

DAPT Therapy in Asians: What May Be Different Between Asian and Caucasian?



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COI

- I, Jeehoon Kang, have no financial conflicts of interest to disclose concerning the presentation

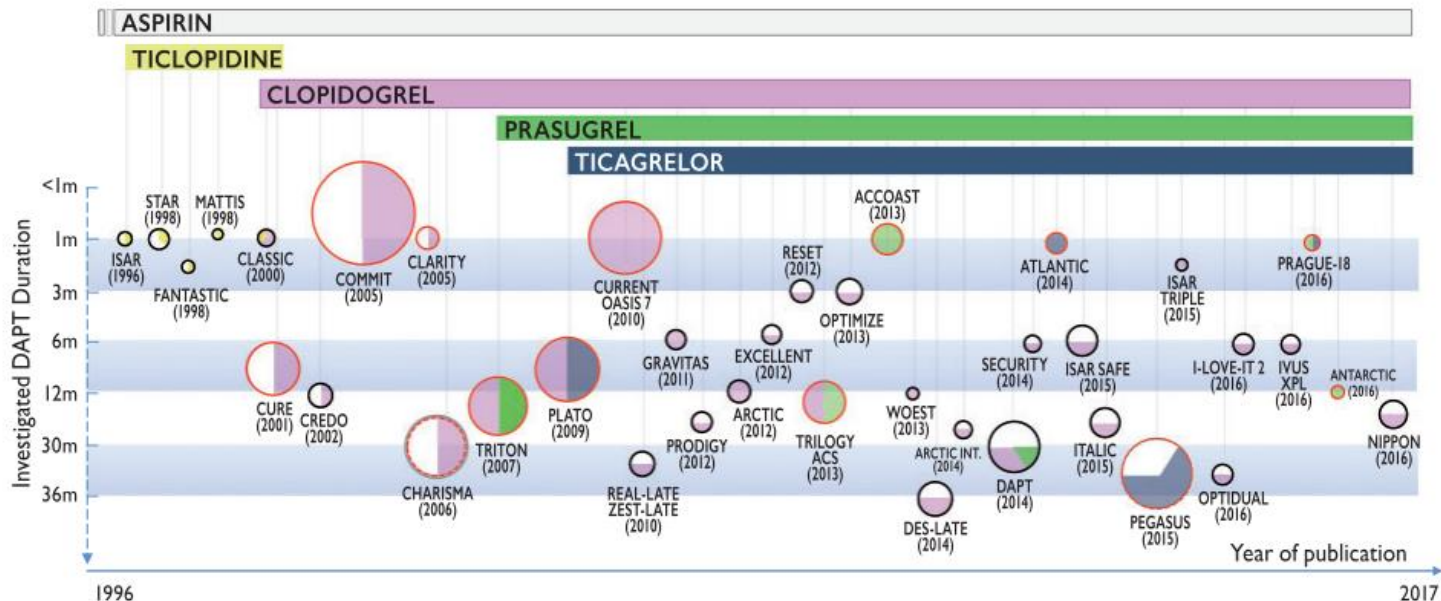
Contents

- 1. Ischemic / Bleeding risk in *East Asians***
- 2. New generation P2Y12 inhibitors in East Asians**
- 3. Proposal of a new Asian score for Ischemia/Bleeding score**

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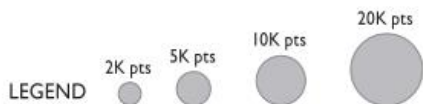
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3. Proposal of a new Asian score for Ischemia/Bleeding score

Current Guidelines for Antiplatelet therapy



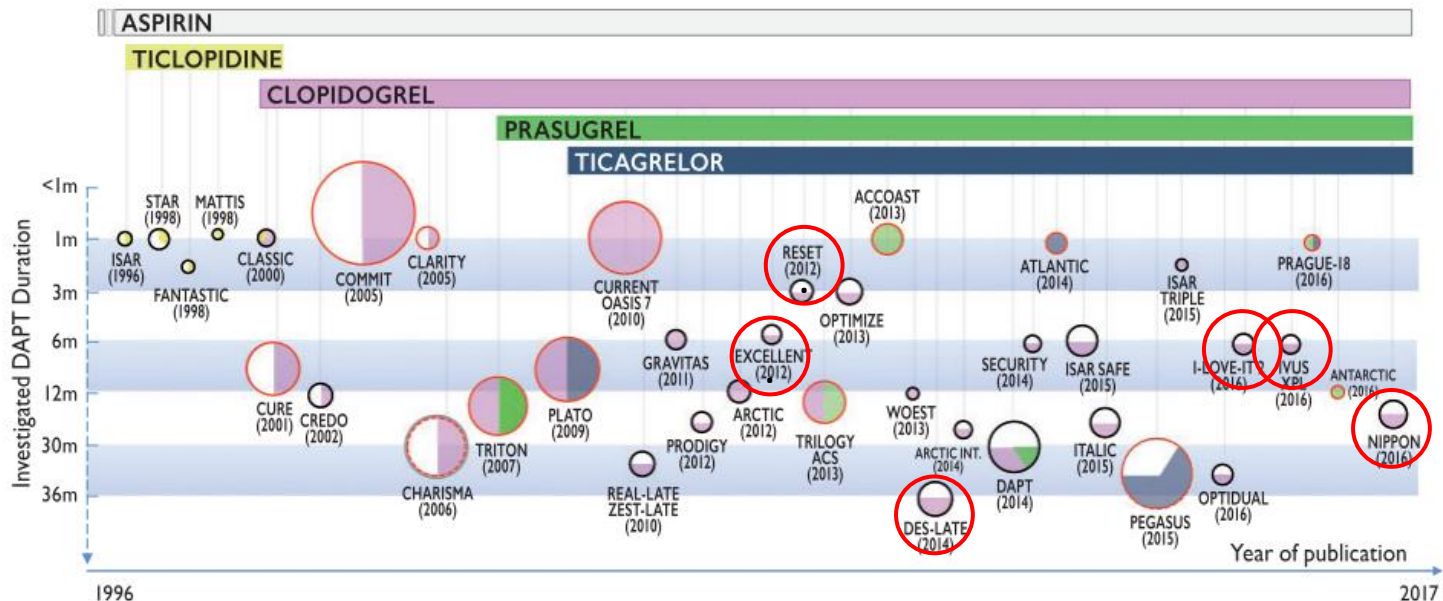
Size of the circles denotes sample size

Perimeter of the circles denotes type of investigated population



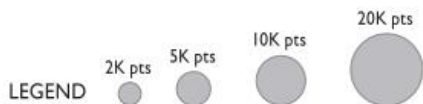
- Mixed clinical presentation at the time of stent implantation
- Acute coronary syndrome at presentation
- DAPT initiated in patients with prior myocardial infarction
- DAPT for primary prevention

Current Guidelines for Antiplatelet therapy



Size of the circles denotes sample size

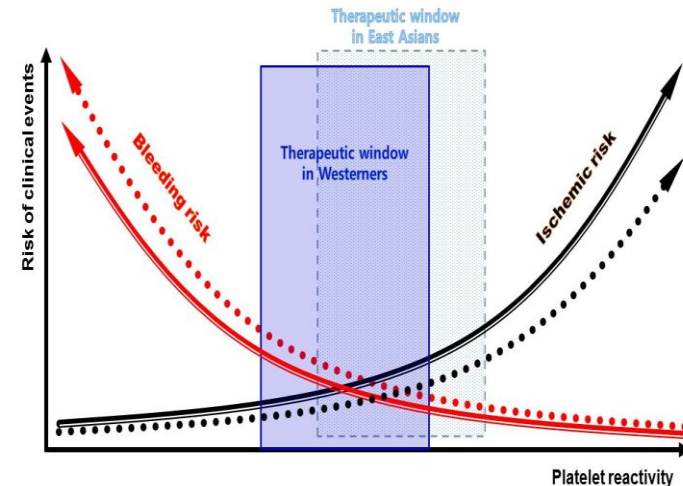
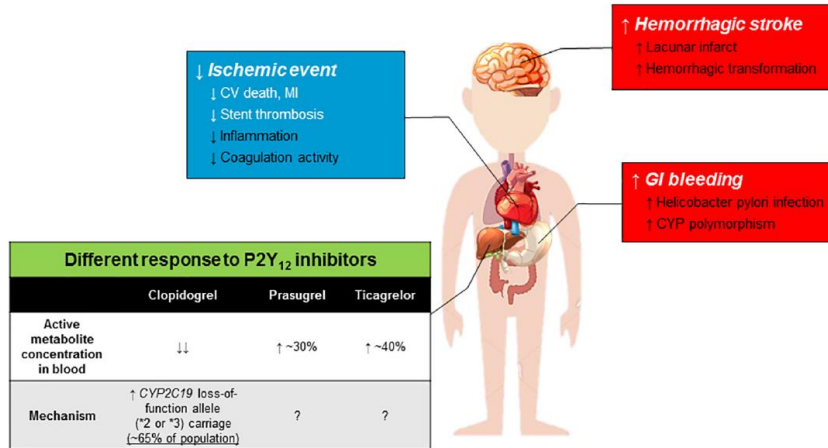
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- Mixed clinical presentation at the time of stent implantation
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- DAPT initiated in patients with prior myocardial infarction
- DAPT for primary prevention

