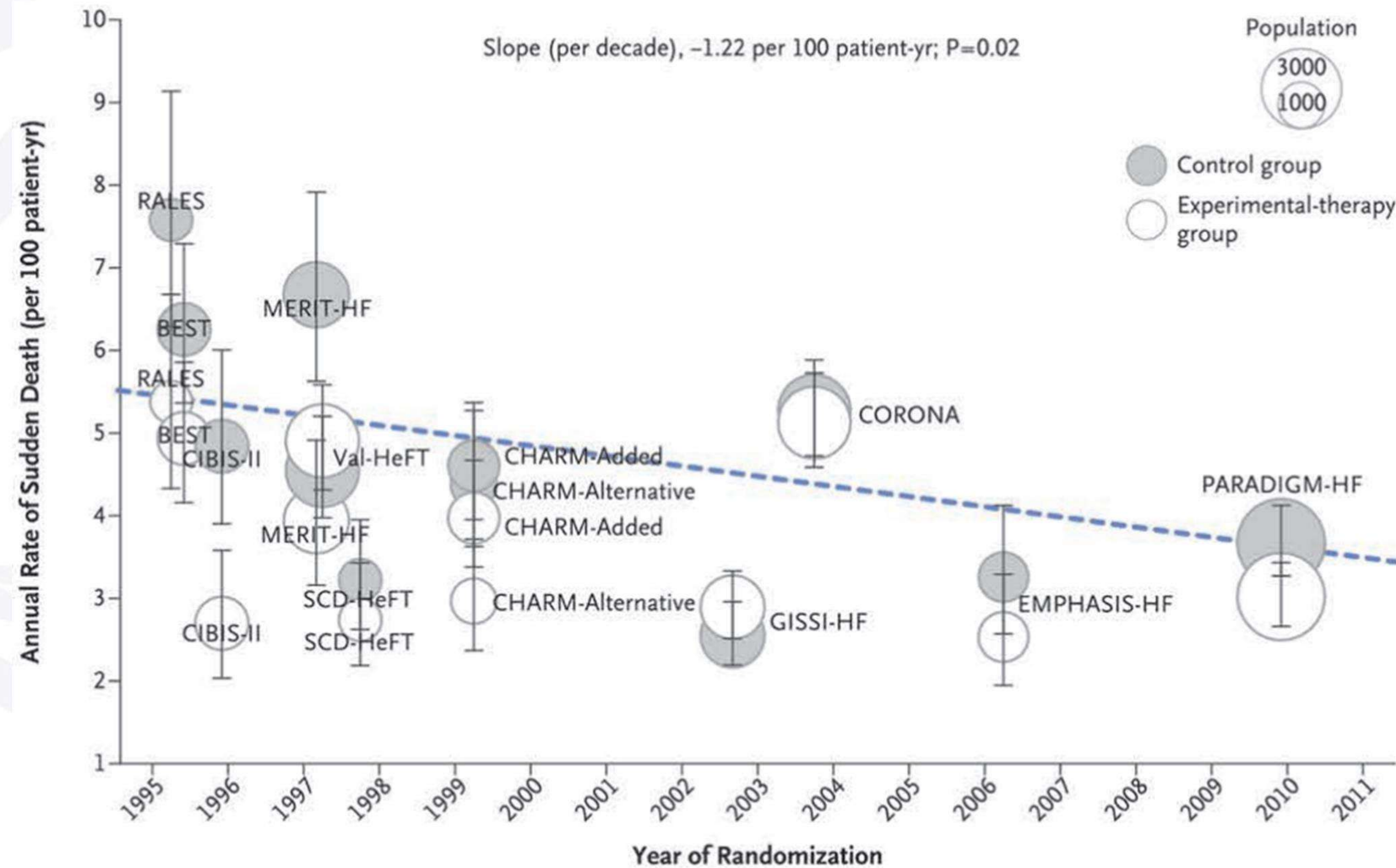
B

- Disponibilità di nuovi farmaci (ARNI, SGLT2i, Vericiguat...)
- Titolazione rapida della terapia

QUAL'È L'EFFETTO SUL RISCHIO IN ACUTO?



I nuovi farmaci hanno ridotto il rischio di SCD nella fase cronica



| PARADIGM HF | DAPA HF |
|---------------------------------------|---------------------------------------|
| Chronic HF Patients HFrEF (EF≤40%) | Chronic HF Patients HFrEF (EF≤40%) |
| 2.7% SCD (annualized) | 2.7% SCD (annualized) |

