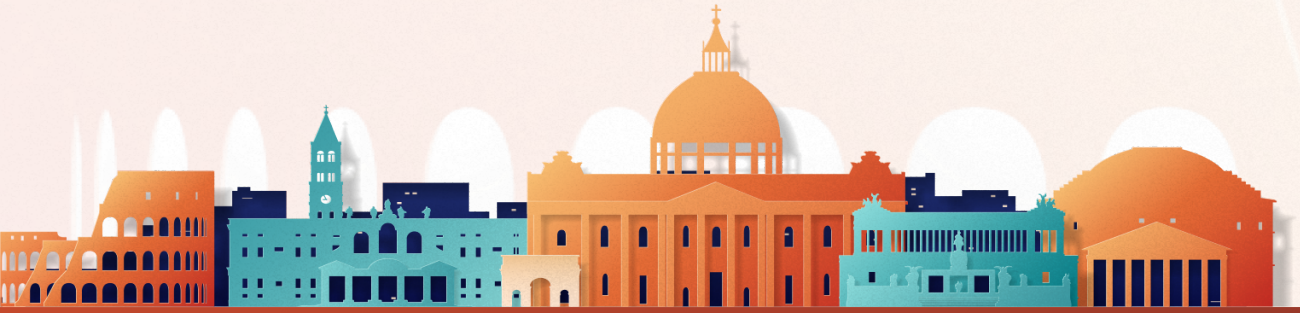
PLACE 2026
PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

CONGRESSO
ROMA, 25 - 27 Giugno 2026

LUNCHEON PANEL: CARDIOPATIA ISCHEMICA

Monitoraggio del rischio aritmico nei pazienti NSTEMI: il ruolo del loop recorder impiantabile nella pratica clinica post BIOGUARD-MI

Mario Volpicelli



Treatment after MI

Treatment approach in early hospital care

Medical treatment according to therapeutic targets:

➢**Myocardial supply-demand mismatch**

Oxygen

Nitrates

Beta-blockers

Calcium-channel blockers

➢**Coronary thrombus**

Antiplatelet therapy

Anticoagulation therapy

➢**Plaque**

Statin therapy

ACE inhibitor

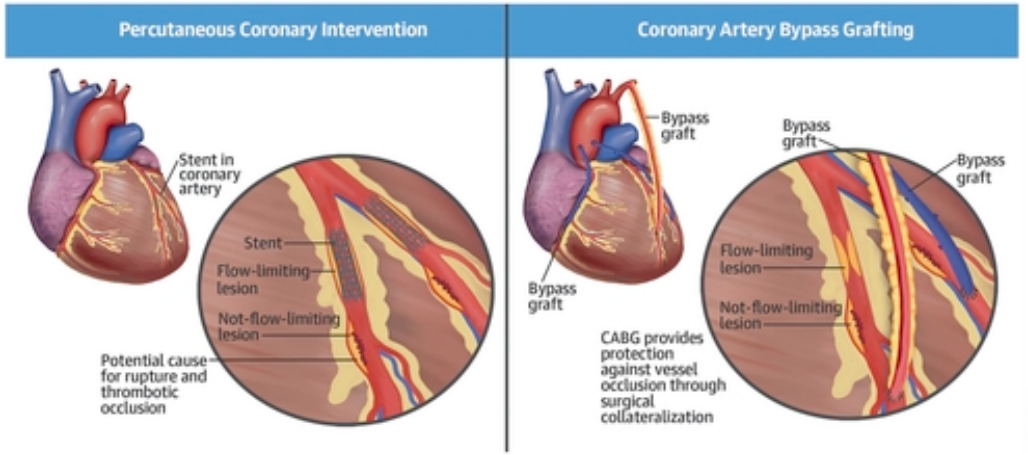
Surgery to restore blood flow:

➢**Percutaneous coronary intervention (PCI)**

Minimal-invasive intervention; insertion of a balloon to open the narrowed artery, sometimes in combination with stent placement

➢**Coronary artery bypass grafting (CABG)**

"Open heart" surgery; use of blood vessels from another part of the body to connect them to blood vessels above and below the narrowed artery



Doenst, T. et al. J Am Coll Cardiol. 2019;73(8):964-76.

