



# CCCCV NEWSLETTER

## Hotlines ESC 2026

Newsletter du collège de cardiologie  
et de chirurgie cardio-vasculaire et vasculaire périphérique



# EDITORIAL



Dear Colleagues,  
Dear Residents,

As we begin this new academic year, we are pleased to welcome you back with a new issue of our newsletter dedicated to the ESC 2026 Hotlines.

This edition highlights the major studies presented at the 2026 European Society of Cardiology Congress, bringing new evidence to our practice, and stimulating our clinical thinking. As in previous editions, we have aimed to provide a concise, practical, and focused overview, highlighting the key messages, and making the most relevant results more accessible for our daily practice.

This newsletter is above all the result of a collaboration between faculty members and residents, providing residents with an opportunity to develop their skills in critical appraisal of the literature, while allowing faculty members to share their expertise and clinical perspective.

We wish you all an enjoyable reading and would like to thank all the faculty members and residents for their valuable contribution to this new edition.



**PR. AFEF BEN HALIMA**  
*President of CCCVP*



**PR. KHADIJA MZOUHI**  
*Coordinator of the Newsletter*

# HOTLINES ESC 2026

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# HOTLINES ESC 2026



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Health Priority

# IMMEDIATE AMBULATORY ELECTROCARDIOGRAPHIC MONITORING IN SYNCOPE: THE ASPIRED TRIAL



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## Number of patients included / number per group

2234 adult patients enrolled and randomized 1:1 across 45 UK NHS hospitals: 1122 to the intervention group (14-day ambulatory ECG monitor) and 1111 to the standard-care group. Primary intention-to-treat analysis included 1970 patients (1004 intervention / 966 standard care).

## Study design

In this open-label, multicentre, randomized controlled superiority trial taking place in 45 UK NHS acute care centers, adults ( $\geq 16$  years) presenting with syncope that was still unexplained after being checked in the emergency department were randomly put into 2 groups assigned 1:1. One group had immediate 14-day ambulatory ECG monitoring, initiated at the visit. the other group had standard-care monitoring. The Patients were followed for 2 years; every 4 weeks they reported any syncope episodes themselves. the main result was checked after 1 year.

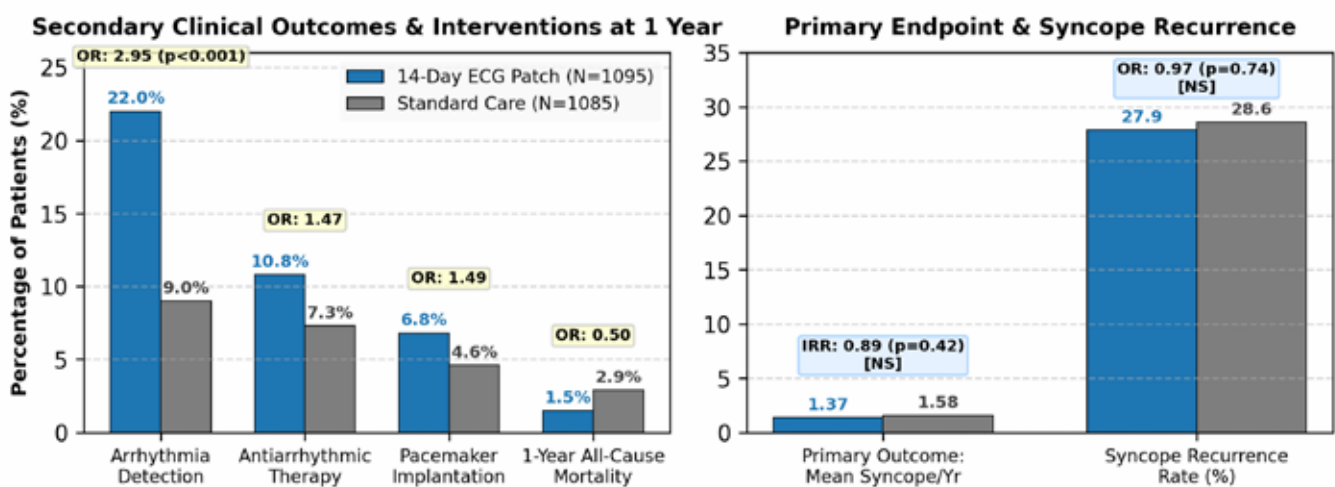
## Aim

To determine whether immediate, enhanced (14-day) ambulatory ECG monitoring started during the index ED visit can reduce the number of patient-reported syncope episodes after one year, compared with standard care, in patients with unexplained syncope.

## Principal results

- Primary outcome: no significant difference in patient-reported syncope episodes at 1 year:  $1.37 \pm 5.10$  (intervention) vs  $1.58 \pm 8.56$  (standard care); incidence rate ratio (IRR) 0.89 (95% CI, 0.68–1.18;  $P=0.42$ ).
- Clinically significant arrhythmia detected more often with early monitoring: 22.0% vs 9.0% (OR 2.95, 95% CI 2.28–3.81); and led to earlier diagnosis (22.0 vs 54.5 days).

- More antiarrhythmic therapy (10.8% vs 7.3%) and pacemaker implantation (6.8% vs 4.6%) in the intervention group.
- monitoring was associated with a 50% reduction in all-cause mortality (1.5% vs. 2.9%) at one year (OR 0.50, 95%



**Figure 1: Primary outcome (syncope episodes/yr) and secondary clinical endpoints (arrhythmia yield, interventions, mortality) in the ASPIRED Trial.**

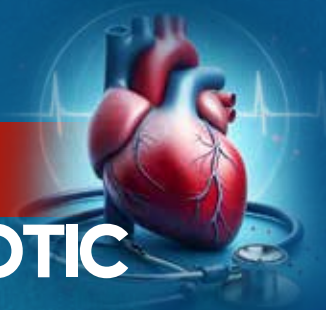
## Study limitations

The recurrence of syncope was lower than expected in both groups, reducing statistical power; device wear or return was incomplete with 17.1% of participants without an analysable recording reflecting real-world adherence challenges; mortality was a secondary, hypothesis-generating outcome requiring cautious interpretation; confidence intervals for secondary outcome were not adjusted for multiplicity.

## Link to the study

Reed MJ, et al. N Engl J Med 2026. DOI: 10.1056/NEJMoa2605812 | Protocol: Reed MJ, et al. BMJ Open 2023;13:e069530 | ISRCTN10278811

# RESPONSE TAILORED OR STANDARD DURATION ANTIBIOTIC TREATMENT FOR INFECTIVE ENDOCARDITIS THE POET II TRIAL



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## Number of patients included / number per group

508 patients were randomised : 255 to response-tailored therapy and 253 to standard-duration therapy.

## Study design

POET-II was an investigator-initiated, multinational, multicentre, open-label randomised trial conducted at 13 centres in Denmark, Sweden and the United States. Adults with definite left-sided infective endocarditis due to streptococci, *Staphylococcus aureus* or *Enterococcus faecalis* were eligible after 2-4 weeks of appropriate antibiotics only if strict clinical, inflammatory and transoesophageal echocardiographic stabilisation criteria were met and no further surgery was planned. Antibiotics were stopped at randomisation in the tailored group and continued to the guideline-based total of 4-6 weeks in the control group. The dual primary framework tested superiority for days alive without antibiotics and non-inferiority for safety at 6 months, using a 7.5-percentage-point margin.

## Aim

To determine whether antibiotic duration guided by early clinical response could reduce treatment exposure without compromising safety in stabilised left-sided infective endocarditis.

## Principal results

Tailored therapy increased the median number of days alive without antibiotics from 169 to 183 (estimated difference, 13 days; 95% CI, 12-13;  $P < 0.001$ ) and shortened total treatment by approximately 2 weeks. The primary safety composite of all-cause death, unplanned cardiac surgery or symptomatic embolism occurred in 21/255 patients (8.2%) with tailored therapy and 27/253 (10.7%) with standard therapy (absolute difference, -2.4 percentage points; 95% CI, -7.7 to 2.7;  $P < 0.001$  for non-inferiority). Nevertheless, relapse of bacte-



raemia or infective endocarditis was significantly more frequent after tailored therapy (13/255 [5.1%] vs 4/253 [1.6%];  $P=0.04$ ). POET-II therefore met both primary objectives, but the relapse signal argues against routine shortening and supports selective use within an experienced endocarditis team and a structured surveillance pathway.

**Study limitations**

The open-label design and highly selected, clinically stable population limited external validity; immuno-compromised patients and those with recent relapse were excluded. Recruitment was geographically concentrated; follow-up was limited to 6 months and the trial was not powered for definitive organism-specific conclusions. Most importantly, relapse was a key secondary outcome but was not included in the prespecified primary safety composite. Consequently, statistical non-inferiority for that composite should not be interpreted as equivalent overall infectious safety.

**Link to the study**

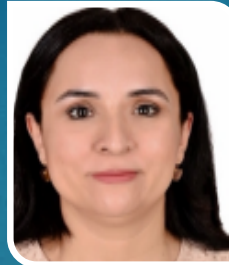
<https://doi.org/10.1056/NEJMoa2607887>

| RESULTS                                                                                                          |                   |                   |             |
|------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|-------------|
|                                                                                                                  | Tailored duration | Standard duration |             |
| Median duration of antibiotics                                                                                   | 26 days ↓         | 41 days           | $p<0.001$   |
| Primary endpoint<br>Median number of days alive without antibiotic treatment within 6 months after randomisation | 183 days ↑        | 169 days          | $p<0.001$   |
| Safety endpoint<br>All-cause mortality, unplanned heart valve surgery or symptomatic embolic events              | 8.2%              | ↔ 10.7%           | Noninferior |

Figure 1. POET-II primary efficacy and safety results, ESC Congress 2026.

# AFFIRMO TRIAL:

## mHEALTH INTEGRATED CARE (ABC PATHWAY + COMPREHENSIVE GERIATRIC ASSESSMENT) IN OLDER MULTIMORBID PATIENTS WITH ATRIAL FIBRILLATION



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### Number of patients included

1,260 patients with AF (mean age  $74 \pm 6$  years, 44.4% female) from 50 clusters in 6 European countries: 634 iABC vs 626 usual care. Median CHA<sub>2</sub>DS<sub>2</sub>-VASc 4, 41.0% >2 comorbidities, 54.2% pre-frail/frail, 97.3% anti-coagulated.

### Study design

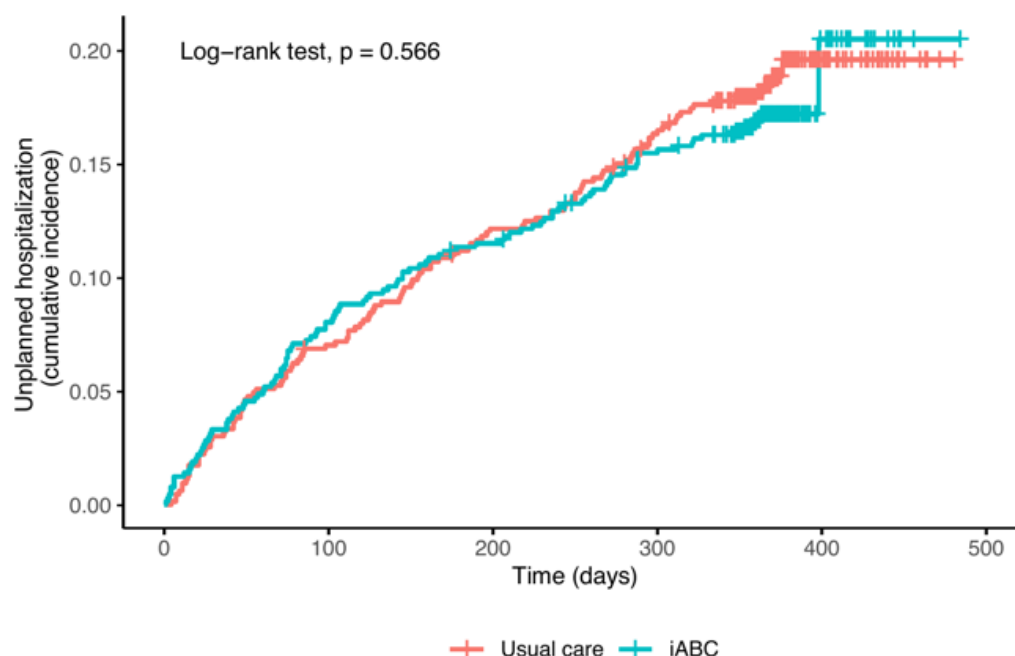
Multicenter, open-label, cluster-randomized trial (50 sites, 1:1). Inclusion: outpatients  $\geq 65$  years with AF and  $\geq 1$  chronic condition. iABC arm: mHealth system (app + clinician dashboard) implementing the ABC pathway plus baseline CGA. Control: guideline-based usual care. Follow-up 12 months; primary endpoint: all-cause unplanned hospitalization.

### Aim

To determine whether a mHealth-based ABC pathway intervention integrating CGA reduces unplanned hospitalizations in older multimorbid AF patients.

### Principal results

- **Primary endpoint:** 17.1% vs 18.2% (adjusted OR 0.95, 95% CI 0.61–1.49;  $p=0.84$ ); consistent across sensitivity and subgroup analyses.
- **Secondary endpoints:** no significant differences (death, hospitalization, stroke/TIA, heart failure, bleeding).
- **App use:** low (median 15.1% of days); no dose-response effect on the primary endpoint.
- **Conclusion:** no incremental benefit in an already well-treated population; integrated care should target higher-need settings.



Cumulative incidence of unplanned hospitalization, iABC vs usual care (log-rank  $p=0.566$ )

## Study limitations

- **Underpowered design:** observed event rate (18.2%) far below the 30% assumed at the design stage, leaving little margin to detect a benefit.
- **High baseline quality of care:** 97.3% anticoagulation and broad guideline adherence in usual care reduced the room for improvement from the intervention.
- **Suboptimal intervention fidelity:** low and heterogeneous app uptake (68.5% of patients in the lowest use tertile) likely diluted the true effect of the iABC system.
- **Ceiling effect on CGA:** a largely autonomous, cognitively preserved population (95.7% normal cognition) limited the potential impact of geriatric-assessment-driven interventions.
- **Design-related biases:** open-label cluster allocation exposes the trial to contamination and Hawthorne effects; baseline imbalances between arms (age, sex, frailty, symptom burden) may have attenuated between-group differences.
- **Generalizability:** limited number of clusters, exploratory (underpowered) subgroup analyses, and recruitment restricted to 6 European countries with sites motivated to participate in AF research.

## Link to the study

<https://pubmed.ncbi.nlm.nih.gov/41580107/>

# ATORVASTATIN, CARDIOVASCULAR EVENTS, AND DISABILITY-FREE SURVIVAL IN OLDER



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## Number of patients included / number per group

9,971 participants; atorvastatin n=4,984, placebo n=4,987.

## Study design

Investigator-initiated, double-blind, randomized, placebo-controlled primary-prevention trial conducted in Australian general practices. Community-dwelling adults aged  $\geq 70$  years without clinical cardiovascular disease, diabetes, or dementia received atorvastatin 40 mg once daily or identical placebo; median follow-up 5.9 years.

## Aim

To determine whether atorvastatin reduces major cardiovascular events and extends disability-free survival in older adults receiving primary prevention.

## Principal results

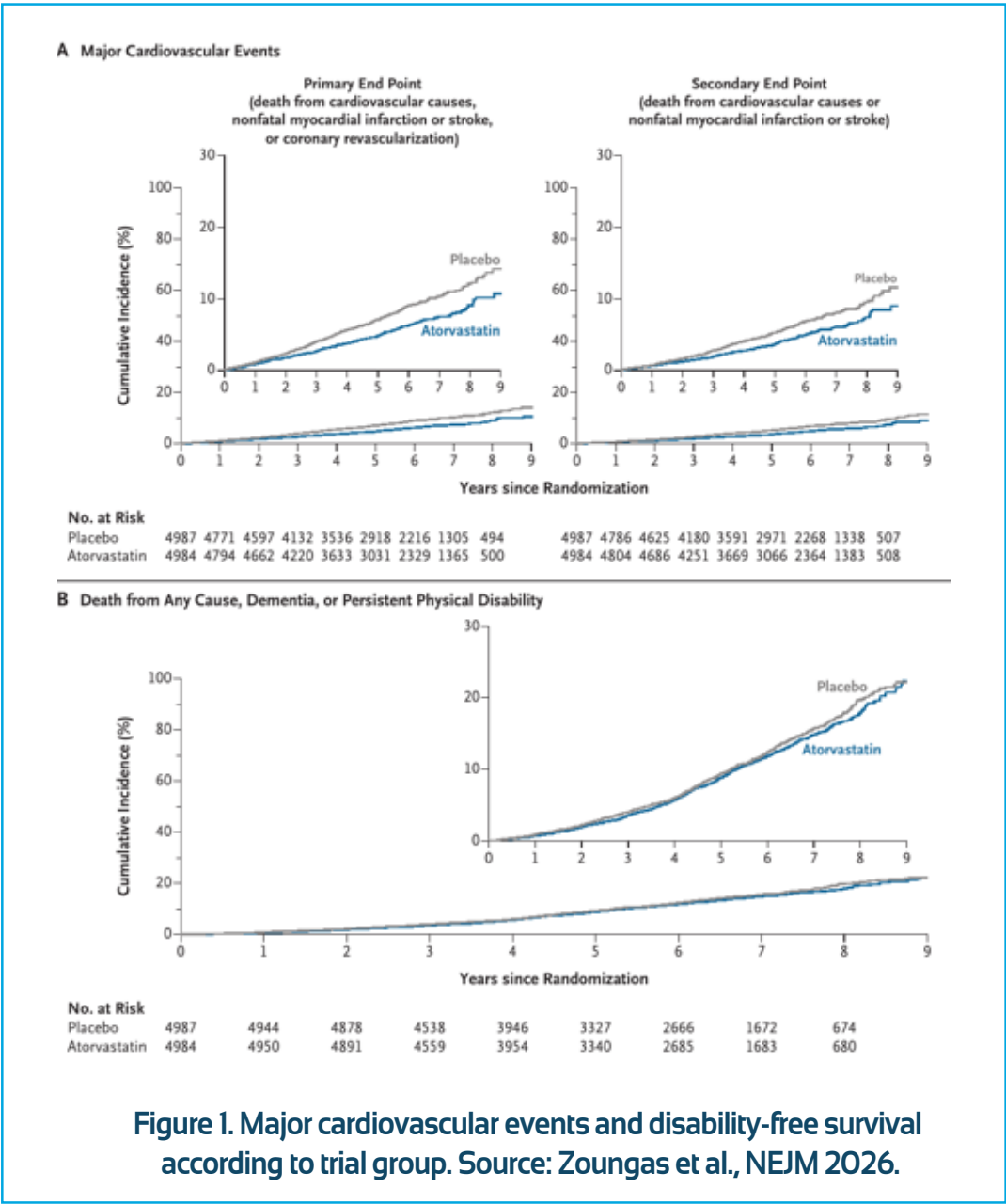
Atorvastatin reduced the primary cardiovascular end point (cardiovascular death, nonfatal myocardial infarction or stroke, or coronary revascularization): 10.9 vs 15.5 events/1,000 person-years; HR 0.70 (95% CI 0.61-0.82),  $P < 0.001$ . The reduction was driven mainly by fewer myocardial infarctions (HR 0.57, 95% CI 0.43-0.75) and coronary revascularizations (HR 0.57, 95% CI 0.45-0.72). Disability-free survival was not significantly improved: 21.6 vs 23.0 events/1,000 person-years; HR 0.94 (95% CI 0.84-1.05),  $P = 0.25$ . All-cause mortality, dementia, persistent physical disability, and hospitalization did not differ substantially. Serious adverse events were similar (2.7% vs 2.7%), although medically important musculoskeletal, hepatobiliary, and diabetes-related events were more frequent with atorvastatin.

### STUDY LIMITATIONS:

Participants were predominantly White and English-speaking; recruitment occurred during the COVID-19 pandemic, requiring many remote assessments. The community-dwelling, relatively independent primary-prevention population limits generalizability to frailer older adults with more comorbidities. The small number of new physical-disability cases limited conclusions for that component of the primary end point.

### LINK TO THE STUDY:

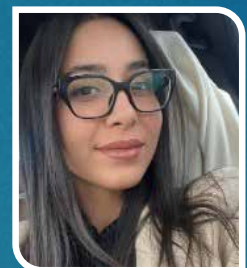
<https://doi.org/10.1056/NEJMoa2607314>



# NEXAF: Long-term exercise in patients with non-permanent atrial fibrillation



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## Number of patients included/ number per group

295 patients randomized 1:1.

147 exercise vs 148 usual care.

## Aim

To determine whether a 1-year tailored exercise programme reduces objectively measured AF burden and improves AF-specific quality of life compared with usual care in previously inactive patients with non-permanent AF.

## Study design

Prospective, multicentre, open-label, two-arm randomized controlled trial including patients with confirmed paroxysmal or persistent atrial fibrillation. Patients were randomized 1:1 to either a combined supervised and eHealth-based exercise intervention or usual care, with 12-month follow-up. All participants had an insertable cardiac monitor for continuous AF monitoring. The exercise intervention consisted of eight supervised high-intensity sessions during the first 4–6 weeks, followed mainly by home-based exercise with remote monitoring and guidance through a smartwatch, app, and web-based platform.

## Principal results

At 12 months, exercise significantly reduced AF burden compared with usual care (3.9% vs 7.1%; **45% relative reduction**,  $p=0.016$ ), while AF-specific quality of life did not improve significantly (AFEQT +5.6 vs +4.4;  $p=0.43$ ).

Exercise also improved cardiorespiratory fitness and was associated with 37% fewer total hospitalizations and **46% fewer AF-related hospitalizations**.

