

Key research findings presented at the HOT LINE sessions of the 2025 European Society of Cardiology Congress

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At the 10 HOT LINE scientific sessions of the 2025 European Society of Cardiology Congress, the results of 40 randomized clinical trials and 1 meta-analysis were presented for the first time. The studies addressed various fields of cardiology, including the treatment of arterial hypertension, myocardial infarction, cardiac arrhythmias, heart failure, dyslipidemia, and hypertrophic cardiomyopathy, as well as the improvement of antiplatelet and anticoagulant therapy, interventional and surgical procedures, and perioperative patient management.

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POTCAST. The study enrolled 1,200 patients at high risk of ventricular arrhythmias, with an implantable cardioverter-defibrillator (ICD), and a baseline plasma potassium level of 4.3 mmol/L or lower. Following a 1:1 randomization, patients received either treatment aimed at increasing plasma potassium levels to 4.5–5.0 mmol/L using potassium supplements, a mineralocorticoid receptor antagonist, or both, combined with dietary advice, or standard therapy. At a median follow-up of 39.6 months, a composite of primary endpoint events (documented sustained ventricular tachycardia or appropriate ICD shock, unplanned hospitalization for more than 24 hours due to arrhythmia or heart failure (HF), or death from any cause) was observed in 22.7% of patients in the high-normal potassium group compared to 29.2% in the standard therapy group ($p=0.01$). The rates of hospitalization for hyperkalemia or hypokalemia were similar in both groups [1].

AMALFI. In a randomized trial in older adults (mean age 78 years) with a median CHA2DS2-VASc thromboembolic risk score of 4 and no history of atrial fibrillation (AF), a single continuous 14-day ambulatory electrocardiographic (ECG) monitoring was performed using an ECG patch to screen for AF and assess its prognostic benefit. The data of patients who received and mailed back the ECG monitoring patch (intervention group; $n=2,520$) were compared with those receiving usual care (control group; $n=2,520$). AF was detected by the patch in 4.2% of participants in the intervention group. At 2.5 years post-randomization, AF was recorded in 6.8% of patients in the intervention group and 5.4% in the control group ($p=0.03$), which was associated with a 0.5-month longer duration of oral anticoagulant therapy in the former group ($p<0.001$). However, the stroke incidence rates in the groups were 2.7% and 2.5%, respectively [2].

DIGIT-HF. The study evaluated the therapeutic efficacy of the cardiac glycoside digitoxin in patients with HF and a reduced left ventricular ejection fraction (LVEF). A total of 1,212 patients with chronic HF New York Heart Association (NYHA) functional class III or IV and an LVEF of $\leq 40\%$, as well as NYHA functional class II and an LVEF of $\leq 30\%$, were randomized in a 1:1 ratio to receive digitoxin (at an initial dose of 0.07 mg once daily) or a placebo, in addition to guideline-directed medical therapy. At a median follow-up of 36 months, the primary endpoint (death from any

cause or hospitalization for worsening HF) was recorded in 39.5% of patients in the digitoxin group and 44.1% in the placebo group ($p=0.03$), with a trend toward reduced mortality (by 14%) in the cardiac glycoside group and a comparable incidence of serious adverse events (4.7% vs. 2.8% in the digitoxin and placebo groups, respectively) [3].

DOUBLE-CHOICE. In this study, patients with a mean age of 83 years were randomized to undergo transcatheter aortic valve implantation (TAVI) using a minimally invasive approach under isolated local anesthesia ($n=377$) or the standard approach using conscious sedation ($n=375$). Primary endpoint events (a composite of all-cause mortality, vascular and bleeding complications, infections requiring antibiotic therapy, and neurological disorders within 30 days) were recorded in 22.9% of patients in the minimally invasive approach group and 25.8% in the standard care group ($p=0.003$ for non-inferiority). In patients from the local anesthesia group, the levels of anxiety, stress, pain, and discomfort during the procedure were comparatively higher [4].

DAPA ACT HF-TIMI 68. In a study involving patients hospitalized for HF (71.5% with LVEF $\leq 40\%$), following clinical stabilization (at 24 hours to 14 days), participants were randomized to receive dapagliflozin at a dose of 10 mg/day ($n=1,218$) or a placebo ($n=1,183$). The primary efficacy endpoint, cardiovascular (CV) death or worsening HF within 2 months, was observed in 10.9% of patients in the dapagliflozin group and 12.7% in the placebo group ($p=0.20$), while all-cause death occurred in 3.0% and 4.5% of cases, respectively. The incidence of symptomatic hypotension was 3.6% and 2.2%, and the incidence of worsening renal function was 5.9% and 4.7% for dapagliflozin and placebo, respectively. According to a pre-specified meta-analysis of DAPA ACT HF-TIMI 68 and two other trials of patients hospitalized for HF, sodium-glucose cotransporter 2 (SGLT2) inhibitors reduced the risk of CV death or worsening HF by 29% ($p=0.012$) and the risk of all-cause death by 43% ($p=0.001$) [5].

