CCCCV NEWSLETTER

HOTLINES ACC 2026

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

EDITORIAL

Chers collègues,
Chers Résidents,

Nous avons le plaisir de vous présenter ce nouveau numéro de la newsletter du Collège de Cardiologie, consacré aux avancées majeures issues du congrès **ACC Orléans 2026**. Ce rendez-vous scientifique international demeure une source incontournable d'actualisation des connaissances et d'évolution des pratiques en cardiologie.

Dans ce numéro, nous mettons en lumière une sélection de travaux récents, incluant les études « hotlines », et les mises à jour des recommandations sur l'embolie pulmonaire et les dyslipidémies afin de vous fournir une synthèse claire et pertinente. Cette newsletter a été élaborée par les résidents, dont l'implication et la rigueur scientifique témoignent d'un engagement remarquable dans la formation continue et la diffusion du savoir. Leur travail a été encadré par des cardiologues seniors, garantissant la qualité, la pertinence et la fiabilité des contenus.

Nous espérons que ce numéro contribuera à enrichir votre pratique et à nourrir votre réflexion clinique.

Bonne lecture à toutes et à tous.

PR. AFEF BEN HALIMA
La Présidente du collège de CCCVP

PR. KHADIJA MZOUGHI
Coordinatrice Newsletter
Chef de Service
Hoiptal Bougdfa Bizerte

HOTLINES ACC 2026

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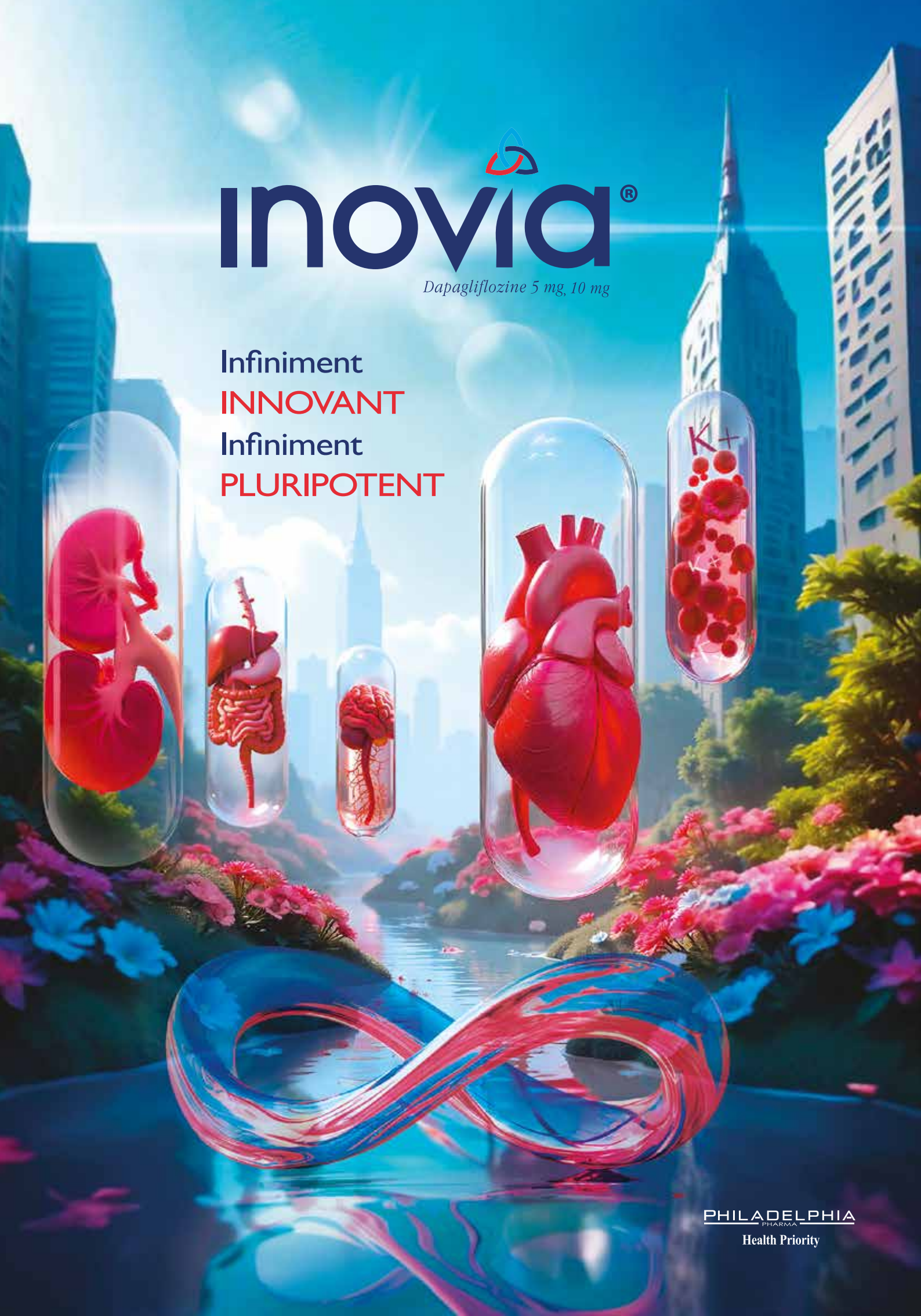
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ALL RISE TRIAL :
Angiography-Derived Fractional Flow Reserve to Guide PCI

Dr Zidi Oumayma Rsdt Slaoui Soumaya

Cardiology Department, Abderrahman Mami Hospital, Ariana

Study design:

In this international, randomized, non-inferiority trial, a total of 1930 patients with at least one intermediate coronary stenosis were randomly assigned in a 1:1 ratio to physiological assessment using angiography-derived FFR (FFRangio group, n=965) or pressure-wire based measurements (pressure-wire group, n=965).

Aim:

The aim of the study was to determine whether angiography-derived FFR is non-inferior to pressure-wire-based assessment in guiding revascularization of coronary stenoses.

The primary endpoint was a composite of all-cause death, myocardial infarction, or unplanned clinically indicated revascularization at 1 year.

Principle results:

Baseline clinical characteristics were well matched between the two groups. Mean age was 68.4 years with 25% women. Most patients had a single lesion, predominantly in the left anterior descending artery (49.6%).

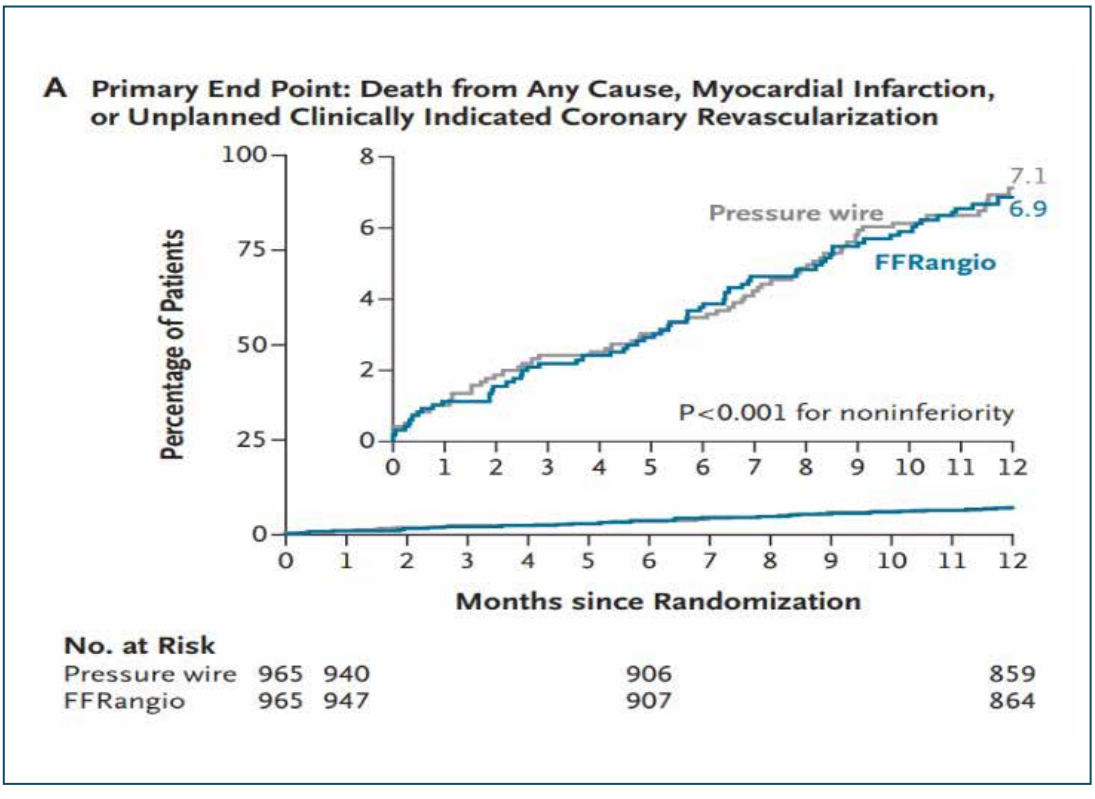
At 1 year, a primary end-point event had occurred in 64 patients (Kaplan–Meier estimate, 6.9%) in the FFRangio group and 65 patients (Kaplan–Meier estimate, 7.1%) in the pressure-wire group (HR 0.98; 95% CI [0.70-1.39]; p<0.001 for noninferiority).