## Study limitations

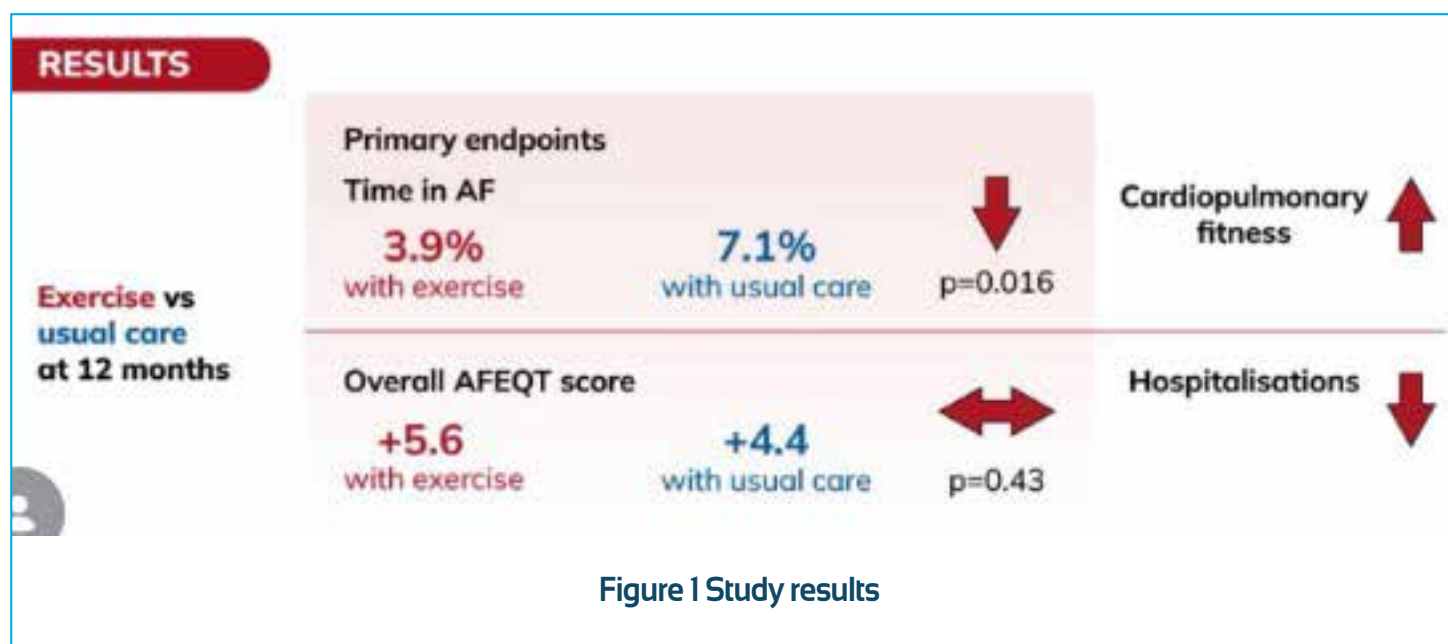
Open-label design.

Relatively small sample size and selected population (previously inactive patients with non-permanent AF managed with a rhythm-control strategy), limiting generalisability.

The two co-primary endpoints were discordant: AF burden improved, whereas AF-specific quality of life did not.

## Link to the study

<https://openheart.bmj.com/content/12/1/e003077>



## PRAGUE-26:

# Catheter-directed thrombolysis in Intermediate-high-risk pulmonary embolism



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### Number of patients included / number per group

558 patients were randomized: 280 to catheter-directed thrombolysis (CDT) plus anticoagulation and 278 to standard anticoagulation. Median age was 64 years and 40.9% were women.

### Study design

Prospective, multicentre, open-label, randomized, active-controlled, parallel-group trial. Patients with hemodynamically stable intermediate-high-risk acute PE, defined by sPESI  $\geq 1$ , right ventricular dysfunction and elevated cardiac troponin or natriuretic peptide, were randomized 1:1.

### Aim

To determine whether simple catheter-directed thrombolysis with alteplase, without ultrasound facilitation, added to anticoagulation, reduces early clinical deterioration compared with anticoagulation alone in intermediate-high-risk acute PE.

### Principal results

The 7-day primary composite endpoint (all-cause death, recurrent PE, cardiorespiratory decompensation or collapse) occurred in 2 patients (0.7%) with CDT versus 19 patients (6.8%) in the standard-care group (RR 0.10; 95% CI 0.02–0.44;  $P < 0.001$ ). This reduction was driven mainly by fewer episodes of cardiorespiratory decompensation or collapse. By day 7, clinically relevant bleeding had occurred in 13 patients (4.6%) in the CDT group and in 14 patients (5.0%) in the standard-care group ( $P = 0.85$ ); major bleeding occurred in 4 (1.4%) and 6 (2.2%) patients, respectively ( $P = 0.54$ ), and intracranial haemorrhage occurred in 2 (0.7%) and 0 patients, respectively.

### Study limitations

The trial was open-label, and the number of primary endpoint events was low. The study was performed mainly in high-volume tertiary centres with 24/7 catheterization facilities, which may limit generalizability to lower-volume hospitals. The composite endpoint was driven mainly by cardiorespiratory decompensation or collapse, with few deaths or recurrent PEs.

## Study reference

Kroupa J, et al. Catheter-Directed Thrombolysis in Intermediate-High-Risk Pulmonary Embolism. N Engl J Med. 2026 Aug 31. doi:10.1056/NEJMoa2608012. ClinicalTrials.gov: NCT05493163.

**Figure 1. Principal findings of PRAGUE-26**

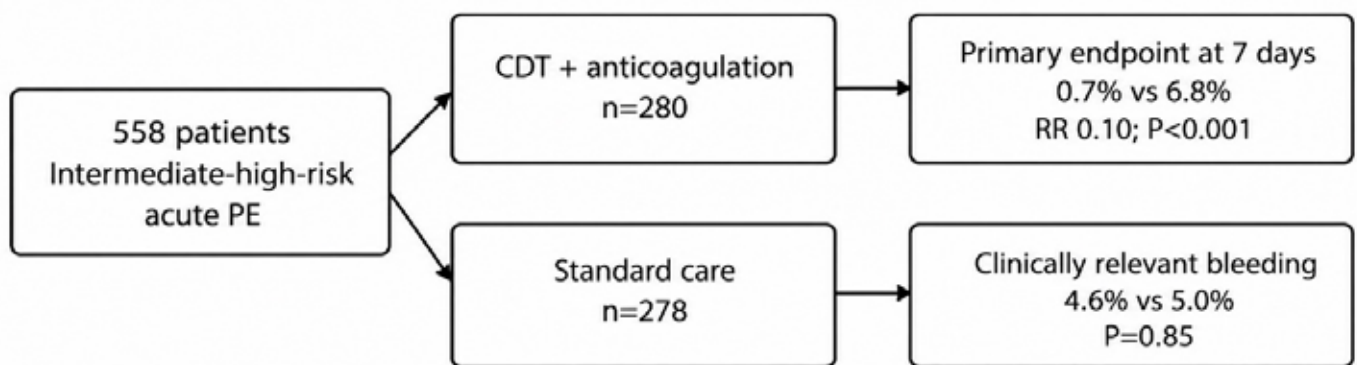


Figure 1. Principal findings of PRAGUE-26. CDT, catheter-directed thrombolysis; PE, pulmonary embolism; RR, relative risk.

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Health Priority



# SINGLE-AF: Anticoagulation for Atrial Fibrillation with Intermediate Stroke Risk



Dr Elyes Lagha



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## Number of patients included / number per group:

Patients randomized; direct oral anticoagulant (DOAC) n=902, no anticoagulation n=901.

## Study design:

Multicentre, randomized, open-label, adjudicator-masked, superiority trial conducted in 18 centres in South Korea. Adults with atrial fibrillation and intermediate thromboembolic risk (CHA<sub>2</sub>DS<sub>2</sub>-VASc score 1 in men or 2 in women) were randomized 1:1 to a direct oral anticoagulant (DOAC) or no anticoagulation and followed for 24 months.

## Aim:

To determine whether DOAC therapy reduces the risk of stroke, systemic embolism, major bleeding, or cardiovascular death compared with no anticoagulation in patients with AF at intermediate stroke risk.

## Principal results:

The primary endpoint was the composite of stroke, systemic embolism, major bleeding, or cardiovascular death at 24 months. It occurred in 4/902 patients in the DOAC group (cumulative incidence 0.5%) versus 13/901 in the no-anticoagulation group (1.5%); hazard ratio 0.31 (95% CI 0.10–0.94), absolute difference –1.0 percentage point (95% CI –2.0 to –0.1), p=0.03. Stroke occurred in 3 patients (0.3%) with DOAC versus 10 (1.1%) without anticoagulation. Systemic embolism and major bleeding were uncommon and appeared similar between groups; no cardiovascular deaths occurred. Serious adverse events occurred in 8.9% and 9.3%, respectively (Figure 1).

## Study limitations:

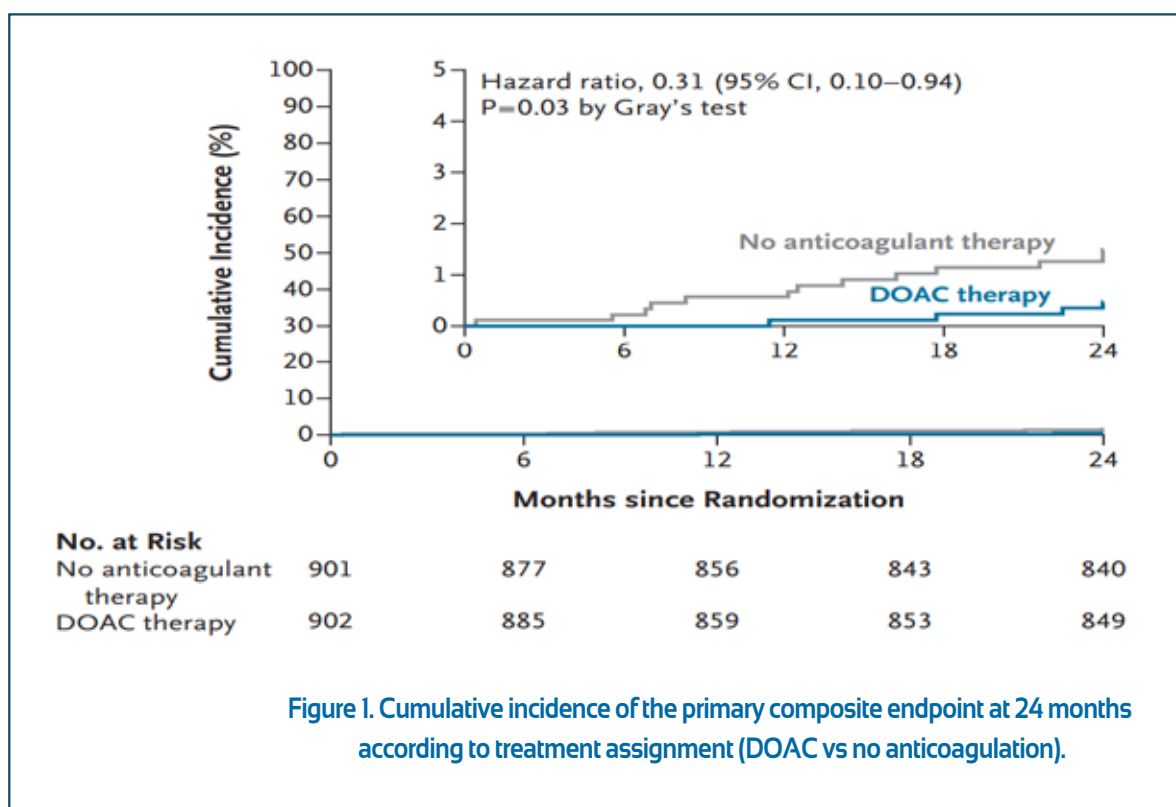
Open-label treatment allocation; low absolute event rate and only 17 primary-endpoint events, resulting in wide confidence intervals; exclusively South Korean population, limiting external generalizability; relatively young cohort (mean age 60.4 years); follow-up limited to 24 months.

## Clinical message:

SINGLE-AF provides randomized evidence that DOAC therapy can reduce the composite of thromboembolic events, major bleeding, and cardiovascular death in AF patients with a single non-sex CHA<sub>2</sub>DS<sub>2</sub>-VASc risk factor. The absolute event rate was low, so the findings should be interpreted in the context of individual thromboembolic and bleeding risk.

## Link to the study:

Kim D, Lee YS, Shim J, et al. N Engl J Med. 2026;395:1155–1165. DOI: 10.1056/NEJMoa2607978



# (China Rural Hypertension Control Program): Intensive Blood Pressure Control Reduces Dementia Risk



Dr Chourabi Chadia



Resident Hassen Amamou

*Hôpital Militaire Principal d'Instruction de Tunis*

## Study design:

Cluster-randomized controlled trial. Villages were randomized 1:1 to a non-physician community health-care provider (NPCHP)-led intensive BP management or usual care. Eligibility: age  $\geq 40$  years, untreated BP  $\geq 140/90$  mmHg or treated BP  $\geq 130/80$  mmHg (any BP  $\geq 130/80$  mmHg with CVD, diabetes, or CKD). Active intervention (years 0–4): target BP  $< 130/80$  mmHg, stepped-care treatment, free antihypertensives, monthly monitoring. Post-trial observation (years 4–7): active support ended; cognitive follow-up continued. Cognitive assessment at years 4 and 7 using MMSE, FAQ, and QDRS.

## Aim:

To determine whether NPCHP-led intensive BP management (target  $< 130/80$  mmHg) reduces the long-term incidence of all-cause dementia over 7 years (4-year active phase + 3-year post-trial follow-up) compared with usual care in rural China, and whether protection persists after the active intervention ends.

## Principal results:

- BP: SBP  $-29.3$  mmHg (intervention) vs.  $-7.3$  mmHg (usual care) at year 4;  $-17.6$  vs.  $-2.4$  mmHg at year 7.
- Primary endpoint — All-cause dementia (7-year overall): 8.85% vs. 10.55%; adjusted RR 0.85 (95% CI 0.78–0.91);  $p < 0.001$  15% relative risk reduction.
- In-trial period (4 years): 4.59% vs. 5.40%; adjusted RR 0.88 (95% CI 0.79–0.98);  $p = 0.023$ .
- Post-trial period (years 4–7): 5.83% vs. 6.97%; adjusted RR 0.84 (95% CI 0.76–0.93);  $p = 0.001$  protection persisted after intervention ended.
- CIND (7-year): 25.0% vs. 29.4%; adjusted RR 0.87 (95% CI 0.83–0.91);  $p < 0.001$ .
- All-cause mortality (7-year): 13.9% vs. 15.5%; adjusted RR 0.91 (95% CI 0.85–0.97);  $p = 0.005$ .
- Safety: No significant excess in symptomatic hypotension (RR 1.14,  $p = 0.08$ ), syncope (RR 1.12,  $p = 0.22$ ), or injurious falls (RR 1.02,  $p = 0.81$ ) over 7 years.

**Study limitations:**

Conducted exclusively in rural China (limited generalizability). Open-label design with unblinded providers and participants. BP measurement frequency differed between arms (potential surveillance bias). Cognitive assessments by local non-specialist staff. Post-trial analysis used landmark methodology with IPTW, which may not fully control for residual confounding.

**Link to study:**

ESC 2026 Congress, Munich, August 30, 2026 — Hot Line session 9. PI: Professor Yingxian Sun, First Hospital of China Medical University, Shenyang, China. Presenter: Dr. Shanshan Zhong.

# Digital Outreach to Improve Statin Refills in Patients With Low Statin Adherence: The ADHERE-ASCVD Randomized Clinical Trial



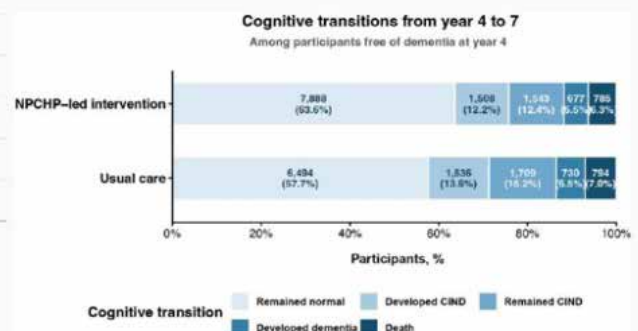
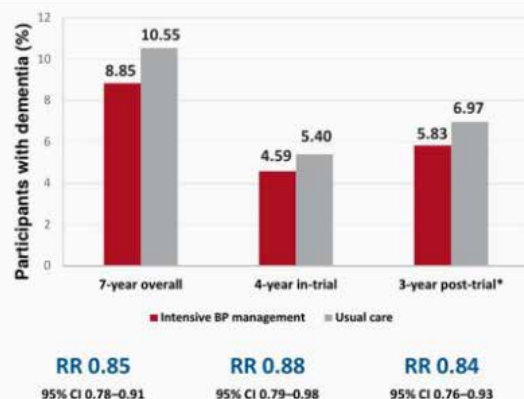
Pr Imen Bouhlef



Rsdet Zemzem Saddem

Farhat Hached Hospital Tunisia

| Outcome  | Analysis period | Intervention         | Usual care            | Unadjusted RR (95% CI) | P value | Adjusted RR (95% CI) | P value |
|----------|-----------------|----------------------|-----------------------|------------------------|---------|----------------------|---------|
| Dementia | Overall         | 1,148/12,978 (8.85%) | 1,259/11,939 (10.55%) | 0.82 (0.76-0.90)       | <0.001  | 0.85 (0.78-0.91)     | <0.001  |
|          | In-trial        | 668/14,541 (4.59%)   | 734/13,594 (5.40%)    | 0.85 (0.76-0.95)       | 0.0035  | 0.88 (0.79-0.98)     | 0.0230  |
|          | Post-trial      | 677/11,616 (5.83%)   | 730/10,469 (6.97%)    | 0.84 (0.76-0.94)       | 0.0018  | 0.84 (0.76-0.93)     | 0.0010  |



## Number of patients included/ number per group

20,604 participants. Stage 1 randomization: secure portal n=5,150; SMS/text n=5,152; nonsecure email n=5,152; usual communication n=5,150. Among 13,231 initial non responders, a prespecified second-stage randomization was performed.

## Aim

To test whether adaptive, sequential digital outreach improves short-term statin refill compared with usual communication in adults with an indication for statin therapy and recent nonadherence.

## Principal results

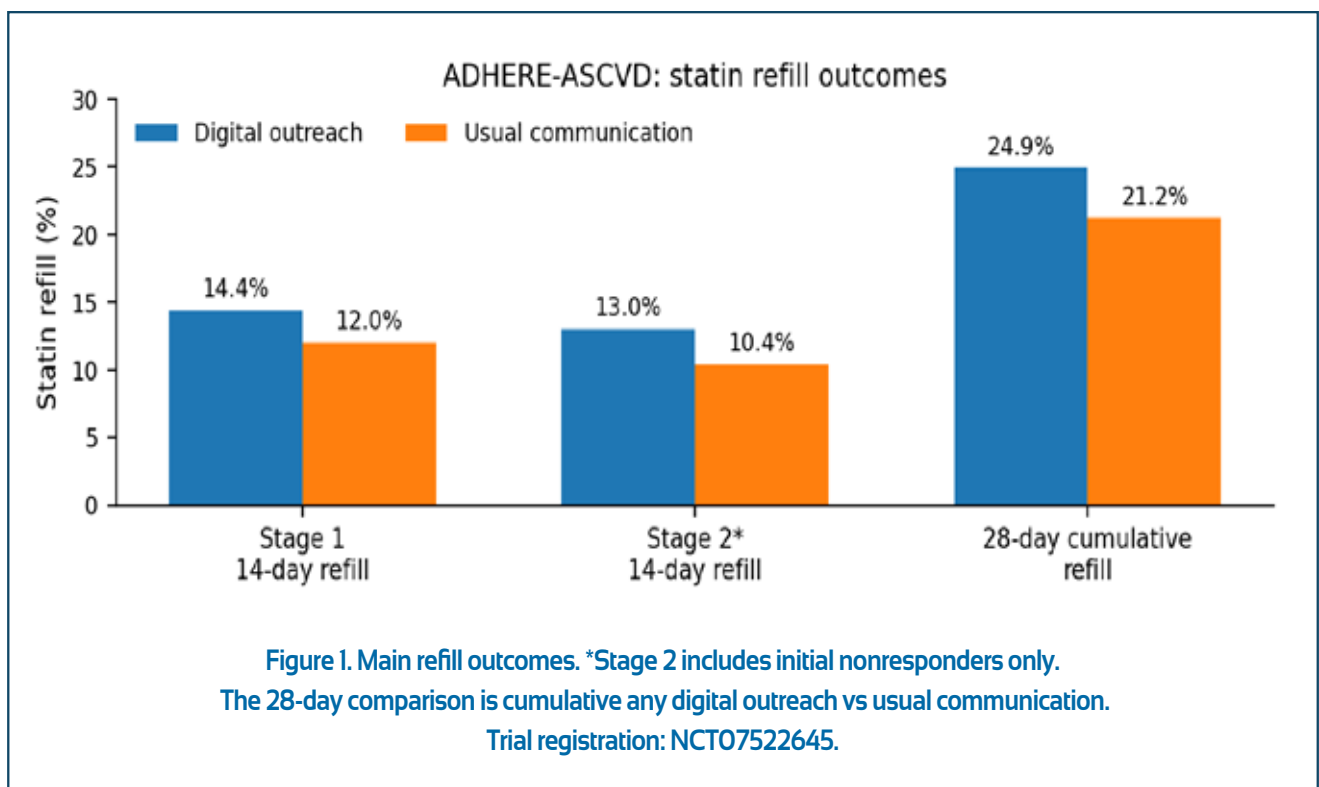
Stage 1: digital outreach increased 14-day refill (14.4% vs 12.0%; adjusted risk difference +2.3 percentage points, 95% CI 1.3–3.4; aRR 1.20, 95% CI 1.10–1.30). Stage 2 among initial nonresponders: 13.0% vs 10.4% (+2.5 points; aRR 1.25, 95% CI 1.11–1.39). Switching modality did not outperform repeating the same modality (13.2% vs 12.5%; aRR 1.06, 95% CI 0.94–1.17). Cumulative refill at 28 days: 24.9% vs 21.2% (aHR 1.21, 95% CI 1.13–1.30).

## Study limitations

Short follow-up and a refill endpoint rather than confirmed pill ingestion; 365-day adherence outcomes are ongoing. Only patients able to receive all digital modalities were eligible. Single integrated US health system; Medicare beneficiaries were excluded. Absolute gains were modest, and most patients still did not refill within 28 days.

## Newsletter take-home

Adaptive digital reminders produce a modest but statistically significant improvement in short-term statin refills. A second reminder adds benefit in initial nonresponders, whereas changing the communication channel does not. Do not present the trial as evidence of improved long-term adherence, LDL-C control, MACE, or mortality.



# VIRTUES ICD: Virtual E-health system for Implantable Cardioverter Defibrillators and VIRTUES PM: Digital health platform for pacemakers



Dr Elyes Lagha



Resident Louay Rekik

*Department of Cardiology, Mongi Slim Hospital, La Marsa, Tunisia*

## Department of Cardiology, Mongi Slim Hospital, La Marsa, Tunisia

**Patients:** Two parallel multicentre randomized trials including 1,963 patients: 1,115 with implantable cardioverter-defibrillators (VIRTUES-ICD) and 848 with pacemakers (VIRTUES-PM), randomized 1:1 to VIRTUES or standard care.