Ischemic / Bleeding risk in *East Asians*

- ✓ East Asians have a different Ischemic/Bleeding threshold, compared to Westerners
- ✓ East Asian paradox
 - ✓ **Higher** clopidogrel resistance, **BUT** with **Lower** ischemic events.
- ✓ East Asians are more prone to Bleeding events



Racial difference in the ischemic/bleeding threshold

Individual patient level, landmark meta-analysis of 7 RCTs



7 Randomized Clinical Trials

DES LATE
12m (n=2514)
vs.
24m (n=2531)

EXCELLENT
6 m (n=722)
vs.
12 m (n=721)

ITALIC
6m (n=953)
vs.
24m (n=941)

OPTIMIZE
3m (n=1563)
vs.
12m (n=1556)

PRODIGY
6m (n=751)
vs.
24m (n=750)

RESET
3m (n=1059)
vs.
12m (n=1058)

SECURITY
6m (n=682)
vs.
12m (n=717)

Asian (n=8605)

Long duration DAPT
n=4310

Short duration DAPT
n=4295

Non-Asian (n=7913)

Long duration DAPT
n=3964

Short duration DAPT
n=3949

Racial difference in the ischemic/bleeding threshold

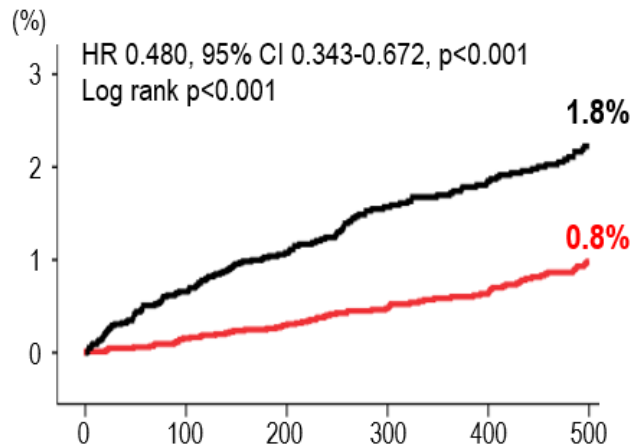
Individual patient level, landmark meta-analysis of 7 RCTs

- Ischemic outcomes and Bleeding outcomes from time of randomization
- Analysis by Race



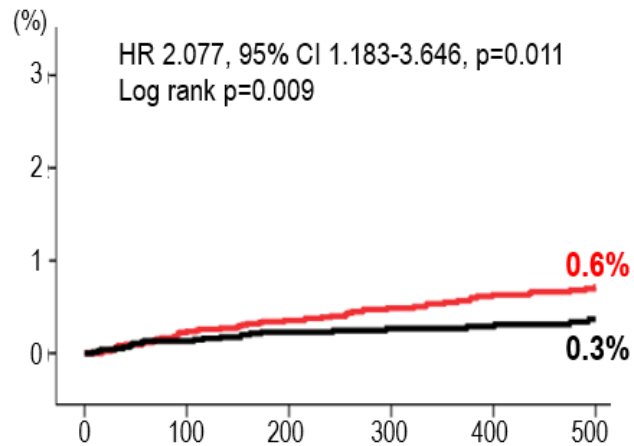
Asian
Non-Asians

A. Ischemic outcomes



No at risk	0	100	200	300	400	500
Asian	8504	8453	8400	6615	6090	
Non-Asian	7564	7344	5369	4671	4510	

B. Bleeding outcomes



No at risk	0	100	200	300	400	500
Asian	8530	8468	8410	6618	6098	
Non-Asian	7676	7439	5437	4727	4570	

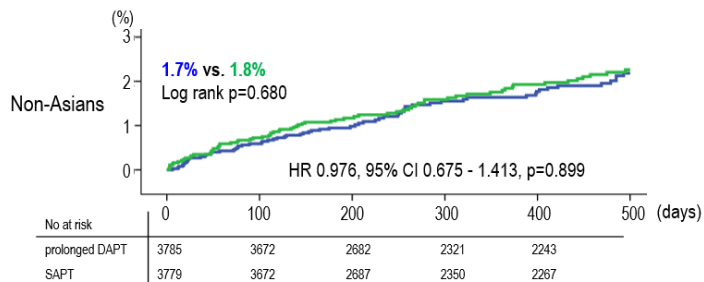
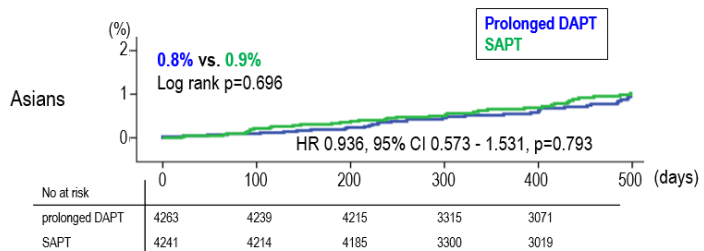
Racial difference in the ischemic/bleeding threshold

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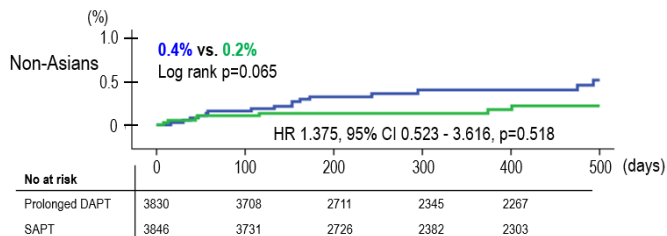
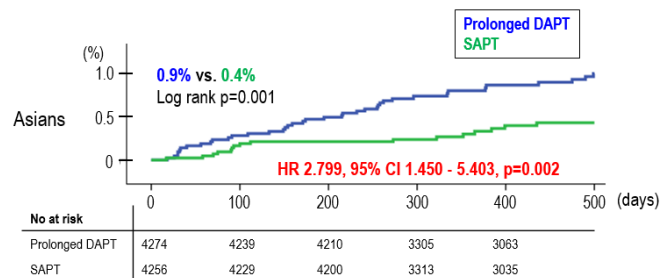
- Ischemic outcomes and Bleeding outcomes from time of randomization
- Analysis by DAPT duration and Race
- *Bleeding events significantly increased by prolonged DAPT, only in Asians!*



< Ischemic outcomes >



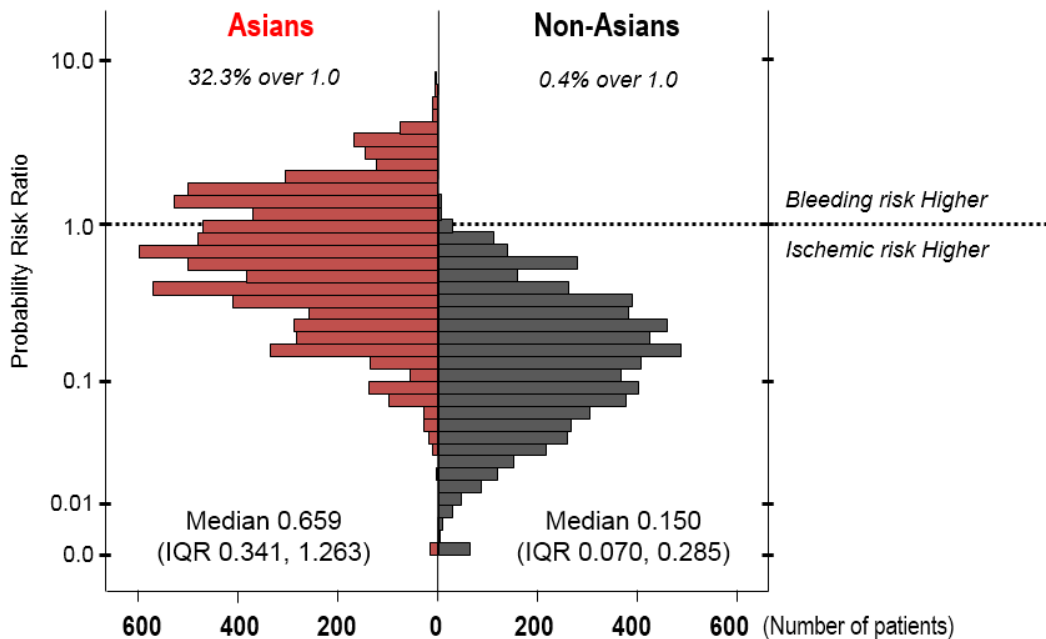
< Bleeding outcomes >



Racial difference in the ischemic/bleeding threshold

Individual patient level, landmark meta-analysis of 7 RCTs

- Probability Risk Ratio of Bleeding to Ischemia
- *Calculated as “Bleeding risk / Ischemic risk”*



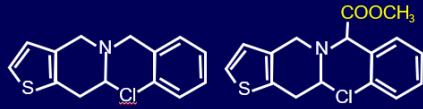
*“Asians have a higher ‘probability risk ratio’ compared to Non-Asians.”
(Asians are more prone to bleeding events)*

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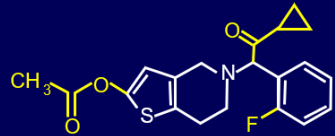
New generation P2Y12 inhibitors in East Asians

(Thienopyridines)