VICTORIA and VICTOR. Following the completion of the VICTORIA trial ($n=5,050$), the soluble guanylate cyclase (sGC) stimulator vericiguat was approved for the treatment of worsening HF with reduced LVEF and received a Class IIb recommendation in European and North American guidelines. A subsequent trial, VICTOR ($n=6,105$), evaluated the use of vericiguat

in patients with HF and reduced LVEF without a recent worsening HF event. A pre-specified pooled analysis of individual patient data from the VICTORIA and VICTOR trials was conducted to determine the impact of vericiguat on clinical outcomes. Participants in both trials received contemporary guideline-directed background HF therapy. The primary endpoint (CV death or HF hospitalization) was observed in 25.9% of the 5,579 patients in the vericiguat group and 27.9% of the 5,576 patients in the placebo group ($p=0.0088$), including significant reductions in the risk of CV death (by 11%; $p=0.020$) and the rate of HF hospitalization (by 8%; $p=0.043$). Consequently, vericiguat can be used as an additional treatment option for selected patients with HF and reduced LVEF [6].

ODYSSEY-HCM. In this study, the cardiac myosin inhibitor mavacamten, approved for the treatment of adult patients with symptomatic obstructive hypertrophic cardiomyopathy, was evaluated in its non-obstructive form. Following randomization, 289 patients received mavacamten (starting dose of 5 mg/day with titration up to a maximum dose of 15 mg/day depending on LVEF) and 291 received a placebo. Over a 48-week follow-up period, no significant differences were observed for the two main endpoints: the mean change in peak oxygen consumption was 0.52 mL/kg/min in the mavacamten group and 0.05 mL/kg/min in the placebo group ($p=0.07$), and the change in quality of life assessed by the 23-item Kansas City Cardiomyopathy Questionnaire was 13.1 points versus 10.4 points ($p=0.06$). In patients with non-obstructive hypertrophic cardiomyopathy, mavacamten did not result in a significantly greater improvement in peak oxygen consumption or symptom reduction compared to placebo [7].

MAPLE-HCM. The study compared the cardiac myosin inhibitor aficamten with metoprolol in patients with obstructive hypertrophic cardiomyopathy. Following randomization, 88 patients received aficamten at a dose of 5 to 20 mg/day plus placebo, and 87 received metoprolol at a dose of 50 to 200 mg/day plus placebo. Over 24 weeks of follow-up, the change in peak oxygen consumption (primary endpoint) was 1.1 mL/kg/min in the aficamten group and -1.2 mL/kg/min in the metoprolol group ($p<0.001$). Patients who received aficamten experienced significant improvements in NYHA HF functional class, quality of life assessed by the Kansas City Cardiomyopathy Questionnaire, left ventricular outflow tract gradi-

ent, N-terminal pro-B-type natriuretic peptide (NT-proBNP) levels, and left atrial volume index compared to those receiving metoprolol. No significant differences were observed in the left ventricular mass index or the incidence of adverse events between the two treatment groups [8].

REBOOT-CNIC. This open-label randomized trial compared the outcomes of contemporary treatment (coronary reperfusion and secondary prevention) in patients with ST-segment elevation or non-ST-segment elevation myocardial infarction (MI) and an LVEF $>40\%$ receiving beta-blocker therapy ($n=4,207$) versus no beta-blocker therapy ($n=4,231$). At a median follow-up of 3.7 years, primary endpoint events (a composite of death from any cause, recurrent MI, or hospitalization for HF) occurred with equal frequency ($p=0.63$) in both groups. There were no differences in the rates of all-cause death, recurrent MI, hospitalization for HF, or treatment safety profiles [9].

BETAMI-DANBLOCK. This open-label randomized trial involved patients with a prior MI and an LVEF $\geq 40\%$ who, within 14 days after the index event, were allocated to receive long-term beta-blocker therapy ($n=2,783$) or no beta-blocker therapy ($n=2,791$). At a median follow-up of 3.5 years, the composite primary endpoint (death from any cause, MI, unplanned coronary revascularization, ischemic stroke, HF, or malignant ventricular arrhythmias) was observed in 14.2% of patients in the beta-blocker group and 16.3% in the no beta-blocker group ($p=0.03$), with no significant differences in the rates of its individual components or therapy safety profiles between the groups. In this trial, among patients with MI and an LVEF $\geq 40\%$, beta-blocker therapy led to a reduced risk of death or major adverse cardiovascular events compared to no beta-blocker therapy [10].

REBOOT/BETAMI/DANBLOCK/CAPITAL. To conduct a meta-analysis on the impact of beta-blockers on clinical outcomes in patients with a recent (within 14 days) ST-segment elevation or non-ST-segment elevation MI, data from 1,885 participants with a mildly reduced LVEF (40–49%) and no history or signs of HF were selected from four randomized trials. The primary composite endpoint (all-cause death, new MI, or HF) was recorded 25% less frequently in the beta-blocker group compared to the no beta-blocker group ($p=0.031$). There was no heterogeneity observed across the trials or between the countries where the studies were conducted. These results

allow extending the known benefits of beta-blockers in patients with MI and reduced LVEF to the subgroup with mildly reduced LVEF [11].