### Study design:

Open-label Canadian randomized trials conducted across 13 centres, with 18 months of follow-up. VIRTUES used remote device transmissions combined with a web-based platform enabling clinical review and direct digital communication with patients; routine in-clinic device visits were replaced by remote follow-up, while unscheduled visits remained available when clinically indicated.

**Aim:** To determine whether a patient-centred digital health strategy could provide safe and effective follow-up of cardiac implantable electronic devices while reducing the burden and costs associated with routine in-person visits.

### Principal results:

VIRTUES was non-inferior to standard care for the prespecified safety outcome. In VIRTUES-ICD, the 18-month safety endpoint occurred in 11.0% versus 11.2% with standard care ( $p=0.007$  for non-inferiority); in VIRTUES-PM, rates were 6.1% versus 7.4% ( $p=0.0213$  for non-inferiority). Time from a clinically important device event to clinical decision was also non-inferior: median difference +1 day in ICD patients and -3.25 days in pacemaker patients ( $p<0.0001$  for non-inferiority). The adjusted total cost was approximately CAD 77 lower per patient with VIRTUES, mainly because of fewer in-clinic visits and lower patient travel costs. Patient acceptance of the digital approach was high.

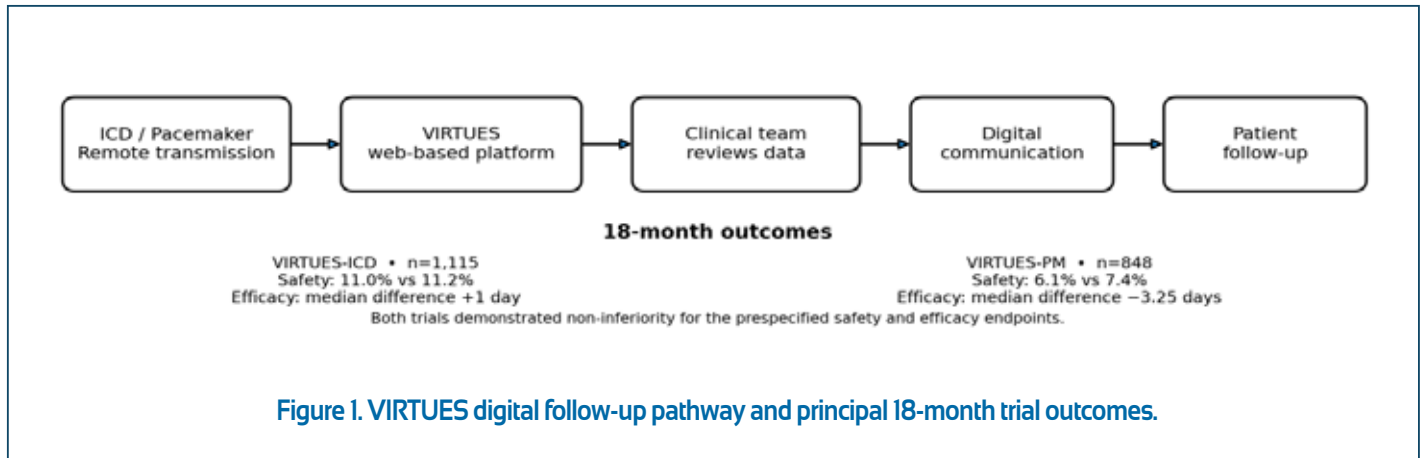
### Study limitations:

The trials were conducted only in Canada, limiting generalizability to other healthcare systems. They were open-label and follow-up was limited to 18 months. The intervention depends on reliable remote-monitoring infrastructure, compatible devices and an organized clinical pathway for reviewing

transmissions and communicating with patients. The control group could also receive conventional remote monitoring, so the comparison was not between remote monitoring and no remote monitoring.

### Link to the study:

ESC 365 – VIRTUES ICD / VIRTUES PM, Hot Line 5, ESC Congress 2026: <mailto:https://esc365.escardio.org/presentation/335372>



# Edoxaban for Intra-Cranial Hemorrhage Survivors with Atrial Fibrillation (ENRICH-AF)



Dr Mohamed Amine SOULA



Resident Naziha GHARSSALLH

*Cardiology Department, Mongi Slim University Hospital – La Marsa.*

**Number of patients included:** 948.

## **Study design:**

Prospective, open-label, blinded-endpoint trial conducted in 20 countries. Patients with high-risk atrial fibrillation (AF) (CHA<sub>2</sub>DS<sub>2</sub>-VASc score $\geq$ 2) and a prior intracranial hemorrhage (ICH) were randomized 1:1 to Edoxaban or standard care (no oral anticoagulation or antiplatelet monotherapy). The primary efficacy endpoint was a composite of stroke (ischemic or hemorrhagic) or systemic embolism, and the primary safety endpoint was ISTH major bleeding.

## **Aim:**

To assess the safety and efficacy of Edoxaban versus standard care in high-risk AF patients with a history of ICH.

## **Principal results:**

Over a mean follow-up of 28 months, Edoxaban did not significantly reduce the primary efficacy endpoint compared to standard care (11.8% vs 12.8%, HR, 0.88; 95% CI, 0.61-1.26;  $p=0.48$ ). However, the Edoxaban demonstrated a lower rate of ischemic stroke (6.2% vs 10.3%), though, counterbalanced by an increased incidence of haemorrhagic stroke (5.8% vs 1.9%). Additionally, the primary safety endpoint was not met, as the incidence of ISTH major bleeding was more than two-fold higher in the Edoxaban group (11.6% vs 5.2%, HR, 2.23; 95% CI, 1.39-3.59;  $p<0.001$ ).

## **Study limitations:**

Open-label design, Protocol adjustment in 2023 restricting lobar ICH enrolment.

Link to the study: Presented at ESC Congress 2026.



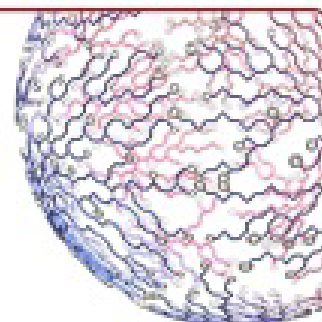
## ENRICH-AF

### Edoxaban in intracranial haemorrhage survivors with AF



#ESC Congress

**Presenter:** Ashkan Shoamanesh (McMaster University - Hamilton, Canada)



#### Conclusion

Edoxaban did not reduce stroke or systemic embolism and increased major bleeding in AF patients with prior intracranial haemorrhage.



#### Implications

Safer stroke-prevention strategies are required in this vulnerable population.

#### OBJECTIVE

To evaluate the efficacy and safety of oral anticoagulation in high-risk patients with AF and prior intracranial haemorrhage.

#### METHODS

- High-risk AF
- Prior intracranial haemorrhage

  
**948**  
patients  
randomised 1:1  
174 sites in  
20 countries

 **Edoxaban**   
**No anticoagulation**

  
Average follow-up:  
28 months

#### RESULTS

| Primary endpoints                     | Edoxaban | No anticoagulation |         |
|---------------------------------------|----------|--------------------|---------|
| Efficacy: Stroke or systemic embolism | 11.8%    | 12.8%              | p=0.48  |
| Safety: ISTH major bleeding           | 11.6%    | 5.2%               | p<0.001 |

# Clopidogrel or Dual Antiplatelet Therapy in High-Ischemic-Risk Patients (A-CLOSE)



Dr Mohamed Amine SOULA



Resident Mohamed Amine BOUGHRARA

Cardiology Department, Mongi Slim University Hospital – La Marsa.

| Clopidogrel or Dual Antiplatelet Therapy in High-Ischemic-Risk Patients |                                                                                                |                                               |                                                                  |                                                                                                                       |                     |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|---------------------|
| A-CLOSE                                                                 | Population                                                                                     | Intervention                                  | Control                                                          | Outcome                                                                                                               | Time                |
|                                                                         | 3,203 patients<br><br>At high risk for ischaemic events<br><br>12 months post DES implantation | Clopidogrel monotherapy<br><br>1,601 patients | Extended DAPT<br><br>Aspirin & Clopidogrel<br><br>1,602 patients | NACE<br>5% vs. 5.1%<br><br>Risk difference -0.1 percentage points, 90% CI -1.3-1.2,<br><br>P=0.001 for noninferiority | 24 months           |
| REAL WORLD NEEDS                                                        | Antiplatelet therapy in high ischaemic risk patients                                           | Reduction of ischaemic & bleeding events      |                                                                  | Translation to clinical outcomes                                                                                      | Long-Term follow up |
|                                                                         |                                                                                                |                                               |                                                                  | Increased ischaemic events ↑<br>Reduced bleeding ↓                                                                    |                     |

## Number of patients included:

3203: 1601 clopidogrel monotherapy vs 1602 extended DAPT.

## Study design:

Prospective, non-inferiority trial in 19 South Korean centers. Patients with high-ischemic risk (clinical or angiographic characteristics), who had undergone PCI with DES 12 months prior, were randomized 1:1 to clopidogrel monotherapy or extended DAPT. The primary endpoint was net adverse clinical events (NACE), a composite of all-cause death, MI, stent thrombosis, stroke and BARC type 2,3 or 5 bleeding at 24 months.

**Aim:**

To determine whether clopidogrel monotherapy is non-inferior to extended DAPT for NACE beyond 12 months after DES implantation.

**Principal results:**

Clopidogrel monotherapy was non-inferior to extended DAPT (5.0% NACE vs 5.1%, respectively;  $p=0.001$  for non-inferiority). However, clopidogrel monotherapy was associated with a higher incidence of ischemic events (3.7% vs 1.6%;  $p<0.001$ ), while clinically relevant bleeding was less frequent (1.8% vs 4.1%;  $p<0.001$ ). Overall, the similar rate of the primary endpoint resulted from a reduction in bleeding that offset the increase in ischemic events with clopidogrel monotherapy.

**Study limitations:**

Open-label design, South Korean-only population limiting generalizability, relatively low event rates limiting interpretation of individual components.

**Link to the study:** <https://www.nejm.org/doi/abs/10.1056/NEJMoa2608533>

# LAACS-2: Left atrial appendage closure with surgery-2



Dr Syrine Dardour



Resident Maalaoui Ala

*Cardiothoracic department of the military hospital of Tunis*

**Number of patients included:** 1500

**Number per group:** LAA closure Group: 747 /control: 753

## **Study design:**

Randomized open label superiority multicenter trial

## **Aim:**

To determine whether prophylactic surgical LAA closure reduces stroke/transient ischemic attack (TIA) in-patient undergoing their first open heart surgery irrespective of their CHA<sub>2</sub>DS<sub>2</sub>-VASc score or preoperative AF status.

## **Principle results:**

The mean age of the study population was 67 years, with a marked predominance of male patients (81%). A previous history of atrial fibrillation was reported in only 4.1% of patients, while oral anticoagulation was prescribed at baseline in 7.5%. The indication for surgery was CABG in almost 60% of cases, whereas mitral and aortic interventions accounted for 7.6% and 30% of procedures, respectively.

Over a median of 4 years of follow up extending from 2019 to 2023 The primary endpoint occurred in 32 patients (4.28%) in the LAA closure group and 38 patients (5.04%) in the control group, corresponding to a hazard ratio of 0.854 (95% CI, 0.534–1.368; p=0.517).

Thus, concomitant surgical LAA closure did not significantly reduce the risk of the primary endpoint.

A subgroup analysis suggested that surgical LAA closure may benefit patients at higher baseline thromboembolic risk (CHA<sub>2</sub>DS<sub>2</sub>-VASc score  $\geq 3$ ), in whom it was associated with a 56% relative reduction in stroke or TIA (p = 0.018). However, this subgroup result should be considered exploratory until confirmed.



### **Study limitations:**

- 1) The open label design may have introduced performance bias
- 2) The lower-than-expected event rate may have reduced the trial's statistical power.
- 3) Population and surgical-procedure heterogeneity may have diluted the treatment effect.

**Link to the study:** <https://doi.org/10.1016/j.ahj.2023.06.003>

# O/1-Hour versus Standard-Care Pathways in Myocardial Infarction: A Systematic Review and Individual Patient Data Meta-Analysis



Dr Houda Belkhiria



Resident Mohamed Abd El Hay Abdelwedoud

Cardiology Department, Medenine Hospital

## Number of patients included / number per group:

5 randomized trials, 46 centres, 14 countries; 110,933 emergency-department presentations for suspected myocardial infarction pooled at individual-patient level.

## Study design:

Systematic review and individual patient data (IPD) meta-analysis of 5 randomized trials comparing the ESC O/1-hour high-sensitivity cardiac troponin (hs-cTn) algorithm with standard-care pathways (predominantly O/3-hour) in patients presenting to the emergency department with suspected myocardial infarction.

## Aim:

To determine, using pooled individual-level data, whether the ESC O/1-hour pathway is as safe as standard-care pathways and whether it improves operational efficiency (emergency-department length of stay, rate of direct discharge).

## Principal results:

- Primary safety endpoint (30-day death or new type 1 MI): OR 0.83, 95% CI 0.45–1.53 — comparable safety between the O/1-h and standard-care pathways.
- Emergency-department length of stay: ratio 1.03, 95% CI 0.85–1.25 — no significant reduction with the O/1-h pathway.

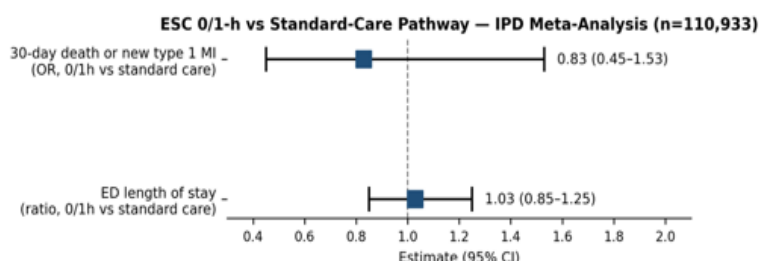


Figure 1. Pooled safety and efficiency estimates, ESC O/1-h vs standard-care pathway (IPD meta-analysis, n=110,933).



- No clear increase in direct-discharge rate with the O/I-h pathway; short-term serious safety events were rare overall in both arms.
- Authors' conclusion: the decision to adopt the O/I-h algorithm should not rest solely on expected gains in ED throughput — diagnostic and organisational factors must also be addressed.

### **Study limitations:**

- Clinical and methodological heterogeneity across the 5 component trials (different hs-cTn assays, cut-offs, and care settings).
- Efficiency endpoints (length of stay, direct discharge) are strongly influenced by local ED workflow and staffing, not solely by the algorithm.
- Despite the large, pooled sample, the trial was not powered to exclude a modest excess risk for rare adverse safety events.

### **Link to the study:**

Boeddinghaus J, Bima P, et al. Performance of the O/I-hour versus standard-care pathways in myocardial infarction: a systematic review and individual participant data meta-analysis. Presented ESC Congress 2026, Hot Line 4, Munich (29 Aug 2026). Accepted for publication in The Lancet (expected September 2026), companion paper to PRESCISE-MI (Lancet. 2026 Aug 29; DOI: 10.1016/S0140-6736(26)01654-5).

## CoCAP Study:

# Graft patency in acute coronary syndrome patients treated with DAPT or single aspirin after CABG



Dr Rim Letaief



Resident Fatma Mefteh

Department of Cardiology, Ibn Al Jazzar Hospital, Kairouan

### Population:

368 patients with acute coronary syndrome (ACS) undergoing CABG (178 Ticagrelor + Aspirin vs 190 Aspirin alone).

### Study design:

Conducted across six Scandinavian centers as a prespecified CCTA imaging substudy of the randomized TACSI trial, CoCAP evaluated post-CABG ACS patients assigned to 12 months of dual antiplatelet therapy (Ticagrelor 90 mg bid + aspirin) versus aspirin monotherapy, with graft patency assessed via coronary CT angiography at 12–36 months by a blinded core laboratory.

### Aim:

To evaluate whether ticagrelor plus aspirin improves vein-graft patency compared with aspirin alone in post-ACS patients following CABG, testing for an anatomical graft benefit despite neutral clinical outcomes in the parent TACSI trial.

### Results:

**Primary Endpoint:** Patient-level vein-graft patency (<50% stenosis) was 83.3% with DAPT vs. 81.6% with aspirin alone (adjusted RD +1.2%, 95% CI: -4.7% to +7.0%;  $P = 0.70$ ).

**Secondary Endpoints:** Non-occlusion rates showed no significant differences at patient (88.2% vs. 85.5%,  $P = 0.42$ ), graft (91.0% vs. 89.2%,  $P = 0.69$ ), or segment levels (91.8% vs. 92.3%,  $P = 0.60$ ). Subgroups & Per-Protocol: Per-protocol and subgroup analyses yielded consistent results (Figure 1).

### Study limitations:

Key limitations include single-time-point CCTA without serial imaging, CCTA-related exclusions (eGFR <45 mL/min/1.73 m<sup>2</sup>, atrial fibrillation, contrast allergy, weight >120 kg), significantly lower 1-year adherence in the dual-therapy arm (73.0% vs. 82.6%,  $P=0.032$ ) and limited statistical power due to the modest sample size ( $n=368$ ).

Link to the study: <https://esc365.escardio.org/presentation/335504>

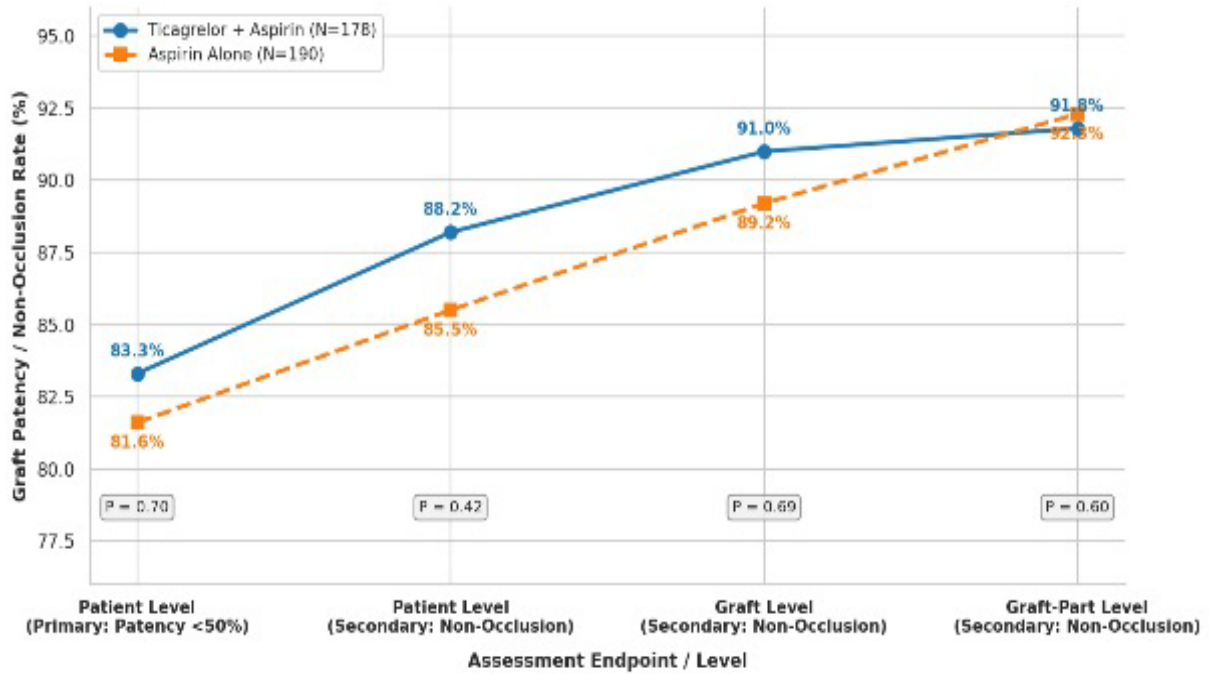


Figure 1: Primary and Secondary Graft Patency Endpoints in the CoCAP Trial

# Blood pressure-lowering treatment across the spectrum of cardiovascular risk



Pr Ag Yosra Messaoudi



Resident Maissa Gaaloul

Department of Cardiology, Ibn Al Jazzar Hospital, Kairouan, Tunisia

## Number of patients included:

357,440 participants from 51 randomized controlled trials.

No fixed number per group, as this was an individual participant data meta-analysis pooling trials with different treatment comparisons.

## Study design:

Individual participant data (IPD) meta-analysis of randomized trials comparing BP-lowering treatment with placebo, active comparators, or less-intensive treatment. Participants were divided into 10 deciles of predicted 5-year cardiovascular risk. Median follow-up was 4.2 years.

## Aim:

To assess whether the cardiovascular benefit of blood pressure-lowering therapy varies according to baseline cardiovascular risk, and to estimate both relative and absolute treatment benefits across the risk spectrum.

## Principal results

(Figure 1): For every 5-mmHg reduction in systolic BP, BP-lowering treatment reduced the risk of major cardiovascular disease by approximately 10% (HR 0.90). The relative treatment effect was consistent across all cardiovascular-risk categories (P for interaction >0.99). However, absolute benefit increased with baseline cardiovascular risk: the 5-year absolute risk reduction rose from 0.4% in the lowest-risk decile to 2.6% in the highest-risk decile (P for trend <0.001).

### Study limitations

The analysis pooled heterogeneous trials with different populations, antihypertensive regimens and comparators. Cardiovascular-risk groups were defined by predicted baseline risk and the median follow-up of 4.2 years limits assessment of lifetime treatment benefit.