Ticlopidine

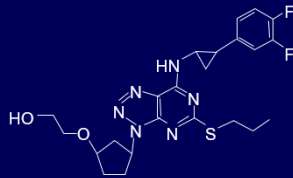
Clopidogrel



Prasugrel

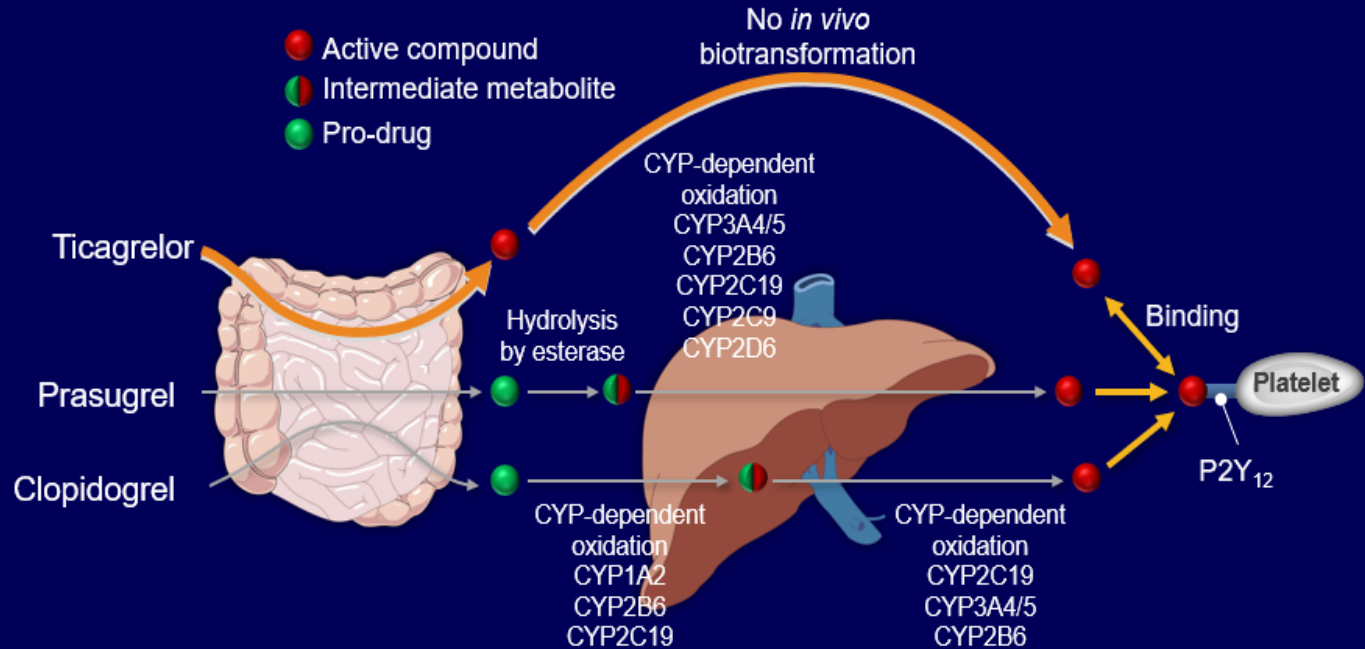
(CPTP)

CPTP
(Cyclo-Pentyl-Triazolo-Pyrimidine; orally active)



HO OH

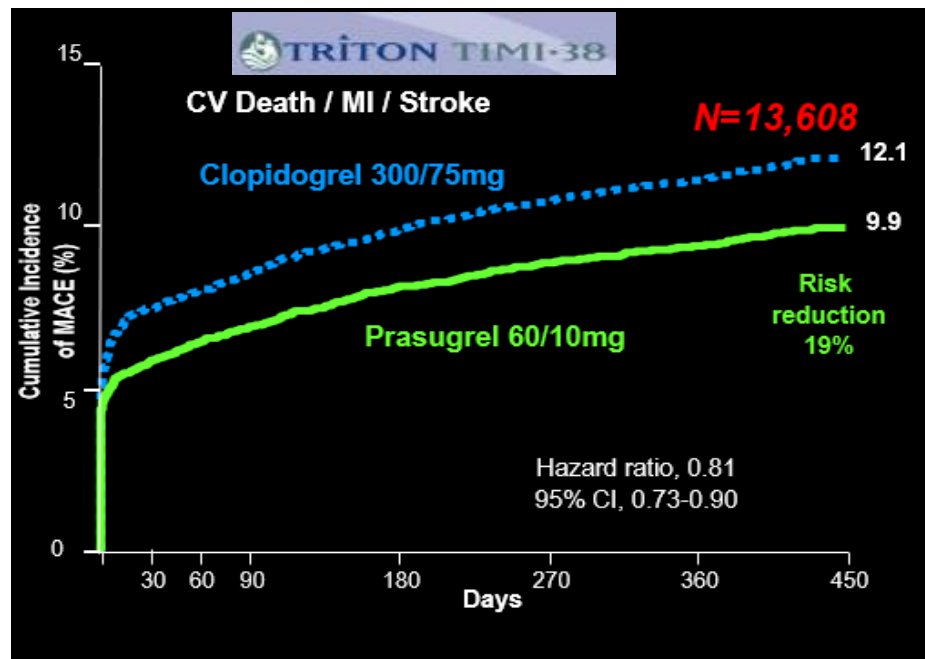
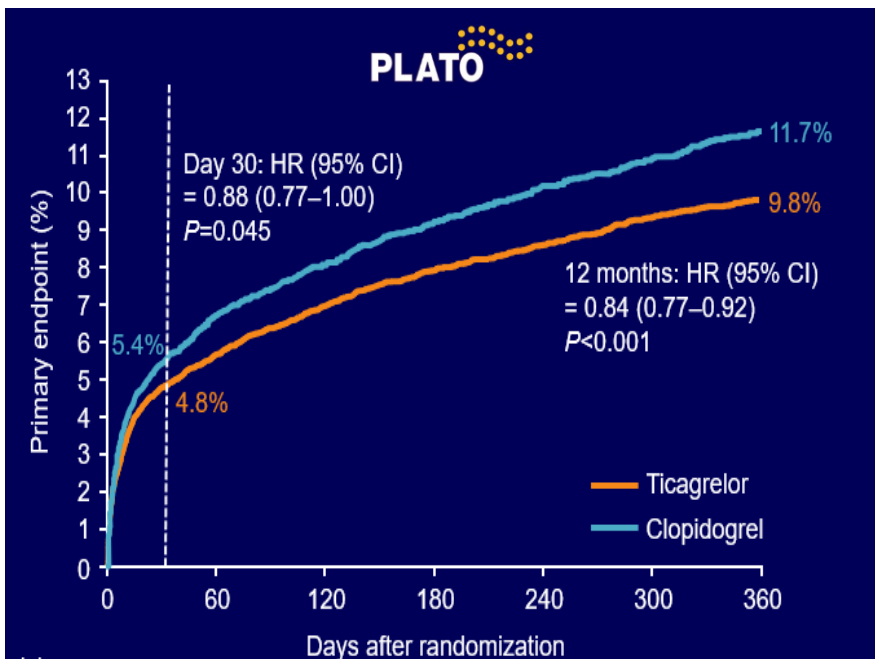
Ticagrelor



New generation P2Y12 inhibitors in East Asians

Results from the TRITON TIMI 38 / PLATO trials

- Primary endpoint : Cardiovascular Death, Myocardial Infarction, Stroke



“Both agents proved efficacy and safety outcomes, mainly in the Western population”

New generation P2Y12 inhibitors in East Asians



Results from the PHILO RCT

- An Asian Mirror study of the PLATO trial
- Absence of the beneficial effect of Ticagrelor, rather a positive HR (*hazardous for Ticagrelor!*)