Treatment after MI - Differences in STEMI and NSTEMI

During hospitalization, NSTEMI patients receive less cardiac medications and PCI[1,2,3,4]

The likelihood of receiving early (within 24 hours of presentation) medications is higher in patients with STEMI than NSTEMI[1]

Aspirin (88% vs 84%)

Beta-blockers (77% vs 72%)

Angiotensin-converting enzyme inhibitors (36% vs 34%)

Two-thirds of all MI-patients receive PCI during hospitalization, broken down as follows:[2]

71% of patients with STEMI

51% of those with NSTEMI (P=0.0001)

Bypass surgery is more frequently performed in patients with NSTEMI than STEMI

4.9% vs 3.1%, P=0.05[2]

1 Roe MT. Quality of Care by Classification of Myocardial Infarction. Arch Intern Med. 2005;165(14):1630. doi: 10.1001/archinte.165.14.1630.
2 Montalescot G, et al. STEMI and NSTEMI: Are they so different? 1 year outcomes in acute myocardial infarction as defined by the ESC/ACC definition (the OPERA registry). Eur Heart J. 2007;28(12):1409–17. doi: 10.1093/eurheartj/ehm031.
3 McManus DD, et al. Recent trends in the incidence, treatment, and outcomes of patients with STEMI and NSTEMI. The American Journal of Medicine. 2011;124(1):40–7. doi: 10.1016/j.amjmed.2010.07.023.
4 Alabas OA, Jernberg T, Pujades-Rodriguez M, Rutherford MJ, West RM, Hall M, et al. Statistics on mortality following acute myocardial infarction in 842 897 Europeans. Cardiovasc Res. 2020;116(1):149–57. doi: 10.1093/cvr/cvz197.

Post-MI Follow-up

Suboptimal patient adherence after hospital in both categories of patients with MI

Care pathway after 1-year discharge from hospital post-MI (STEMI and NSTEMI):

Patients had a mean number of 11 general practitioner consultations during the year

Almost 41% of patients did not have a consultation with a cardiologist

Medication adherence was around 83% for aspirin and 75% for lipid-lowering drugs

45% went to a cardiac rehabilitation center

23% had at least one hospital readmission (for various reasons)

4% of patients died after leaving hospital

Rehabilitation and general practitioner consultations were associated with adherence

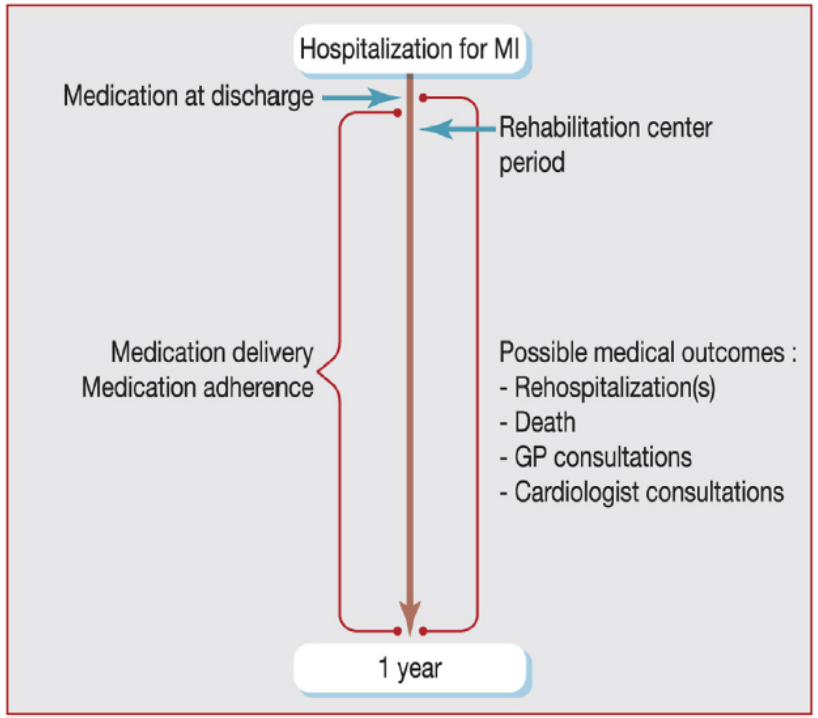


Figure 1. Care pathway after myocardial infarction (MI), according to the French health and reimbursement organizations, and possible medical outcome. GP: general practitioner.

