P2Y12 Inhibitor Monotherapy versus Dual Antiplatelet Therapy in Patients Undergoing Percutaneous Coronary Intervention

The SMART-CHOICE randomized, open-label, noninferiority trial

ACC.19 Late-Breaking Clinical Trials

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On the behalf of SMART-CHOICE trial investigators

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

- CONSULTING FEES/HONORARIA:
  - AstraZeneca, Daiichi Sankyo, and Sanofi-Aventis
- RESEARCH/RESEARCH GRANTS:
  - Abbott Korea
  - Biotronik
  - Boston Scientific Korea
  - Medtronic Korea

Primary objective of study

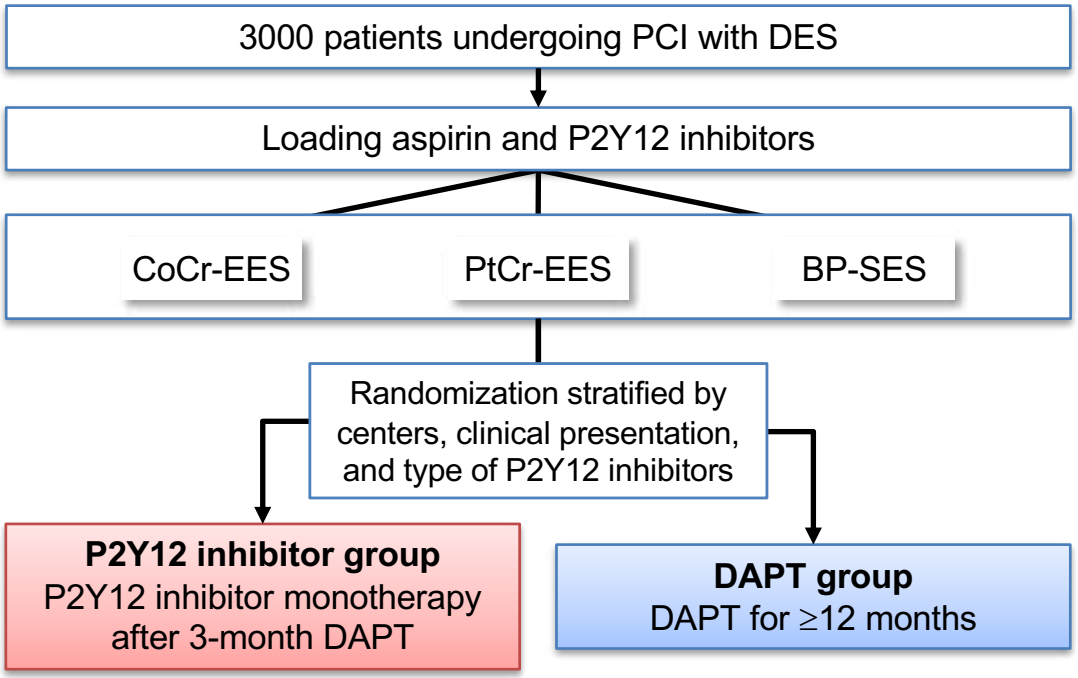
To compare P2Y12 inhibitor monotherapy after 3-month DAPT with 12-month DAPT in a broad spectrum of patients receiving current generation drug-eluting stents (DES).

Working hypothesis

P2Y12 inhibitor monotherapy after 3-month DAPT would be noninferior to 12-month DAPT at 12 months after the index procedure.

Study design

A prospective, multicenter, randomized, open-label, noninferiority trial



- CoCr-EES: cobalt-chromium everolimus eluting stent (Xience series)
- PtCr-EES: platinum-chromium everolimus-eluting stent (Promus series and Synergy)
- BP-SES: bioresorbable polymer- sirolimus-eluting stent (Orsiro)

