

TICO-STEMI: **A Randomized Trial of** **Ticagrelor Monotherapy vs.** **Ticagrelor With Aspirin in STEMI**

Late-Breaking Clinical Trial at 2020 TCT Connect

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On the behalf of the TICO trial investigators

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Disclosure Statement of Financial Interest

I, Byeong-Keuk Kim DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Background

- From the randomized trials,¹⁻³ the **potent P2Y12 inhibitor monotherapy after brief period of DAPT** has been considered as the optimal treatment strategy for high-risk patients balancing the ischemic and bleeding risks.

1. Vranckx P, et al. GLOBAL-LEADERS. *Lancet* 2018;392:940-9.
2. Mehran R, et al. TWILIGHT. *N Engl J Med* 2019;381:2032-42.
3. Kim BK, et al. TICO. *JAMA* 2020;323:2407-16.

- However, prior studies regarding potent P2Y12 inhibitor monotherapy excluded the patients with STEMI, but the **TICO trial** (Ticagrelor Monotherapy After 3 Months in the Patients Treated With New Generation Sirolimus-eluting Stent for Acute Coronary Syndrome) targeting for **ACS patients included all subsets of ACS, including STEMI**.³

	GLOBEAL LEADERS ¹	TWILIGHT ²	TICO ³
ACS, %	47%	65%	100%
STEMI, %	0% (excluded)	0% (excluded)	36% (included)
DAPT duration after PCI	1 M	3 M	3 M

TICO-STEMI study

- To assess the safety and feasibility of **ticagrelor monotherapy after 3 months of DAPT in STEMI patients** treated with ultrathin bioresorbable polymer sirolimus-eluting stents, using a prespecified subgroup analyses of the STEMI cohort of the TICO trial

TICO trial ...

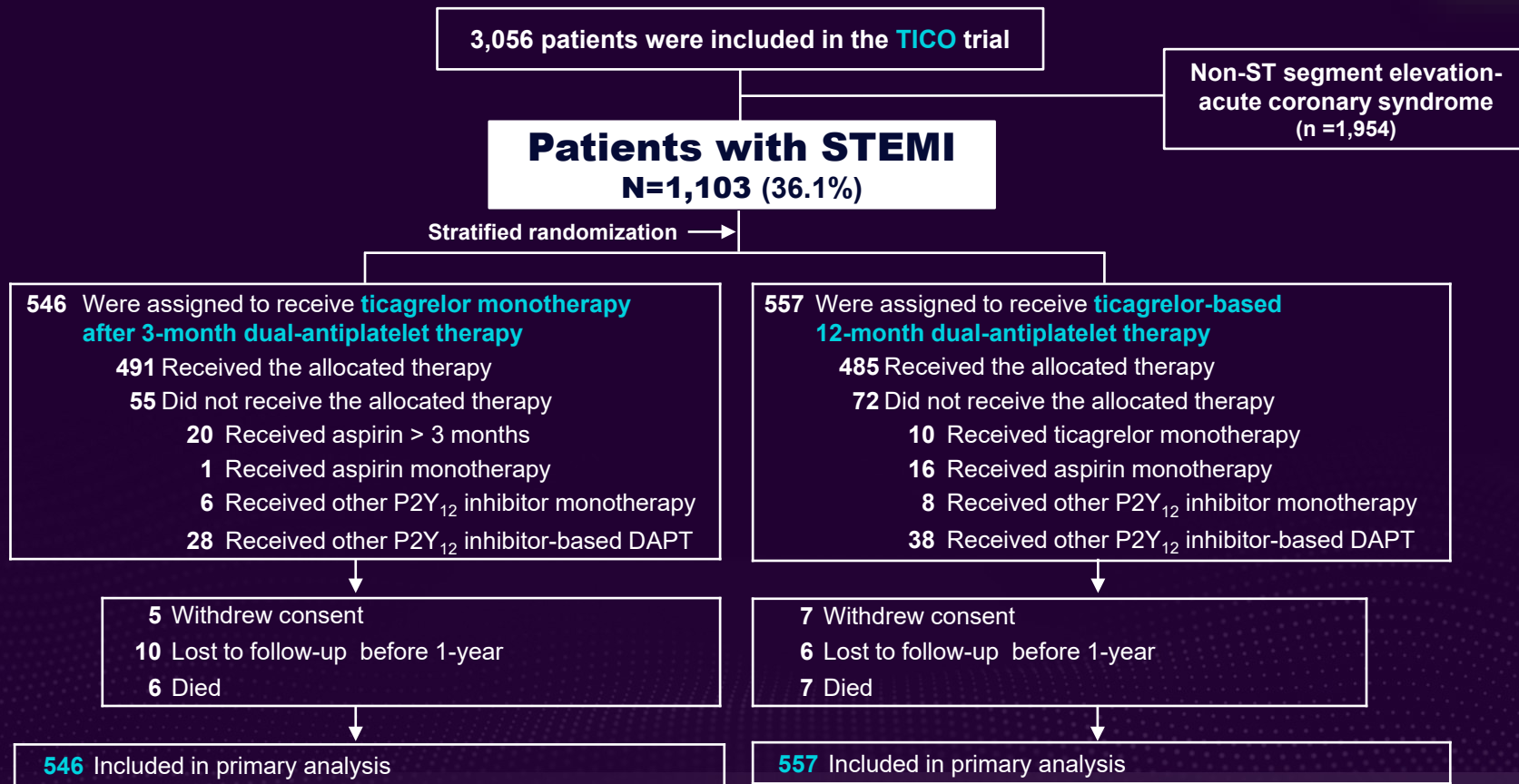
- A prospective, randomized, multi-center trial conducted at 38 centers in South Korea
- All types of ACS (UA, 30.3%; NSTEMI, 33.6%; and **STEMI, 36.1%**) were enrolled.
- According to the presence of STEMI, **stratified randomization** was performed.