### Link to the study:

ESC 365 – Blood Pressure-Lowering Treatment Across the Spectrum of Cardiovascular Risk

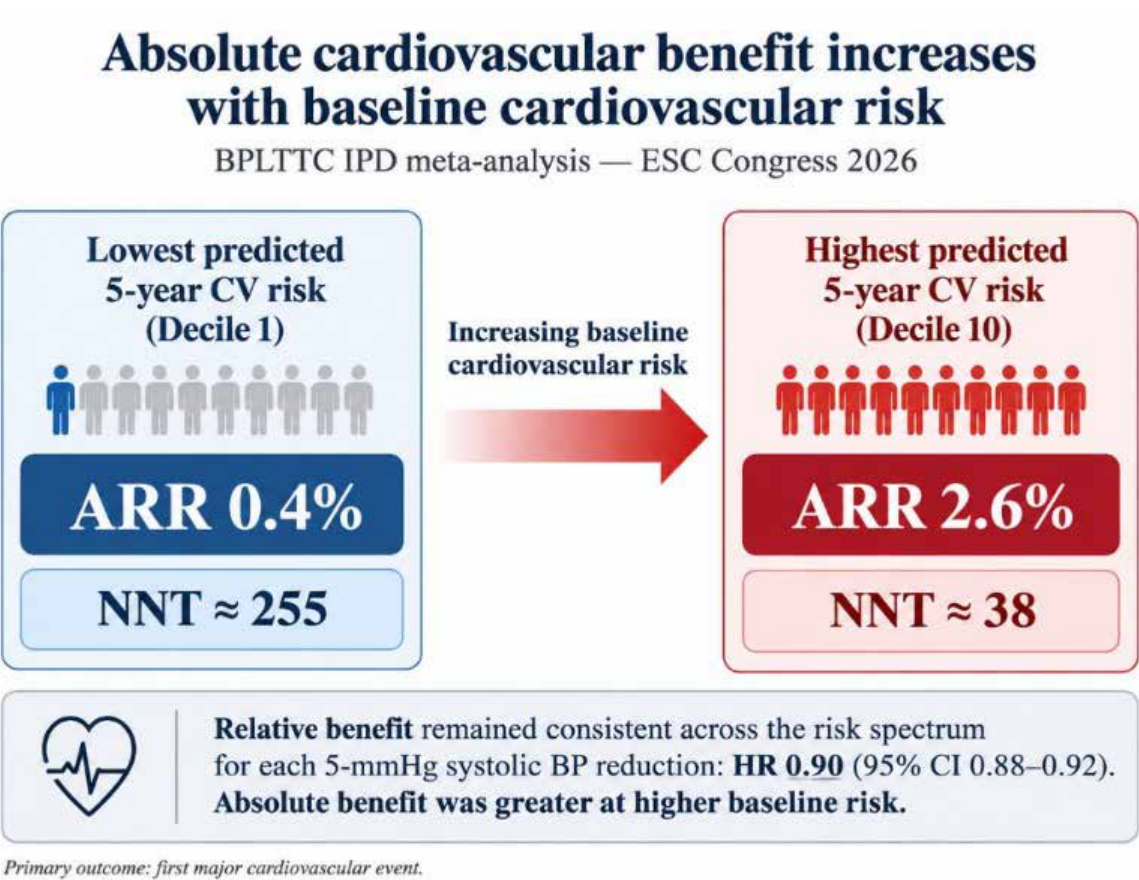


Figure 1: Cardiovascular benefit according to baseline cardiovascular risk

**VAL<sup>®</sup>**  
Valsartan 80, 160 mg

**BIVAL<sup>®</sup>**  
Valsartan/Hydrochlorothiazide 80/12.5, 160/12.5, 160/25 mg

**DuoFor<sup>®</sup>**

Valsartan + Amlodipine

**DuoFor<sup>®</sup> Plus**

Valsartan + Amlodipine + HCT

*Valsartan  
Le Maestro  
des Sartans*



**PHILADELPHIA**  
PHARMA

Health Priority

# AIR-STEMI: Complete revascularization guided by functional coronary angiography in STEMI



Dr Aymen Najjar



Resident Iheb Boujneh

Cardiology department, Fattouma Bourguiba university hospital, Monastir

## Number of patients included / Number per group:

1823 patients hospitalized for STEMI with successful culprit-lesion PCI, and multivessel coronary artery disease: 913 patients in the physiology-guided group (Phys.G) and 910 in the angiography-guided group (Angio.G).

## Study design:

Prospective, multicenter, open-label, superiority, randomized trial conducted in 21 centers in Italy and Pakistan. After successful PCI of the culprit lesion, patients were randomized 1:1 to complete revascularization of nonculprit lesions (NCL), during the index hospitalization if vessel diameter  $\geq 2.5\text{mm}$  and: NCL  $\geq 50\%$  + angiography-derived distal FFR  $\leq 0.80$  (Phys.G) or NCL  $\geq 50\%$  (Angio.G)

Primary endpoint: composite of all-cause death, myocardial infarction (MI), cerebrovascular accident, or ischemia-driven revascularization.

Primary safety outcome: composite of contrast-associated acute kidney injury or major bleeding.

## Aim:

To assess whether a physiology-guided strategy could improve outcomes and avoid unnecessary PCI of NCL compared with an angiography-guided strategy in patients with STEMI and multivessel disease.

## Principal results:

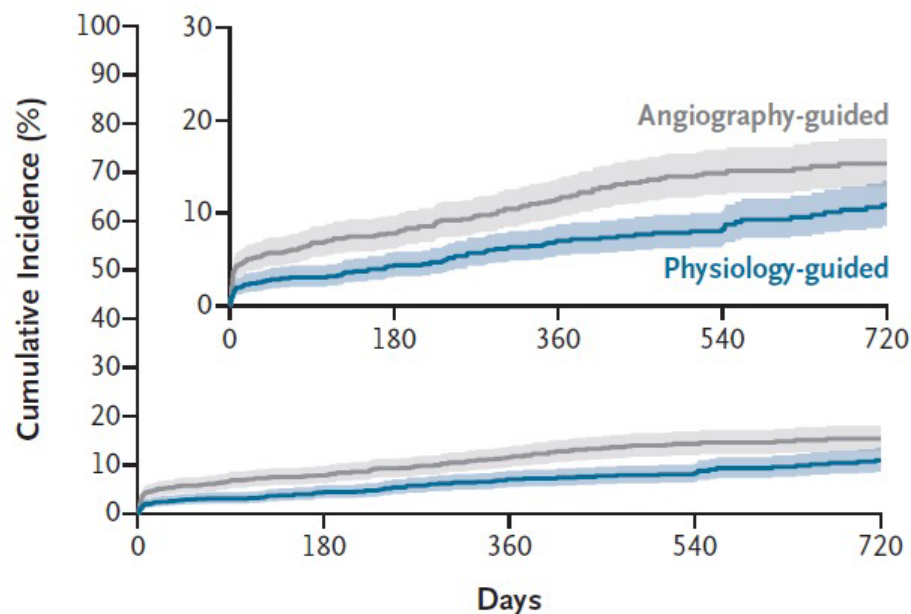
- Median follow-up: 17.9 months, median age: 66 years, 24% women.
- Primary endpoint: 8.9% (Phys.G) vs 13.7% (Angio.G), HR 0.62, 95% CI 0.47–0.83;  $p < 0.001$ . The difference was mainly driven by fewer MI and ischemia-driven revascularizations.
- Primary safety outcome: 4.6% (Phys.G) vs 7.1% (Angio.G), HR 0.63, 95% CI 0.43–0.93;  $p = 0.02$ .

- Cardiovascular death or MI (secondary endpoint): 5.7% (Phys.G) vs 10.5% (Angio.G), HR 0.52, 95% CI 0.37–0.73).
- Reduced nonculprit PCI in the Phys.G: 51.9% vs 94.9% (Angio.G), with less contrast use and a shorter total stent length.

### Study limitations:

Open label design, functional angiography analysis performed by an experienced central core laboratory, exclusion of complex cases, predominance of Italian centers, short follow-up and the high rate of nonculprit PCI in the Angio.G (where intermediate lesions are more often deferred).

Link to the study: <https://www.nejm.org/doi/full/10.1056/NEJMoa2605373>



#### No. at Risk

|                    |     |     |     |     |     |
|--------------------|-----|-----|-----|-----|-----|
| Angiography-guided | 910 | 838 | 801 | 339 | 234 |
| Physiology-guided  | 913 | 874 | 849 | 358 | 212 |

#### No. of Events

|                    |   |    |     |     |     |
|--------------------|---|----|-----|-----|-----|
| Angiography-guided | 1 | 71 | 105 | 121 | 125 |
| Physiology-guided  | 1 | 40 | 64  | 71  | 81  |

Figure 1: Primary-Outcome Events after Revascularization

# SWITCH-SWEDEHEART: Prasugrel vs Ticagrelor in Acute Coronary Syndromes



Dr Aymen Najjar



Resident Anouar Slama

Cardiology department, Fattouma Bourguiba university hospital, Monastir

## Number of patients included / number per group:

17095 patients with acute coronary syndrome (ACS) treated by percutaneous coronary intervention (PCI) in Sweden: 9444 under a default ticagrelor policy vs 7651 under a default prasugrel policy.

## Study design:

Prospective, multicenter, open-label, registry-based (SWEDEHEART), stepped-wedge cluster-randomized trial: 3 clusters switched from ticagrelor to prasugrel as the default P2Y12 inhibitor in a random order over four 9-month periods (2021–2024). All-comers (elderly, prior stroke, oral anticoagulation); 1-year outcomes from national registries; intention-to-treat analysis.

## Aim:

To assess whether a default prasugrel policy, vs ticagrelor, reduces 1-year death, myocardial infarction (MI) or stroke in unselected ACS patients treated by PCI.

## Principal results:

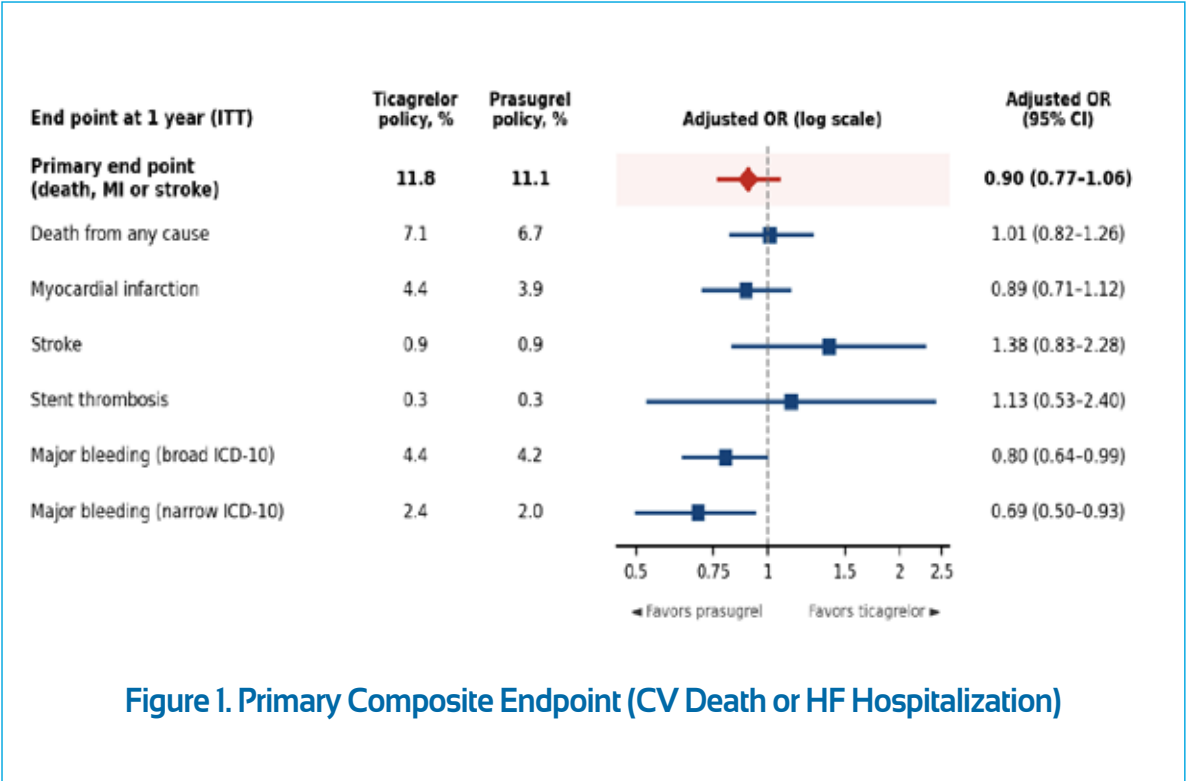
- Mean age  $69.8 \pm 11.5$  years; 36.8%  $\geq 75$  years; 27.8% women; 39.4% STEMI
  - Primary end point: 11.8% (ticagrelor) vs 11.1% (prasugrel), OR 0.90 (0.77–1.06;  $P=0.22$ ): no significant difference.
  - Major bleeding (secondary end point): 4.4% (ticagrelor) vs 4.2% (prasugrel), OR 0.80 (0.64–0.99)
- Among unselected patients undergoing PCI for an ACS, treatment under a default policy of prasugrel did not lead to a lower risk of a composite of death, MI or stroke at 1 year than treatment under a default policy of ticagrelor.

### Study limitations:

Open-label design; no central adjudication but registry coding for endpoints; only 3 clusters randomization; confounding by calendar time; low adherence to prasugrel (60.6% vs 75.8%).

### Link to the study:

<https://doi.org/10.1056/NEJMoa2609057>



# CARDIO-TTRansform: Eplontersen for Transthyretin Amyloid Cardiomyopathy



Dr Feriel BEN GHORBEL



Resident Nour OUENNICHE

*Regional Hospital of Menzel Bourguiba, Department of Cardiology*

## Number of patients included:

A total of 1,432 patients with transthyretin amyloid cardiomyopathy were included and randomly assigned in a 1:1 ratio to receive Eplontersen (n=715) or placebo (n=717).

## Study design:

CARDIO-TTRansform was an international, multicentre, randomised, double-blind, placebo-controlled phase III trial conducted at 130 centres across 20 countries. Patients with ATTR-CM were randomly assigned to receive subcutaneous Eplontersen 45 mg or placebo every four weeks and were followed for 140 weeks.

## Aim:

The aim of the study was to evaluate the efficacy and safety of Eplontersen, an RNA-targeted transthyretin gene-silencing therapy, in patients with transthyretin amyloid cardiomyopathy.

## Principal results:

The primary endpoint was a composite of cardiovascular mortality and recurrent cardiovascular events. A total of 381 primary endpoint events occurred in 210 patients receiving Eplontersen compared with 392 events in 231 patients receiving placebo, corresponding to a rate ratio of 0.89 (95% CI, 0.73–1.09;  $p=0.277$ ). Despite rapid, profound and sustained suppression of circulating serum TTR concentrations through week 140, Eplontersen did not significantly reduce the primary composite endpoint in the overall population. The treatment effect appeared to differ according to baseline use of TTR stabiliser therapy, with a lower incidence of primary endpoint events among patients not receiving stabiliser therapy, whereas no additional benefit was observed in patients receiving background stabiliser treatment. Eplontersen was associated with preservation of functional capacity and health-related quality of life and was generally well tolerated.

**Study limitations:** The primary endpoint did not reach statistical significance in the overall study population. The findings according to baseline TTR stabiliser use should be interpreted in the context of subgroup analyses and do not establish the efficacy of combination therapy. The study population was predominantly male, which may limit the generalisability of the findings to women with ATTR-CM. Longer-term clinical outcomes beyond the 140-week study period remain uncertain.

**Link to the study:**

New England Journal of Medicine: Eplontersen for Transthyretin Amyloid  
<https://www.nejm.org/doi/full/10.1056/NEJMoa2608510>

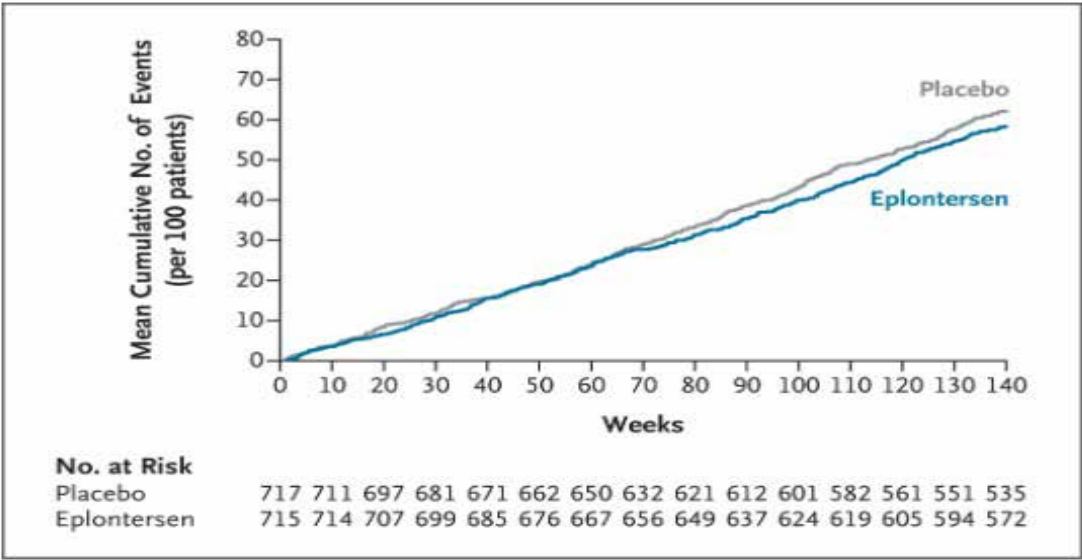


Figure 1: Death from Cardiovascular Causes and Cardiovascular Events up to Week 140.

# Remote Exercise SWEDEHEART Study



Dr Feriel BEN GHORBEL



Resident Eya ABAYED

*Regional Hospital of Menzel Bourguiba, Department of Cardiology*

## Number of patients included:

The Remote Exercise SWEDEHEART study included 3,112 patients aged 18–79 years with a recent type 1 myocardial infarction, identified through the Swedish SWEDEHEART registry.

## Study design:

This was a national, multicentre, registry-based, cluster-randomized crossover clinical trial. Cardiac rehabilitation centres were randomized to start with either a 15-month intervention period or a 15-month control period, followed by crossover. During the intervention period, patients were offered real-time, video-based remote exercise cardiac rehabilitation (EBCR), centre-based rehabilitation, or a combination of both. During the control period, patients received conventional centre-based EBCR only. The exercise programme consisted of at least 24 supervised sessions over 3 months, combining aerobic and resistance training individually prescribed and progressed by physiotherapists.

## Aim:

The primary objective was to determine whether offering remote EBCR as an alternative to conventional centre-based rehabilitation could increase patient participation in exercise-based cardiac rehabilitation after myocardial infarction. The study also assessed the safety, exercise capacity, quality of life, patient-reported outcomes, cost-effectiveness and long-term cardiovascular events associated with the two rehabilitation strategies.

## Principal results:

The proportion of patients completing the prescribed rehabilitation programme was very similar between the two strategies: 13.8% during the remote-exercise period versus 13.6% during the centre-based control period. The number of completed exercise sessions was also comparable between groups. Importantly, exercise capacity improved in both groups, with no relevant difference between remote and centre-based rehabilitation.



Remote rehabilitation was also associated with a low incidence of serious exercise-related adverse events, supporting its safety when exercise is individually prescribed and supervised by healthcare professionals. Overall, the study suggests that remote EBCR does not increase participation compared with conventional centre-based rehabilitation, but can provide a safe and effective alternative mode of delivery.

### **Study limitations:**

The study population was relatively young and predominantly male, limiting generalizability to older and higher-risk patients. The Swedish setting, digital requirements, and relatively low uptake of remote rehabilitation may also limit broader applicability. Long-term cost-effectiveness and clinical outcomes require further evaluation.

### **Link to the study:**

European Heart Journal – Digital Health, 2025: Feasibility, safety and patient perceptions of exercise-based cardiac telerehabilitation <https://academic.oup.com/ehjdh/article/6/3/508/8051875>.

# ACACIA-HCM: Aficamten for Symptomatic Nonobstructive Hypertrophic Cardiomyopathy



Pr Ag Sarra Chenik

*Department of Cardiology, Military Hospital of Tunis, Tunis, Tunisia*



Resident Syrine Bahri

## Number of patients included / number per group:

517 patients; Aficamten n=258 and placebo n=259.

## Study design:

Phase 3, multinational, randomized, double-blind, placebo-controlled trial in adults with symptomatic nonobstructive hypertrophic cardiomyopathy. Participants were randomized 1:1 to Aficamten (starting dose 5 mg, maximum 20 mg) or placebo for up to 72 weeks. The dual primary endpoints were change from baseline to week 36 in peak oxygen uptake ( $pVO_2$ ) and Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS).

## Aim:

To determine whether selective cardiac myosin inhibition with Aficamten improves exercise capacity and patient-reported health status in patients with symptomatic nonobstructive hypertrophic cardiomyopathy.

## Principal results:

At week 36, KCCQ-CSS increased by 11.4 points with Aficamten versus 8.4 with placebo (least-squares mean difference 3.0 points; 95% CI 0.5–5.5;  $P=0.02$ ).  $pVO_2$  increased by 0.64 mL/kg/min with Aficamten versus -0.03 mL/kg/min with placebo (difference 0.67 mL/kg/min; 95% CI 0.22–1.11;  $P=0.003$ ). Aficamten also improved NYHA functional class, ventilatory efficiency/exercise performance and NT-proBNP. LVEF <50% occurred in 27 patients (10.5%) receiving Aficamten and 2 (0.8%) receiving placebo and was reversible with treatment interruption or dose adjustment. Serious adverse events occurred in 20.2% and 14.7%, respectively.



**Study limitations:**

The placebo response in KCCQ-CSS reduced the between-group effect size. The trial was not powered to demonstrate differences in cardiovascular clinical events, and no significant benefit was observed for time to first cardiovascular event or left atrial volume index at week 36. Aficamten requires echocardiographic surveillance because reversible reductions in LVEF occurred more frequently than with placebo.

**Link to the study:**

N Engl J Med. 2026. "Aficamten for Symptomatic Nonobstructive Hypertrophic Cardiomyopathy." DOI: 10.1056/NEJMoa2603021 | ClinicalTrials.gov: NCT06081894.

| Endpoint                  | Aficamten       | Placebo         | Treatment effect         |
|---------------------------|-----------------|-----------------|--------------------------|
| KCCQ-CSS, change          | +11.4 points    | +8.4 points     | +3.0 points; P=0.02      |
| pVO <sub>2</sub> , change | +0.64 mL/kg/min | -0.03 mL/kg/min | +0.67 mL/kg/min; P=0.003 |

Figure 1. ACACIA-HCM dual primary endpoints at Week 36

# CorCal Trial: Effectiveness of a Proactive Cardiovascular Primary Prevention Strategy, With or Without the Use of Coronary Calcium Screening, in Preventing Future Major Adverse Cardiac Events



Dr Hela BOUZIDI



Resident Ghadhab Abdellaziz

*Cardiology department Habib Thameur Hospital*

**Number of patients included:** 5772

## **The Primary aim:**

The CorCal Outcomes trial was designed to assess whether coronary artery calcium (CAC)-guided statin initiation is as effective as the pooled cohort equations (PCE) strategy in preventing atherosclerotic cardiovascular disease (ASCVD) events.

## **Study Design:**

The CorCal Outcomes trial was a randomized controlled trial in which 75,539 eligible individuals were invited to participate, and 5,772 provided informed consent and were enrolled. Eligible participants were men aged 50–80 years and women aged 60–80 years, with no documented history of coronary, cerebrovascular, or peripheral vascular disease, no diabetes mellitus, and no prior statin therapy. The treatment recommendation generated by the assigned strategy was communicated to both the participant and their treating physician.