Primary endpoint: 12-month MACCE

ClinicalTrials.gov NCT02079194

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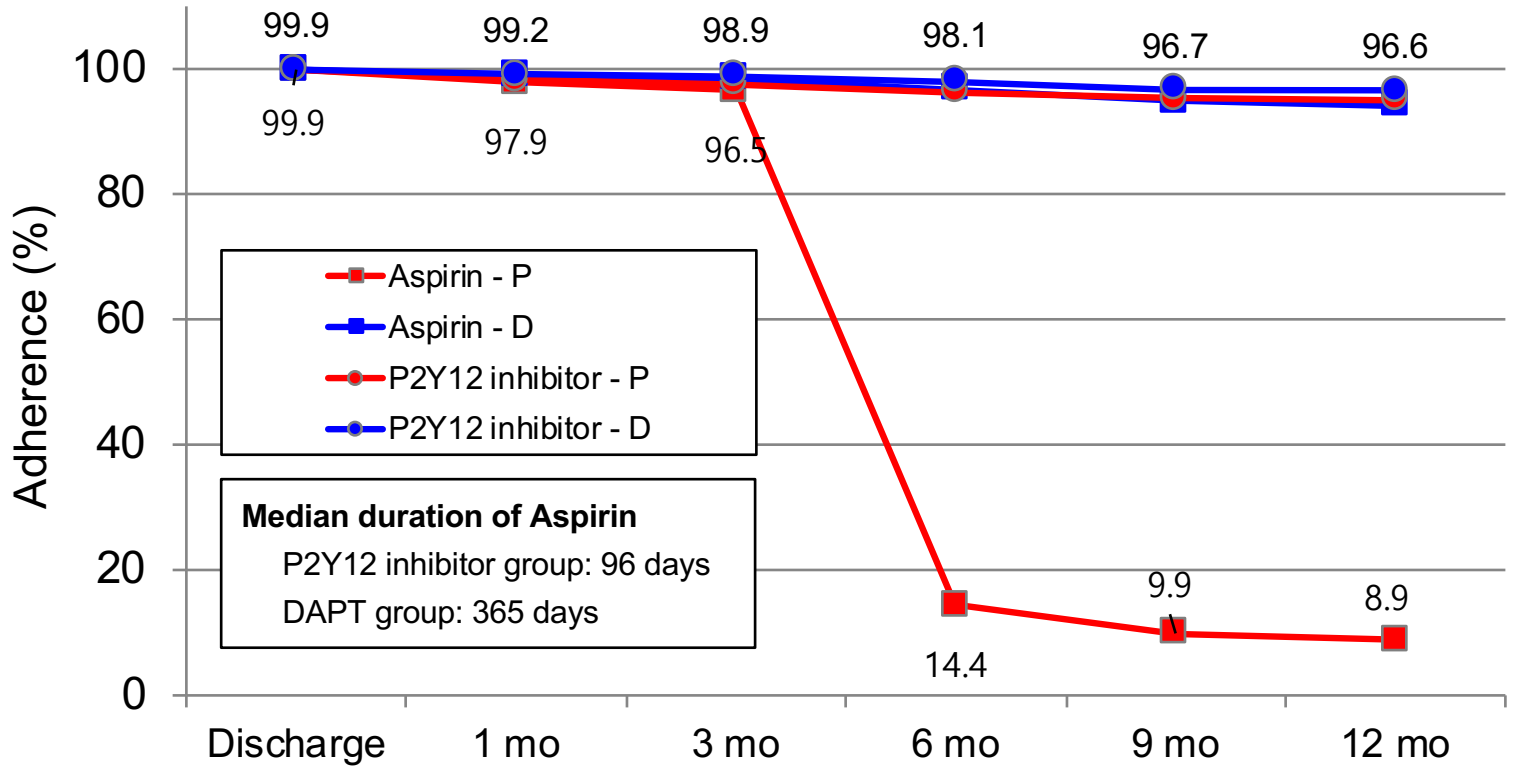
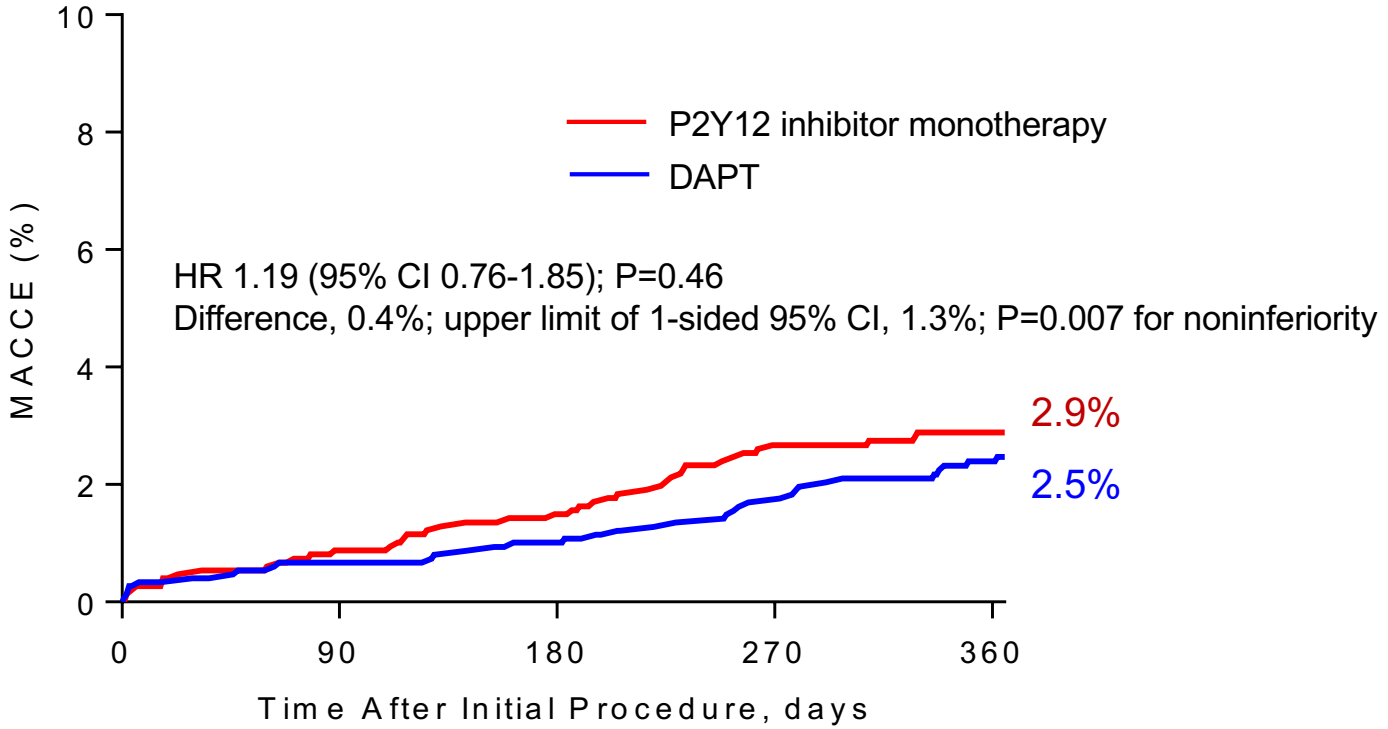
Adherence of antiplatelet therapy