Individual endpoint components appeared to be similar between the two approaches. FFRangio lowered procedural time (-5 minutes;95% CI, -7 to -3), radiation exposure (-3 minutes; 95% CI, -3 to -2), and contrast use (-14 ml; 95% CI, -20 to -10).

Study limitations:

The study population was limited to patients with coronary anatomy suitable for both FFRangio and pressure-wire assessment, with most patients presenting with stable coronary disease or no biomarker elevation.

Link to the study: https://www.nejm.org/doi/full/10.1056/NEJMoa2600949



CADENCE Phase 2

Randomized Controlled Trial: Sotatercept in Combined Post- and Pre-capillary Pulmonary Hypertension Associated With Heart Failure

Dr Sarra Chenik Rsdte Rahma Harbaoui

Cardiology Department, Military Hospital of Tunis

Number of patients included / number per group : 164 patients with Cpc-PH associated with heart failure (predominantly HFpEF), randomized in a **1:1:1 ratio** to receive placebo (n=55), sotatercept 0.3 mg/kg (n=54), or sotatercept 0.7 mg/kg (n=55)

Study design:

CADENCE trial is a **multicenter, randomized, double-blind, placebo-controlled Phase II study** with a **24-week follow-up period**. The primary endpoint is the change in **pulmonary vascular resistance** (PVR) assessed by right heart catheterization, with secondary endpoints including additional pulmonary hemodynamic parameters, **NT-proBNP levels**, and functional capacity

Aim

To evaluate whether sotatercept (activin signaling pathway inhibitor) improves pulmonary vascular remodeling, hemodynamics, and right ventricular–pulmonary arterial coupling in patients with heart failure–associated Cpc-PH.

Principal results

-Significant reduction in pulmonary vascular resistance (PVR) in the sotatercept group vs placebo

-Improvement in pulmonary arterial pressures and overall pulmonary hemodynamics

-Favorable trend toward improved RV–PA coupling, suggesting reduced right ventricular afterload

-Acceptable safety and tolerability profile, consistent with prior sotatercept studies

-Findings support a potential disease-modifying vascular remodeling effect

Study limitations

- Moderate sample size, limiting statistical power
- Short follow-up duration (24 weeks), precluding assessment of long-term outcomes
- Reliance on an intermediate endpoint (PVR) without demonstrated direct impact on mortality
- Phenotypic heterogeneity within the HFpEF population
- Non-linear dose–response relationship, suggesting complex pharmacodynamic effects

Link to the study https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.126.079918

CHAMPION-AF Trial :
Left Atrial Appendage Closure or Anticoagulation for Atrial Fibrillation

Associate Prof Marouane Mahjoub

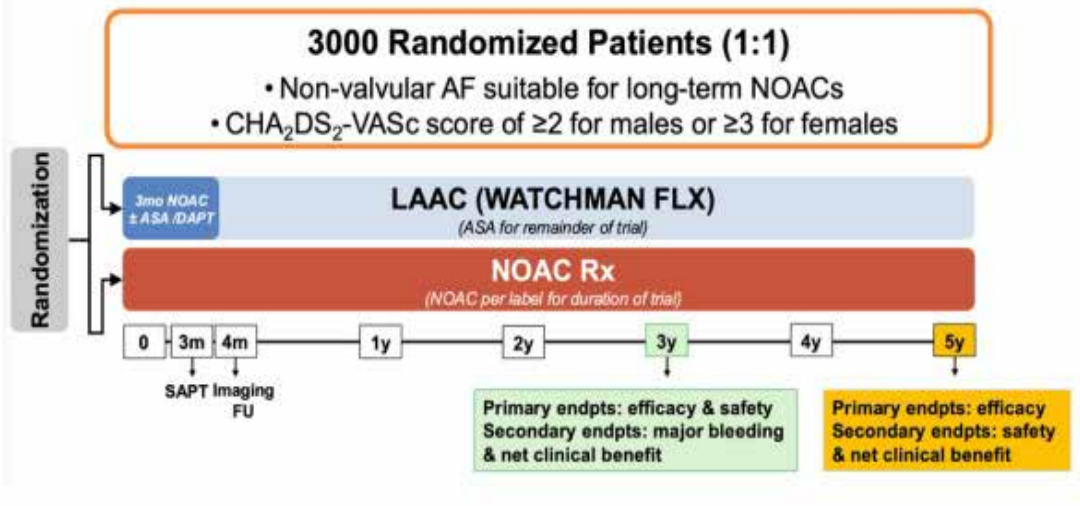
Dr Mohamed Ben Younes

Department of Cardiology, [CHU Fattouma bourguiba – Monastir, Tunisia]

Study design:

CHAMPION-AF is a large international study in which 3,000 patients with atrial fibrillation and potential candidates for anticoagulant treatment were randomized, 1 to 1, between left atrial appendage closure and anticoagulant treatment with DOACs.

Population



Total: 3000 patients : LAAC group: 1499 | DOAC group: 1501

Aim

To determine whether closure of the left atrial appendage (LAAC) using the Watchman FLX® device constitutes a reasonable alternative in patients with atrial fibrillation who are considered suitable for long-term treatment with direct oral anticoagulants (DOACs).

Principal Results

No difference in terms of cardiovascular deaths (2.7% in both groups), systemic embolisms (0.1%), or hemorrhagic strokes (0.4% in both groups) but a slight increase in ischemic strokes in patients in the LAAC group (3.2% vs 2%). The primary safety endpoint consisted of all non-procedure-related bleeding, whether major or non-major, but clinically relevant. At 3 years, these bleedings occurred in 10.9% of patients in the left atrial appendage closure group vs 19% of those in the OAC group, a difference achieving the superiority goal ($p < 0.001$). The secondary evaluation criterion was the combined rate of major hemorrhages related or unrelated to the procedure at 3 years :5.9% of patients in LAAC group and 6.4% in the DOAC group ($p< 0.001$ for non-inferiority). clinical benefit, including cardiovascular mortality, stroke, systemic embolism, non-procedure-related hemorrhages with superiority for the LAAC compared to medical treatment (15.1% vs 21.8%, respectively).

Study Limitations

- Low number of patients in the two groups
- Relatively low bleeding-risk population (mean HAS-BLED ≈1.3)
- Limited long-term follow-up for device strategy
- No generalization to high-risk patients

Link to the study: https://www.nejm.org/doi/10.1056/NEJMoa2517213

CHIP-BCIS3 Trial : Left Ventricular Unloading in High-Risk Percutaneous Coronary Intervention

Dr Mohamed Amine SOULA

Resident Younes EL KHARRAS

Cardiology Department, Mongi Slim University Hospital – La Marsa.

Number of patients included:
300 patients: 148 (microaxial flow pump) vs 152 (standard care).

Study design:
The CHIP-BCIS3 trial is a randomized, multicenter and open-label trial, funded by the National Institute for Health and Care Research in the United Kingdom. Patients with severe LV dysfunction and extensive coronary artery disease were randomized 1:1 to an elective unloading with an Impella CP during planned complex PCI or to standard care. The primary outcome was a hierarchical composite of death, stroke, myocardial infarction, cardiac hospitalization, or periprocedural myocardial injury at a minimum of 12 months, as analyzed with a win ratio.

Aim:
To assess whether elective LV unloading with a microaxial flow pump improves outcomes in high-risk PCI with severe LV dysfunction.

Principal results:
Over a median follow-up 22 months, there was no benefit in the primary outcome with Impella CP (36.6% wins with Impella CP vs 43.0% with standard care (win ratio, 0.85; 95% CI, 0.63-1.15; p=0.30)). Instead, there was a higher rate of CV death in the Impella arm (26.7% vs. 14.5%; HR,1.91; 95% CI, 1.11-3.30). There was no reduction in myocardial infarction, stroke or cardiovascular hospitalization.

Study limitations:
Moderate sample size, open-label design, exclusion of cardiogenic shock, UK-only population.

Link to the study: https://www.nejm.org/doi/full/10.1056/NEJMoa2515704

Dig-RHD trial:

Digoxin in rheumatic heart disease: Rationale and design of a multicenter, placebo-controlled double-blind randomized controlled trial

Dr Houssem Thabet

Resident Hajer Dellai

Cardiology Department, Sahloul Hospital

Number of patients included:

A total of **1769 patients** with symptomatic rheumatic heart disease (RHD) were enrolled and randomized to receive either digoxin or placebo.

