HOTLINES ESC 2025

EDITORIAL

Hotlines ESC 2025: A Rendezvous with Scientific Progress

For this second issue of the 2025 College of Cardiology Newsletter, we have chosen to highlight the ESC Hotlines 2025.
Each year, they represent a key moment in Cardiology showcasing innovative research, presented for the first time, that shapes the medical practice of tomorrow.
In this issue, each resident has worked on one of the Hotline articles, providing a critical review under the supervision of a university hospital faculty member.
We hope that these clear and structured summaries will help everyone grasp the key advances presented at ESC 2025, while also emphasizing the importance of critical reading in our continuing medical education.
A warm thank you to all the residents and senior physicians who enthusiastically contributed to this project.

Happy reading!

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PR. Khadija Mzoughi
Coordinator of the Newsletter

STUDIES 2025
HOTLINES ESC

Table of Contents :

Article 1

RHYTHMOLOGY HOTLINES

Pr. Ag Manel BEN HALIMA
Coordinator

1- Comparing pulsed field electroporation and radiofrequency ablation for the treatment of paroxysmal atrial fibrillation: design and rationale of the BEAT PAROX-AF randomized clinical trial *Pr Sana Ouali Rsdte Rihab Mars*

2- POTCAST Trial: Increasing the Potassium Level in Patients at High Risk for Ventricular Arrhythmias *Dr Rahma Kallel Rsdt Ouassim Mejber*

3- Digital Twin-Guided Patient Specific Rotor Ablation for Persistent Atrial Fibrillation: The CUVIA Randomized Clinical trial *Dr Zeyneb Jebbari Rsdt Maroeun Krid*

4- Remote Screening for Asymptomatic Atrial Fibrillation: The AMALFI Randomized Clinical Trial *Pr Ag Emna Allouche Rsdte Wissal Jomni*

5- Biomarker-based ABC-AF Risk Scores for Personalized Treatment to Reduce Stroke or Death in Atrial Fibrillation – a Registry-based Multicenter Randomized Controlled Study *Pr Ag Emna Allouche Rsdte Islem Kharrat*

6- Long-term Anticoagulation Discontinuation After Catheter Ablation for Atrial Fibrillation : The ALONE-AF Randomized Clinical Trial Pr Ag Manel Ben Halima Rsdt Wassim Souissi

7- REFINE-ICD: Efficacy of ICD therapy in higher risk post-MI patients with better-preserved LV function *Dr Mariem Jabeur Rsdte Zeineb Henchiri*

8- DOUBLE-CHOICE: Peri-interventional Anesthesia Strategies for Transcatheter Aortic Valve Implantation: A Multicenter, Randomized, Controlled, Non-inferiority Trial *Dr Malek Elarbi Rsdt Heithem Hedhli*

COMPARING PULSED FIELD ELECTROPORATION AND RADIOFREQUENCY ABLATION FOR THE TREATMENT OF PAROXYSMAL ATRIAL FIBRILLATION: DESIGN AND RATIONALE OF THE BEAT PAROX-AF RANDOMIZED CLINICAL TRIAL

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Résidente Rihab Mars
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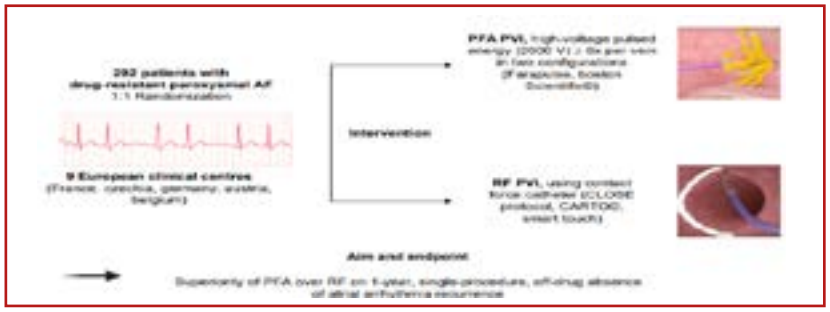
Number of patients included: 292 patients with drug resistant paroxysmal AF

Number per group: randomized 1:1 → ≈ 146 per arm based on 292 recruited

Study design:



Aim: Compare pulsed field ablation (PFA) with RF ablation in terms of efficacy and safety for patients with drug resistant paroxysmal AF.

Principle results:

- Efficacy: Single-procedure success at 12 months was 77.2% (PFA) vs 77.6% (RFA) — no superiority for PFA (adjusted difference 0.9%, 95% CI -8.2 to 10.1; P = 0.84).
- Procedure time: PFA procedures were substantially shorter.
- Safety: Overall safety profile excellent in both arms. Reported procedure-related serious adverse events were lower with PFA (≈3.4%) vs RFA (≈7.6%) in the reported summaries; RFA arm had more tamponades and more cases of significant pulmonary-vein stenosis.

Study limitations

The trial's main limitations are its open-label design (risk of bias), limited power for detecting small differences due to its superiority design, and restricted generalizability because it used a specific PFA system and RFA protocol. It was also conducted in high-volume expert centers, so results may not apply to lower-volume settings, and the 12-month follow-up may not fully capture long-term durability or late complications.

Link to the study: https://www.escardio.org/The-ESC/Press-Office/Press-releases/Pulsed-field-ablation-was-not-superior-to-radiofrequency-ablation-in-paroxysmal-atrial-fibrillation?utm_source.

POTCAST TRIAL:

INCREASING THE POTASSIUM LEVEL IN PATIENTS AT HIGH RISK FOR VENTRICULAR ARRHYTHMIAS

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CHU Gabès

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Résident Cardiologie
CHU Gabès

Number of patients included: 1200 patients randomized 1:1 into two groups:
Intervention group: (n=600) High-normal potassium group (target plasma K^+ 4.5–5.0 mmol/L using dietary guidance, potassium supplements and/or mineralocorticoid receptor antagonist therapy)
Control group: (n=600) Standard care group

Study design: Multicenter, open-label, event-driven, randomized superiority trial
Patients at high risk of ventricular arrhythmias (with Implantable Cardiac Defibrillator) + baseline Potassium<= 4.3mm/L

Aim: To test whether raising serum potassium to the high-normal range (4.5–5.0 mmol/L) reduces the risk of ventricular arrhythmias, ICD therapies, unplanned hospitalizations (arrhythmia or HF), and all-cause mortality.

Principal Results: Median follow-up: 39.6 months.

- **Primary composite outcome:** sustained VT or appropriate ICD therapy, unplanned hospitalization for arrhythmia or HF, or all-cause death
- **The Number Needed to Treat** to prevent one event in this population was **12.3 persons** (95% CI, 2.0 to 14.0).
- **Fewer** unplanned hospitalizations for arrhythmia or HF, and lower all-cause mortality
- **Safety outcomes:** Hospitalization for hypo- or hyperkalemia ~1% in both groups.

		Intervention Group	Control Group	HR 95%CI	p
Primary outcomes	N (%)	136 (22.7%)	175 (29.2%)	0.76 [0.61;0.95]	0.01
	Event/100person/year	7.3	9.6		
ICD appropriate therapy N (%)		92 (15.3%)	122 (20.3%)	0.75 [0.57;0.98]	-
Death		34 (5.7%)	4 (6.8%)	0.85 [0.54;1.34]	-

Study limitations

- Restricted to ICD carriers → may limit generalizability to broader populations.
- Excluded patients with severe renal dysfunction → safety in this subgroup uncertain.
- Open-label design: clinicians aware of treatment allocation.
- Modest increase in potassium (~+0.3 mmol/L) but requires careful monitoring.

Link to the study: https://www.nejm.org/doi/full/10.1056/NEJMoa2509542

DIGITAL TWIN-GUIDED PATIENT SPECIFIC ROTOR ABLATION FOR PERSISTENT ATRIAL FIBRILLATION: THECUVIARANDOMIZEDCLINICAL TRIAL

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Prospective:
Randomized 1:1 [PVI+Digital twin-guided ablation (CUVIA) and PVI alone]

Applied digital twin concept:
Personalized heart model constructed from the CT scan and the electroanatomical map Identification of stable phase singularity points

Inclusion criteria: Persistent AF refractory to AADs undergoing first-time AF ablation

Exclusion criteria: Paroxysmal AF or Permanent AF

Primary endpoint: Any documented atrial arrhythmia lasting ≥30 s after the blanking period (with or without the use of AADs)

Study design

Aim of the study: is combining PVI and digital twin guidance ablation more effective than PVI alone?

Number of patients: 304 patients: 155 patients in PVI+CUVIA vs 149 in PVI alone

Principle results: Median age: 61.3 years ; Gender differences: 20.7% women

Procedure-related results	CUVIA	PVI alone
Freedom from recurrence	**77.9%**	59.5%
Complications rates	No significant difference	
Total procedure time	142 minutes	137 minutes

Study limitations: Need for longer-term follow-up and need for a multicentre validation

Link to the study: Not yet published

REMOTE SCREENING FOR ASYMPTOMATIC ATRIAL FIBRILLATION: THE AMALFI RANDOMIZED CLINICAL TRIAL

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Aim: to assess the long-term efficacy of remote screening for asymptomatic AF in older individuals at increased risk of stroke using a 14-day continuous ECG monitoring patch.

Study design: The AMALFI trial utilized a remote, parallel-group, unblinded, randomized clinical trial design. The study enrolled individuals in the UK aged 65 and over with a moderate to high risk of stroke, but no prior diagnosis of AF.

Number of patients included: +Of the 22 044 individuals invited, 5040 (22.9%) were randomized 1:1. In the intervention group only 2126 participants (84.4%) wore and returned the patch.

Principal Results: .

- **Increased AF diagnosis:** The trial found a modest, but statistically significant, increase in the diagnosis of AF in the group (ratio of proportions, 1.26 [95% CI, 1.02 to 1.57]; p=0.03).
- **Anticoagulation use:** The intervention group had a greater exposure to oral anticoagulation (difference, 0.50 months; p<0.001).
- **Time to diagnosis:** Screening with the ECG patch led to a significantly faster time to AF diagnosis compared to usual care.
- **Stroke and other clinical events:** The trial was not powered to detect a difference in clinical outcomes such as stroke. The observed rate of stroke was similar between the groups.
- **AF Burden:** In over half (55%) of the participants whose AF was detected by the patch, the AF burden was low (less than 10% of the monitoring time).

Aim of the study: The trial was not designed or powered to detect a difference in the rate of clinical events, such as stroke, transient ischemic attack (TIA), or death.
Potential for Selection Bias: The 22.9% participation rate may mean that the enrolled population, while representative of those willing to participate in a remote trial, may not be fully representative of the entire at-risk population.
Short-Duration Screening: The trial used a single, 14-day ECG patch. It is possible that individuals who were missed by this one-off screening might have gone on to develop AF later.

Link to the study: doi: 10.1001/jama.2025.15440

BIOMARKER-BASED ABC-AF RISK SCORES FOR PERSONALIZED TREATMENT TO REDUCE STROKE OR DEATH IN ATRIAL FIBRILLATION – A REGISTRY-BASED MULTICENTER RANDOMIZED CONTROLLED STUDY

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Aim: Evaluate whether personalized treatment strategy based on the biomarker-based ABC-AF risk score reduces the occurrence of the composite outcome of stroke or death, without increasing the risk of bleeding in patients with AF.

Study design: It was a multicenter, prospective, randomized controlled open-label study. 3933 Patients were randomized 1:1 to either an ABC-AF risk score-guided treatment strategy or to standard of care.

Principal Results: .
Patients were followed until 12 May 2024, with at least 12 months of follow-up after the last patient was enrolled. A total of 323 primary outcome events (stroke or death) occurred, with no significant difference between the active and control groups (3.18 vs. 2.67 per 100 patient-years, p=0.12). Major bleeding events (n=293), including 43 intracranial hemorrhages, were also comparable between groups. The secondary composite outcome of stroke, death, or major bleeding (n=521) showed no significant difference (5.21 vs. 4.55 per 100 patient-years, p=0.13). Subgroup analyses, including CHA_2DS-VASc and ABC-AF risk categories, revealed consistent results. Overall, the individually tailored multidimensional treatment strategy based on ABC-AF risk scores did not provide additional clinical benefit compared with standard guideline-based care in patients with AF.

	ABC-AF N=1971		Standard of care, N = 1962		
	events (%)	rate/100 patient years	events (%)	rate/100 patient years	log-rank test, p-value
Primary outcome (stroke or death)	175 (8.87%)	3.18	148 (7.54%)	2.67	0.12
Major bleeding	152 (7.71%)	2.82	141 (7.19%)	2.61	0.50
Death, stroke or major bleeding	277 (14.05%)	5.12	244 (12.4%)	4.55	0.13
Stroke	48 (2.44%)	0.87	41 (2.09%)	0.74	0.44
Death	136 (6.90%)	2.44	113 (5.76%)	2.02	0.13
Myocardial infarction	30 (1.52%)	0.54	29 (1.48%)	0.52	0.86
Hospitalization for heart failure	120 (6.09%)	2.22	112 (5.71%)	2.06	0.58

Primary and secondary outcomes

Study limitations: The study was underpowered, due to the premature termination of recruitment because of a safety concern. The recruited patients had a higher rate of pre-study OAC treatment, and lower than anticipated event rates.

Link to the study:
https://www.ahajournals.org/doi/epdf/10.1161 CIRCULATIONAHA.125.076725

LONG-TERM ANTICOAGULATION

DISCONTINUATION AFTER CATHETER ABLATION FOR ATRIAL FIBRILLATION : THE ALONE-AF RANDOMIZED CLINICAL TRIAL

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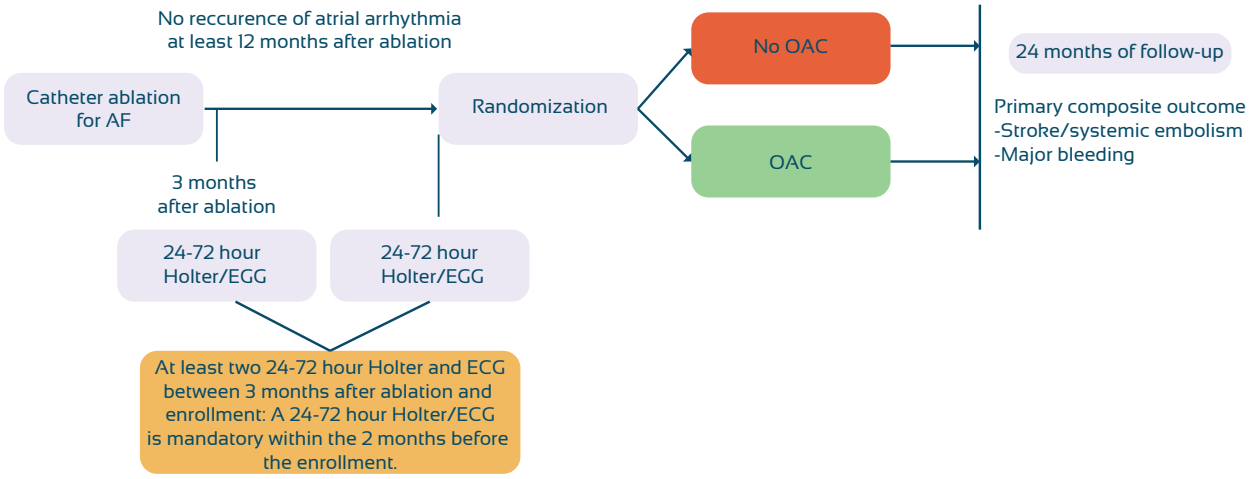
Wassim Souissi
Abderrahmen Mami Hospital

Number of Patients Included / Number Per Group:

- **Total : 840 a**dult patients (Discontinue OAC group **: 417** patients vs Continue OAC group : **423** patients).

Study design: TRandomized clinical trial



AIM: To evaluate whether discontinuing OAC therapy provides superior outcomes compared with continuing OAC therapy in patients having at least one non-sex-related stroke risk factor (i.e. CHA_2DS_2-VASc ≥1 excluding sex).

Principal Results:

Outcome (2-yr follow-up)	Stop OAC (n = 417)	Continue OAC (n = 423)	Absolute Difference (95% CI)	P value
Primary composite (ischemic stroke + systemic embolism + major bleeding)	0.3 %	2.2 %	-1.9 % (-3.5 to -0.3)	0.02
Ischemic stroke	0.3 %	0.8 %	-0.5 % (-1.6 to 0.6)	NS*
Systemic embolism	0.%	0 %	0	— (no events)
Major bleeding	0 %	1.4 %	-1.4 % (-2.6 to -0.2)	NS*

NS (not significant*)

Study Limitations:

- Low event rates overall, especially for ischemic stroke/systemic embolism, making statistical power for those components limited.
- Patient selection : mix of paroxysmal and persistent AF ; results may not generalize to patients with high AF burden or frequent recurrences.
- Monitoring for arrhythmia recurrence was relatively limited : only two Holter sessions (24- to 72-hour) including one in the 2 months before randomization. Might miss asymptomatic or intermittent recurrences.

Link to the study: https://pubmed.ncbi.nlm.nih.gov/40886309/

REFINE-ICD: EFFICACY OF ICD THERAPY IN HIGHER RISK POST-MI PATIENTS WITH BETTER-PRESERVED LV FUNCTION

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Number of patients included / number per group: Randomized n = 597 (ICD + medical therapy n = 306; Medical therapy n = 291).

Study design: Randomized, prospective, open-label, investigator-initiated, multicentre trial. Prior MI with LVEF 36–50% measured ≥ 2 months after index MI. Holter assessment of heart rate turbulence (HRT) and modified moving average T-wave alternans (TWA) using consensus criteria.

Aim: To determine whether prophylactic ICD implantation improves survival in post-MI patients with LVEF 36–50% who also have impaired HRT and abnormal TWA.

Principal Results: .

- Primary outcome (all-cause mortality, ITT): The ICD did not improve overall survival versus medical therapy (HR 1.07; 95% CI 0.77–1.50; p = 0.69) and Event rates were ICD 24.5% vs Medical 21.3%.
- Cardiac mortality: No significant difference between groups (8.8% vs 7.6%; HR 1.11; 95% CI 0.63–1.945).
- Sudden cardiac death: ICD showed a non -significant reduction (HR 0.66; 95% CI 0.27–1.62) event rates (2.6% vs 3.8%).
- Follow-up / context: Mean follow-up 5.7 years. 47% of deaths were non-cardiac, which an ICD cannot prevent.

Study limitations: High proportion of non-cardiac deaths, cross-over between arms, open-label design, and evolving contemporary post-MI care.

Link to the study: Not yet published

DOUBLE-CHOICE: PERI-INTERVENTIONAL

ANESTHESIA STRATEGIES FOR TRANSCATHETER AORTIC VALVE IMPLANTATION: A MULTICENTER, RANDOMIZED, CONTROLLED, NON-INFERIORITY TRIAL

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Cardiology department

Number of patients included / number per group: The trial compares two aspects of the TAVI approach and simultaneously tests two different interventions in a single study. the first arm of the study is the anesthesia strategy which included (n=752) patients divided into 377 participants receiving a minimalist approach (local anesthesia without sedation, with use of central venous and arterial lines, as well as urinary catheters);versus 375 patients receiving standard approach (conscious sedation).The second arm of the study is the type of the expanding valve used ,which included (n=855) patients randomized into 427 patients in ACURATE neo2 valve group and 428 patients in EVOLUT PRO ,Pro+ and FX valve group.

Study design: patients with symptomatic severe aortic stenosis, an indication for TAVI, suitability for transfemoral access and anatomy amenable to treatment with either type of valve, at intermediate surgical risk. For the Anesthesia Strategies: The trial compares a minimalist anesthesia approach with standard anesthesia care; defining all-cause mortality, vascular and bleeding complications, infections requiring antibiotic treatment and neurologic events as the primary combined endpoint at 30 days .For the Valve Types: it compares two different latest-generation self-expanding heart valves, defining all-cause mortality, stroke, moderate or severe prosthetic valve regurgitation and permanent pacemaker implantation as the primary combined endpoint at 30 days .

