Escalation and De-Escalation Strategy for CHIP-PCI Patients: The TAILORED-CHIP Trial

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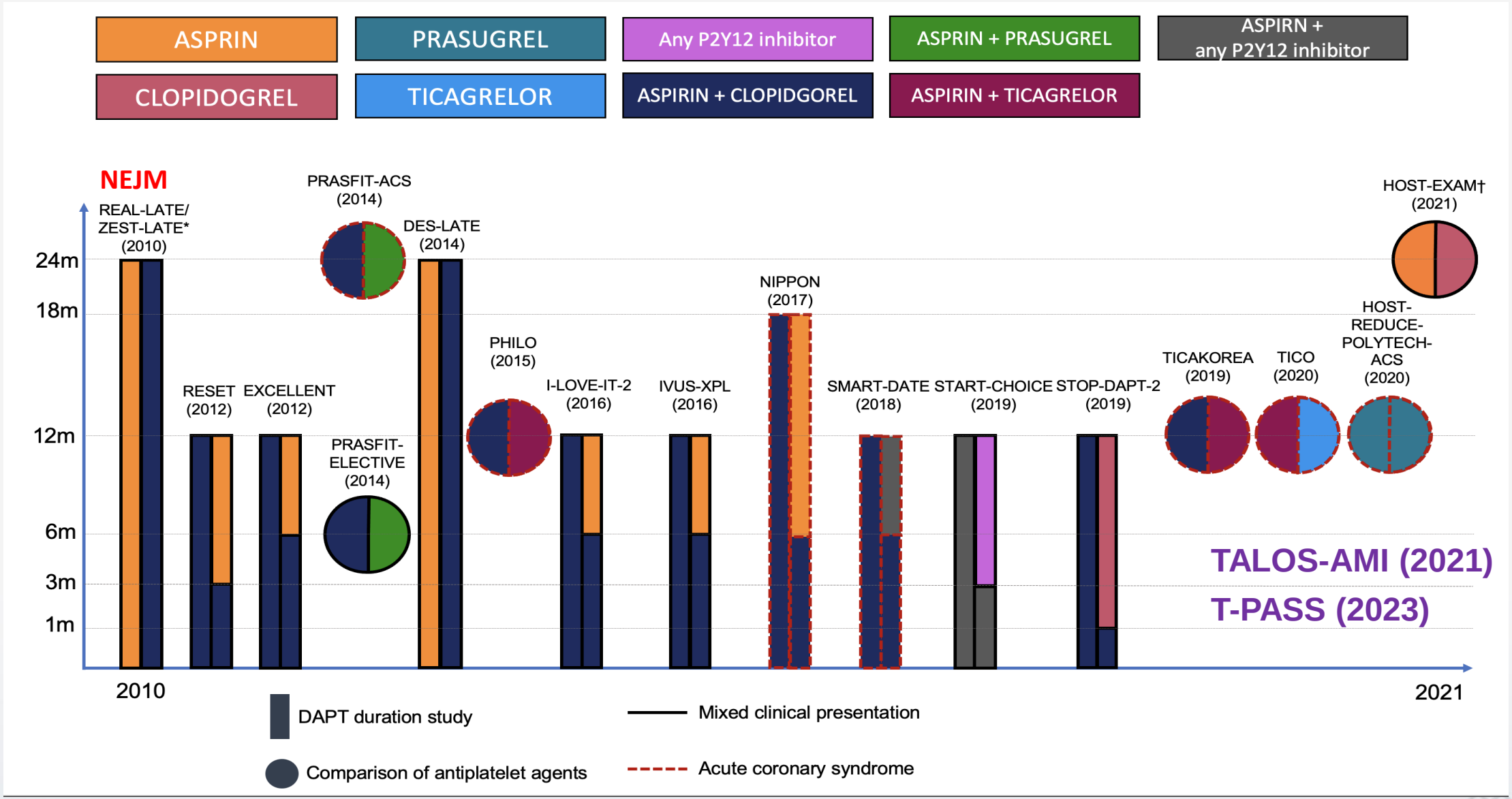
Disclosure

Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Abbott
	Medtronic
	Boston Scientific
	Daiichi-Sankyo
	Edwards Lifescience
	Daewoong Pharm
	HK InnoN
	ChongKunDang Pharm

Several Key RCTs in Asia-Pacific Region



OS Kwon and DW Park. JACC: Asia 2022;2:1–18

Novel Contemporary Trend of Pragmatic Anti-thrombotic Strategy After High-Risk (Ischemic or Bleeding) PCI
: Escalation and De-escalation