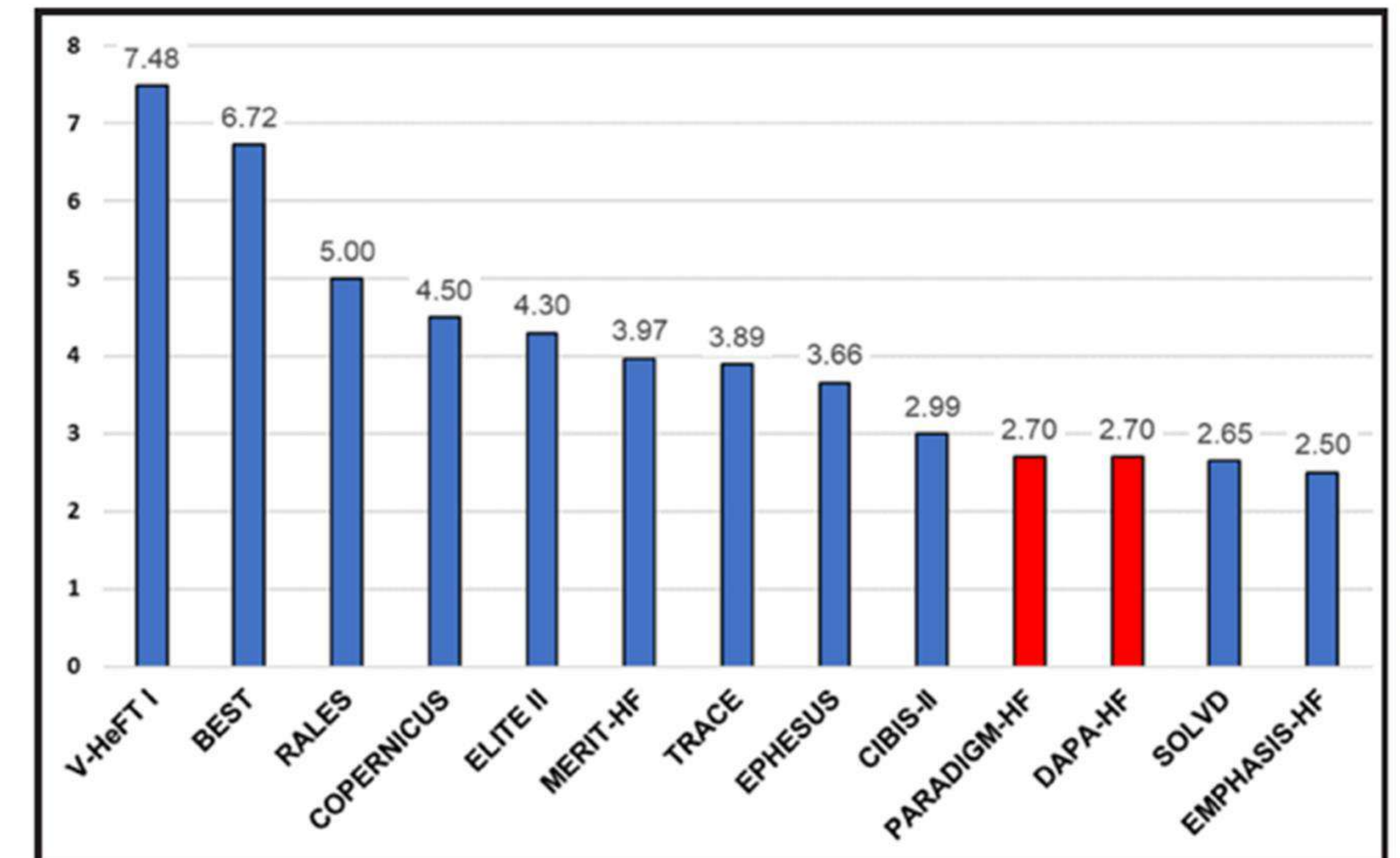


Figure 2. Residual risk of SCD in HF trials.