## **Results:**

**Lipid profile:** Among participants receiving a statin recommendation, CAC-guided therapy achieved a greater LDL-C reduction than PCE-guided therapy (37.0 vs. 18.3 mg/dL; 27.7% vs. 14.0%;  $p < 0.0001$ ), with final LDL-C levels of 87.1 vs. 103.2 mg/dL.

**Cardiovascular outcomes:** 145 primary events occurred versus 458 expected. The primary composite endpoint occurred in 2.7% of participants in both groups (HR 0.99, 95% CI 0.72–1.38; log-rank  $p = 0.99$ ). No significant differences were observed in individual cardiovascular outcomes. Non-inferiority was not demonstrated because of the lower-than-expected event rate.

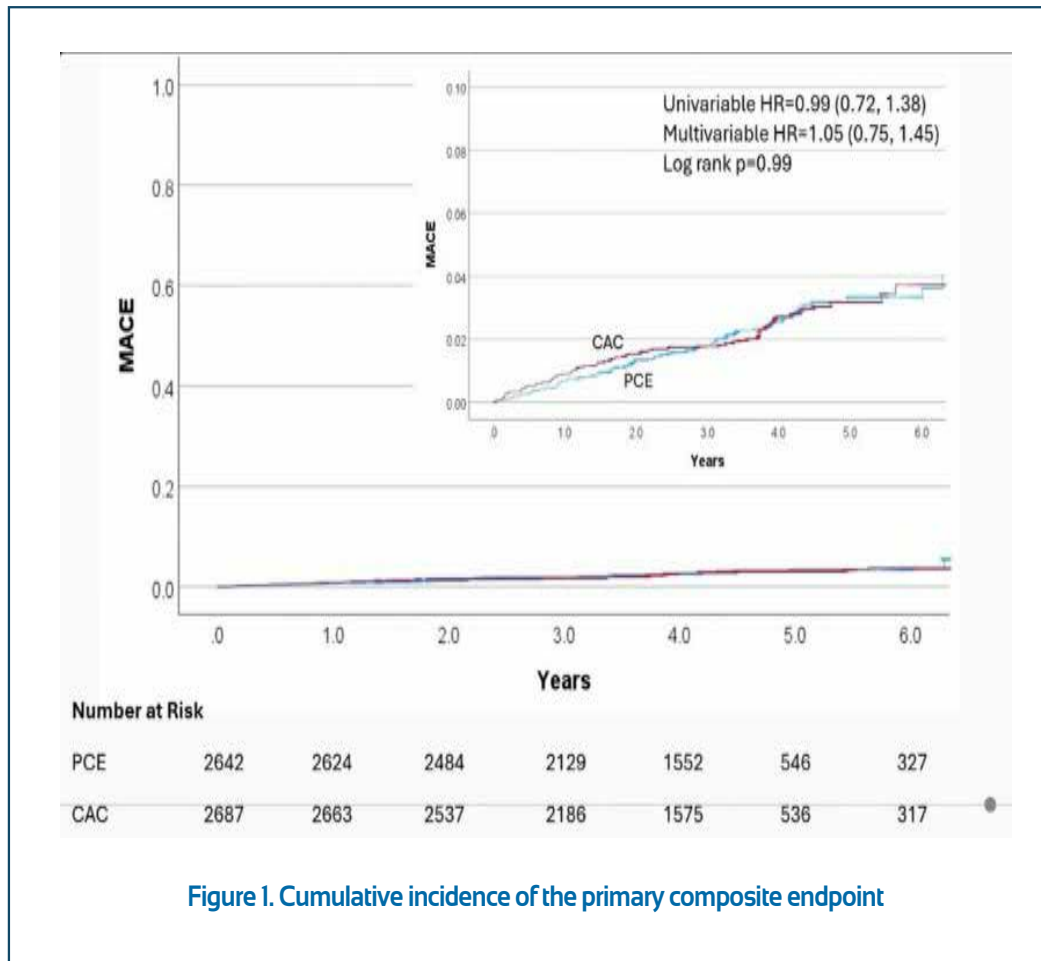


Figure 1. Cumulative incidence of the primary composite endpoint

### Study limitations:

- Lower-than-expected cardiovascular event rate reduced statistical power, Non-inferiority of CAC-guided treatment was therefore not demonstrated.
- Treatment recommendations were protocol-directed, but final treatment decisions remained with patients and physicians.

### Link to the study:

<https://www.escardio.org/news/press/press-releases/new-data-presented-on-the-use-of-coronary-artery-calcium-for-cardiovascular-risk-assessment/>

# Transcatheter Interventions for Severe Tricuspid Regurgitation in Heart Failure



Pr Ag Sarra Chenik



Resident Rayen SEBTI

*The Principal Military Hospital of Instruction of Tunis*

## Number of patients included / number per group

- Data synthesized from 3 pivotal randomized controlled trials (RCTs) evaluating transcatheter tricuspid valve interventions (e.g., TRILUMINATE Pivotal, Tri.FR) vs. medical therapy in patients with severe symptomatic tricuspid regurgitation (TR).
- Prevalence context: Severe TR affects 9% to 20% of patients with chronic heart failure (both HFrEF and HFpEF).

## Study design

- Multicenter prospective randomized controlled trials (RCTs) comparing transcatheter valve interventions (predominantly Tricuspid Transcatheter Edge-to-Edge Repair [TEER]) against conservative Guideline-Directed Medical Therapy (GDMT) alone in symptomatic severe TR.

## Aim

- To evaluate the clinical efficacy, safety, functional impact, and prognostic outcomes (quality of life, heart failure hospitalizations, and all-cause mortality) of percutaneous transcatheter tricuspid interventions as a surgical alternative in selected heart failure patients.

## Principal results

- Quality of Life (QoL): All 3 major RCTs demonstrated a statistically significant improvement in quality of life (KCCQ scores) and functional status in patients receiving transcatheter tricuspid repair compared to medical therapy.
- 1-Year Mortality & Hospitalizations: At 1-year follow-up, the combined RCT data showed no statistically significant reduction in overall mortality or overall heart failure hospitalization (HFH) rates between groups.



- Emerging TEER Data: More recent data and registry insights (e.g., EuroTR) indicate a potential benefit in reducing heart failure hospitalizations specifically with tricuspid TEER, though observed alongside a high crossover rate after 1 year.

### **study limitations**

- High rate of crossover from medical control arm to intervention after 1 year of follow-up.
- Unblinded trial designs influencing patient-reported outcome measures (QoL).
- Lack of dedicated RCTs specifically stratified or powered for distinct heart failure subgroups (HFrEF vs. HFpEF).
- Limited medical treatment options specifically targeting secondary TR pathophysiology.

### **Link to the study**

- 2026 ESC Guidelines for the management of heart failure (European Heart Journal 2026; doi:10.1093/eurheartj/ehag100).

## PRESCISE-MI:

# ESC 0/1-hour vs 0/3-hour troponin pathway in suspected myocardial infarction



Dr Housseem Thabet



Resident Amira Bouchelliga

Cardiology Department, Sahloul University Hospital

### Number of patients included:

A total of 67,624 consecutive patients presenting to the emergency department (ED) with suspected myocardial infarction (MI) were included among 71,983 patients screened. Of these, 36,464 patients were managed according to the ESC 0/3-hour pathway, while 31,160 were managed according to the ESC 0/1-hour pathway.

### Study design:

The PRESCISE-MI trial was an international, pragmatic, stepped-wedge, cluster-randomised controlled trial with masked endpoint adjudication, conducted across 19 hospitals in 10 countries, between December 2020 and December 2024. Hospitals routinely using the ESC 0/3-hour troponin pathway as standard care were randomly assigned to switch to the ESC 0/1-hour pathway either after 6 months (early implementation) or 12 months (late implementation). The trial had two co-primary outcomes:

1. **Safety:** the composite of all-cause mortality or new type 1 myocardial infarction within 30 days, assessed using a non-inferiority margin of an odds ratio (OR) of 1.30.
2. **Efficacy:** length of stay in the emergency department, assessed for superiority.

Aim: To evaluate the safety and efficacy of implementing the guideline-recommended ESC 0/1-hour pathway, compared with the ESC 0/3-hour pathway, in hospitals that had not previously adopted the 0/1-hour strategy.

### Principal results:

The median age was at 59 years, with 44.3% were women. MI was adjudicated in 8.7%. The ESC 0/1-hour pathway was non-inferior to the 0/3-hour pathway with regard to safety. The incidence of the composite outcome of all-cause mortality or new type 1 MI at 30 days was 1.1% in the 0/1-hour group compared with 1.2% in the 0/3-hour group (adjusted OR 0.93, 95% CI 0.77–1.13; p for non-inferiority = 0.0004) (Figure 1). However, implementation of the 0/1-hour pathway did not reduce ED length of stay, with a median stay of 309 minutes

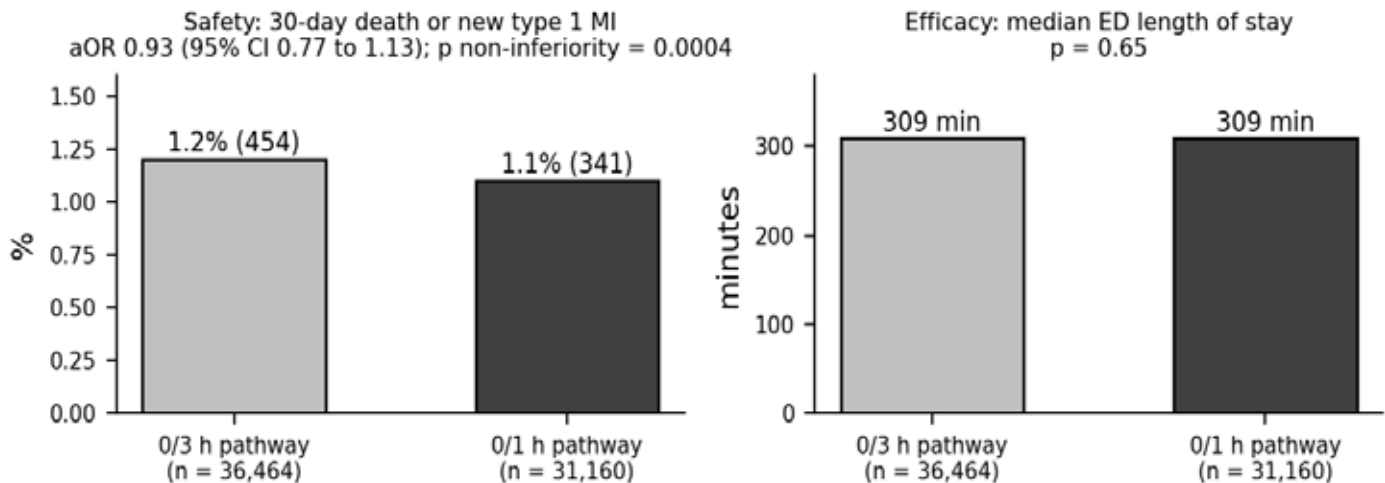


Figure 1: Co-primary outcomes of PRESCISE-MI according to the troponin pathway.

### Study limitations:

Stepped-wedge design exposing results to secular trends over time; unblinded pragmatic implementation, with possible variability in pathway adherence and laboratory turnaround times between sites; ED length of stay strongly dependent on local organization, limiting generalizability; analysis per ED presentation rather than per patient.

**Link to the study:** Lancet 2026. [https://doi.org/10.1016/S0140-6736\(26\)01654-5](https://doi.org/10.1016/S0140-6736(26)01654-5)

# Timing of PCI in Patients Undergoing Transcatheter Aortic-Valve Implantation: TAVI PCI trial



Dr Mohamed Ali Tekaya

*Department of Cardiology, Abderahmen Mami Hospital, Ariana.*



Résident Touati Haithem

## Patients:

986 with severe aortic stenosis and concomitant coronary artery disease (498 TAVI-first vs 488 PCI-first); median age 82 years, median STS-PROM ~3%.

## Design:

International, open-label, randomized (1:1), noninferiority trial in 48 European centers; TAVI then angiography-guided PCI vs PCI then TAVI (second procedure within 1 to 45 days); blinded event adjudication  
Aim: To test whether a TAVI-first strategy is noninferior to a PCI-first strategy

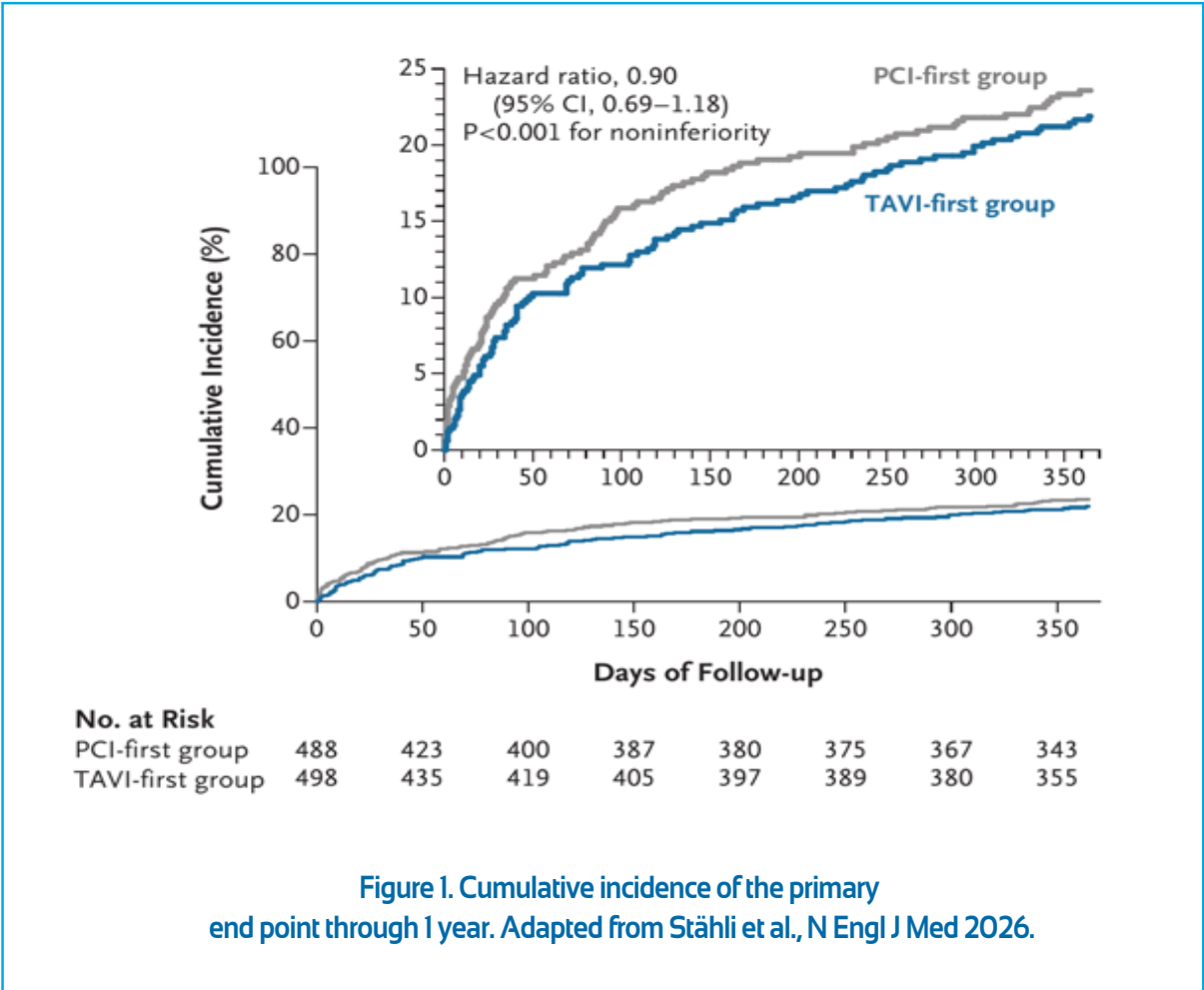
## Principal results

- 1-year composite (death, MI, ischemia-driven revascularization, valve-/procedure-/HF-related rehospitalization, major bleeding): 105/473 vs 112/463, i.e. 22.2% vs 24.2% (Figure 1); RD -2.0 points (95% CI -7.4 to 3.4);  $P < 0.001$  for noninferiority (margin 6.6 points);  $P = 0.47$  for superiority
- Death 9.5% vs 9.5%; major bleeding 6.6% vs 9.7%; serious adverse events 53.0% vs 55.9%
- Fewer TAVI-first patients underwent PCI (no vessel treated: 12.7% vs 3.5%); PCI failure due to the valve prosthesis was uncommon
- PCI does not necessarily have to come first; the sequence can be individualized by the Heart Team

## Study limitations

- Open-label design (key events adjudicated by a blinded committee)
- Event rate higher than planned (22–24% vs 15% assumed): reduced power; upper CI bound (3.4) still compatible with a relative excess of events with TAVI-first
- Low coronary complexity (median SYNTAX II 10;  $\geq 33$  excluded); acute MI, prior CABG and prior aortic stenosis treatment excluded
- Women underrepresented; not generalizable to non-transfemoral TAVI or supra-annular valves

**Link to the study:** <https://www.nejm.org/doi/full/10.1056/NEJMoa2606924>





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# Met-HeFT = Metformin in chronic Heart Failure



Dr Ameni Mardessi



Resident Wissal Hamdi

*Habib Thameur Hospital*

## 1. Number of patients included:

A total of 940 patients were included in the final analysis (470 in the Metformin group vs. 470 in the Placebo group). Participants had a mean age of ~70 years and symptomatic chronic HFrEF (LVEF  $\leq 40\%$ ) with prediabetes, T2DM, or increased metabolic risk (only ~10% had established type 2 diabetes). Patients with significant renal dysfunction (eGFR  $\leq 35$  mL/min/1.73 m<sup>2</sup>) were excluded.

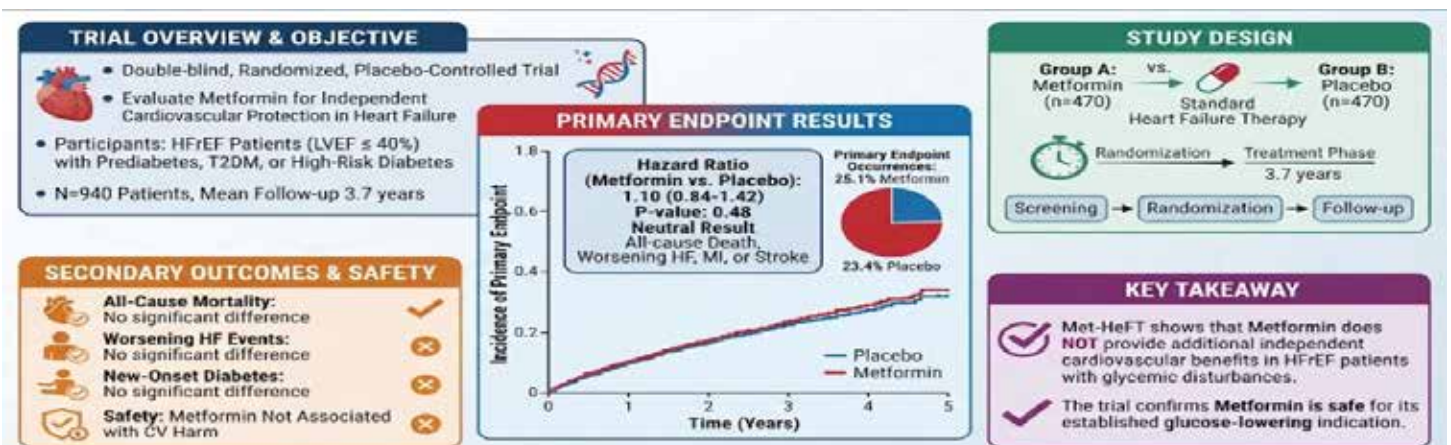
## 2. Study Design:

Met-HeFT was a multicenter, randomized, double-blind, placebo-controlled trial conducted as part of the DANHEART 2x2 factorial trial. Patients were randomized 1:1 to receive metformin or a matching placebo alongside guideline-directed heart failure therapy, with a target dose up to 2,000 mg/day.

## 3. Aim:

Patients were followed for a mean of 3.7 years. The primary objective was to determine if metformin reduced a composite of all-cause death, worsening heart failure, acute myocardial infarction, and stroke

## 2. Principle results:





### **3. Study limitations:**

- Population Characteristics: Only ~10% of patients had established type 2 diabetes, meaning the trial primarily evaluated patients with prediabetes or increased metabolic risk rather than an established T2DM population.
- Sample Size & Event Rates: The final sample size of 940 patients was lower than the initially planned ~1,100, and a relatively low event rate in contemporary HFrEF management may have limited the power to detect a modest treatment effect.
- Generalizability: Because patients with significant renal dysfunction were excluded, results cannot be directly extrapolated to advanced chronic kidney disease patients.

### **Link to the study :**

<https://www.escardio.org/news/press/press-releases/no-significant-evidence-for-protection-against-cardio-vascular-outcomes-with-metformin-in-heart-failure>

## ECLIPSE-CKD

# Effect of a Potassium-Enriched Salt Substitute on Blood Pressure in Patients with Chronic Kidney Disease



Dr Malek ElArbi



Resident Mohamed Aziz Reguigui

*Cardiology Department, Charles Nicole Hospital*

### Number of patients included / number per group:

A total of 640 patients with hypertension and mild-to-moderate chronic kidney disease (CKD stages G2–G3a) were included and randomly assigned in a 1:1 ratio, with approximately 320 patients in the salt-substitute group and 320 in the regular-salt group.

### Study design:

ECLIPSE-CKD was a multicentre, randomized, open-label, parallel-group superiority trial with a 3-month follow-up. Patients were assigned either to a potassium-enriched salt substitute containing 75% sodium chloride and 25% potassium chloride or to regular salt containing 100% sodium chloride.

### Aim:

The aim of the study was to determine whether replacing regular salt with a potassium-enriched salt substitute could reduce blood pressure in patients with hypertension and CKD, while assessing the safety of this strategy, particularly with regard to the risk of hyperkalaemia.

