Neuigkeiten vom europäischen Kardiologie-Kongress 2024

London

Kard. Kolloquium KSSG 11.9.24

Supplement: Zusammenfassung Hotlines

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Übersicht

1. **Neue Guidelines: Das wichtigste in Kürze**
   - Arterielle Hypertonie
     Roman Brenner
   - Chronisches Koronarsyndrom
     Marco Cederqvist
   - Vorhofflimmern
     Florian Franzeck
2. **Update Herzinsuffizienz**

   Marc Buser
3. **Hotlines, Symposien, Seminare, Abstract-Sessions, ….**

   Hans Rickli

ESC Guidelines

ESC Guidelines and patients

Since 2021, the guidelines have been created in collaboration with patients from the ESC's Patient Forum, to ensure the recommendations consider the patient perspective and experience of the people they are designed to treat.

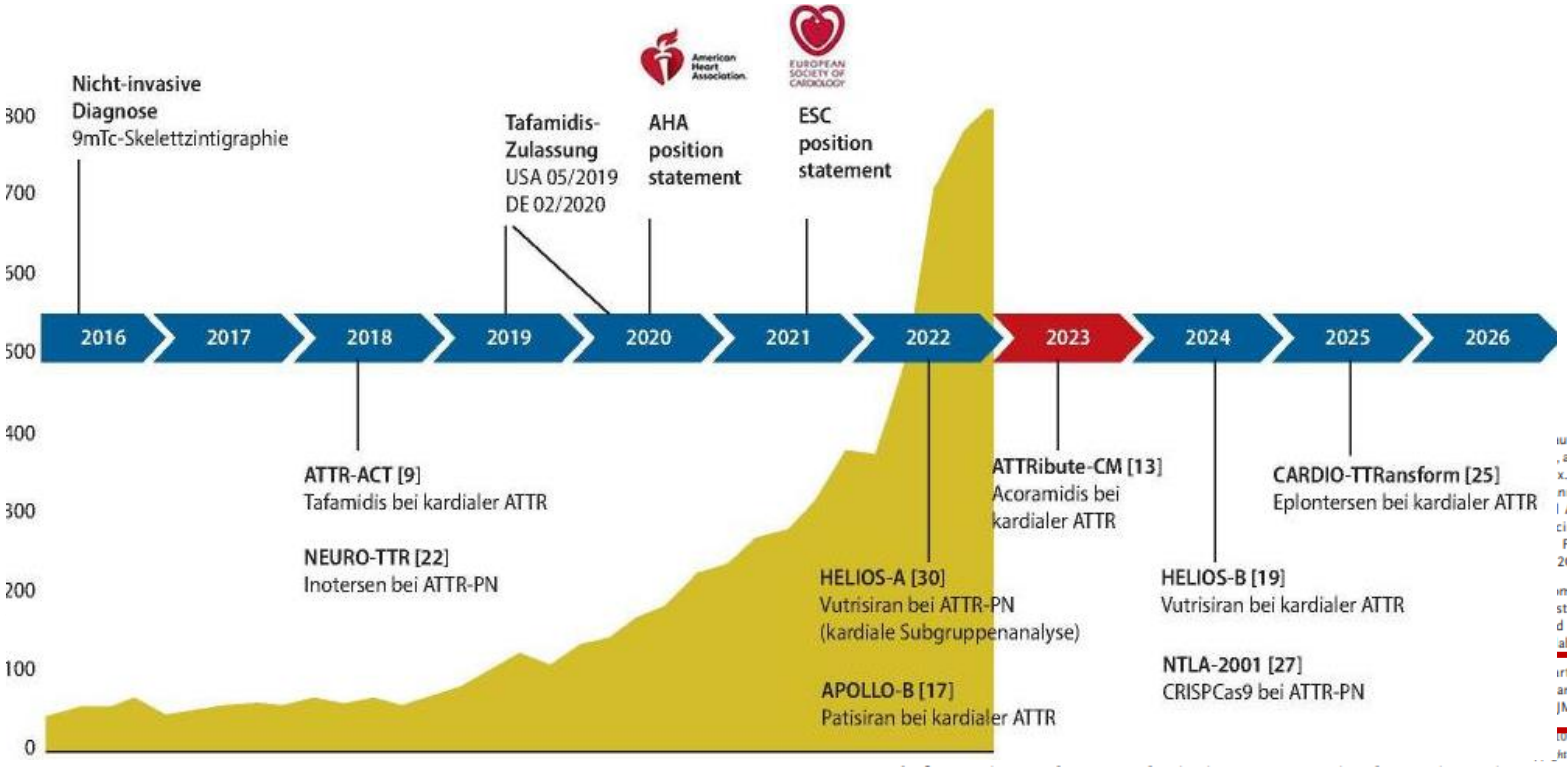
"Building the patient perspective Into ESC Guidelines is game-changing. They ensure we treat the person. Not just the disease."

Eva Prescott, CPG Committee Chair 2022–2024

Hotlines -

- **12 Sessions à 38 Themen über 4 Tage**
- **Zusammenfassung im Handout**

HELIO S-B: Vutrisiran bei ATTR-Amyloidose



HELIOS-B: Vutrisiran bei ATTR-

ESC European Society of Cardiology
European Heart Journal (2021) **42**, 1554–1568
doi:10.1093/eurheartj/ehab072

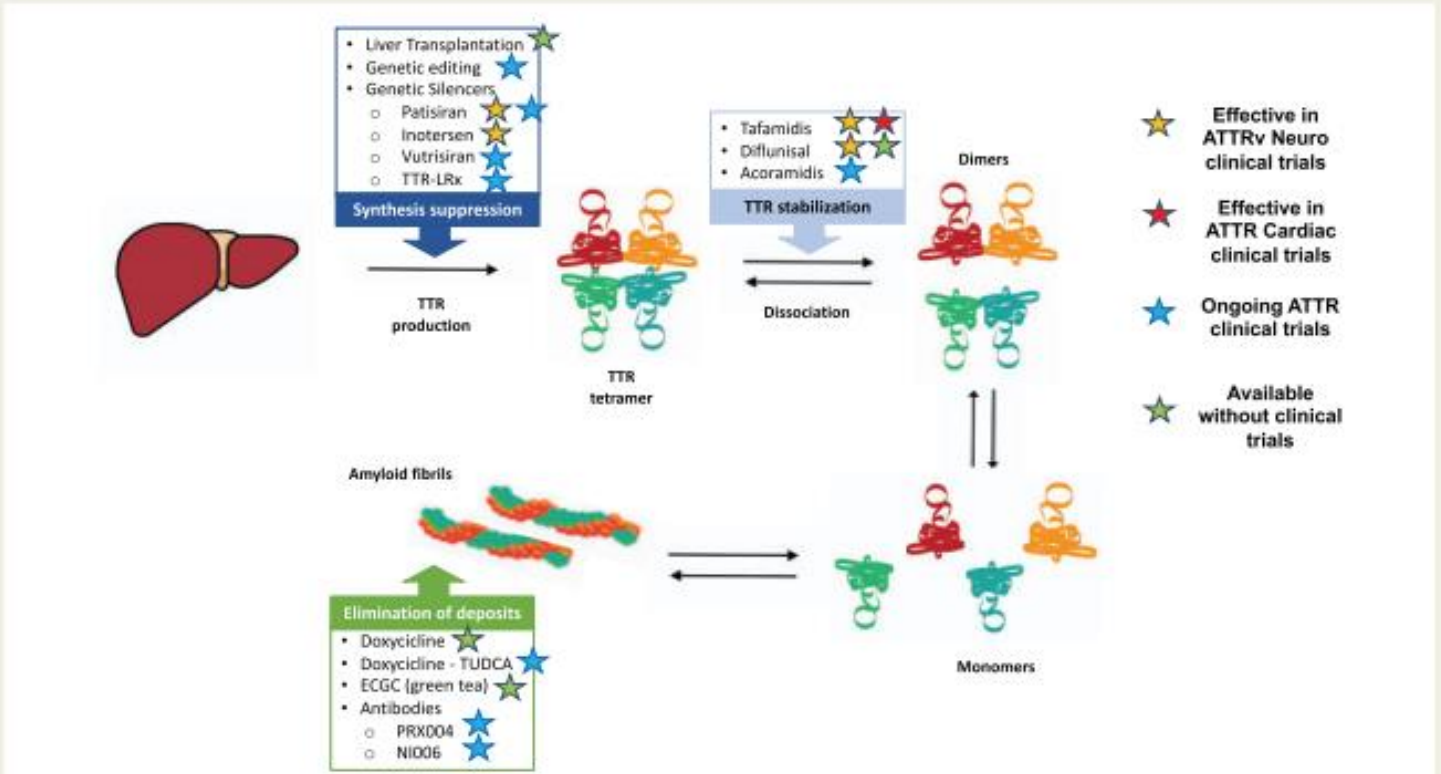


Figure 6 Available and future disease-modifying therapies in transthyretin amyloidosis (ATTR). ATTRv, hereditary transthyretin amyloidosis; TTR, transthyretin.