6-12 MONTHS

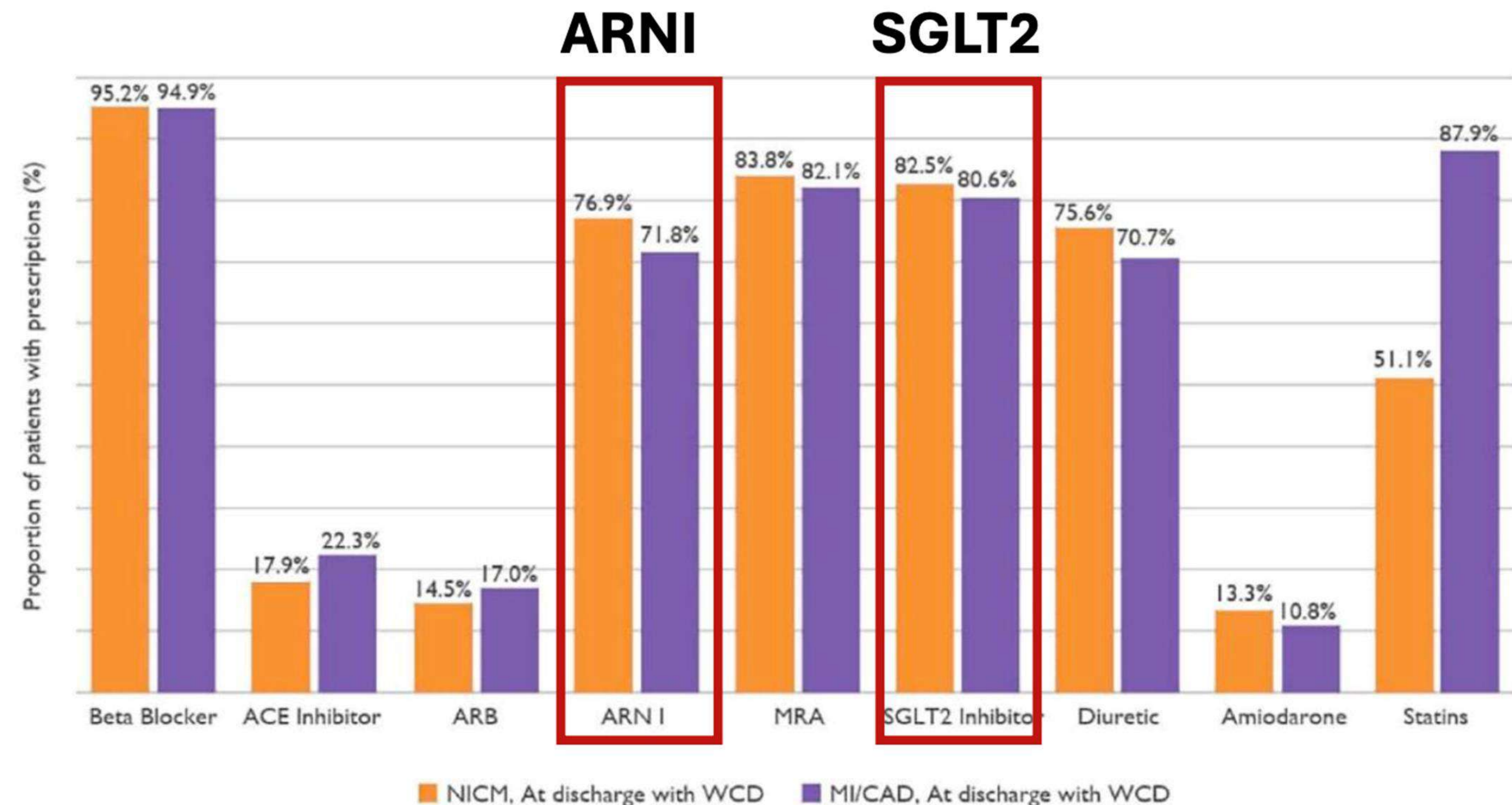
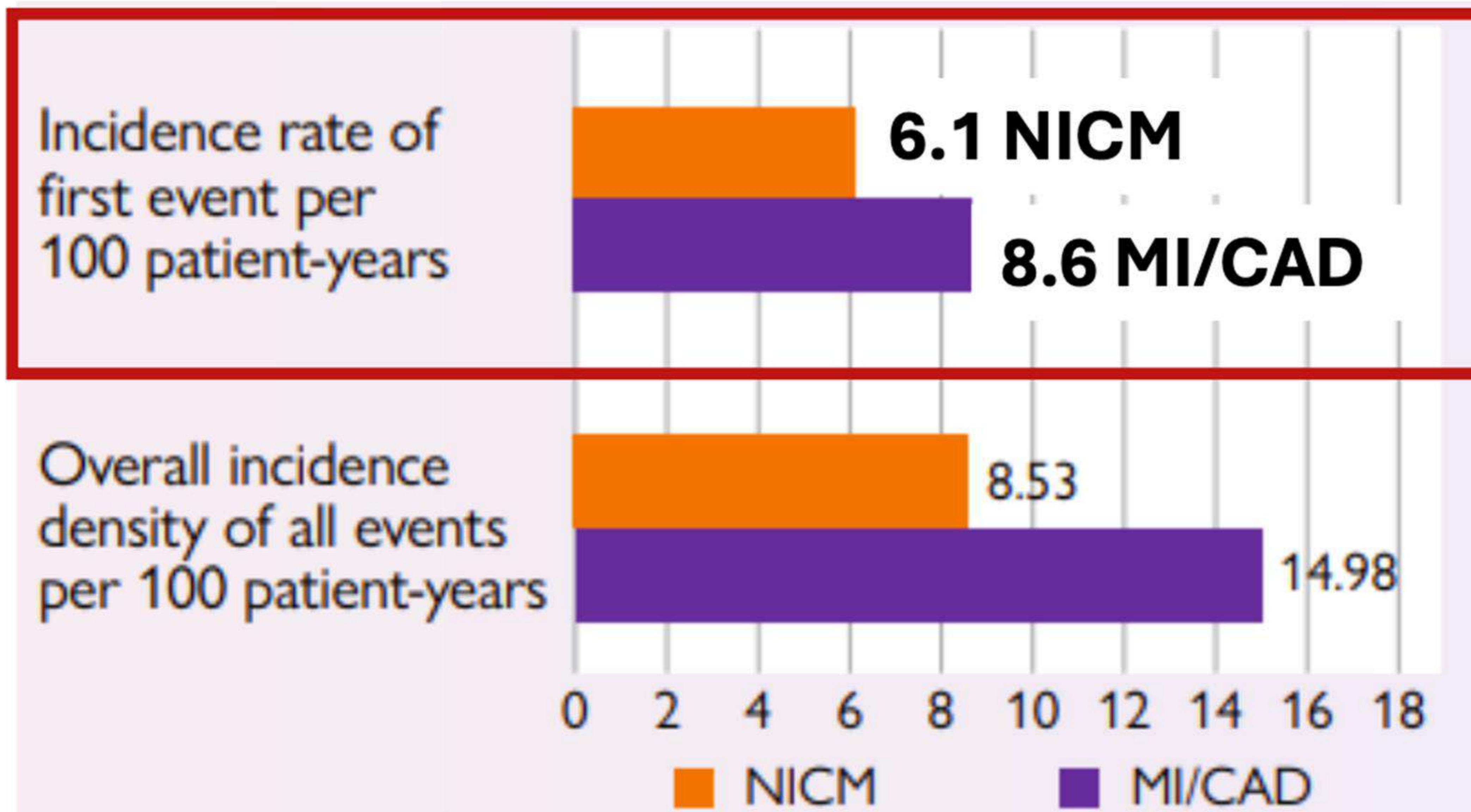
Il rischio di SCD nella fase acuta è alto nonostante i nuovi farmaci