Modulation of antiplatelet therapy
: reducing (ie, de-escalation) or increasing (ie, escalation) the intensity of platelet inhibition

Circulation

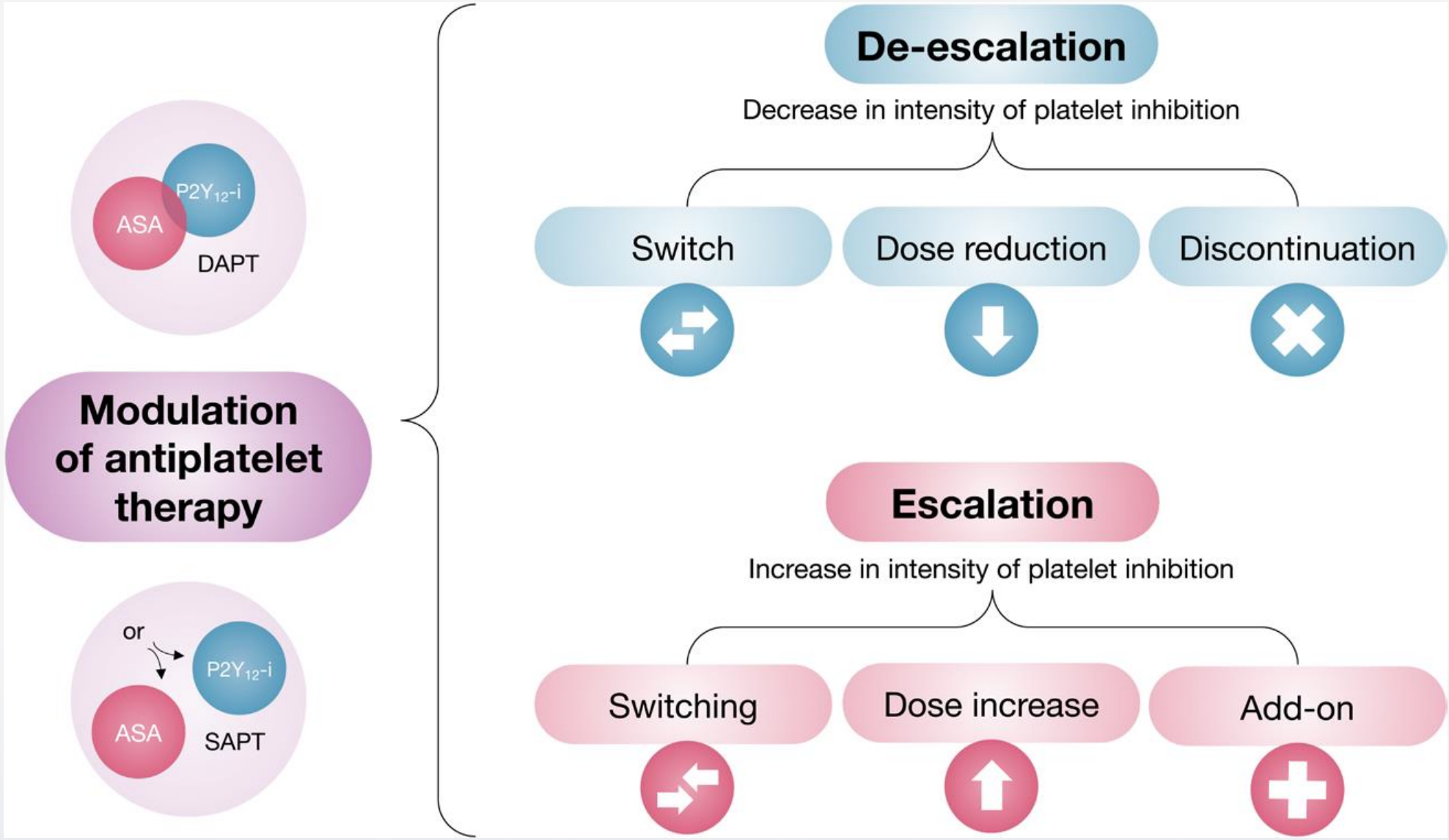
CONSENSUS REPORTS

Defining Strategies of Modulation of Antiplatelet Therapy in Patients With Coronary Artery Disease: A Consensus Document from the Academic Research Consortium