- **Primary outcome:**

Net adverse clinical event (NACE) including bleeding & ischemic outcomes

- **Bleeding outcomes – TIMI major bleeding**
- **Ischemic outcomes – Major adverse cardiac & cerebrovascular event (MACCE); all-cause death, MI, stent thrombosis, stroke, or TVR**

Study Flow of the *TICO-STEMI* study

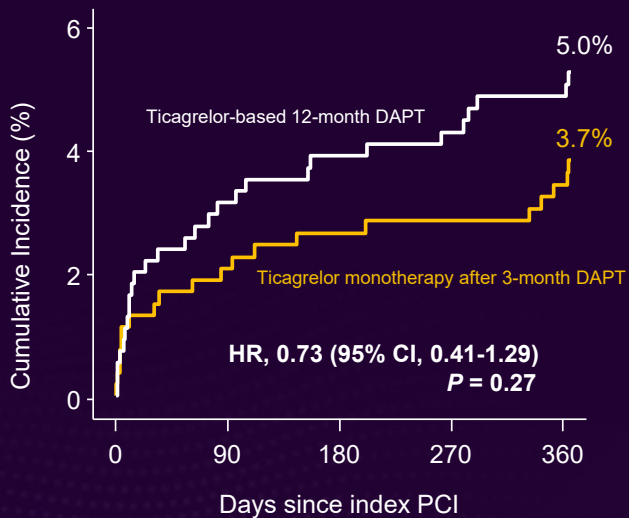


Baseline Characteristics

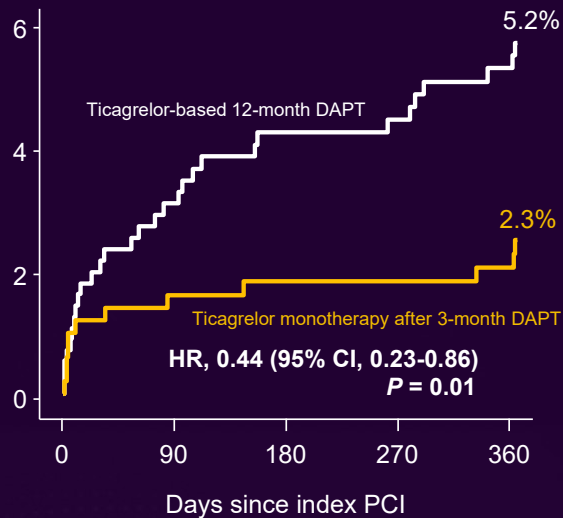
Characteristics	Ticagrelor Monotherapy after 3-m DAPT (N=546)	Ticagrelor-based 12-m DAPT (N=557)	P value
Age, yrs	59 ± 11	59 ± 11	0.47
Women	87 (16%)	82 (15%)	0.64
Body mass index, kg/m ²	24.7 ± 3.1	24.9 ± 3.3	0.27
Hypertension	252 (46%)	242 (43%)	0.84
Diabetes mellitus	113 (21%)	119 (21%)	0.84
Chronic kidney disease	120 (22%)	130 (23%)	0.64
Current smoker	246 (45%)	272 (49%)	0.23
Prior myocardial infarction	21 (4%)	14 (3%)	0.28
Prior percutaneous coronary intervention	35 (6%)	23 (4%)	0.12
Prior coronary bypass surgery	3 (0.5%)	1 (0.2%)	0.60
Prior stroke	11 (2%)	19 (3%)	0.22
Admission via emergency room	523 (96%)	538 (97%)	0.59
Transradial approach	183 (34%)	192 (35%)	0.79

