

T-PASS randomized noninferiority trial

Stopping Aspirin Within 1 Month After Stenting for Ticagrelor Monotherapy in Acute Coronary Syndrome

Conclusions

- Orsiro™ DES showed significantly less net adverse clinical events when stopping aspirin within 1 month compared to 12-month DAPT in ACS patients.^{a,1}
- ACS patients treated with Orsiro™ DES have a reduced bleeding risk when stopping aspirin within 1 month compared to 12-month DAPT.^{b,1}
- Orsiro™ DES proves to be safe when combined with <1-month DAPT in ACS patients.^{a,1}

Study design

Investigator-initiated, prospective, multicenter, open-label, randomized (1:1), non-inferiority trial comparing ticagrelor monotherapy after <1 month of DAPT to 12 months of DAPT after using Orsiro™ in ACS Patients.

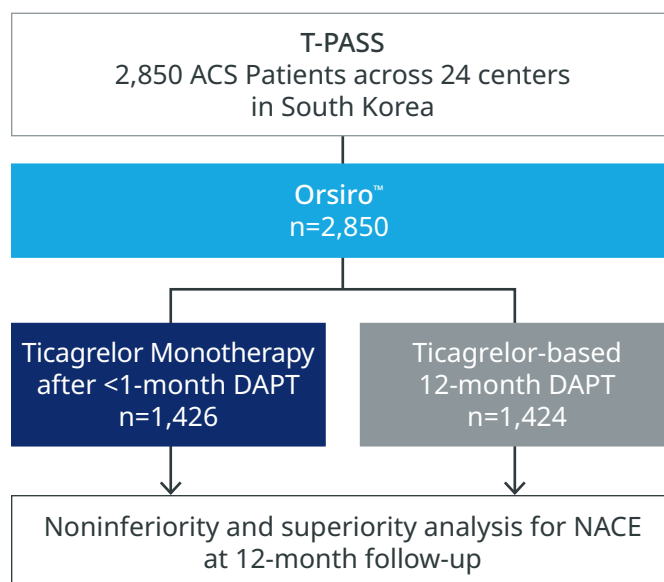
Endpoints at 12-month follow-up

Primary endpoint

- Net Adverse Clinical Events (NACE)

Selected secondary endpoints

- Major Bleeding (BARC 3-5)
- Death, myocardial infarction, stent thrombosis or stroke



Patient characteristics¹

| | TICAGRELOR MONOTHERAPY AFTER <1-M DAPT N=1,426 | | TICAGRELOR-BASED 12-M DAPT N=1,424 | |
|-----------------------------------|--|------|------------------------------------|------|
| Age, mean (SD), years | 61±10 | | 61±10 | |
| Men | 1,193 | 84 % | 1,181 | 83 % |
| BMI, mean (SD), kg/m ² | 25.1±3.6 | | 25.0±3.5 | |
| Hypertension | 669 | 47 % | 679 | 48 % |
| Diabetes mellitus | 422 | 30 % | 408 | 29 % |
| Chronic kidney disease | 118 | 8 % | 104 | 7 % |
| Current smoker | 557 | 39 % | 537 | 38 % |
| Prior MI | 27 | 2 % | 25 | 2 % |
| Prior PCI | 92 | 7 % | 92 | 7 % |
| Prior CABG | 4 | <1 % | 2 | <1 % |
| Prior stroke | 43 | 3 % | 49 | 3 % |

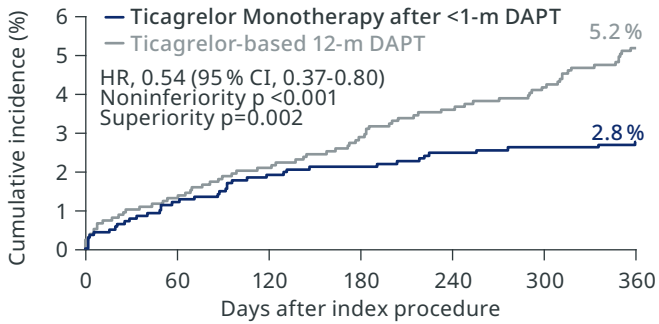
Procedural characteristics¹

| | TICAGRELOR MONOTHERAPY AFTER <1-M DAPT N=1,426 | | TICAGRELOR-BASED 12-M DAPT N=1,424 | |
|-------------------------------------|--|------|------------------------------------|------|
| Admission via emergency room | 1,056 | 74 % | 1,050 | 74 % |
| Clinical presentation | | | | |
| Unstable angina | 347 | 24 % | 361 | 25 % |
| Non-ST-elevation MI | 507 | 36 % | 485 | 34 % |
| ST-elevation MI | 572 | 40 % | 578 | 41 % |
| Transfemoral approach | 467 | 33 % | 470 | 33 % |
| Bifurcation lesion | 219 | 15 % | 215 | 15 % |
| Multivessel coronary artery disease | 749 | 53 % | 738 | 52 % |
| Multi-lesion intervention | 299 | 21 % | 279 | 20 % |
| Multi-vessel intervention | 233 | 16 % | 231 | 16 % |
| Treated lesions per patient, mean | 1.3±0.5 | | 1.2±0.5 | |
| Number of stents per patient, mean | 1.4±0.8 | | 1.4±0.7 | |
| Stent length per patient, mm | 38±23 | | 37±22 | |