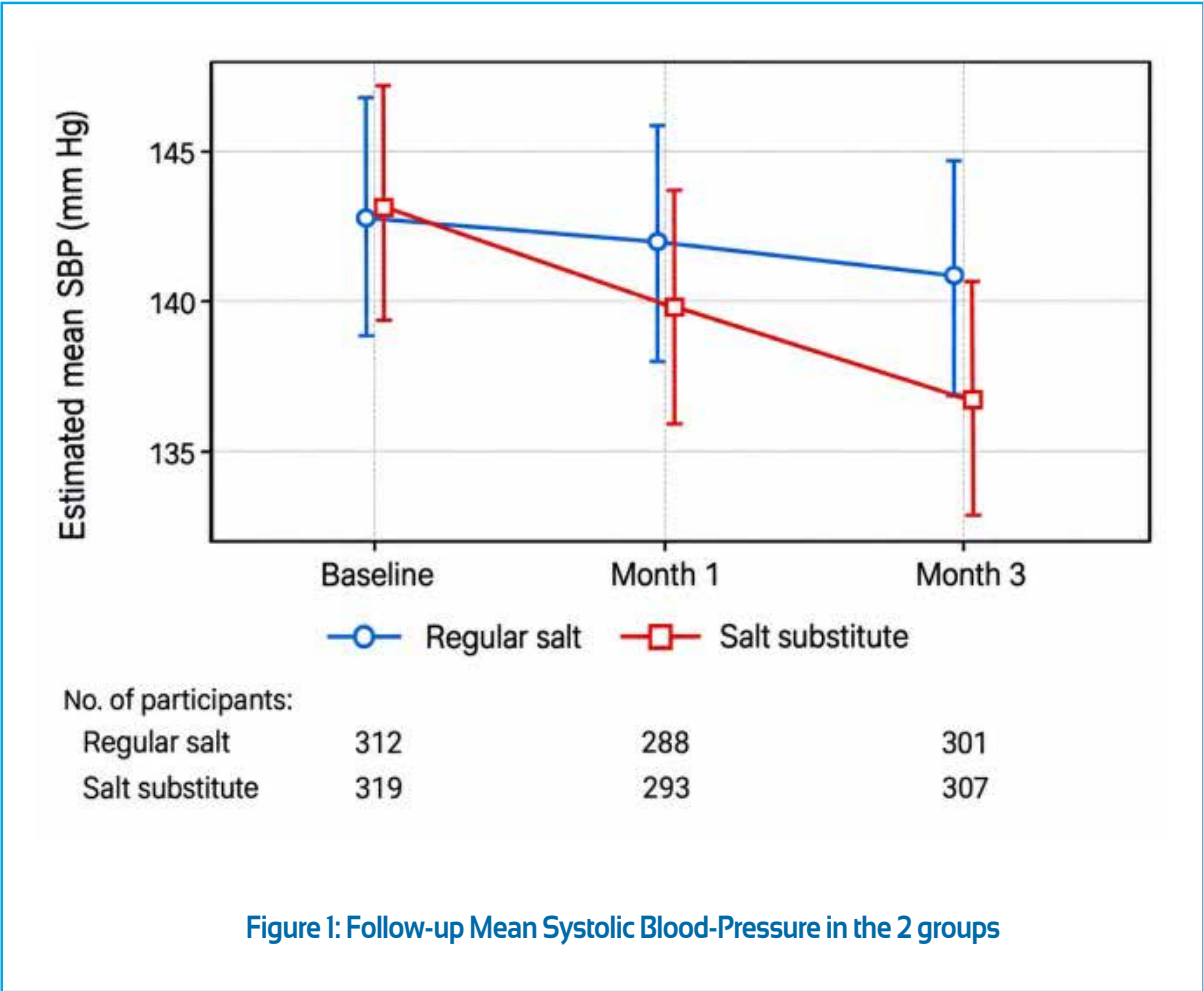
### Principal results:

At 3 months, systolic blood pressure decreased by approximately 6.6 mmHg in the salt-substitute group compared with 2.0 mmHg in the regular-salt group, resulting in a between-group difference of approximately -4.3 mmHg (95% CI -6.4 to -2.2;  $p < 0.001$ ). Diastolic blood pressure also showed a significantly greater reduction with the salt substitute. Serum potassium increased modestly, by approximately 0.2 mmol/L, but no episodes of hyperkalaemia were reported during the study period.

### Study limitations:

The main limitations were the short follow-up of only 3 months, the inclusion of patients predominantly with mild-to-moderate CKD (G2–G3a), and the exclusion of patients with previous hyperkalaemia or high baseline potassium levels. Therefore, the long-term effects on renal function and cardiovascular outcomes remain uncertain, and the findings cannot necessarily be extrapolated to patients with advanced CKD or a high risk of hyperkalaemia.

**Link to the study:** ESC – ECLIPSE-CKD presentation



# EVAOLD: Evaluation of reperfusion strategies in elderly patients



Dr Malek ElArbi



Resident Mani Yasmin

*Charles Nicole Hospital, Cardiology department*

## Number of patients included:

587 randomized at interim analysis (planned n=1,756). Modified ITT: 572 patients.

Number per group: 282 imaging-guided vs 290 routine invasive.

## Study design:

The EVAOLD trial is a multicenter, prospective, open label, randomized controlled non-inferiority trial with two parallel arms conducted across 25 centers in France

## Aim:

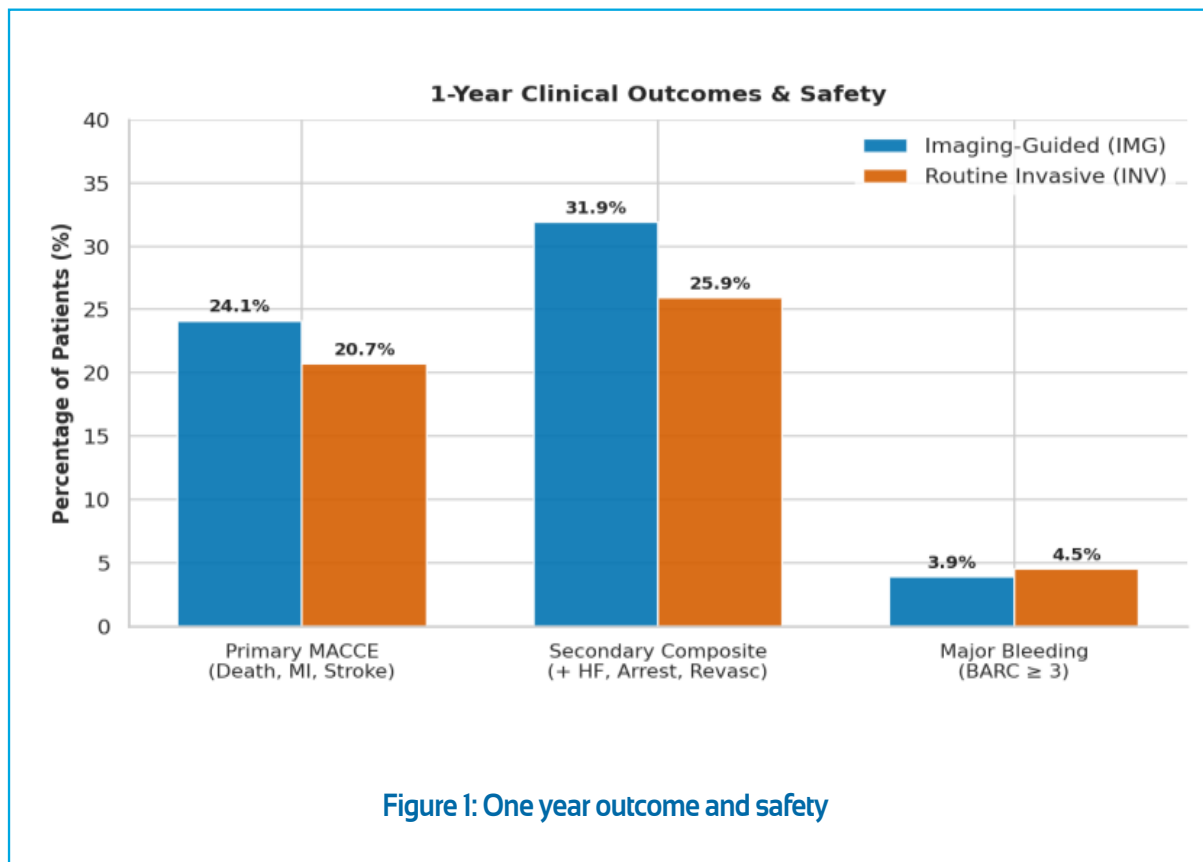
The primary aim of the trial is to test whether a selective invasive strategy guided by noninvasive ischemia stress imaging is noninferior to a routine invasive strategy in preventing 1-year Major Adverse Cardiac and Cerebrovascular Events (MACCE) in patients aged 80 years or older hospitalized for NSTEMI. Secondary aims include evaluating potential superiority if noninferiority is demonstrated, measuring impacts on patient frailty, autonomy, and quality of life through detailed geriatric assessments, and evaluating 12-month cost-effectiveness and budget impact.

## Principal results:

The trial was stopped early for futility after 587/1,756 planned patients were randomized. At 1 year, the primary endpoint of all-cause death, non-fatal MI or non-fatal stroke occurred in 24.1% with stress-imaging-guided selective invasive management versus 20.7% with routine invasive management (HR 1.22; 95% CI 0.86–1.72; p=0.27). Non-inferiority was not demonstrated. The selective strategy reduced coronary angiography and angiography-related complications but did not demonstrate comparable clinical outcomes.

## Study limitations:

The trial was terminated prematurely after only 587 of the planned 1,756 patients had been randomized, limiting statistical power and precision of the estimates. The event rate was lower than anticipated, contributing to the futility decision. In addition, implementation of the stress-imaging-guided strategy was challenging in this very elderly population, which may have affected its feasibility.



**Link to the study:** [ClinicalTrials.gov: NCT03289728](https://clinicaltrials.gov/ct2/show/study/NCT03289728) | ESC EVAOLD trial report, ESC Congress 2026

# Timing of Coronary Angiography After Cardiac Arrest Without ST-Elevation: an Individual Patient Data Meta-Analysis of Five Randomized Trials (DISCO, COACT, TOMAHAWK, COUPE, PEARL)



Doctor Chaima Ghorbel



Resident Soyed Syrine

*Department of Cardiology, Kasserine Hospital – Abderrahmen Mammi Ariana Hospital*

## Number of patients included / number per group:

2,173 patients pooled from 5 RCTs — Immediate CAG strategy: n = 1,091; Deferred/selective CAG strategy: n = 1,082.

## Study design:

Individual patient data (IPD) meta-analysis of 5 randomized controlled trials (DISCO, COACT, TOMAHAWK, COUPE and PEARL) comparing an immediate versus a deferred/selective coronary angiography (CAG) strategy in patients successfully resuscitated after out-of-hospital cardiac arrest (OHCA) without ST-segment elevation on the post-ROSC ECG. Presented as a Hot Line at ESC Congress 2026 (Munich, 31 August 2026).

Aim: To determine whether an immediate CAG strategy improves 30-day survival compared with a deferred/selective strategy in OHCA patients without ST-elevation, and to identify subgroups that may derive differential benefit.

## Principal results:

No significant difference in the primary endpoint (30-day survival): 54% with immediate CAG vs 57% with deferred/selective CAG (HR 1.09, 95% CI 0.96–1.23; log-rank p = 0.192). CAG was performed far more often in the immediate arm (96% vs 57%, p<0.001) and much earlier (median 1h vs 90h), but a culprit lesion was found at a similar rate in both groups (22% vs 24%, p = 0.460), with no significant difference in PCI performed (30% vs 35%, p = 0.059). These findings are consistent with the neutral results of DISCO alone and with the prior COACT/TOMAHAWK IPD meta-analysis (Spoormans et al., JAMA Cardiol 2025) at 1-year follow-up.

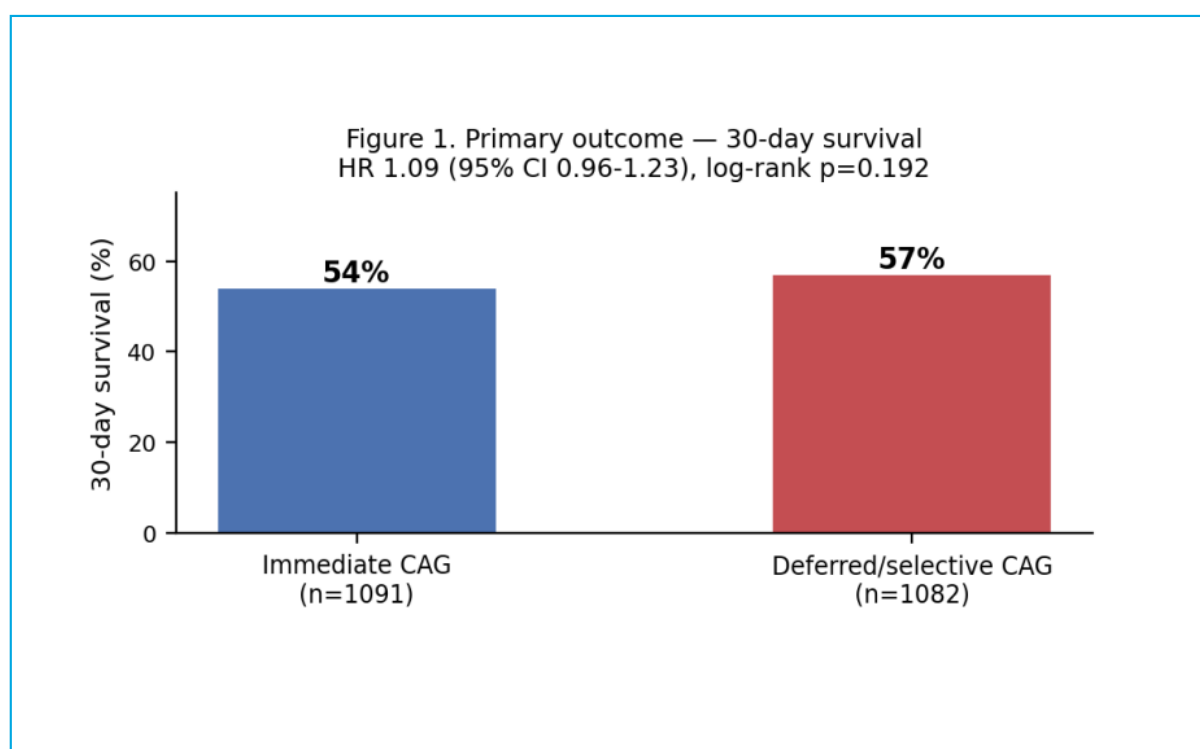
## Study limitations:

## Study limitations:

Open-label design in all included trials (no blinding of treatment strategy); heterogeneity across trials in the definition and timing of the "deferred/selective" strategy; predominantly shockable-rhythm populations in some trials (e.g., COACT), limiting generalizability to non-shockable OHCA; results presented at a congress Hot Line session and not yet published as a full peer-reviewed IPD article for this pooled 5-trial cohort; potential residual confounding despite patient-level pooling.

## Link to the study:

ESC Congress 2026 press release — [escardio.org](https://escardio.org) ("Should patients with an out-of-hospital cardiac arrest and without an ECG ST-elevation receive immediate coronary angiography?", 31 Aug 2026); related publication: Spoormans EM et al., JAMA Cardiology 2025;10(8):779-786 (COACT/TOMAHAWK IPD, 1-year outcomes).



# Anticoagulation Monotherapy vs Antiplatelet Monotherapy After Transcatheter Aortic Valve Implant The ACASA-TAVI Randomized Clinical Trial



Dr Oumayma Zidi



Resident Rania Aouini

*Cardiology Department Abderrahman Mami Hospital*

## **Number of patients included / number per group:**

360 patients randomized 1:1 (180 NOAC / 180 aspirin); 336 completed the 12-month follow-up.

## **Study design:**

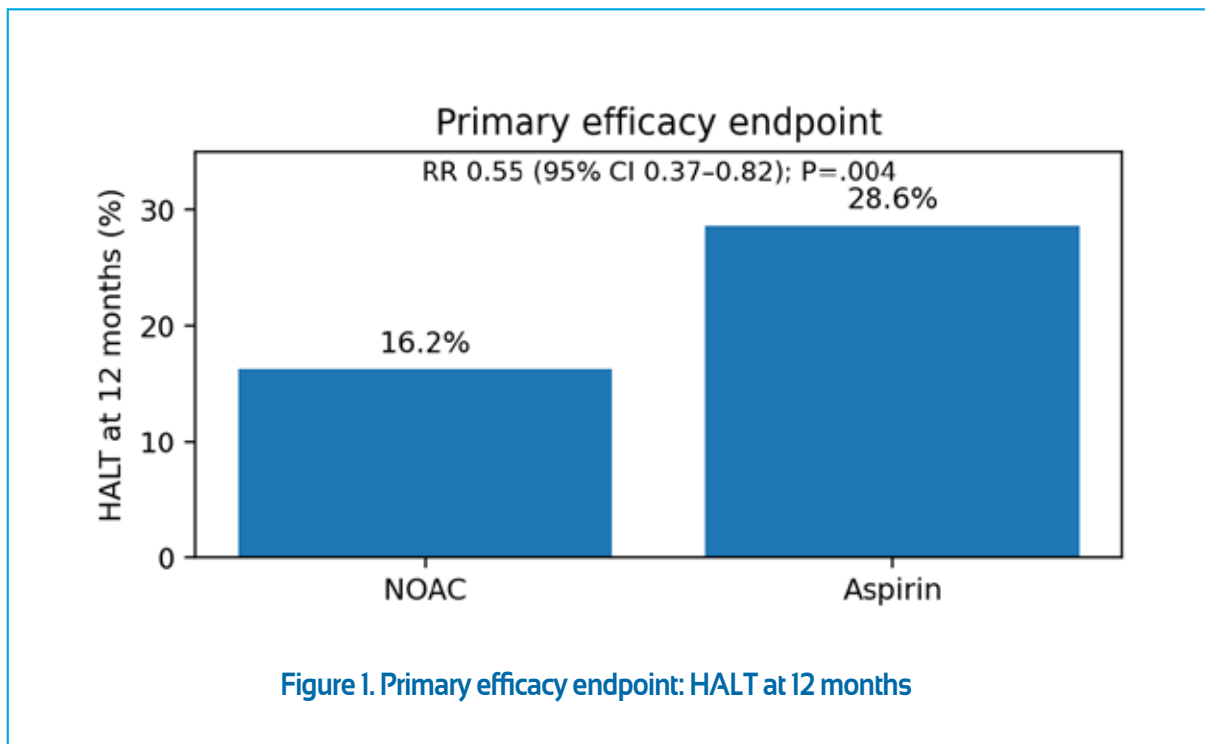
Prospective, multicenter, randomized, open-label, blinded-endpoint trial conducted at 3 Norwegian centres. Patients aged 65–80 years after successful TAVI for severe aortic stenosis were assigned to 12 months of factor Xa inhibitor NOAC monotherapy or aspirin monotherapy.

## **Aim:**

To determine whether NOAC monotherapy, compared with aspirin monotherapy, reduces subclinical leaflet thrombosis (HALT) after TAVI (primary efficacy endpoint), without compromising safety (primary safety endpoint: VARC-3 bleeding events, thromboembolic events, or all-cause death).

## **Principal results:**

At 12 months, HALT occurred in 16.2% of the NOAC group versus 28.6% of the aspirin group (RR 0.55; 95% CI, 0.37–0.82;  $P=0.004$ ). The primary safety endpoint occurred in 7.5% versus 10.6%, respectively (risk difference – 3.3%; 95% CI, –9.5% to 2.8%), meeting the prespecified criterion for noninferiority ( $P<0.001$ ).



### Study limitations:

The open-label design may have influenced behaviour and event reporting. Inclusion was restricted to patients aged 65–80 years, limiting generalizability to older TAVI populations.