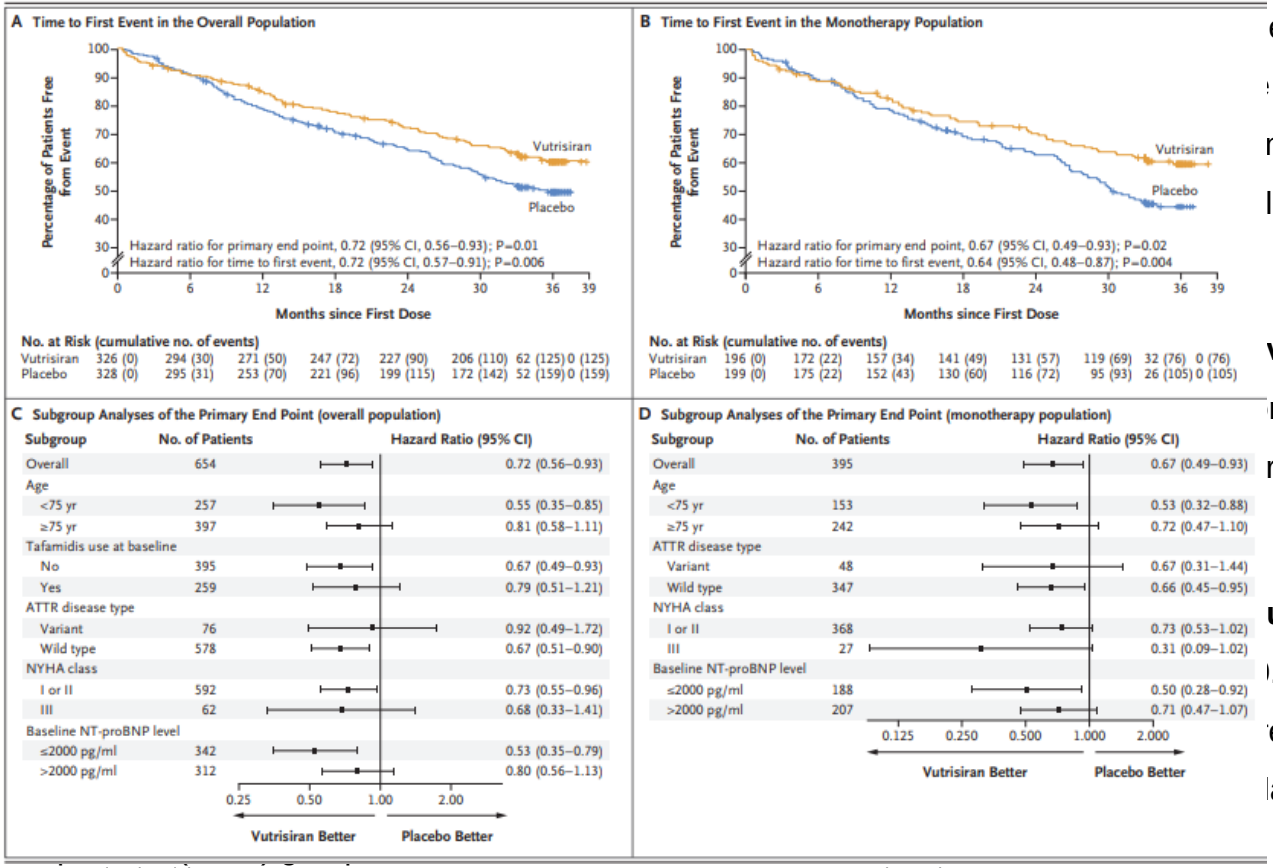
The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Fontana can be contacted at marianna.fontana@nhs.net or at the National Amyloidosis Centre, Division of Medicine, University College London, Royal Free Hospital, Pond St., London NW3 2QG, United Kingdom.

*A complete list of the HELIOS-B trial investigators and collaborators is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on August 30, 2024, and updated on Septembber 4, 2024, at NEJM.org.

DOI: 10.1056/NEJMoa2409134

HELIOS-B: Vutrisiran bei ATTR-Amyloidose



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HELIOS-B: Vutrisiran bei ATTR-Amyloidose

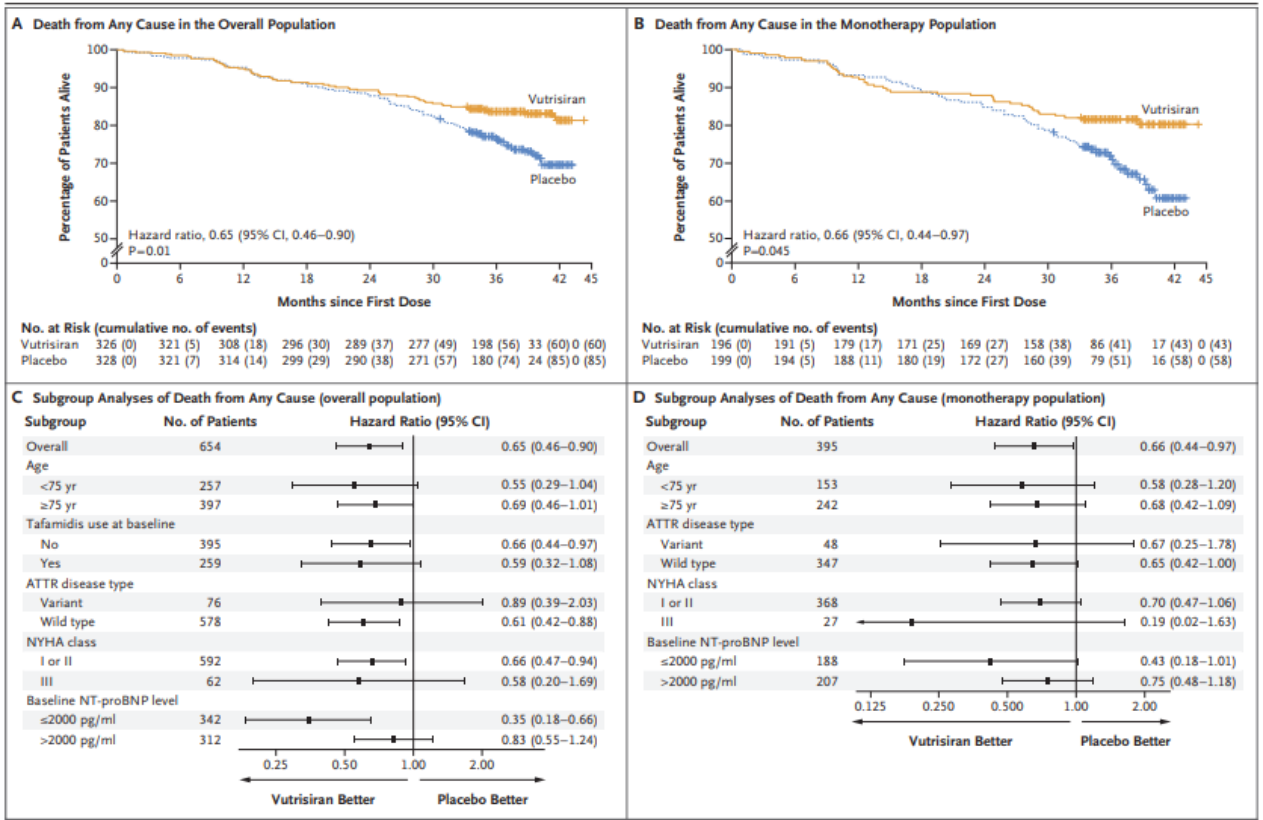

Figure 2. Death from Any Cause.

Panels A and B show death from any cause through 42 months in the overall population and the monotherapy population, respectively. The Kaplan–Meier curves were adjusted according to disease severity characteristics at baseline with the use of the inverse probability of treatment weighting method. Tick marks indicate censored data. Panels C and D show subgroup analyses of death from any cause through 42 months in the overall population and the monotherapy population, respectively.

