EUROPCR 2024 TRIALS

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PODCAST OVERVIEW

- How was the euroPCR 2024?
- which trials presented?
- How this year's meeting will change my practice?

Detailed Summary of the POLMIDES Hybrid Revascularization Study

Background: The POLMIDES trial explores the long-term efficacy of hybrid coronary revascularization (HCR) compared to traditional coronary artery bypass grafting (CABG) in patients with multivessel disease. HCR involves a combination of minimally invasive grafting and percutaneous coronary intervention (PCI) with drug-eluting stents (DES).

Aims: To assess the 10-year survival rates and clinical outcomes of HCR versus CABG.

Methods:

- **Study Design:** Randomized controlled trial.
- **Participants:** Patients with multivessel coronary artery disease.
- **Procedures:** Patients were randomized to receive either HCR or CABG.
- **Endpoints:** Primary endpoint was 10-year all-cause mortality. Secondary endpoints included myocardial infarction, stroke, major adverse cardiovascular events (MACCE), and repeat revascularization.

Results:

- **Population:** 200 patients were included in the study, with 100 patients in each group (HCR and CABG).
- **10-Year Survival:**
- HCR group had a significantly higher 10-year survival rate (79.6%) compared to the CABG group (63.7%).
- **MACCE Rates:**
- The rates of MACCE, including myocardial infarction and stroke, were comparable between the two groups.
- **Repeat Revascularization:**
- The need for repeat revascularization was slightly higher in the HCR group but not statistically significant.

Conclusions: The POLMIDES trial demonstrates that HCR provides better 10-year survival rates compared to traditional CABG in patients with multivessel coronary artery disease, with comparable rates of myocardial infarction, stroke, and MACCE. Despite the need for slightly more repeat revascularizations, HCR shows promise as an effective

revascularization strategy, warranting further large-scale studies to confirm these findings and address practical challenges.

FFR-Derived Metric Can Identify Focal CAD Best Suited to PCI

Authors:

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Background:

The study investigates the utility of the pullback pressure gradient (PPG), a metric derived from fractional flow reserve (FFR) pullback, in determining which patients with stable coronary artery disease (CAD) will benefit most from percutaneous coronary intervention (PCI).

Aims:

To assess the ability of PPG to distinguish between focal and diffuse CAD, and its effectiveness in predicting physiological improvements post-PCI.

Methods:

- **Study Design:** Investigator-initiated, multicenter PPG Global Registry.
- **Participants:** 993 patients scheduled for PCI, each with at least one epicardial lesion with an FFR ≤ 0.80.
- **Procedures:** Manual FFR pullbacks performed to obtain PPG values before intervention.

Results:

- **Baseline Metrics:**
- Mean FFR: 0.68
- Mean PPG: 0.62
- Post-PCI mean FFR: 0.87
- **Correlations:** Baseline PPG values correlated with changes in FFR post-PCI ($r = 0.65$; $p < 0.001$) and predicted optimal revascularization (AUC 0.82).
- **Disease Classification:**
- PPG < 0.62: Diffuse disease
- PPG ≥ 0.62: Focal disease
- Diffuse disease predominantly found in LAD (89.6%).

Conclusions: PPG enhances FFR by classifying CAD into focal or diffuse categories, improving decision-making for PCI suitability. Patients with diffuse disease showed less benefit from PCI and higher risk of periprocedural MI. Future studies like PPG Primetime will further refine PCI strategies based on PPG guidance.

Clinical Implications: PPG values inform treatment decisions, shifting some patients to CABG or medical management, and shaping future PCI planning.

PCI for Multivessel Disease More Cost-effective Than CABG at 3 Years: FAME 3

Background:

The FAME 3 trial investigates the cost-effectiveness of fractional flow reserve (FFR)-guided percutaneous coronary intervention (PCI) compared to coronary artery bypass grafting (CABG) in patients with three-vessel coronary artery disease (CAD).

Aims:

To evaluate the 3-year cost-effectiveness of FFR-guided PCI versus CABG.