Evidence for ICM use after MI

Evidence for ICM use after MI

Given the high cardiovascular risk and suboptimal follow-up after MI, will patients after MI benefit from long-term cardiac monitoring?

3 different studies use ICMs to monitor arrhythmias in post-MI patients:

1) CARISMA (Thomsen et al 2010)

Non-randomized study, n=297

2) SMART-MI (Bauer et al 2022)

Randomized study, n=400

3) BIO|GUARD-MI (publication in progress)

Randomized study, n=~800

BIO|GUARD-MI Study

Design Paper

Jons *et al. Trials* (2019) 20:563
https://doi.org/10.1186/s13063-019-3644-5

Trials

STUDY PROTOCOL Open Access

The clinical effect of arrhythmia monitoring after myocardial infarction (BIO-GUARD|MI):study protocol for a randomized controlled trial

Christian Jons[1*], Peter Sogaard[2], Steffen Behrens[3], Jürgen Schrader[4], Sascha Mrosk[4] and Poul Erik Bloch Thomsen[2]

Objective:

To investigate whether the early diagnosis of cardiac arrhythmias, provided by the BIOMONITOR with Home Monitoring, and the consequent treatment of the patient will decrease the risk to experience a MACE in post-MI patients with high risk and LVEF >35 %

Study Design:

Randomizes study, 1:1 ICM with RM or conventional care

~ 800 patients

Patients after acute or chronic MI with LVEF > 35% and a high risk defined by the CHA_2DS_2-VASc score ≥4 (men) or ≥5 (women)

Devices: BioMonitor 2 or BIOMONITOR III with BIOTRONIK Home Monitoring

Primary Endpoint:

Time to first major adverse cardiac event (MACE)

clinicaltrials.gov (NCT02341534)

Jons C, Sogaard P, Behrens S, Schrader J, Mrosk S, Bloch Thomsen PE. The clinical effect of arrhythmia monitoring after myocardial infarction (BIO-GUARD|MI):study protocol for a randomized controlled trial. Trials. 2019;20(1):563. doi: 10.1186/s13063-019-3644-5

BIO|GUARD-MI Risk Marker

CHA_2DS_2-VASc acronym	Score
Congestive heart failure •Signs/symptoms of heart failure or objective evidence of reduced left-ventricular ejection fraction	+1
Hypertension •Resting blood pressure >140/90 mmHg on at least two occasions or current antihypertensive treatment	+1
Age 75 years or older	+2
Diabetes mellitus •Fasting glucose >125 mg/dL (7 mmol/L) or treatment with oral hypoglycaemic agent and/or insulin	+1
Previous stroke, transient ischaemic attack, or thromboembolism	+2
Vascular disease •Previous myocardial infarction, peripheral artery disease, or aortic plaque	+1
Age 65–74 years	+1
Sex category (female)	+1

Other risk markers than LVEF are of interest to adequately identify patients post-MI with a high risk for adverse outcomes (MACE)

The CHA_2DS_2-VASc score
Was originally constructed to estimate the risk of stroke in AF patients
Contains the most important cardiovascular clinical risk factors
Provides a strong association between increasing scores and the risk of clinical arrhythmias as well as MACE
Is well-known and easy to estimate

Jons C, Sogaard P, Behrens S, Schrader J, Mrosk S, Bloch Thomsen PE. The clinical effect of arrhythmia monitoring after myocardial infarction (BIO-GUARD|MI):study protocol for a randomized controlled trial. Trials. 2019;20(1):563. doi: 10.1186/s13063-019-3644-5.