**Link to the study:** JAMA. Published online August 30, 2026. doi:10.1001/jama.2026.17036

# The Heart Runner Trial: Out-of-Hospital Cardiac Arrest Survival following Community First Responder activation



Dr Ridha FEKIH

*Cardiology Department; Regional Hospital of Kébili*



Resident Amany CHAOUECH

*Cardiology Department Abderrahmen Mami Hospital*

## Number of patients included / number per group

Of 4,581 randomised suspected cardiac arrests, 2,060 confirmed eligible cases were analysed: 1,041 with volunteer activation and 1,019 controls without activation. <sup>[1]</sup>

## Study design

This randomised superiority trial in Denmark's Capital Region (2019–2026) compared standard care with or without smartphone activation of community first responders (volunteers). Eligible arrests were non-traumatic, in patients aged  $\geq 8$  years, outside nursing homes, with no defibrillator on scene. Volunteers were directed to provide cardiopulmonary resuscitation (CPR) or retrieve a defibrillator. Allocation was 1:1 within estimated volunteer arrival strata ( $< 3$  or 3–9 minutes after activation), blinded to dispatchers and investigators. <sup>[1,2]</sup>

## Aim

To determine whether volunteer activation improves 30-day survival after out-of-hospital cardiac arrest compared with standard care alone. <sup>[1,2]</sup>

## Principal results

Thirty-day survival did not differ significantly in either stratum (Figure 1). At  $< 3$  minutes, activation increased bystander CPR (85% vs 78%;  $p=0.004$ ) and defibrillation (19% vs 11%;  $p=0.0014$ ). At 3–9 minutes, CPR increased to 86% vs 75% and defibrillation to 14% vs 6% (both  $p<0.0001$ ). <sup>[1]</sup> Survival with a favourable neurological outcome and return of spontaneous circulation were reported as similar between groups. <sup>[3]</sup>

### Study limitations

In the control group receiving standard care without volunteer activation, 75–78% of patients already received bystander CPR before ambulance arrival. This high rate, approximately 30% initial shockable rhythms and five minutes from volunteer activation to ambulance arrival may have limited survival gains. These explanations remain hypotheses. Confidence intervals allow benefit or harm; generalisability to slower emergency responses is uncertain. [1]

### Link to the study

- 1. Hot Line presentation: Folke F. European Society of Cardiology Congress 2026. [Link](#)
- 2. Protocol: Folke F, et al. Resusc Plus. 2026;31:101420. [Link](#)
- 3. Press release: European Society of Cardiology. 31 August 2026. [Link](#)

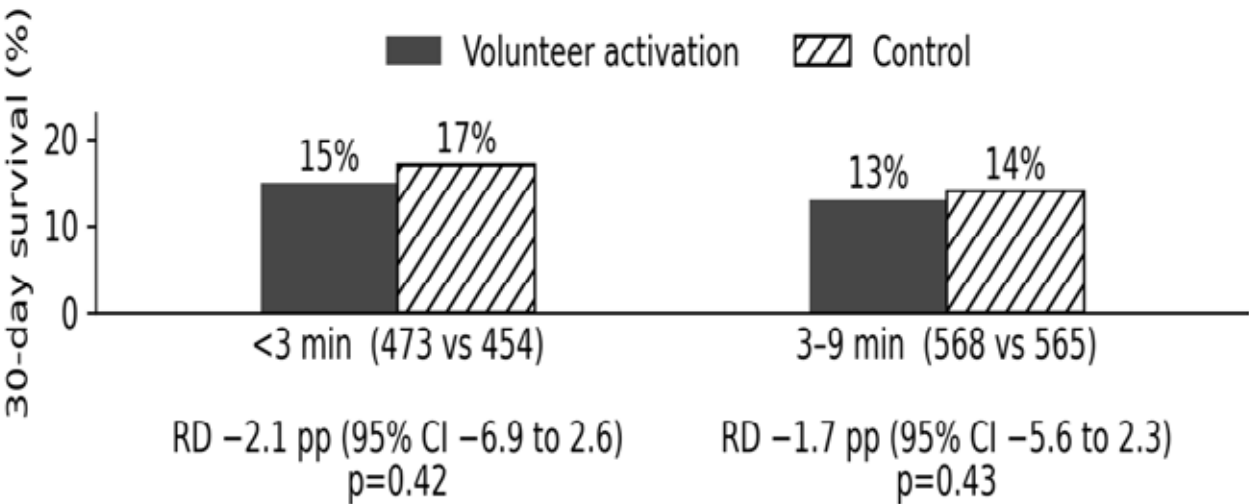


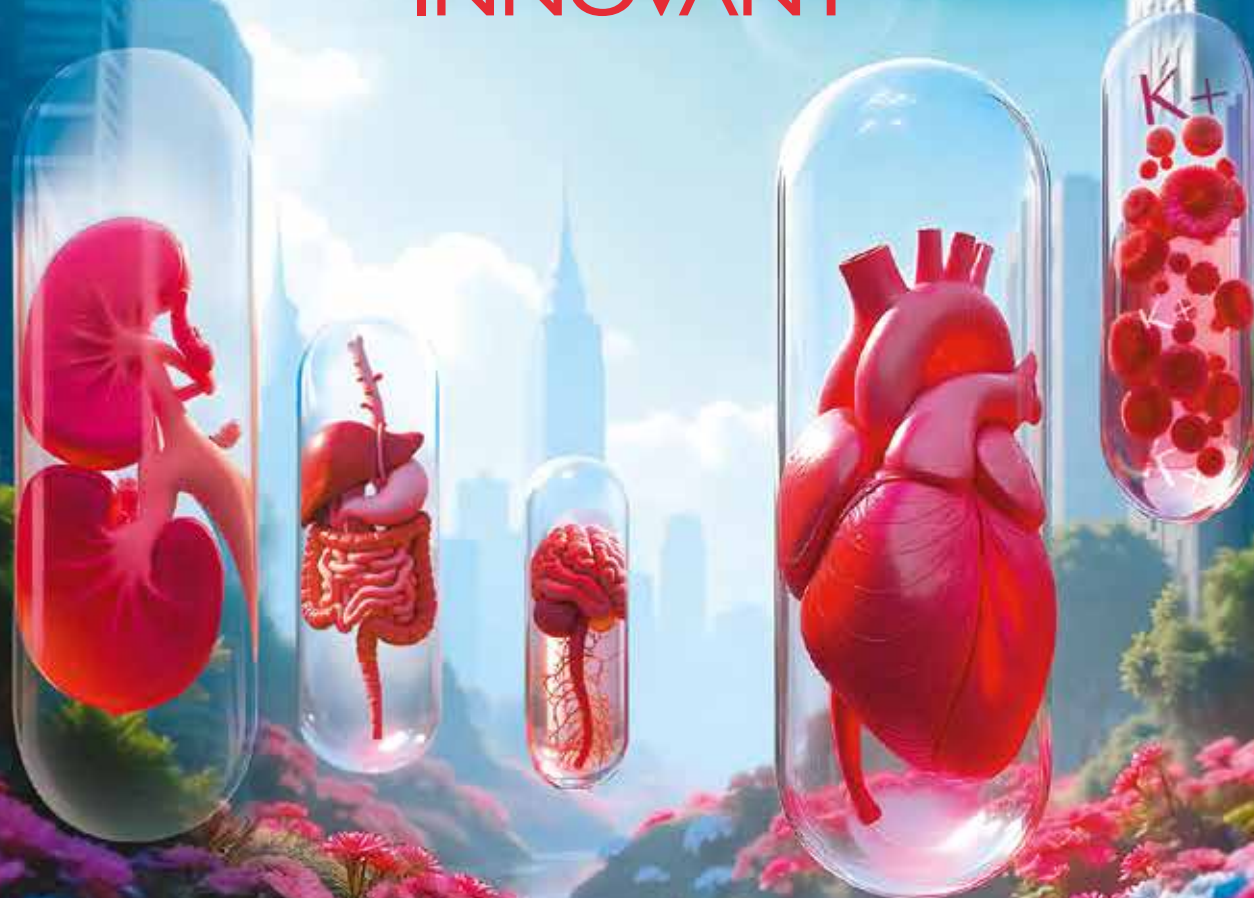
Figure 1. Thirty-day survival. Group sizes: activation/control. RD, risk difference; pp, percentage points; CI, confidence interval. [1]



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# A Randomized Clinical Implementation Trial Testing a Digital Strategy to Increase SGLT2 Inhibitor Initiation in Heart Failure



Dr Oumayma Zidi

*Cardiology Department, Abderrahman Mami Hospital, Ariana*



Resident Wiem Satouri

## Study design:

In this pragmatic, randomized, registry-based trial conducted in Denmark, a total of 5,996 patients with heart failure who were not receiving an SGLT2 inhibitor were randomly assigned in a 1:1 ratio to a digital implementation strategy (n=2,979) or usual care (n=3,017).

Patients in the intervention group received a Digital Post letter providing information on SGLT2 inhibitors and an invitation to undergo specialist assessment through a telephone consultation. The specialist reviewed the patient's medical record and assessed the indication for treatment with dapagliflozin or empagliflozin.

## Aim:

The aim of the study was to determine whether a proactive digital strategy for identifying and contacting patients with heart failure could increase the initiation of SGLT2 inhibitor therapy within 6 months.

The primary endpoint was initiation of dapagliflozin or empagliflozin within 6 months after randomization.

The key secondary endpoint was the first hospitalization for heart failure or all-cause death.

## Principal results:

At 6 months, SGLT2 inhibitor initiation was significantly higher in the digital strategy group than in the usual-care group (18.6% vs. 8.2%;  $p < 0.001$ ), corresponding to an absolute difference of 10.4 percentage points and a more than two-fold increase in treatment initiation.

The first hospitalization for heart failure or all-cause death occurred in 13.0% of patients in the digital strategy group compared with 14.0% in the usual-care group ( $p = 0.28$ ), with no statistically significant difference between the two groups.

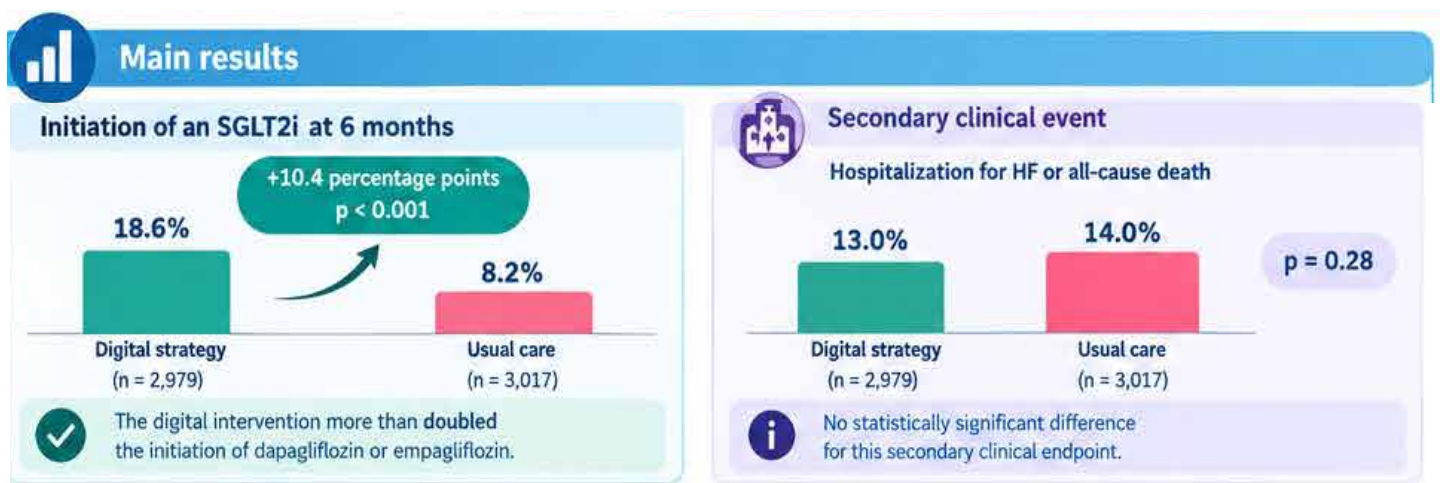
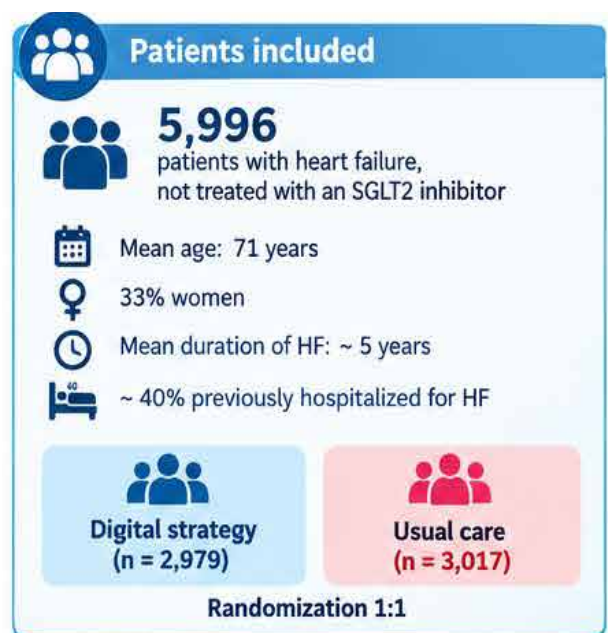
Among patients receiving the digital invitation, approximately 60% responded to the intervention.

## Study limitations:

The intervention could not be blinded, and its effectiveness may depend on the availability of a well-developed national digital infrastructure. The generalizability of the findings to healthcare systems with different digital and organizational structures may therefore be limited.

In addition, approximately 40% of patients in the digital strategy group did not respond to the invitation, and most patients in the intervention group did not initiate an SGLT2 inhibitor within 6 months.

**Link to the study:** <https://www.jacc.org/doi/10.1016/j.jchf.2026.103176?utm>



# Low-Voltage Ablation in Persistent Atrial Fibrillation IDEAL-AF Randomized clinical trial



Dr Manel Ben Halima



Resident Ben Fraj Nour El Ouyoun

*Service de Cardiologie Hôpital la Rabta*

## Number of patients included / Number per group

209 patients randomized (out of 936 adults undergoing a first ablation with voltage mapping for persistent AF): 102 in the PVI + low-voltage zone (LVZ) ablation group and 107 in the PVI-alone group. Median age 72 years; 109 females (52.2%).

## Study design

Multicenter randomized clinical trial conducted at 5 Swedish ablation centers (May 18, 2020 to April 9, 2026), with 12 months of follow-up. After pulmonary vein isolation (PVI), patients with LVZ of 3.0 cm<sup>2</sup> or greater were randomized to individualized adjunctive LVZ ablation or no further ablation.

## Aim

To determine whether adjunctive individualized LVZ ablation improves arrhythmia outcomes and health-related quality of life beyond PVI alone in patients with persistent atrial fibrillation (AF) and significant LVZ.

## Principal results

Primary outcome (freedom from documented atrial arrhythmia without antiarrhythmic drugs at 12 months, after 1 or 2 procedures): 67.6% (69 patients) with PVI + LVZ ablation vs 37.4% (40 patients) with PVI alone (unadjusted difference 30.3%, 95% CI 17.4%-43.2%; OR 3.5, 95% CI 2.0-6.2;  $P < .001$ ). Time to first recurrence after a single procedure without antiarrhythmic drugs also favored LVZ ablation (HR 0.4, 95% CI 0.3-0.6;  $P < .001$ ). Quality-of-life improvement was greater in the LVZ ablation group, with similar rates of serious adverse events in both groups.

## Study limitations

Only patients with significant LVZ ( $\geq 3.0$  cm<sup>2</sup>) were randomized, so the results cannot be extrapolated to persistent AF without LVZ. Conducted in Swedish ablation centers only, with a 12-month follow-up. (Note: derived from the design in the abstract; to be completed with the authors' own limitations section from the full text.)

**Link to the study** <https://jamanetwork.com/journals/jama/article-abstract/2853398> (JAMA 2026; doi:10.1001/jama.2026.17274; ClinicalTrials.gov NCT04377594)

# Catheter ablation for symptomatic atrial fibrillation (PVI-SHAM-AF)



Dr Manel Ben Halima



Resident Nour Saidi

*Service de Cardiologie Hôpital la Rabta*

## Number of patients included / Number per group

262 patients randomised (out of 1199 screened and invited; 937 declined): 173 to catheter ablation (168 actually treated, 5 withdrew consent before the procedure) and 89 to the sham procedure.

## Study design

Investigator-initiated, multicentre (9 sites, Germany and Poland), randomised, double-blind, sham-controlled trial (2021–2025).

**Population:** adults with symptomatic paroxysmal or persistent AF and a class I/IIa indication for catheter ablation (ESC 2020); LVEF <35% and prior PVI excluded. Median age 67 years, 51% women; 54% vs 45% persistent AF (ablation vs sham).

**Randomisation:** 2:1 (ablation vs sham), variable blocks, stratified by site; separate masked and unmasked teams; blinding index 0.06 (95% CI -0.07 to 0.19). Interventions: PVI (radiofrequency 61%, cryoballoon 34%, pulsed-field 5%) vs sham (deep analgesedation ≥60 min, two venous sheaths, no catheter, no transseptal puncture, cardioversion if in AF).

**Primary endpoint:** change in AFEQT summary score from baseline to 6 months (ITT, multiple imputation, Wilcoxon–Mann–Whitney test, Hodges–Lehmann estimate). Sample size 260 for 80% power to detect an 8-point difference. 12-month follow-up ongoing.

## Aim

To determine whether catheter ablation improves AF-related quality of life more than a sham procedure at 6 months in patients with symptomatic AF.

## Principal results

**Primary endpoint (not met):** AFEQT summary score rose from 61.3 to 81.1 with ablation and from 59.2 to 74.9 with sham; between-group difference in change 2.6 points (95% CI -2.7 to 8.0;  $p=0.36$ ). Prespecified mixed-model sensitivity analysis: 5.4 points (95% CI 1.0 to 9.8). Probability of stochastic superiority 0.54 (95% CI 0.47–0.62).



**Rhythm outcomes (favoured ablation):** AF on 7-day Holter at 6 months 21% vs 41% (adjusted difference -20.1 points, 95% CI -32.6 to -7.7); mean AF burden 11.6% vs 23.6%; clinically detected recurrence 13% vs 19% (HR 0.66, 95% CI 0.35–1.24).

**Other endpoints:** no clear difference in EQ-5D-3L, SF-36 or NT-proBNP; AFEQT subscale symptoms and daily activities showed nominal differences (exploratory). Nominal subgroup interaction by NT-proBNP ( $p=0.005$ ), hypothesis-generating only.

**Safety:** one death in each group both unrelated to the procedure. Related or possibly related serious adverse events in 10 patients (6 ablation vs 4 sham), including one ischaemic stroke in the sham group. Five vascular access complications (3 vs 2), one sham pseudoaneurysm requiring embolisation.

**Conclusion:** catheter ablation did not show superiority over sham for AF-related quality of life at 6 months, despite better rhythm control; part of the symptomatic improvement after ablation may not be attributable to the procedure itself (placebo, Hawthorne effect, regression to the mean, optimised follow-up).

### Study limitations

**Selection:** 78% of invited patients declined (willingness to accept a sham may have selected patients with different symptom burden or expectations); no AFEQT cut-off for inclusion; imbalance in sex between groups (45% vs 63% women). Rhythm assessment: AF burden not assessed at baseline; no continuous ECG monitoring, so recurrences may be underestimated.

**Heterogeneity:** mixed ablation techniques with few pulsed-field procedures (5%), limiting generalisability; antiarrhythmic drug changes may have attenuated the effect.

**Follow-up and analyses:** 6 months may be too short to capture the full benefit; subgroup and secondary analyses not adjusted for multiplicity nor powered; the sham was an active care pathway, so the trial estimates the incremental effect of ablation only, and sham-group improvement was large.

### Link to the study

Wachter R, et al. Lancet 2026; 408: 999–1009. [https://doi.org/10.1016/S0140-6736\(26\)01558-8](https://doi.org/10.1016/S0140-6736(26)01558-8) (ClinicalTrials.gov NCT051

# Cardiovascular Magnetic Resonance to Guide Defibrillator Implantation for LVEF of 36% to 50%: The CMR GUIDE Randomized Clinical Trial



Pr Ag Emna ALLOUCHE

*Charles Nicole Hospital*



Resident Nawel SOLI

## Number of patients included/number per group:

353 randomized patients (median age 65 years; 18% female; 72% ischemic cardiomyopathy; 70% with LVEF  $\geq$  40%; median follow-up 6.3 years). ICD group 180 and ILR group 173.

## Study design:

International, multicenter (18 centers across Australia, Germany and the UK), open-label, randomized controlled trial with blinded endpoint evaluation (PROBE design)

## Aim:

To determine whether primary-prevention ICD therapy reduces the composite endpoint of SCD or hemodynamically significant ventricular arrhythmia (HSVA) compared with ILR in patients with mildly-to-moderately reduced LVEF (LVEF 36% to 50%) and myocardial scar identified by LGE-CMR.

## Principle results:

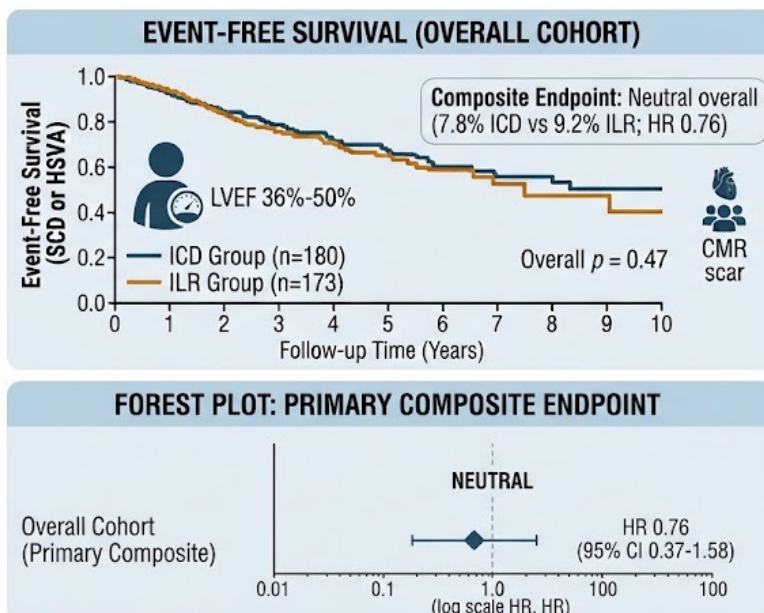
The primary composite endpoint (SCD or HSVA): neutral overall across the study cohort, occurring in 14 patients (7.8%) in the ICD group vs. 16 patients (9.2%) in the ILR group (HR 0.76; 95% CI, 0.37–1.58;  $p=0.47$ ). However, evaluating individual components revealed a significant reduction in SCA with ICD implantation (1.7% vs. 5.8%; HR 0.26; 95% CI, 0.07–0.95), offset by a higher detection rate of HSVA in the ICD group (6.7% vs. 3.5%; HR 1.77), due to intracardiac lead sensitivity. However, a prespecified subgroup analysis showed a marked clinical benefit of ICD therapy on the primary composite outcome in patients younger than 70 years (HR 0.28; 95% CI, 0.09–0.89), whereas no benefit was observed in patients aged 70 or older.

## Study limitations:

The trial was primarily constrained by limited statistical power due to an overall lower-than-expected primary event rate in an intermediate-LVEF cohort treated with modern guideline-directed medical therapy. Additionally, differences in arrhythmia detection sensitivity between intracardiac ICD leads and subcutaneous ILR monitors introduced an inherent diagnostic asymmetry, while open-label device allocation and an extended recruitment period during an era of evolving heart failure pharmacotherapy represent further methodological limitations despite blinded endpoint adjudication.

**Link to the study:** <https://doi.org/10.1001/jama.2026.17078>

### CMR GUIDE TRIAL: PRIMARY COMPOSITE ENDPOINT COMPARISON (LVEF 36%-50% WITH SCAR)



**KEY TAKEAWAY:** ICD therapy was neutral overall for the primary endpoint ( $p=0.47$ ). However, in patients younger than 70 years, a marked clinical benefit was observed (HR 0.28). This supports age-stratified decision-making in LGE-scar(+) intermediate-LVEF cohorts.

Figure 1 Primary Composite Endpoint

# Pulmonary-Artery Denervation For Pulmonary Hypertension Associated with Left Heart Disease and Heart Failure — The Padn-Ph-Lhd Trial



Dr Hanen BRAHMI



Resident Amdouni Baraa

*Hospital Ibn Al Jazzar Kairouan, service de cardiologie*

## Number of patients included /per group

264 patients — PADN + GDMT: n = 134 | GDMT alone (control): n = 130. Multicenter trial across up to 39 centers in China.

## Study design

Prospective, multicenter, randomized controlled trial (NCT05824923). Chronic HF patients on stable GDMT (2023 ESC HF Guidelines) with PH-LHD confirmed by right heart catheterization, randomized 1:1 to PADN (radiofrequency ablation at the left PA ostium and distal main PA bifurcation) + GDMT, or GDMT alone. Median follow-up 338 days.

## Aim

To evaluate whether pulmonary-artery denervation, added to guideline-directed medical therapy, reduces clinical worsening in patients with pulmonary hypertension associated with left heart disease and heart failure — a population with no approved targeted therapy.

## Principal results

2-year Kaplan-Meier clinical worsening (composite of death, heart/lung transplantation, HF hospitalization, outpatient HF worsening, or 6-minute walk distance decline): 25.7% (PADN + GDMT) vs 51.5% (GDMT alone) — HR 0.49 (95% CI 0.30–0.82),  $P = 0.006$ .