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HELIO S-B: Vutisiran bei ATTR-Amyloidose (Phase III)

- Prof. Fontana concluded: “Vutrisiran was highly effective and well tolerated in this contemporary population representative of patients that we see in our clinics, with consistent benefits regardless of background tafamidis therapy. Our findings indicate that vutrisiran has the potential to become the new standard of care. **This trial is also important as it is the first to show the benefit of gene silencers in any type of cardiomyopathy.**

ORIGINAL ARTICLE

Beta-Blocker Interruption or Continuation after Myocardial Infarction

J. Silvain, G. Cayla, E. Ferrari, G. Range, E. Puymirat, N. Delarche, P. Guedeney, T. Cuisset, F. Ivanes, T. Lhermusier, T. Petroni, G. Lemesle, F. Bresoles, J.-N. Labeque, T. Pommier, J.-G. Dillinger, F. Leclercq, F. Boccara, P. Lim, T. Besseyre des Horts, T. Fourme, F. Jourda, A. Furber, B. Lattuca, N. Redjimi, C. Thuaire, P. Deharo, N. Procopi, R. Dumaine, M. Slama, L. Payot, M. El Kasty, K. Aacha, A. Diallo, E. Vicaut, and G. Montalescot, for the ABYSS Investigators of the ACTION Study Group*

ABSTRACT

BACKGROUND

The appropriate duration of treatment with beta-blocker drugs after a myocardial infarction is unknown. Data are needed on the safety and efficacy of the interruption of long-term beta-blocker treatment to reduce side effects and improve quality of life in patients with a history of uncomplicated myocardial infarction.

METHODS

In a multicenter, open label, randomized, noninferiority trial conducted at 49 sites in France, we randomly assigned patients with a history of myocardial infarction, in a 1:1 ratio, to interruption or continuation of beta-blocker treatment. All the patients had a left ventricular ejection fraction of at least 40% while receiving long-term beta-blocker treatment and had no history of a cardiovascular event in the previous 6 months. The primary end point was a composite of death, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for cardiovascular reasons at the longest follow-up (minimum, 1 year), according to an analysis of noninferiority (defined as a between-group difference of <3 percentage points for the upper boundary of the two-sided 95% confidence interval). The main secondary end point was the change in quality of life as measured by the European Quality of Life–5 Dimensions questionnaire.

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Silvain can be contacted at johanne.silvain@aphp.fr or at ACTION Group, Sorbonne Université, Pitié–Salpêtrière Hospital, Paris Institut de Cardiologie, 83 Boulevard de l'Hôpital, 75013 Paris, France.

*A complete list of the investigators in the ABYSS trial is provided in the Supplementary Appendix, available at NEJM.org.

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DOI: 10.1056/NEJMoa2404204

ABYSS: Betablocker nach MI mit EF > 40%

ABYSS: Betablocker nach MI mit erhaltener LV-Funktion (nicht-Non-inferior)

- **Over median follow-up of 3 years, interruption of long-term beta-blockers was not shown to be non-inferior to beta-blocker continuation.**

- A primary-outcome event occurred in 23.8% of patients in the interruption group and in 21.1% in the continuation group (risk difference 2.8 percentage points; 95% CI <0.1–5.5), with a hazard ratio of 1.16 (95% CI 1.01–1.33; p=0.44 for non-inferiority).

- Death occurred in 4.1% in the interruption group and 4.0% in the continuation group, while MI occurred in 2.5% and 2.4%, respectively. **Of note, hospitalisation for CV causes occurred in 18.9% in the interruption group and 16.6% in the continuation group. Beta-blocker interruption was also associated with increases in systolic and diastolic blood pressure and heart rate at 6 months (all p<0.001 vs. beta-blocker continuation) and during follow up. Beta-blocker interruption did not improve QoL**.

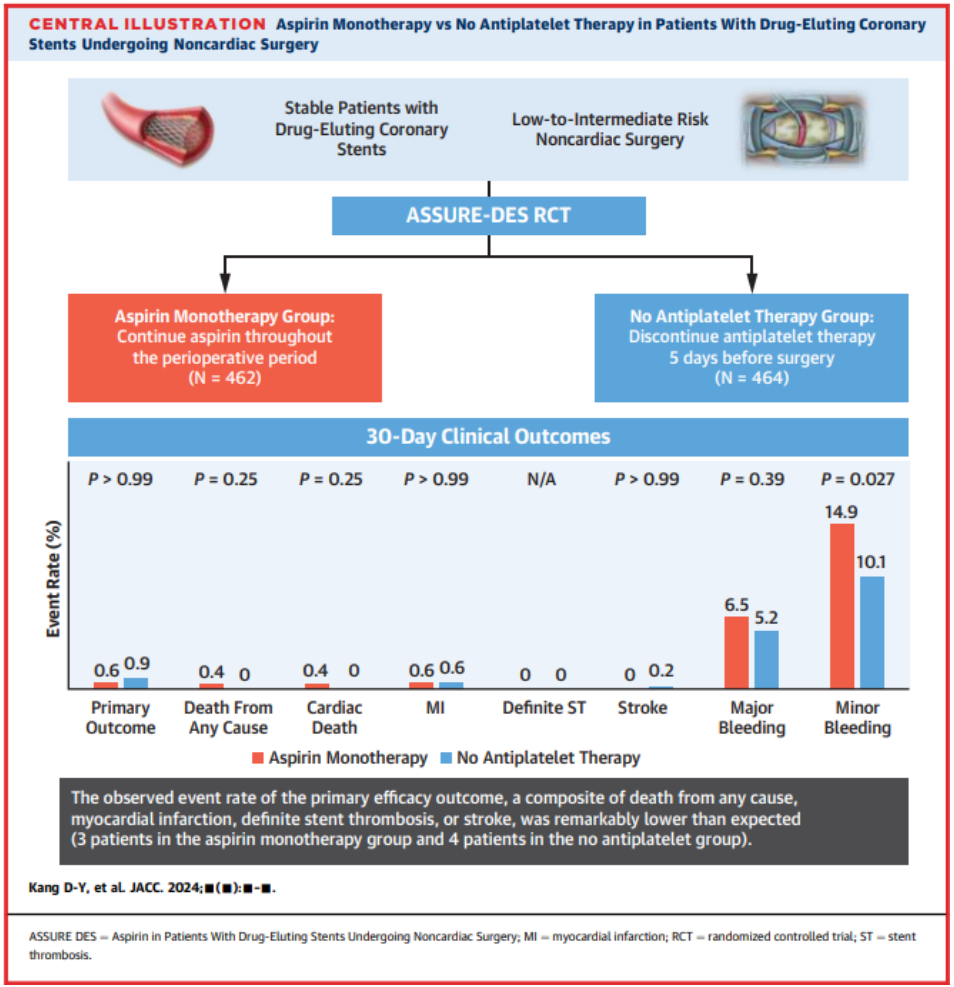
ABYSS: Betablocker nach MI mit erhaltener LV-Funktion (nicht-Non-inferior)

- Summing up the evidence, Prof. Silvain concluded: **“Differences between the groups with respect to hospitalisation for CV reasons** and the **negative effect on blood pressure levels, together with the absence of QoL improvement** do **not support interruption of a chronic beta-blocker treatment in post-MI patients**. These results must be put into context with recent findings from the open-label REDUCE-MI[5] trial and ongoing trials to provide additional evidence on the optimal use of beta-blockers after MI.”

Should aspirin be interrupted in patients with coronary stents undergoing non-cardiac surgery? **ASSURE DES trial**

- “Current guidelines recommend continuing aspirin in patients with drug-eluting stents (DES) undergoing non-cardiac surgery;[1] however, supporting evidence is limited. The ASSURE DES trial compared the efficacy and safety of continuing aspirin monotherapy vs. temporarily withholding all antiplatelet therapy around the time of non-cardiac surgery,” explained Doctor Jung-Min Ahn (Asan Medical Center - Seoul, South Korea).

- ASSURE DES was an **investigator-initiated, open-label trial, in which patients who had undergone DES implantation more than 1 year earlier, and who were now undergoing elective non-cardiac surgery**, were randomised to continue aspirin or discontinue all antiplatelet therapy **5 days before surgery**. Antiplatelets were recommended to be **resumed no later than 48 hours after surgery**, unless contraindicated. The primary outcome was a composite of death from any cause, myocardial infarction (MI), stent thrombosis or stroke between 5 days before to 30 days after non-cardiac surgery.



Should aspirin be interrupted in patients with coronary stents undergoing non-cardiac surgery? **ASSURE DES trial**

Should aspirin be interrupted in patients with coronary stents undergoing non-cardiac surgery? **ASSURE DES trial**

- The trial included **926 patients, who had a mean age of 68.5 years and 24% were women**. On average, **DES was implanted 6.3 years before non-cardiac surgery** and 84% had second-generation or newer stents. At randomisation, 39% of patients were on aspirin monotherapy, 23% on P2Y12 inhibitor monotherapy and 34% were on dual antiplatelet therapy.

- **There was no significant difference in the primary outcome between the groups at 30 days.**

- The primary outcome occurred in 0.6% of patients with aspirin and 0.9% with no antiplatelets (absolute difference −0.2 percentage points; 95% CI −1.3 to 0.9; p>0.99). Rates of the primary outcome events were low: 2 patients died from cardiac causes and 3 had an MI in the aspirin group, while 3 patients had an MI and 1 had a stroke in the no antiplatelets group.