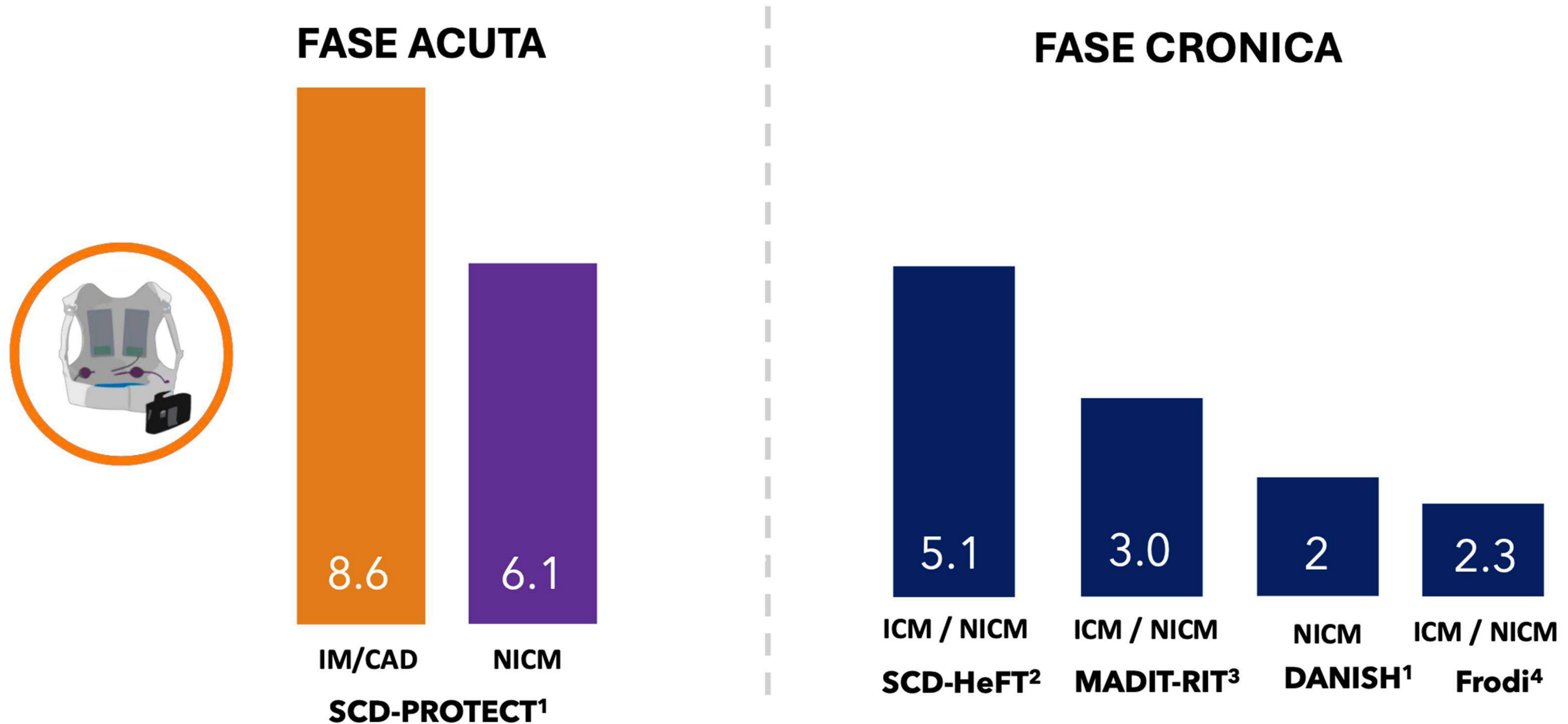
3 MESI

SCD-PROTECT¹

Incidenza cumulativa di SCA



Il rischio di SCD nella fase acuta è più alto



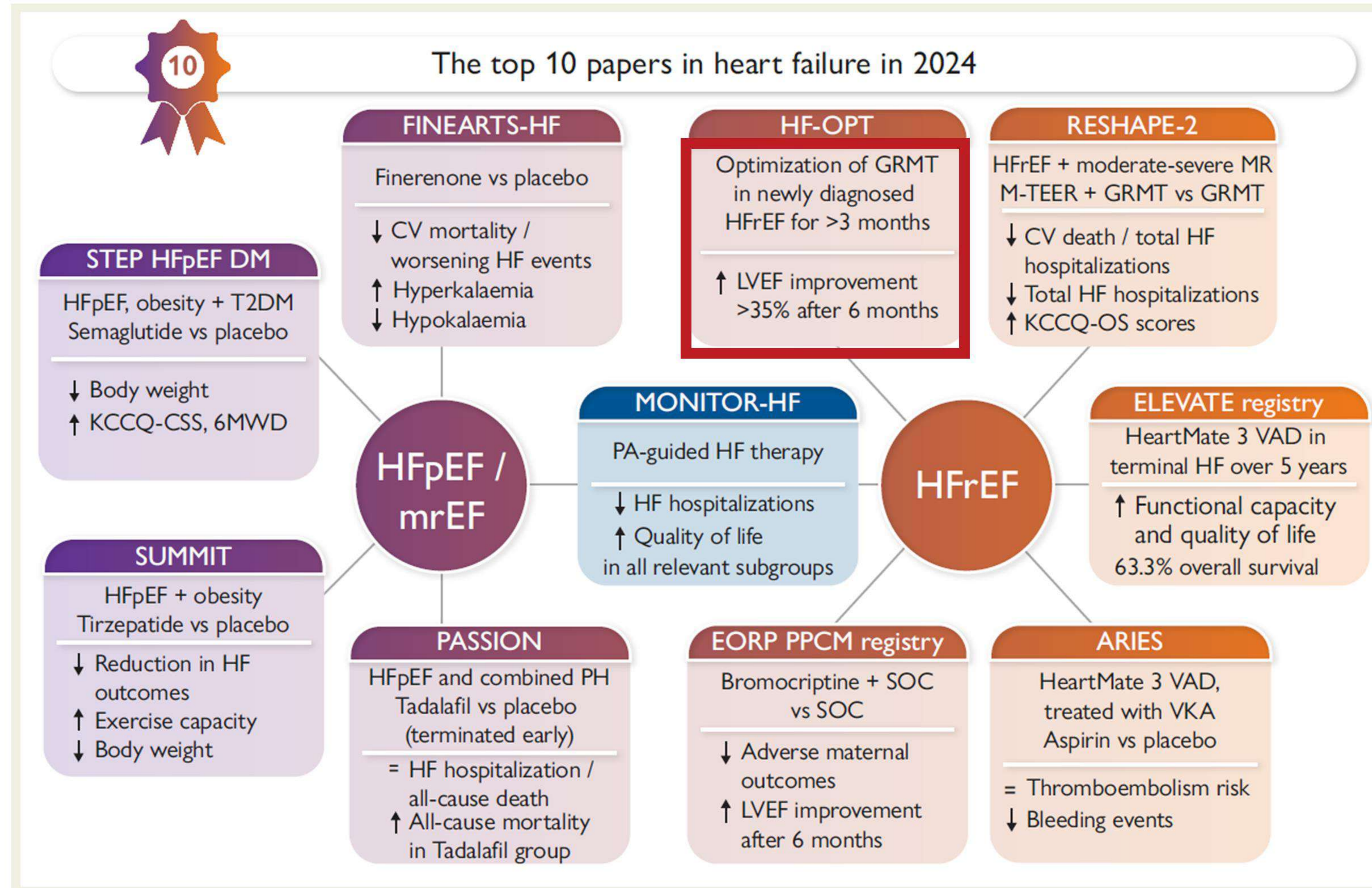
Statement 4: it's reducing..... but still significant and focus on the early phase!