Primary outcome, **NACE** at 12-months

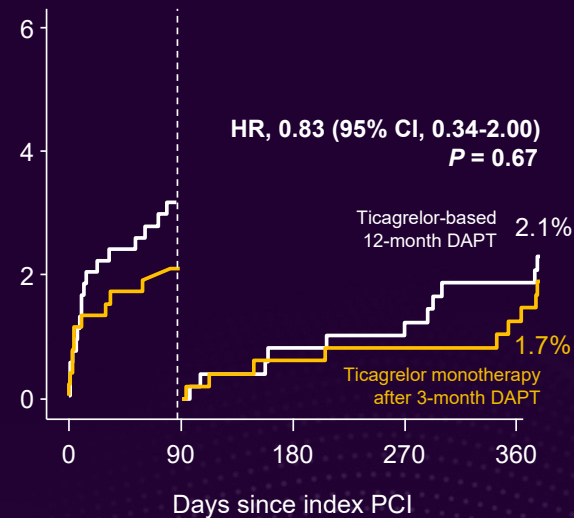
Intention-to-Treat



As-Treated



Landmark (ITT)



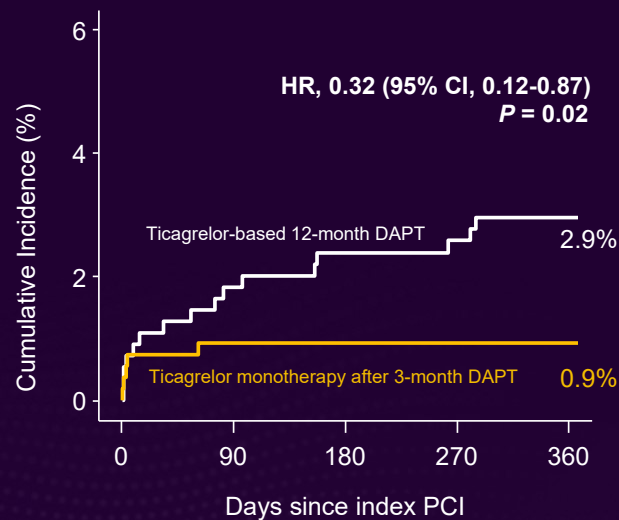
12M Ticagrelor + Aspirin	557	534	527	521	518
Ticagrelor monotherapy	546	529	520	516	513