BIO|GUARD-MI Workflow

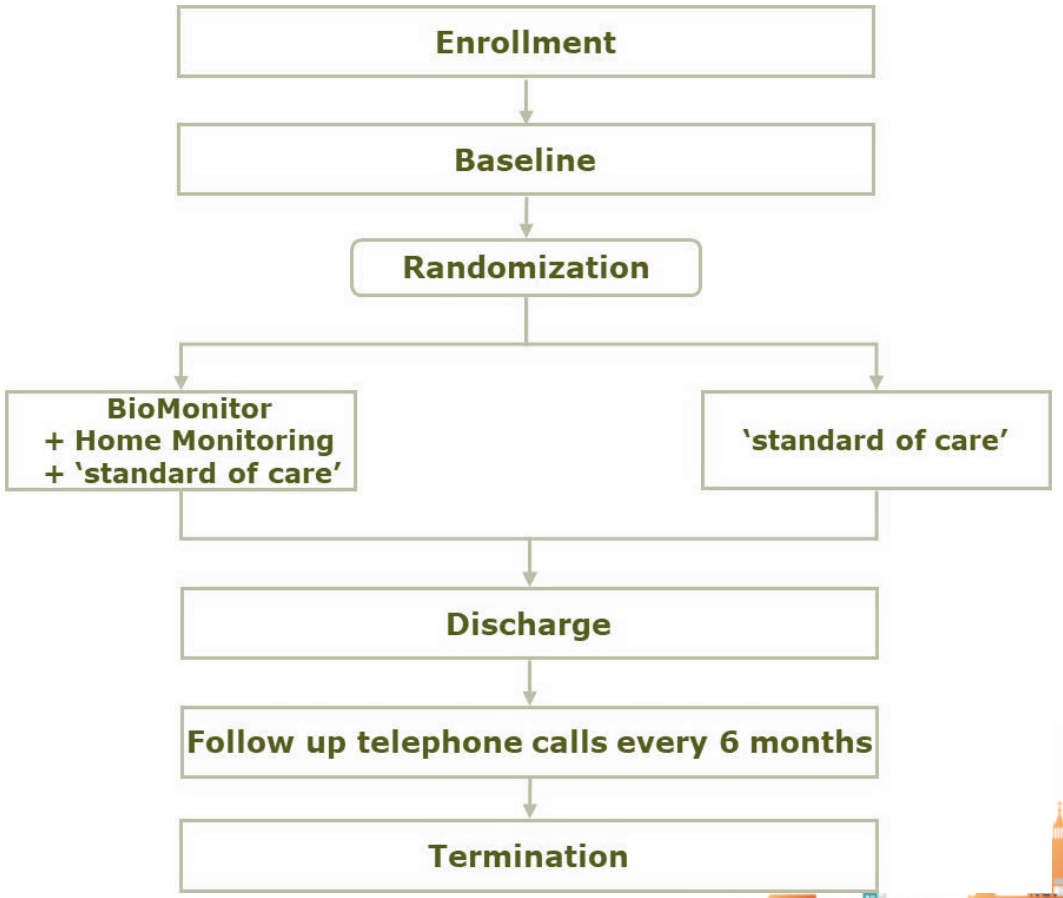
Protocol:

Follow-up by general practitioner or cardiologist according to local standard post-MI practice

Patient visit at the site only after relevant arrhythmias were detected by remote monitoring

Patients are called by phone every 6 months to ensure adverse event reporting

Flowchart:



Jons C, Sogaard P, Behrens S, Schrader J, Mrosk S, Bloch Thomsen PE. The clinical effect of arrhythmia monitoring after myocardial infarction (BIO-GUARD|MI):study protocol for a randomized controlled trial. Trials. 2019;20(1):563. doi: 10.1186/s13063-019-3644-5.

Conclusion

Post-MI patients have a high risk for clinically significant arrhythmias

Cardiac arrhythmias in MI patients are a predictor for adverse outcomes

ICMs are a highly effective tool for early detection of subclinical arrhythmia in post-MI patients

Will an early detection and consequent treatment of ICM-detected arrhythmias improve long-term outcome in these patients?