Davide Capodanno, MD, PhD; Roxana Mehran, MD; Mitchell W. Krucoff, MD; Usman Baber, MD; Deepak L. Bhatt, MD, MPH; Piera Capranzano, MD, PhD; Jean-Philippe Collet, MD, PhD; Thomas Cuisset, MD, PhD; Giuseppe De Luca, MD, PhD; Leonardo De Luca, MD, PhD; Andrew Farb, MD; Francesco Franchi, MD; C. Michael Gibson, MD; Joo-Yong Hahn, MD, PhD; Myeong-Ki Hong, MD, PhD; Stefan James, MD, PhD; Adnan Kastrati, MD; Takeshi Kimura, MD; Pedro A. Lemos, MD; Renato D. Lopes, MD, MHS, PhD; Adrian Magee, MD; Ryosuke Matsumura, MD; Shuichi Mochizuki, MD; Michelle L. O'Donoghue, MD; Naveen L. Pereira, MD; Sunil V. Rao, MD; Fabiana Rollini, MD; Yuko Shirai, MD; Dirk Sibbing, MD; Peter C. Smits, MD, PhD; P. Gabriel Steg, MD; Robert F. Storey, MD; Jurrien ten Berg, MD, PhD; Marco Valgimigli, MD, PhD; Pascal Vranckx, MD; Hirotoshi Watanabe, MD; Stephan Windecker, MD; Patrick W. Serruys, MD, PhD; Robert W. Yeh, MD, MBA; Marie-Claude Morice, MD; Dominick J. Angiolillo, MD, PhD

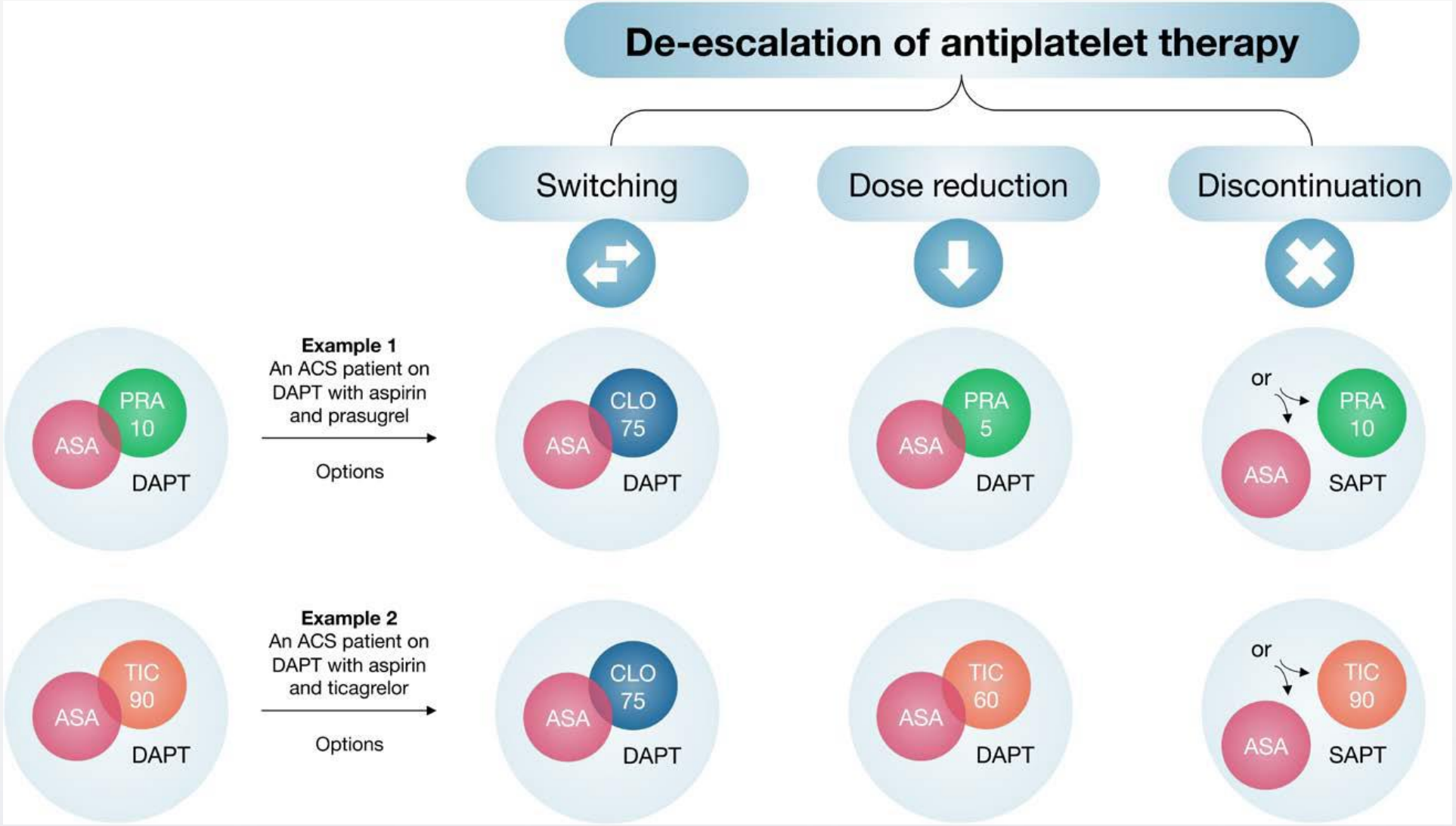
Circulation. 2023;147:1933–1944.