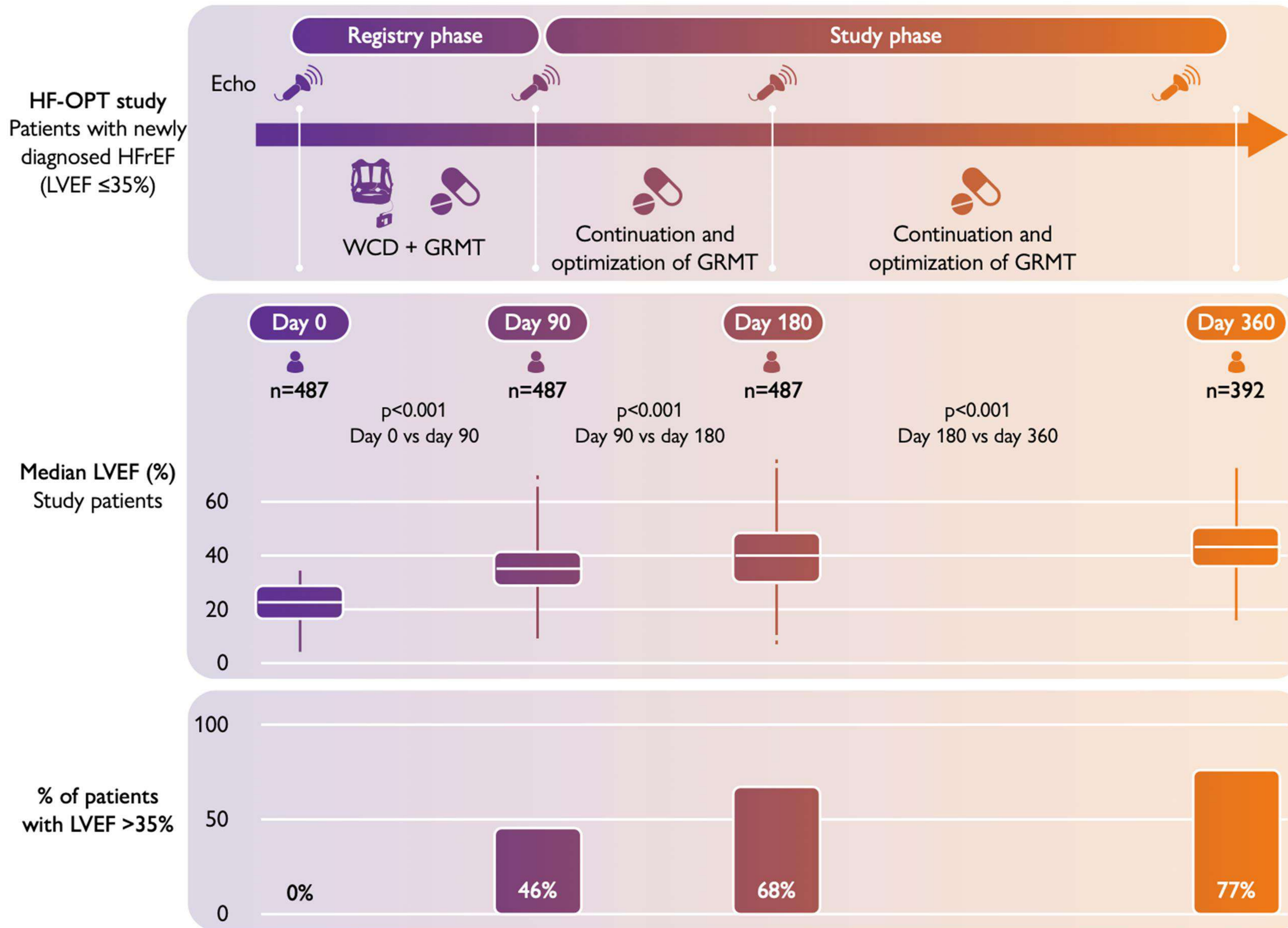
**Question #5:
Does time matter?**

Il rischio acuto di SCD è spesso transitorio