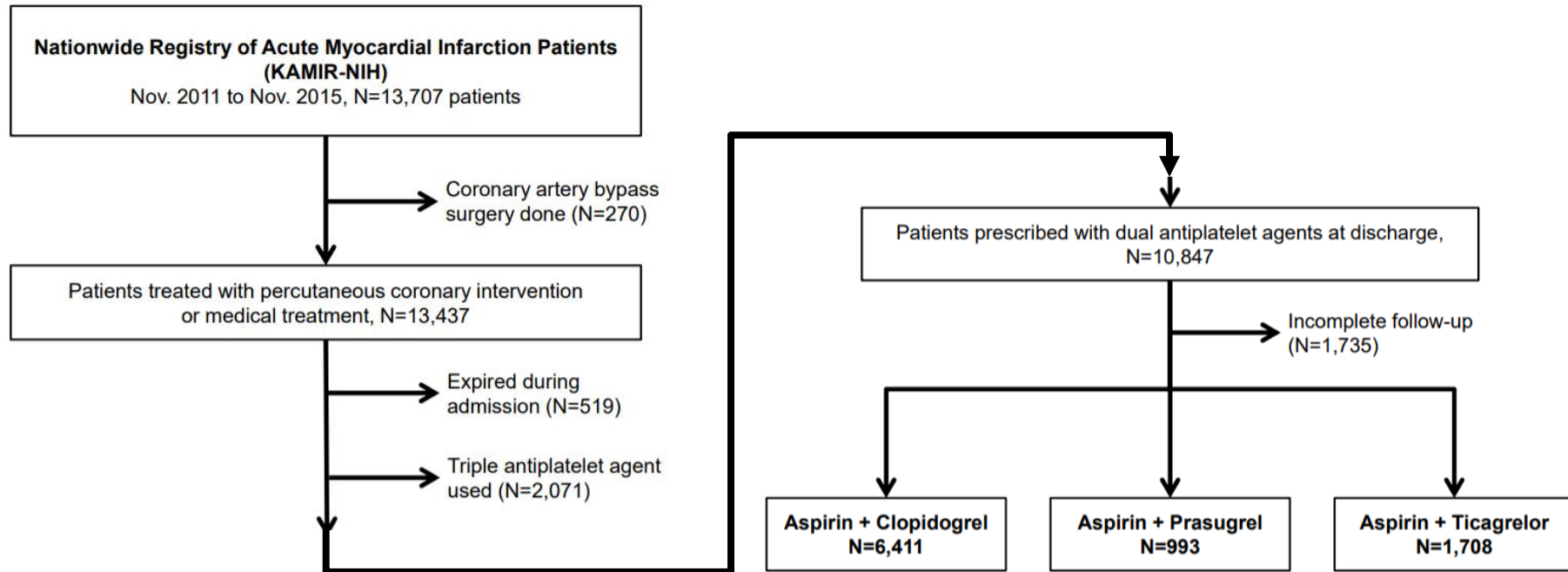
	Ticagrelor 90 mg b.i.d. (n=401)	Clopidogrel 75 mg o.d. (n=400)	HR (95% CI)
Primary			
Composite of CV death/MI (excluding silent MI)/stroke	36 (9.0)	25 (6.3)	1.47 (0.88–2.44)
Post-hoc			
Composite of CV death/spontaneous MI/stroke	18 (4.5)	13 (3.3)	1.39 (0.68–2.85)
Secondary			
Composite of all-cause mortality/MI (excluding silent MI)/stroke	37 (9.2)	25 (6.3)	1.51 (0.91–2.50)
Composite of CV death/total MI/stroke/RI (including SRI)/TIA/Other ATE	38 (9.5)	32 (8.0)	1.20 (0.75–1.93)
MI (excluding silent MI)	24 (6.0)	15 (3.8)	1.63 (0.85–3.11)
Peri-procedural MI	18	12	–
Spontaneous MI	6	3	–
CV death	9 (2.2)	7 (1.8)	1.28 (0.48–3.45)
Stroke	9 (2.2)	6 (1.5)	1.50 (0.54–4.23)
All-cause mortality	10 (2.5)	7 (1.8)	1.42 (0.54–3.74)

New generation P2Y12 inhibitors in East Asians



Analysis of the KAMIR-NIH

- 13,707 consecutive AMI patients, a Nationwide Prospective registry of AMI patients.



New generation P2Y12 inhibitors in East Asians



Analysis of the KAMIR-NIH

- 13,707 consecutive AMI patients, a Nationwide Prospective registry of AMI patients.
- Highly distinct baseline characteristics between patients using clopidogrel, ticagrelor and prasugrel.

	AC (6,411)	AP (993)	AT (1,708)	p-value
<i>Demographics</i>				
Age (y)	64.7 ± 12.7	56.7 ± 10.0 ^a	62.5 ± 12.1 ^{b,c}	<0.001
Male	4,755 (72.1%)	911 (89.4%) ^a	1,350 (77.4%) ^{b,c}	<0.001
BMI (kg/m ²)	23.9 ± 3.5	25.1 ± 3.2 ^a	24.2 ± 3.4 ^{b,c}	<0.001
Hypertension	4,387 (72.4%)	570 (66.1%) ^a	1,126 (71.9%) ^b	0.001
Diabetes	2,145 (32.6%)	317 (31.2%)	499 (28.7%) ^c	0.006
Dyslipidemia	755 (15.3%)	118 (18.4%)	187 (15.9%)	0.138
Chronic renal failure	2,373 (37.1%)	120 (12.0%) ^a	453 (26.5%) ^{b,c}	<0.001
Previous MI	694 (10.6%)	99 (13.1%)	151 (11.6%)	0.079
Fhx. of CAD	451 (7.1%)	78 (7.8%)	103 (6.1%)	0.216
Current smoking	2,489 (38.8%)	560 (55.3%) ^a	740 (42.9%) ^{b,c}	<0.001
Index presentation with STEMI	3,089 (47.0%)	604 (59.4%) ^a	939 (53.8%) ^{b,c}	<0.001
<i>Laboratory findings</i>				
LVEF (%)	51.8 ± 11.2	52.5 ± 10.3	52.8 ± 10.3 ^c	0.001
• RWMI	1.42 ± 0.39	1.43 ± 0.36	1.41 ± 0.37	0.745
WBC (/μL)	10,410 ± 5,090	11,140 ± 4,090 ^a	10,460 ± 1,980 ^b	<0.001
Haemoglobin (g/dL)	13.7 ± 3.0	14.7 ± 4.6 ^a	14.1 ± 2.0 ^{b,c}	<0.001

	AC (6,411)	AP (993)	AT (1,708)	p-value
<i>Angiographic findings</i>				
Type B2/C of target vessel	4,901 (82.5%)	874 (89.8%)	1,514 (90.3%)	<0.001
Vessel disease				<0.001
• One-vessel disease	3,054 (48.5%)	578 (57.5%) ^a	841 (48.6%) ^b	<0.001
• Two-vessel disease	1,884 (29.9%)	267 (26.5%)	509 (29.4%)	0.096
• Three-vessel disease	1,106 (17.5%)	126 (12.5%) ^a	310 (17.9%) ^b	<0.001
• Left main disease	259 (4.1%)	35 (3.5%)	72 (4.2%)	0.621
Stent generation				
• BMS	266 (4.0%)	37 (3.6%)	66 (3.8%)	0.765
• First-generation DES	69 (1.3%)	10 (1.1%)	24 (1.6%)	0.577
• Second-generation DES	4,990 (94.9%)	856 (95.6%)	1,439 (95.6%)	0.413
Stent length	29.2 ± 14.1	28.6 ± 13.8	29.9 ± 13.8	0.056
Stent number	1.0 ± 0.6	1.1 ± 0.5 ^a	1.1 ± 0.5 ^c	<0.001

New generation P2Y12 inhibitors in East Asians



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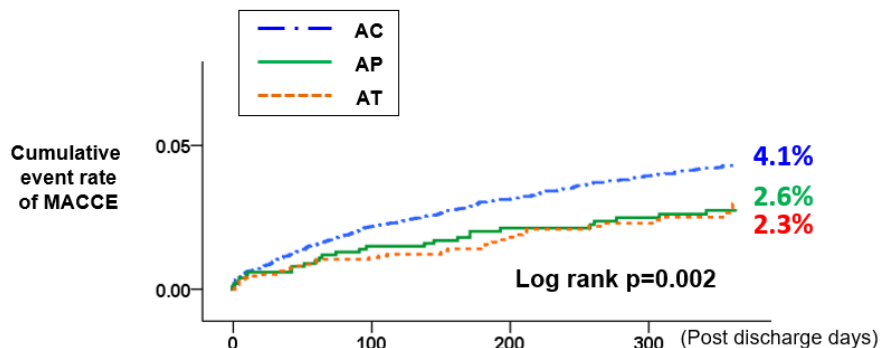
New generation P2Y12 inhibitors in East Asians



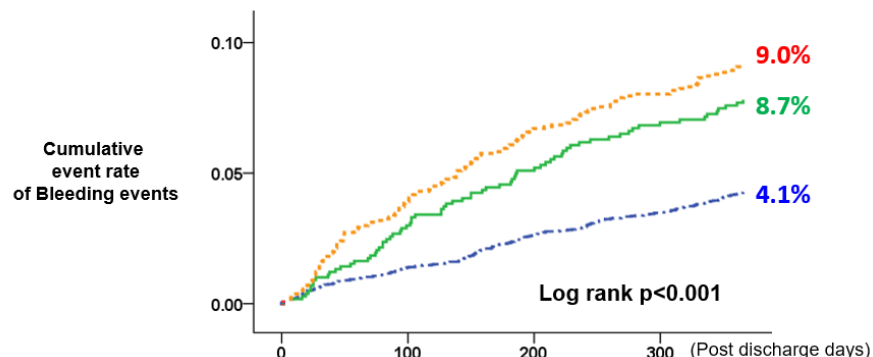
Results from the KAMIR-NIH

- 13,707 consecutive AMI patients, a Nationwide Prospective registry of AMI patients.
- Primary endpoint : MACCE (Cardiac death, MI, stent thrombosis, stroke), Major bleeding
- Crude outcome analysis

Can AP and AT decrease events compared to AC ? Which may neutralize the increased bleeding risk?