REFINE ICD. To select participants for the study, Holter ECG monitoring was performed in patients who had suffered a type 2 MI or more months prior ($n=1,943$). Based on the results, 597 patients meeting the inclusion criteria (LVEF 36–50%, impaired heart rate turbulence, T-wave alternans) were identified and randomized to receive an ICD in addition to medical therapy or medical therapy alone. Another 1,053 examined individuals comprised the registry group. The risk of all-cause death was 2.01 times higher in the high-risk group included in the trial compared to the registry group. However, over a mean follow-up of 5.7 years for patients with abnormal ECG findings participating in the randomized trial, overall mortality (the primary endpoint) did not decrease in the ICD group: 24.5% vs. 21.3% in the control group ($p=0.69$). Furthermore, there were no significant differences between the two study groups in the rates of CV death (8.8% vs. 7.6%), sudden cardiac death (2.6% vs. 3.8%, respectively), or non-cardiovascular death.

BaxHTN. This phase 3 trial enrolled patients with a seated systolic blood pressure (BP) ranging from 140 mmHg to 170 mmHg despite therapy with two antihypertensive drugs—uncontrolled arterial hypertension (AH)—or 3 or more drugs, including a diuretic (resistant AH). Following a two-week placebo run-in period, patients with a seated systolic BP of 135 mmHg or higher were randomized to receive the selective aldosterone synthase inhibitor baxdrostat at a dose of 1 mg ($n=264$), baxdrostat at a dose of 2 mg ($n=266$), or a placebo ($n=264$) once daily. At 12 weeks, the change in seated systolic BP from baseline (the primary endpoint) was -14.5 mmHg with 1 mg of baxdrostat, -15.7 mmHg with 2 mg of baxdrostat, and -5.8 mmHg with placebo. The placebo-corrected difference was -8.7 mmHg for 1 mg of baxdrostat and -9.8 mmHg for 2 mg of baxdrostat ($p<0.001$ for both comparisons). A potassium level greater than 6.0 mmol/L was recorded in 2.3% of patients in the 1 mg baxdrostat group, 3.0% in the 2 mg baxdrostat group, and 0.4% in the placebo group. In patients with uncontrolled or resistant AH, the addition of baxdrostat to background therapy resulted in a significant reduction in seated systolic BP at 12 weeks compared to placebo [12].

KARDIA-3. Zilebesiran is a small interfering ribonucleic acid (siRNA) that inhibits the production of angiotensinogen in the liver, thereby reducing the activity of the renin-angiotensin-aldosterone system (RAAS). This phase 2 trial enrolled adults with established CV disease or high CV risk (10-year atherosclerotic CVD risk >15%). An additional inclusion criterion was uncontrolled AH (mean office systolic BP of 140–170 mmHg and mean systolic BP of 130–170 mmHg based on 24-hour ambulatory BP monitoring for 7 days prior to randomization) despite the use of 2–4 antihypertensive drugs, including calcium channel blockers or diuretics. Participants were randomized to receive a single subcutaneous injection of zilebesiran at a dose of 300 mg ($n=91$), 600 mg ($n=91$), or a placebo ($n=89$). During the first 3 months, antihypertensive therapy remained unchanged except for cases of systolic BP >160 mmHg or clinical indications. After 3 months, intensification of antihypertensive therapy was permitted if systolic BP remained >140 mmHg. The mean reduction in office systolic BP at 3 months (the primary endpoint) in the zilebesiran 300 mg or 600 mg groups compared to placebo was not statistically significant, amounting to 5.0 mmHg and 3.3 mmHg, and at 6 months, 3.9 mmHg and 3.6 mmHg, respectively.

Essence-TIMI 73b. Olezarsen is an antisense oligonucleotide that inhibits the synthesis of apolipoprotein C-III, leading to a reduction in plasma triglyceride levels. This drug was evaluated in a phase 3 randomized trial involving patients with moderate hypertriglyceridemia (triglyceride levels from 150 to 499 mg/dL) and high CV risk, or with severe hypertriglyceridemia (triglyceride levels ≥ 500 mg/dL), who were randomized in a 1:3 ratio to receive monthly subcutaneous injections of olezarsen at a dose of 50 mg ($n=254$), olezarsen at a dose of 80 mg ($n=766$), or a placebo ($n=329$). After 6 months of treatment, the mean placebo-adjusted change in triglyceride levels was -58.4% in the olezarsen 50 mg group ($p<0.001$) and -60.6% in the olezarsen 80 mg group ($p<0.001$). The frequency of serious adverse events was similar across all study groups [13].