Lo studio HF-OPT

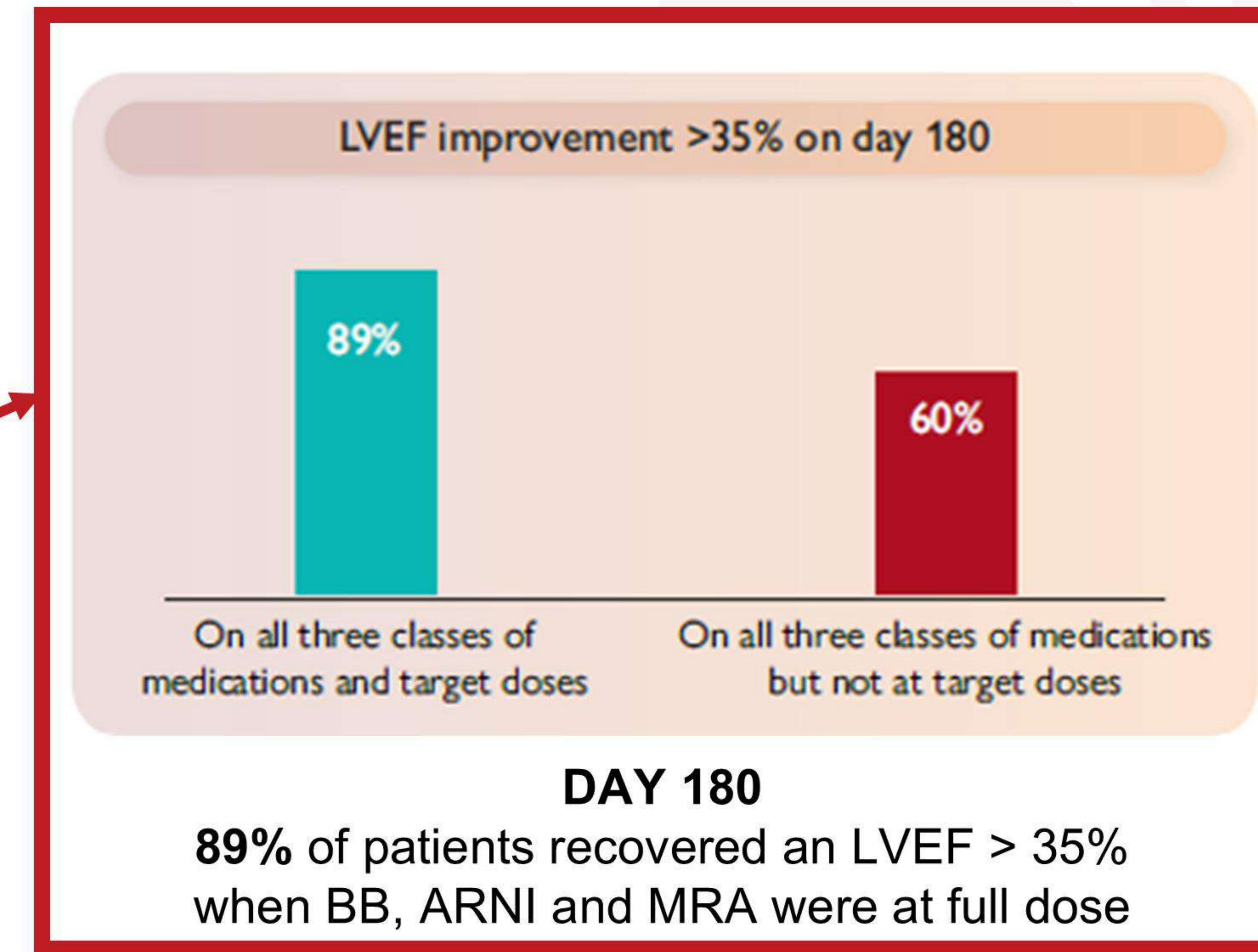
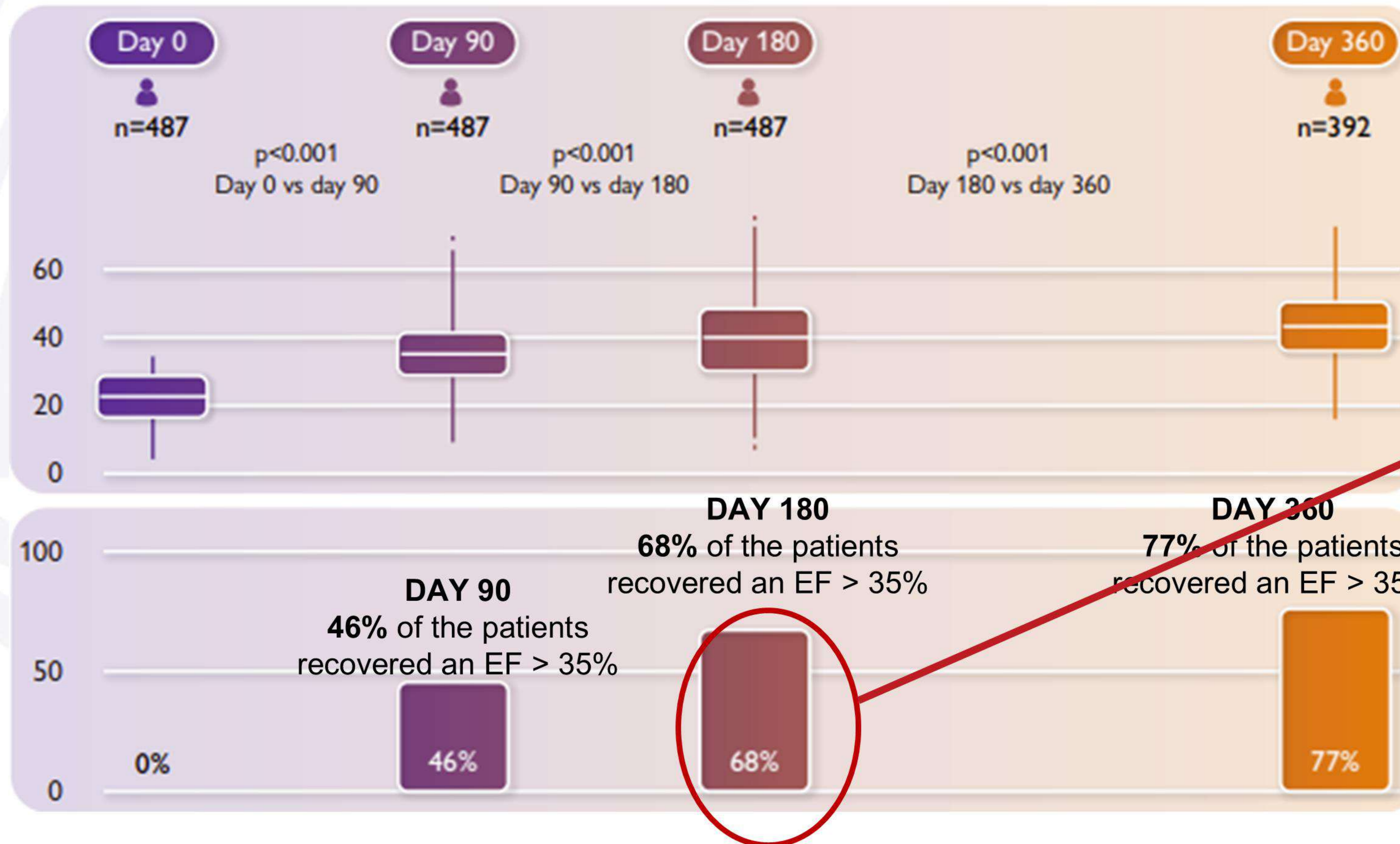