Aim: to show that the minimalist anesthesia approach is non-inferior to standard care, and that one specific self-expanding valve type is non-inferior to the others

Principal Results: minimalist approach was non inferior to the standard approach for a composite primary outcome of cardiovascular events and complications at 30 days, (p for non-inferiority=0.003). ACURATE neo2 self-expanding valves were non inferior and superior to Evolut Pro/Pro+/Fx self-expanding valves (p for non-inferiority<0.00, p for difference<0.001).

Study limitations :

- The trial was conducted in highly experienced centers and including very selected patients,
- The short follow-up (30 days) limiting the evaluation of long-term durability and late complications
- The high cross-over occurred from the minimalist arm to the standard approach
- The Acurate neo2 valve, has since been withdrawn from the market.

Link to the study:
https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.125.076557


ELIXTRA
1er AOD PRESCRIT DANS LE MONDE*
1er APIXABAN EN TUNISIE
RECORDATI
ZANEXTRA
MIX
ANTIHYPERTENSEUR
EMPERIAL
Imperial POWER
RECORDATI
IRBEXTRA
IRBEXTRA PLUS
UNLEASH THE POWER,
PROTECT WITH CONFIDENCE
RECORDATI

RECORDATI

Article 2

HEART FAILURE AND CARDIOMYOPATHY HOTLINES

Pr. Ag Imen BOUHLEL
Coordinator

1-Transcatheter Valve Replacement in Severe Tricuspid Regurgitation: TRISCEND II
Dr Emna Bennour Rsdte Sahar Jridi

2- PARACHUTE-HF TRIAL: Prospective Comparison Of Sacubitril/valsartan Versus Enalapril In Patients With Chagas-related Heart Failure With Reduced Ejection Fraction
Dr Amal Ben Salem Rsdte Oumayma Garci

3-HELIOS-B STUDY *Pr Ag Imen Bouhlel Rsdte Imane Boualaoui*

4- Vericiguat in Patients with Heart Failure and Reduced Ejection Fraction
Pr. Ag Chenik Sarra Rsdte Trifi Rahma

5- Beta-Blockers after Myocardial Infarction in Patients without Heart Failure
Pr. Mehdi SLIM Rsdt Ahmed Chelly

6-The DIGIT-HF Trial: Digitoxin in Heart Failure with Reduced Ejection Fraction
Pr Meriem Drissa Rsdte Nesrine Baya

7- Mavacamten in Symptomatic Nonobstructive Hypertrophic Cardiomyopathy (ODYSSEY-HCM trial) *Dr Syrine Saidane Rsdte Islem Zarrougui*

8- Dapagliflozin in Patients Hospitalized for Heart Failure: Primary Results of the DAPA ACT HF-TIMI 68 Randomized Clinical Trial *Dr Elyes Lagha / Rsdte Ouissam EL Ourf*

9- Aficamten vs Metoprolol for Obstructive Hypertrophic Cardiomyopathy
Dr Syrine Neji Rsdte Imen Ellouz

10-Sacubitril-Valsartan and Prevention of Cardiac Dysfunction During Adjuvant Breast Cancer Therapy: The PRADA II Randomized Clinical Trial
Pr Khadija Mzoughi Rsdt El Welaty Lefghih

Article 2

HEART FAILURE AND CARDIOMYOPATHY HOTLINES

Pr. Ag Imen BOUHLEL
Coordinator

11-VICTOR Trial: Vericiguat in patients with chronic heart failure and reduced ejection fraction without worsening HF *Dr Ameni Mardessi Rsdt Oar Haddar*

12- Arrhythmic genotypes in dilated cardiomyopathy and risk of advanced heart failure *Dr Faten YAHIA Rsdt Arwa MABROUK*

13- ENVAD-HF: Angiotensin–Neprilysin Inhibition and Left Ventricular Assist Device Therapy *Dr Houssem Thabet Rsdte Oumaima Ayadi*

14- Beta-blockers did not reduce cardiovascular events in selected heart attack patients in the REBOOT trial *Dr Mahfoudhi Houaida Rsdt Kerkani Fares*

TRANSCATHETER VALVE REPLACEMENT IN SEVERE TRICUSPID REGURGITATION: TRISCEND II

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Number of patients included / per group: 400 patients randomized (267 tricuspid valve replacement vs 133 control).
Study design: International, multicenter, prospective and randomized controlled trial (2:1 allocation).

Aim: To evaluate the safety and efficacy of transcatheter tricuspid-valve replacement with the EVOQUE system plus medical therapy compared with medical therapy alone in patients with severe symptomatic tricuspid regurgitation.
Principal results

- At 1 year, the win ratio for the composite primary endpoint significantly favored valve replacement (2.02; 95% CI 1.56–2.62; P <0.001).
- Quality of life improved markedly in the valve-replacement group (66.4% achieved 10-point KCCQ-OS improvement vs. 36.5% in control).
- NYHA functional class improved in 78.9% vs. 24.0%, and 6-min walk distance improved in 47.6% vs. 31.8%.
- Echocardiography: ≥95% of treated patients had TR reduced to mild or less, compared with only 16.1% in controls.
- Safety: Severe bleeding (15.4% vs. 5.3%) and new pacemaker implantation (17.4% vs. 2.3%) were significantly higher with valve replacement.

Study limitations

- 2:1 randomization led to a relatively small control group.
- Crossovers and missing follow-up data may bias results.
- Not powered to detect mortality or HF hospitalization differences individually.
- Procedural risks include bleeding and need for pacemaker.

Link to the study:
https://www.nejm.org/doi/full/10.1056/NEJMoa2401918

Principal Figure (Win ratio and composite outcomes at 1 year):

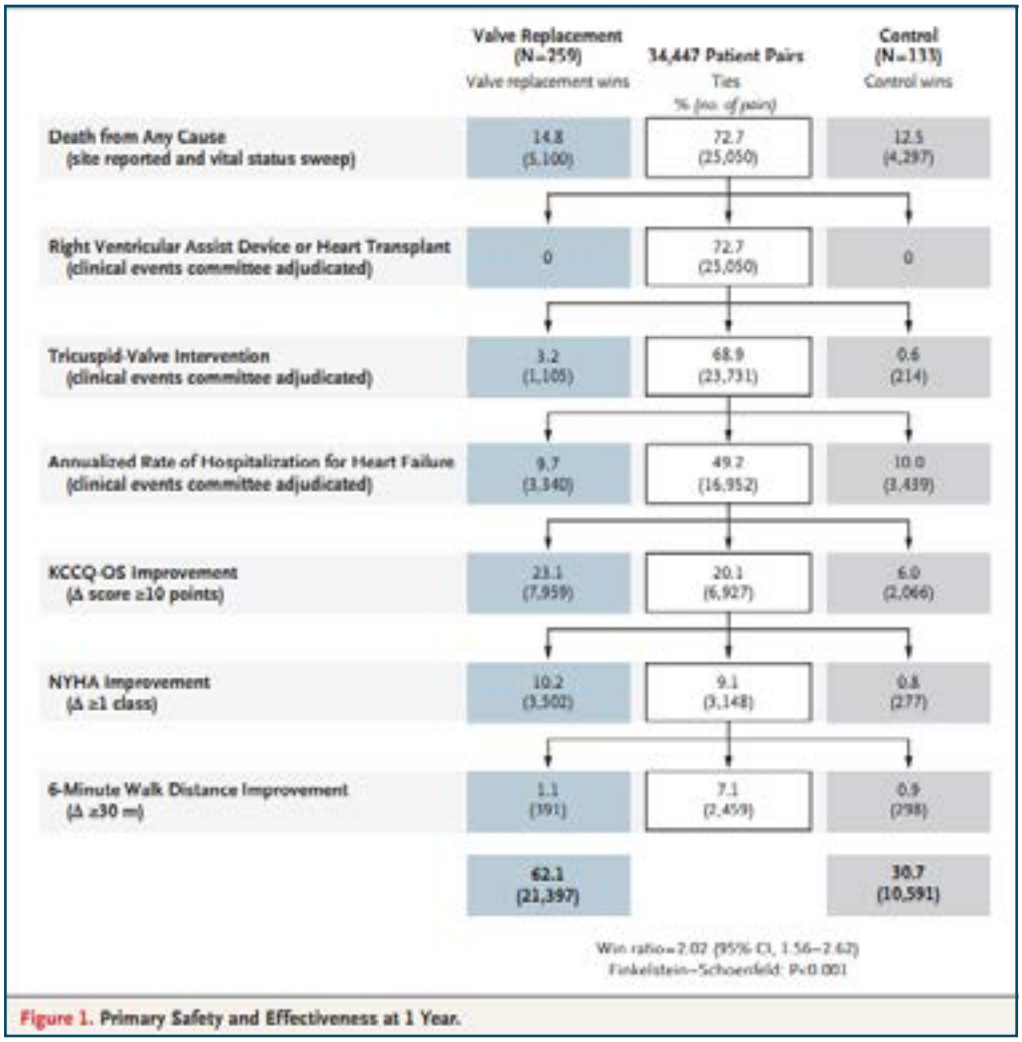

Figure 1. Primary Safety and Effectiveness at 1 Year.

PARACHUTE-HF TRIAL: PROSPECTIVE COMPARISON OF SACUBITRIL/VALSARTAN VERSUS ENALAPRIL IN PATIENTS WITH CHAGAS-RELATED HEART FAILURE WITH REDUCED EJECTION FRACTION

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Oumayma GARCI
Rsdte en cardiologie
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Number of patients included / per group: 922 patients with chronic Chagas cardiomyopathy and HFrE were included : 462 in the sacubitril/valsartan arm, and 460 in the enalapril arm

Study design: A phase IV, multicenter, randomized, open-label study with blinded endpoint adjudication. A total of 922 patients with confirmed Chagas disease (positive by ≥2 different serological tests for Trypanosoma cruzi) and HFrEF (LVEF ≤ 40%), with NYHA class II to IV symptoms, elevated NT-proBNP ≥600 pg/mL (or BNP ≥150) OR NT-proBNP ≥400 (or BNP ≥100) if recent HF hospitalization, and/or prior HF hospitalization, were enrolled across multiple centers in Latin America (including Brazil, Argentina, Mexico, and Colombia) and were randomly assigned in a 1:1 ratio to receive either sacubitril/valsartan (target dose 200 mg twice daily) or enalapril (10 mg twice daily), in addition to standard heart failure therapy. Main exclusion criteria include severe hypotension, hyperkalaemia, severely reduced renal function (eGFR <30 mL/min/1.73 m²), other cardiac conditions that might dominate HF, prior use of sacubitril/valsartan (unless >3 months before)
The primary endpoint was a hierarchical composite of cardiovascular death, first heart failure hospitalization, and change in NT-proBNP levels from baseline to 12 weeks. The median follow-up period was approximately 25 months.

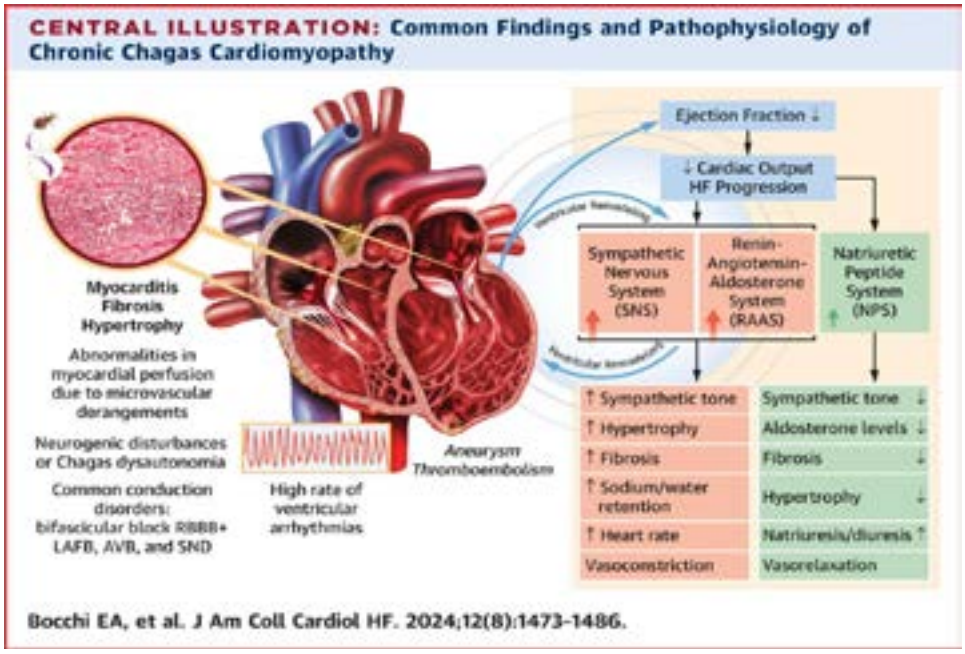
Aim: To evaluate whether sacubitril/valsartan is more effective than enalapril in improving clinical and biomarker outcomes in patients with chronic Chagas cardiomyopathy and heart failure with reduced ejection fraction (HFrEF).

Principle results: The primary endpoint significantly favored sacubitril/valsartan, with a win ratio of 1.52 (95% CI: 1.28–1.82; p < 0.001). This benefit was primarily driven by a greater reduction in NT-proBNP levels (-30.6% with sacubitril/valsartan vs. -5.5% with enalapril). However, there were no statistically significant differences between the two groups in

cardiovascular death or first heart failure hospitalization. Both treatments had comparable safety profiles, although symptomatic hypotension was slightly more common with sacubitril/valsartan (31.6% vs 27.4%). Other adverse events of interest (hyperkalaemia, renal dysfunction, arrhythmia, angioedema) had similar frequencies between the two groups.

Study limitations: Its open-label design, while using blinded endpoint adjudication, could introduce bias in patient management and symptom reporting. The study did not demonstrate a statistically significant reduction in cardiovascular death or heart failure hospitalizations, possibly due to limited statistical power and a median follow-up of only 25 months. Variations in dose titration and adherence were also potential factors, and the study placed less emphasis on patient-reported outcomes or quality of life measures.

Link to the study:
https://www.jacc.org/doi/epdf/10.1016/j.jchf.2024.05.021



PARACHUTE-HF TRIAL: PROSPECTIVE COMPARISON OF SACUBITRIL/VALSARTAN VERSUS ENALAPRIL IN PATIENTS WITH CHAGAS-RELATED HEART FAILURE WITH REDUCED EJECTION FRACTION

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Number of patients included / per group: Total: 655 patients, Vutrisiran: 326 vs Placebo: 329, 40% on Tafamidis at baseline, 90% wild-type ATTR

Study design :

- Phase III, multicenter, international, randomized, double-blind, placebo-controlled trial.
- Patients with hereditary or wild-type transthyretin (ATTR) cardiac amyloidosis.
- Vutrisiran 25 mg SC every 12 weeks vs placebo, follow-up 36–42 months.
- Randomization stratified by: ATTR type, NYHA class, age, Tafamidis use.

Aim: To evaluate the efficacy and safety of Vutrisiran, an RNA interference therapeutic that reduces hepatic transthyretin synthesis, in patients with ATTR cardiac amyloidosis.

Principal results :

- **Primary endpoint (all-cause mortality + recurrent CV events):**
  - HR = 0.72 (95% CI: 0.56–0.93; p=0.01) – overall population.
  - HR = 0.67 (95% CI: 0.49–0.93; p=0.02) – patients not on Tafamidis.
- **All-cause mortality at 42 months: HR = 0.65 (95% CI: 0.46–0.90; p=0.01).**
- **Significant improvement in:**
  - 6-minute walk test (p<0.001),
  - Kansas City Cardiomyopathy Questionnaire (p<0.001),
  - NYHA class (p=0.02).
- **No significant benefit** in patients already receiving Tafamidis.

- **Safety:** No significant difference in serious adverse events (49% Vutrisiran vs 59% placebo).

Study limitations :

- Delayed onset of efficacy (benefit emerging after ~12 months).
- No prognostic benefit in patients on Tafamidis → raises the question of dual therapy vs monotherapy.
- Further trials needed to assess head-to-head or combination strategies.

Link to the study:
https://www.sciencedirect.com/science/article/abs/pii/S0248866324011974

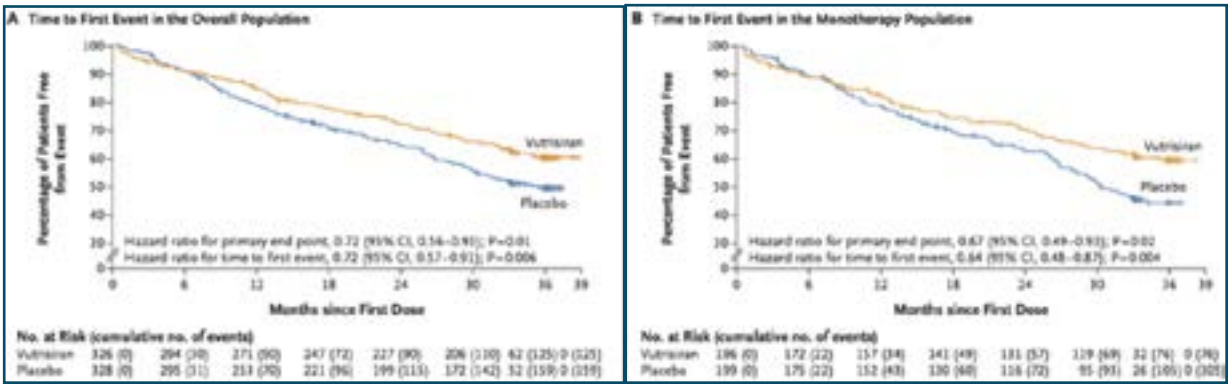

Figure 1: All-cause mortality in the overall population (A) and in the population without Tafamidis (B)

VERICIGUAT IN PATIENTS WITH HEART FAILURE AND REDUCED EJECTION FRACTION

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Population: 5050 patients with chronic HFrEF (LVEF < 45%, NYHA II–IV) who had a recent hospitalization for HF or required intravenous diuretics.

Study design: Randomized, double-blind, placebo-controlled trial comparing vericiguat (up to 10 mg once daily) versus placebo, both added to standard heart failure therapy, with a median follow-up of 10.8 months.

Aim: The objective of the VICTORIA trial was to assess whether vericiguat, an oral soluble guanylate cyclase stimulator, could reduce the composite risk of cardiovascular mortality or first hospitalization for heart failure when administered in addition to guideline-directed medical therapy in patients with chronic heart failure with reduced ejection fraction who had experienced a recent worsening event.

Principal Results: Over a median follow-up of 10.8 months, vericiguat significantly reduced the composite of cardiovascular death or first hospitalization for heart failure compared with placebo (35.5% vs 38.5%; HR 0.90; 95% CI, 0.82–0.98; p=0.02), mainly through a reduction in hospitalizations. Cardiovascular mortality alone was not significantly different. Safety analysis showed slightly higher rates of symptomatic hypotension (9.1% vs 7.9%), syncope (4.0% vs 3.5%), and anemia (7.6% vs 5.7%) in the vericiguat group, but overall the drug was well tolerated.

Outcome	Vericiguat (N = 2526)		Placebo (N = 2524)		Hazard Ratio (95% CI)†	P Value‡
	no. (%)	*events/100 patient-yr*	*no. (%)*	*events/100 patient-yr*		
Primary composite outcome and components						
Death from cardiovascular causes or first hospitalization for heart failure	897 (35.5)	33.6	972 (38.5)	37.8	0.90 (0.82–0.98)	0.02
Death from cardiovascular causes§	206 (8.2)		225 (8.9)			
Hospitalization for heart failure	691 (27.4)		747 (29.6)			
Secondary outcomes						
Death from cardiovascular causes	414 (16.4)	12.9	441 (17.5)	13.9	0.93 (0.81–1.06)	
Hospitalization for heart failure	691 (27.4)	25.9	747 (29.6)	29.1	0.90 (0.81–1.00)	
Total hospitalizations for heart failure¶	1223	38.3	1336	42.4	0.91 (0.84–0.99)	0.02
Secondary composite outcome and components						
Death from any cause or first hospi talization for heart failure	957 (37.9)	35.9	1032 (40.9)	40.1	0.90 (0.83–0.98)	0.02
Death from any cause§	266 (10.5)		285 (11.3)			
Hospitalization for heart failure	691 (27.4)		747 (29.6)			
Death from any cause	512 (20.3)	16.0	534 (21.2)	16.9	0.95 (0.84–1.07)	0.38

Study limitations :

- Short median follow-up (10.8 months), limiting long-term assessment.
- Benefit mainly from fewer hospitalizations; no significant mortality reduction.
- Results may not apply to more stable HFrEF patients.
- Reduced efficacy in patients with very high NT-proBNP levels

Link to the study:
//www.nejm.org/doi/full/10.1056/NEJMoa1915928

BETA-BLOCKERS AFTER MYOCARDIAL INFARCTION IN PATIENTS WITHOUT HEART FAILURE

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Number of patients included: 5574 patients were included: 2783 in the beta-blocker group and 2791 in the no-beta-blocker group.