Study design:

DIG-RHD was a multicenter, randomized, double-blind, placebo-controlled and a superiority trial, evaluating the use of digoxin in reducing death or new onset or worsening heart failure. The trial enrolled eligible patients between February 2022 and August 2024, from 12 medical centers in India.

Aim:

To evaluate the effect of digoxin treatment compared to placebo among patients with symptomatic RHD, on the composite of all-cause death and new or worsening HF at 2 years.

Principal results :

- Mean age was at 46 years, with a female predominance (71,2%). The most frequent symptom was dyspnoea II NYHA (78.9%).

-Most patients had mixed mitral and aortic valve disease. Mitral stenosis was the most common valve lesion in 93% of patients.

-The primary endpoint was significantly reduced in the digoxin group, with 18% relative risk reduction in the composite outcome .

-This benefit was mainly driven by a reduction in heart failure events. However, no statistically significant reduction in all-cause mortality alone.

-The secondary composite endpoint of HF-related death and new or worsening HF was similarly reduced by 18%. Effects were consistent across sex and BMI with a possible greater benefit among patients with atrial fibrillation.

Study limitations :

- Composite endpoint mainly driven by heart failure outcomes
- Limited data on long-term outcomes beyond follow-up
- Results may be influenced by background therapies and access to valve intervention

Link to the study: Available via the American College of Cardiology scientific sessions (ACC 2026).

DKCRUSH VIII

Randomized Clinical Trial: IVUS or Angiography Guidance for Percutaneous Coronary Intervention in Complex Coronary Bifurcation Lesions:

Dr Amal Ben Salem

Rsdt Mohamed Amine Mahfoudhi

Cardiovascular surgery Department of La Rabta Hospital

Number of patients included

The study included 555 patients with clinical indications for percutaneous coronary intervention (PCI) and a complex bifurcation lesion who were enrolled and randomly assigned to two groups:

- Intravascular ultrasound (IVUS)-guided PCI group: 277 patients
- Angiography-guided PCI group: 278 patients

Study design

The DKCRUSH VIII trial was a multicenter, randomized, open-label trial conducted across 24 centers in China.

Aim

This study aimed to investigate the treatment effect of IVUS-guided PCI, as compared with angiography-guided PCI, in patients with complex bifurcation lesions.

Principle results

At a one-year-follow up, a primary endpoint defined as a composite of target vessel failure (cardiac death), target vessel myocardial infarction or clinically driven target vessel revascularization occurred in 17 patients (6.1%) in the IVUS-guided PCI group and in 41 patients (14.7%) in the angiography-guided PCI group (HR: 0.4; 95% CI:0.23-0.71, p=0.002). This benefit was driven primarily by reductions in myocardial infarction and repeat revascularization.

Study limitations

This study had some limitations. First, although the trial was multicenter in design, it was conducted exclusively in China, which may limit the generalizability of the findings to other regions with different patient populations and healthcare systems. Second, the follow-up period was limited to 1 year; longer-term adverse outcomes, including very late stent thrombosis and late target vessel failure, remain unknown. Extended follow-up data are awaited.

Link to the study: https://www.jacc.org/doi/10.1016/j.jacc.2026.01.08

ESSENCE–TIMI 73b TRIAL :
Targeting APOC3 with Olezarsen in Moderate Hypertriglyceridemia

Dr. Lagha Elyes

Résidente Belgaied Raghda

Affiliation: Department of Cardiology, UHC Mongi Slim La Marsa, Tunisia

Number of patients included / number per group

A total of 1,349 patients were enrolled in the ESSENCE–TIMI 73b trial. Participants were randomized to receive olezarsen 50 mg (n=254), olezarsen 80 mg (n=766), or placebo (n=329). Patients had moderate hypertriglyceridemia with elevated cardiovascular risk or severe hypertriglyceridemia. The median baseline triglyceride level was approximately 238 mg/dL. Most patients were receiving background lipid-lowering therapy at baseline.

Study Design

It was a phase 3, randomized, double-blind, placebo-controlled trial conducted across multiple international centers. Olezarsen, a hepatocyte-targeted antisense oligonucleotide designed to inhibit apolipoprotein C-III synthesis, was administered subcutaneously every 4 weeks. The primary endpoint was assessed at 6 months. The primary outcome was the least-squares mean percent change in triglyceride levels from baseline to 6 months among patients with moderate hypertriglyceridemia. Results were reported as the placebo-adjusted difference between each olezarsen dose group and the placebo group.

Aim

To evaluate the efficacy and safety of olezarsen in patients with moderate hypertriglyceridemia and elevated cardiovascular risk, as well as in those with severe hypertriglyceridemia.

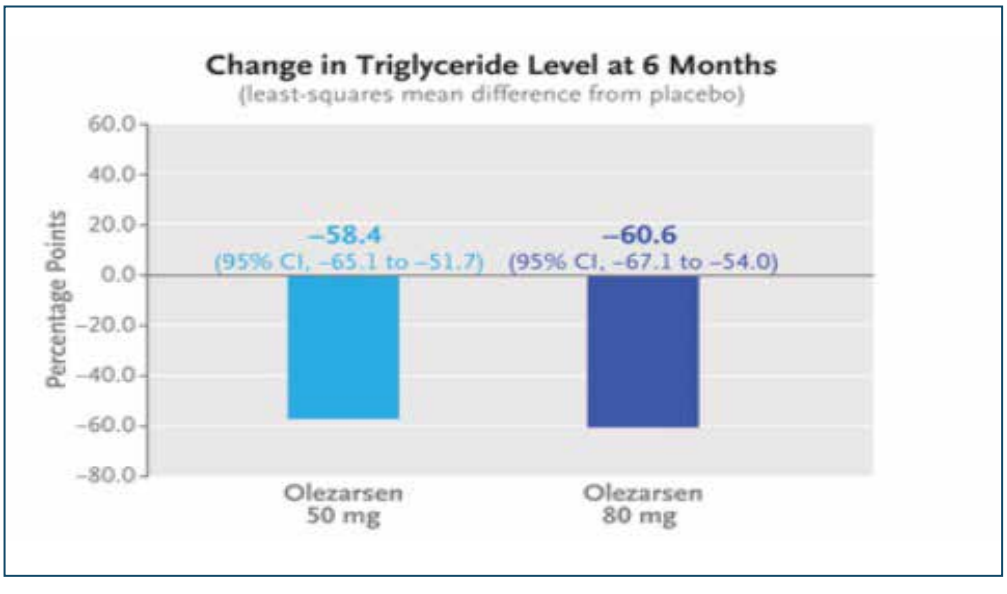
Principle results

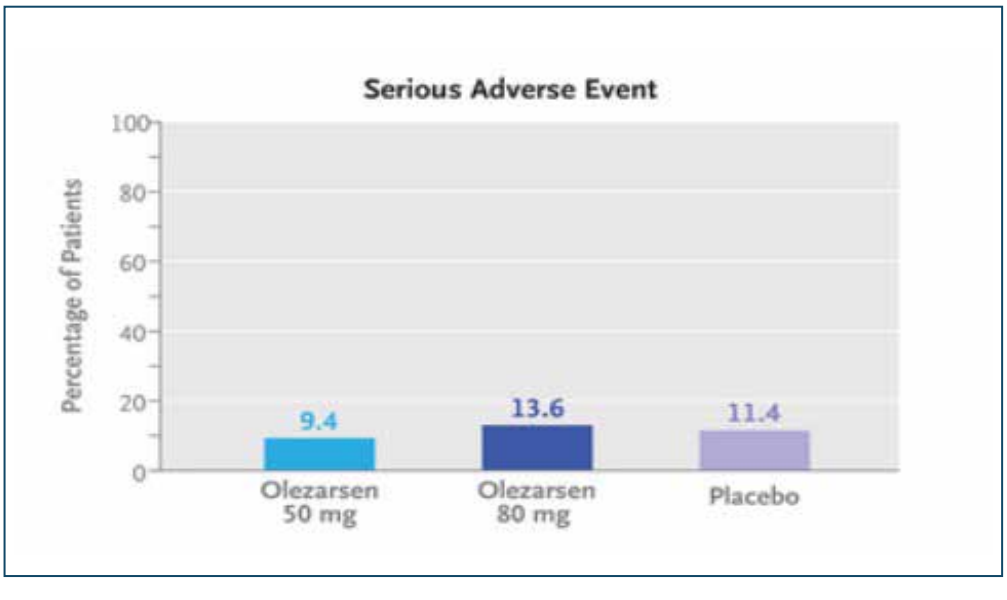
Olezarsen reduced triglycerides by 58.4% (50 mg) and 60.6% (80 mg) vs placebo ($p < 0.001$), with significant decreases in ApoC-III and atherogenic lipoproteins. A large proportion of patients achieved TG <150 mg/dL (85–89% vs 13% placebo). Safety was favorable, with more injection-site reactions but similar rates of serious adverse events.