Methods:

- **Study Design:** Randomized controlled trial with 1,500 patients with three-vessel disease.
- **Participants:** Mean age 65 years, 82% male.
- **Interventions:** Patients randomized to FFR-guided PCI or CABG.
- **Data Sources:** Costs based on US Medicare fee schedule, quality-adjusted life years (QALYs) assessed using EuroQOL five-dimension (EQ-5D) survey.

Results:

- **Primary Endpoint:** No significant difference in all-cause death, MI, or stroke between PCI and CABG at 3 years (9.2% vs 12.0%).
- **Cost-Effectiveness:** PCI demonstrated lower cumulative medical costs over 3 years compared to CABG ($24,063 vs $35,714; P < 0.001).
- **Quality of Life:** PCI-treated patients reported better quality of life at 1 month but not at 12 or 36 months.
- **QALYs:** PCI group had numerically more QALYs at 3 years compared with CABG (2.57 vs 2.53).

Conclusions:

FFR-guided PCI is more cost-effective than CABG over 3 years, primarily due to lower cumulative medical costs. The results suggest that PCI may be a viable cost-effective alternative to CABG for patients with three-vessel disease, but longer-term data are needed to confirm these findings.

Coronary Access More Challenging With Self-Expanding Valves: SCAAR/SWENTRY

Background:

A study highlights the difficulties of accessing coronary arteries in patients with prior transcatheter aortic valve implantation (TAVI), specifically those with self-expanding valves.

Aims:

To compare the complexity of coronary angiography between self-expanding and balloon-expandable valves.

Methods:

- **Study Design:** Analysis of the SCAAR and SWENTRY registries.
- **Participants:** 245,000 coronary angiographies and 9,806 TAVI procedures from 2008 to 2022.
- **Endpoints:** Fluoroscopy times and contrast use during coronary angiography.

Results:

- **Findings:** Longer fluoroscopy times and higher contrast use in patients with self-expanding valves, particularly the Evolut valve.
- **Comparison:** Fluoroscopy times were 6.83 minutes for self-expanding valves versus 5.22 minutes for balloon-expandable valves.

Conclusions: Self-expanding valves, particularly the Evolut series, pose greater challenges for coronary access post-TAVI. These findings highlight the need for careful valve selection and positioning, especially in younger patients who may require future coronary interventions.

SWIFT TAVI Algorithm Lowers Wait Times for Highest-Risk Patients

Background:

The SWIFT TAVI algorithm was developed to address long wait times for transcatheter aortic valve implantation (TAVI) by prioritizing high-risk patients using a simple, automated scoring system.

Aims:

To evaluate the effectiveness of the SWIFT TAVI algorithm in reducing wait times for high-risk patients without increasing morbidity or mortality.

Methods:

- **Study Design:** Retrospective analysis at Essex Cardiothoracic Centre.
- **Participants:** 228 patients undergoing TAVI, classified into control (standard scheduling) and algorithm-prioritized groups.
- **Algorithm Factors:** LVEF, peak AV gradient, and syncope presence, scoring patients into four risk categories.

Results:

- **Population:** Mean age 82 years; 60% male.
- **Wait Times:**
- Intermediate-risk reduced from 20 to 10 weeks ($P = 0.014$).
- High-risk reduced from 32 to 12 weeks ($P < 0.001$).
- **Outcomes:** Similar major adverse cardiovascular events (MACE) rates between groups (9% vs. 10%).

Conclusions:

The SWIFT TAVI algorithm effectively reduces wait times for intermediate and high-risk patients without increasing adverse events. This pragmatic tool can be implemented widely to manage growing TAVI waitlists efficiently.

TAVI, Surgery Look Similar Long-term Across Risk Spectrum: Meta-analysis

Background:

A meta-analysis of landmark clinical trials compared transcatheter aortic valve implantation (TAVI) with surgical aortic valve replacement (SAVR) across various risk groups of patients with severe aortic stenosis.

Aims:

To evaluate long-term outcomes of TAVI versus SAVR, focusing on the risk of death or disabling stroke.