VICTORION-Difference. The study enrolled patients with hypercholesterolemia and high or very high CV risk. Participants were randomized to receive inclisiran sodium (300 mg subcutaneously; $n=898$) or a placebo ($n=872$) in combination with individually tailored rosuvastatin therapy until the low-den-

sity lipoprotein cholesterol (LDL-C) target was reached or at the maximum tolerated dose. On day 90, the LDL-C target level was achieved significantly more frequently in the inclisiran group compared to the control group (84.9% vs. 31.0%; $p < 0.001$). The mean reduction in LDL-C from baseline to day 360 was -59.5% and -24.3% in the inclisiran and control groups, respectively ($p < 0.001$). A lower proportion of participants receiving inclisiran reported muscle-related adverse events (11.9% vs. 19.2% in the control group; $p < 0.001$). No new treatment safety issues were identified [14].

DANCAVAS II. In this study, Danish men aged 60–64 were invited to participate in screening for sub-clinical CVD based on computer-generated random numbers for comparison with a control group (1:4 ratio). Screening included assessment of coronary artery calcification, arterial aneurysms, AF, peripheral artery disease, AH, diabetes, and hypercholesterolemia. The intervention involved prescribing statins, aspirin, and observation. Of the 5,946 invitees, 62.6% ($n=3,720$) attended and underwent the screening; the control group consisted of 25,322 individuals. In an intention-to-treat analysis after a median follow-up of 7.0 years, 9.3% of men in the intervention group and 9.9% in the control group died ($p=0.169$). Major adverse CV events occurred in 10.2% and 10.6% ($p=0.319$). Major bleeding was recorded in 6.0% and 5.1% of participants, respectively ($p=0.007$), with intracranial hemorrhages occurring 23% more frequently ($p=0.097$) and gastrointestinal bleeding 18% more frequently ($p=0.014$) in the screening and subsequent intervention group [15].

PERI-CRIT. Perioperative beta-blockade reduces heart rate and the risk of MI but increases the risk of hypotension, death, and stroke. It was hypothesized that ivabradine, which selectively reduces heart rate, could prevent prognostically significant myocardial damage after non-cardiac surgery without causing hemodynamic instability. The study involved patients aged ≥ 45 years with atherosclerotic disease or a risk of its development who were scheduled for non-cardiac surgery. They were randomized to receive ivabradine ($n=1,050$) at a dose of 5 mg twice daily for 1 hour before surgery and for 7 days, or a placebo ($n=1,051$). The mean heart rate during surgery was 3.2 beats per minute lower in the ivabradine group than in the placebo group, while the mean BP during surgery did not differ between the groups. However, an elevated post-

operative cardiac troponin level in ≥ 1 sample above the 99th percentile of the upper reference limit within 30 days after randomization (the primary endpoint) was observed in 17.0% of patients in the ivabradine group and 15.1% in the placebo group ($p=0.25$) [16].

ABC-AF. The biomarker-based ABC-AF-stroke score (age, NT-proBNP, and high-sensitivity troponin T, and clinical history of stroke/transient ischemic attack) provides a quantitative assessment of stroke risk both with and without oral anticoagulant treatment. Similarly, the biomarker-based ABC-AF-bleeding score (age, growth differentiation factor 15, hemoglobin, high-sensitivity troponin T, and past history of bleeding) provides a quantitative assessment of the risk of major bleeding during oral anticoagulant treatment, which can be compared with the quantitative risk of stroke. In a randomized registry-based trial involving 3,933 patients with AF (mean age 73.9 years), researchers in the intervention group obtained stroke and bleeding risk information for each patient using the ABC-AF score to support decision-making and treatment recommendations, including the choice of anticoagulant therapy. In the control group, patient management was left to the researchers' discretion, who typically followed clinical guidelines. Enrollment was terminated early due to safety concerns when, at a median follow-up of 2.6 years, 19% ($p=0.12$) more primary endpoint events (stroke or death) occurred in the active group compared to the control. There were also trends toward increased risks of major bleeding (by 8%; $p=0.50$), stroke (by 18%; $p=0.44$), and death (by 21%; $p=0.13$) in the group using the ABC-AF-stroke and ABC-AF-bleeding scores compared to the control. These findings highlight the need for prospective testing of the clinical utility of risk stratification and precision medicine tools in various clinical settings before their implementation into everyday medical practice [17].

HI-PRO. The optimal duration of anticoagulant therapy following venous thromboembolism (VTE) in patients with a transient provoking factor (e.g., surgery, trauma, or immobilization) and concurrent persistent risk factors remains undefined. In a randomized trial, patients with VTE following a transient provoking factor who had at least one persistent risk factor and had received at least 3 months of anticoagulant therapy were randomized to groups receiving apixaban 2.5 mg twice daily ($n=300$) or a placebo ($n=300$) for 12 months. During the follow-up period,

primary efficacy endpoint events (the first symptomatic VTE recurrence) were recorded in 1.3% of patients in the apixaban group and 10.0% in the placebo group ($p<0.001$). Primary safety endpoint events (the first episode of major bleeding according to International Society on Thrombosis and Haemostasis criteria) occurred with comparable frequency: major bleeding was seen in 1 patient in the apixaban group and none in the placebo group; clinically relevant non-major bleeding was observed in 4.8% of patients in the apixaban group and 1.7% in the placebo group ($p=0.06$). Rare fatal outcomes were not related to cardiovascular or hemorrhagic causes [18].