- **Major bleeding rates were similar between the groups**: 6.5% with aspirin and 5.2% with no antiplatelets (p=0.39), while minor bleeding was more frequent with aspirin (14.9% vs. 10.1%; p=0.027).

Should aspirin be interrupted in patients with coronary stents undergoing non-cardiac surgery? **ASSURE DES trial**

- “**Continuing aspirin monotherapy did not reduce ischaemic events**, although it was **associated with a modest increase in minor bleeding**. The low event rate – which may reflect the safety profile of contemporary DES – led to the trial being **underpowered** and our overall findings should be interpreted with caution. However, it seems a **flexible approach to perioperative antiplatelet management may be considered**, without compromising patient safety,” concluded Dr. Ahn.

Hot Line ESC 2024 – Senior-Rita Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Invasive Treatment Strategy for Older Patients with Myocardial Infarction

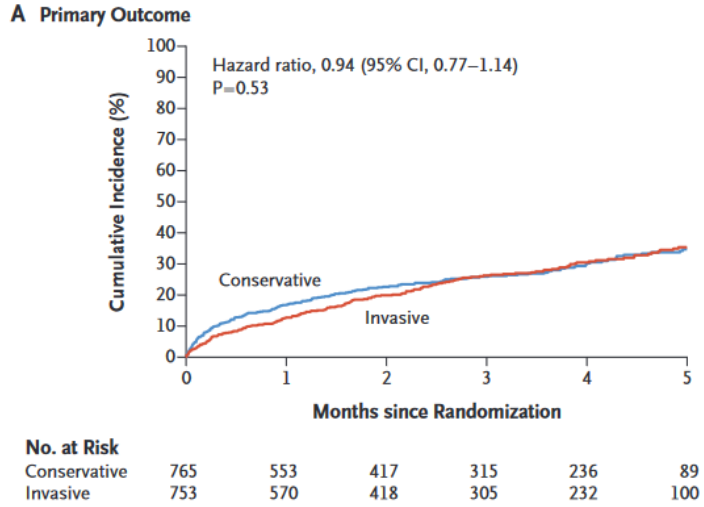
V. Kunadian, H. Mossop, C. Shields, M. Bardgett, P. Watts, M.D. Teare, J. Pritchard, J. Adams-Hall, C. Runnett, D.P. Ripley, J. Carter, J. Quigley, J. Cooke, D. Austin, J. Murphy, D. Kelly, J. McGowan, M. Veerasamy, D. Felmeden, H. Contractor, S. Mutgi, J. Irving, S. Lindsay, G. Galasko, K. Lee, A. Sultan, A.G. Dastidar, S. Hussain, I.U. Haq, M. de Belder, M. Denvir, M. Flather, R.F. Storey, D.E Newby, S.J. Pocock, and K.A.A. Fox, for the British Heart Foundation SENIOR-RITA Trial Team and Investigators*

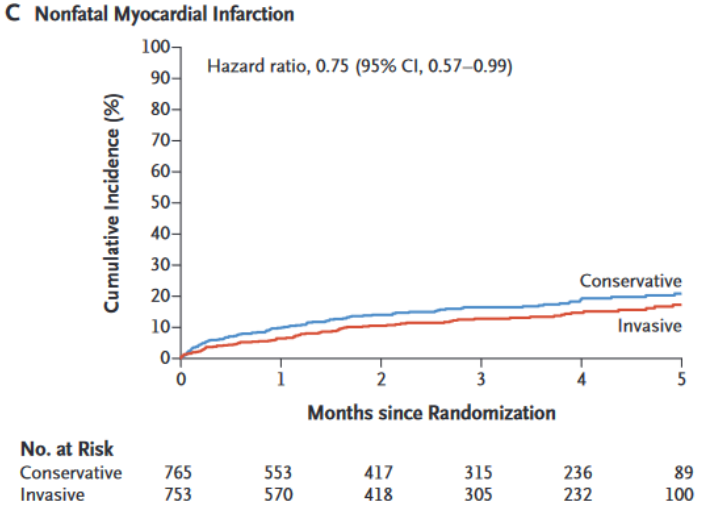
- Prospektiv, randomisiert, 48 Zentren in UK, NSTEMI bei Pat. >75y (mean 82y), invasiv vs. kons., median FU 4.1y
- PE: cv death, nonfatal myocardial infarction assessed in a time-to-event analysis

Kunadian et al., NEJM 2024

Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.*

Characteristic	Invasive Strategy (N=753)	Conservative Strategy (N=765)
Age		
Mean — yr	82.5±4.7	82.2±4.7
Distribution — no. (%)		
≥75 to <80	211 (28.0)	246 (32.2)
≥80 to <85	304 (40.4)	291 (38.0)
≥85 to <90	182 (24.2)	171 (22.4)
≥90 to <95	47 (6.2)	51 (6.7)
≥95	9 (1.2)	6 (0.8)
Female sex — no. (%)	337 (44.8)	342 (44.7)
Median no. of days from admission to randomization (IQR)	2 (1–3)	2 (1–3)
MoCA score†		
Median (IQR)	25 (21–27)	24 (21–26)
Impaired — no./total no. (%)	433/724 (59.8)	476/731 (65.1)
Rockwood Clinical Frailty Scale score‡		
Median (IQR)	3 (2 to 4)	3 (2 to 4)
Category — no./total no. (%)		
Frail	153/753 (20.3)	164/765 (21.4)



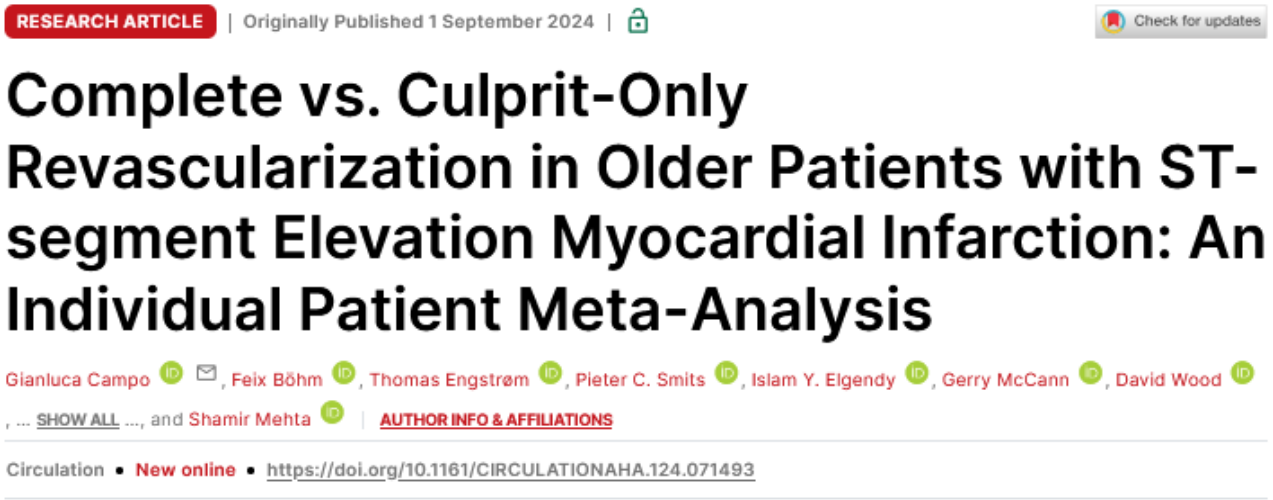


SENIOR-RITA, EARTH-STEMI and SCOFF

- open-label SENIOR-RITA trial compared **CV outcomes with an invasive strategy** (angiography and, if deemed necessary, coronary revascularisation) **on top of optimal medical therapy vs. optimal medical therapy alone** in 1,518 patients aged ≥75 years admitted with a **non-ST-elevation MI (NSTEMI**). After median follow-up of 4.1 years, there was **no difference in the primary endpoint of CV death or non-fatal MI between the invasive strategy group (25.6%) and the conservative strategy group (26.3%;** hazard ratio [HR] 0.94, 95% CI 0.77 to 1.14; p=0.53). **No differences were observed for CV death, but there was a significant reduction in non-fatal MI (11.7% with invasive vs. 15.0% with conservative;** HR 0.75; 95% CI 0.57 to 0.99). Patients in the invasive strategy group also **required fewer subsequent revascularisation procedures vs. the conservative strategy group (3.9% vs. 13.7%; HR 0.26; 95% CI 0.17 to 0.39)**. The rate of procedural complications was less than 1%.

- Prof. Kunadian concluded: “An invasive strategy did not reduce the primary endpoint, but we did see some benefits. Importantly, the invasive strategy appeared to be safe overall in our older patients. Including older patients in trials enables us to challenge current practice and highlights **that age should not be a barrier to individualised care**, including access to angiography and percutaneous coronary intervention.”

