6-month versus 12-month or longer dual antiplatelet therapy after percutaneous coronary intervention in patients with acute coronary syndrome (SMART-DATE): a randomized, open-label, non-inferiority trial

ACC.18 Late-Breaking Clinical Trials

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On the behalf of SMART-DATE trial investigators

Study objective

- Background

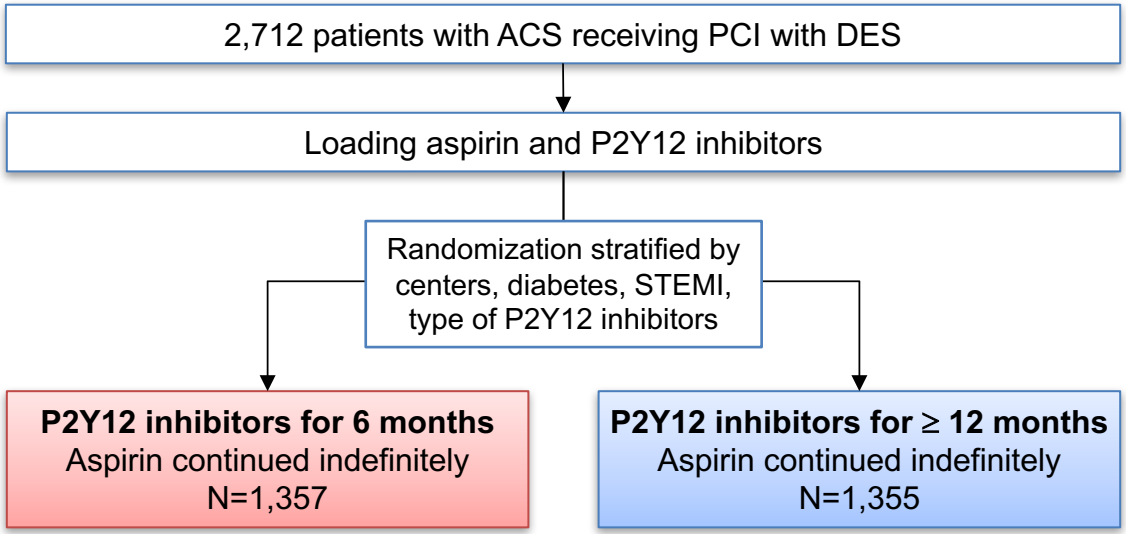
  Current guidelines recommend dual antiplatelet therapy (DAPT) for 12 months or longer in patients with acute coronary syndrome (ACS), unless there are no excessive risk of bleeding. These recommendations, however, were not based on randomized controlled trials dedicated to the optimal duration of DAPT in this population.

- Study objective

  To investigate whether a 6-month duration of DAPT would be non-inferior to the conventional 12-month or longer duration of DAPT after implantation of drug-eluting stents (DES) in ACS patients.

Study Design

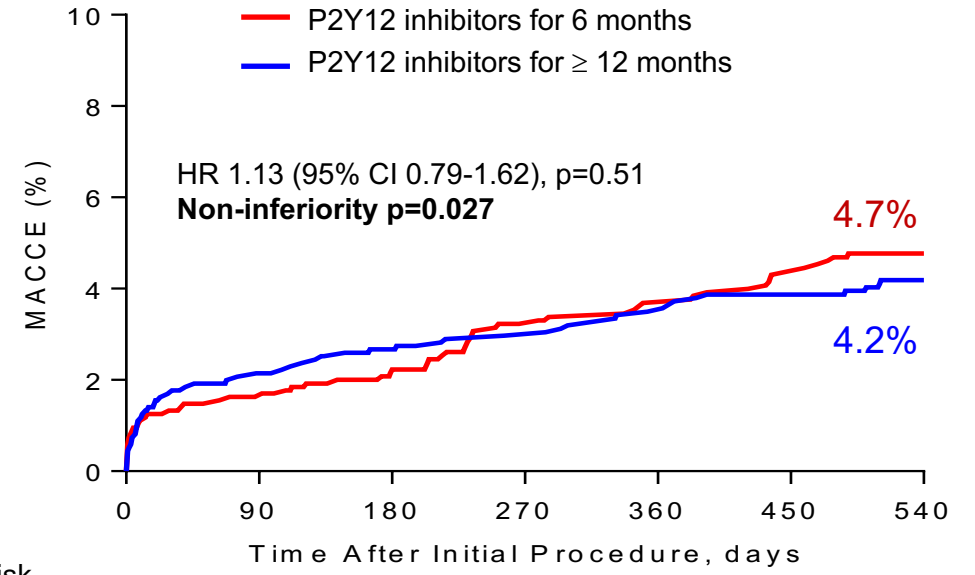
A prospective, multicenter, randomized, open-label, and non-inferiority trial



Primary endpoint: 18-month major cardiac and cerebrovascular event (MACCE), a composite of all-cause mortality, myocardial infarction, and cerebrovascular events

ClinicalTrials.gov NCT01701453

Primary endpoint (MACCE)



No. at risk							
Long-term	1355	1312	1299	1290	1283	1278	1043
Short-term	1357	1318	1296	1271	1264	1255	1032

Cumulative proportional MACCE estimate at 18 months (Kaplan-Meier Analysis)

- Pre-estimated event rate 4.5%
- Pre-specified non-inferiority margin 2.0%
- Actual difference 0.5%
- Upper margin of 95 CI 1.8%
- **Non-inferiority p=0.027**

* MACCE = A composite of all-cause mortality, myocardial infarction, and cerebrovascular events

Secondary endpoints

	6-month DAPT (n=1357)	≥12-month DAPT (n=1355)	HR (95% CI)	p value
MACCE	63 (4.7%)	56 (4.2%)	1.13 (0.79-1.62)	0.51
Death	35 (2.6%)	39 (2.9%)	0.90 (0.57-1.42)	0.90
Myocardial infarction	**24 (1.8%)**	**10 (0.8%)**	**2.41 (1.15-5.05)**	**0.02**
Target vessel MI	14 (1.1%)	7 (0.5%)	2.01 (0.81-4.97)	0.13
Non-target vessel MI	10 (0.8%)	3 (0.2%)	3.35 (0.92-12.2)	0.07
Cerebrovascular accident	11 (0.8%)	12 (0.9%)	0.·92 (0.41-2.08)	0.84
Cardiac death	18 (1.4%)	24 (1.8%)	0.75 (0.41-1.38)	0.36
Cardiac death or MI	39 (2.9%)	32 (2.4%)	1.22 (0.77-1.95)	0.40
Stent thrombosis	15 (1.1%)	10 (0.7%)	1.50 (0.68-3.35)	0.32
Bleeding BARC type 2-5	35 (2.7%)	51 (3.9%)	0.69 (0.45-1.05)	0.09
Major bleeding (BARC type 3,4,or 5)	6 (0.5%)	10 (0.8%)	0.60 (0.22-1.65)	0.33
Net adverse clinical and cerebral events	96 (7.2%)	99 (7.4%)	0.97 (0.73-1.29)	0.84

Conclusions

- 6-month DAPT was non-inferior to 12-month or longer DAPT for the primary end point of MACCE at 18 months after the index procedure in ACS patients undergoing PCI with DES.
- However, the increased risk of myocardial infarction with 6-month DAPT and the wide non-inferiority margin prevent us from concluding that short-term DAPT is safe in this population.
- Prolonged DAPT in patients with acute coronary syndrome without excessive risk of bleeding should remain the standard of care.

End of presentation