SWEDEPAD 1 and 2. These trials were conducted to evaluate the prognostic efficacy and the impact on quality of life of drug-eluting stents used in endovascular revascularization of infrainguinal arteries in patients with peripheral artery disease. The SWEDEPAD 1 project enrolled patients with chronic limb-threatening ischemia (Rutherford stages 4–6) who, after successful guidewire passage, were randomized to receive either paclitaxel-coated stents ($n=1,206$) or uncoated stents ($n=1,194$). At a median follow-up of 2.67 years, the incidence of the primary endpoint (ipsilateral major amputation (above the ankle)) did not differ significantly ($p=0.61$), nor did all-cause mortality ($p=0.54$) between the groups. Thus, in patients with chronic limb-threatening ischemia undergoing endovascular revascularization, the use of paclitaxel-coated stents did not reduce the rate of major ipsilateral amputations [19]. The SWEDEPAD 2 project involved patients with intermittent claudication (Rutherford stages 1–3) who, after successful guidewire passage, were randomized to receive either paclitaxel-coated stents ($n=577$) or uncoated stents ($n=578$). No difference in quality of life was observed between the groups at 1 year as assessed by the VasuQoL-6 questionnaire (the primary endpoint) ($p=0.96$). All-cause mortality over a mean follow-up of 7.1 years also did not differ significantly ($p=0.16$), although 5-year mortality was higher in patients randomized to the paclitaxel-coated stent group ($p=0.010$). These findings do not support the routine use of expensive paclitaxel-coated stents for endovascular revascularization of infrainguinal arteries [20].

PULSE. The study aimed to evaluate the clinical benefit of routine coronary computed tomographic angiography (CCTA) following percutaneous coronary

intervention (PCI) for unprotected left main coronary artery stenosis. A total of 606 patients who received second-generation drug-eluting stents were examined and randomized 1:1 to undergo CCTA at 6 months (experimental group) or receive standard care (control group). At 18 months, the incidence of the composite primary endpoint (all-cause death, spontaneous MI, unstable angina, definite or probable stent thrombosis) was 11.9% in the experimental group versus 12.5% in the control group ($p=0.80$). Compared to the control group, the CCTA group showed a reduced risk of spontaneous MI (0.9% vs. 4.9%; $p=0.004$) and an increased risk of imaging-driven target lesion revascularization (4.9% vs. 0.3%; $p=0.001$), while the rate of clinically-driven target lesion revascularization was similar (5.3% vs. 7.2%; $p=0.32$) [21].

AQUATIC. The study included patients with chronic coronary syndrome who had undergone stent implantation more than 6 months prior to enrollment, had high atherothrombotic risk, and were receiving maintenance oral anticoagulant therapy. Following randomization, either aspirin at a dose of 100 mg ($n=433$) or a placebo ($n=439$) was added to the anticoagulant therapy once daily. The study was terminated early on the recommendation of an independent data and safety monitoring board after a median follow-up of 2.2 years due to an excess number of all-cause deaths in the aspirin group. The primary efficacy endpoint (a composite of CV death, MI, stroke, systemic embolism, coronary revascularization, or acute limb ischemia) was observed in 16.9% of patients in the aspirin group and 12.1% in the placebo group ($p=0.02$), while all-cause death occurred in 13.4% versus 8.4% of cases, respectively ($p=0.01$). The key safety indicator (major bleeding) was recorded in 10.2% of patients in the aspirin group and 3.4% in the placebo group ($p<0.001$) [22].

DUAL-ACS. This study compared the outcomes of 3-month and 12-month dual antiplatelet therapy (DAPT) in a real-world clinical practice population, which included 5,052 patients who had suffered a type 1 MI within the previous 12 weeks and had received treatment in the form of PCI (70%), coronary artery bypass grafting (CABG) (6%), or medical therapy alone (23%). After 15 months of follow-up, the primary endpoint (all-cause death) occurred in 2.7% of patients in the 3-month DAPT group and 3.4% in the 12-month DAPT group ($p=0.1232$), with no difference in the rate of CV death or non-fatal MI ($p=0.6149$).

Major bleeding, whether fatal or non-fatal, was recorded in 3.2% of patients in the 3-month group and 4.0% in the 12-month DAPT group ($p=0.0977$). No evidence was obtained that DAPT administered for 12 months after MI, in accordance with current guidelines, provided any additional benefit.

