Stopping Aspirin Within 1 Month After Stenting Ticagrelor Monotherapy in Acute Coronary Syndrome: The T-PASS Randomized Noninferiority Trial

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[c,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.

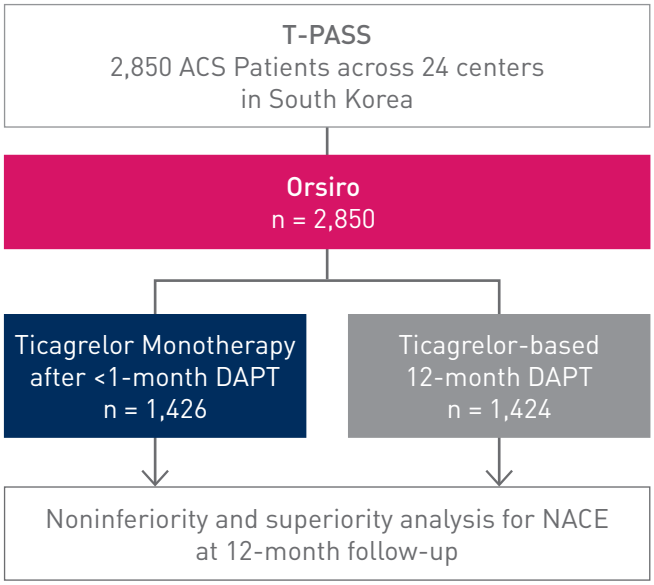
Endpoints at 12-month follow-up

Primary endpoint

- Net Adverse Clinical Events (NACE)

Selected Secondary Endpoints

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



Patient characteristics[1]	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/m²	25.1 ± 3.6		25.0 ± 3.5	
Hypertension	669	47%	679	48%
Diabetes mellitus	422	30%	408	29%
Chronic kidney disease	292	19%	328	22%
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 characteristics[1]	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%
2- or 3-vessel diseases	749	53%	738	52%
Multi-lesion intervention	299	21%	279	20%
Multi-vessel intervention	233	16%	231	16%
Treated lesions per patient, n	1.3 ± 0.5		1.2 ± 0.5	
Number of stents per patient, n	1.4 ± 0.8		1.4 ± 0.7	
Stent length per patient, mm	39 + 22		37 + 22	

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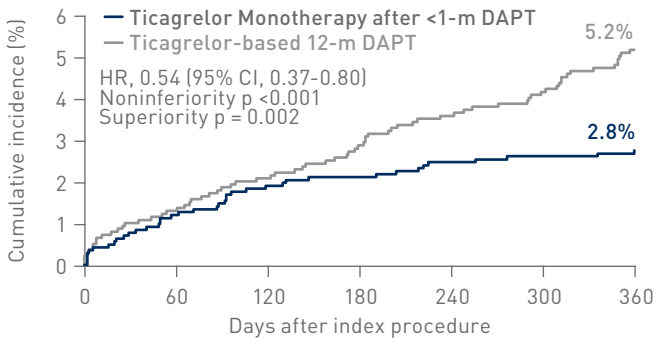
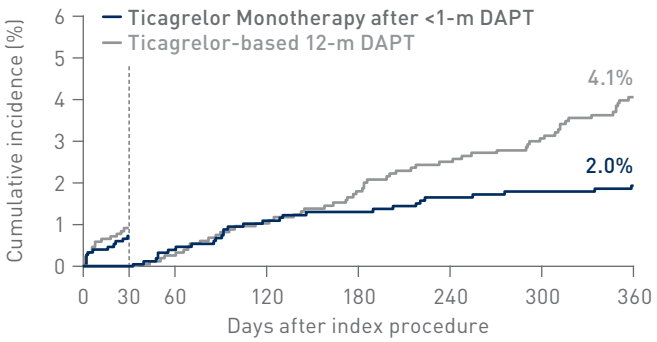
Primary Endpoint - NACE at 12-month follow-up[1]

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



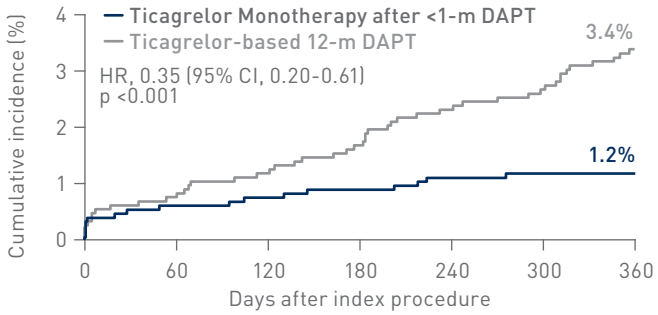
NACE Landmark Analysis at 1 month



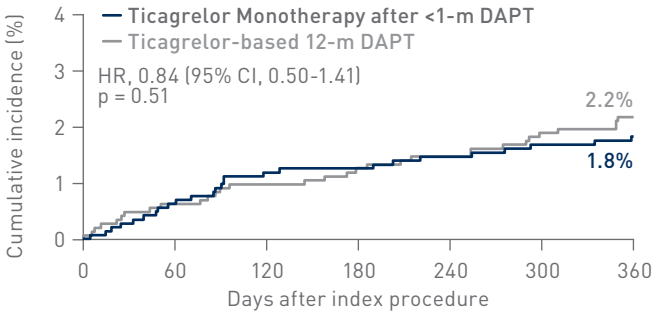
Selected Secondary Endpoints at 12-month follow-up[1]

With **Orsiro DES** less than 1-month DAPT reduces major bleeding without compromising safety compared to 12-months DAPT in ACS patients.[d,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			0.99
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)	0.49
Ischemic	6		8			
Hemorrhagic	2		3			
Target-vessel revascularization	11	0.8%	18	1.3%	0.61 (0.29-1.29)	0.20

Principal investigator

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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, MI: Myocardial Infarction, 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

a. At 1 year, for DAPT with ticagrelor and NACE. Orsiro DES is not indicated for DAPT of one month or less in ACS patients*; b. At 1 year, for DAPT with ticagrelor and major bleeding BARC 3-5*; c. At 1 year, for DAPT with ticagrelor and NACE*; d. At 1 year, for DAPT with ticagrelor, major bleeding as BARC 3-5, and MACE*. 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.

* 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.

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