Study Limitations

The trial had a short follow-up (6 months), did not assess cardiovascular clinical outcomes, and was industry-funded.

Link to the study : https://www.nejm.org/do/10.1056/NEJMdo008225/full/





Essence-TIMI 73b Imaging Study: Effect of APOC3 Inhibition with Olezarsen on Coronary Atherosclerosis

Dr Ben Othman Rihab

Rdte Fatima Zahra Ahmed

Pediatric Cardiology department, Rabta Hospital, Tunis, Tunisia

Number of patients included

Total: 468 patients: Olezarsen group: 349patients / Placebo group: 119 patients

Study design

Randomized, double-blind, placebo-controlled, multicenter imaging substudy within the Essence-TIMI 73b trial (12 months follow-up).

Aim

To investigate the effect of intensive triglyceride lowering via APOC3 inhibition with Olezarsen on coronary non-calcified plaque volume (NCPV) in patients with moderate hypertriglyceridemia and established cardiovascular disease or high cardiovascular risk, on top of standard lipid-lowering therapy

Principle results

Despite significant reductions in lipid parameters vs. placebo at 6 months:

- Triglycerides: -63.9%
- Remnant cholesterol: -71.9%
- ApoB: -16.0%
- LDL-cholesterol : no significant change

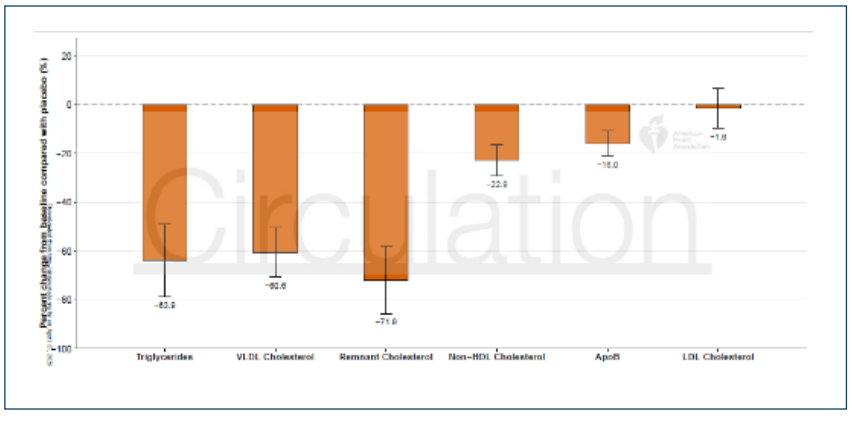


Figure: Placebo-adjusted percent change in lipid endpoints at 6 months.

Olezarsen had no significant effect on non-calcified plaque volume at 12 months (p=0.36), nor on any secondary plaque endpoints (low-attenuation, calcified, fibrous, or total plaque volume

Study limitations

12-month follow-up may be too short to detect plaque changes
Modest apoB reduction (-16%) likely insufficient to drive measurable plaque regression
Most patients already on background lipid-lowering therapy, limiting additional detectable benefit
Study restricted to patients with non-calcified plaque (only 56% of screened patients)
Inherent variability in plaque volume measurement may have contributed to neutral results.

Link to the study : https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.126.080012

FAST III TRIAL:
Novel Minimally Invasive vFFR Noninferior to FFR For Revascularization

Dr Manel Ben Halima

Resident Wissal Hamdi

Number of patients included/ number per group

A total of 2,211 patients were randomized in the study, with 1,116 patients assigned to the vFFR (vessel Fractional Flow Reserve) guided strategy and 1,095 patients to the FFR (Fractional Flow Reserve) guided strategy.

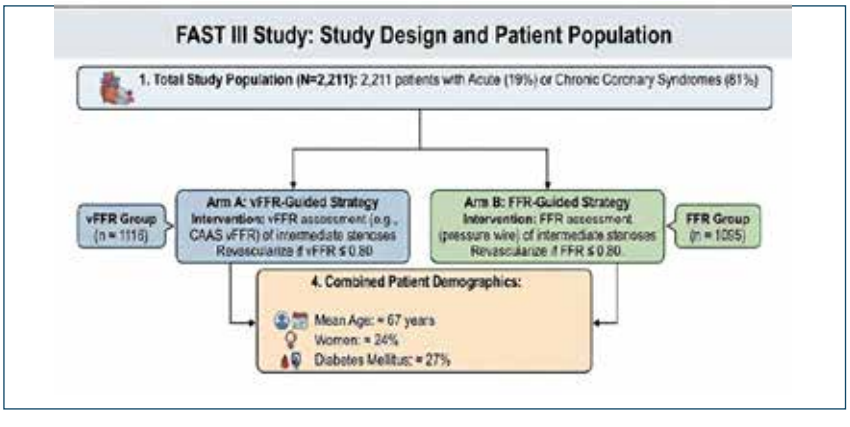
Study design

International, open-label, randomized, noninferiority study conducted at **37 centers across Europe.**
Population: patients with intermediate coronary lesions (30–80% stenosis) presenting with either chronic or acute coronary syndromes
Intervention: patients randomly assigned **1:1 to vFFR-guided or pressure-wire FFR–guided revascularization.**

Aim

To evaluate if vFFR-guided revascularization is noninferior to FFR-guided revascularization for 1-year major cardiovascular events in patients with intermediate coronary lesions

Principle results:



At 1 year, the primary outcome occurred similarly in both groups (7.5%), confirming vFFR was noninferior to FFR. vFFR reduced procedure time, procedural complications (3.7% vs. 6.0%), and avoided hyperemic drugs or extra devices. Adverse events were comparable.

Study limitations

its open-label design, small percentage of patients with an acute coronary syndrome, lack of investigator experience with vFFR compared to FFR, an a solely European patient population and follow-up duration.

Link to the study : https://www.nejm.org/doi/full/10.1056/NEJMoa2601841

HI-PEITHO TRIAL :

Ultrasound-facilitated, Catheter-directed Thrombolysis (UF-CDT) in Intermediate-high Risk Pulmonary Embolism

Professor Khadija Mzoughi Resident Hedhli Heithem

Cardiology Department Habib Bougatfa Hospital, Bizerte

Number of patients included/ number per group

A total of 4313 patients from 59 sites in the US and Europe were screened, and **544** patients were randomly assigned to a treatment group and included in the intention-to-treat analysis: **273** in the intervention group and **271** in the control group.

Study design

It's a postmarket, multinational, adaptive-design, open-label, 1:1 randomized trial with blinded adjudication for the primary composite outcome , including adult patients 18 to 80 years of age with acute, intermediate-risk pulmonary embolism(PE) confirmed by computed tomographic pulmonary angiography (CTPA) ,presenting with a ratio of right ventricular end-diastolic diameter to left ventricular end-diastolic diameter of 1.0 or higher and abnormal cardiac troponin levels, and met at least two criteria for cardiorespiratory distress. Patients were randomized 1:1 to receive anticoagulation alone or in combination with catheter-directed procedures performed with the EkoSonic endovascular system. Follow up was for 12 months. The primary outcome was a composite of PE–related death, cardiorespiratory collapse or decompensation, or nonfatal, symptomatic recurrence of PE, as confirmed by CTPA ; within 7 days after randomization.

Aim

To validate the clinical efficacy and safety of UF-CDT by comparing its clinical benefit when associated with anticoagulation, with those of anticoagulation alone in patients with intermediate-high risk PE at a higher estimated risk of early decompensation

Principle results

A primary-outcome event occurred in 11 patients (4.0%; 95% confidence interval [CI], 2.3 to 7.1) in the intervention group and 28 (10.3%; 95% CI, 7.2 to 14.5) in the control group [relative risk= 0.39; 95% CI, 0.20 to 0.77; P=0.005]. No clear differences were observed between the two treatment groups regarding the

incidence of major bleeding or serious adverse events through 30 days of follow-up, and no intracranial hemorrhage occurred in either group. Major bleeding occurred within 7 days in 11 patients (4.1%) in the intervention group and 6 (2.2%) in the control group (P=0.32); and within 30 days in 11 patients (4.1%) and 8 patients (3.0%), respectively (P=0.64) .

Study limitations

Patient randomization was not blinded, and not stratified by site, potential center-level effects cannot be excluded. Owing to the overall low frequency of events and mortality, the trial did not have the power to compare treatment efficacy in specified patient subgroups.