Hot Line ESC 2024 – Earth-STEMI Meta-Analysis



RESEARCH ARTICLE | Originally Published 1 September 2024 |

Check for updates

Complete vs. Culprit-Only Revascularization in Older Patients with ST-segment Elevation Myocardial Infarction: An Individual Patient Meta-Analysis

Gianluca Campo, Feix Böhm, Thomas Engstrøm, Pieter C. Smits, Islam Y. Elgendy, Gerry McCann, David Wood, ... SHOW ALL ..., and Shamir Mehta | AUTHOR INFO & AFFILIATIONS

Circulation • New online • https://doi.org/10.1161/CIRCULATIONAHA.124.071493

- 7 RCTs, 1733 Patienten, STEMI bei Pat. >75y (median 79y), kompl. Revask vs nur Culprit, median FU 2.5y
- PE: Tod, MI, IDR → PE bis 4y FU reduziert bei kompl. Revask; danach nur cv Tod, MI, IDR reduziert

Campo et al., Circulation 202

SENIOR-RITA, **EARTH-STEMI** and SCOFF

- EARTH-STEMI meta-analysis assessed data from **1,733 older patients (aged ≥75 years) included in 7 trials comparing complete revascularisation vs. culprit-lesion only revascularisation for the treatment of STEMI and multivessel disease**. Follow-up ranged from 6 months to 6.2 years (median 2.5 years), with 20% of patients having follow-up data at 4 years.

- The **primary endpoint** – **death, MI and ischaemia-driven revascularisation** – was **significantly reduced with complete revascularisation vs. culprit-only revascularisation at 4 years** (adjusted HR [aHR] 0.78; 95% CI 0.63 to 0.96; p=0.005).

- At the longest follow-up, there was a **24% reduction in CV death or MI with complete vs. culprit-only revascularisation** (aHR 0.76; 95% CI 0.58 to 0.99; p=0.046), but **no difference for all-cause mortality, CV death or non-CV death. Ischaemia-driven revascularisation was significantly reduced with complete vs. culprit-only revascularisation** (HR 0.52; 95% CI 0.34 to 0.85; p=0.002). There were no significant differences between the groups for safety endpoints. “At least in the first 4 years, complete revascularisation improved outcomes in older patients with STEMI and multivessel disease.

SENIOR-RITA, EARTH-STEMI and **SCOFF**

- SCOFF trial, which investigated complications in 716 patients who **did or did not fast before cardiac cath lab procedures requiring conscious sedation**.

- The primary endpoint of hypotension, aspiration pneumonia, hyperglycaemia and hypoglycaemia occurred in 19.1% in the fasting group and 12.0% in the no-fasting group (the estimate of the mean posterior difference was −5.2% [95% CI −9.6 to −0.9] and within the prespecified non-inferiority margin).

- Patient satisfaction was significantly better without fasting vs. with fasting. “There is now a strong case that fasting is not needed in patients undergoing these types of procedures. Removing fasting has been consistently shown to be safe, patients often prefer not to fast and there are logistical benefits to the healthcare system if patients can eat and drink normally. With this new evidence, **I think it is now time to reconsider fasting requirements in clinical guidelines,” concluded Dr. Ferreira.**

STEEER-AF, OCEANIC-AF and EPIC-CAD

- STEEER-AF was a cluster randomised trial conducted in France, Germany, Italy, Poland, Spain and the UK, which tested **whether a structured educational programme for healthcare professionals could improve guideline-adherent provision of AF care**.

- Treatment centres were **randomised** to receive a **structured education programme over 16 weeks or to their existing educational activities**.

- no significant change in guideline adherence **for stroke prevention**, which improved from 63.4% to 67.5% in the intervention group and from 58.6% to 60.9% in the control group (adjusted risk ratio [RR] 1.10; 95% CI 0.97–1.24; p=0.13). however, a **significant 51% improvement** was observed in **guideline adherence for rhythm control**, which increased from **21.4% to 33.9%** in the intervention group and from **20.5% to 22.9% in the control group** (adjusted RR 1.51; 95% CI 1.04–2.18; p=0.03).

STEEER-AF, OCEANIC-AF and EPIC-CAD

- **Targeted education for healthcare professionals can improve patient-level guideline adherence** where there are substantial gaps in implementation, as clearly demonstrated for rhythm control in AF.

- **Overall, the care of AF was poorly adherent to prior guideline recommendations**, requiring a **total re-think of how guidelines are constructed,** disseminated and implemented.

- As a result of STEEER-AF, the new 2024 ESC Guidelines for the management of AF[1] **incorporate numerous approaches to enhance 'AF-CARE', with new patient pathways designed to make implementing recommendations easier and more consistent," concluded Professor Kotecha.**

STEEER-AF, **OCEANIC-AF** and EPIC-CAD

- Double-blind OCEANIC-AF trial, which **compared asundexian, an inhibitor of activated factor XI (XIa), with apixaban in 14,830 patients with AF with a high stroke risk**. T
- he independent data monitoring committee **recommended that the trial was stopped early**. After a median follow-up of 160 days, the **occurrence of stroke or systemic embolism was higher in those receiving asundexian (1.3%) compared with apixaban (0.4%)**, and **asundexian was considered to be inferior (hazard ratio [HR] 3.79; 95% CI 2.46–5.83).**
- **Major bleeding was lower with asundexian vs. apixaban** (0.2% vs. 0.7%; HR 0.32; 95% CI 0.18–0.55).
- Results show that the **dose of asundexian tested was inferior for stroke or systemic embolism compared with apixaban**. We could speculate that near-total factor XIa suppression may be needed to prevent thrombus formation. We also noted a **lower-than-expected rate of stroke or systemic embolism in the apixaban** group, which may reflect prior use of oral anticoagulants and improved medical therapy. Finally, we were able to demonstrate lower bleeding rates with asundexian, which has to be put into context with the stroke findings.”

STEEER-AF, OCEANIC-AF and **EPIC-CAD**

- trial designed to optimise antiplatelet therapy in patients with high-risk AF and stable coronary artery disease (CAD), The investigator-initiated, **open-label EPIC-CAD trial randomised 1,040 patients with high-risk AF and stable CAD to either monotherapy of standard-dose edoxaban or dual antithrombotic therapy of standard-dose edoxaban plus a single antiplatelet agent.**

- After 1 year, edoxaban monotherapy significantly reduced the primary endpoint (all-cause death, stroke, systemic embolism, myocardial infarction, unplanned revascularisation, and major or clinically relevant non-major bleeding) by 56% compared with dual antithrombotic therapy (6.8% vs. 16.2%; HR 0.44; 95% CI 0.30−0.65; p<0.001).

- This difference was mainly driven by a 66% reduction in the risk of major bleeding or clinically relevant non-major bleeding with edoxaban monotherapy vs. dual-antithrombotic therapy. There were no differences in major ischaemic events and all-cause mortality between the groups. “Our results are similar to the AFIRE trial in patients with AF and stable CAD, which showed that rivaroxaban monotherapy was non-inferior to dual therapy for efficacy and superior for safety.[2] EPIC-CAD used a globally approved dosing regimen. EPIC-CAD provides additional new evidence on the appropriate antithrombotic strategy with standard-dose edoxaban to guide the treatment of patients with AF and stable CAD,” concluded EPIC-CAD’s Principal Investigator, Professor Duk-Woo Park (Asan Medical Center - Seoul, Republic

Answering questions about AF procedures: **SHAM-PVI trial**

- Despite considerable evidence in favour of performing PVI for symptomatic AF, there are concerns that PVI has a substantial placebo effect and there have been no trials comparing PVI with a sham procedure. Doctor Rajdip Dulai (University College London - London, UK) presented results from the first trial of its kind, the **SHAM-PVI trial**, which involved **126 patients with symptomatic paroxysmal or persistent AF, previously treated with at least one antiarrhythmic drug who had been referred for catheter ablation**. Patients were **randomised to undergo either PVI using cryoablation or a sham procedure involving phrenic nerve pacing to simulate an ablation procedure**.

- The researchers found that at **6-month follow-up, average reduction in AF burden**, assessed using an implantable heart monitor, was **60% in the ablation group and 35% in the sham intervention group**. Measures of **health-related quality of life improved in the ablation group vs. the sham intervention group at 6 months.**

- “We expected that PVI would be more effective than a placebo procedure in patients with symptomatic AF, and indeed, the results proved our hypothesis was correct,” said Dr. Dulai. “Going forward we would expect that patients with symptomatic AF be referred for ablation treatment without hesitation.”