No at risk	0	100	200	300 (Post discharge days)
AC	6411	6236	5352	4998
AP	993	978	837	796
AT	1708	1682	1103	916



No at risk	0	100	200	300 (Post discharge days)
AC	5302	5154	4841	4786
AP	938	904	854	838
AT	1493	1424	1312	1291

New generation P2Y12 inhibitors in East Asians



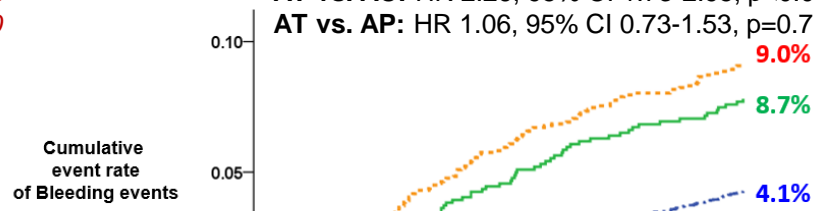
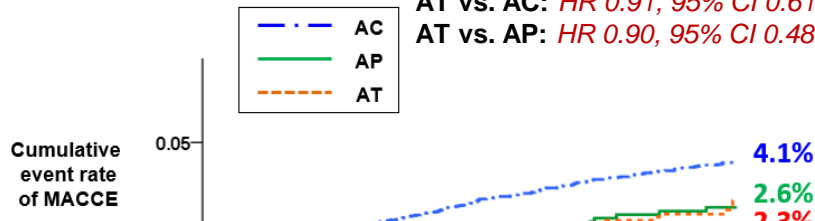
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Can AP and AT decrease events compared to AC ? Which may neutralize the increased bleeding risk?

AP vs. AC: HR 1.02, 95% CI 0.59-1.74, p=0.953
 AT vs. AC: HR 0.91, 95% CI 0.61-1.36, p=0.655
 AT vs. AP: HR 0.90, 95% CI 0.48-1.69, p=0.740

AP vs. AC: HR 2.14, 95% CI 1.53-2.99, p<0.001
 AT vs. AC: HR 2.26, 95% CI 1.73-2.95, p<0.001
 AT vs. AP: HR 1.06, 95% CI 0.73-1.53, p=0.767



After multivariate analysis, the beneficial effect of new generation P2Y12 inhibitors **to decrease MACCE was neutralized**, while the **bleeding risk was still high**.

AT 1708 1682 1103 916

AP 930 904 634 600
 AT 1493 1424 1312 1291

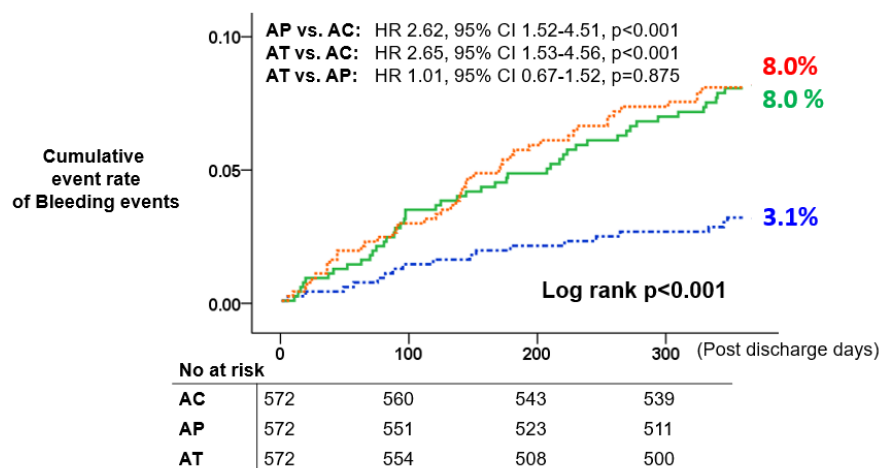
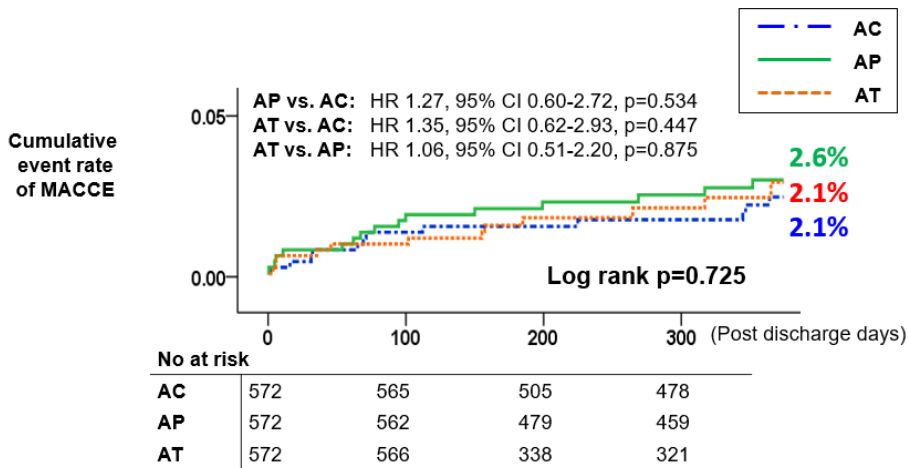
(t discharge days)

New generation P2Y12 inhibitors in East Asians



Results from the KAMIR-NIH

- 13,707 consecutive AMI patients, a Nationwide Prospective registry of AMI patients.
- Primary endpoint : MACCE (Cardiac death, MI, stent thrombosis, stroke), Major bleeding
- **PSM analysis**
 - : showed **NO DECREASE** in ischemic events, with a **INCREASE** in bleeding events, by both ticagrelor and prasugrel.

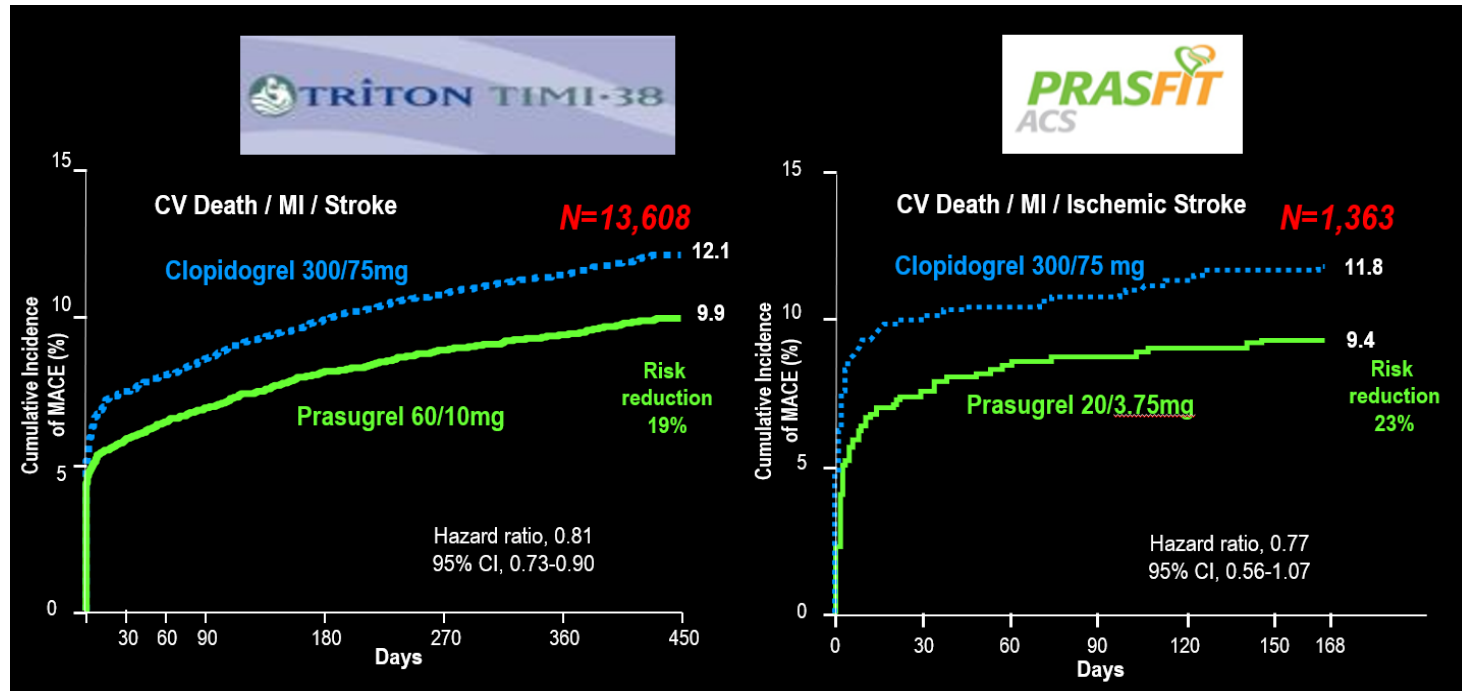


New generation P2Y12 inhibitors in East Asians



Reduced dose of new generation P2Y12 inhibitors may be a breakthrough Results from the PRASFIT-ACS trial

- Efficacy outcomes similar to the TRITON-TIMI38 trial despite **1/3 dose of prasugrel**