Study design: Two Scandinavian superiority trials, BETAMI and DANBLOCK2, were conducted using a PROBE design (prospective, randomized, open-label, with blinded endpoint evaluation). Eligible patients had acute myocardial infarction with a left ventricular ejection fraction (LVEF) ≥40% and no clinical signs of heart failure. Randomization to beta-blocker therapy or no beta-blocker was performed within 7 days of the index event in BETAMI and within 14 days in DANBLOCK2.

Aim: To determine whether long-term beta-blocker therapy reduces the risk of death or major cardiovascular events after myocardial infarction in patients with preserved left ventricular ejection fraction (≥ 40%).

Principal results: Metoprolol was the most frequently prescribed beta-blocker, administered in 95% of patients at a median dose of 50 mg. The primary endpoint (a composite of death from any cause or major adverse cardiovascular events) occurred in 14.2% of patients in the beta-blocker group compared with 16.3% in the non–beta-blocker group (HR 0.85; 95% CI, 0.75–0.98; p=0.03). All-cause mortality was similar between groups (4.2% vs. 4.4%; HR 0.94; 95% CI, 0.73–1.21). Rehospitalization for myocardial infarction was less frequent with beta-blocker therapy (5.0% vs. 6.7%; HR 0.73; 95% CI, 0.59–0.92), whereas no significant differences were observed for other components of major adverse cardiovascular events (MACE).

The 30-day safety endpoint was comparable across groups. In the subgroup of patients with moderately reduced left ventricular ejection fraction (LVEF 40–49%, ≈16% of the cohort), a non-significant trend toward benefit with beta-blocker therapy was observed (HR 0.82; 95% CI, 0.65–1.02).

Study limitation: The DANBLOCK and BETAMI trials were combined during enrollment due to low recruitment and event rates, which would have left each trial underpowered. Nearly all patients received long-acting metoprolol at a median dose of 50 mg, limiting generalizability to other beta-blocker classes or higher doses. The subgroup with mildly reduced ejection fraction (40–49%) was small, resulting in less precise estimates. Finally, the trial was conducted mainly in Northern Europe, which may limit applicability to more diverse populations and healthcare systems.

Link to the study:
https://www.nejm.org/doi/full/10.1056/NEJMoa2505985

THE DIGIT-HF TRIAL:

DIGITOXIN IN HEART FAILURE WITH REDUCED EJECTION FRACTION

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Number of patients included / Number per group: The DIGIT-HF trial enrolled 1,212 patients across 65 centers in Austria, Germany, and Serbia between May 2015 and November 2024. Following 1:1 randomization, 613 patients were assigned to the digitoxin group and 599 to the placebo group, with a median follow-up duration of 36 months.

Study design: This phase 4, randomized, double-blind, placebo-controlled trial evaluated digitoxin efficacy in heart failure patients with reduced ejection fraction. Digitoxin was initiated at 0.07 mg once daily with dose adjustments based on serum concentrations. Eligible patients had symptomatic chronic heart failure with left ventricular ejection fraction ≤40% and NYHA class III-IV symptoms, or ejection fraction ≤30% with class II symptoms, receiving evidence-based therapy for at least six months.

Aim: The primary objective was to evaluate the efficacy and safety of digitoxin at low serum concentrations in patients receiving contemporary guideline-directed medical therapy. The primary endpoint was a composite outcome of death from any cause or hospitalization for worsening heart failure. Secondary endpoints included all-cause mortality analyzed for noninferiority and recurrent events of deaths and heart failure hospitalizations.

Principal results: The primary composite endpoint occurred in 242 digitoxin patients (39.5%) compared with 264 placebo patients (44.1%), yielding a hazard ratio of 0.82 (95% CI: 0.69-0.98, p=0.03), representing an 18% relative risk reduction and a number needed to treat of 22. Death from any cause occurred in 167 digitoxin patients (27.2%) versus 177 placebo patients (29.5%), with a hazard ratio of 0.86 satisfying the prespecified noninferiority threshold.

The study population had a mean age of 66 years with 20.4% female participation and received optimal therapy with 95.7% on beta-blockers and 94.3% on ACE inhibitors/ARBs/ARNIs. Serum digitoxin concentrations achieved target therapeutic ranges with mean levels of 17.0±5.9 ng/mL. The safety profile was acceptable with serious adverse events in 4.7% of digitoxin patients versus 2.8% of placebo patients.

Study limitations: The DIGIT-HF trial encountered several limitations. Enrollment challenges resulted in 1,212 participants instead of the originally planned 2,190 patients due to slower recruitment rates. Generalizability is constrained as results are specific to digitoxin and cannot be extrapolated to other cardiac glycosides, particularly digoxin. Additionally, digitoxin availability is restricted in numerous countries compared to digoxin. The high treatment discontinuation rate of 58.9% in the digitoxin group and 55.1% in the placebo group may have attenuated the observed treatment effect

Link to the study:
https://www.nejm.org/doi/full/10.1056/NEJMoa2415471

MAVACAMTEN IN SYMPTOMATIC NONOBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY (ODYSSEY-HCM TRIAL)

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Study population: 580 patients with symptomatic nonobstructive hypertrophic cardiomyopathy (HCM) :

- 289 received mavacamten
- 291 received placebo

Study design: Phase 3, randomized, double-blind, placebo-controlled, international trial
Two parallel groups:

- mavacamten (starting at 5 mg per day and adjusted up to a maximum of 15 mg per day on the basis of left ven tricular ejection fraction)
- placebo (with sham dose adjustment)

Conducted across 22 countries from December 2022 through March 2024.
Duration : 48 weeks

Aim: To evaluate whether mavacamten improves functional capacity and patient-reported health status in patients with symptomatic nonobstructive HCM.

Principal results: Mavacamten did not result in a significantly greater improvement in exercise capacity measured by peak oxygen uptake (95% CI : [-0.03 - 0.98]; p = 0.07) or a significantly greater de crease in symptoms as assessed by the KCCQ-CSS (95% CI : [-0.1 to 5.6]; p= 0.06) than placebo (Figure 1).

Safety: Adverse events were similar, though slightly more frequent with mavacamten.

Study limitations: Did not reach statistical significance for primary endpoints.
Limited follow-up (48 weeks only).
Excluded patients with advanced disease (results may not apply to all nonobstructive HCM populations).
Study powered for modest improvements, but effect size may have been too small to detect clinically relevant benefit.

Link to the study: [Mavacamten in Symptomatic Nonobstructive Hypertrophic Cardiomyopathy | New England Journal of Medicine]

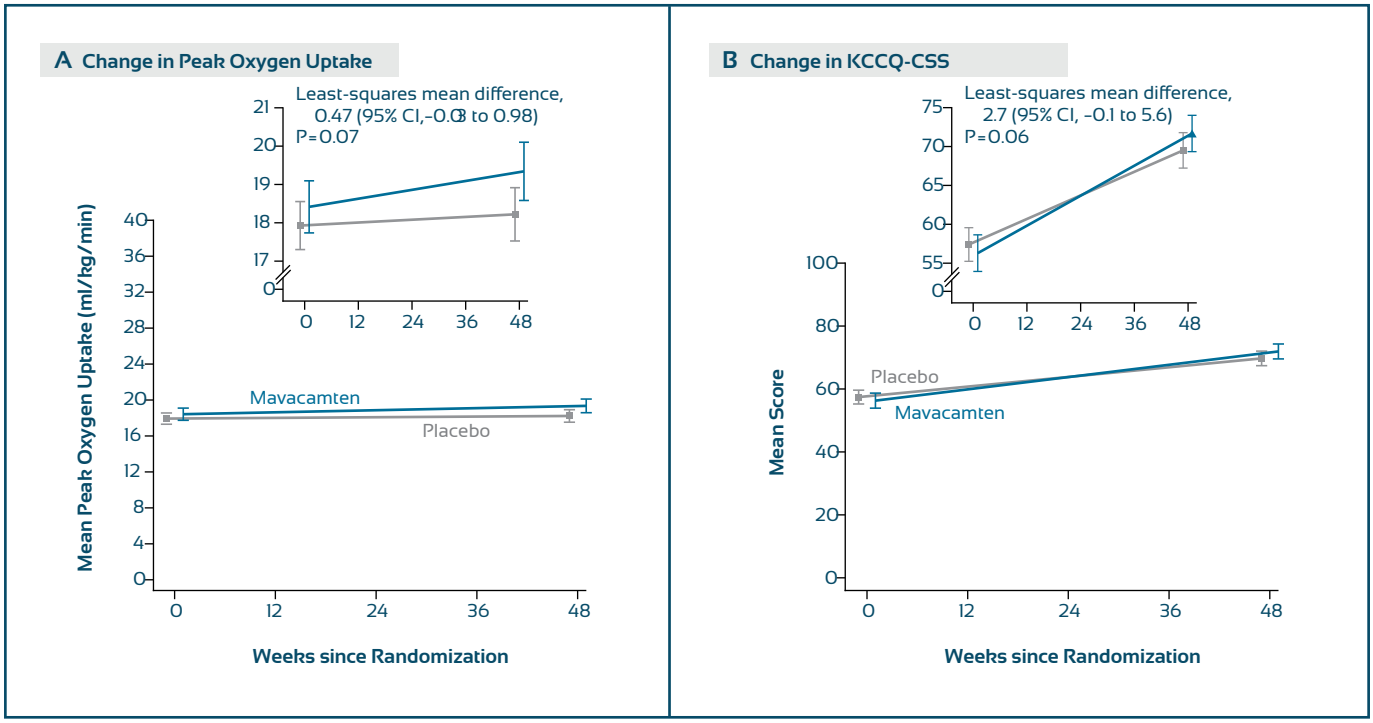

Figure 1. Primary End Points
Panels A and B show the change from baseline to week 48 in the mean peak oxygen uptake and the mean 23-item Kansas City Cardiomyopathy Questionnaire clinical summary score (KCCQ-CSS), respectively.

DAPAGLIFLOZIN IN PATIENTS HOSPITALIZED FOR HEART FAILURE: PRIMARY RESULTS OF THE DAPA ACT HF-TIMI 68 RANDOMIZED CLINICAL TRIAL

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Number of patients included: Of 2401 patients, 1218 were assigned to dapagliflozin and 1183 to placebo

Study design: This study was designed as a randomized, double-blind, placebo-controlled trial involving patients hospitalized for acute heart failure. Once clinical stabilization was achieved, participants were initiated on dapagliflozin at a daily dose of 10 mg and were afterwards monitored over a 60-day follow-up period.

Aim: To test whether initiating dapagliflozin while the patient is still hospitalized for acute heart failure reduces the early (first 60 days) composite risk of cardiovascular (CV) death or worsening heart failure (WHF), and to evaluate safety (symptomatic hypotension, renal events).

Principal results: The DAPA ACT HF trial evaluated dapagliflozin initiated during hospitalization for acute heart failure. At two months, the primary composite of cardiovascular death or worsening heart failure occurred in 10.9% of the dapagliflozin group versus 12.7% of placebo. This difference did not reach statistical significance (HR 0.86, 95% CI 0.68–1.08; p=0.20) (Figure 1). Cardiovascular death (2.5% vs 3.1%) and worsening heart failure (9.4% vs 10.3%) were also not significantly different. Symptomatic hypotension occurred in 3.6% of patients on dapagliflozin compared with 2.2% on placebo. Worsening kidney function was reported in 5.9% versus 4.7%, respectively. The overall safety profile was acceptable and consistent with prior SGLT2 inhibitor trials. A pooled meta-analysis of three trials (n=3,527) demonstrated significant reductions in cardiovascular death or worsening heart failure and in all-cause mortality, supporting the benefit of early in-hospital SGLT2i initiation.

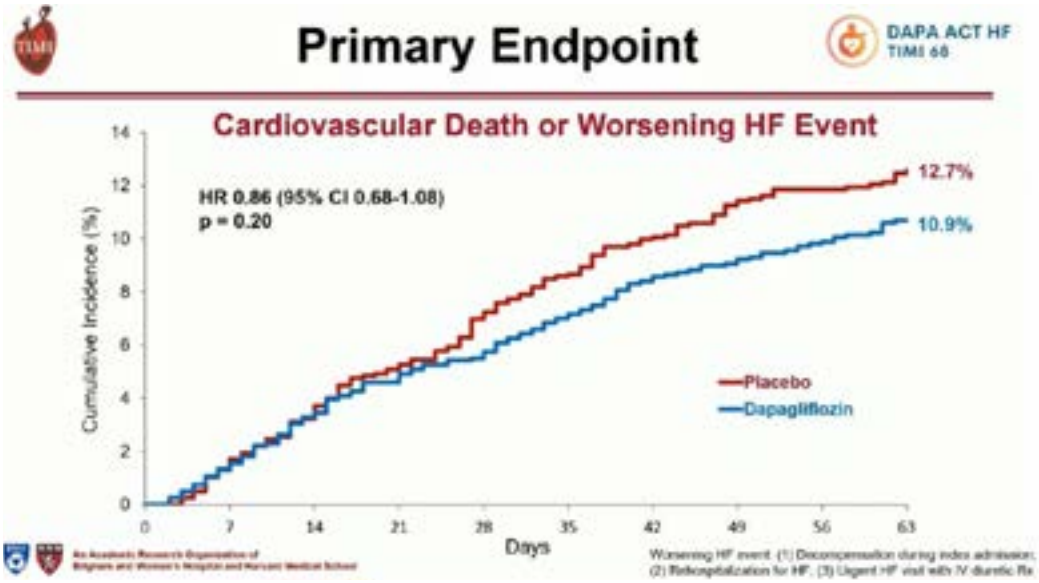

Figure: Primary Outcome (CV Death or Worsening HF at 2 months).

Study limitations:

- Short follow up duration: the follow up duration was limited to 60 days. This period may not be enough to capture the impact of Dapagliflozin on long-term outcomes.
- Underpowered study design: the primary endpoint (time to cardiovascular death or worsening HF through two months) occurring in 10.9% vs. 12.7% of dapagliflozin and placebo groups, yielding a hazard ratio of 0.86 (95% CI 0.68–1.08; p=0.20), limiting the ability to demonstrate a significant treatment effect.
- Limited geography : Although the study included several countries in North America and Europe, it does not reflect the situation in other countries with different health care systems.

Link to the study:
https://www.ahajournals.org/doi/abs/10.1161/CIRCULATIONAHA.125.076575

MAPLE HCM : AFICAMTEN VS METOPROLOL FOR OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY

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Number of patients included: A total of 175 adults with symptomatic obstructive HCM were included / Aficamten's group included 88 patients versus 87 patients on metoprolol

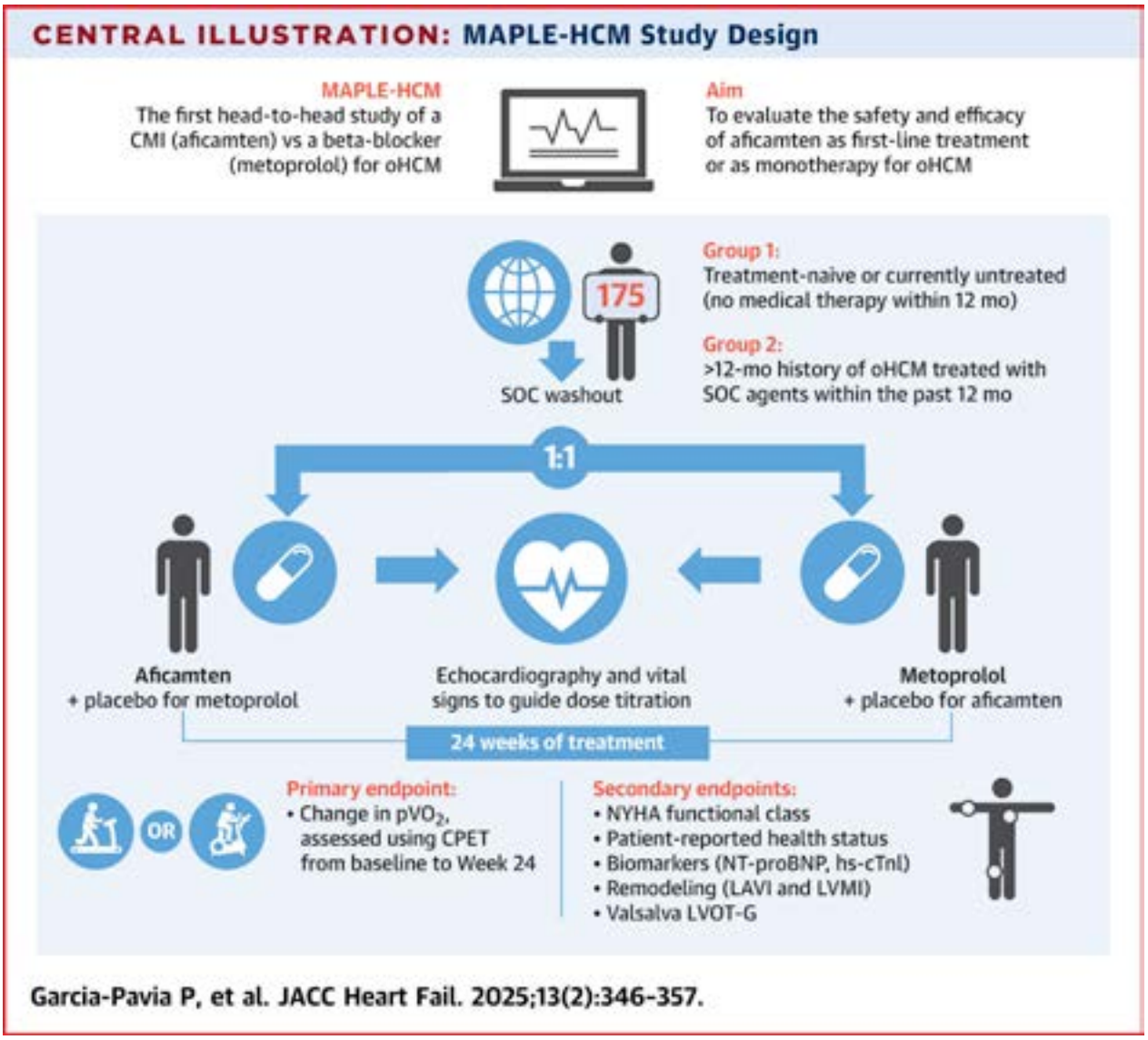
Study design: MAPLE-HCM is a multicentric , ongoing head-to-head, phase 3 clinical trial in patients with symptomatic oHCM . It is a double blind randomized(1:1) , controlled study . The first group included patients on metoprolol (50-200mg/day) as a monotherapy , the second group included patients on Aficamten as monotherapy with the dose of 5-20mg/day . Primary end was the change in peak oxygen consumption (VO_2 max) at 24 weeksSecondary Endpoints included : functional class of NYHA , clinical score KCCQ-CSS, left ventricular outflow tract (LVOT) gradient at rest and after Valsalva , level of NT-pro-BNP , left atrial volume and left ventricular mass.

Aim: was to evaluate effect of aficamten vs metoprolol on exercise capacity in participants with symptomatic oHCM and on LVOT gradient.