Answering questions about AF procedures: **SUPPRESS-AF trial**

- **SUPPRESS-AF trial comparing PVI alone with PVI and LVA ablation in 1,347 patients with persistent AF undergoing their first ablation**.
- For the primary endpoint of recurrence of AF and **atrial tachycardia (AT) without antiarrhythmic drugs at 1 year, there was no significant difference between the groups, with 61% of patients who had the additional LVA ablation and 50% of standard treatment patients recurrence free**.
- Similarly, freedom from **AF/AT recurrence with antiarrhythmic drugs was not different between the two groups** (63% with LVA ablation vs. 55% with standard).
- However, in the **subgroup of patients with left atrium enlargement (diameter ≥45 mm), additional LVA ablation reduced recurrence by 40%**. There was no difference in the rates of serious complications such as stroke, which were low in both groups (1.7% vs. 1.8%).
- “Ablation targeting the diseased myocardium is widely performed, but our results show that **routine addition to PVI is not recommended.** This ablation should be performed only in cases of advanced atrial remodelling,” concluded Dr. Masuda

Answering questions about AF procedures: **CRABL-HF trial**

- Kengo Kusano (National Cerebral and Cardiovascular Center Hospital - Osaka, Japan) who described the **CRABL-HF trial** comparing **cryoballoon vs. radiofrequency ablation in 110 patients with AF and HFrEF**.

- One year after the procedure, there **was no significant difference in rates of atrial tachyarrhythmias (lasting 30 seconds or more), which occurred in 21.8% of patients receiving radiofrequency ablation and 22.2% of patients receiving cryoballoon ablation**. Additionally, **cryoballoon ablation could be performed with a significantly shorter procedure time (median 101 vs. 165 minutes)** and **less fluid volume without increasing left atrial pulse pressure**. Left ventricular ejection fraction improved and left arterial volume index decreased significantly after the procedure in both groups.

- There were **no significant differences in the overall safety profiles**, with 1 procedure-related complication in each group, and a similar incidence of the composite of death from any cause and/or heart failure hospitalisations between the two groups. **Taking these results together, the presenter concluded that the cryoballoon procedure should be the treatment of choice for AF in the majority of patients with HFrEF**

OCCUPI, INFINITY-SWEDEHEART and REC-CAGEFREE I

- Whether the use of optical coherence tomography (OCT) to guide PCI of anatomically complex coronary lesions improves clinical outcomes as compared with angiographic guidance has not been fully studied.
- the OCCUPI trial **compared OCT with angiography in 1,604 patients with anatomically complex lesions requiring PCI using drug-eluting stents (DES).**
- At **1 year follow-up**, patients who received OCT guidance experienced a **38% reduction in the combined risk of cardiac death, myocardial infarction (MI), stent thrombosis and target-vessel revascularisation (4.6% vs. 7.4%, respectively).**
- OCT guidance was 64% less likely to experience a **spontaneous MI** (excluding periprocedural MI) or **require target-vessel revascularisation** than angiography-guidance (0.9% vs. 2.4% and 1.5% vs. 4.1%, respectively).
- “Our findings provide more evidence **that OCT guidance of PCI procedures in patients with complex lesions improves outcomes over conventional angiography guidance**,” said Prof. Kim. “We now need to establish detailed standard for optimal use of OCT for the improvement of clinical outcomes of PCI for complex cases based on the OCCUPI trial,” he concluded.

OCCUPI, **INFINITY-SWEDEHEART** and REC-CAGEFREE I

- David Erlinge (Lund University - Lund, Sweden) described the INFINITY-SWEDEHEART registry-based randomised trial with the DynamX bioadaptor, which has been designed with a mechanism of action that involves uncaging the vessel 6 months after PCI.

- INFINITY-SWEDEHEART compared the bioadaptor with a contemporary DES in a broad population of **2,400 patients requiring PCI with *de novo* coronary artery disease (CAD).** The primary endpoint was the target lesion failure rate, defined as a composite of CV death, target-vessel MI and ischaemia-driven target lesion revascularisation at 1 year. There was an **18% reduction in the primary endpoint with the bioadaptor compared with the DES (2.35% vs. 2.77%), demonstrating non-inferiority (p<0.001), which was driven by lower rates of target-vessel MI and ischaemia-driven target lesion revascularisation compared with DES**.

- **Further prespecified powered landmark analyses showed a significant reduction and plateau in target lesion failure (0.2% vs. 1.3%, p=0.003) after 6 months.** “INFINITY-SWEDEHEART is the largest, most rigorous trial of the bioadaptor to date,” concluded Prof. Erlinge. “The results confirm the novel impact of the bioadaptor in CAD treatment through its unique design and mechanism of action of restoring the physiology of a diseased artery in a population representative of everyday clinical practice.”

OCCUPI, INFINITY-SWEDEHEART and **REC-CAGEFREE I**

- Primary drug-coated balloon (DCB) angioplasty with provisional stenting has been shown to be non-inferior to primary stenting for *de novo* coronary small vessel disease. However, the long-term efficacy and safety of a DCB strategy vs. primary stenting in *de novo* lesions without vessel diameter restrictions remain uncertain.

- The REC-CAGEFREE I trial, presented by Professor Ling Tao (Xijing Hospital of the Fourth Military Medical University - Xi'an, China), was designed to answer this question. The trial was conducted in **2,272 patients with non-complex CAD requiring PCI** who had achieved a successful target lesion pre-dilatation.

- The primary endpoint – 2-year combined rate of cardiac death, target vessel MI and clinically and physiologically indicated target lesion revascularisation **– was 6.4% in the DCB group and 3.4% in the DES group**, with an absolute risk difference of 3.04% (which was above the prespecified 2.68% threshold for non-inferiority). Rates were particularly high with DCB vs. DES for clinically and physiologically indicated target lesion revascularisation (3.1% vs. 1.2%).

- In **subgroup analyses**, **DES was more favourable in non-small vessel disease** (device diameter >3.0 mm), while in those with small vessel disease, the results were in line with previous studies showing non-inferiority between DCB and DES. It was concluded that DES implantation should continue to be the standard of care in *de novo* non-complex CAD.

PROTEUS, RAPID xAI and WESTCOR-POC

- As discussed by Doctor Ross Upton (University of Oxford - Oxford, UK), the PROTEUS trial evaluated the **use of EchoGo Pro, which provides automated interpretation of stress echocardiography (SE) based on artificial intelligence (AI) image analysis**. More than 2,000 patients were randomised to **standard clinical decision-making (control) or AI-augmented decision-making**, during which clinicians received an EchoGo Pro AI report indicating the **likelihood of severe CAD**. The primary analysis evaluated the **appropriateness of standard clinical decision-making vs. AI-augmented decision-making** when selecting patients **for invasive coronary angiograms and related acute coronary events within 6 months.**

PROTEUS, RAPID xAI and WESTCOR-POC

- Overall, the analyses found that **AI-assisted decision-making did not demonstrate non-inferiority vs. clinical decision-making for correctly selecting patients for coronary angiography**. Of those sent for angiography, 27 out of 36 referrals were correct in the control arm and 34 out of 49 referrals were correct in the AI arm. **Of the patients that should have been sent for an angiogram and who subsequently experienced an event, 22 were in the control group and 19 in the AI group**, but the **difference was not statistically significant**. However, further analyses found that **AI performed better than current practice in female patients**, **those with pre-existing CAD and low-volume SE centres**. “It is well reported that clinician performance in interpreting SEs ranges widely according to the experience level of the operator,” explained Dr. Upton. **“These results suggest that AI can bring all operators, regardless of experience, up to the same level of accuracy and may be a useful training aid.** While the PROTEUS trial did not demonstrate non-inferiority in all-comers, **the AI diagnostic may benefit specific groups of patients in whom decision-making is known to be more complex.”**

PROTEUS, **RAPID xAI** and WESTCOR-POC

- The next presentation, by Professor Derek Chew (Victorian Heart Hospital - Melbourne, Australia), described the use of **AI to aid clinical decision-making in identifying and managing MI, based on the 4th Universal Definition, in patients presenting to the emergency department (ED)**. The RAPIDx AI cluster-randomised trial enrolled 14,131 patients from **12 centres across South Australia**: **6 were randomised to the intervention arm** (i.e. implementation of AI-based clinical decision support) and **6 to the control arm** (i.e. unchanged standard of practice).

- In the intention-to-treat analysis, there was **no difference between the groups**, with 26.0% in the intervention group and 26.4% in the control group experiencing a CV death, MI or unplanned CV readmission within 6 months. **Importantly, among patients *not* classified as type 1 MI by AI-driven decision support, invasive coronary angiography was 47% less likely to be undertaken in the intervention group vs. the control group (5% vs. 9.4%).** Additionally, where patients *were* classified as having a type 1 MI by the AI-based decision support, they were more likely to receive recommended medical therapies. **Patients directly discharged from EDs with the decision support were less likely to die or have an MI within 30 days than those who received usual care (0.86% vs. 1.1%; non-inferiority p<0.001).**

PROTEUS, **RAPID xAI** and WESTCOR-POC

- “We found **no increase in early hazards or negative impacts on ED discharge decisions**, establishing **the safety of AI-based clinical decision support**,” said Prof. Chew.