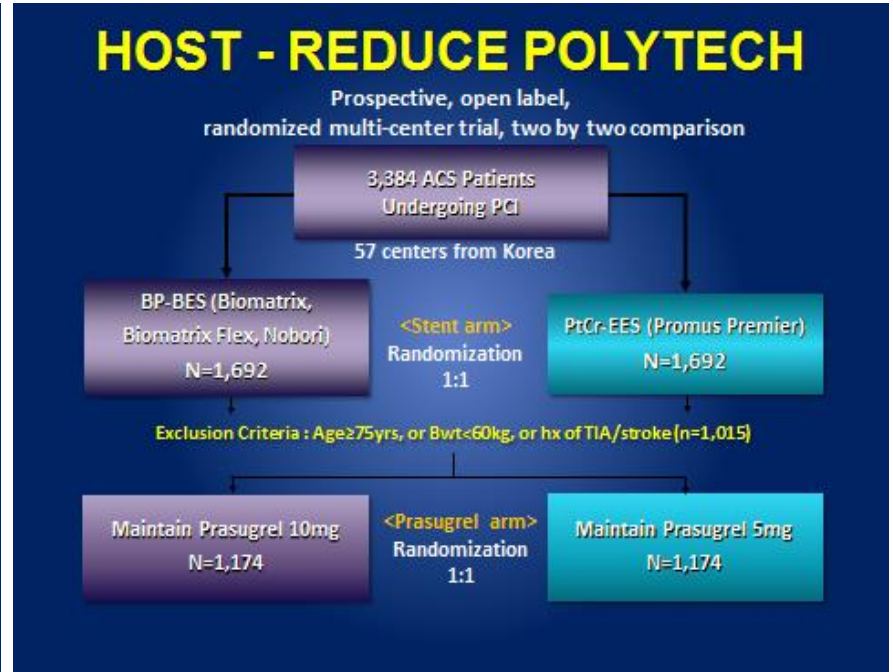
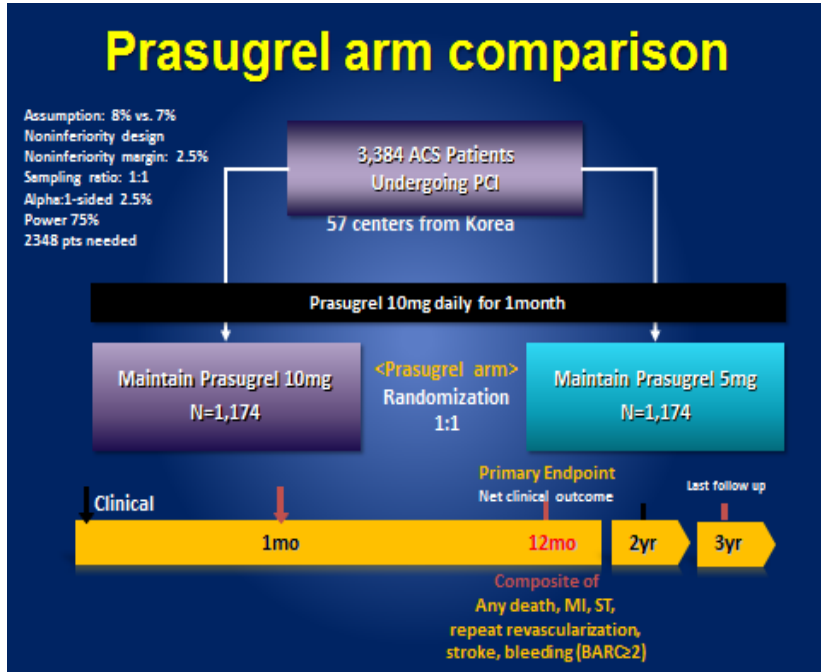


New generation P2Y12 inhibitors in East Asians



Great expectations of the results from the HOST-RP-ACS trial

- low dose prasugrel in Korean patients.
- RCT of ~3,400 ACS patients, enrolled finished, in clinical follow-up.
- First report expected in mid 2020



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3. **Proposal of a new Asian score for Ischemia/Bleeding score**

Ischemic and bleeding risk in East Asians



- ✓ How can we assess the ischemic and bleeding risk in East Asians?
- ✓ Previous scores include the **DAPT score, PRECISE-DAPT score, and the PARIS score**
- ✓ Are these scores applicable to East Asians?


	Setting	Predicted Outcome	Development cohort	Validation cohort	Number of variables
DAPT	PCI patients in DAPT event free for 12 mon	Ischemic/Bleeding endpoints between 12-30 months	DAPT RCT (11648 pts)	C Index: 0.64 for ischemic and bleeding	5 clinical 3 procedural
PARIS	PCI patients on DAPT	Ischemic/Bleeding endpoints at 24 months after PCI	4190 multicenter registry	0.65 for ischemia / 0.64 for bleeding	Thrombotic: 6 clinical Bleeding: 6 clinical
PRECISE-DAPT	PCI patients on DAPT	Bleeding events at 12 months after PCI	14963 patients of pooled RCTs	0.66	5 clinical

Grand-DES Registry

10 years of clinical excellence

Dedicated 3-year follow-up for contemporary DESs

Seoul National University Hospital &
other 55 centers across the country



Allocated stent(s)	Biomatrix/ Nobori/ Biomatrix Flex	Xience Prime	Xience V/ Promus	Resolute Integrity	Resolute
Enrollment	2010.4~2014.11.	2010.12~2012.8.	2008.4~2010.5.	2011.10~2014.7	2009.1~2010.6.
Patients	3007	2076	3078	3004	2007
Lesions	4070	2899	4176	4099	2801
Participating centers	24	26	29	22	25

13172 patients

18045 lesions

**Biolimus-
3000-Korea**

**Excellent
Prospective
Cohort**

**Resolute
Korea**

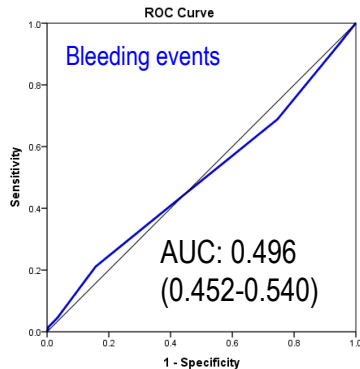
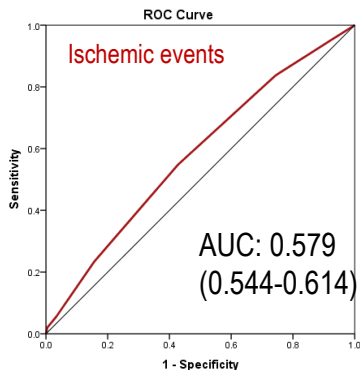
**Excellent
Prime**

Resolinte

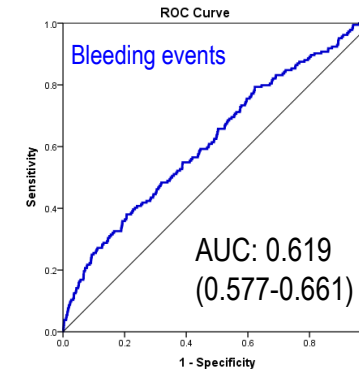
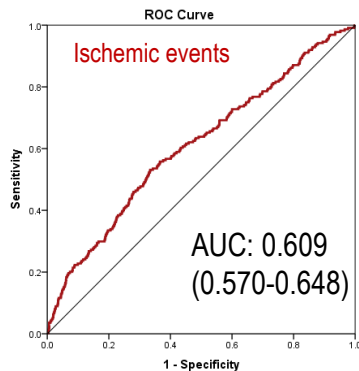
Ischemic and bleeding risk in East Asians

Discriminative value of Previous scores: Based on the Grand-DES registry

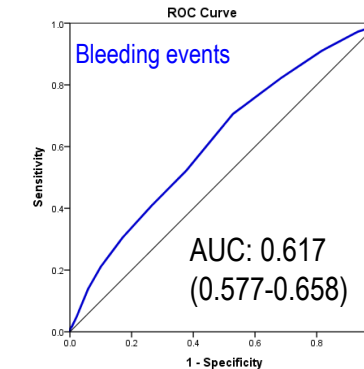
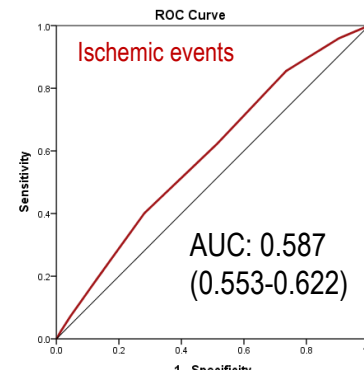
DAPT score



PRECISE-DAPT score



PARIS score



Proposal of a new Asian score

- Uniquely for East-Asians

Proposal of a new Asian score for Ischemia/Bleeding score

- ✓ In *real world* **East Asian patients** receiving PCI with **2nd generation DESs**,
- ✓ To assess **both** ischemic risk and bleeding risk
- ✓ To assess **HBR** patients
- ✓ To evaluate the **optimal DAPT** strategy for PCI patients (*escalation, de-escalation of DAPT strategy*)
- ✓ **Better** than current scoring systems
- ✓ With a **clinically applicable** scoring system.