579	540	508	494	480
524	488	463	458	456

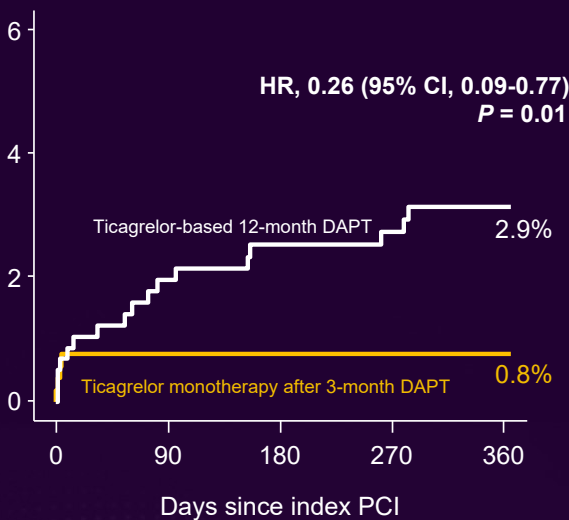
557	534	527	521	518
546	529	520	516	513

Bleeding outcome; TIMI Major bleeding at 12 months

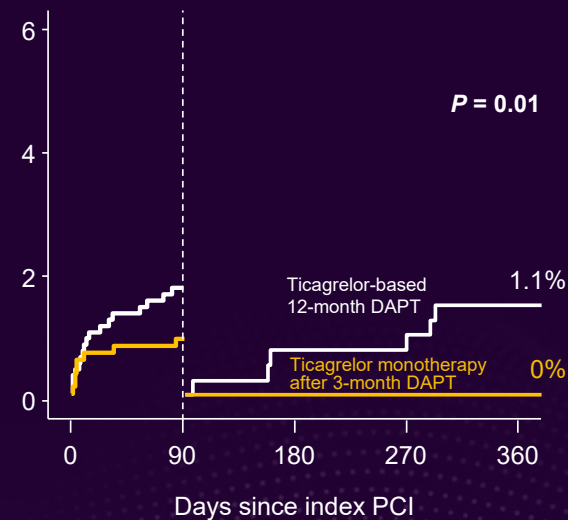
Intention-to-Treat



As-Treated



Landmark (ITT)



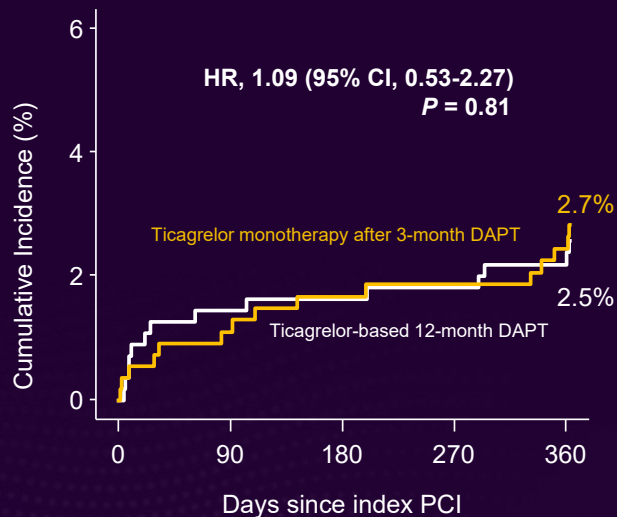
12M Ticagrelor + Aspirin	557	536	530	525	523
Ticagrelor monotherapy	546	532	525	521	520

579	542	513	499	487
524	490	465	460	458

557	536	530	525	523
546	532	525	521	520

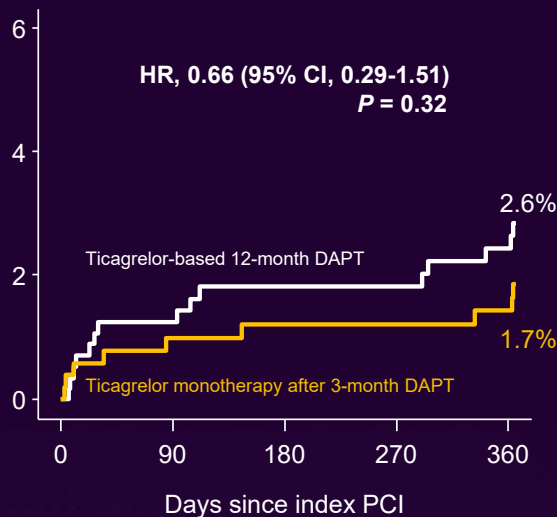
Ischemic outcome; Major Adverse Cardiac and Cerebrovascular Event at 12 months

Intention-to-Treat



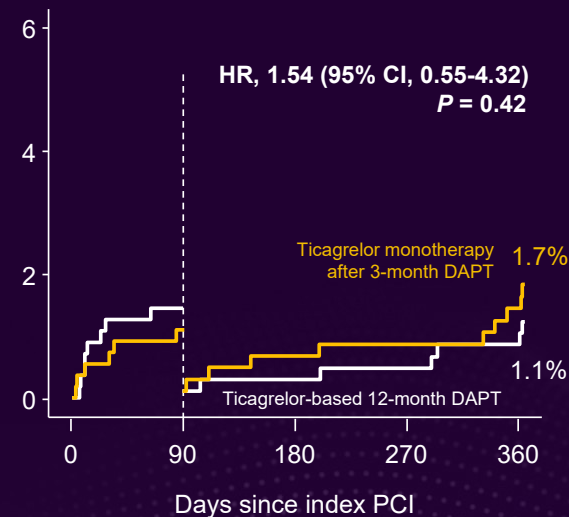
12M Ticagrelor + Aspirin	557	543	539	534	532
Ticagrelor monotherapy	546	534	525	521	518