Principal results: At 24 weeks, the aficamten group (n=88) showed a significant increase in VO_2 max (+1.1 ml/kg/min) while VO2 max decreased in the metoprolol group (-1.2 ml/kg/min), the mean difference was +2.3 ml/kg/min ($p<0.001$). 51% of patients on aficamten improved by at least one NYHA functional class compared with 26% in the metoprolol group. The mean reduction in LVOT gradient was -40.7 mmHg with aficamten versus -3.8 mmHg with metoprolol. Other secondary endpoints had a statistically significant improvement with aficamten compared with metoprolol, except for left ventricular mass.After a 4-week; washout period for aficamten , effects of aficamten were no longer observed. The two treatments were both safe, they had the same rate of side effects (8% with aficamten versus 7% with metoprolol).

Study limitations: The 24-week treatment duration was sufficient to detect changes in exercise capacity and symptoms, but longer follow-up may be needed to assess the comparative effects of aficamten versus beta-blockade on clinical events, cardiac remodeling, and disease progression. This 24-week period may not adequately capture the long-term implications of avoiding side effects associated with beta-blocker therapy.

Link to the study:
Aficamten vs Metoprolol for Obstructive Hypertrophic Cardiomyopathy: MAPLE-HCM Rationale, Study Design, and Baseline Characteristics | JACC: Heart Failure



Garcia-Pavia P, et al. JACC Heart Fail. 2025;13(2):346-357.

SACUBITRIL-VALSARTAN AND PREVENTION OF CARDIAC DYSFUNCTION DURING ADJUVANT BREAST CANCER THERAPY: THE PRADA II RANDOMIZED CLINICAL TRIAL

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Number of patients included/ per group:

- Total: 138 women with early breast cancer.
- Groups: 69 randomized to Sacubitril/Valsartan and 69 to placebo

Study design:

- Type: Multicenter, randomized, placebo controlled, double-blind, parallel-group clinical trial.
- Duration: Treatment during anthracycline-based chemotherapy and follow-up for 18 months.

Aim: To test whether Sacubitril/Valsartan can prevent or attenuate cancer therapy-related cardiac dysfunction and myocardial injury in patients receiving anthracycline-based adjuvant breast cancer therapy

Principal results:

-Primary outcome (LVEF by CMR): Placebo: decreased to 2.2 percentage points while Sacubitril/Valsartan: decreased to 1.1 percentage points, the between-group difference was not statistically significant o (p=0.16).

Secondary outcomes:

- Global longitudinal strain declined under placebo but remained stable under Sacubitril/ Valsartan: the between-group difference was -0.85 (95% CI, -1.52
- to -0.18).
- Biomarkers: The mean increases in NT-proBNP and cardiac troponin I concentrations from
- baseline to 18 months were greater to 18 months were greater in the placebo than in

the sacubitril-valsartan group (log difference 0.303 (95% CI 0.0547 to 0.552) for NT-proBNP and 0.534 (95% CI 0.114 to 0.954) for cardiac troponin I).

Study limitations:

- Reduced sample size: original target was 300 patients; only 138 included due to recruitment and funding issues inducing reduced statical power.
- Primary endpoint (LVEF) may not be sensitive enough compared to GLS or biomarkers.
- Population: mostly low-moderated cardiovascular risk and ethnically homogenous, limiting generalizability.
- Placebo-controlled design does not separate the effect of Sacubitril from Valsartan

Link to the study:
https://www.ahajournals.org/doi/epdf/10.1161/CIRCULATIONAHA.125.076616

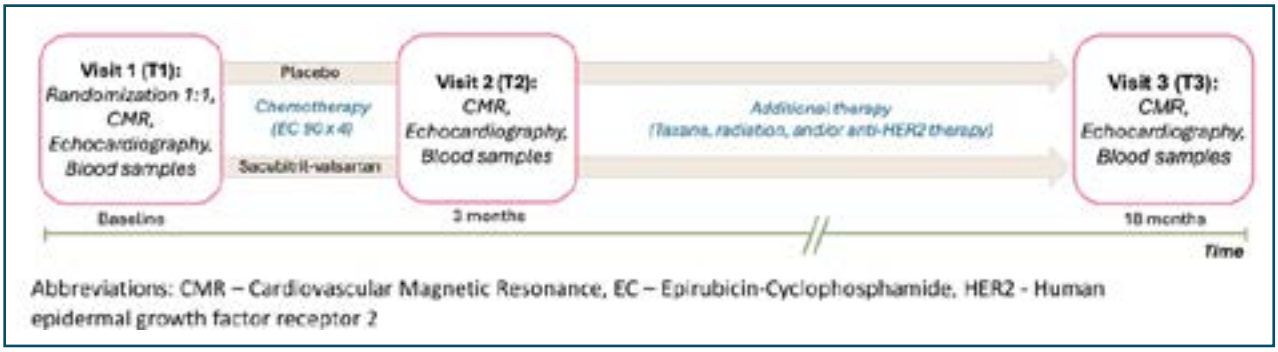

Figure 1: PRADA II study flow chart

VICTOR TRIAL: VERICIGUAT IN PATIENTS WITH CHRONIC HEART FAILURE AND REDUCED EJECTION FRACTION WITHOUT WORSENING HF

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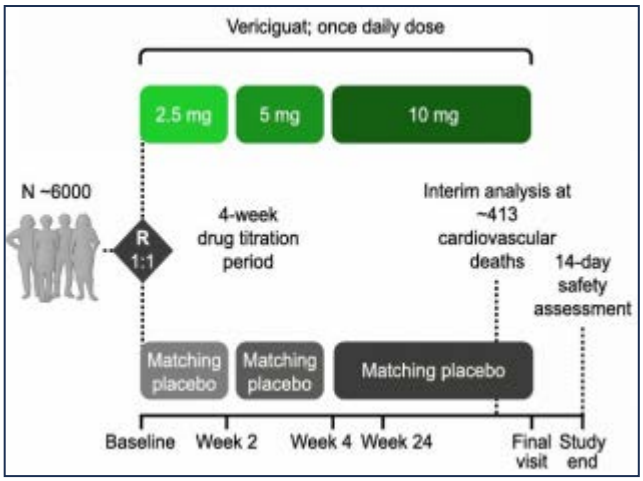
Population: 6105 participants were randomized (1:1) between November 2021 and December 2023 to receive vericiguat or placebo (3053 vs. 3052).

Aim: The VICTOR trial was designed to assess the efficacy and safety of vericiguat in patients with ejection fraction ≤40% without recent worsening HF on a background of current foundational HFrEF therapy

Study design:

double-blind, placebo-controlled, parallel group, 1:1 randomized, event-driven trial testing the effects of oral vericiguat at a target dose of 10 mg versus placebo in ambulatory patients with HFrEF and no recent worsening HF

Treatment began at 2.5 mg once daily, with planned titration to 5 mg at day 14 ± 4 and 10 mg at day 28 ± 4, according to systolic blood pressure and tolerance. Following this 4-week titration phase, patients were scheduled for follow-up visits every 24 weeks until study completion.



Primary endpoint: first event for the composite of HHF or cardiovascular death:
It occurred in 549 (18·0%) patients in the vericiguat group and 584 (19·1%) patients in the placebo group (hazard ratio [HR] 0·93 [95% CI 0·83–1·04]; p=0·22)

Secondary endpoint: all analyses of secondary endpoints are considered nominal

- Cardiovascular death occurred in 292 (9.6%) patients in the vericiguat group and 346 (11·3%) patients in the placebo group (HR 0·83 [95% CI 0·71–0·97], P=0.02).
- Hospitalization for heart failure occurred in 348 (11.4%) patients in the vericiguat group and in 362 (11·9%) patients in the placebo group (HR 0·95 [95% CI 0·82–1·10], p=)
- All cause death was lower with vericiguat vs placebo (377 [7.3 %] vs 440 [8.6 %]; HR 0.84, P = .015)
- Sudden cardiac death was lower with vericiguat vs placebo (1.6 % vs 2.2 %; HR 0.75, P = .042)
- HF-related death was lower with vericiguat vs placebo (1.7 vs 2.4 %; P = .016)

Conclusion: Among patients with HFrEF and no recent worsening, vericiguat did not reduce the risk of a composite endpoint of time to cardiovascular death or heart failure hospitalization. Fewer cardiovascular deaths were observed in the vericiguat group than in the placebo group.

Limitations: The study population was relatively stable, already receiving optimized contemporary therapy, limiting the ability to demonstrate an additional treatment effect.

Link to the study:
DOI: 10.1016/S0140-6736(25)01665-4

ARRHYTHMIC GENOTYPES IN DILATED CARDIOMYOPATHY AND RISK OF ADVANCED HEART FAILURE

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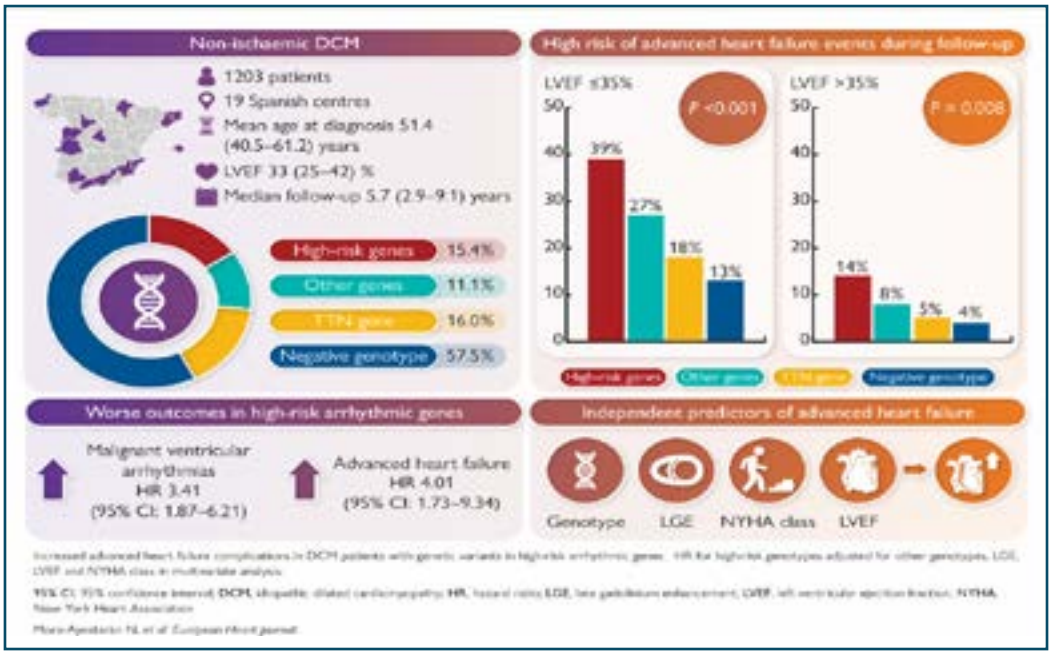
Study design: Multicentre, retrospective, observational cohort conducted in 19 Spanish referral hospitals from 2015 to 2022, enrolling 1,203 genotyped non-ischaemic dilated cardiomyopathy (DCM) patients. Data were collected with a uniform protocol, and CMR LGE was reviewed centrally. Patients were assigned to four genotype groups: high-risk arrhythmic genes, TTN, other DCM genes, and genotype-negative. The primary endpoint was advanced heart failure (AHF) defined as HF-related death, LVAD implantation, or heart transplantation. The secondary endpoint was malignant ventricular arrhythmias (MVA) comprising SCD, aborted SCD, sustained VT, and appropriate ICD therapy.

Aim: To determine whether DCM patients with high-risk arrhythmic genotypes not only exhibit increased MVA but also face higher rates of AHF complications.

Principal results:

Group	N (%)	AHF events (%)	MVA events (%)	Adjusted HR for AHF (95% CI)	Adjusted HR for MVA (95% CI)
High-risk genotypes	185 (15.4%)	24.3	29.7	4.01 (1.73–9.34)	3.41 (1.87–6.21)
TTN	193 (16.0%)	13.0	12.4	1.51 (0.58–3.92)	1.00 (0.47–2.11)
Other genotypes	134 (11.1%)	18.7	15.7	3.20 (1.29–7.90)	0.95 (0.37–2.45)
Genotype-negative	691 (57.4%)	10.1	11.9	Reference Group	Reference Group

Over a median follow-up of 5.7 years (IQR 2.9 to 9.1), patients with high-risk genotypes had the greatest burden of AHF and MVA compared with TTN, other genotypes, and Genotype-negative. In adjusted Cox models, genotype was the strongest predictor of AHF, and for MVA, genotype and LGE were independent predictors, whereas LVEF and NYHA class were not independently associated. The excess risk with high-risk genotypes persisted across LVEF strata.



Study limitations:

- Retrospective observational design, potential bias in treatment allocation and outcome adjudication
- Genetic panels varied between centres and across years
- Cohort recruited from specialized units, possibly limiting generalizability

Link to the study:
European Heart Journal, 2025 – doi:10.1093/eurheartj/ehaf605

ENVAD-HF: ANGIOTENSIN–NEPRILYSIN INHIBITION AND LEFT VENTRICULAR ASSIST DEVICE THERAPY.

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Number of patients included: Sixty adult HeartMate 3 (HM3) LVAD recipients, in 6 European sites across 4 countries, divided into equal groups of thirty.

Study design: This is a european prospective, multicenter, randomized, open-label, parallel group pilot trial. Eligible* patients were randomized 1:1 (with Block randomization and block permutation) to receive Sacubitril/Valsartan (Sac/Val) or standard of care (SOC) used for treating blood pressure (BP) (MAP Target [75-90 mmHg]). Follow-up assessments were performed at post-randomisation weeks 2, 5, 8 and months 3, 6, 9 and 12.
Primary outcome was defined as a composite of: death, worsening renal function, hyperkalemia and severe hypotension leading to drug withdrawal.

Aim: Evaluate the **safety and tolerability** of the Angiotensin–Neprilysin Inhibitor in HM3 LVAD recipients compared to standard of care used for optimal management of BP.

Principal results: 17% were women, the mean age was 57±12 years, with 25% receiving the HM3 as destination therapy. No significant difference in primary outcome between the two groups. It occurred in 7.6% in Sac/Val group versus 18.2% in SOC group (HR=0.42 p=0.30). Death was the most frequent component, occurring in 1 patient in sac/val group and 2 patients in SOC group. No cases of hyperkalemia were reported.

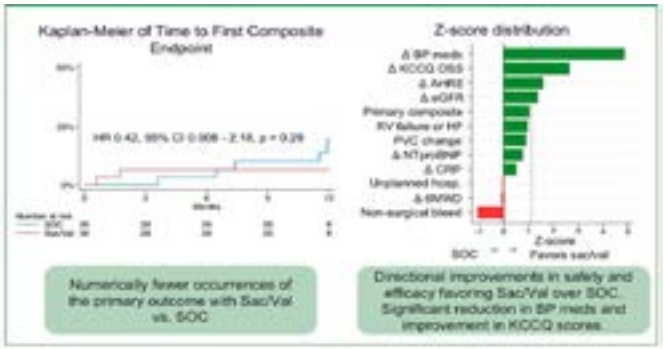


Figure 1: ENVAD-HF main results

- However, multiple parameters were in favor of Angiotensin-Neprilysin Inhibitor:
  - Significant change in the number of BP lowering medications was achieved, with a reduction by one BP lowering agent at 12 months (p<0.0001).
  - Improvements in the KCCQ scores from baseline to 12 months were noted (p=0.011).
  - Most other tested outcomes showed trends toward improvement in the Sac/Val group, although not statistically significant: lower NT-pro BNP levels, smaller decline in eGFR, and fewer episodes of acute heart failure.

Principal results:

1/ Related to the study population:

- Small sample size as the number of participants for this study to prove/disprove efficacy should be around 380 patients; And, under-representation of female patients (17%).
- Limited to hemodynamically stable LVAD patients (relatively at low-risk), well medicated before randomization receiving 2 to 3 neurohromonal blockers for 90% of the patients (unrepresentative of LVAD population where this percentage is less than 50%, in a large INTERMACS analysis of all continuous flow LVAD recipients).
- Uneven distribution between groups in aspects that may affect outcomes (time from LVAD implantation to randomization, heart failure etiology).

2/ Related to the study methodology:

- The open label design.
- Use of different laboratories (lack of standardized biomarker quantification).
- Interpretation of DOBP as systolic blood pressure, whereas it is more closely correlated with mean blood pressure.

3/ Unpublished data:

Hemodynamic and echocardiographic findings were not reported.

Link to the study:
DOI: 10.1016/j.jchf.2025.102657

BETA-BLOCKERS DID NOT REDUCE CARDIOVASCULAR EVENTS IN SELECTED HEART ATTACK PATIENTS IN THE REBOOT TRIAL

Dr. Houaida Mahfoudhi
Department of Cardiology, Military Hospital of Tunis

Fares Kerkani
Department of Cardiology, Military Hospital of Tunis

Number of patients included/ per group:

Total enrolled for analysis: **8,438 patients randomized**:

- **Beta-blocker group: 4,219** patients
- **No beta-blocker group: 4,219** patients

Study design:

- **Type:** Open-label, multicenter, randomized controlled trial
- **Population:** Patients with acute myocardial infarction and LVEF **> 40% in italy and spain**
- **Intervention:** Beta-blocker therapy versus no beta-blocker
- **Follow-up:** Median **3.7 years**
- **Primary outcome:** Composite of all-cause death, reinfarction, or hospitalization for heart failure

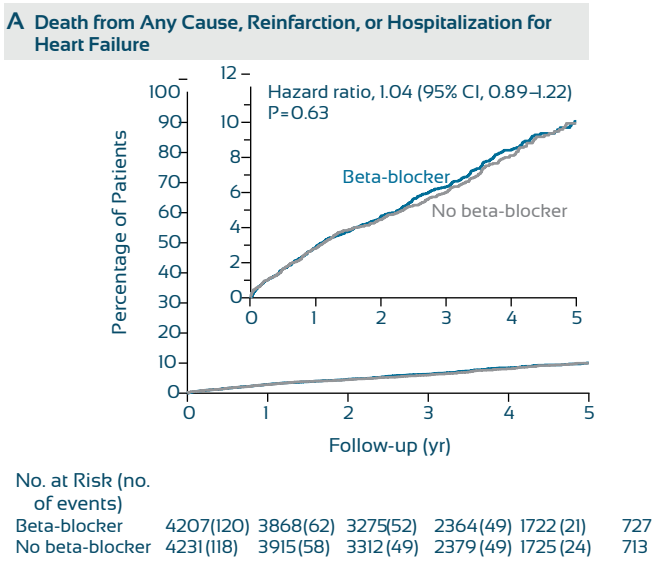
Aim: To re-examine the role of beta-blockers among patients with uncomplicated MI and LVEF>40%

Principal results:

- **No difference** in death, heart attack, or heart failure between groups :

316 (22.5/1000 py) vs 307 (21.7/1000 py)

-Death : HR : **1.06**; 95% CI, 0.85 to 1.33);
-Reinfarction : HR **1.01**; 95% CI, 0.80 to 1.27);
-**Hospitalization :** HR **0.89**; 95% CI, 0.58 to 1.38).



- Beta-blockers **did not improve** outcomes in patients with preserved heart function.