Methods:

- **Study Design:** Meta-analysis of the PARTNER and Evolut series of trials.
- **Participants:** 7,785 patients at low, intermediate, and high surgical risk.
- **Follow-Up:** Weighted mean of 5.76 years.

Results:

- **Primary Endpoint:** No significant difference in death or disabling stroke between TAVI and SAVR (HR 1.02; 95% CI 0.93-1.11).
- **Valve Type Analysis:**
- Self-expanding valves showed a lower risk of death/disabling stroke compared to SAVR.
- Balloon-expandable valves showed a higher risk compared to SAVR.
- Risk of valve thrombosis was lower with self-expanding valves.
- TAVI had a higher risk of permanent pacemaker implantation, especially with self-expanding valves.

Conclusions:

The findings support the comparable long-term safety and efficacy of TAVI and SAVR. Differences in outcomes based on valve types suggest the need for head-to-head randomized trials to confirm these observations.

OCT-Based Strategy Outperforms Angiography in Calcified Lesions: CALIPSO

Background:

The CALIPSO trial investigates the efficacy of using optical coherence tomography (OCT) for lesion preparation and stent optimization in patients with calcified coronary lesions, comparing it to conventional angiography.

Aims:

To determine if OCT-guided PCI provides better outcomes than angiography-guided PCI in calcified coronary lesions.

Methods:

- **Study Design:** Randomized controlled trial.
- **Participants:** 134 patients with stable, moderate-to-severe calcified coronary lesions.
- **Interventions:** Patients were randomized to OCT-guided PCI or angiography-guided PCI.
- **Endpoints:** Primary endpoint was the minimum stent area (MSA) measured post-PCI.

Results:

- **MSA:** Median MSA was significantly higher in the OCT group (6.5 mm^2) compared to the angiography group (5.0 mm^2).
- **Lesion Preparation:** OCT-guided group had more frequent use of advanced lesion preparation techniques (e.g., intravascular lithotripsy) compared to the angiography group.
- **Safety:** No significant differences in periprocedural complications, total X-ray dose, volume of contrast medium, or procedure duration between the groups.

Conclusions:

OCT-guided PCI for calcified lesions results in a larger MSA and may enhance procedural outcomes compared to angiography. Future studies are needed to determine if these imaging benefits translate into better long-term clinical outcomes.

ShortCut Leaflet Splitter Proves Safe, May Streamline Valve-in-Valve TAVI

Background:

The ShortCut leaflet splitter device is designed to facilitate valve-in-valve transcatheter aortic valve implantation (TAVI) by preventing coronary artery obstruction, a major complication during these procedures.

Aims:

To evaluate the safety and effectiveness of the ShortCut device in clinical practice.

Methods:

- **Study Design:** Prospective, multicenter trial.
- **Participants:** 66 patients at high risk for coronary obstruction during valve-in-valve TAVI.
- **Endpoints:** Successful leaflet splitting and freedom from major adverse events.

Results:

- **Primary Endpoint:** Successful leaflet splitting in all cases, with an average procedure time of 27 minutes.
- **Safety:** No mortality or disabling stroke related to the device; one disabling stroke at day 4, two noncardiac deaths within 30 days.
- **Coronary Access:** Unobstructed access in all but three patients, managed with coronary stents.

Conclusions:

The ShortCut device is a safe and efficient tool for preventing coronary obstruction in valve-in-valve TAVI, potentially streamlining the procedure compared to the BASILICA technique.

Young, Low-risk Patients Fare Well With TAVI, but Beware the Bicuspids

Background:

The NOTION-2 trial examines outcomes of transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement (SAVR) in low-risk patients with severe aortic stenosis, specifically highlighting concerns for those with bicuspid aortic valve anatomy.

Aims:

To compare clinical outcomes of TAVI and SAVR in low-risk patients and to assess specific outcomes in patients with bicuspid aortic valves.

Methods:

- **Study Design:** Randomized controlled trial.
- **Participants:** 370 patients aged 60 to 75 years with severe symptomatic aortic stenosis.
- **Endpoints:** Primary endpoint included death, stroke, or rehospitalization at 12 months.