BIO|GUARD-MI was designed to investigate benefits of providing continuous arrhythmia monitoring to 'high-risk' patients post-MI that currently only receive conventional calendar-based follow-up

NSTEMI-ICM study

Esperienza pilota di monitoraggio a lungo termine con monitor cardiaco di pazienti con significativa stenosi residua dopo infarto miocardico acuto senza sopraslivellamento del stratto ST

Razionale

- I pazienti sopravvissuti ad un infarto miocardico acuto con frazione di eiezione depressa hanno un'alta incidenza di morte improvvisa o arresto cardiaco.
- Circa il 20% degli eventi accade nei primi 30 giorni post-IMA, ma l'incidenza continua poi ad aumentare progressivamente fino a 36 mesi. [1]
- La frazione di eiezione è uno stratificatore significativo (<30%, 31%-40%, >40%).
- Lo studio CARISMA ha investigato l'incidenza di aritmie cardiache a lungo termine registrate con monitor cardiaco (ICM) in pazienti sopravvissuti ad infarto del miocardio con frazione di eiezione ventricolare sinistra ridotta, documentando aritmie clinicamente significative nel 50% dei pazienti. [2]
- Lo studio SMART-MI ha investigato l'incidenza di aritmie cardiache a lungo termine registrate dall'ICM in pazienti sopravvissuti ad infarto del miocardio con frazione di eiezione ventricolare sinistra middle-range. Il monitoraggio remoto con ICM si è dimostrato efficace nella detection precoce di aritmie subcliniche e prognosticamente rilevanti. [3]
- Lo studio randomizzato BIOGUARD-MI con monitoraggio continuo delle aritmie in pazienti ad alto rischio post-IMA ha identificato aritmie che richiedono un trattamento nel 40% dei pazienti entro 2 anni rispetto al 6% nel gruppo di controllo. In tutta la popolazione di studio, questo non ha portato un beneficio statisticamente significativo nell'outcome. Nel sottogruppo dei pazienti NSTEMI, i MACE (major adverse cardiovascular events) si sono ridotti del 31%. [4]

1. Solomon SD, et al. Sudden death in patients with myocardial infarction and left ventricular dysfunction, heart failure, or both. N Engl J Med. 2005 Jun 23;352(25):2581-8.
2. Bloch Thomsen PE, et al. Long-term recording of cardiac arrhythmias with an implantable cardiac monitor in patients with reduced ejection fraction after acute myocardial infarction: the Cardiac Arrhythmias and Risk Stratification After Acute Myocardial Infarction (CARISMA) study. Circulation. 2010 Sep 28;122(13):1258-64.
3. Bauer A, et al. Telemedical cardiac risk assessment by implantable cardiac monitors in patients after myocardial infarction with autonomic dysfunction (SMART-MI-DZHK36): A prospective, investigator-

Collaborazione scientifica: NSTEMI-ICM

NSTEMI-ICM: Monitoraggio a lungo termine tramite Loop Recorder Impiantabile di pazienti con Stenosi Residua dopo NSTEMI.

Obiettivo: non disperdere la prima esperienza di monitoraggio con ICM e monitoraggio remoto in questi pazienti.

Centro promotore: Ospedale Santa Maria della Pietà di Nola

Dr. Mario Volpicelli

Dr. Michele Capasso

Centro partecipanti: Ospedale Santa Maria della Pietà di Nola (referenti Dr. Mario Volpicelli, Dr. Michele Capasso), Ospedale di Ciriè (referente Dr. Gaetano Senatore).

NSTEMI-ICM: criteri di inclusione

Criteri di inclusione: (i) Pazienti con precedente Infarto Miocardico senza sopraslivellamento del tratto ST (NSTEMI).

(ii) Frazione di eiezione ventricolare sinistra (LVEF) >35%.

(iii) Almeno 18 anni di età.

(iv) Stenosi coronarica epicardica residua (Diametro ≥50%)*.

(v) Pazienti impiantati con ICM secondo pratica clinica e seguiti con monitoraggio remoto.

*Rientrano nello studio pazienti in presenza di stenosi che non sono suscettibili di angioplastica, ma piuttosto di sola terapia medica, secondo i seguenti criteri:

- Non criticità allo studio funzionale
- Miocardio non vitale
- Non critica angiograficamente
- Bilancio rischio/beneficio sfavorevole

La metodica di non valutare la severità è sotto giudizio dello specialista interventista, che di volta in volta può decidere o meno di fare test funzionali come ffr per valutare la fisiologia ischemizzante della placca.