Study limitations:

- Open label design
- Variable beta blocker dosing
- Follow-up ~3.7 years → long-term effects unknown

Link to the study:
https://pubmed.ncbi.nlm.nih.gov/40888702/

Article 3

HOTLINES EN INSUFFISANCE CORONAIRE

Pr. Majed HASSINE
Coordinator

1-Early Withdrawal of Aspirin after PCI in Acute Coronary Syndromes *Dr Mohamed Amine SOULA Rsdte Raghda BELGAIED*

2- TARGET-FIRST Study Pr Ag Houaida Mahfoudhi *Rsdt Besseghaier Arbi*

3-Dual ASC trial: 12months vs. 3monthes DAPT following acute MI *Dr Hela Bouzidi Resident Aymen Boubzizi*

4-TAILORED-CHIP trial *Dr Elyes LAGHA / Rsdte Eya REZGUI*

5-OPTION–STEMI Trial *Dr Mohamed Ali Tekaya Resident: Haithem Touati*

6-PipLine Study *Dr Ameni Mardessi Rsdte Nourchene Amdouni Moussi*

7-Physiology-Guided Complete Revascularization in Older Patients With Myocardial Infarction *Dr Oumayma Zidi Rsdte Olfa Ferchichi*

8-AQUATIC study *Pr Majed Hassine Rsdt Omar Haddar*

9-Computed Tomography Angiography or Standard Care After Left Main PCI? *Dr Syrine Neji Rsdte Wissal Aloui*

10-ANDAMAN Trial *Dr Syrine Saidane Rsdt Younes El-Kharras*

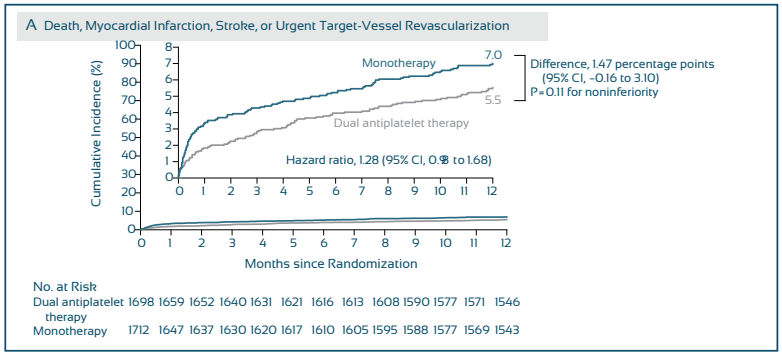
11-The TADCLOT Trial *Dr Chetoui Ahmed Rsdt Amine Hdiji*

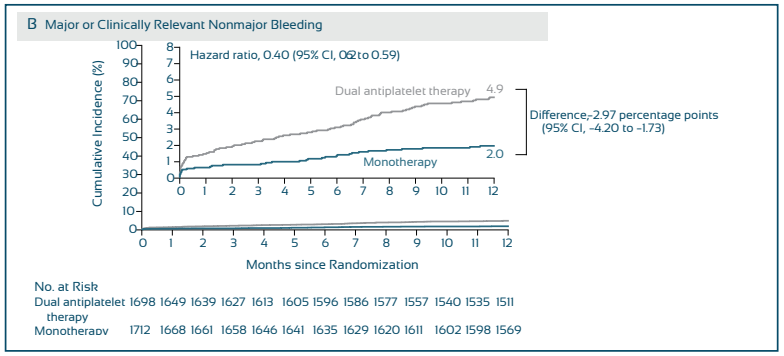
12-Ticagrelor and Aspirin or Aspirin Alone after Coronary Surgery for Acute Coronary Syndrome *Dr Mohamed Amine SOULA Rsdte Oumeyma HIDRI*

EARLY WITH DRAWAL OF ASPIRIN AFTER PCI IN ACUTE CORONARY SYNDROMES

Rsdte Raghda BELGAIED
Cardiology Department,
Mongi Slim University Hospital,
La Marsa.

Dr .Mohamed Amine SOULA
Cardiology Department,
Mongi Slim University Hospital,
La Marsa.





Population: 3410 patients: 1712 in the monotherapy group / 1698 in the DAPT group.

Study design: The NEO-MINDSET is an open-label trial with blinded outcome adjudication, conducted at 50 sites in Brazil. Patients with acute coronary syndromes (ACS) undergoing successful percutaneous coronary intervention (PCI) with drug-eluting stents (DES) were randomized 1:1 within the first 4 days of hospitalization to stop aspirin and receive potent P2Y12 inhibitor monotherapy (ticagrelor or prasugrel) or to DAPT (aspirin plus a potent P2Y12 inhibitor) for 12 months.

Aim: To compare the efficacy and safety of a potent P2Y12 inhibitor monotherapy strategy against DAPT in patients with ACS undergoing PCI with DES.

Principal results: For the primary ischemic endpoint, a composite of death from any cause, myocardial infarction, stroke, urgent target-vessel revascularization, potent P2Y12 inhibitor monotherapy was not non-inferior to DAPT (7.0% vs. 5.5%). However, major or clinically relevant non-major bleeding was lower in the early aspirin withdrawal group (2.0% vs. 4.9%). A higher rate of stent thrombosis was seen in the monotherapy group (0.7% vs. 0.2%).

Study limitations: Patients with high bleeding or ischemic risk were excluded, which means the results may not apply to more complex cases / The choice of the potent P2Y12 inhibitor was made at the discretion of the investigator.

Link to the study:
https://www.nejm.org/doi/full/10.1056/NEJMoa2507980

TARGET-FIRST STUDY

Dr. Houaida Mahfoudhi
Department of Cardiology, Military Hospital of Tunis

Rsdt Besseghaier Arbi
Department of Cardiology, Military Hospital of Tunis

Patients included:

- A total of **2246** patients were included in the study, of whom **1942** were randomized.
- **961** patients were in the P2Y12 inhibitor monotherapy group.
- **981** patients were in the dual antiplatelet therapy (DAPT) group.

Study Design:

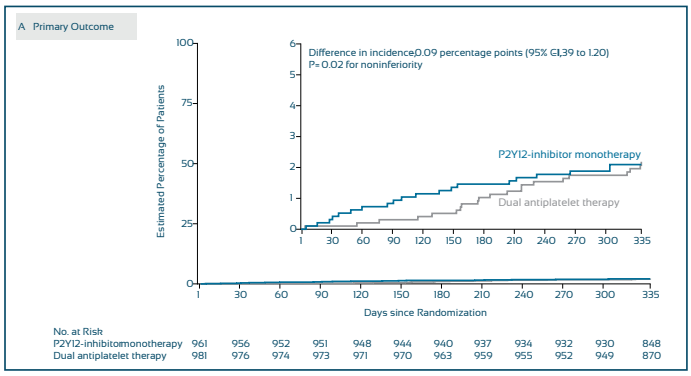
- **Study Type:** A prospective, multicenter, randomized controlled trial.
- **Patient Population:** The study included adults who had an acute myocardial infarction (STEMI or NSTEMI) and underwent complete revascularization via PCI within 7 days using a specific type of stent (Firehawk Liberty). Patients at high risk for bleeding or ischemic events were excluded.
- **Treatment Strategy:** After a month of uneventful DAPT (dual antiplatelet therapy, aspirin + P2Y12 inhibitor), patients were randomized into two groups:

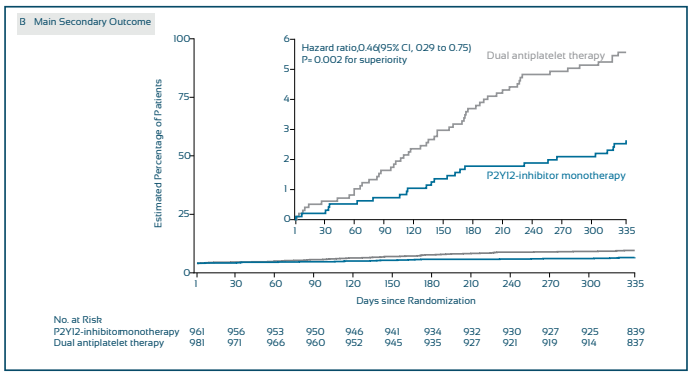
-Monotherapy: Aspirin was discontinued, and patients continued with a P2Y12 inhibitor alone.

-Prolonged DAPT: Patients continued on DAPT for 12 months.

Aims:

- Primary Aim: To show that monotherapy was non-inferior to prolonged DAPT for a composite endpoint of death, MI, stent thrombosis, stroke, or major bleeding.
- Secondary Aim: To see if monotherapy would reduce bleeding.
- Principle results:
- Monotherapy was indeed found to be non-inferior. The primary endpoint occurred in 2.1% of the monotherapy group versus 2.2% of the DAPT group.
- Monotherapy significantly reduced clinically relevant bleeding (2.6% vs. 5.6%).





Conclusion of Findings:

- P2Y12 inhibitor monotherapy after one month of DAPT is a safe and effective alternative for low-risk post-MI patients.
- This strategy provides similar protection against ischemic events while significantly lowering the risk of bleeding.

Study limitations:

- Highly selected low-risk population with complete revascularization.
- Lower-than-expected event rates, widening the noninferiority margin.
- No platelet function or genetic testing, relevant particularly for clopidogrel.

Link to the study:

1. Tarantini G, Honton B, Paradies V, Lemesle G, Range G, Godin M, et al. Early Discontinuation of Aspirin after PCI in Low-Risk Acute Myocardial Infarction. N Engl J Med. 2025 Aug 31;NEJMoa2508808.

DUAL ASC TRIAL: 12MONTHS VS. 3MONTHS DAPT FOLLOWING ACUTE MI

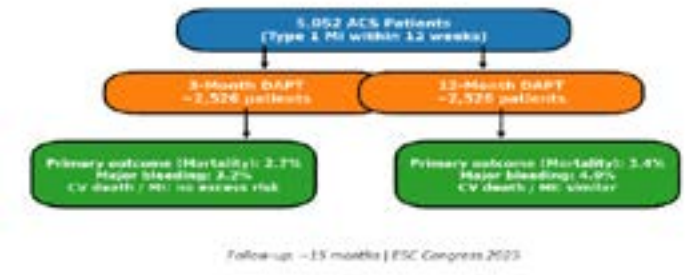
Dr.Hela Bouzidi
Habib Thameur hospital, cardiology department

Rsdt Aymen Boubzizi
Habib Thameur hospital, cardiology department

Number of patients included: A total of 5,052 patients were randomised 1:1 to 3 months vs 12 months of dual antiplatelet therapy (DAPT). The DAPT regimen was aspirin associated to a P2Y12 inhibitor as per local practice.

Study design: International, open-label, 1:1 randomized, active controlled, pragmatic trial. Aim: evaluate the optimal duration of DAPT, comparing 3-month versus 12-month regimens, following myocardial infarction (MI).

Principle results: After follow-up of 15 months, the primary endpoint of all-cause mortality occurred in 2.7% of patients in the 3-month DAPT group and 3.4% of patients in the 12-month DAPT group (hazard ratio [HR] 0.78, 95% confidence interval [CI] 0.57 to 1.07, p=0.12) with no difference in cardiovascular death or non-fatal MI (HR 1.04, 95% CI 0.87 to 1.26, p=0.61). Fatal and non-fatal major bleeding occurred in 3.2% of patients in the 3-month DAPT group and 4.0% of patients in the 12-month DAPT group (HR 0.78, 95% CI 0.58 to 1.06, p=0.09).



Study limitations: The trial stopped short of its recruitment goal; only about 30% of planned patients were enrolled. This reduced power means the ability to detect modest differences is compromised. Furthermore, endpoints like mortality are hard outcomes and open label design can introduce bias in assessments. Moreover, the duration of follow-up of 15 months is reasonable but longer-term outcomes aren't yet known.

Link to the study:
https://www.pcronline.com/News/Whats-new-on-PCRonline/2025/ESC/Duration-of-DAPT-in-ACS-The-DUAL-ACS-Trial

TAILORED-CHIP TRIAL

Rsdte Eya REZGUI
Department of Cardiology, CHU Mongi Slim, La Marsa

Dr Elyes LAGHA
Department of Cardiology, CHU Mongi Slim, La Marsa

Number of patients included/ number per group:

Among 2018 patients included, 1005 were assigned to tailored antiplatelet therapy and 1013 to standard DAPT.

Study design:

This open-label, multicenter randomized trial enrolled patients at 24 sites in South Korea with high-risk clinical or anatomical characteristics undergoing complex PCI. Participants were randomized 1:1 to either a tailored antiplatelet strategy consisting of early escalation with low-dose ticagrelor (60 mg twice daily plus aspirin for 6 months), followed by de-escalation to clopidogrel monotherapy for 6 months or standard antiplatelet therapy with aspirin and clopidogrel for 12 months. Clinical follow-up was performed at 1, 3, 6, and 12 months.

Aim:

Investigate the efficacy and safety of tailored antiplatelet therapy compared with standard dual antiplatelet therapy in patients undergoing complex high-risk PCI.

Principle results : Principle results

Most patients were male (83%) with a mean age of 64 years. Almost all patients had at least one high-risk anatomical or procedural criteria, and almost half had a high-risk clinical condition. Intravascular-guided PCI was used in 71% of cases. At 12 months, net adverse clinical events, defined by the composite of all-cause death, myocardial infarction, stroke, stent thrombosis, unplanned urgent revascularization, or clinically relevant bleeding, were similar between tailored antiplatelet therapy and standard DAPT (10.5% vs. 8.8%; HR 1.19; 95% CI 0.90–1.58; p=0.21), as were major ischemic events (3.9% vs. 5.0%; HR 0.78; 95% CI 0.52–1.19; p=0.25). Clinically relevant bleeding was higher with tailored therapy (7.2% vs. 4.8%; p=0.002), while major bleeding rates were comparable (1.7% vs. 1.5%; p=0.70).

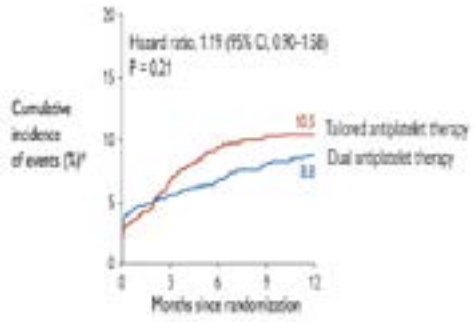


Figure 1:Cumulative Incidence of Net Adverse Clinical Events at 12 Months: Tailored vs. Standard Antiplatelet Therapy

Study limitations:

The trial's limitations include the combined bleeding/ischemic endpoint with a lower-than-expected event rates which may have biased results favoring less potent therapy, the conduct in an East Asian population using low-dose ticagrelor limiting its generalizability, the exclusion of high bleeding risk patients, and the underrepresentation of women (17%).

Link to the study:
Temporal modulation of antiplatelet therapy in high-risk patients undergoing complex percutaneous coronary intervention: the TAILORED-CHIP randomized clinical trial | European Heart Journal | Oxford Academic

OPTION–STEMI TRIAL

Dr. Mohamed Ali Tekaya
Cardiology Department,
Abderrahmen Mami Hospital, Ariana

Haithem Touati
Cardiology Department,
Abderrahmen Mami Hospital, Ariana

Number of patients included / number per group:

A total of 994 patients with acute ST-segment elevation myocardial infarction (STEMI) and multivessel coronary artery disease were enrolled between December 2020 and December 2023 across 14 hospitals in South Korea. Patients were randomized after successful culprit-lesion PCI into two groups:

- Immediate complete revascularization (n= 498).
- Staged complete revascularization during index admission (n= 496). The follow-up rate at 12 months was 99%.

Study design:

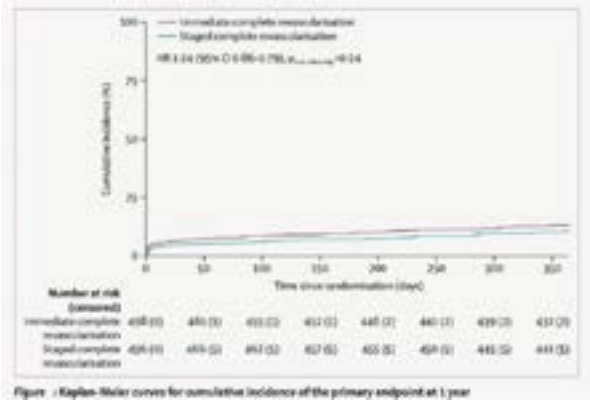
The OPTION–STEMI trial was a prospective, multicenter, open-label, randomized controlled trial designed with a non-inferiority margin. All participants were ≥19 years old, presenting with acute STEMI and angiographically proven multivessel coronary disease. Fractional Flow Reserve (FFR) was used to guide revascularization in lesions of 50–69% stenosis, while those ≥70 % were treated directly.

- In the Immediate PCI arm, all non-culprit lesions were treated during the index procedure.
- In the Staged PCI arm, non-culprit PCI was performed during the same hospitalization, with a median delay of ~3 days.

The primary endpoint was a composite of all-cause death, non-fatal myocardial infarction, or unplanned revascularization at 12 months. Secondary endpoints included stent thrombosis, stroke, major bleeding (BARC 3–5), and contrast-induced nephropathy.

Aim:

To evaluate whether Immediate complete revascularization is non-inferior to Staged complete revascularization during the index admission in STEMI patients with multivessel disease, and to explore the clinical impact of hemodynamic instability (Killip class II–III).



Principal results:

The primary composite endpoint of all-cause death, non-fatal myocardial infarction, or unplanned revascularization at 12 months occurred in 13% of patients in the Immediate PCI group compared with 11% in the Staged PCI group (HR 1.24; 95% CI 0.86–1.79) (Fig), and thus the criterion for non-inferiority was not met. Regarding the individual components, all- cause mortality was higher with Immediate PCI (7% vs. 5%; HR 1.44), while non-fatal MI was slightly lower (4% vs. 5%; HR 0.77) and unplanned revascularization rates were similar (6% vs. 5%; HR 1.19). Importantly, the incidence of early stent thrombosis was numerically greater in the Immediate arm (8 cases vs. 1). Safety outcomes—including stroke, major bleeding, and contrast-induced nephropathy—were comparable between strategies. Subgroup analysis revealed a significant interaction with Killip class (p = 0.04), showing that patients with acute heart failure (Killip II–III) had worse outcomes under Immediate PCI (23% vs. 13%).

Study limitations:

This study has several important limitations. First, it was conducted exclusively in South Korea, which may limit the generalizability of the findings to other healthcare systems and populations. Second, the open-label design raises the potential for bias in clinical decision-making and event adjudication. Third, the median interval for staged PCI was relatively short (approximately 3 days), making direct comparisons with international trials such as MULTISTARS AMI (45 days) and BIOVASC (42 days) more challenging. Finally, the trial was underpowered to detect differences in rare but clinically relevant safety endpoints, such as stroke, major bleeding, or stent thrombosis.

Link to the study : https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)01529-6/abstract?rss=yes

Clinical message:

In patients with STEMI and multivessel disease, Immediate complete PCI failed to demonstrate non-inferiority compared with Staged PCI during the same admission. Importantly, outcomes were significantly worse in those presenting with acute heart failure (Killip II–III). Staged PCI should be favored in unstable patients, whereas Immediate PCI may remain a reasonable option in hemodynamically stable STEMI (Killip I). These findings add nuance to current revascularization strategies and highlight the importance of individualizing PCI timing based on clinical status.

PIPLINE STUDY

Dr. Ameni MARDESSI : AHU
Habib Thameur Hospital,
cardiology department

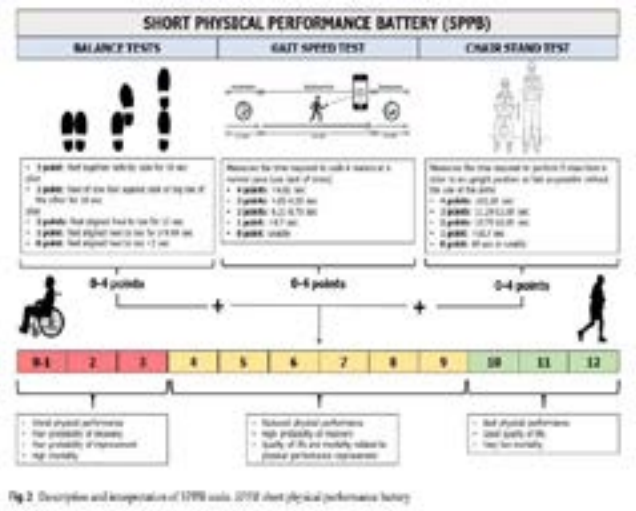
Rsdte Nourchene AMDOUNI MOUSSI
Habib Thameur Hospital,
cardiology department

Planned enrollment:
456 patients (304 intervention group vs. 152 control group).

Study design:
Prospective, randomized, multicenter, investigator-driven trial with blinded adjudication of outcomes (PROBE design).

Aim:
To evaluate whether a multi-domain lifestyle intervention (exercise training, dietary counseling, intensive risk factor management) reduces cardiovascular death or rehospitalization in older adults (≥65 years) with reduced physical performance after myocardial infarction compared to standard care.