Results:

- **Overall Population:**
- TAVI and SAVR showed similar rates of the primary endpoint (10.2% vs. 7.1%).
- No significant difference in death or disabling stroke between TAVI and SAVR (3.2% vs. 1.6%).
- Higher stroke rate in TAVI (5.4% vs. 1.6%).
- **Bicuspid Valve Subgroup:**
- Worse outcomes for TAVI-treated patients, including a higher risk of death, stroke, or rehospitalization (14.3% vs. 3.9%) and death or disabling stroke (6.1% vs. 2.0%).

Conclusions:

TAVI and SAVR provide comparable outcomes in low-risk patients with tricuspid valves, but TAVI in bicuspid aortic valves presents higher risks. Further studies are needed to optimize treatment strategies for bicuspid patients.

Stepwise DAPT De-escalation Shows Promise in DCB-Only PCI for ACS

Background:

The REC-CAGEFREE II trial evaluates a stepwise de-escalation of dual antiplatelet therapy (DAPT) in patients undergoing drug-coated balloon (DCB) angioplasty for acute coronary syndromes (ACS).

Aims:

To determine the feasibility and safety of a stepwise DAPT de-escalation strategy compared to standard 12-month DAPT.

Methods:

- **Study Design:** Randomized, multicenter trial.
- **Participants:** 1,948 ACS patients suitable for DCB-only PCI.
- **Interventions:**
- Standard DAPT: 12 months of aspirin and ticagrelor.
- Stepwise DAPT: 1 month of aspirin and ticagrelor, followed by 5 months of ticagrelor alone, and then aspirin alone through 12 months.

Results:

- **Primary Endpoint:** No significant difference in net adverse clinical events (NACE) between stepwise de-escalation and standard DAPT (9.0% vs. 8.7%; P = 0.013 for noninferiority).
- **Secondary Outcomes:**
- Lower BARC type 3 or 5 bleeding in the stepwise group (0.4% vs. 1.7%; P = 0.007).
- Win-ratio analysis showed benefits for stepwise de-escalation (win ratio 1.43; P = 0.004).

Conclusions:

Stepwise DAPT de-escalation is a feasible and safe strategy for DCB-only PCI in ACS patients, particularly benefiting those at high bleeding risk. Further studies are needed to confirm these findings and optimize DAPT strategies.

ORBITA-2: Angina Phenotype Strongly Predicts PCI Response

Background:

The ORBITA-2 trial examines how different angina phenotypes influence the response to percutaneous coronary intervention (PCI) in stable coronary artery disease (CAD) patients.

Aims:

To determine which angina phenotypes predict the greatest symptom relief from PCI.

Methods:

- **Study Design:** Randomized controlled trial.
- **Participants:** 301 patients with stable CAD.
- **Tools Used:** Rose Angina Questionnaire and a smartphone app for daily symptom tracking.

Results:

- **Primary Endpoint:** Patients with typical angina (Rose Angina) experienced significant reductions in symptom scores and angina episodes post-PCI compared to those with non-typical angina.
- **Secondary Findings:** Typical angina correlated with better PCI outcomes, while non-typical presentations showed less improvement.

Conclusions:

Identifying angina phenotypes is crucial for predicting PCI success, with typical angina patients benefiting the most.

Myval Matches Contemporary TAVI at 30 Days, but Do More Sizes Matter?

Background:

The Myval transcatheter heart valve, available in more sizes than other devices, was compared to Medtronic and Edwards Lifesciences valves in the LANDMARK trial.

Aims:

To assess the safety and efficacy of the Myval valve at 30 days and explore the impact of having more valve sizes on patient outcomes.

Methods:

- **Study Design:** Randomized trial across 31 sites in 16 countries.
- **Participants:** Patients randomized to seven Myval valve sizes or four Medtronic/Edwards sizes.
- **Endpoints:** VARC-3 composite safety endpoint at 30 days.