As-Treated



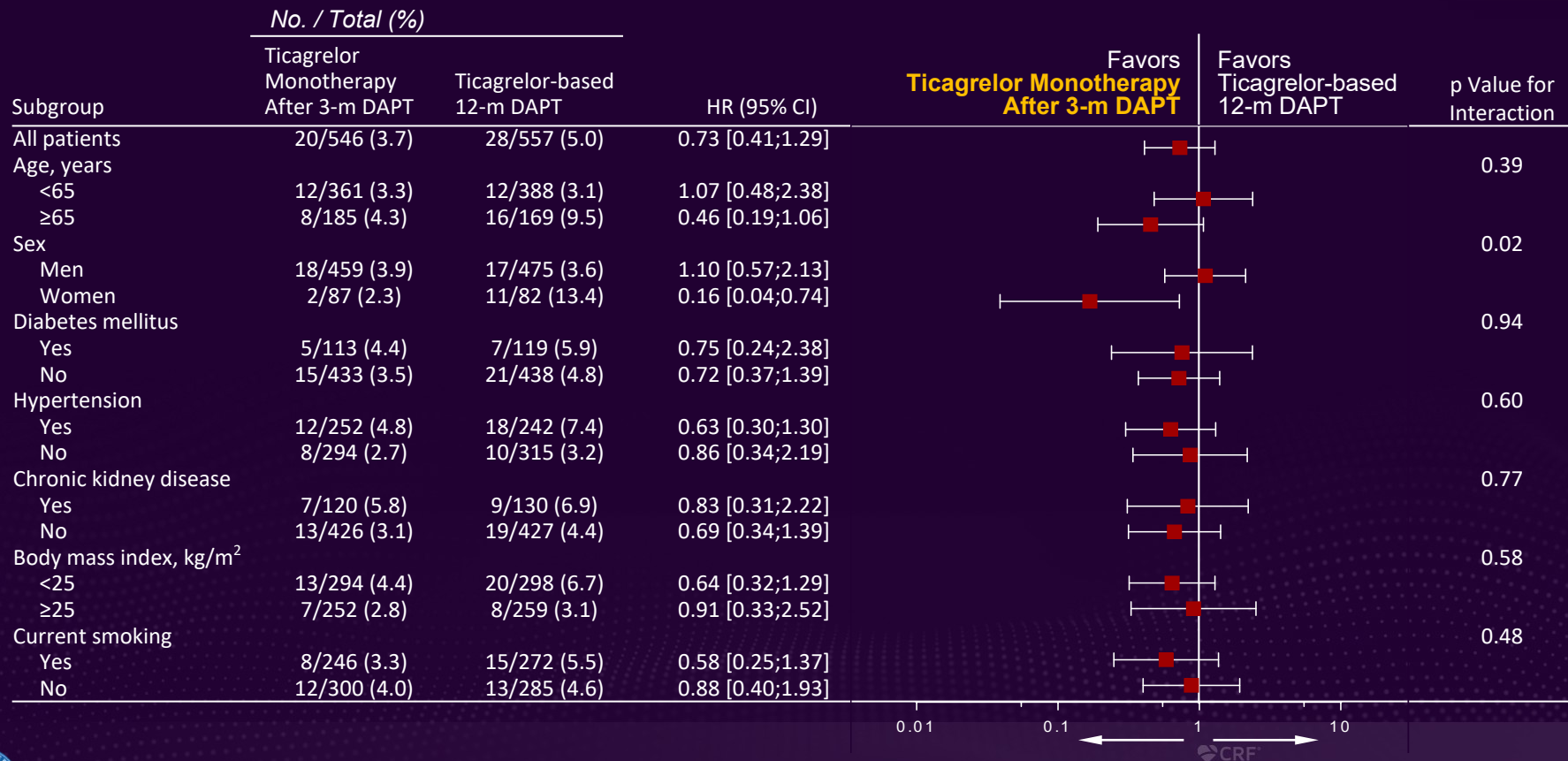
579	546	515	502	489
524	492	467	462	460

Landmark (ITT)