Principle results:
Recruitment for the PIpELINe trial began in March 2020. Progress was initially slowed by the COVID-19 pandemic, which reduced hospital admissions for myocardial infarction and limited patient enrollment.
The trial aims to recruit 456 older patients (≥65 years) with low physical performance (SPPB score 4–9) one month after MI discharge. Patients will be randomized in a 2:1 ratio to receive either a multi-domain lifestyle intervention (n ≈ 304) or standard health education (n ≈ 152).



The primary endpoint is the one-year occurrence of cardiovascular death or hospital readmission for cardiovascular causes.

Secondary endpoints include:

- All-cause death
- Myocardial infarction
- Cerebrovascular accident
- Hospital readmission for any cause
- Quality of life (assessed with EQ-5D)
- Long-term outcomes up to three years of follow-up.

The trial is powered to detect a 40% reduction in primary endpoint events, based on an estimated baseline risk of 25% at one year.
The intervention combines exercise training, dietary counselling, and strict cardiovascular/metabolic risk factor management, making it broader than the earlier HULK study, which focused mainly on exercise. Completion of enrollment is expected by September 2023, with primary endpoint data available in 2024.

Study limitations:

- Recruitment delayed due to the COVID-19 pandemic.
- Results are pending (design paper, not outcome data yet).
- Adherence to a multi-domain program in older adults may be challenging.

Link to the study:
https://doi.org/10.1007/s40520-023-02389-9

PHYSIOLOGY-GUIDED COMPLETE REVASCULARIZATION IN OLDER PATIENTS WITH MYOCARDIAL INFARCTION

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Abderrahman Mami's Hospital, Cardiology Department

Rsdte Olfa FERCHICHI
Abderrahman Mami's Hospital, Cardiology Department

Number of patients included/ number per group: A total of 1445 patients with acute myocardial infarction (MI) and multivessel coronary artery disease were randomized to physiology-guided multivessel revascularization (n=720) or culprit-only revascularization (n=725).

Study design: This randomized, investigator-initiated, multicenter, prospective superiority trial was conducted at 34 centers across 3 countries between July 18, 2019, and October 25, 2021. Data were analyzed from March to May 2025. Eligible participants were patients ≥75 years with MI (ST-segment elevation or non–ST-segment elevation) and multivessel disease who were hospitalized after successful culprit-lesion treatment. Major exclusion criteria were nonculprit left main disease and uncertain culprit-lesion identification.

Aim: To assess whether the benefit of physiology-guided complete revascularization over culprit-only treatment persists at 3 years in patients ≥75 years with MI and multivessel disease. The primary endpoint was a composite of death, MI, stroke, or ischemia-driven revascularization; secondary endpoints included a composite of cardiovascular death or MI and rate of heart failure hospitalizations.

Principle results:

- At 3 years, the primary outcome occurred in 165 patients (22.9%) in the physiology-guided complete revascularization group and 216 patients (29.8%) in the culprit-only group (hazard ratio [HR], 0.72; 95% CI, 0.58-0.88; P=0.002).
- The key secondary outcome of cardiovascular death or MI occurred in a significantly lower number of patients in the physiology-guided complete revascularization group (92 patients [12.8%]) compared with the culprit-only group (132 patients [18.2%]; HR, 0.66; 95% CI, 0.50-0.88; P=0.004).
- Hospitalizations for heart failure were more frequent in the culprit-only group compared with the physiology-guided complete group (143 [19.7%] vs 103 [14.3%]; HR, 0.73; 95% CI, 0.54-0.97; P=0.03).

Link to the study:
https://jamanetwork.com/journals/jamacardiology/article-abstract/2838323#

AQUATIC STUDY :
ASPIRIN IN PATIENTS WITH CHRONIC CORONARY SYNDROME RECEIVING ORAL ANTICOAGULATION

Pr. Majed Hassine
Cardiology Department, Monastir

Rsdt Omar Haddar
Cardiology Department, Monastir

Background

Long-term antithrombotic management in patients with chronic coronary syndrome (CCS), a history of stenting >6 months, and an indication for oral anticoagulation (OAC) (mainly atrial fibrillation) remains challenging. Prolonged addition of aspirin is still common, despite an increased bleeding risk and limited evidence in the chronic phase. The AQUATIC trial was designed to address this uncertainty.

Objective

To compare the efficacy and safety of a dual therapy strategy (OAC + aspirin 100 mg/day) versus monotherapy (OAC + placebo), more than 6 months after stenting, in a population at high atherothrombotic risk.

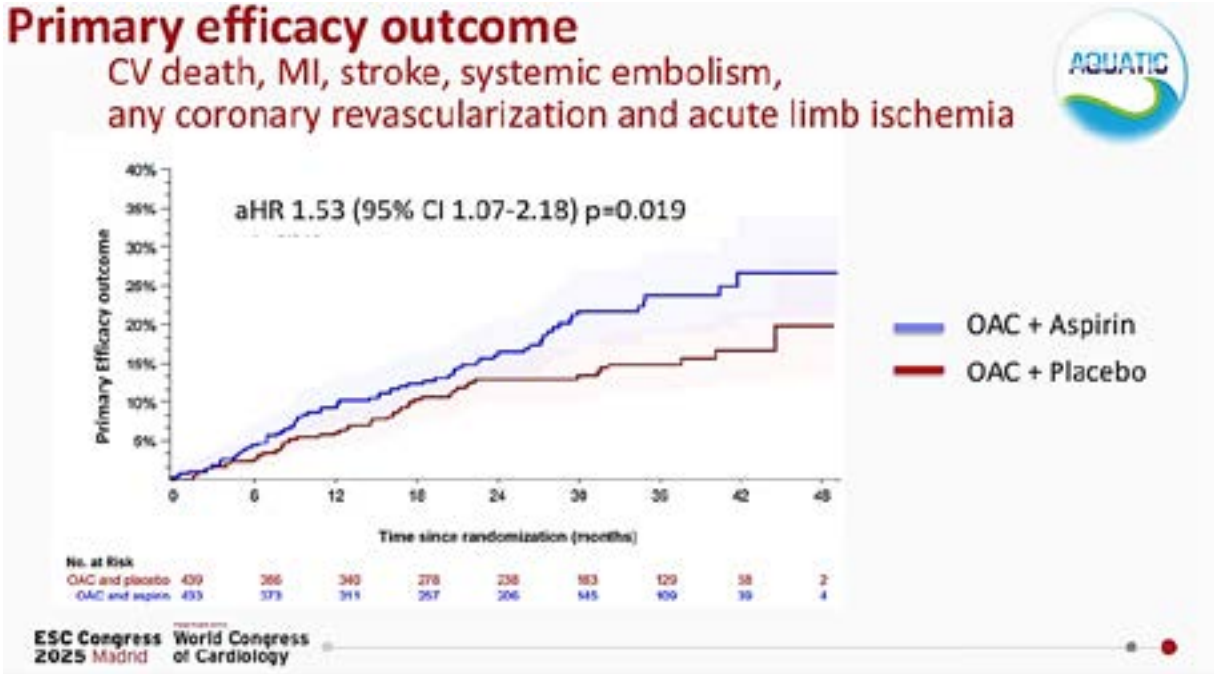
Design

Randomized, double-blind, placebo-controlled, multicenter trial (51 centers in France). A total of 872 patients were enrolled before the trial was prematurely stopped due to an excess mortality in the aspirin group.

Results

1.Primary efficacy endpoint: Composite of cardiovascular death, myocardial infarction, stroke, systemic embolism, any coronary revascularization, or acute limb ischemia: **16.9%** in the aspirin group versus **12.1%** in the placebo group. Adjusted hazard ratio (HR) = **1.53** [95% CI: 1.07–2.18], p = 0.01.

This excess was mainly driven by **higher cardiovascular mortality** (7.6% vs. 4.3%), while other components were not significantly different.



2.All-cause mortality:
13.4% in the OAC + aspirin group versus **8.4%** in the OAC alone group. Adjusted HR = **1.72** [95% CI: 1.14–2.58], p = 0.01.

3.Safety (bleeding):
Major ISTH bleeding: 10.2% with aspirin versus **3.4%** without, representing a tripling of risk (HR = **3.35** [95% CI: 1.87–6.00], p < 0.001).

4.Trial safety and early termination:
The study was prematurely halted following recommendation by the Data Safety Monitoring Board due to **excess mortality** in the aspirin arm.

5.Clinical relevance and impact:
This is the first trial to include a high-risk Western cohort. It provides strong randomized, double-blind evidence against prolonged aspirin use.
The estimated number needed to harm (NNH) was **46**, corresponding to a projected **30,000–50,000** potentially preventable deaths annually in this population.

Conclusion

In patients with CCS, prior drug-eluting stents, and chronic OAC therapy, the addition of aspirin carries a **clearly demonstrated risk**, with higher rates of ischemic events, mortality, and bleeding. The study strongly discourages this strategy.

Take-home message

In the **chronic phase** (≥6 months post-stenting) and in high-risk patients, **anticoagulant monotherapy (OAC alone) should be preferred**. Long-term aspirin use should be avoided, even in patients considered at high thrombotic risk.

Link to the study:
DOI : 10.1056/NEJMoa2507532 PubMed

COMPUTED TOMOGRAPHY ANGIOGRAPHY OR STANDARD CARE AFTER LEFT MAIN PCI?

Dr. Syrine Neji
Cardiology department of Charles Nicolle Hospital,Tunis

Rsdt Wissal ALOUI
Cardiology department of Charles Nicolle Hospital,Tunis

606 patients were included and divided into 2 groups, each one contained 303 patients

Study design:

PULSE study was an open-label, blinded-endpoint, investigator-initiated, prospective, multicenter, randomized trial conducted at 15 sites in Europe and South America. Participants were patients undergoing percutaneous coronary intervention (PCI) of the unprotected left main coronary artery. This population was randomized into two groups ; first one had a routine coronary CT angiography (CCTA) at 6 months after PCI, the second group got a standard follow-up guided by clinical symptoms and ischemia testing.

The primary endpoint was a composite of all-cause death, spontaneous MI, unstable angina or definite/probable stent thrombosis (MACE) at 18 months.

Aim:

The PULSE trial investigated the value of routine coronary computed tomography (CCT) for monitoring patients with critical stenosis undergoing PCI for left main coronary artery disease.

Principle results:

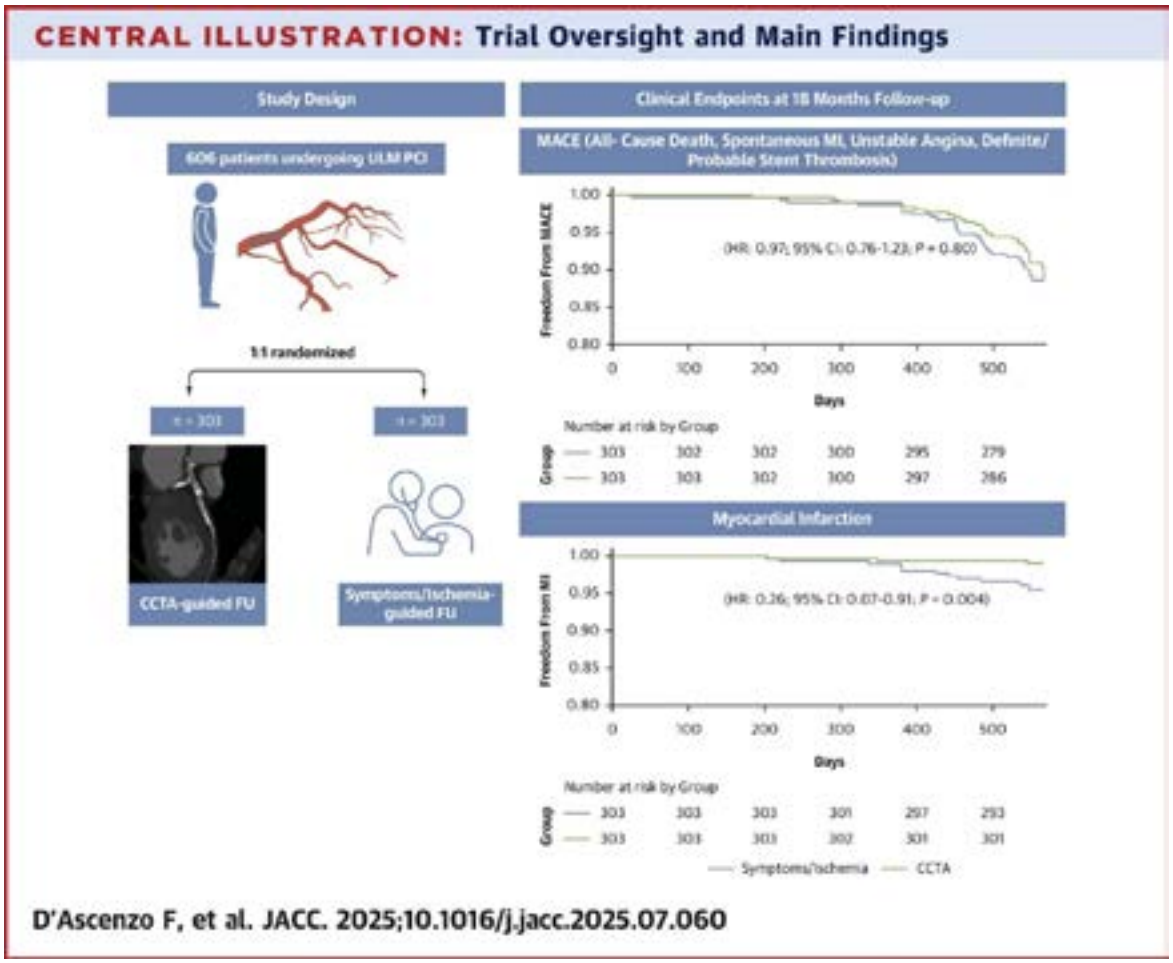
There was a reduced risk of spontaneous MI in the CCT arm vs. the control arm (0.9% vs. 4.9%; HR 0.26; 95% CI 0.07 to 0.91; p=0.004). An increase in imaging-triggered target-lesion revascularization was observed in the CCT arm compared with the control arm (4.9% vs. 0.3%; HR 7.7; 95% CI 1.70 to 33.7; p=0.001); however, the incidence of clinically driven target-lesion revascularization was similar between the arms (5.3% vs. 7.2%; HR 0.74; 95% CI 0.38 to 1.41; p=0.32). The study did not show a reduction in MACE occurred in patients in the CCT arm at 18 months (11.9% vs 12.5%. hazard ratio [HR] 0.97; 95% confidence interval [CI] 0.76 to 1.23; p=0.80).

Study limitations:

Performing CCT in patients with left main coronary artery lesions may increase the cost and the risk of radiation exposure. CCT imaging is not available in all centers and requires expert interpretation for accurate assessment of the lesions.

Link to the study:

https://www.sciencedirect.com/science/article/abs/pii/S0735109725074017



D'Ascenzo F, et al. JACC. 2025;10.1016/j.jacc.2025.07.060

ANDAMAN TRIAL

Dr Syrine SAIDANE
Cardiology Department, Habib Bougatfa University Hospital, Bizerte

Rsdt Younes EL-KHARRAS
Cardiology Department, Habib Bougatfa University Hospital, Bizerte

Study Population:

2,574 patients with diabetes mellitus (DM) or clinical aspirin resistance following acute coronary syndrome (ACS), randomized 1:1 before hospital discharge.

Study Design:

Prospective, randomized, open-label, blinded-endpoint (PROBE) trial.
Two parallel groups:

- Aspirin once daily (100 mg OD)
- Aspirin twice daily (100 mg BID)

Follow-up: 18 months.

Aim:

To determine whether twice-daily low-dose aspirin provides superior protection against ischemic events compared to standard once-daily dosing in high-risk post-ACS patients with diabetes or clinical aspirin resistance.
Principal Endpoints

- Primary endpoint: Major adverse cardiovascular events (MACE), a composite of all-cause death, myocardial infarction, stroke, urgent coronary revascularization, or arterial thrombotic events.
- Key secondary endpoint: Major bleeding (BARC 3–5).

Key Rationale:

Prior pharmacodynamic data indicate that a twice-daily aspirin regimen achieves more stable and prolonged COX-1 inhibition over 24 hours, particularly in patients with high platelet turnover (Figure 1).

ESC 2024 Guidelines Context:

- 2024 ESC Guidelines for chronic coronary syndromes recommend aspirin 75–100 mg once daily as Class I in secondary prevention.
- No specific guidance exists for adjusting aspirin dosing in aspirin resistance.
- The ANDAMAN trial may inform future recommendations for individualized antithrombotic strategies in diabetic or aspirin-resistant patients post-ACS. If validated, the ANDAMAN trial may support a shift toward personalized aspirin regimens in ESC guidelines, especially for diabetic or aspirin-resistant patients.

Study Limitations:

- Open-label design.
- Event-driven trial; results pending final endpoint accrual.
- Bleeding risk of BID dosing yet to be determined.

Link to the study:
DOI: https://doi.org/10.1016/j.ahj.2025.04.016
ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02520921

Principal Figure:

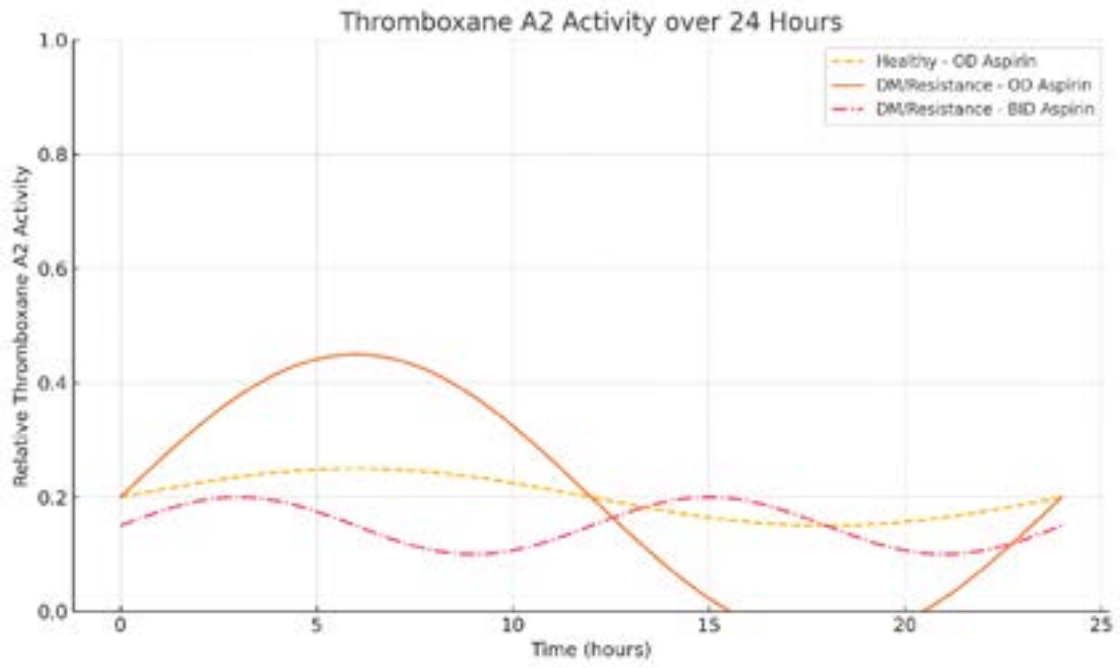


Figure 1: Thromboxane A2 activity over 24 hours. Comparison between OD aspirin in healthy controls, OD aspirin in diabetic/aspirin-resistant patients, and BID aspirin in diabetic/aspirin-resistant patients.

THE TADCLOT TRIAL

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Cardiology Department

Rsdt Amine HDIJI
Charles Nicolle Hospital
Cardiology Department

Number of patients included/ number per group:

2,201 participants in 2 patient groups :
Treatment Group: Patients will be provided ticagrelor twice daily for first 30 days after primary PCI.
Control Group: Patients will be provided clopidogrel twice daily for first 30 days after primary PCI.

Study design:

A double-blind, randomized superiority trial at the National Institute of Cardiovascular Diseases, Karachi, Pakistan (February 19, 2024–January 30, 2025), randomized 2,201 patients with STEMI within 24 hours of primary PCI 1:1 to ticagrelor (180 mg loading dose, 90 mg BID) or BID clopidogrel (600 mg loading dose, 75 mg BID) for 1 month.