Strategies of modulation of DAPT



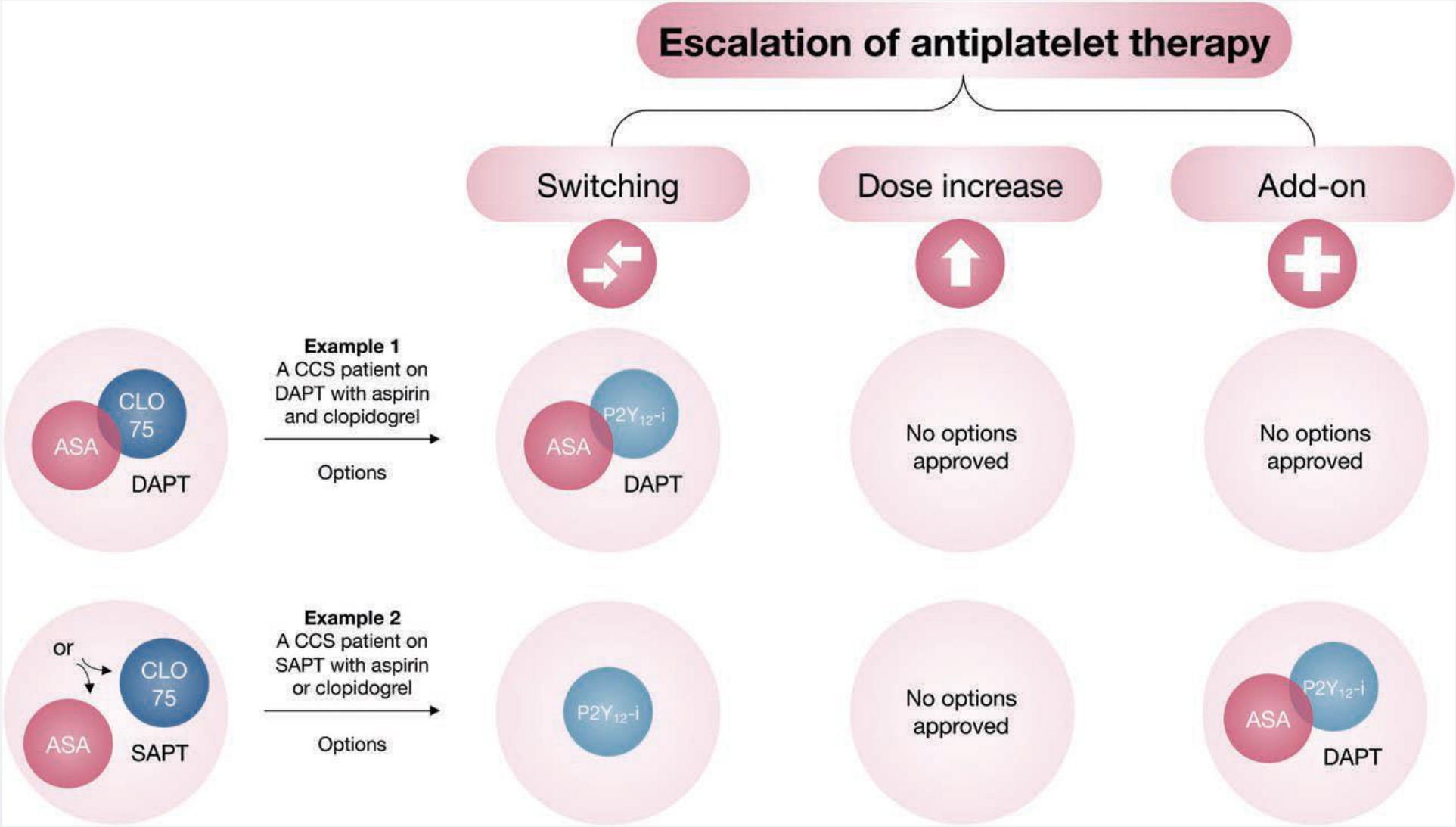
Circulation. 2023;147:1933–1944.

