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EuroPCR 2025 – One-month dual antiplatelet therapy followed by prasugrel monotherapy at a reduced dose: the 4D-ACS randomised trial

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Paris, France, 20-23 May 2025. *The EuroPCR Course Directors have selected 3 major late-breaking trials that will be presented for the first time during the 2025 edition of EuroPCR. These trials were selected because of their design, results, and potential to impact practice, among them is the 4D-ACS randomised clinical trial (RCT).*

Background

While dual antiplatelet therapy (DAPT) has long been the standard of care for the management of acute coronary syndrome (ACS) patients undergoing percutaneous coronary intervention (PCI), there is an increasing awareness of the need to find a more patient-centred approach that strikes a balance between the ischaemic protection DAPT offers and the risk of bleeding complications it can create.

The effect of DAPT in dosage and duration on cardiovascular events and bleeding after implantation of drug-coated stents (DCS) in ACS patients, the 4D-ACS trial[1], is a Korean trial in which 656 East Asian ACS patients were randomised 1:1 to either a 1-month DAPT with aspirin 100 mg and prasugrel 10 mg (patients ≥75 years or body weight <60 kg received 5 mg of prasugrel) followed by prasugrel 5 mg monotherapy (1M-DAPT) regimen or a 12-month DAPT protocol with aspirin and prasugrel 5 mg (12M-DAPT).

While earlier trials also addressed the issue of DAPT reduction or de-escalation regimes, the 4D-ACS trial is one of the first to randomise patients immediately post-PCI to compare two DAPT protocols, short and long.

The primary endpoint was 12-month net adverse clinical events (NACE), defined as a composite of death, non-fatal myocardial infarction, stroke, ischaemia-driven target vessel revascularisation, and Bleeding Academic Research Consortium (BARC) type 2-5 bleeding.

Results

At 12-months, NACE occurred in 4.9% of the 1M-DAPT group and 8.8% of the 12M-DAPT group meeting criteria for both non-inferiority and superiority.

Major bleeding occurred in 0.6% vs 4.6% (HR 0.13; p=0.007) in the 1M-DAPT vs 12M-DAPT group, respectively.

Ischaemic outcomes were similar in both groups.

Key learnings

While long-term DAPT has been shown to provide early ischaemic benefits reducing life-threatening events such as stent thrombosis, bleeding complications emerging over the long-term maintenance phase can result in clinically significant events associated with increased levels of

mortality. Thus, the possibility of having proven de-escalation strategies for DAPT, especially for populations at high risk for bleeding, is a critical addition to available management choices for these patients.
GLOBAL LEADERS, TICO and TWILIGHT, focused on dropping aspirin and continuing P2Y12 inhibitor monotherapy; others, like HOST-REDUCE-POLYTECH RCT and TALOS-AMI, chose to reduce the dose of the P2Y12 inhibitor itself, while TOPIC and TROPICAL-ACS evaluated switching from potent agents to clopidogrel[2].
The results of the 4D-ACS trial – one-month DAPT followed by prasugrel 5 mg monotherapy in ACS patients who received a DCS – showed a reduction in NACE by 49%, driven in large part by a 77% reduction in bleeding events compared to the 12-month DAPT regime using the same DCS, demonstrating that this type of de-escalation protocol and DCS implantation enhanced safety and reduced bleeding without compromising ischaemic protection for these ACS patients.

Choice of device
All patients underwent PCI with a biolimus-coated drug-eluting stent, the BioFreedom™ Ultra (Biosensors).

Conclusions and PCR recommendations
The 4C-ACS trial demonstrated the safety and feasibility in East Asian ACS patients of a 1-month DAPT de-escalation protocol with DCS implantation that offered enhanced safety and reducing bleeding without compromising ischaemic protection for these patients.

The trial has certain limitations which prevents its conclusions from being applied to the general population of patients undergoing PCI: only one type of stent platform was used; the de-escalation was unguided and the same for all patients in the short-term DAPT arm; the study population was ethnically similar and further trials would need to study the same approach in a more diverse patient population. Still, the results open the door to an attractive option for patients at increased bleeding risk.

Supporting the viability of a shorter DAPT course followed by low-dose prasugrel monotherapy which can minimise bleeding without compromising ischaemic safety offers the physician a viable option for managing their patients. The 4C-ACS trial is another welcome step in the transition from a “rigid, uniform approach” to DAPT to a “risk-adapted, dynamic and patient-centred model of care”.[3]

References

1. Jang Y, Park S-D, Lee JP, et al. One-month dual antiplatelet therapy followed by prasugrel monotherapy at a reduced dose: the 4D-ACS randomised trial. *EuroIntervention*. 2025. In press. DOI: 10.4244/EIJ-D-25-00331

2. Capodanno D, Mehran R, Krucoff MW, et al. Defining strategies of modulation of antiplatelet therapy in patients with coronary artery disease: a consensus document from the Academic Research Consortium. *Circulation*. 2023;147:1933-44. doi: 10.1161/CIRCULATIONAHA.123.064473. Epub 2023 Jun 19.

3. Cuisset, T, Cayla G. DAPT de-escalation post-ACS: a new rule or just a new option? Lessons from the 4D-ACS trial. *EuroIntervention*. 2025 In press. Doi: 10.4244/EIJ-E-25-00023

NOTES TO EDITORS

Key information

• Session: Hotline /Late-Breaking Trials: Major Late-Breaking Trials from EuroPCR 2025
• Presentation: One-month DAPT followed by dose reduction of prasugrel after drug-coated stent insertion in Acute Coronary Syndrome
• Presenter: Woong Chol Kang
• Palais des Congrès Porte Maillot – Paris, France
• 21/05 11:15-12:15 Theatre Bleu

About EuroPCR 2025

The World-Leading Course in interventional cardiovascular medicine and the official annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) will take place from 20 to 23 May 2025, onsite at the Palais des Congrès, Paris, France. A digital package is also available for those unable to join in person.

The detailed Course Programme is available on:
https://www.pcronline.com/Courses/EuroPCR/Programme

About PCR

The mission of PCR is to serve the needs of each individual patient by helping the cardiovascular community to share knowledge, experience and practice. PCR offers a large range of many other educational meetings and resources for the continuing education of the interventional cardiovascular community. These include major annual Courses across the globe, e-Learning with high-profile PCR Webinars, Courses specifically dedicated to valvular heart disease, tailor-made PCR Seminars on specific topics, online resources and medical publications such as EuroIntervention, the official journal of the EAPCI.

Gateways to all PCR activities are available on www.pcronline.com.

For further information, please contact Sally Collingridge: scollingridge@europa-group.com

About the EAPCI

The European Association of Percutaneous Cardiovascular Interventions (EAPCI) is a branch of the European Society of Cardiology. Its mission is to reduce the burden of cardiovascular disease through percutaneous cardiovascular interventions. This dynamic association represents a large community of over 8K EAPCI associates and over 1K full EAPCI members by helping them remain up to date in the constantly evolving field of PCI by publishing research and providing educational, training and certification programmes. The EAPCI also advocates for the best possible access to life saving treatments for patients through data-based advocacy at a European level.

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