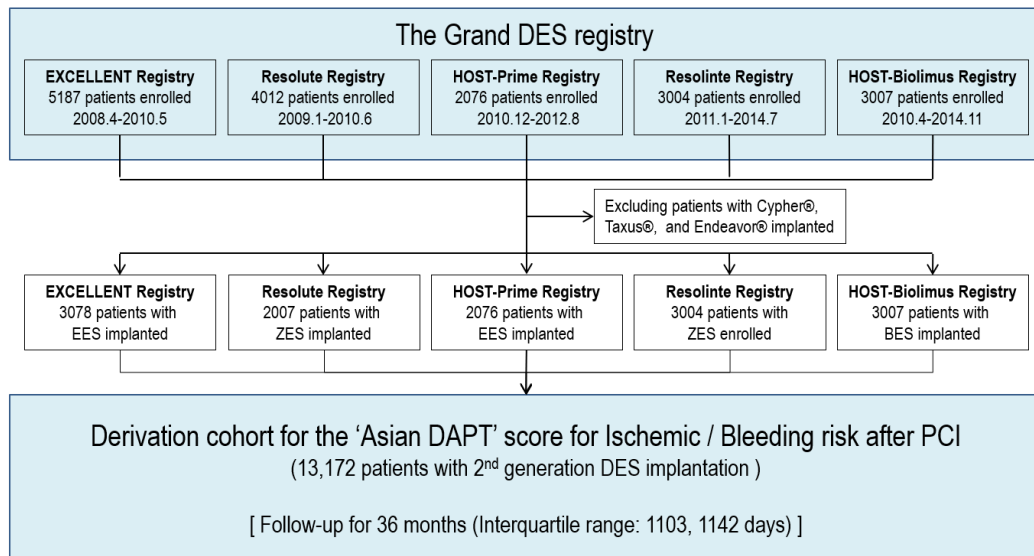
The A-DAPT score
(Asian Dual Antiplatelet Therapy Score)



Proposal of a new Asian score for Ischemia/Bleeding score

✓ The ADAPT score

- ✓ Derived from the 'Grand DES registry'
- ✓ Validated in the HOST-ASSURE, NIPPON RCT pooled cohort



Validation



Adjunctive Cilostazol Versus Double-Dose Clopidogrel After Drug-Eluting Stent Implantation

The HOST-ASSURE Randomized Trial (Harmonizing Optimal Strategy for Treatment of Coronary Artery Stenosis-Safety & Effectiveness of Drug-Eluting Stents & Anti-platelet Regimen)

Kyung Woo Park, MD, PhD,* Si-Hyuck Kang, MD,* Jin Joo Park, MD,* Han-Mo Yang, MD, PhD,* Hyun-Jae Kang, MD, PhD,* Bon-Kwon Koo, MD, PhD,* Byoung-Eun Park, MD, PhD,† Kwang-Soo Cha, MD, PhD,‡ Juy Young Rhew, MD, PhD,§ Hui-Kyoung Jeon, MD, PhD,|| Ean Seok Shin, MD, PhD,*¶ Ju Hyeon Oh, MD, PhD,## Myung-Ho Jeong, MD, PhD,** Sanghyun Kim, MD, PhD,†† Kyung-Kuk Hwang, MD, PhD,‡‡ Jung-Han Yoon, MD, PhD,§§ Sung Yun Lee, MD, PhD,||| Tae-Ho Park, MD, PhD,¶¶ Keon Woong Moon, MD, PhD,## Hyuck-Moon Kwon, MD, PhD,*** In-Ho Chae, MD, PhD,††† Hyo-Soo Kim, MD, PhD*

Seoul, Cheonan, Busan, Jeonju, Uijeongbu, Ulsan, Changwon, Gwangju, Cheongju, Wonju, Goyang, Suwon, and Seongnam, Republic of Korea

KW Park, HS Kim. JACC Cardiovasc Interv. 2013

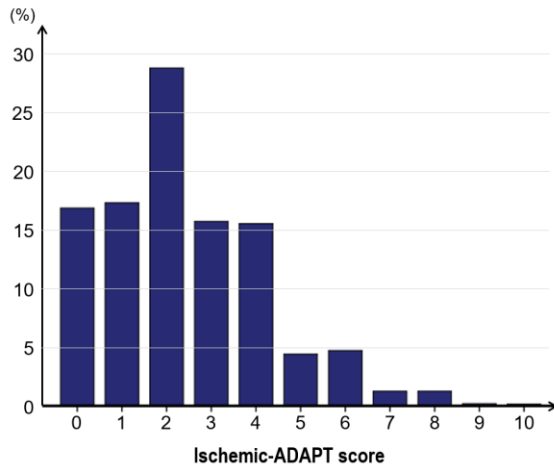
Dual Antiplatelet Therapy for 6 Versus 18 Months After Biodegradable Polymer Drug-Eluting Stent Implantation

Masato Nakamura, MD, PhD,† Ralsuke Iijima, MD, PhD,† Junya Aoki, MD, PhD,† Toshiro Shinke, MD, PhD,† Hisayuki Okada, MD, PhD,† Yoshiaki Ito, MD, PhD,† Kenji Ando, MD,† Hitoshi Anzai, MD, PhD,† Hiroyuki Tanaka, MD, PhD,† Yasunori Ueda, MD, PhD,† Shin Takuchi, MD, PhD,† Yasunori Nishida, MD,† Hiroshi Ohira, MD,† Katsuhiko Kawaguchi, MD, PhD,† Makoto Kadotani, MD, PhD,† Hiroyuki Niinuma, MD, PhD,† Kazuto Omiya, MD, PhD,† Takashi Morita, MD, PhD,† Kan Zen, MD, PhD,† Yoshinori Yasaka, MD, PhD,† Kenji Inoue, MD, PhD,† Sugao Ishiwata, MD, PhD,† Masahiko Ochiai, MD, PhD,† Toshimitsu Hamasaki, MSc, PhD,† Hiroyoshi Yokoi, MD,† on behalf of the NIPPON Investigators

M Nakamura. JACC Cardiovasc Interv. 2017

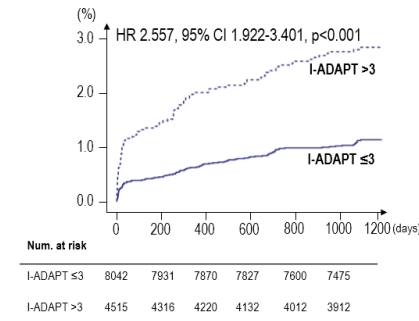
The ADAPT score

- Model for the **Ischemic ADAPT score**

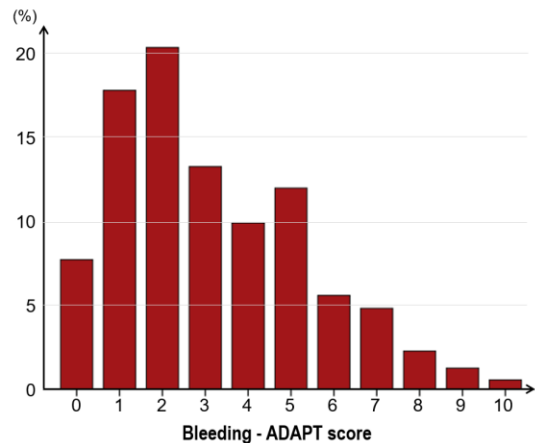


Variable	Score	Weight	Weighted score
Previous MI or PCI	1	2	2
Presentation as AMI	1	2	2
Anemia			
- Hb \geq 12mg/dL	0	2	0
- 10 mg/dL \leq Hb < 12mg/dL	1	2	2
- Hb < 10mg/dL	2	2	4
Total Stent Length \geq 30mm	1	1	1
Minimal stent diameter <3mm	1	1	1
Total score			10

Ischemic events

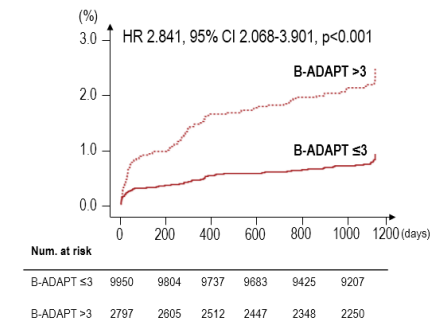


- Model for the **Bleeding ADAPT score**



Variable	Score	Weight	Weighted score
Old Age			
- Age <50 years old	0		0
- 50 \leq Age < 60 years old	1	1	1
- 60 \leq Age < 70 years old	2	2	2
- 70 \leq Age < 80 years old	3	3	3
- Age \geq 80 years old	4	4	4
Previous CKD or CrCl <60ml/min	1	2	2
Anemia			
- Hb \geq 12mg/dL	0	2	0
- 10 mg/dL \leq Hb < 12mg/dL	1	2	2
- Hb < 10mg/dL	2	2	4
Total score			10