Ciò non toglie che qualche paziente può comunque fare angioplastica, ma possono persistere stenosi su altri rami, che sono giudicate non significative e quindi non trattate

NSTEMI-ICM: follow-up e endpoint di studio

Il follow-up dello studio non prevede visite in persona obbligatorie, ma è basato sul monitoraggio remoto del ICM. Ogni paziente sarà seguito per un minimo di 18 mesi.

Endpoint Primario:

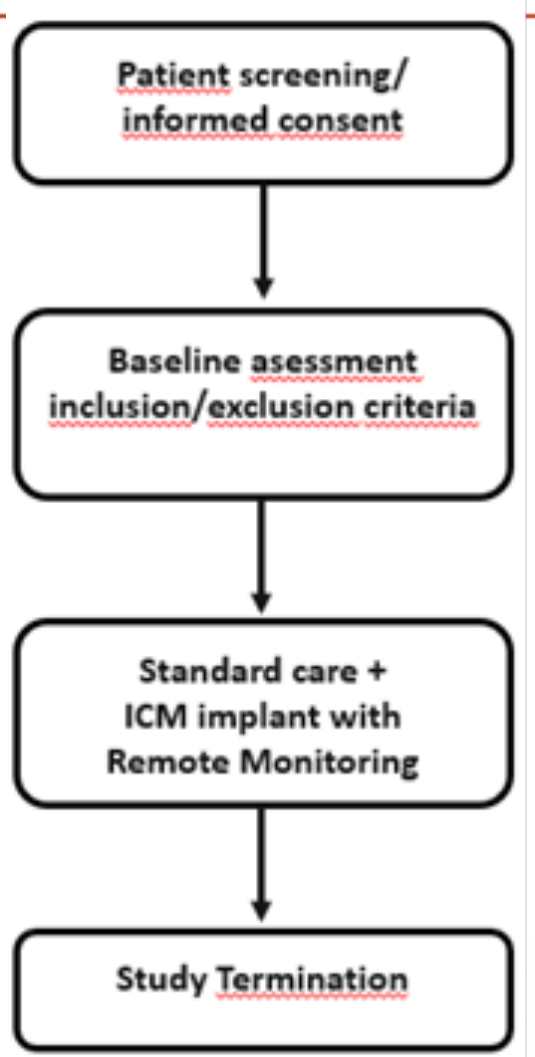
- Tempo di rilevamento di aritmie cardiache

Endpoint Secondario:

- Percentuale di pazienti con reazione medica a seguito di diagnosi di aritmia cardiaca
- Tempo fino agli eventi cardiaci avversi maggiori (MACE)

Il MACE è definito come mortalità cardiovascolare o ricovero ospedaliero per:

Aritmia
Sindrome coronarica acuta
Peggioramento dell'insufficienza cardiaca
Ictus
Embolia sistemica
Sanguinamento grave



Sintesi dello studio NSTEMI-ICM

Follow-up e pazienti coinvolti

Il follow-up medio è di 1,5 anni e ha incluso 33 pazienti con monitoraggio ICM (BIOMONITOR IIIm e BIOMONITOR IV)

Popolazione	N=33
Modello ICM	
Biomonitor IIIm (%)	30 (90.9%)
Biomonitor IV (%)	3 (9.1%)
Età (years)	63 (58-69)
Uomini (%)	27 (81.8%)
Altezza (cm)	172 (166-175)
Peso (Kg)	84 (80-92)

Popolazione	N=33
Precedente angioplastica (%)	29 (87.9%)
Numero di altre stenosi non rivascolarizzate*	1 (1-2)
Motivo di non rivascolarizzazione §	
Non critica allo studio funzionale	29 (85.3%)
Miocardio non vitale	4 (11.8%)
Non critica angiograficamente	1 (2.9%)
Famil. Cardiopatia ischemica (%)	15 (45.4%)
Famil. Morte improvvisa (%)	0 (0%)
Tabagismo (%)	8 (24.2%)
Storia di aritmie (%)	6 (18.2%)
Ipertensione (%)	25 (75.7%)
Dislipidemia (%)	16 (48.5%)
BPCO (%)	3 (9.1%)
Diabete (%)	7 (21.2%)
CHF (%)	3 (9.1%)
Pregresso Stroke o TIA (%)	1 (3.0%)
FA (%)	6 (18.2%)
IRC (%)	0 (0%)
Disturbi neurologici/psichiatrici (%)	0 (0%)
Palpitazioni (%)	6 (18.2%)
Sincope (%)	1 (3.0%)
Frazione di eiezione (%)	50 (45-50)
Frequenza cardiaca a riposo (bpm)	75 (60-84)
CHA2DS2-VASc	3 (2-4)