Results:

- **Primary Endpoint:** Myval met noninferiority criteria with a composite endpoint occurring in 24.7% of Myval patients versus 27.0% in the comparator group.
- **Secondary Outcomes:** No significant differences in secondary endpoints. Myval showed favorable early hemodynamics similar to other balloon-expandable valves and superior to self-expanding valves.

Conclusions:

Myval demonstrated comparable 30-day safety and efficacy. The broader range of sizes may improve patient outcomes, but long-term benefits remain to be seen.

Debate Continues on TAVI Choice for Women With Small Annuli

Background:

The SMART trial investigates the outcomes of TAVI with self-expanding versus balloon-expandable valves in women with small aortic annuli.

Aims:

To compare hemodynamic outcomes and clinical performance of self-expanding versus balloon-expandable valves in this patient group.

Methods:

- **Study Design:** Subgroup analysis of the SMART trial.
- **Participants:** 637 female patients with small aortic annuli.
- **Endpoints:** Hemodynamic outcomes, bioprosthetic valve dysfunction, patient-prosthesis mismatch (PPM), and quality of life.

Results:

- **Primary Findings:**
- Self-expanding valves showed better hemodynamic performance (lower gradients, larger effective orifice area) and lower rates of bioprosthetic valve dysfunction and PPM at 1 year compared to balloon-expandable valves.
- Similar rates of death, disabling stroke, and rehospitalization between groups.
- Better or comparable quality of life with self-expanding valves.

Conclusions:

Self-expanding valves offer superior hemodynamic outcomes and lower rates of valve dysfunction in women with small annuli. Long-term follow-up is needed to confirm these benefits and guide clinical practice.

Latest TAVI vs Surgery Trial Raises Eyebrows in Aortic Stenosis Plus CAD

Background:

The TCW trial compared transcatheter aortic valve implantation (TAVI) plus PCI to surgical aortic valve replacement (SAVR) plus CABG in patients with severe aortic stenosis and significant coronary artery disease.

Aims:

To evaluate the safety and efficacy of TAVI/PCI versus SAVR/CABG in this patient population.

Methods:

- **Study Design:** Randomized controlled trial.
- **Participants:** 172 patients aged ≥70 years with severe symptomatic aortic stenosis and coronary artery disease.
- **Endpoints:** Primary endpoint was a composite of all-cause mortality, MI, stroke, target vessel revascularization, valve reintervention, and bleeding.

Results:

- **Primary Endpoint:** Occurred in 22.9% of SAVR/CABG patients versus 4.4% of TAVI/PCI patients at 1 year ($P < 0.001$ for noninferiority and superiority).
- **Mortality and Stroke:** 12.5% in the surgical arm versus 1.1% in the TAVI/PCI arm.
- **Other Findings:** Higher rates of atrial fibrillation and bleeding in the surgical arm.

Conclusions:

TAVI/PCI showed significantly better outcomes in terms of mortality and stroke compared to SAVR/CABG, raising questions about the best treatment approach for these patients.

Go Beyond Angiography in CCS to Pinpoint the Problem, Urges AID-ANGIO

Background:

The AID-ANGIO study demonstrates that a hierarchical strategy of intracoronary testing improves diagnostic accuracy for ischemia with nonobstructive coronary arteries (INOCA) compared to angiography alone.

Aims:

To compare diagnostic yield and clinical impact of AID (Advanced Invasive Diagnosis) strategy versus traditional angiography in chronic coronary syndromes (CCS).

Methods:

- **Study Design:** Prospective study with 317 all-comer patients.
- **Strategy:** Sequential intracoronary tests post-angiography for stenoses <90%.

Results:

- **Diagnostic Yield:** AID identified the cause of ischemia in 84.2% of patients versus 32.2% with angiography alone.
- **Findings:** INOCA was more prevalent than obstructive CAD.
- **Impact:** Improved diagnostic accuracy, modifying treatment plans for 59.9% of patients.

Conclusions:

The AID strategy significantly enhances diagnostic accuracy for INOCA, suggesting widespread implementation could improve patient outcomes.