Link to the study: https://clinicaltrials.gov/study/NCT04790370

EZ-PAVE Trial:

Effect of Intensive LDL-Cholesterol Reduction on Cardiovascular Outcomes in Patients with ASCVD:

Professor Khadija Mzoughi

Rsdte Farhane Safoua

Cardiology Department Habib Bougatfa Hospital, Bizerte

Number of patients included/ number per group

A total of 3,048 patients with established atherosclerotic cardiovascular disease (ASCVD) were included: 1,526 patients: LDL-cholesterol target <55 mg/dL and 1,522 patients: LDL-cholesterol target <70 mg/dL Study design EZ-PAVE was a multicenter randomized controlled trial conducted at 17 centers in South Korea between 2021 and 2022. Patients with ASCVD were randomly assigned in a 1:1 ratio to LDL-cholesterol targets of <55 mg/dL or <70 mg/dL. Treatment was adjusted at the clinician's discretion according to guideline-directed lipid-lowering therapy. The follow-up duration was 3 years.

Aim

To determine whether a lower LDL-cholesterol target (<55 mg/dL) reduces major cardiovascular events compared with the conventional target of <70 mg/dL in patients with ASCVD.

Principal results

After 3 years of follow-up, the primary composite endpoint (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization, or hospitalization for unstable angina) occurred in: 6.6% of patients in the <55 mg/dL group vs9.7% of patients in the <70 mg/dL group.This corresponds to a 33% relative reduction in major cardiovascular events with the more intensive LDL-cholesterol target. The benefit was mainly driven by reductions in non-fatal myocardial infarction and coronary revascularization. No major safety differences were observed between groups.

Study limitations

Open-label design

- Population consisted exclusively of East Asian patients
- Newer lipid-lowering therapies (inclisiran, bempedoic acid) were not available during the study
- Not all patients in the intensive group achieved LDL <55 mg/dL

Link to the study: https://www.nejm.org/doi/full/10.1056/NEJMoa2600283

GoFRESH trial :

Effects of DASH Groceries on Blood Pressure in Black Residents of Urban Food Deserts Without Treated Hypertension

Dr Ameni Mardessi

Cardiology Department, Siliana Hospital

Residente Siwar Khammeri

Cardiology Department, Habib Bougatfa Hospital

Number of patients included/ number per group

180 participants
Intervention group: DASH groceries and dietitian counseling
Control group: Financial stipend for self-directed grocery shopping

Study design

The GoFresh trial was a parallel group randomized controlled trial included 180 Black adults with elevated or untreated hypertension. Participants were randomly assigned to either 12 weeks of home-delivered DASH groceries with dietitian counseling or financial stipends for self-directed grocery shopping. Follow-up assessments were conducted at 3, 6, and 12 months, and the RE-AIM framework was used to evaluate reach, sustainability, and cost-effectiveness.

Aim

To determine whether dietitian-assisted, home-delivered DASH groceries reduce systolic blood pressure and improve long-term adherence to the DASH dietary pattern among Black adults with elevated or untreated hypertension, while evaluating the intervention's reach, and cost-effectiveness.

Principle results

At 3 months, the intervention group showed a reduction in systolic blood pressure of -5.7 mmHg, compared with -2.3 mmHg in the control group (difference -3.4 mmHg; p = 0.009).
Diastolic blood pressure decreased by -2.4 mmHg in the intervention group relative to the control group.
LDL cholesterol decreased by -8 mg/dL and Urinary sodium decreased by -545 mg/24h in the intervention group.
No significant changes were observed in BMI or hemoglobin A1c.
However, these effects were not maintained at 6 months after the end of the intervention.

Study limitations

The beneficial effects of the DASH grocery intervention on blood pressure and LDL cholesterol were **not maintained** after the program ended. The study population consisted exclusively of Black adults living in urban areas of Boston, which limits the generalizability of the findings. Participant **adherence to the DASH diet varied**, and the relatively short duration of the intervention may have limited its long-term impact. Additionally, **environmental, and socio-economic factors** may have influenced the observed outcomes.

Link to the study: ClinicalTrials.gov Identifier: NCT05121337

IVUS-CHIP TRIAL:
Intravascular Ultrasound–Guided or Angiography-Guided Complex High-Risk PCI

Dr Lagha Elyes

Rsdt Feres Montasri

Department of Cardiology, CHU Mongi Slim La Marsa, Tunisia

Number of patients included/ number per group

The trial enrolled 2020 patients undergoing complex high-risk percutaneous coronary intervention (PCI), randomized in a 1:1 ratio to intravascular ultrasound (IVUS)-guided or angiography-guided procedures. The population included patients with complex coronary lesions such as severe calcification, left main disease, bifurcation lesions, chronic total occlusions (CTO), ostial lesions, in-stent restenosis (ISR), or lesions longer than 28 millimeters.

Study design

It was an investigator-initiated, international, multicenter, randomized controlled study conducted in 37 European centers, comparing IVUS-guided with angiography-guided percutaneous coronary intervention. Randomization was stratified by center and clinical presentation, with up to 2 years of follow-up and intention-to-treat analysis.

Aim

To evaluate whether **routine use of IVUS during complex high-risk PCI** could improve clinical outcomes compared with **angiography-guided PCI alone**, particularly by reducing the incidence of adverse ischemic events related to stent failure.

Principal results

After a median follow-up of **19 months**, the primary endpoint (target vessel failure) occurred in **13.9% of patients in the IVUS-guided PCI group** compared with **11.1% in the angiography-guided PCI group (hazard ratio 1.25; 95% CI 0.97–1.60; P=0.08)**, showing **no statistically significant difference between the two strategies**. Procedural complications were also similar **(11.3% vs 10.2%)**. However, **definite stent thrombosis occurred less frequently in the IVUS group (0.2% vs 1.0%),** suggesting a possible protective effect of imaging guidance for this complication. IVUS-guided procedures were longer **(88.8 vs 66.2 minutes)** and more frequently involved post-dilation.

Study limitations

The study was limited by its open-label design, lower-than-expected event rates reducing statistical power, and operator-dependent intravascular ultrasound use. It was conducted in high-expertise centers, which may limit generalizability, and had only 2 years of follow-up.

Link to the study: https://www.nejm.org/doi/full/10.1056/NEJMoa2601521

KARDINAL TRIAL :A Randomized, Double-Blind, Placebo-Controlled Study Assessing the Efficacy and Safety of Monthly Subcutaneous Tonlamarsen in Patients with Uncontrolled Hypertension

Pr. Yosra Messaoudi

Rsdt Dedde El Bechir

Department of Cardiology, Ibn El Jazzar Hospital, Kairouan, Tunisia.

Number of patients included/ number per group

A total of 206 participants were enrolled and randomized in a parallel-group phase 2 trial.

Study design

The KARDINAL trial is a phase 2, randomized, double-blind, placebo-controlled study conducted across 39 sites in the United States.

All participants received an initial dose of tonlamarsen during the run-in phase, prior to randomization:

- Experimental group: one dose of placebo and 5 doses of tonlamarsen was administered by sub cutaneous injection.
- Placebo comparator group: five doses of placebo and 1 dose of tonlamarsen was administered by subcutaneous injection.

The trial used quadruple masking (participants, care providers, investigators, and outcomes assessors).

Aim

The primary aim was to evaluate the efficacy of tonlamarsen in reducing systolic blood pressure and its effect on plasma angiotensinogen (AGT) levels in patients with uncontrolled hypertension. Secondary outcomes included safety, tolerability, and achievement of target systolic blood pressure.

Principal results Tonlamarsen achieved a significant reduction in angiotensinogen levels (67.2% vs 23%), confirming effective target engagement. Despite this, systolic blood pressure decreased modestly (6-7mmHg) with no significant difference versus placebo at week 20, and no improvement in home BP or target BP achievement.

Serious adverse events were infrequent (5% vs 2%), supporting an overall acceptable safety profile.

Study limitations

Run-in exposure to tonlamarsen may have blunted between-group differences
Possible prolonged pharmacodynamic effect
Short follow-up (20 weeks)
Unclear mechanistic link between AGT reduction and blood pressure response

Link to the study: Study Details | NCT06864104 | A Study to Investigate Tonlamarsen for the Treatment of Adults with Uncontrolled Hypertension (KARDINAL) | ClinicalTrials.gov

ORBITA-CTO TRIAL:

A Randomized, Placebo-Controlled Trial of Chronic Total Occlusion Percutaneous Coronary Intervention in Stable Angina

Dr ZIDI Oumayma

Dr JRIDI Sahar

Abderahmen Mami Ariana Teaching Hospital- Cardiology Department

Number of patients included/ number per group

50 proceeded to randomization to either CTO PCI (25 patients) or placebo (25 patients).

Study design

multicenter, randomized, double-blind and placebo-controlled trial.

Aim

The aim of this study was to assess the efficacy of CTO PCI in the first randomized, placebo controlled trial of CTO PCI.