Long-term optimised GDMT + WCD allow recovery in HFrEF



Lo studio HF-OPT

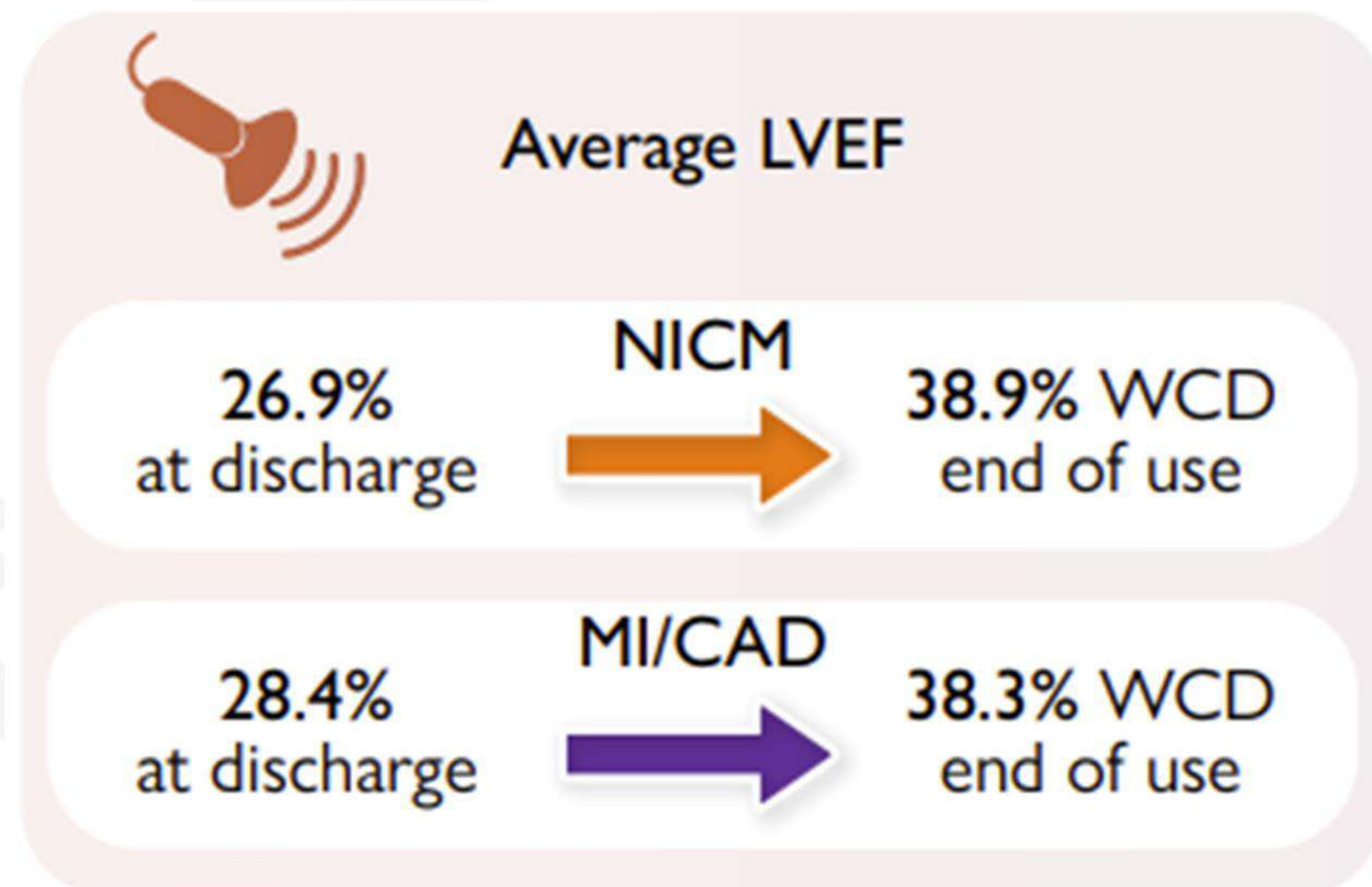
Pazienti con nuova diagnosi di HFrEF



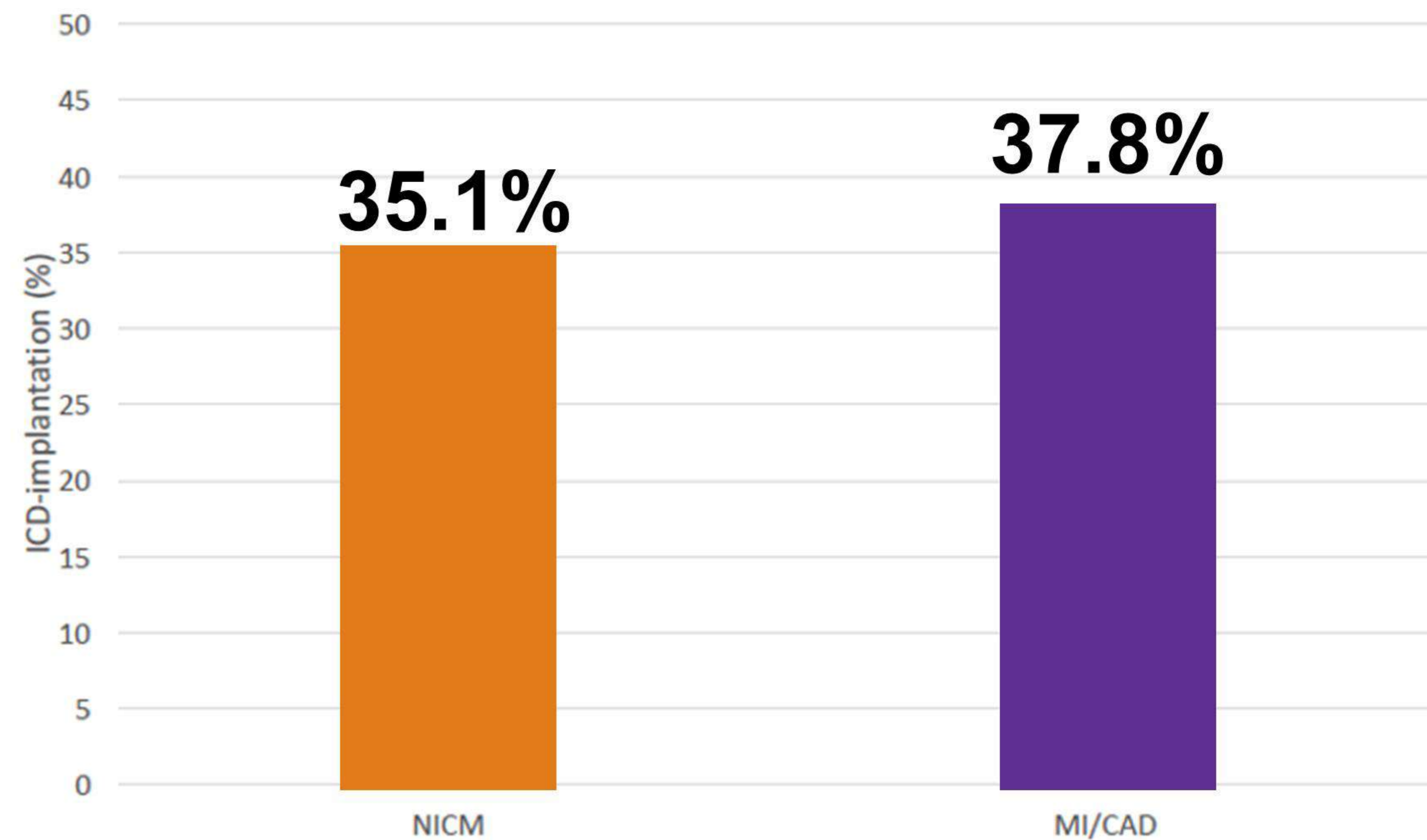
Studio SCD PROTECT

Oltre il 50% dei pazienti ha recuperato la FE

Traiettorie della FE



% Impianti ICD



Statement 5: safely waiting could be better!



Cost-Effectiveness of WCD in the Italian Healthcare System

The value of wearable cardioverter defibrillator in adult patients with recent myocardial infarction: Economic and clinical implications from a health technology assessment perspective

Giovanni Luca Botto^{a,*}, Lorenzo Giovanni Mantovani^{b,c}, Paolo Angelo Cortesi^b, Roberto De Ponti^d, Antonio D'Onofrio^e, Mauro Biffi^f, Alessandro Capucci^g, Gavino Casu^h, Pasquale Notarstefanoⁱ, Marco Scaglione^j, Gabriele Zanutto^k, Giuseppe Boriani^l, on behalf of the Italian Association of Arrhythmology and Cardiac Pacing (AIAC)

ABSTRACT

Aims: Sudden cardiac death (SCD) causes high mortality and substantial societal burdens for healthcare systems (HSs).

The risk of SCD is significantly increased in patients with reduced left ventricular ejection fraction after myocardial infarction (MI). Current guidelines recommend re-evaluation of cardioverter-defibrillator implantation 40 days post-MI, earliest. Medical therapy alone does not provide sufficient protection against SCD, especially in the first month post-MI, and needs time. Consequently, there is a gap in care of high-risk patients upon hospital discharge. The wearable cardioverter defibrillator (WCD) is a proven safe, effective therapy, which temporarily protects from SCD. Little information on WCD cost-effectiveness exists. We conducted this research to demonstrate the medical need of the device in the post-MI setting defining WCD cost-effectiveness.

Methods & results: Based on a randomized clinical trials (RCTs) and Italian and international data, we developed a Markov-model comparing costs, patient survival, and quality-of-life, and calculated the Incremental Cost-Effectiveness Ratio (ICER) of a WCD vs. current standard of care in post-MI patients. The rather conservative base case analysis – based on the RCT intention-to-treat results - produced an ICER of €47,709 per Quality Adjusted Life Year (QALY) gained, which is far lower than the accepted threshold of €60,000 in the Italian National HS. The ICER per Life Year (LY) gained was €38,276.