Aim:

Evaluate the efficacy of ticagrelor over twice daily clopidogrel in reducing MACE events within the first one month post primary PCI. The primary endpoint was MACE (death, myocardial infarction, stent thrombosis, stroke, or target lesion revascularization) at 1 month, analyzed by intention-to-treat. Secondary endpoints included individual MACE components and clinically significant bleeding .

Principle results:

Among 2,201 randomized patients, MACE occurred in 24 (2.2%) ticagrelor patients vs. 32 (2.9%) in BID clopidogrel patients (HR 0.75; 95% CI, 0.44-1.27; P=0.28). Cardiovascular death or definite stent thrombosis occurred in 21 (1.9%) vs. 27 (2.5%) patients (HR 0.77; 95% CI, 0.44-1.37). Clinically significant bleeding (BARC type 2, 3, or 5) occurred in 6 patients (0.5%) with ticagrelor versus 4 (0.4%) with clopidogrel (HR 1.50, 95% CI 0.42–5.31). Major bleeding (BARC 3 or 5) was infrequent and similar between the groups: 3 patients (0.3%) in the ticagrelor arm and 2 (0.2%) in the clopidogrel arm (HR 1.50, 95% CI 0.25–8.97). At both

7 (HR 0.15, 95% CI 0.04-0.5; p=0.002) and 14 days (HR 0.46, 95% CI 0.23-0.91; p=0.02), MACE was significantly lower with ticagrelor compared with BID clopidogrel, although these differences were no longer statistically significant at 30 days.

Study limitations:

Short Duration: The study's primary endpoint was measured at 30 days post-procedure, **Lower-Than-Anticipated Event Rates**: The study observed a much lower rate of major adverse cardiac events (MACE) than initially expected. This makes it difficult to definitively prove a difference between the two treatments, **Genetic and Geographic Specificity:** The Pakistani population has a higher prevalence of a specific genetic mutation (CYP2C19).

Link to the study:
https://www.jacc.org/doi/10.1016/j.jacc.2025.08.041

TICAGRELOR AND ASPIRIN OR ASPIRIN ALONE AFTER CORONARY SURGERY FOR ACUTE CORONARY SYNDROME

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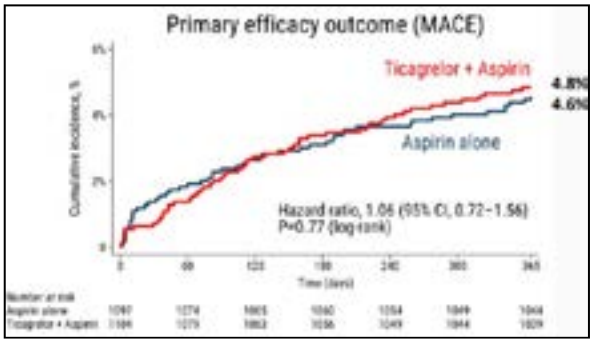
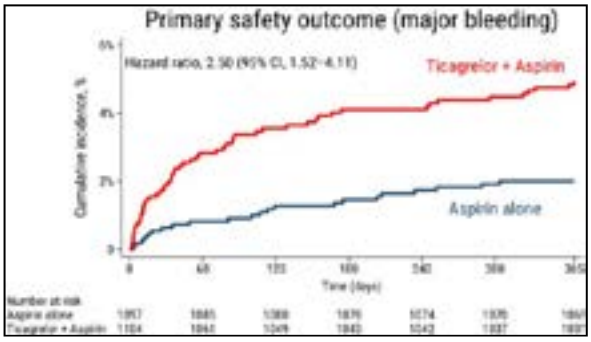
Mongi Slim University Hospital
La Marsa

Dr.Mohamed Amine SOULA
Cardiology Department,
Mongi Slim University Hospital
La Marsa





Population:2201 patients: 1104 received ticagrelor plus aspirin and 1097 received aspirin alone.

Study design: The TACSI trial is a registry-based and open-label trial, conducted at 22 Nordic cardiothoracic surgery centers. Patients with acute coronary syndrome (ACS) undergoing isolated coronary-artery bypass grafting (CABG) were randomized 1:1 after surgery to receive either ticagrelor plus aspirin or aspirin alone for 12 months. The primary efficacy endpoint was a composite of all-cause death, myocardial infarction, stroke, or repeat revascularization at 1 year, while the primary safety endpoint was major bleeding leading to hospitalization.

Aim: To investigate whether 12 months of dual antiplatelet therapy (DAPT) with ticagrelor and aspirin would improve outcome, compared with aspirin alone, in patients with ACS undergoing CABG.

Principle results: The study found no significant reduction in the primary efficacy endpoint with DAPT compared to aspirin alone (4.8% vs. 4.6%). However, ticagrelor plus aspirin was associated with a markedly higher risk of major bleeding (4.9% vs. 2.0%).

Study limitations: Lower-than-expected event rate meaning that the trial was underpowered for the detection of small differences in clinical events / Low-adherence to trial treatment, especially in the DAPT group (Only 64.1% of patients assigned to DAPT were adherent to this regimen at 12-month follow-up) / The bleeding definition did not align with the standardized definitions recommended by the Bleeding Academic Research Consortium.

Link to the study:
https://www.nejm.org/doi/full/10.1056/NEJMoa2508026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PROTECT WITH CONFIDENCE
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Article 4

HYPERTENSION AND CARDIOVASCULAR PREVENTION HOTLINES

Pr. Hichem Denguir
Coordinator

1.Cost-effectiveness of apixaban vs. aspirin for the reduction of thrombo-embolism in high-risk patients with device-detected atrial fibrillation: insights from the ARTESiA trial *Dr Ahmed Chetoui Rsdte Ranim Lahbib*

2.Smoking and the risk of sudden cardiac arrest in young-aged adults: a Korean nationwide population-based study. *Pr Rania Hammami Rsdte Fatma Oumarou*

3.Do obesity and visceral adiposity promote heart failure with reduced ejection fraction? *Pr Ag Sarra Chenik, Rsdte Syrine Bahri*

4.C-reactive protein and cardiovascular risk among women with no standard modifiable risk factors: evaluating the 'SMuRF-less but inflamed'. *Pr Rania Hammami Rsdte Asma Agourame*

5.Patient perceptions on Lp(a) testing and treatment for secondary prevention of cardiovascular disease - results from the INTERASPIRE study in seven countries across six WHO regions. ? *Pr Ag Sarra Chenik, Rsdt Saif Eddine Ben Amor*

6.Artificial intelligence-based identification of thin-cap fibroatheromas and clinical utcomes: the PECTUS-AI study. *Rsdte Mariem Bechargui Pr Saoussen Antit*

7.Artificial intelligence-based identification of thin-cap fibroatheroma: a new paradigm for risk stratification? *Rsdte Soumaya Slaoui, Pr Saoussen Antit*

8.Cardiovascular Imaging – Association between inflammatory biomarkers, chronic stress, and pericoronary adipose tissue attenuation obtained with coronary CT.
Dr Malek ELarbi ,Rsdt Aziz Labidi

9.Lipid-lowering Therapy and Mortality in Adults ≥75 Years Without Cardiovascular Disease.
Pr Khadija MZOUGHI , Rsdt : AHMED Yassine VALL

10.Major cardiovascular events in first-degree relatives of individuals with elevated plasma lipoprotein(a): a registry-based cohort study. *Dr Rahma Kallel Rsdt Yassine Ammari*

COST-EFFECTIVENESS OF APIXABAN VS. ASPIRIN FOR THE REDUCTION OF THROMBO-EMBOLISM IN HIGH-RISK PATIENTS WITH DEVICE-DETECTED ATRIAL FIBRILLATION: INSIGHTS FROM THE ARTESIA TRIAL

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Cardiology Department

Rsdte Ranim Lahbib
Charles Nicolle Hospital
Cardiology Department

Number of patients included/number per group:
4012 participants from 16 countries between May 2015 and July 2021
Group1: Apixaban: 5 mg twice daily (BID)
Group2:Aspirin (ASA): 81 mg once daily (OD)
Eligibility criteria : Age ≥ 55 years **with subclinical atrial fibrillation (SCAF)** and a CHA□DS□-VASc score ≥ 3 ,Age ≥ 75 years **with a history of stroke**, even if no other risk factors were present

Study design: The study calculated the average healthcare cost per participant (with a **CHA_2DS_2-VASc score > 4**) over 3.5 years of follow-up, using 2023 USD values. Costs included hospitalization for strokes and bleeds, plus study drugs. The daily cost of apixaban was **$0.63 in Canada, $0.11 in the UK, $2.26 in Germany, and $6.06 in the USA**.

Aim: Apixaban was more effective than aspirin at preventing stroke or systemic embolism in patients with subclinical atrial fibrillation. Evaluating the cost-effectiveness of treating this group is crucial for healthcare decision-making.

Principle results: In-trial results were not cost-saving (below $0), the prospective plan was to perform a lifetime cost-effectiveness analysis using a Markov model and a willingness-to-pay of 50 000 USD per quality-adjusted life year (QALY). After considering the cost of study medication and clinical events over 3.5 years, apixaban was dominant (cost-saving and more effective) in Canada (-$2301) and the UK (-$902) but cost more in Germany and the USA ($600 and $1990, respectively). Over a lifetime, treatment with apixaban produced a net gain of 0.107 QALYs, but with costs in both Germany ($2623 more) and the USA ($9110 more), yielding an incremental cost-effectiveness ratio of $24 514 per QALY for Germany and $85 140 for the USA.

Study limitations: **Increased Bleeding Risk:** The study found that while apixaban significantly reduced the risk of stroke or systemic embolism compared to aspirin, it was also associated with an increased risk of major bleeding .
Limited Applicability to All Subclinical AF Patients: The study's findings are specific to the patient population included. The participants were elderly (mean age 76.8 years) and had multiple stroke risk factors (mean CHA_2DS_2-VASc score of 3.9.
Exclusion of Clinical AF Patients: It excluded patients with clinically detected atrial fibrillation, which is an important distinction.

Link to the study:
https://academic.oup.com/europace/article/27/9/euaf195/8244471?login=false#532739606

SMOKING AND THE RISK OF SUDDEN CARDIAC ARREST IN YOUNG-AGED ADULTS: A KOREAN NATIONWIDE POPULATION-BASED STUDY

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Rsdte Fatma OUMAROU
Military University Hospital of Sfax

Number of patients included/ number per group:

- 6 293 672 individualsagedbetween 20 and 39 yearswhounderwenthealth screening from 2009 to 2012 wereincluded.
- The burden of smoking wasclassified as mild (<10 pack-years), moderate (<20 pack-years), and heavysmokers (≥20 pack-years).

Study design:

- Retrospective Analysis,
- an observational longitudinal cohort
- from the national health screening database in South Korea

Aim:

the linkage between smoking and the risk of SCA in young-age dadults
The primary outcome was the occurrence of SCA during follow-up.

Principle results:

- Non-smokers were most prevalent (55.2%), followed by current smokers (34.8%) and ex-smokers (10.1%).
- The incidence of SCA increased from non-smokers (0.06 per 1000 person-years), ex-smokers (0.08), to current smokers (0.14).
- Current smokers showed increased risk of SCA compared with non-smokers (adjusted hazard ratio 1.69, 95% confidence interval 1.57–1.81, $P < 0.001$).
- The risk of SCA was not increased in ex-smokers (0.96, 0.86–1.07, $P = 0.420$).
- Higher smoking burden was associated with accelerated risk of SCA (adjusted hazard ratio in heavy smokers 2.15, 1.90–2.43, $P < 0.001$).

Study limitations:

- Retrospective and Observational Design
- Self-Reported Smoking Status
- Single Time-Point Measurement: Smoking behaviorwasmeasuredonly once, whichmeansitdid not account for changes in smoking habits over the long follow-up period, such as smoking reduction or quitting.
- Limited Data on Other Risk Factors
- Lack of Data on Non-Combustible Products

Link to the study:
Smoking and the risk of suddencardiacarrest in young-agedadults: aKoreannationwide population-basedstudy | European Journal of PreventiveCardiology | Oxford Academic

DO OBESITY AND VISCERAL ADIPOSITY PROMOTE HEART FAILURE WITH REDUCED EJECTION FRACTION?

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The military Hospital of Tunis

Rsdte Cyrine Bahri
Cardiology department,
The military Hospital of Tunis

Study design :

Narrative review, It summarizes experimental and clinical data regarding the connection between heart failure with reduce dejection fraction (HFrEF) in addition to heart failure with preserve dejection fraction (HFpEF) and obesity.

Aim of the study :

To review the therapeutic implications (GLP-1 agonists, SGLT2 inhibitors, bariatricsurgery, etc.) and investigatewhetherobesity and visceraladiposity have distinct roles in the pathophysiology and outcomes of heartfailurewithreducedejection fraction (HFrEF) as opposed to heartfailurewithpreservedejection fraction (HFpEF).

Principal results :

- Visceral fat and obesity have differenteffects on HFrEFcompared to HFpEF.
- Obesity and visceraladiposity are major factorsinfluencingsymptoms, hemodynamics, and outcomes in HFpEF.
- The role of obesity in HFrEFislessevident;somestudiesindicate no consistent negative impact, and the so-called "obesityparadox" stillexists.
- Weight-losstreatments (such as bariatricsurgery, SGLT2 inhibitors, tirzepatide, and GLP-1 receptoragonists) clearlyimproveHFpEF in obese patients, but theireffects on HFrEF are inconsistent or nonexistent.

Study limitations:

- Being a narrative review, conclusions rely on heterogeneous trials withdifferent populations, endpoints, and subgroup analyses.

- Evidence for HFrEFislimited and sometimescontradictory.
- Meta-analyses are based on subgroup data, sofindingsshouldbeinterpretedcautiously.
- Somereferencedstudies have smallnumbers, non-standardizeddefinitions of obesity, or observational designs withresidualconfounding.

Link to the study:
https://doi.org/10.1093/eurheartj/ehaf645

	Heart failure with reduced ejection fraction (HFrEF)	Heart failure with preserved ejection fraction (HFpEF)
Visceral adiposity in the general community	Not predictive of the subsequent development of HFrEF	Harbinger of later development of HFpEF
Prevalence of central obesity in patients with established heart failure	Obesity in 25%, and central obesity in 50%–60%—values similar to that seen in the general population	Nearly all patients with HFpEF have an expanded fat mass. Obesity in 60%–70%, and central obesity in >95%
Clinical significance of central obesity and visceral adiposity	Little evidence that visceral adiposity correlates with haemodynamic severity. Prognostic only with extreme values	Visceral adiposity correlates with haemodynamic severity. Linear association with poor prognosis
Epicardial adipose tissue	Diminished, with degree of shrinkage having prognostic significance	Increased, with degree of expansion having prognostic significance
Presence and source of systemic inflammation	The primary feature of HFrEF is cardiac injury and stretch, not inflammation. Major sources of inflammation are atherosclerotic disease and peripheral congestion	The primary feature of HFpEF is the activation of proinflammatory pathways. Inflammation is driven by obesity, and it is ameliorated by weight loss
Imbalances in the secretion of adipokines	Imbalances (driven by cardiomyocyte secretion and the effects of neurohormonal signalling on adipocytes) may be cardioprotective	Imbalances (driven by changes in secretion by hypertrophied or inflamed adipose tissue) can promote cardiac hypertrophy and fibrosis
Response to mineralocorticoid receptor antagonism	Central obesity influences efficacy	Central obesity influences efficacy
Response to neprilysin inhibition	Central obesity does not influence efficacy	Central obesity influences efficacy
Response to incretin-based drugs	No evidence of favourable effect following weight loss	Reduced risk of worsening heart failure events following weight loss
Response to bariatric surgery	Experience in HFrEF is extremely limited	Case series indicate a benefit in morbid obesity

C-REACTIVE PROTEIN AND CARDIOVASCULAR RISK AMONG WOMEN WITH NO STANDARD MODIFIABLE RISK FACTORS: EVALUATING THE 'SMURF-LESS BUT INFLAMED'

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Military University Hospital of Sfax

Rsdte Asma Agourame
Military University Hospital of Sfax

Number of patients included/ number per group:
12,530 initially healthy women without standard modifiable risk factors (SMuRF-less).
No randomized groups — participants were analyzed across quintiles of hsCRP.

Study design:
Prospective cohort study from the Women's Health Study (WHS). Baseline hsCRP measured; participants followed up for 30 years for major cardiovascular events.

Aim:
To evaluate whether high-sensitivity C-reactive protein (hsCRP) predicts cardiovascular risk among women without standard modifiable risk factors (no hypertension, diabetes, dyslipidemia, or smoking).
Principle results

- Over 30 years, 973 first major cardiovascular events occurred.
- Women with events had higher median baseline hsCRP (2.22 vs 1.50 mg/L).
- Age-adjusted analyses: risk of CHD increased progressively across hsCRP quintiles (HR 2.23, highest vs lowest quintile).
- Clinical cutoffs: hsCRP >3 mg/L vs <1 mg/L → 77% higher CHD risk, 39% higher ischemic stroke risk, 52% higher total CVD risk.
- After further adjustment (BMI, kidney function): CHD HR ≈ 1.86 (95% CI 1.35–2.58) for top vs bottom quintile; HR ≈ 1.52 (95% CI 1.20–1.92) for >3 vs <1 mg/L.

Study limitations:

- Competing risk bias: primary conditional analyses assume independence, though results were consistent in Fine–Gray competing risk models.
- Only US women without standard risk factors were included → generalizability limited.
- Potential unmeasured confounding (e.g., genetics, environmental exposures, other biomarkers).
- Single baseline hsCRP measurement — does not capture changes over time.
- Not all cardiovascular events may have been captured during follow-up.

Link to the study:
C-reactive protein and cardiovascular risk among women with no standard modifiable risk factors: evaluating the 'SMuRF-less but inflamed' | European Heart Journal | Oxford Academic

PATIENT PERCEPTIONS ON LIPOPROTEIN (a)

TESTING TREATMENT FOR SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE: RESULTS FROM THE INTERASPIRE STUDY IN SEVEN COUNTRIES ACROSS FIVE WORLD HEALTH ORGANIZATION REGIONS

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Associate Professor
INTERASPIRE investigators

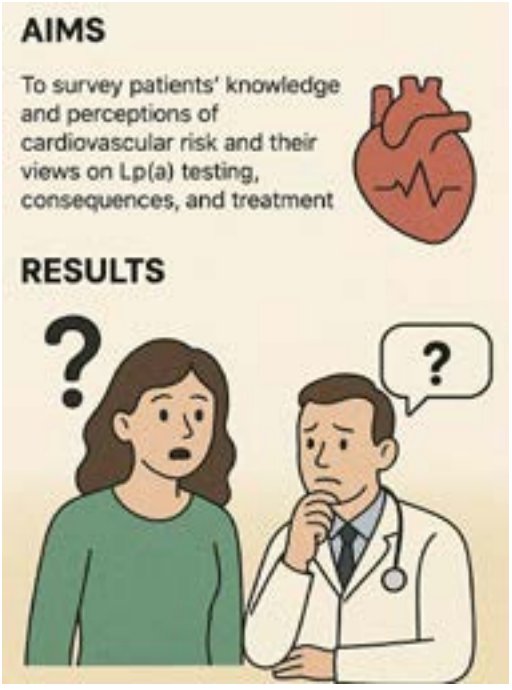
Rsdt Seif Eddine BEN AMOR
Cardiology Resident
INTERASPIRE investigators

Number of patients included/number per group:
856 patients in total:
523 with normal Lp(a),
333 with elevated Lp(a).

Study design:
Multicountry survey study in seven European countries across five World Health Organization regions with patient interviews and questionnaires.

Aim:
To assess patients' knowledge and perceptions of cardiovascular risk and their views on Lp(a) testing, consequences, and treatment.

Principal results:
Knowledge of cardiovascular disease was similar between groups (62.1% vs 59.6%, P=0.073).
Knowledge of Lp(a) was poor in both groups.
Patients with elevated Lp(a) were worried but accepted testing, appreciated the benefits and were motivated to reduce their CVD risk.