## Study limitations

Single-country cohort (China); relatively short median follow-up for a chronic progressive disease; procedural blinding not established in this design — sham-controlled confirmatory trials (PULSE-LHD, US/EU) are ongoing; long-term durability and broader HFpEF/HFrEF generalizability remain unconfirmed.

**Link of the study** ESC Congress 2026 Hot Line — PADN-PH-LHD; simultaneously published in the New England Journal of Medicine (2026). ClinicalTrials.gov: NCT05824923.

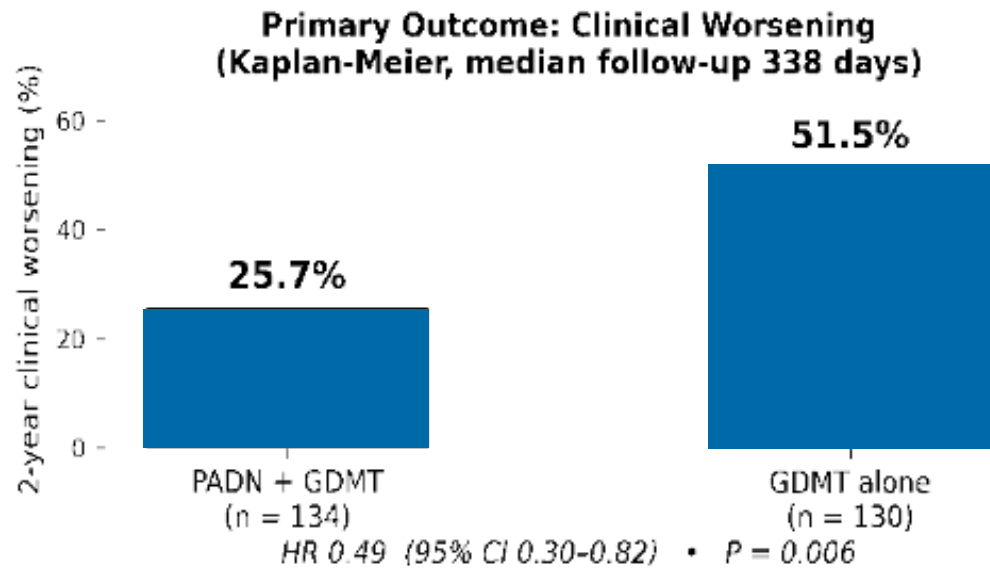


Figure 1 Primary Outcome

# DANISH-CRT : Targeting the Left Ventricular Lead to the Site of Latest Electrical Activation in Cardiac Resynchronization Therapy



Pr Ag Mariem Jabeur



Résident Hassen Dahmen

*Department of Cardiology, Hedi Chaker University Hospital, Sfax*

## Number of patients :

- 1001 patients were enrolled, with 1000 patients included in the modified intention-to-treat analysis.
- Targeted LV lead placement : 499 patients
- Conventional LV lead placement: 501 patients

## Study design :

- Randomized, multicenter, double-blind controlled trial conducted in five Danish university centers
- Recruitment period : March 2018 – June 2024
- Targeted strategy : LV lead positioned in the coronary sinus branch corresponding to the site of latest local electrical activation, assessed using the Q–LV interval.
- Conventional strategy : LV lead positioned in a posterolateral, non-apical location without electrical targeting.

## Aim of the study :

To determine whether targeting the LV lead to the site of latest electrical activation reduces all-cause mortality or first unplanned hospitalization for heart failure compared with conventional posterolateral, non-apical LV lead placement.

## Principal results :

**1/ Primary outcome :** All-cause death or first unplanned hospitalization for heart failure

Targeted strategy : 139/499 (27.9%) VS Conventional strategy : 128/501 (25.5%)

HR 1.10 (95% CI 0.86–1.39) ;  $p=0.45$  >>> No significant difference between the two strategies.

**2/ Secondary outcomes :** No significant benefit of targeted LV lead placement was demonstrated for :

All-cause mortality / Cardiovascular mortality / Heart-failure hospitalization / Sudden death

LV remodeling and systolic function / NYHA functional class / 6-minute walk distance / Quality of life

**3/Safety :** Overall complications were similar (14% vs 13%), while lead-related complications were more frequent with the targeted strategy.



### **Study limitations :**

Conducted in five specialized Danish university centers, potentially limiting generalizability.

The study evaluated a specific electrical targeting strategy and does not exclude potential benefits from other individualized LV lead-placement approaches.

The difference in electrical activation achieved was relatively modest ( $\approx 9$  ms), which may have limited the biological impact of the intervention.

### **Conclusion :**

In patients undergoing CRT, targeting the LV lead to the site of latest electrical activation did not reduce all-cause mortality or first unplanned hospitalization for heart failure compared with conventional posterolateral, non-apical lead placement.

### **Link to the study**

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(26\)01597-7/abstract?dgcid=twitter\\_organic\\_clinical\\_esc26\\_red\\_lancet](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(26)01597-7/abstract?dgcid=twitter_organic_clinical_esc26_red_lancet)

# Direct or subacute coronary angiography for out of hospital cardiac arrest DISCO Trial



Dr Hela BOUZIDI



Resident Mariem Othmen

*Cardiology department, Habib Thameur Hospital*

## Number of patients: 1,006 patients were randomized

Immediate coronary angiography group: 504 patients and Deferred/standard care group: 502 patients

### Aim

The aim of the large DISCO trial was to determine whether immediate coronary angiography does or does not improve survival in patients after an out-of-hospital cardiac arrest (OHCA) without an ST-elevation. A prospective, multicenter, open-label randomized controlled trial conducted in Sweden, Denmark and the Netherlands, sponsored by Uppsala University (the study aimed to recruit 1,006 patients to detect a 20% relative improvement of 30-day survival, from 45% to 54%, with 80% power and  $\alpha=0.05$ )

### Main Results:

- Primary Endpoint: Immediate coronary angiography (within 120 minutes) did not significantly improve 30-day survival compared to a deferred/selective strategy (delayed for at least 72 hours unless clinically indicated) (53.6% vs. 54.6%; OR= 0.95, 95% CI: 0.74-1.21,  $p = 0.67$ ).
- Long-Term Survival: No significant difference in 180-day survival (48.8% vs. 50.2%; OR = 0.93,  $p = 0.60$ ).
- Neurological Outcomes: Functional status measured by Modified Rankin Scale (mRS 0–3) and Cerebral Performance Category (CPC 1–2) showed no statistically significant differences at 30 days or 6 months.
- Coronary Pathology: Culprit lesions were identified in only 17% of patients who underwent angiography, demonstrating a low yield for immediate invasive intervention in post-OHCA cases without ST-elevation

### Study limitations:

- Selective vs. Fixed Strategy: The control arm represented a deferred/selective strategy rather than mandatory delayed catheterization; only 47% of the deferred group ultimately underwent angiography.



- **Low Culprit Rate:** With only ~1 in 6 patients presenting with a true culprit lesion, the vast majority of patients had no clear target for percutaneous coronary intervention (PCI), diluting potential treatment benefit.
- **Statistical Power Limits:** The trial was powered to detect a large relative benefit (20% improvement). Because overall survival in the trial exceeded the initial assumptions, smaller clinically meaningful benefits cannot be entirely ruled out.

**Link to the study:** <https://clinicaltrials.gov/study/NCT02309151>

# STAREE: Atorvastatin for Primary Prevention After Age 70



Pr Ag Messaoudi Yosra



Resident El Bechir Dedde

*Department of Cardiology, Ibn El Jazzar Hospital, Kairouan, Tunisia  
Faculty of Medicine of Sousse, Tunisia*

## Number of Participants:

9,971 randomized participants: 4,984 to atorvastatin and 4,987 to placebo.

Study design Randomized, double-blind, placebo-controlled trial conducted in primary care settings in Australia.

- Population: community-dwelling adults aged  $\geq 70$  years without established cardiovascular disease, diabetes, or dementia.
- Recruitment period: 2015–2023.
- Intervention: atorvastatin 40 mg/day versus placebo.

## Results

After a median follow-up of 5.9 years, the mean age was 74.7 years, 51.9% of participants were women, and more than 40% were aged  $>75$  years. Mean baseline LDL-C was 3.27 mmol/L.

## Main findings

- LDL-C: The between-group difference was  $-0.81$  mmol/L (95% CI 0.76–0.86), corresponding to an approximately 38% reduction in LDL-C with atorvastatin versus 13% with placebo.
- Major cardiovascular events (MACE):  
10.9 vs 15.5 events per 1,000 person-years (6.0% vs 8.3%); HR 0.70 (95% CI 0.61–0.82),  $p < 0.001$ .  
The number needed to treat (NNT) was 37 over 5.9 years.
- Disability-free survival:  
21.6 vs 23.0 events per 1,000 person-years; HR 0.94 (95% CI 0.84–1.05),  $p = 0.25$ .  
There was no significant effect on all-cause mortality or dementia.
- Safety:  
Serious adverse events were similar in both groups (2.7% in each group). Medically significant adverse events were more frequent with atorvastatin (8.8% vs 6.7%)



- Treatment discontinuation because of adverse events: 7.2% vs 6.1%.

### Study Limitations

- Potential dilution of treatment effect: Adherence at 5 years was 55.6% in the atorvastatin group and 47.0% in the placebo group, while 19.4% of participants in the placebo group were taking open-label statins. The true treatment effect on MACE may therefore have been underestimated.
- Endpoint composition: The MACE composite included coronary revascularization, a potentially less hard clinical endpoint that accounted for 24% of first events. Disability-free survival was largely driven by non-cardiovascular mortality, which accounted for 80% of deaths.
- External validity: The study population was 98.3% White, with exclusion of people with diabetes and those considered frail. Recruitment also partly overlapped with the COVID-19 pandemic.
- Exploratory analyses: Secondary endpoints and subgroup analyses were not adjusted for multiplicity and should therefore be interpreted cautiously.

**Link to the study:** <https://www.nejm.org/doi/full/10.1056/NEJMoa2607314>

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### **Main results:**

The trial was stopped prematurely by the Data and Safety Monitoring Board (DSMB) for safety reasons:

- Ischemic efficacy: No superiority of the potent P2Y12 arm ( $p=0.61$ ). Rates of stent thrombosis and myocardial infarction were comparable.
- Bleeding safety : Treatment escalation increased the risk of major bleeding by 3.5-fold. BARC  $\geq 3$  (3,1 % vs 0,9 % ; HR 3,54 ;  $p = 0,028$ ).

### **Study limitations:**

- Premature termination: Reduced overall statistical power (602 patients enrolled out of the 1,474 planned).
- Low number of events: An unexpected numerical signal of increased ischemic stroke at 6 months in the potent P2Y12 arm remains purely exploratory.

### **Link to the study**

<file:///C:/Users/Kad/Desktop/s41591-026-04629-7.pdf>

# Direct His/LBB pacing as an alternative to biventricular pacing in patients with HFrEF and a typical LBBB: Design and rationale for the His-Alternative II trial



Pr Ag Rahma Kallel



Resident Asmae Agourram

*Cardiology Department; Mohamed Ben Sassi Hospital, Gabes- Tunisia*

## Number of patients included

A total of 150 patients with symptomatic heart failure, left ventricular ejection fraction (LVEF)  $\leq 35\%$ , and LBBB (Strauss criteria) were included. Two patients withdrew their consent before implant. Group 1 : 85 patients (57 %) were treated with CSP-CRT (26 His-CRT, 59 patients LBB-CRT). Group 2: 63 patients (43 %) with BiV-CRT.

## Study design

A prospective, randomized, multicenter non-inferiority trial comparing conduction system pacing (His-bundle or left bundle branch pacing) with conventional biventricular CRT (ratio 2:1) in patients with heart failure, LVEF  $\leq 35\%$ , and typical LBBB, with a 6-month follow-up.

## Aim

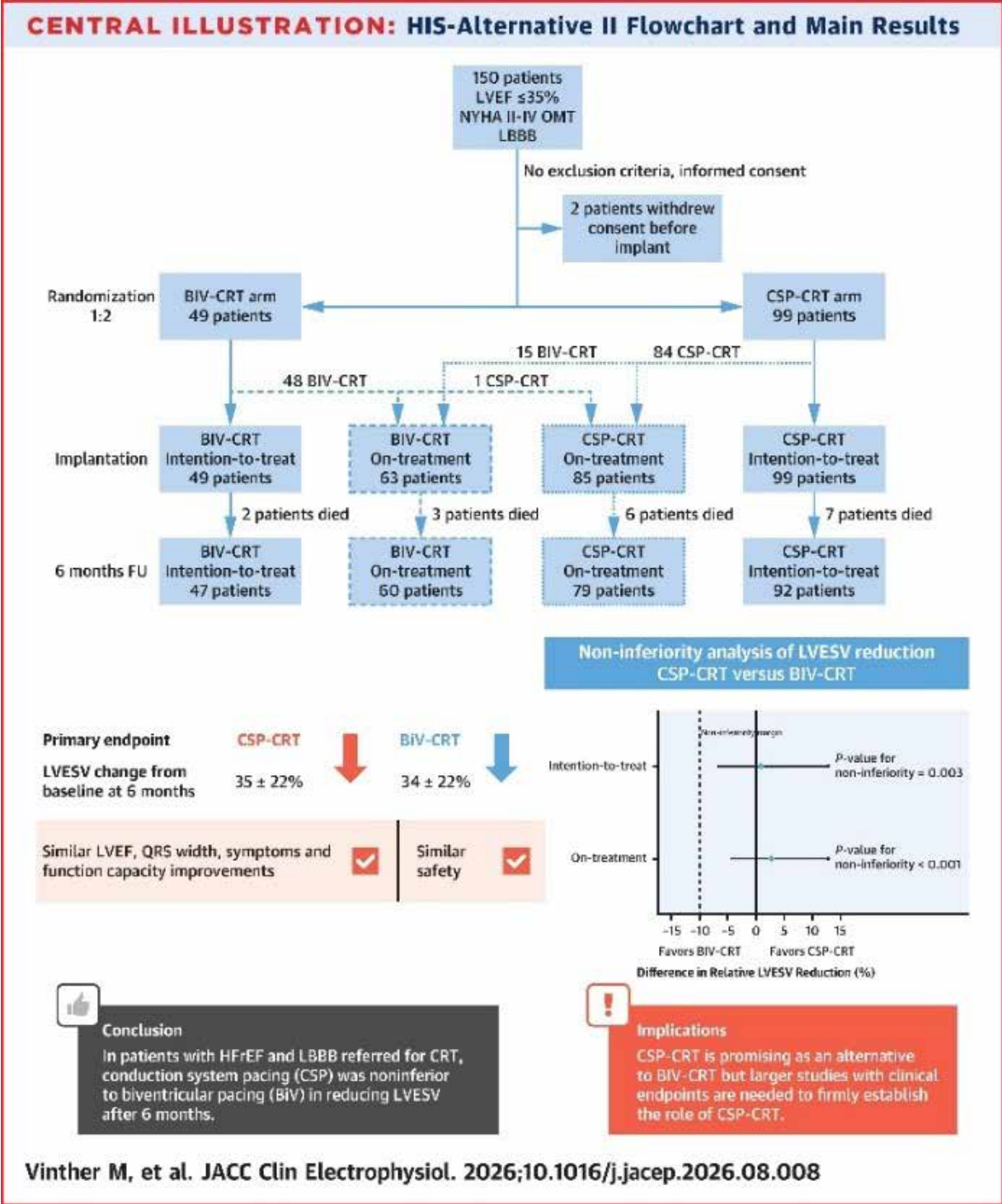
The main objective was to determine whether conduction system pacing (His-bundle or left bundle branch pacing) was non-inferior to conventional biventricular pacing for cardiac resynchronization therapy. Secondary outcomes included changes in LVEF, QRS duration, NYHA functional class, exercise capacity, quality of life, and heart failure biomarkers.

## Principal results

At 6 months, LVESV decreased by  $35 \pm 22\%$  with CSP-CRT compared with  $34 \pm 22\%$  with BiV-CRT. The between-group difference was 0.9% (95% CI -6.0 to 7.8%), meeting the predefined criterion for non-inferiority. LVEF increased by  $14 \pm 8\%$  versus  $14 \pm 9\%$ , respectively, while QRS duration decreased by approximately 31 ms in both groups. Both strategies were associated with improvements in NYHA functional class and exercise capacity. Overall, CSP-CRT demonstrated a degree of reverse remodeling comparable to BiV-CRT at 6 months.

## Study limitations

The results may not be applicable to CRT candidates in general (overrepresentation of nonischemic cardiomyopathy, small sample size). The follow-up was short.



## ISOLEDES TRIAL:

# OCT vs IVUS guidance for PCI of distal left main bifurcation lesions



Dr Rahma KALLEL



Resident Salsabil ROUABHIA

Cardiology Département Mohamed BEN SASSI Hospital, Gabes

### Number of patients included:

Total of 664 patients, included 332 per group, randomized 1 :1

### Study design:

ISOLEDES TRIAL was a prospective, multicentre, open-label, randomized non inferiority trial conducted across 24 centres in China. All patients with true distal left main coronary artery bifurcation lesions were randomized 1:1 ratio to undergo PCI guided by OCT or IVUS. the study included Medina I, I, I or O, I, I bifurcation lesions, with a follow-up of 12 months

### Aim:

To determine whether OCT-guided PCI was non-inferior to IVUS-guided PCI in patient undergoing PCI for true distal left main bifurcation lesions. The primary endpoint was 12-month target lesions failure, defined as a composite of cardiac death, target lesion-related myocardial infarction, or clinically driven target lesion revascularization.

### Principle results:

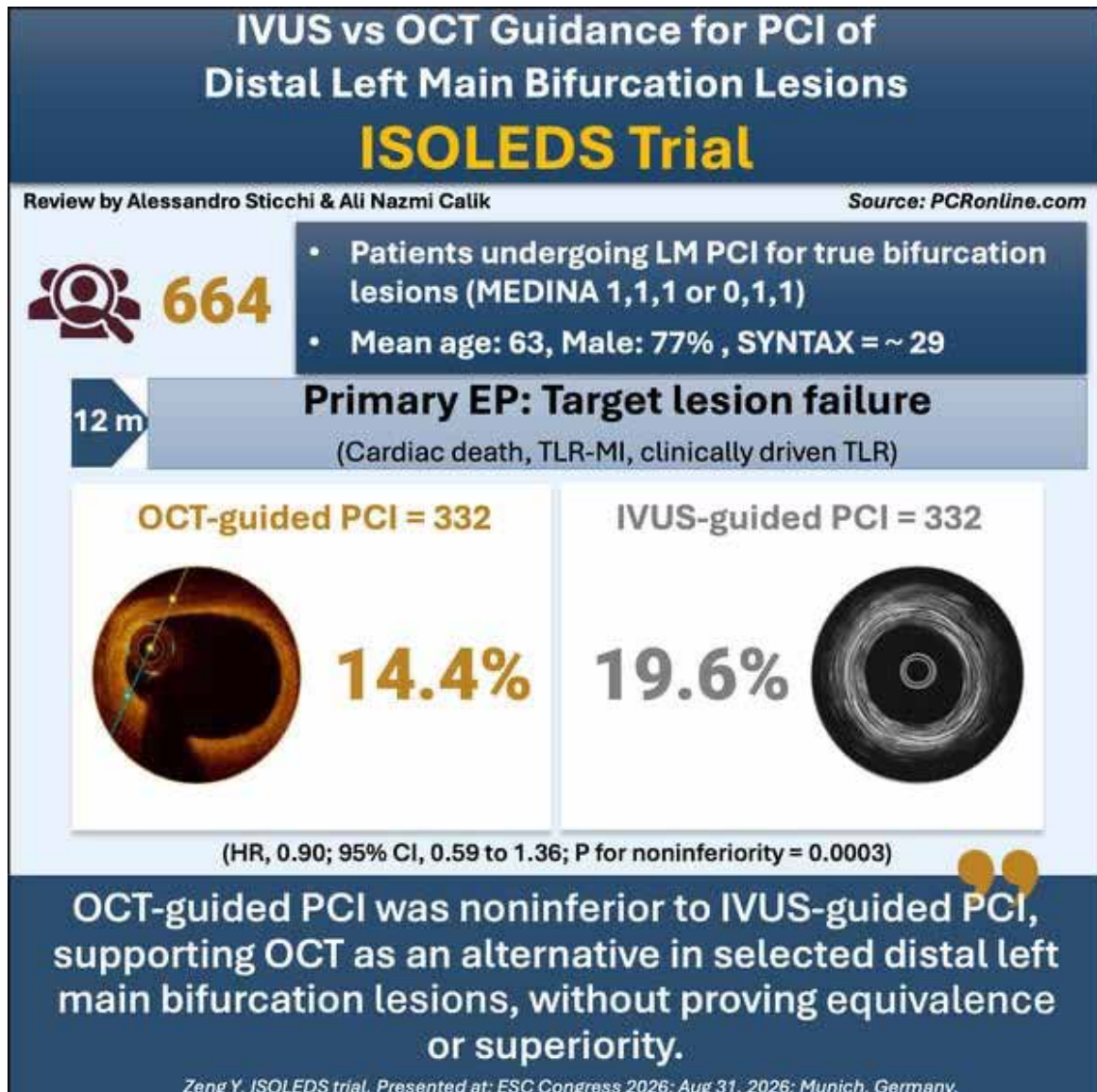
The mean age of the study population was 63.5 years old, women in 22.1% of cases. At 12 months, High-resolution OCT was not inferior to IVUS with the incidence of TLF was 14.4% in the OCT-guided group compared with 19.6% in the IVUS-guided group. OCT-guided PCI was non inferior to IVUS guided for the treatment of distal left main bifurcation lesions

### Study limitations :

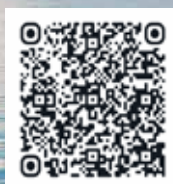
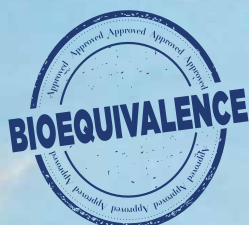
- Open-label design → potential operator bias
- Single -country study → limited generalizability
- Selected population → true distal left –main bifurcation lesions only
- Short follow –up → mainly 12-month outcomes

## Link to the study

<https://www.pcronline.com/News/Congress-coverages/ESC/2026/ISOLEDs-IVUS-vs-OCT-guidance-for-PCI-of-distal-LM-bifurcation-lesions>



# Les Fondamentaux de l'Insuffisance Cardiaque en



Scannez-moi pour lire le full texte  
des Guidelines ESC 2026 pour la gestion  
de l'insuffisance cardiaque