Principle results

In this controlled randomized trial, CTO PCI led to a clear and sustained improvement in angina-related symptoms compared with placebo. Despite one procedural withdrawal in the PCI group, all 50 randomized patients were included in the primary analysis. CTO PCI significantly improved the angina symptom score (OR 4.38, 95% CrI 1.57–12.69; Pr[Benefit]=0.996), mainly through a reduction in angina episodes (OR 4.38, 95% CrI 1.55–11.78; Pr[Benefit]=0.997). This translated into an additional 30.6 angina-free days (95% CrI 11.1–50.7; Pr[Benefit] >0.999). Improvements were also seen in SAQ angina frequency (+10.7, 95% CrI 1.4–20.2; Pr[Benefit]=0.988), as well as in physical limitation, quality of life, summary score, and CCS class. Blinding was successfully maintained for patients, staff, and researchers.

Study limitations

the study has several limitations, including its small sample size, conduct in two highly experienced UK CTO centers, and exclusion of the most complex CTO lesions, which may limit generalizability. In addition, the trial was not powered on a prespecified ORBITA-app effect estimate, and the treatment strategy, including anti-anginal withdrawal, may not fully reflect routine practice.

Link to the study: https://www.jacc.org/doi/10.1016/j.jacc.2026.03.027

OPTIMAL trial:

IVUS-Guided versus Angiography-Guided PCI in Unprotected Left main Coronary Disease

Dr Ghassen TLILI

Rsdte Eya REZGUI

Department of Cardiology, Habib Thameur University Hospital, Tunis

Number of patients included/ number per group

Among 806 patients with unprotected left main coronary artery disease included, 401 were assigned to IVUS-guided PCI and 405 to angiography-guided PCI.

Study design

This international, multicenter, randomized, open-label, superiority trial enrolled patients with unprotected left main coronary artery disease undergoing percutaneous coronary intervention at 28 centers in Italy, Spain and the United Kingdom, from July 2020 through June 2023. Participants were randomly assigned in a 1:1 ratio to undergo PCI guided either by intravascular ultrasound (IVUS) or by angiography alone. The primary outcome was a composite of death, myocardial infarction, stroke or repeat revascularization. Clinical follow-up was performed at 1, 12 and 24 months.

Aim

To compare the efficacy and safety of IVUS-guided PCI versus angiography-guided PCI in patients with unprotected left main coronary artery disease.

Principle results

Most patients were male (78.4%) with a mean age of 71.4 years, and 34% had diabetes. Clinical presentation included NSTEMI (39.1%), unstable angina (10.1%) and chronic coronary syndrome (50.8%), with an intermediate-to-high anatomical complexity (mean SYNTAX score of 29.7). Procedural characteristics and periprocedural complications were similar between groups, although procedure duration was longer in the IVUS-guided PCI group. At a median follow-up of 2.9 years, the primary composite endpoint occurred similarly in the IVUS-guided PCI and angiography-guided PCI groups (33.7% vs. 30.9%; p=0.40). Rates of all-cause death, myocardial infarction and repeat revascularization were comparable between groups, while stroke was more frequent in the IVUS group.

Study limitations

The trial has several limitations including its open-label design, which may introduce bias. Recruitment during the COVID-19 pandemic may have affected enrollment and follow-up. In addition, the overall event rates were relatively low, which may have reduced the power to detect small differences between groups. Finally, as the trial was conducted exclusively in European centers, its generalizability to other populations and clinical settings is limited.

Link to the study: IVUS-Guided versus Angiography-Guided PCI in Unprotected Left Main Coronary Disease

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PRO-TAVI TRIAL :

Percutaneous Coronary Intervention before Transcatheter Aortic Valve Implantation

Dr Emna Allouche

Rsdte Aicha DHIFI

Cardiology Department Charles Nicolle Hospital, Tunis.

Number of patients

The number of patients included is 466 patients, randomized in a 1:1 ratio into two groups: 233 patients assigned to PCI before TAVI and 233 patients assigned to no routine PCI before TAVI. Patients with left main disease or lesions unsuitable for PCI were excluded.

Study design

The PRO-TAVI trial is a prospective, nationwide, multicenter, open-label, randomized controlled non-inferiority trial conducted in 12 centers across the Netherlands.

The aim

of the study was to determine whether deferring routine PCI is non-inferior to performing PCI before TAVI in terms of major cardiovascular and bleeding events at one year.

Principal Results

At one year, the primary composite endpoint of all-cause death, myocardial infarction, stroke, or moderate-to-severe bleeding occurred in 24% of patients in the deferral group versus 26% in the PCI-first group (HR 0.89; p for non-inferiority = 0.0008), with no superiority of either strategy.

A major advantage of the conservative strategy was a significant reduction in bleeding complications. Major bleeding occurred in 6% of patients in the deferral group compared with 15% in the PCI-first group, likely related to less exposure to dual antiplatelet therapy.

Only 11% of patients assigned to the deferral strategy required PCI after TAVI because of persistent or worsening symptoms. These findings suggest that routine pre-TAVI PCI may be avoided in many elderly, intermediate- to high-risk patients without compromising major clinical outcomes, while substantially reducing hemorrhagic events.

Limitations

- open-label design In addition
- patients with left main disease and very complex coronary anatomy were excluded, reducing applicability to more severe CAD cases.

Link to the study: https://doi.org/10.1016/j.ahj.2024.12.003

PROTECT H2H Trial:
A Randomized Comparison Of Emboliner Embolic Protection System vs. Sentinel Cerebral Protection System During Transcatheter Aortic Valve Replacement

Dr Hela BOUZIDI

Rsdte Nourchene AMDOUNI MOUSSI

Habib Thameur Hospital, Cardiology Department

Number of patients included/ number per group

Total patients: 522 patients ≥18 y/o presenting with severe aortic stenosis eligible for treatment via primary TAVR using an FDA-approved bioprosthesis randomized in a 1:1 ratio

Emboliner group: 258 **/Sentinel group:** 264

Study design

Prospective, randomized, multicenter, open-label trial with head-to-head comparison of two embolic protection devices during TAVR and conducted across international centers US (11 sites) , Germany (5 sites) and Brazil (2 sites)

Aim

To evaluate whether the Emboliner full-body embolic protection system is non-inferior or superior to the Sentinel cerebral protection device in preventing periprocedural complications in patients undergoing TAVR (stroke and MACCE).

Principle results

- **Primary endpoint (30-day MACCE: death, stroke, AKI):** No difference : 4.9% (Emboliner) vs 5.0% (Sentinel)
- Stroke at 30 days: Similar and very low 2.0% vs 2.1%
- **Safety outcomes**: → Comparable rates of bleeding and complications
- **Procedural success**: Higher with Emboliner 96% vs 87%
- **Debris capture:** Significantly higher with Emboliner (Larger particles**: 93 vs 31** Total debris: **1575 vs 801**)

Study limitations

- Short follow-up (30 days)
- Low event rates limited power for clinical endpoints
- Not powered to assess systemic embolization benefits
- Surrogate endpoint mismatch (debris vs clinical outcomes)
- DW-MRI was not included in this study

Link to the study: https://clinicaltrials.gov/study/NCT05684146

SCOUT-HCM :
Mavacamten in Adolescents with Obstructive Hypertrophic Cardiomyopathy

Dr Emna Allouche

Rdste Wissal Aloui

Cardiology Department Charles Nicolle Hospital, Tunis.

Number of patients

A total of 44 adolescents were included in the study and divided into two groups: the placebo group (21 patients) and the Mavacamten group (23 patients).

Study design

SCOUT-HCM is an ongoing phase 3, double-blind, randomized, placebo-controlled trial with active-treatment and long-term extension periods. Adolescents aged 12 to <18 years with hypertrophic cardiomyopathy were eligible if they had a left ventricular outflow tract gradient of ≥30 mm Hg during the Valsalva maneuver, a peak gradient of ≥50 mm Hg at rest, during Valsalva, or after exercise, a left ventricular ejection fraction of ≥60%, and were symptomatic with NYHA class II or III. Following enrollment, patients were randomly assigned in a 1:1 ratio to receive either Mavacamten or placebo.

Aim

Evaluation of the impact of Mavacamten on the Valsalva-provoked left ventricular outflow tract (LVOT) gradient from baseline to week 28.

Principle results

Baseline mean Valsalva left ventricular outflow tract gradients were comparable between the two groups (78.4±34.1 mm Hg vs. 80.8±47.4 mm Hg). By week 28, the least-squares mean change was -48.5 mm Hg in the Mavacamten group compared with -0.5 mm Hg in the placebo group, yielding a between-group difference of -48.0 mm Hg (95% CI, -67.7 to -28.3; P<0.001). HCMSQ shortness-of-breath scores changed similarly between groups (-1.1 vs. -0.8; difference -0.3). Peak oxygen uptake improved in 73% vs. 44% (difference 29.6%), with greater reductions in biomarkers in the Mavacamten group (NT-proBNP 0.23, troponin I 0.37, troponin T 0.55). Adverse event rates were comparable between the two groups. Serious adverse events occurred in two patients per group. No patient had a left ventricular ejection fraction below 50%, and no deaths were reported during the study.