Conclusion: WCD utilization in post-MI patients is clinically beneficial and cost-effective. While improving guideline directed patient care, the WCD can also contribute to a more efficient use of resources in the Italian HS, and potentially other HSs as well.

Cost-minimization analysis of a wearable cardioverter defibrillator in adult patients undergoing ICD explant procedures: Clinical and economic implications

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Roberto De Ponti MD⁴ | Antonio D'Onofrio MD, FESC⁵ | Giuseppe Arena MD⁶ |
Antonio Curnis MD⁷ | Giovanni Forleo MD⁸ | Federico Guerra MD, FESC⁹ |
Maurizio Porcu MD¹⁰ | Giuseppe Sgarito MD¹¹ |
Giovanni Luca Botto MD, FEHRA, FESC¹²

Results: In the base case scenario, the WCD was less expensive compared to standard therapy. The cost-minimization analysis showed a cost reduction of €1782 per patient using the WCD. If costs of standard care were changed, cost savings associated with the WCD varied from €3500 to €0, assuming costs for standard care of €6800 to €3600.

Conclusion: After ICD explantation, patients can be safely and effectively protected from SCD after hospital discharge through WCD utilization. Furthermore, the use of a WCD for this patient group is cost saving when compared to standard therapy.

Tea-home messages



Acute SCD risk after major CV events is still not negligible but frequently limited to the early phase



WCDs are increasingly recognized as a cost-effective interim solution for high-risk patients awaiting EF recovery



The WCD allows for better risk stratification, potentially reducing unnecessary ICD implants and associated healthcare costs.



The identification of patients who could benefit from an ICD under study following advancements in invasive interventions and new therapies.



WCDs provide effective protection against SCD in cancer patient