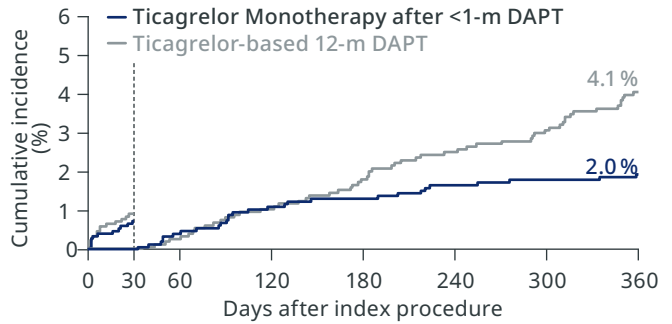
Primary endpoint – NACE at 12-month follow-up¹

Orsiro™ DES shows significantly less net adverse clinical events with <1-month DAPT compared to 12-month DAPT in ACS patients.^{a,1}

NACE at 12-month follow-up



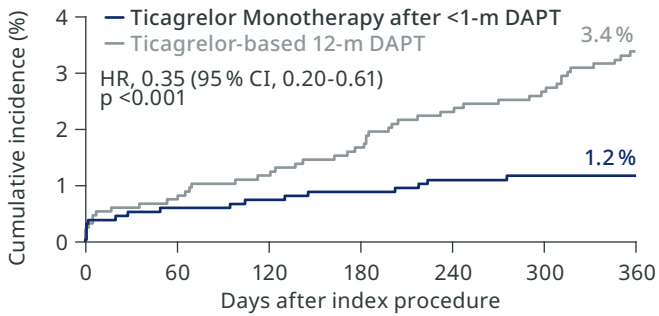
NACE Landmark Analysis at 1 month



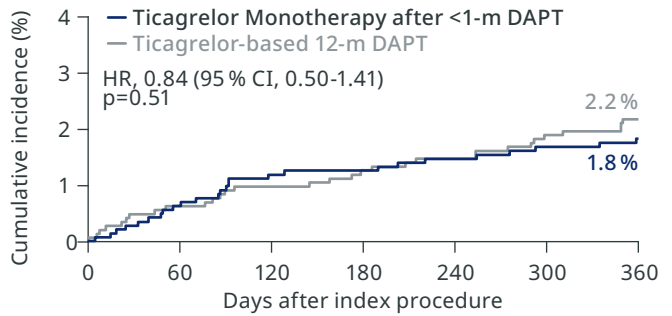
Selected secondary endpoints at 12-month follow-up¹

With Orsiro™ DES less than 1-month DAPT reduces major bleeding without compromising safety compared to 12-months DAPT in ACS patients.^{c,1}

Major Bleeding at 12-month follow-up



Death, Myocardial Infarction, Stent Thrombosis or Stroke at 12-month follow-up



| | TICAGRELOR MONOTHERAPY AFTER <1-M DAPT N=1,426 | | TICAGRELOR-BASED 12-M DAPT N=1,424 | | HAZARD RATIO (95% CI) | P-VALUE |
|---|---|-------|--|-------|--------------------------|---------|
| Primary outcome | | | | | | |
| Net adverse clinical event | 40 | 2.8 % | 73 | 5.2 % | 0.54 (0.37–0.80) | 0.002 |
| Secondary outcome | | | | | | |
| Major bleeding (BARC type 3-5) | 17 | 1.2 % | 48 | 3.4 % | 0.35 (0.20–0.61) | <0.001 |
| Any bleeding (BARC type ≥2) | 28 | 2.0 % | 64 | 4.5 % | 0.43 (0.28–0.68) | <0.001 |
| Death, myocardial infarction, stent thrombosis or stroke (post-hoc) | 26 | 1.8 % | 31 | 2.2 % | 0.84 (0.50–1.41) | 0.51 |
| Death | 14 | 1 % | 14 | 1 % | 1.00 (0.48–2.10) | >0.99 |
| Cardiac | 6 | | 9 | | | 0.44 |
| Acute MI | 7 | 0.5 % | 8 | 0.6 % | 0.88 (0.32–2.41) | 0.80 |
| Stent thrombosis | 2 | 0.1 % | 2 | 0.1 % | 1.00 (0.14–7.09) | 0.99 |
| Stroke | 8 | 0.6 % | 11 | 0.8 % | 0.73 (0.29–1.81) | 0.49 |
| Ischemic | 6 | | 8 | | | |
| Hemorrhagic | 2 | | 3 | | | |
| Target-vessel revascularization | 11 | 0.8 % | 18 | 1.3 % | 0.61 (0.29–1.29) | 0.20 |

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Reference

1 Hong, Sung-Jin, et al. "Stopping Aspirin Within 1 Month After Stenting for Ticagrelor Monotherapy in Acute Coronary Syndrome: The T-PASS Randomized Noninferiority Trial." *Circulation*, 2023.

ACS: Acute Coronary Syndrome, BARC: Bleeding Academic Research Consortium, CABG: Coronary Artery By-Pass Graft, CI: Confidence Interval, DAPT: Dual Antiplatelet Therapy, DES: Drug-Eluting Stent, HR: Hazard Ratio, MACE: Major Adverse Cardiac Events (cardiovascular death, myocardial infarction, stent thrombosis, and ischemia-driven target-vessel revascularization), NACE: Net Adverse Clinical Event (all-cause death, myocardial infarction, stent thrombosis, stroke, and major bleeding), PCI: Percutaneous Coronary Intervention, SD: Standard Deviation, ST: Stent Thrombosis

At 1 year, for DAPT with ticagrelor and NACE *At 1 year, for DAPT with ticagrelor and major bleeding BARC 3-5* *At 1 year, for DAPT with ticagrelor, major bleeding as BARC 3-5, and MACE*.

*Orsiro DES is not indicated for DAPT of one month or less in ACS patients. Please refer to the IFU for indications and post-procedure antiplatelet therapy recommendations. Clinical data collected with the Orsiro DES device within the Orsiro family clinical program. Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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