Study limitations

The study was limited by a small sample size, short follow-up, limited diversity, lack of validated adolescent outcome measures, and exclusion of patients under 12 years.

Link to the study: https://www.nejm.org/doi/full/10.1056/NEJMoa2601103#sec-1

SIRPAS TRIAL :
Sirolimus-Coated Balloon Angioplasty for Infrainguinal Artery Disease

Dr.kallel Rahma

Rdst Ejdoud Hamoud

Faculty of Medicine of Sfax, Gabès University Hospital

Number of patients

N= 1,252 patients | 626 sirolimus-coated balloon vs. 626 uncoated balloon

Study design

Phase 3, multicenter, prospective, open-label, randomized, noninferiority trial (with pre-specified superiority testing). 44 vascular care centers in Switzerland (Nov 2020 – Dec 2024).

The primary outcome: a composite of unplanned major amputation (major UA) of the target limb or revascularization of the target lesion (TL) for critical limb ischemia. The key secondary outcome: a composite of any UA of the target limb or revascularization of the TL for critical or noncritical limb ischemia within 1 year after randomization.

Aim

To determine if sirolimus-coated balloon (SCB) angioplasty achieves noninferiority — and if confirmed, superiority — to uncoated balloon angioplasty (UBA) in the reduction of major adverse limb events (MALE) at 1 year in patients with symptomatic infrainguinal artery disease.

Principal results

Primary outcome (MALE at 1 year): 8.8% vs.15.0% (ARD* -4.9 pp; 95% CI -8.5 to -1.3; P<0.001 noninferiority; P=0.009 superiority)

Key secondary outcome (any amputation or revascularization): 23.0% vs. 30.8% (ARD -7.8 pp; 95% CI -12.7 to -2.9; P=0.002)

All-cause mortality: 11.8% vs. 12.8% — no significant difference (ARD -1.0 pp; P=0.67). Adverse event rates were similar between groups.

Study limitations

① Not powered to detect differences in unplanned amputations alone.
② Follow-up limited to 1 year — long-term durability unknown (5-year follow-up ongoing).
③ Open-label design may have influenced adjunctive treatment decisions.
④ Single health-care system, predominantly White population — limited generalizability

Link to study https://www.nejm.org/doi/10.1056/NEJMoa2600360

SMART-DECISION Trial :
Discontinuation of Beta-Blocker Therapy after Myocardial Infarction

Dr Manel Ben Halima

Rsdt Salmen Hachicha

Cardiology Department, Rabta Hospital

Number of Patients Included / Number per Group

Total: 2,540 patients (randomized population)

• Discontinuation group: 1,246 /Continuation group: 1,294

Study Design

Multicenter, randomized, open-label, noninferiority trial

- Population: Stable post-MI patients on long-term β-blockers
- Intervention: Discontinuation vs continuation of β-blocker therapy
- Follow-up: Median of 3.1 years
- Analysis: Intention-to-treat

Aim

To determine whether stopping β-blockers in stable patients with preserved systolic function ≥1 year after myocardial infarction is noninferior to continued therapy regarding major cardiovascular outcomes.

Principal Results

• **Primary endpoint:**

o Discontinuation was noninferior to continuation

• No significant increase in:

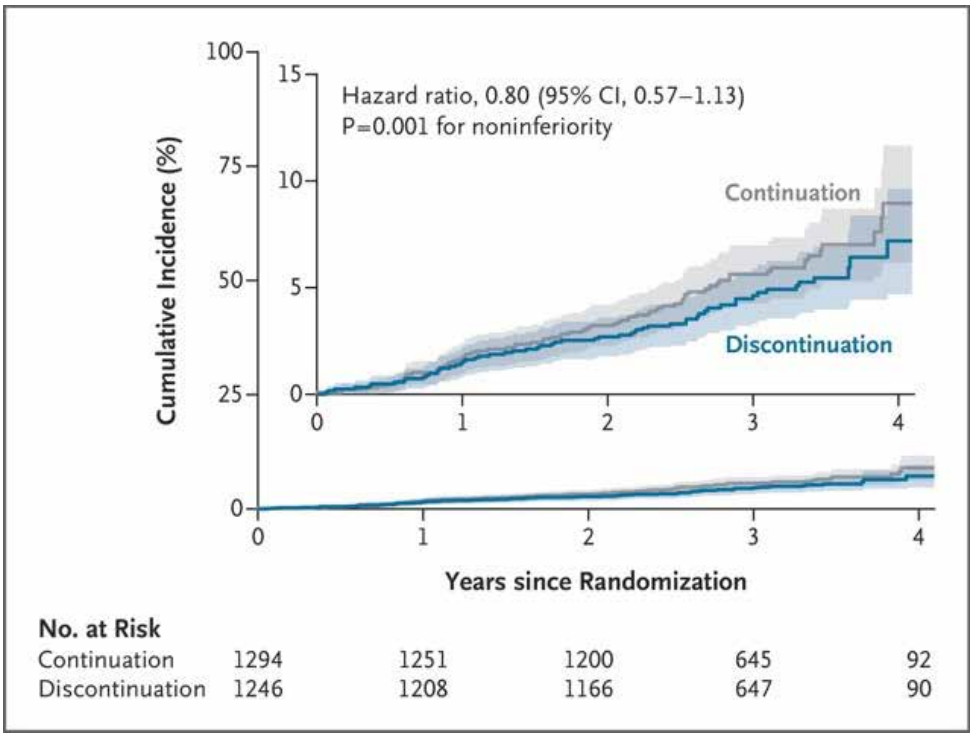
o All-cause mortality

o Recurrent MI

o Heart failure hospitalization

• Results were consistent across subgroups (age, sex, comorbidities)

• **Secondary endpoints:**
o No meaningful difference in cardiovascular death
o No excess safety signal after discontinuation



Study Limitations

- Open-label design (potential bias)
- Exclusively patients with preserved LVEF not generalizable to HFrEF
- Mostly East Asian population limited external validity
- Adherence and crossover may affect outcomes
- Follow-up duration may not capture very long-term effects

Link to the Study: DOI: 10.1056/NEJMoa2601005

SPIRIT-HF:

Spironolactone in the Treatment of Heart Failure with Preserved or Mildly Reduced Ejection Fraction

Dr. Faten Yahia

Rsdt Hassen Dahmen

Department of Cardiology, Sahloul Hospital

Number of Patients Included

730 patients in 56 centers across 4 European countries:

• Spironolactone group: 365 patients Placebo group: 365 patients

~80% HFpEF | ~20% HFmrEF | Median age ~78 years | ~50% women

Study Design

Randomized, double-blind, placebo-controlled trial with parallel groups conducted from 2018 to 2024. Median follow-up: 24 months.

Aim

To determine whether spironolactone reduces the composite of HF hospitalizations and cardiovascular death in patients with HFpEF (LVEF ≥50%) or HFmrEF (LVEF 41–49%).

Principal Results

No significant difference between groups for the primary endpoint at 24 months (Figure 1.):

- Event rates: 12.7 vs 10.8 per 100 patient-years (spironolactone vs placebo)
- Consistent across subgroups (age, sex, ejection fraction)
- Safety: spironolactone showed a worse safety profile : ↑ hypotension, renal events, and hyperkalemia

Study Limitations

• Underpowered due to lower-than-planned recruitment

• High treatment discontinuation rate (>50% in spironolactone arm) largely due to COVID-19