Terapia farmacologica	
ACE	20 (60.6%)
Sartanici	2 (6.1%)
Betabloccanti	22 (66.7%)
Calcio Antagonista	5 (15.1%)
Diuretici	13 (39.4%)
Antiaggreganti	33 (100%)
Anticoagulanti	6 (18.2%)
Antiaritmici classe Ic	0 (0%)
Amiodarone	4 (12.1%)
Sotalolo	0 (0%)
Insulina	6 (18.2%)
Altro	0 (0%)

Sintesi dello studio NSTEMI-ICM

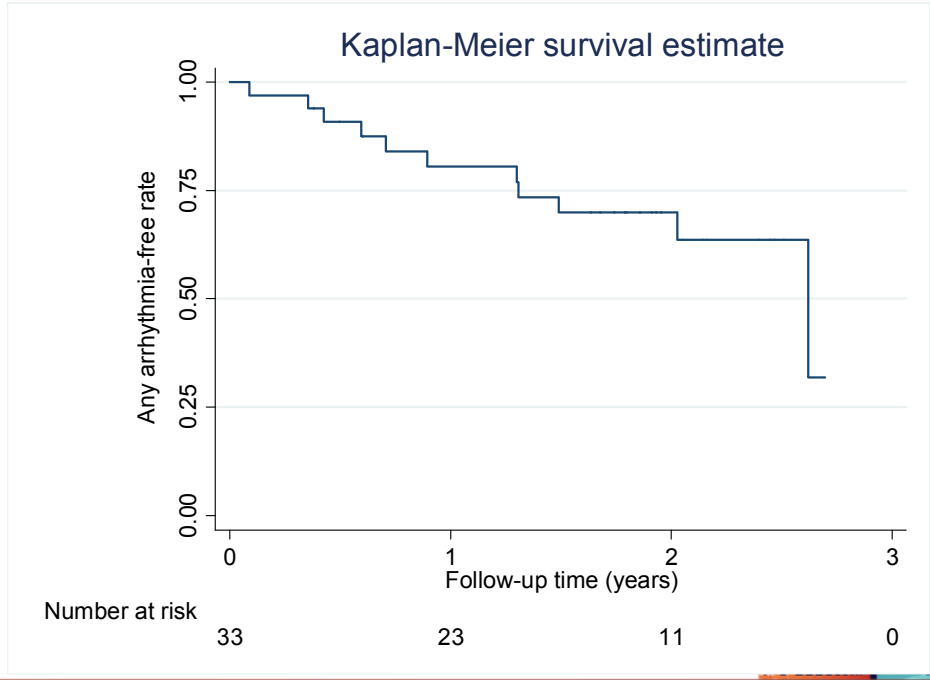
Diagnosi e azione clinica

Un totale di 11 (33%) pazienti hanno ricevuto diagnosi di aritmia.
In tutti i casi la diagnosi ha comportato almeno un'azione clinica.

Tipo di aritmia	N=33
TV sostenuta	1 (3.0%)
Bigeminismo ventricolare	1 (3.0%)
Blocco AV	2 (6.1%)
Arresto sinusale	3 (9.1%)
Flutter	1 (3.0%)
Fibrillazione atriale	2 (6.1%)

Tipo di azione clinica	N=33
Impianto defibrillatore/CRT-D	2 (6.1%)
Prescrizione ablazione BEV	1 (3.0%)
Impianto pacemaker	1 (3.0%)
Modifica pregressa terapia farmacologica	1 (3.0%)
Inizio NOAC	3 (9.1%)
CVE	1 (3.0%)
Prescrizione SEF	1 (3.0%)
Prescrizione ablazione per FA	1 (3.0%)
Inizio terapia di controllo del ritmo	3 (9.1%)
Prescrizione impianto pacemaker	1 (3.0%)