Study limitations:
Absence of specific licensed therapies for Lp(a), findings based on self-reported knowledge and perceptions.

Link to the study:
https://academic.oup.com/eurjcn/advance-article-abstract/doi/10.1093/eurjcn/zvaf174/8243737

ARTIFICIAL INTELLIGENCE-BASED IDENTIFICATION OF THIN-CAP FIBROATHEROMAS AND CLINICAL OUTCOMES: THE PECTUS-AI STUDY

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Cardiology Department, Internal Security Forces Hospital of Marsa

Rsdte Mariem Bechargui
Cardiology Department, Internal Security Forces Hospital of Marsa

414 patients who had experienced a myocardial infarction were included. Among them, **143 (34.5%)** had artificial intelligence thin-cap fibroatheromas(AI-TCFA), while 1**24 (30.0%)** had core-lab identified TCFA (CL-TCFA).

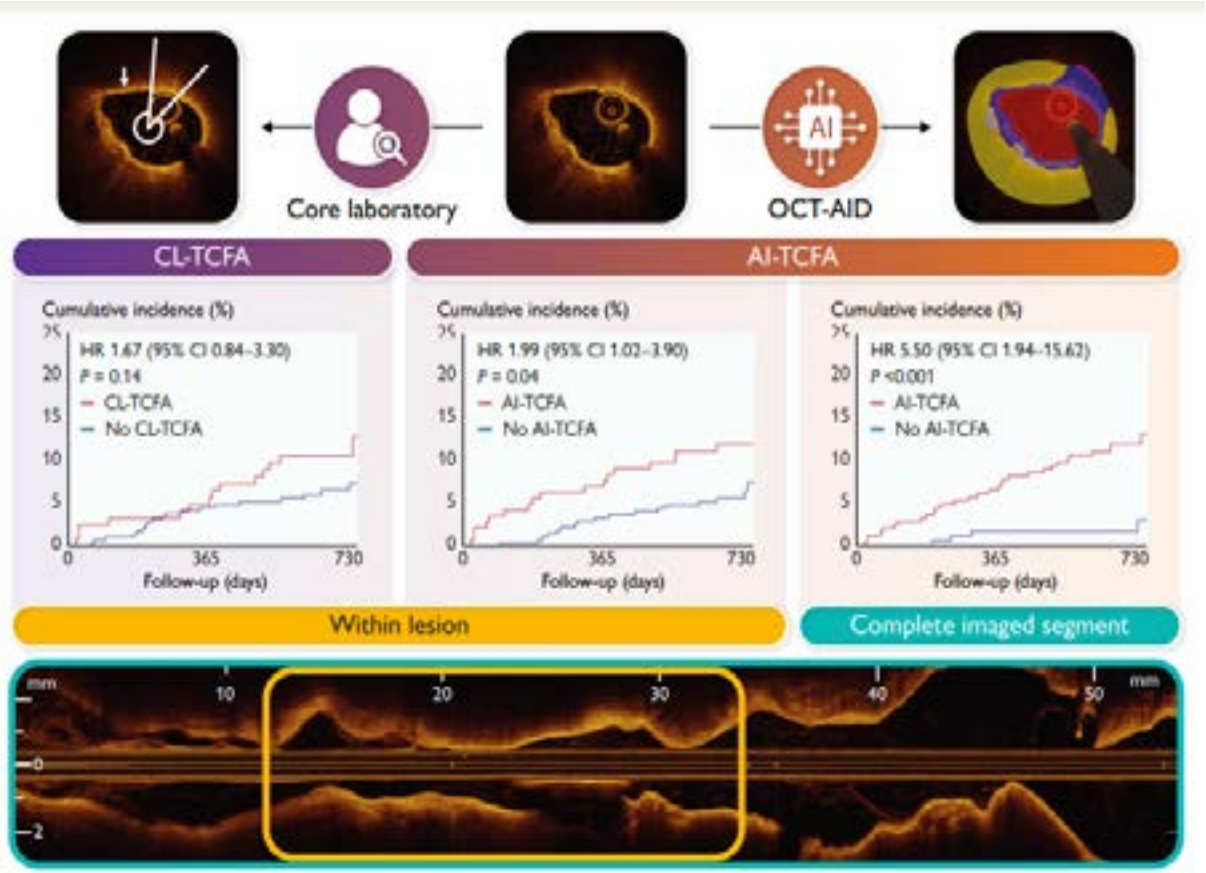
Studydesign: The **PECTUS-AI study** was a **secondary analysis** of the prospective, observational **PECTUS-obs study (NCT03857971)**. Patients with myocardial infarction underwent optical coherence tomography (OCT) of all fractional flow reserve (FFR)-negative non-culprit lesions. OCT images were analyzed by both an independent **core laboratory (CL-TCFA)** and a validated artificial intelligence algorithm **(OCT-AID, AI-TCFA)**. **The primary endpoint** was a composite of all-cause death, non-fatal myocardial infarction, or unplanned revascularization at 2 years (±30 days), excluding procedural and stent-related events.

Aim: To assess whether **AI-based OCT image analysis** can reliably identify thin-cap fibroatheromas (TCFA) and predict adverse cardiovascular outcomes compared with expert core laboratory readings.

Principle results: In target lesions, the presence of **AI-TCFA** was significantly associated with the primary outcome **(HR 1.99, 95% CI 1.02–3.90; p = 0.04)**, whereas **CL-TCFA** was not **(HR 1.67, 95% CI 0.84–3.30; p = 0.14)**. When analyzing **the entire OCT pullback**, AI-TCFA demonstrated an even stronger prognostic association **(HR 5.50, 95% CI 1.94–15.62; p < 0.001)** with a very high negative predictive value of 97.6% (95% CI 94.0–99.3%). Patients with AI-TCFA had significantly higher rates of death (5.3% vs. 0.6%; p = 0.009) and unplanned revascularization (7.4% vs. 1.8%; p = 0.01).

Study limitation: This study was based on single-center observational data, with AI analysis performed offline and core laboratory assessments limited to target lesions. Moreover, it was not powered to detect lesion-level or individual outcome differences.

Link to the study:
https://academic.oup.com/eurheartj/advance_article/doi/10.1093/eurheartj/ehaf595/8244402?login=false



Artificial intelligence-based versus core laboratory-based TCFA identification

AI-TCFA, artificial intelligence-identified thin-cap fibroatheroma; CI, confidence interval; CL-TCFA, core laboratory-identified thin-cap fibroatheroma; HR, hazard ratio; TCFA, thin-cap fibroatheroma

Volleberg R, *et al. European Heart Journal*

ARTIFICIAL INTELLIGENCE-BASED OF THIN-CAP FIBROATHEROMA: A NEW PARADIGM FOR RISK STRATIFICATION?

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Rsdte Soumaya Slaoui
Cardiology Department, Internal Security Forces Hospital of Marsa

Study design: The PECTUS-AI study evaluated 414 post-myocardial infarction patients, comparing AI-based OCT analysis (OCT-AID) with traditional core laboratory assessment for thin-cap fibroatheroma (TCFA).

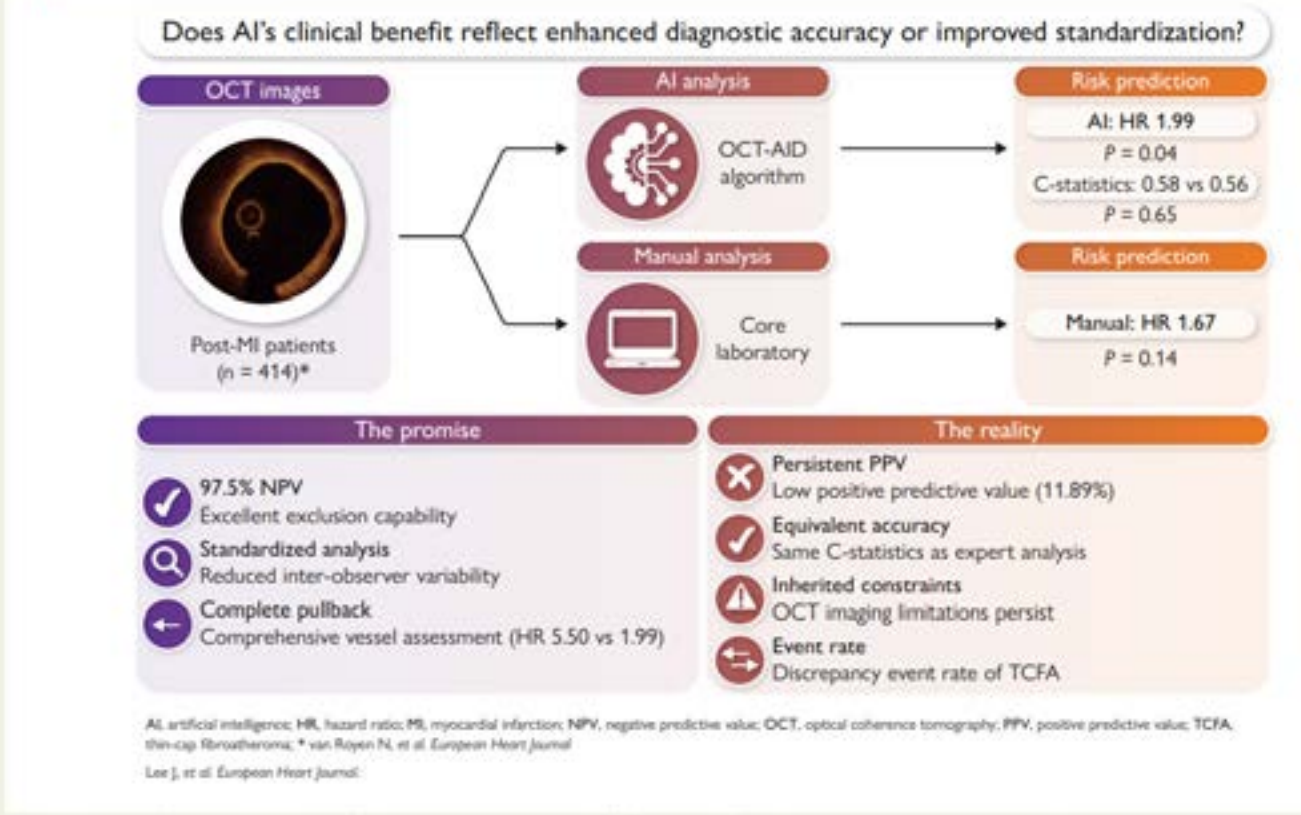
Aim: The study aimed to assess whether OCT-AID can enhance the diagnostic accuracy of TCFA detection and improve prognostic risk stratification

Results: AI and manual assessments demonstrated only fair concordance, with notable discrepancies in TCFA identification.Hazard ratios for outcomes were similar (AI HR 1.99 vs manual HR 1.67), and overall discriminatory power was equivalent (C-statistics 0.58 vs 0.56). A major finding was the stronger prognostic signal when complete vessel pullbacks were analyzed (HR 5.50) compared with lesion-only assessment (HR 1.99). AI achieved excellent negative predictive value (97.5%), but the positive predictive value remained low (11.9%), reflecting the discrepancy event rate of TCFA as many plaques appear vulnerable, but few cause clinical events.

Limitations: Limitations include significant AI–manual discordance in cap thickness, OCT's intrinsic subjectivity in lipid border definition, reliance on 2D imaging that misses 3D plaque complexity, and lack of core lab analysis outside target lesions. Low positive predictive value continues to restrict clinical applicability.

Link to the study:
https://doi.org/10.1093/eurheartj/ehaf662

Graphical Abstract



The clinical benefits and limitations of AI-based versus manual OCT analysis for thin-cap fibroatheroma detection.

CARDIOVASCULAR IMAGING – ASSOCIATION BETWEEN INFLAMMATORY BIOMARKERS, CHRONIC STRESS, AND PERICORONARY ADIPOSE TISSUE ATTENUATION OBTAINED WITH CORONARY CT

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Number of patients included/number per group: 98 patients were enrolled, all of whom underwent clinically indicated coronary CT angiography (CCTA) at the University Hospital Zurich between January 2020 and December 2023. None of the patients had a prior diagnosis of coronary artery disease (CAD), and all presented with a very low to moderate pretest probability of CAD. Patients were stratified according to levels of inflammatory biomarkers (hs-CRP, IL-6, TNF-α) as well as chronic stress scores derived from validated psychosocial questionnaires.

Study Design: It is a prospective, observational cohort study. Quantitative assessments included measurement of hair cortisol concentration (HCC), serum IL-6 and TNF-α levels, and evaluation of vital exhaustion using the short version of the Maastricht Vital Exhaustion Questionnaire (MVEQ). Eligibility criteria comprised an age of ≥18 years, provision of written informed consent, and sufficient proficiency in the German language. In contrast, patients with a history of coronary stenting, bypass grafting, implanted cardiac devices, diabetes mellitus, or smoking within the preceding five years were excluded.

Aim: The study aimed to examine links between pro-inflammatory cytokines, chronic stress, and pericoronary adipose tissue (PCAT) attenuation in patients with suspected CAD. Secondarly ,it also assessed how elevated PCAT attenuation relates to coronary stenosis, total plaque volume, and vulnerable plaque features. Finally, it explored whether chronic stress markers (HCC and vital exhaustion) influence the relationships between PCAT attenuation, plaque burden, and circulating cytokines.

Principal Results : Patients within the ≥95th percentile of IL-6 exhibited significantly higher PCAT attenuation compared with all other IL-6 groups (P = 0.004). Likewise, patients in the ≥95th percentile of TNF-α displayed greater PCAT attenuation than those in the 10th percentile (P = 0.027) and the 11th–75th percentile groups (P = 0.035). Furthermore, HCC was identified as a significant moderator, interacting synergistically with IL-6 to increase PCAT attenuation. In contrast, no significant direct effects of chronic stress were observed on TPV (HCC:mean difference -0.12, 95% CI -5.13 to 4.89, P = 0.962; vital exhaustion: mean difference 5.43, 95% CI -1.49 to 12.35, P = 0.122). In addition, higher vital exhaustion scores were found to acts synergistically with IL-6, further enhancing PCAT attenuation.

Study Limitations: This study has several limitations. The short follow-up (30 days) prevented assessment of long-term outcomes. The open-label design may have introduced bias, and restricting the population to elderly patients in specialized centers limits generalizability. A 19.5% crossover from conscious to general sedation could have influenced results. Finally, the Acurate neo2 valve used has since been withdrawn, reducing the trial's current relevance.

Link to the study:
https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.125.076557

LIPID-LOWERING THERAPY AND MORTALITY IN ADULTS ≥75 YEARS WITHOUT CARDIOVASCULAR DISEASE

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Number of patients:

- Total: 6,409 adults ≥75 years without baseline cardiovascular disease (CVD)
- Users of lipid-lowering therapy: 1,227Non-users: 5,182
- Study design :
- Population-based cohort study
- Data sources: NHANES III (1988–1994) and 10 continuous NHANES cycles (1999–2018)
- Follow-up : Median 6.5 years
- Outcomes: All-cause mortality & cardiovascular mortality

Aim:

To evaluate whether lipid-lowering therapy is associated with reduced all-cause and cardiovascular mortality among adults aged ≥75 years without established CVD, and whether effects differ across subgroups.

Principal results :

- All-cause mortality:
  - ◊ Adjusted HR: 0.74 (95% CI 0.67–0.81; P< 0.001)
  - ◊ ≈ 26% lower risk
- Cardiovascular mortality:
  - ◊ Adjusted HR: 0.64 (95% CI 0.54–0.76; P< 0.001)
  - ◊ ≈ 36% lower risk
- Survival gain: Users lived +1.6 years longer on average
- Consistency: Effect significant across age groups (including ≥85), sex, hypertension, diabetes, baseline 10-year CVD risk, and concomitant medications

Study limitations :

- Observational design → potential residual confounding
- Data limited to US population; may not generalize globally
- Some subgroups underpowered
- Medication adherence not directly assessed

Link to the study:
https://pubmed.ncbi.nlm.nih.gov/40876853/

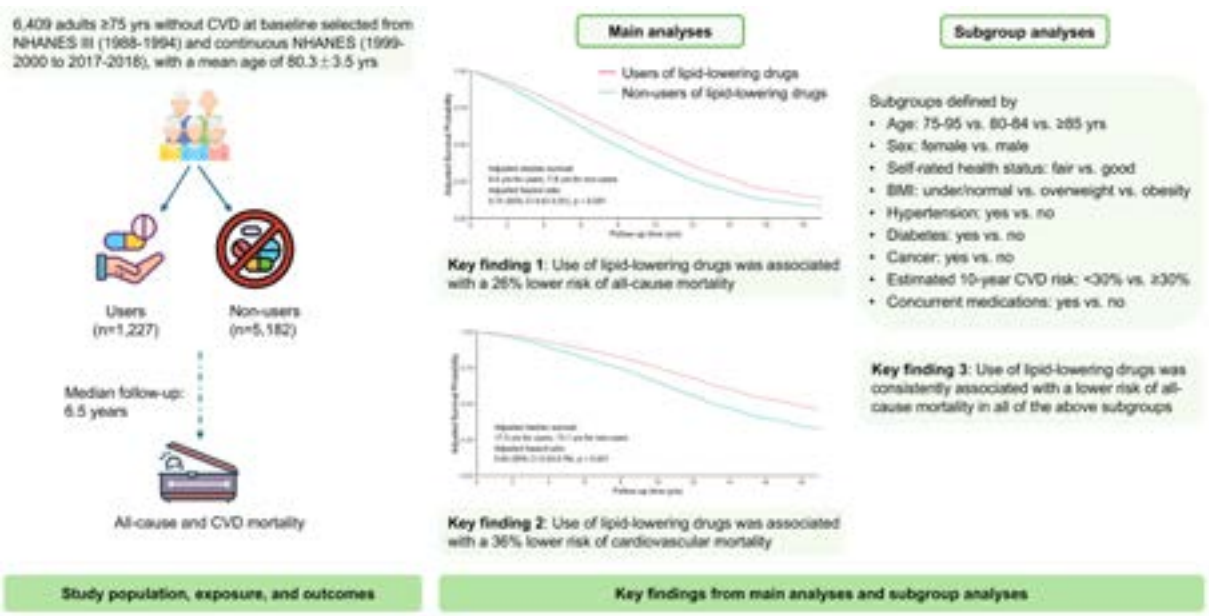

Figure 1 : Résumé de l'étude

MAJOR CARDIOVASCULAR EVENTS IN FIRST-DEGREE RELATIVES OF INDIVIDUALS WITH ELEVATED PLASMA LIPOPROTEIN(a): A REGISTRY-BASED COHORT STUDY

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Number of patients:

The study included **index patients with measured plasma lipoprotein(a)** (Lp(a))→ N_1=41,304 and Their **first-degree relatives (FDRs) without measured Lp(a)** → N_2=61,715
FDRs were stratified according to the index Lp(a) percentile:
<50th(n=30,915)/**50–<80th** (n=18,426) / **80–<95th** (n=9,291) /**≥95th** (n=3,083)

Study design:

This was an observational registry-based, cohort study using the STRIREG database.
The follow-up lasted a median of 19 years (range 11–26).

Aim:

To determine **whether first-degree relatives** of individuals with elevated plasma Lp(a) (≥80th percentile) have an **increased risk of major adverse cardiovascular events** (MACE), including cardiovascular death, myocardial infarction, ischaemic stroke, and coronary revascularization.

Principal results:

- 2043 MACE occurred among FDRs during follow-up.
- The cumulative incidence of MACE by age 65 was per Lp(a) percentile as **%** (Figure 1)

- Hazard ratiosfor MACE increased across Lp(a) strata, with ~30% higher risk in FDRs of individuals with elevated Lp(a).
- Concordance of elevated Lp(a) between first-degree relatives was 53%.
  - The excess risk was mainly linked to coronary events, but not to ischemic stroke.

Study limitations

- Lack of information on lifestyle factors (e.g., smoking, diet, BMI).
- Analysis limited to ages 35–69 years.
- Potential selection bias because Lp(a) testing in index cases was not systematic.

Link to the study:
https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehaf677/8244427