557	543	539	534	532
546	534	525	521	518

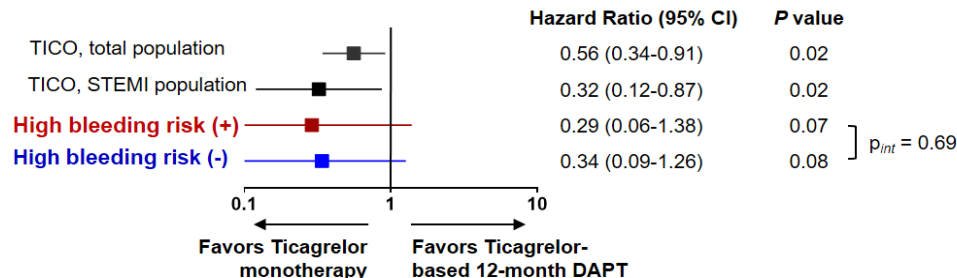
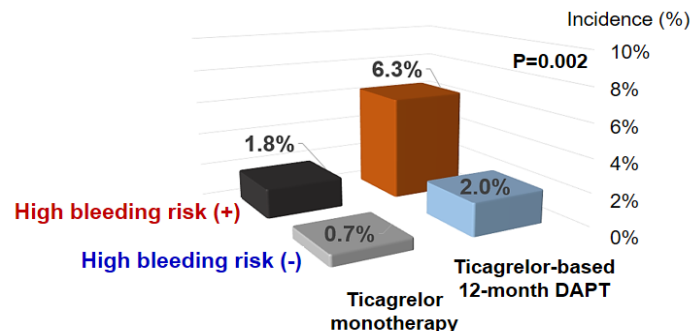
Subgroup analysis for primary outcome



Post-hoc analyses in patients/ lesions with high risks

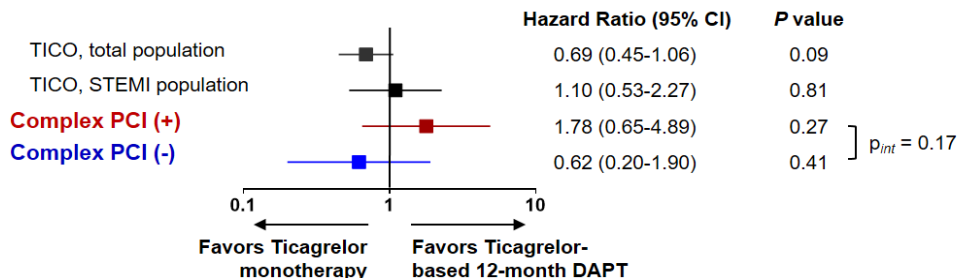
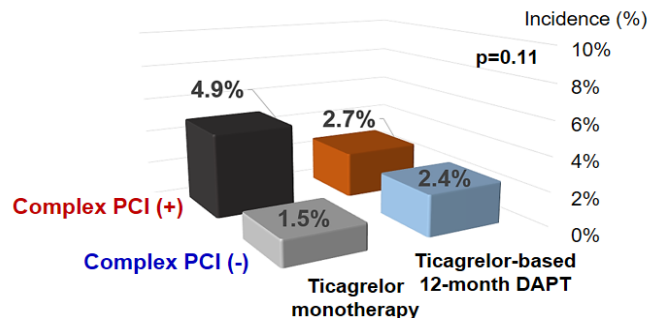
Major bleeding

- **High bleeding risk (+)** PRECISE-DAPT score ≥ 25



Major adverse cardiac and cerebrovascular event

- **Complex PCI (+)** 3 vessels treated; ≥ 3 lesions treated; total stent length >60 mm; bifurcation c 2 stents; left main PCI; or CTO as target lesions



Conclusions

This is the first report assessing the feasibility of the ticagrelor monotherapy after short-term DAPT for STEMI patients with DES.

Among patients with STEMI treated with ultrathin bioresorbable polymer sirolimus-eluting stents,

- **Ticagrelor monotherapy after 3-month DAPT**, compared with ticagrelor-based 12-month DAPT, resulted in a **reduced risk of major bleeding**.
- As for **MACCE**, there were **no significant differences between the two treatment groups, without significant interaction** with clinical presentation in this study.
- However, care should be taken in applying these results to the overall STEMI population, especially those at high risk for ischemia.

Severance



Thank you for your attention!



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