Time from ICM insertion (year)	N=33
1	80.9% (62.2% - 90.9%)
2	67.7% (46.5% - 82.0%)
3	46.9% (19.8% - 70.2%)



Case Report

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DOI: 10.19102/icrm.2024.15094

THE JOURNAL OF INNOVATIONS IN CARDIAC RHYTHM MANAGEMENT™

VENTRICULAR ARRHYTHMIAS

CARDIAC MONITORING

CASE REPORT

Detection of Ventricular Tachycardia by an Implantable Cardiac Monitor 8 Months Post–myocardial Infarction

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ABSTRACT. *Following a non–ST-elevation myocardial infarction (MI), a 68-year-old hypertensive, severely obese woman with 45% left ventricular ejection fraction underwent an implantable cardiac monitor (ICM) insertion. After 8 months, the ICM remotely transmitted multiple non-sustained ventricular tachycardia episodes. Symptomatic during these events, the patient underwent an invasive electrophysiologic stimulation, which induced ventricular arrhythmia. Subsequently, implantable cardioverter-defibrillator implantation was recommended. Continuous remote monitoring via an ICM detected critical arrhythmias in this post-MI patient, facilitating timely intervention.*

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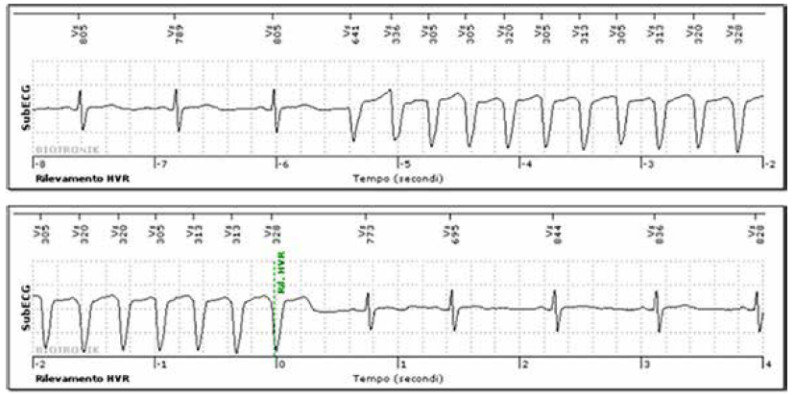

Figure 1: Monomorphic non-sustained ventricular tachycardia recorded and transmitted by the implantable cardioverter defibrillator. *Abbreviations:* HVR, high ventricular rate; subECG, subcutaneous electrocardiogram; Vs, sensed ventricular beat.

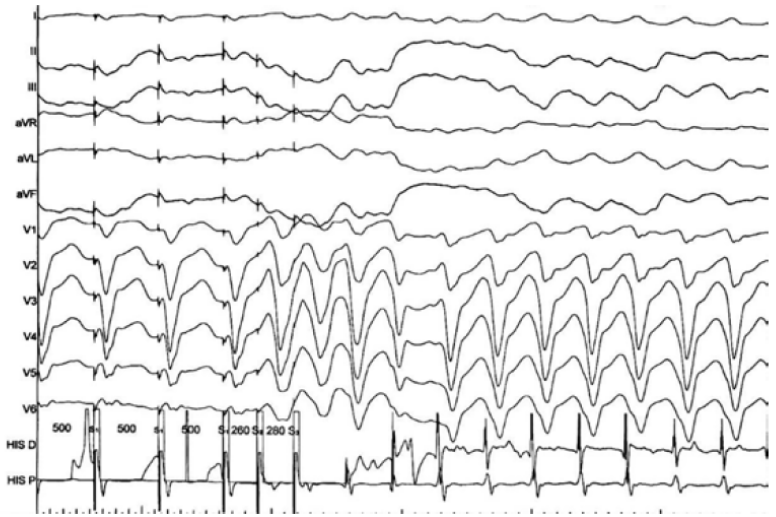

Figure 2: Ventricular tachycardia induced during the electrophysiologic stimulation with a basic drive cycle of 500 ms and two extrastimuli (S_1 = 260 ms; S_2 = 280 ms).

Grazie