Bleeding events

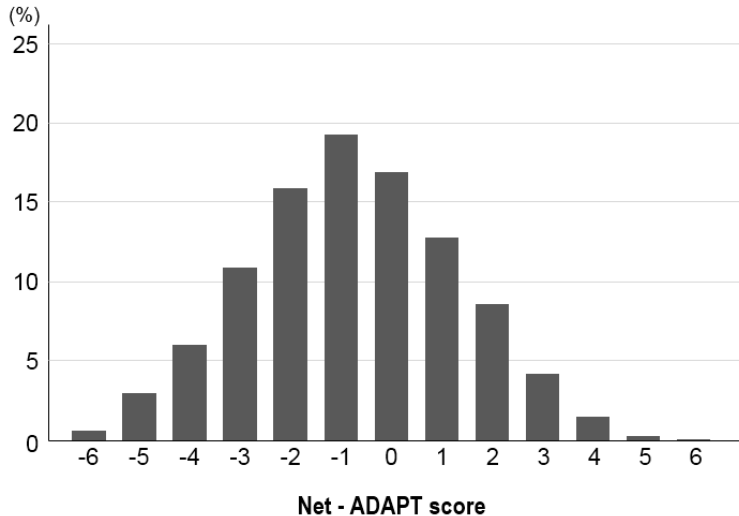


* Best cutoff value of "3" for both scores

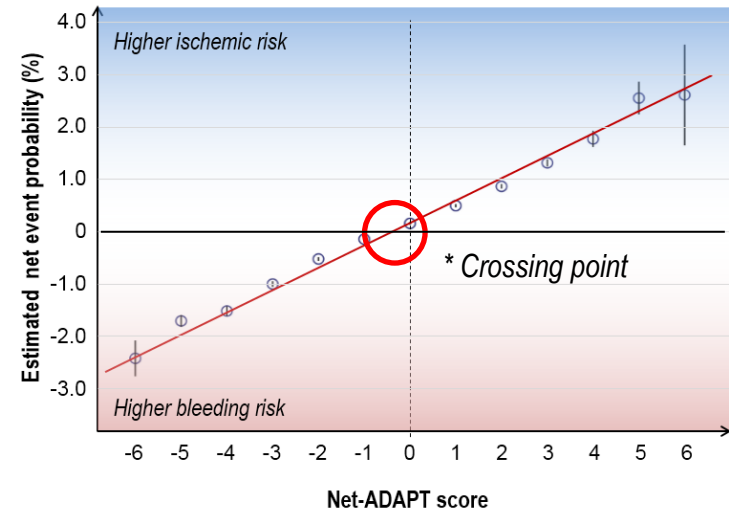
The ADAPT score

✓ Calculation of a “Net ADAPT score”

- ✓ (Ischemic ADAPT score) – (Bleeding ADAPT score)
- ✓ Well-plotted with the ‘estimated net event probability’, with a crossing point around the ‘**Net ADAPT score = 0**’
- ✓ ‘Net ADAPT score > 0’ denotes a higher ‘ischemic risk’, with a need of **HIGHER** intensity antiplatelet therapy
- ✓ ‘Net ADAPT score < 0’ denotes a higher ‘bleeding risk’, with a need of **LOWER** intensity antiplatelet therapy



Variable	Score
Previous MI or PCI	2
Presentation as AMI	2
Total Stent Length ≥30mm	1
Minimal stent diameter <3mm	1
Previous CKD or CrCl <60ml/min	-2
Old Age	
- Age <50 years old	0
- 50 ≤ Age < 60 years old	-1
- 60 ≤ Age < 70 years old	-2
- 70 ≤ Age < 80 years old	-3
- Age ≥ 80 years old	-4
Total score range	-6 to 6

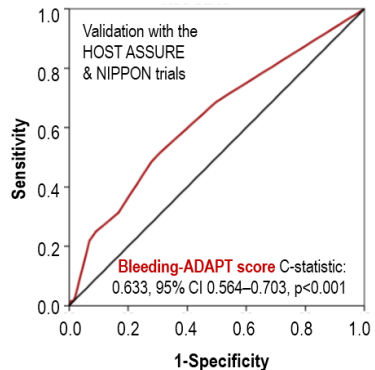
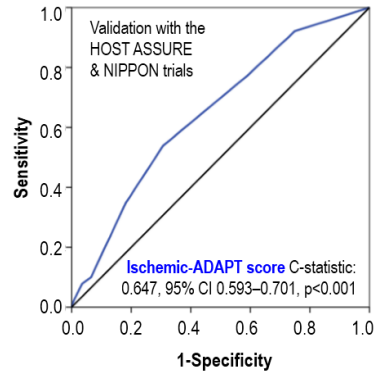


The ADAPT score

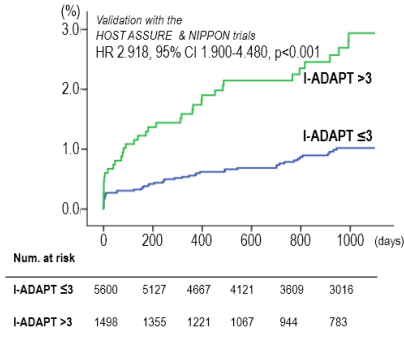
✓ Validation cohort (HOST-ASSURE, NIPPON RCT pooled cohort)

✓ Moderate discriminative value with the ROC curve

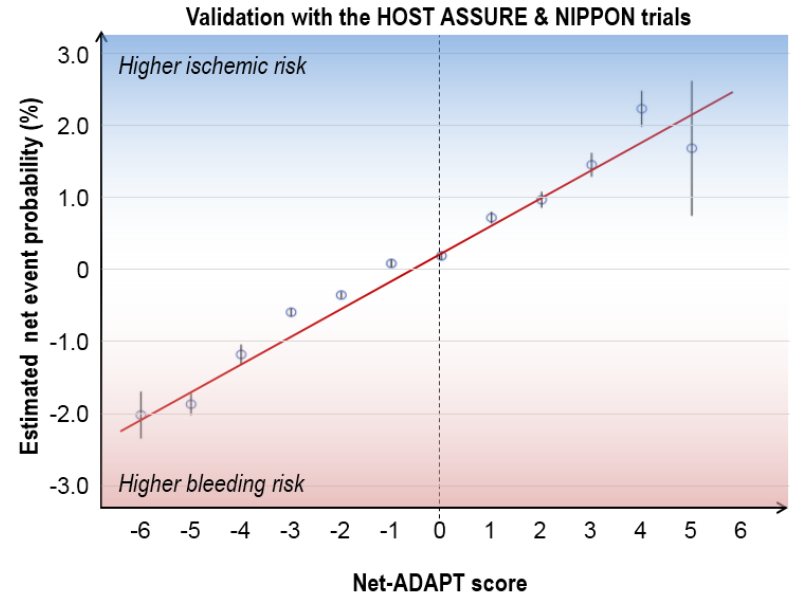
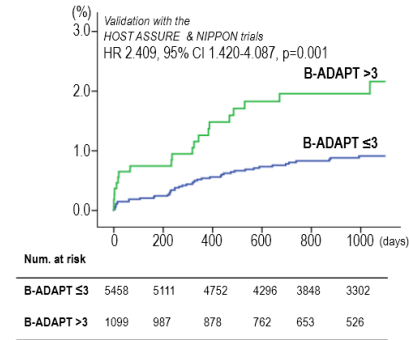
✓ Well-plotted Net-ADAPT score



Ischemic events



Bleeding events

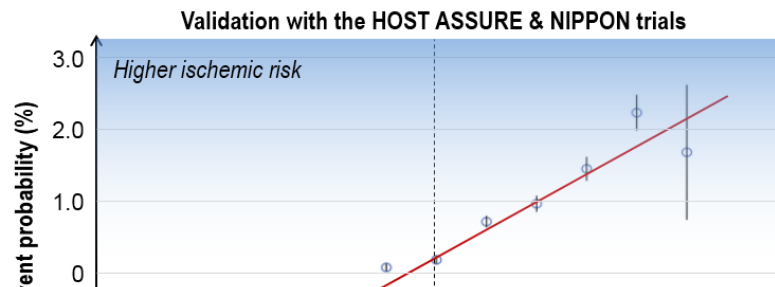
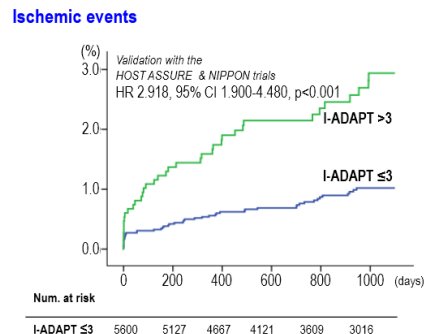
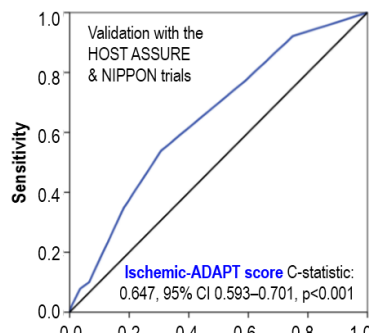


The ADAPT score

✓ **Validation cohort** (*HOST-ASSURE, NIPPON RCT pooled cohort*)

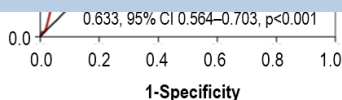
✓ Moderate discriminative value with the ROC curve

✓ Well-plotted Net-ADAPT score



The ADAPT score is

- #. A unique '*Asian oriented*' scoring system
- #. In real-world patients receiving PCI with *2nd generation DESs*.
- #. Can evaluate *both ischemic and bleeding risk*.
- #. Can integrate ischemic and bleeding risks to guide *optimal antiplatelet therapy intensity*.



	Num. at risk					
B-ADAPT ≤3	5458	5111	4752	4296	3848	3302
B-ADAPT >3	1099	987	878	762	653	526

Ischemic and Bleeding risk in East Asians

- ✓ East Asians have a ***distinct ischemic/bleeding trade-off*** compared to the Western population.
 - ✓ Lower ischemic risk with a higher bleeding risk
 - ✓ Therefore, ***high bleeding risk*** is a very important issue in East Asians.
- ✓ New generation P2Y12 inhibitors should be prescribed with caution in ***East Asians***.
 - ✓ A lower dose may be a feasible strategy to maintain efficacy and minimize bleeding events.
- ✓ The ***'ADAPT score'*** can be used to assess the ischemic and bleeding risk of an individual, and the ***Net-ADAPT*** score can be used to guide optimal DAPT therapy.

Thank you for your attention!