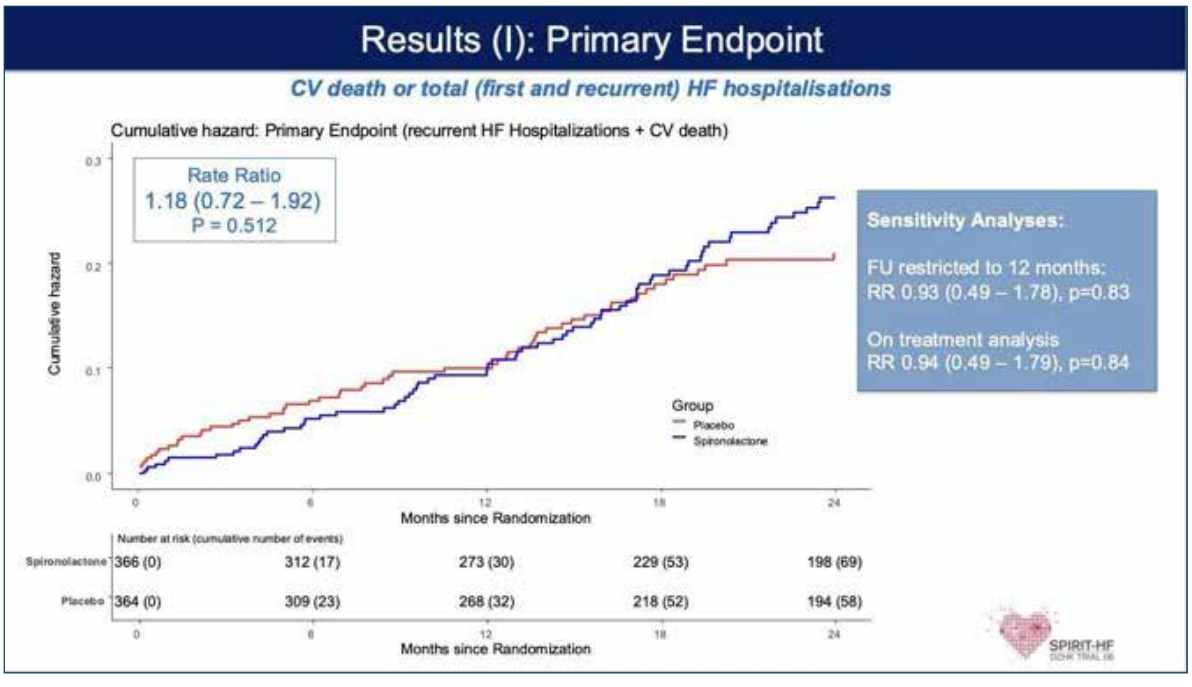


Figure 1. Primary Composite Endpoint (CV Death or HF Hospitalization)

Link to the Study:
https://www.acc.org/latest-in-cardiology/articles/2026/03/25/21/27/sun-1045am-spirithf-acc-2026

STEMI-DTU Trial:
Primary Unloading and Delayed Reperfusion in ST-Elevation Myocardial Infarction

Dr Hela BOUZIDI

Rsdte Soumaya Yahyaoui

Habib Thameur Hospital, Cardiology Department

Number of patients included/ number per group

527 patients with anterior STEMI without cardiogenic shock were enrolled.

Treatment group → LV unloading (Impella + delayed PCI): 262 patients.

Control group → Standard PCI (immediate reperfusion): 265 patients.

Study design

Multicenter, randomized controlled trial conducted across six countries from December 2019 to September 2024.

Patients were randomly assigned (1:1) to either LV unloading using Impella CP for 30 minutes before PCI (treatment group) or PCI alone (control group).

Primary endpoint: Infarct size normalized to LV mass (IS/LVM) assessed by cardiac magnetic resonance imaging 3-5 days after PCI.

Aim

To evaluate whether the combination of mechanical LV unloading plus a 30-minute delay before PCI reduces infarct size compared with immediate PCI alone in patients with anterior STEMI without cardiogenic shock.

Principle results

Mean age was 61±11 years and 417 (79.1%) were men.

Total ischemic time was longer in the treatment arm.

Primary endpoint not met: Infarct size: 30.8% in the treatment group vs 31.9% in the control group; mean difference -1.1% , [p=0.50].

No significant difference in mortality, heart failure, or cardiogenic shock.
Safety: Major bleeding (BARC 3-5) and vascular complications occurred in 34% of patients in the treatment arm vs 6% of the control patients.

Study limitations

Small sample size and early termination.

Link to the study

https://www.acc.org/Latest-in-Cardiology/Articles/2026/03/25/21/27/sat-930am-stemidtu-acc-2026

SURVIV TRIAL:

Randomized Trial of Transcatheter Valve-in-Valve vs Redo Surgery for Bioprosthetic Mitral Dysfunction

Dr Neji Syrine

Rsdt Chalbi Khaled

Charles Nicolle Hospital – Cardiology Department

Number of patients

150 patients included/ 75 per group

Study design

Multicenter, prospective, and controlled trial. Patients were randomized 1:1 to undergo either transcatheter, transseptal mitral valve-in-valve replacement (ViV-TMVR) using the SAPIEN 3 transcatheter heart valve or redo surgical mitral valve replacement with one of three commercially available bioprosthetic valves.

Aim

The aim of the study was to determine whether Valve in Valve transcatheter mitral valve replacement is superior to redo surgery in reducing the composite outcome of all-cause mortality or disabling stroke at 1 year.

Principle results

The primary endpoint of all-cause death or disabling stroke was lower in the mVIV group compared with redo surgery, occurring in 5.3% versus 20.8% of patients, respectively (HR = 0.23; p=0.005).

For the secondary endpoints at 30 days, death from cardiovascular causes was higher in the surgical than the mViV group (12.5% vs. 0%).

Acute kidney injury (15.3% vs. 0%; p<0.001) and life-threatening or major bleeding complications (11.1% vs. 1.3%; p=0.016) occurred more frequently in the surgical group.

The rate of stroke was low in the two groups (1.4% vs. 0%).

The mean mitral gradient was higher in the mViV measuring 5.9 mm Hg and 5.3 mm Hg at three months and 6.7 mm Hg and 5.4 mm Hg (p=0.07) at 12 months. Although, his difference was not statistically significant at one year.

The mitral valve area was larger after redo surgery (1.8 vs 1.5 , p < 0.001 at three months and 1.8 vs 1.4 at 12 months, p = 0.003).

Both procedures resulted in improvement in symptoms and quality of life.

Study limitations :

This study has several limitations, including a small sample size and a single country design. Additionally a high proportion of patients had rheumatic heart disease and pulmonary hypertension, potentially increasing surgical risk and influencing outcomes in favor of the transcatheter approach.

Link to the study

https://www.acc.org/Latest-in-Cardiology/Articles/2026/03/25/21/27/sun-4pm-surviv-acc-2026

THRIVE Pilot Trial :
Applications of Human-Centered Design to Food Is Medicine Interventions

Dr Syrine Saidane

Rsdt Ahmed Yassine Vall

Cardiology Department, Habib Bougatfa University Hospital, Bizerte

Number of patients included

Total: 36 : 29 female / 6 male (≈1 not specified) ,17 English-speaking and 18 Spanish-speaking or bilingual

Study design

Qualitative study using a **human-centered design approach (double diamond framework)** based on **social cognitive theory**

- **3 iterative co-design sessions:**
  Virtual orientation/listening session
  Two in-person sessions (prototyping and process mapping)
- Participants: patients with hypertension, healthcare providers, food system representatives, and community leaders

Aim

To co-design the THRIVE program (Adaptive Personalized Dietitian Coaching and Messaging With Produce Prescriptions to Improve Healthy Dietary Behaviors) among Black and Hispanic adults with hypertension living in healthy food priority areas.

Principal results

Three key themes emerged:

Healthcare system integration : Importance of personalized dietitian support and need for culturally competent care

Food access and education Flexible produce prescription programs and Practical nutrition education

Community empowerment Strong role of peer support networks

Process evaluation: 100% reported meaningful contribution

• 92% recommended this approach for future cardiovascular interventions

Study limitations

Small sample size (n = 36)

• Qualitative design :no direct clinical efficacy outcomes
• No control group
• Limited generalizability :specific to Maryland population
• Possible selection bias

Link to the Study: https://www.ahajournals.org/doi/suppl/10.1161/JAHA.125.041846

VESALIUS-CV Trial :
Evolocumab in Patients without a Previous Myocardial Infarction or Stroke

Dr Syrine Saidane **Rsdte Sara Boufrahi**

Cardiology Department, Habib Bougatfa University Hospital, Bizerte

Number of patients included

12,257 patients randomized 1:1 to receive evolocumab at a dose of 140 mg every 2 weeks or placebo.

Study design

- Phase 3, randomized, double-blind, placebo-controlled, global clinical trial.
- Patients with known ASCVD or high-risk diabetes, without prior myocardial infarction (MI) or stroke, LDL-C ≥90 mg/dL, on optimized statin therapy.

Aim

To evaluate whether LDL-C lowering with evolocumab (PCSK9 inhibitor) added to optimized statin therapy reduces the risk of major adverse cardiovascular events (MACE) in high-risk patients without a previous MI or stroke.

Principle results

Both dual primary endpoints were met with statistical and clinical significance:

- CHD death, MI, or ischemic stroke: 25% relative risk reduction (RRR) with evolocumab vs. placebo (HR 0.75).
- CHD death, MI, ischemic stroke, or ischemia-driven revascularization: 19% RRR with evolocumab (HR 0.81).
- Additional: 27% reduction in CV death/MI/ischemic stroke; 36% reduction in MI alone.

LDL-C was reduced by ~55% at 48 weeks (median 45 mg/dL vs. 109 mg/dL in the placebo group). Results were consistent across key subgroups including high-risk diabetes. No new safety signals were observed.

Study limitations

8% of patients were not on any cholesterol-lowering therapy at baseline.
The majority of participants were White, limiting generalizability to diverse racial and ethnic populations.

Link to the study: https://www.nejm.org/doi/full/10.1056/NEJMoa2514428

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