- “Our next steps include exploring approaches to enhancing trust and adoption of AI-based clinical decision support in the clinical community, investigating new models of care within which such AI-based decision support tools could be integrated to drive health system effectiveness and efficiency, and evaluating AI-based decision support for other acute cardiac conditions where early recognition represents a key challenge and driver in optimising outcomes.”

PROTEUS, RAPID xAI and **WESTCOR-POC**

- Last, but not least, Doctor Viola Thulin (Haukeland University Hospital - Bergen, Norway) presented the WESTCOR-POC trial that **compared a 0-hour and 1-hour novel point-of-care (POC) high sensitivity cardiac troponin (hs-cTn) test (Atellica VTLi, Siemens Healthineers) with conventional 0-hour and 1-hour central laboratory hs-cTn testing**.

- In total, 1,494 consecutive patients with symptoms suggestive of acute coronary syndrome presenting to the ED were randomised to the **novel POC test with a turn-around time of 8 minutes** or standard **central lab testing**.

- The **median length of stay in the ED was 174 minutes for the POC testing group compared with 180 minutes in the standard testing group**. However, among patients who were seen more quickly by a physician (within 60 minutes), POC testing reduced the length of ED stay by 15 minutes (147 vs. 162 minutes). **Notably, POC testing provided the most benefit for patients diagnosed with non-ST-elevation MI, shortening their ED stay by 43 minutes compared with standard testing (median 137 vs. 180 minutes), with high-risk patients being admitted to the cardiac ward faster**.

PROTEUS, RAPID xAI and **WESTCOR-POC**

- **Rates of combined deaths, MIs and acute revascularisations within 30 days were similar with POC and standard testing (11.4% vs. 9.4%, respectively).**

- “POC troponin assays hold great promise to improve patient care. But our findings underscore the need for a process to map out and address obstacles to efficient patient flow, such as lack of relevant staff or lack of efficient discharge procedures, to realise the full potential of POC tests to manage chest pain patients in the ED,” said lead author, Doctor Kristin Aakre (Haukeland University Hospital - Bergen, Norway).

- **STOP-or-NOT: Impact of Renin-angiotensin-system inhib continuation vs discontinuation in major non-cardiac surgery (publ. In JAMA)**
  - 3d vorher gestoppt, vs weitergeführt
  - Weniger intraop. Hypotonie in «Stop»Gruppe» 4-Min. Unterschied, keine erhöhte kv Ereignisrate

TEER is non-inferior to surgery in patients with secondary mitral regurgitation

- Transcatheter edge-to-edge repair (TEER) is commonly used to treat patients with secondary mitral regurgitation (MR), but there has been no randomised trial comparing it with traditional surgery.
- The investigator-initiated **MATTERHORN** trial recruited patients with secondary MR, LVEF ≥20%, with symptoms of heart failure (NYHA class ≥2) despite optimal guideline-directed medical therapy, who were considered at high surgical risk by the local Heart Team. Patients were randomised to mitral TEER or surgical mitral valve therapy (mitral valve repair or replacement at the surgeon's discretion).
- The primary efficacy endpoint was the composite of death, hospitalisation for heart failure, mitral reintervention, assist device implantation and stroke at 1 year. The primary composite safety endpoint, assessed at 30 days, included death, myocardial infarction, major bleeding, stroke or transient ischaemic attack, rehospitalisation, all reinterventions, non-elective cardiovascular surgery, renal failure, deep wound infection, mechanical ventilation >48 hours, gastrointestinal complications requiring surgery, new-onset atrial fibrillation (AF), septicaemia and endocarditis.

TEER is non-inferior to surgery in patients with secondary mitral regurgitation

- In total, 210 patients were randomised, with an average age of 70.5 years and 40% were female. The mean LVEF was 43% and 86% were NYHA class III or IV. The median EuroSCORE II score was 3%. In the surgical group, 72% underwent mitral valve repair and 28% underwent mitral valve replacement.
- **There was no significant difference in the primary efficacy endpoint.**
- The primary efficacy endpoint occurred in 16.7% of patients in the TEER group and 22.5% in the surgical group at 1 year (odds ratio [OR] 0.69; 95% CI 0.33–1.44; p=0.320), with non-inferiority confirmed (p<0.01 for non-inferiority).
- There was no significant difference in the recurrence of MR grade ≥3 at 1 year: 8.9% of patients in the TEER group vs. 1.5% in the surgical group (OR 6.22; 95% CI 0.75– 51.95; p=0.091). After 1 year, 73.2% of patients in the TEER group and 87.3% of patients in the surgical group had MR grade ≤ 1.

TEER is non-inferior to surgery in patients with secondary mitral regurgitation

- The primary safety endpoint occurred in significantly more patients in the surgical group (54.8%) than in the TEER group (14.9%; p<0.001), which was largely driven by more major bleeding (29% vs. 3%, respectively), all reinterventions (19% vs. 8%) and new-onset AF (33% vs. 9%).

- Study presenter, Professor Volker Rudolph (Heart and Diabetes Center NRW - Bad Oeynhausen, Germany), said: “In the MATTERHORN trial, we were able to show non-inferiority between the two techniques for improving MR – both methods worked well – with some safety benefits favouring TEER.”

- Principal Investigator, Professor Stephan Baldus (University of Cologne - Cologne, Germany), concluded: “This is the first randomised trial to demonstrate the non-inferiority of TEER and surgery in patients with secondary MR. These new data may become important to guide decision making as European guidelines[1] currently recommend TEER may be considered in patients who are judged inoperable or at high surgical risk by the Heart Team.”

Can a quadruple single-pill combination help when 3 medications fail?

- Patients with resistant hypertension on 3 blood pressure (BP)-lowering medications, namely a diuretic, a renin-angiotensin system inhibitor and a calcium channel blocker, often require the addition of a fourth medication. However, adherence decreases with the number of pills prescribed. In the QUADRO trial, we investigated adding bisoprolol, as part of an SPC of 4 different BP-lowering medications, compared with receiving 3 BP-lowering medications as separate pills."

- In this double-blind trial, patients with resistant hypertension initially entered an 8-week run-in where they received optimal doses of perindopril (10 mg), indapamide (2.5 mg) and amlodipine (5 or 10 mg). Adherent patients with office SBP ≥140 mmHg and 24-hour ambulatory SBP ≥130 mmHg after 8 weeks were randomised to either continue the same triple therapy or to receive an SPC containing perindopril, indapamide, amlodipine and bisoprolol (5 mg) for 8 weeks. To preserve the blinding, both groups received two capsules and one tablet.

Can a quadruple single-pill combination help when 3 medications fail?

- In total, 183 patients were randomised who had a mean age of 57 years (47% were female). At baseline, mean office BP was 150.3/90.0 mmHg.
- After 8 weeks, the primary endpoint, mean office sitting SBP, had reduced by 20.67 mmHg (SD 15.37) in the quadruple SPC group and by 11.32 mmHg (SD 14.77) in the triple group.
- **The adjusted difference between the groups significantly favoured the quadruple SPC (−8.04 mmHg; 95% CI −11.99 to −4.09; p<0.0001).**
- A significant difference was also seen for the main secondary endpoint of mean 24-hour ambulatory SBP in the quadruple single-pill group vs. the triple group (−7.53 mmHg; 95% CI −10.95 to −4.11; p<0.0001). Overall, BP control (office sitting BP <140/90 mmHg) was achieved by 66.3% of patients on the quadruple SPC vs. 42.7% on triple therapy (p=0.001). There were no major differences in terms of adverse events (AEs) and no serious AEs were reported.
- “The availability of a quadruple SPC could help with non-adherence and provide much-needed effective BP control in patients with resistant or difficult-to-treat hypertension,” concluded Prof. Taddei.

Timing of dosing of blood-pressure medication makes no difference

- “Whether preferential lowering of night-time BP could lower CV risk has been previously studied but with varying results,[1-3]” explained Professor Scott Garrison (University of Alberta - Edmonton, Canada) who presented results from the BedMed trial in the general primary-care population and the BedMed-Frail trial in nursing-home residents.

- In the open-label, pragmatic BedMed trial, 3,357 Canadian primary-care patients prescribed at least one once-daily antihypertensive medication were randomised to take all antihypertensives in the morning or at bedtime. The primary outcome was major adverse CV events (all-cause death, hospitalisation/ED visit for stroke, myocardial infarction [MI]/acute coronary syndrome or congestive heart failure). The BedMed-Frail trial had a similar design except that the 776 participants were residents of Canadian continuing care wards assigned to either bedtime dosing or to usual care (predominantly morning use). Their median age was 88 years.

- Over a median follow-up of 4.6 years in the BedMed trial, the primary outcome occurred in 9.7% of participants in the bedtime group and 10.3% in the morning group (adjusted hazard ratio [HR] 0.96; 95% CI 0.77–1.19; p=0.70). There were no differences in safety outcomes and all-cause hospitalisation/ED visits between the groups.