OPTION-STEMI. Patients with STEMI and multivessel disease who underwent PCI of the culprit lesion were randomized to either immediate complete revascularization (PCI of non-culprit stenoses during the index procedure; $n=498$) or staged complete revascularization (PCI of remaining stenoses on a different day during the index hospitalization; $n=496$). Non-culprit lesions with 50–69% diameter stenosis were assessed using fractional flow reserve (FFR). The primary endpoint (all-cause death, non-fatal MI, or any unplanned revascularization) at 1 year occurred in 13% of the immediate intervention group and 11% of the staged intervention group (p for non-inferiority = 0.24). The rates of stroke, major bleeding, and contrast-induced nephropathy did not differ significantly between the two groups. Cardiogenic shock during the index hospitalization was observed in 4% of patients in the immediate revascularization group and 2% in the staged complete revascularization group [23].

NEO-MINDSET. The study involved patients after successful PCI for acute coronary syndromes (ACS) who, within the first 4 days of hospitalization, were randomized to aspirin discontinuation followed by monotherapy with a potent P2Y12 inhibitor (ticagrelor or prasugrel) ($n=1,712$) or DAPT (aspirin plus a potent P2Y12 inhibitor) ($n=1,698$) for 12 months. During the follow-up period, primary endpoint events (all-cause death, MI, stroke, or urgent revascularization) occurred in 7.0% of patients in the monotherapy group and 5.5% in the DAPT group ($p=0.11$ for non-inferiority). Major or clinically relevant non-major bleeding was observed in 2.0% of the monotherapy group and 4.9% of the DAPT group, while stent thrombosis occurred in 12 and 4 patients in the respective groups. Among patients who underwent successful PCI for ACS, monotherapy with a potent P2Y12 inhibitor was non-inferior to dual antiplatelet therapy in preventing the composite risk of death and ischemic events over 12 months [24].

TAILORED-CHIP. The study evaluated the efficacy and safety of individually tailored antiplatelet therapy with temporal modulation of platelet inhibition inten-

sity in 2,018 patients undergoing complex PCI with high-risk anatomical or clinical features. Individually tailored antiplatelet therapy with early escalation (ticagrelor 60 mg twice daily plus aspirin for 6 months) was compared with DAPT (clopidogrel plus aspirin for 12 months). PCI of the left main coronary artery was performed in 22.6% of cases, complex bifurcation PCI in 19.5%, PCI of diffuse long lesions in 84.1%, multivessel PCI in 93.7%, and PCI in medically treated diabetic patients in 36.7%. The primary endpoint (a composite of all-cause death, MI, stroke, stent thrombosis, unplanned urgent revascularization, and clinically significant Bleeding Academic Research Consortium type 2, 3, or 5 bleeding) at 12 months occurred in 10.5% of patients receiving individually tailored antiplatelet therapy and 8.8% of those receiving DAPT ($p=0.21$). The frequency of major ischemic events was similar in both groups, while the rate of clinically significant bleeding at 12 months was 7.2% in the tailored therapy group and 4.8% in the DAPT group. No benefits of individually tailored antiplatelet therapy were shown for high-risk patients undergoing complex PCI [25].

TARGET-FIRST. The study enrolled patients who underwent successful complete coronary revascularization with modern drug-eluting stent implantation within 7 days after an MI and who completed 1 month of DAPT without ischemic complications or major bleeding. Following randomization, patients received either P2Y12 inhibitor monotherapy ($n=961$) or DAPT ($n=981$) for 11 months. During the follow-up period, the primary composite endpoint (all-cause death, MI, stent thrombosis, stroke, or Bleeding Academic Research Consortium type 3 or 5 bleeding) occurred in 2.1% of patients in the P2Y12 inhibitor monotherapy group and 2.2% in the DAPT group ($p=0.02$ for non-inferiority). The major secondary endpoint (Bleeding Academic Research Consortium type 2, 3, or 5 bleeding) was observed in 2.6% of patients in the P2Y12 inhibitor monotherapy group and 5.6% in the DAPT group ($p=0.002$ for superiority). Stent thrombosis was rare, and its incidence was identical in the compared groups [26].

DAPT-SHOCK-AMI. The exclusion of patients with MI complicated by cardiogenic shock from landmark antiplatelet therapy trials had left gaps in evidence, forcing clinicians to rely on extrapolations from registries and small pharmacodynamic studies, leading to heterogeneity in clinical care. This project was the

first randomized controlled trial of antiplatelet agents involving 605 patients with MI complicated by cardiogenic shock, who were randomized to receive either cangrelor (IV bolus of 30 µg/kg followed by a continuous infusion of 4 µg/kg) or ticagrelor (crushed tablets administered orally in a 180 mg loading dose, followed by a maintenance dose of 90 mg twice daily). The primary laboratory efficacy endpoint (platelet reactivity index 50% at the end of primary PCI) was achieved in 100% of patients receiving cangrelor and 22.1% of those receiving ticagrelor ($p < 0.0001$). At 30 days, the clinical primary endpoint (all-cause death, MI, or stroke) was recorded in 37.6% of patients in the cangrelor group and 41.0% in the ticagrelor group (p for non-inferiority = 0.13), while the rate of major bleeding was 6.4% and 5.2%, respectively. All-cause death at 12 months occurred in 43.6% of patients in the cangrelor group compared to 49.2% in the ticagrelor group. There was a reduction in the risk of disability and total healthcare costs over 12 months for patients treated with cangrelor.