Primary end point (MACCE)



No. at risk					
DAPT	1498	1471	1454	1436	1220
P2Y12 inhibitor	1495	1456	1430	1402	1202

* MACCE = A composite of all-cause death, myocardial infarction, or stroke

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Clinical outcomes at 12 months

Outcome	P2Y12 inhibitor monotherapy (n=1495)	Dual antiplatelet therapy (n=1498)	HR (95% CI)	P Value
MACCE	42 (2.9%)	36 (2.5%)	1.19 (0.76-1.85)	0.46
Death	21 (1.4%)	18 (1.2%)	1.18 (0.63-2.21)	0.61
Myocardial infarction	11 (0.8%)	17 (1.2%)	0.66 (0.31-1.40)	0.28
Cerebrovascular accident	11 (0.8%)	5 (0.3%)	2.23 (0.78-6.43)	0.14
Death or myocardial infarction	31 (2.1%)	32 (2.2%)	0.98 (0.60-1.61)	0.94
Cardiac death	11 (0.8%)	13 (0.9%)	0.86 (0.38-1.91)	0.70
Cardiac death or myocardial infarction	22 (1.5%)	27 (1.9%)	0.83 (0.47-1.45)	0.50
Stent thrombosis	3 (0.2%)	2 (0.1%)	1.51 (0.25-9.02)	0.65
Bleeding BARC type 2-5	28 (2.0%)	49 (3.4%)	0.58 (0.36-0.92)	0.02
Major bleeding	12 (0.8%)	14 (1.0%)	0.87 (0.40-1.88)	0.72
Net adverse clinical and cerebral events	65 (4.5%)	81 (5.6%)	0.81 (0.58-1.12)	0.20

Major bleeding was defined as BARC type 3-5 bleeding.
Net adverse clinical and cerebral events were defined as MACCE plus BARC type 2-5 bleeding.

Conclusions

- In this prospective randomized trial, P2Y12 inhibitor monotherapy after 3-month DAPT was noninferior to 12-month DAPT for the primary end point of MACCE at 12 months after the index procedure.
- The 3-month landmark analysis and per-protocol analysis showed consistent results.
- Moreover, P2Y12 inhibitor monotherapy reduced the risk of bleeding compared with prolonged DAPT.
- P2Y12 inhibitor monotherapy after short duration of DAPT is a novel antiplatelet strategy balancing ischemic and bleeding risk in patients undergoing PCI.

감사합니다.
Thank you for your attention.