- Over a median of 415 days in the BedMed-Frail trial, the primary outcome occurred in 40.6% of participants with bedtime dosing and 41.9% with usual dosing (adjusted HR 0.88; 95% CI 0.71–1.11; p=0.28), and in both groups it was mostly driven by deaths. Secondary efficacy and safety outcomes were no different, except for all-cause unplanned hospitalisation/ED visits, which favoured bedtime use (HR 0.74; 95% CI 0.57–0.96; p=0.02).

- Summing up, Prof. Garrison said: “We found bedtime vs. morning administration to provide no difference in major CV events, nor in potential hypotensive, visual, cognitive or other safety events in a general population and importantly, in frail older patients who are generally excluded from trials. We can now dismiss the treatment timing as being important and advise patients to take their BP medication when they are least likely to forget.”

Timing of dosing of blood-pressure medication makes no difference

- Professor Ricky Turgeon (University of British Columbia - Vancouver, Canada) then presented a systematic review and meta-analysis of all parallel-group trials comparing CV outcomes with night-time and morning administration. The primary endpoint was a different composite of major CV events (death from any cause, non-fatal MI, non-fatal stroke or heart failure exacerbation).

- BedMed, BedMed-Frail, TIME,[1] Hygia[2] and MAPEC[3] trials were included, with data analysed from 46,606 patients. The BedMed, BedMed-Frail and TIME trials were judged to be at overall low risk of bias using the Cochrane Risk of Bias 2 tool, while there were some bias concerns with Hygia and MAPEC, particularly regarding the randomisation process.

- **Across the 5 trials, the incidence of the primary endpoint was not affected by evening vs. morning dosing (HR 0.71; 95% CI 0.43–1.16).**

- In a sensitivity analysis, the HR was 0.94 (95% CI 0.86–1.03) in the 3 trials judged to have low bias and 0.43 (95% CI 0.26–0.72) in the two trials with bias concerns.

- There was no difference in all-cause mortality for evening and morning dosing (HR 0.77; 95% CI 0.51–1.16). Similarly, all other secondary endpoints were not affected by evening vs. morning dosing, including for fractures, glaucoma events and cognitive events.

- “Results from the meta-analysis provide conclusive evidence that there is no difference between evening and morning dosing. Patients should take their once-daily BP-lowering medications at whatever time best suits their preferences and circumstances,” concluded Prof. Turgeon.

Should patients undergo PCI to treat CAD in addition to TAVI?

- NOTION-3 trial: patients selected for transcatheter aortic valve implantation (TAVI) who also have coronary artery disease (CAD) should undergo percutaneous coronary intervention (PCI)?

- open-label, investigator-initiated trial in pts selected for TAVI with **at least one physiologically significant PCI-eligible coronary artery stenosis (fractional flow reserve ≤0.80 or diameter stenosis >90% in a coronary artery ≥2.5 mm in diameter).** Randomisation to either **complete revascularisation with PCI in addition to TAVI** or **conservative management with TAVI** alone. The **primary endpoint** was the composite of all-cause mortality, myocardial infarction (MI) or urgent revascularisation until the last included patient was followed for 1 year after TAVI.

- 455 patients (mean age of 81 years/ 1/3 female). PCI was performed before TAVI in 74% of patients, concomitantly with TAVI in 17% and shortly after in 9%.

- **The incidence of the primary endpoint was significantly lower in the PCI group than the conservative group (26% vs. 36%, respectively; hazard ratio [HR] 0.71; 95% CI 0.51–0.99; p=0.041) after a median follow-up of 2 years.**

Should patients undergo PCI to treat CAD in addition to TAVI?

- Significantly **lower rates** were observed with PCI vs. conservative treatment **for MI** (8% vs. 14%; HR 0.54; 95% CI 0.30–0.97; p=0.037) and for **urgent revascularisation** (2% vs. 11%; HR 0.20; 95% CI 0.08–0.51; p<0.001), with **similar rates for all-cause mortality**.

- The rate of **bleeding events** – minor, major, life-threatening or disabling – was 28% in the PCI group and 20% in the conservative group (HR 1.51; 95% CI 1.03–2.22).

- **Conclusion:** TAVI patients with CAD with benefits from PCI, **driven by reductions in MI and urgent revascularisation**. We suggest that performing **PCI should be the recommended treatment for patients undergoing TAVI that have CAD**, but the **final decision should be made based on the patient's age, comorbidities, life expectancy and their bleeding risk**," concluded Principal Investigator, Doctor Jacob Thomsen Loenborg (Copenhagen University Hospital - Copenhagen, Denmark).

Dedicated trial in women demonstrates TAVI superiority: RHEIA trial

- The RHEIA trial compared the relative merits of the two methods in a women-only population.
- In total, 443 women all-comers with severe symptomatic aortic stenosis, with any (except prohibitive) surgical risk status, were **randomised to either TAVI with a third-generation balloon-expandable system using transfemoral access or surgical aortic valve replacement**. The **primary composite endpoint** was all-cause **mortality, stroke and rehospitalisation for valve- or procedure-related symptoms** or **worsening heart failure** at 1 year.
- **The incidence of the primary endpoint was significantly lower with TAVI (8.9%) vs. surgery (15.6%; hazard ratio 0.55; 95% CI 0.34 to 0.88; p=0.03).**

Dedicated trial in women demonstrates TAVI superiority: RHEIA trial

- Both the **non-inferiority and superiority of TAVI were demonstrated**. The significant reduction in the primary endpoint was predominantly driven by a **reduction in rehospitalisation for valve- or procedure-related symptoms or worsening heart failure**, which occurred in **4.8% in the TAVI group and 11.4% in the surgical group** (difference −6.6%; 95% CI −11.9% to −1.4%; p=0.02). There was **no significant difference in all-cause mortality or stroke**. TAVI was associated with a lower incidence of new-onset atrial fibrillation (3.3% vs. 28.8%; p<0.001) and **shorter median length of index hospital stay (4 days vs. 9 days**), **but higher rates of new permanent pacemaker implantation (8.8% vs. 2.9%;** p=0.01) and mild paravalvular aortic regurgitation at 1 year (15.5% vs. 2.4%; p<0.001).

- “In this first dedicated randomised TAVI trial in women, we confirmed its superiority over surgery, particularly with respect to reducing rehospitalisations. The added benefit of shorter index hospitalisations meant that TAVI was able to reduce healthcare resource utilization. Although we acknowledge the short post-intervention interval and longer follow-up will be useful, our findings suggest that in women with severe symptomatic aortic stenosis, TAVI using balloon-expandable devices could be considered the preferred therapy,” concluded Prof. Eltchaninoff.

Oral anticoagulants should be paused before TAVI: POPular PAUSE TAVI trial

- “Whether oral anticoagulants (OAC) should be interrupted in patients with a long-term indication, such as those with atrial fibrillation (AF), was uncertain. Observational evidence suggests that continuation may decrease the risk of thromboembolic events and does not increase the risk of bleeding. We conducted the POPular PAUSE TAVI trial to investigate continuing vs. interrupting OAC.”

- This was an **open-label, investigator-initiated, non-inferiority trial in patients on OAC with planned TAVI**, which **excluded those who were at high risk for thromboembolism for whom OAC interruption was not an option**. Participants were randomised to continue OAC or to stop OAC at least 48 hours before TAVI. The primary endpoint was a composite of CV mortality, stroke of any cause, myocardial infarction, major vascular complications and major bleeding within 30 days after TAVI.

- In total, **858 patients were randomised who had a mean age of 81 years**, with 34.5% women. The mean CHA_2DS_2-VASC score was 4.5. Over 80% were taking direct oral anticoagulants (81.9%), with the rest taking vitamin K antagonists (18.1%).

Oral anticoagulants should be paused before TAVI: POPular PAUSE TAVI trial

- The primary endpoint occurred in **16.5% of patients with continued OAC and 14.8% with interrupted OAC** (risk difference 1.7%; 95% CI −3.1 to 6.6; p=0.18 for non-inferiority).

- The non-inferiority margin (4% for the absolute between-group difference) was not met and therefore the investigators were not able to state that continuation was non-inferior to interruption.

- **Any bleeding occurred in 31.1% of patients in the continued group and 21.3%** in the interrupted group (risk difference 9.8; 95% CI 3.9 to 15.6). There was **no difference in thromboembolic events with continued vs. interrupted OAC** (8.8% vs. 8.2%; risk difference 0.6; 95% CI −3.1 to 4.4).

- “We now have evidence from a randomised trial that **continuing OAC provides no apparent benefit in terms of thromboembolic events**. Given the higher incidence of bleeding, our data support interrupting OAC in patients undergoing TAVI,” concluded Professor Jur ten Berg, the trial’s Principal Investigator.