ALONE-AF. Patients included in the study had at least one non-sex-related stroke risk factor (determined by the CHA₂DS₂-VASc score, mean 2.1) and no documented recurrence of atrial tachyarrhythmia for at least 1 year following catheter ablation of AF. Participants were randomized to the oral anticoagulant discontinuation group ($n=417$) or the maintenance direct oral anticoagulant (DOAC) group ($n=423$). At the 2-year follow-up, the primary endpoint (a composite of stroke, systemic embolism, and major bleeding) occurred in 0.3% of patients in the anticoagulation discontinuation group and 2.2% in the maintenance DOAC group ($p=0.02$). Specifically, the incidence of ischemic stroke was 0.3% versus 0.8%, and major bleeding was 0% versus 1.4% in the discontinuation and maintenance groups, respectively. These results suggest that lifelong oral anticoagulation may not be necessary for all patients who have undergone successful AF ablation [27].

BEAT-PAROX-AF. Pulmonary vein isolation has undergone a paradigm shift with the emergence of pulsed field ablation (PFA)—a relatively simple procedure providing more tissue-selective treatment than thermal energy sources. In a study of 289 patients with symptomatic paroxysmal AF resistant to ≥ 1 antiarrhythmic drug, pulmonary vein isolation via PFA was compared to radiofrequency (RF) ablation using the CLOSE protocol. The primary endpoint

was the success rate (no arrhythmia recurrence lasting ≥ 30 seconds, cardioversion, class I/III antiarrhythmic drug use after 2 months, and repeat ablation) 12 months after a single procedure, which was 77.2% in the PFA group and 77.6% in the RF group ($p=0.84$). Serious procedure-related adverse events, including unplanned or prolonged hospitalizations, were observed in 3.4% vs. 7.6% of patients in the PFA and RF groups, respectively. No deaths, permanent phrenic nerve palsies, or strokes occurred. The total procedure time was shorter with PFA (56 minutes vs. 95 minutes).

CUVIA-PRR. Digital twin technology allows for the precise identification of specific atrial regions that likely drive AF persistence, facilitating a personalized approach to ablation. In a study involving 304 patients with persistent AF refractory to antiarrhythmic drugs, participants were randomized to either individualized pulmonary vein isolation targeting selected phase singularity points or standard pulmonary vein isolation. At 18 months post-ablation, the rate of freedom from atrial arrhythmia recurrence was significantly higher with individualized ablation compared to the standard approach (77.9% vs. 59.5%; $p=0.004$), including patients not receiving antiarrhythmic drugs (45.7% vs. 31.7%). The mean total procedure time was comparable between the two ablation strategies.

PARACHUTE-HF. The study enrolled patients with confirmed Chagas disease and HF with an LVEF $\leq 40\%$ and NT-proBNP levels ≥ 600 pg/mL (or ≥ 150 pg/mL), or ≥ 400 pg/mL (or ≥ 100 pg/mL) in those hospitalized for HF within the previous 12 months. Patients were randomized to receive sacubitril/valsartan (target dose 200 mg twice daily; $n=462$) or enalapril (target dose 10 mg twice daily; $n=460$), added to standard therapy. At a median follow-up of 25.2 months, CV death occurred in 23.8% vs. 25.4% of participants, and the first HF hospitalization was recorded in 22.1% vs. 24.1% of patients in the sacubitril/valsartan and enalapril groups, respectively. Thus, no significant differences in clinical outcomes were found between the compared therapies, although patients in the sacubitril/valsartan group showed a more pronounced reduction in NT-proBNP levels (22.5% vs. 5.5%) at 12 weeks [28].

HELP-MISWEDEHEART. The study aimed to establish the effect of routine *Helicobacter pylori* screening using a urea breath test on the incidence of upper gastrointestinal bleeding in 18,466 patients hospital-

ized with MI. Upon admission, 2,284 patients during the screening period and 2,275 patients during the non-screening period reported taking proton pump inhibitors (PPIs). During the screening, 6,480 patients (70%) underwent testing, and 23.6% of them tested positive for *Helicobacter pylori*. At a median follow-up of 1.9 years, no significant difference was found in the incidence of upper gastrointestinal bleeding (the primary endpoint), which occurred in 4.1% of patients in the *Helicobacter pylori* screening group and 4.6% in the control group ($p=0.18$). According to the authors, these results do not exclude a clinically significant benefit of *Helicobacter pylori* screening in MI populations with a higher prevalence of infection or in subgroups at increased risk of bleeding [29].

Project MHYH. This project represented a protocol for the cleaning, testing, and safety evaluation of the implantation of refurbished, used pacemakers. Export approval for such devices was obtained from the U.S. Food and Drug Administration (FDA) to countries where governments had granted permission. The study was conducted in Kenya, Mexico, Mozambique, Nigeria, Paraguay, Sierra Leone, and Venezuela in 306 patients randomized to receive either a refurbished or a new pacemaker. The infection rate within 12 months after the procedure was comparable: 1.6% with refurbished and 3.1% with new pacemakers. No device malfunctions were recorded in either group. According to the authors, this experience could be expanded, including to the use of refurbished ICDs, which are even more expensive and remain inaccessible to many patients worldwide.

IMPACT-BP. The study evaluated the effectiveness of home-based interventions using technology to improve BP control for AH in resource-limited rural South Africa. A total of 744 patients with uncontrolled AH were randomized into three groups: (1) standard clinic-based care (control); (2) home-based BP self-monitoring provided with blood pressure monitors, involvement of community health workers who visited patients at home for data collection and medication delivery, and remote nurse monitoring via a mobile app with decision-support functions; (3) an expanded community health worker group where monitors were equipped with cellular technology for automatic transmission of BP readings to the mobile app. At 6 months, mean systolic BP was lower in group 2 (-7.9 mmHg; $p<0.001$) and group 3 (-9.1 mmHg; $p<0.001$) compared to standard therapy. In the stan-

dard care group, the AH control rate at 6 months was 57.6%, compared to 76.9% and 82.8% in groups 2 and 3, respectively. In both investigated interventions, the patient retention rate in the treatment program was over 95%. According to the authors, these results serve as a clear example that equal access to medical care can be provided in disadvantaged communities, potentially improving AH control in other remote, resource-limited areas.

NEWTON-CABG CardioLink-5. Saphenous vein graft (SVG) occlusion following CABG remains a serious challenge. The study included patients who underwent CABG with ≥ 2 SVGs and were receiving moderate- or high-intensity statin therapy. Participants were randomized within 21 days after CABG to receive subcutaneous injections of evolocumab at a dose of 140 mg ($n=389$) or a placebo ($n=393$) every 2 weeks. At baseline, median LDL-C levels were 1.85 mmol/L and 1.86 mmol/L, with a subsequent change in LDL-C at 24 months of -52.4% vs. -4.0% in the evolocumab and placebo groups, respectively. The primary endpoint (venous graft occlusion of $\geq 50\%$ on CCTA or clinically indicated invasive angiography) at 24 months occurred in 21.7% of grafts in the evolocumab group and 19.7% in the placebo group ($p=0.44$). In patients who underwent CABG, evolocumab did not reduce the risk of venous graft restenosis 24 months after surgery, despite a significant reduction in LDL-C levels [30].

TACSI. In this open-label clinical trial based on cardiothoracic surgery center registries, patients after CABG for acute coronary syndrome were randomized to receive ticagrelor plus aspirin ($n=1,104$) or aspirin alone ($n=1,097$) for 1 year. During this follow-up period, the composite primary endpoint (death, MI, stroke, or repeat revascularization) occurred in 4.8% of patients in the ticagrelor plus aspirin group and 4.6% in the aspirin-only group ($p=0.77$). The key secondary endpoint was all-cause net adverse clinical events, defined as primary endpoint events plus major bleeding, and its rate was 9.1% in the ticagrelor plus aspirin group versus 6.4% in the aspirin-only group. Major bleeding was observed in 4.9% of patients in the ticagrelor plus aspirin group and 2.0% in the aspirin monotherapy group. In patients undergoing CABG for acute coronary syndrome, adding ticagrelor to aspirin does not reduce the risk of death, MI, stroke, or repeat coronary revascularization compared with aspirin alone for 1 year [31].

TOP-CABG. In this study, 2,290 patients undergoing their first elective CABG with at least one saphenous vein graft were randomized to either a DAPT de-escalation group (ticagrelor 90 mg twice daily plus aspirin 100 mg once daily for 3 months, followed by placebo twice daily plus aspirin 100 mg once daily for 9 months) or a DAPT group (ticagrelor 90 mg twice daily plus aspirin 100 mg once daily for 1 year). The primary efficacy endpoint (100% occlusion of the venous graft within 1 year) was observed in 10.79% of patients in the de-escalation group and 11.19% in the group without DAPT de-escalation ($p=0.008$ for non-inferiority). Meanwhile, clinically relevant bleeding occurred significantly less frequently in the de-escalation group (8.26% vs. 13.19% with standard DAPT; $p<0.001$). According to the study authors, these results may be considered when developing future

guidelines regarding the benefits of a shorter DAPT period during the early stage following CABG.

OPINION. The study compared the effectiveness of surgical left atrial appendage occlusion versus no occlusion in 2,118 high-risk patients following heart valve surgery in the absence of AF. The primary endpoint event rate (ischemic stroke, transient ischemic attack, or CV death) within 1 year did not differ significantly between the groups, occurring in 6.9% of patients in the surgical left atrial appendage occlusion group and 8.2% of patients in the control group ($p=0.25$). No significant differences in the incidence of bleeding were observed either. The study authors have planned to extend the patient follow-up period to 3 years.

Conflict of interest: none declared.

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