Strategies of de-escalation of antiplatelet therapy



Circulation. 2023;147:1933–1944.

Strategies of escalation of antiplatelet therapy



Circulation. 2023;147:1933–1944.

“Story About Temporal Antithrombotic Tuning”

REVIEW ARTICLE

Dan L. Longo, M.D., *Editor*

Management of Antithrombotic Therapy after Acute Coronary Syndromes

Fatima Rodriguez, M.D., M.P.H., and Robert A. Harrington, M.D.

From the Division of Cardiovascular Medicine, Department of Medicine, and the Stanford Cardiovascular Institute (F.R., R.A.H.), Stanford University, Palo Alto, CA. Address reprint requests to Dr. Harrington at the Department of Medicine, Stanford University, 300 Pasteur Dr., S102, MC:5110, Stanford, CA 94305, or at robert.harrington@stanford.edu.

N Engl J Med 2021;384:452-60.
DOI: 10.1056/NEJMra1607714

BECAUSE OF RAPIDLY CHANGING GUIDELINES IN RESPONSE TO MULTIPLE clinical trials of new therapies, the management of antithrombotic agents for patients after an acute coronary syndrome is becoming increasingly complex. Patients and clinicians must make treatment decisions by weighing the antithrombotic benefits of antiplatelet agents and the anti-ischemic benefits of anticoagulant agents against the risk of bleeding, including severe, life-threatening bleeding. Treatment decisions should be individualized by incorporating additional variables in this risk–benefit assessment, including but not limited to demographic characteristics of the patient, examination findings, laboratory testing, and imaging, as well as the patient's values and preferences.

The pathobiology of acute coronary syndromes is characterized by disruption of coronary atherosclerotic plaque through fissure, erosion, or rupture, resulting in activation of platelets and the coagulation system; the clinical result is myocardial ischemia or infarction, depending on the extent of coronary-artery occlusion.[1,2] Acute coronary syndromes are initially categorized on the basis of the 12-lead electrocardiogram (ECG), with patients separated into two treatme pathways: one for patients with ST-segment elevation (STE) and one for pati without persistent STE. This initial ECG-guided risk stratification drive treatment decisions during hospitalization and is also important for prog

Story About Temporal Antithrombotic Tuning

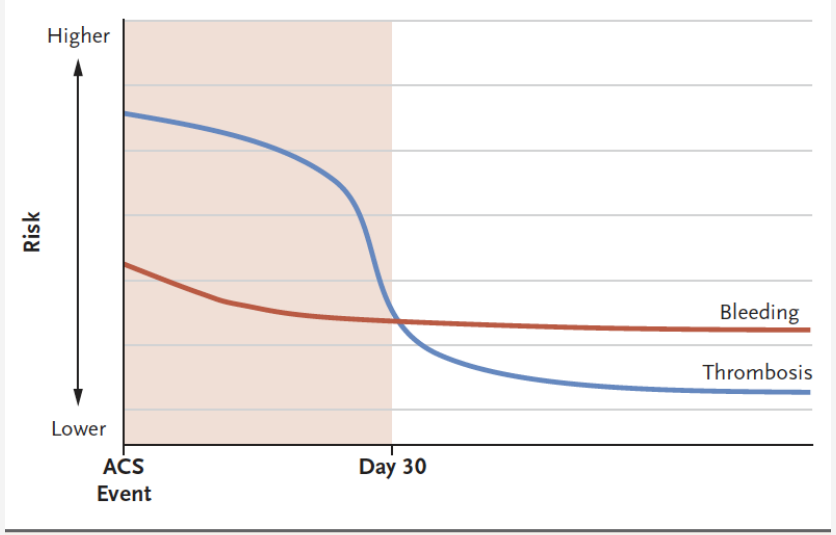


Figure 1. Risks of Thrombosis and Bleeding after an Acute Coronary Syndrome (ACS).

In the first 30 days after an ACS event, the benefits of intensive antithrombotic therapy generally outweigh the increased risk of bleeding. However, this benefit dissipates with additional time after the ACS event, favoring a therapeutic approach that considers the risks of both bleeding and thrombosis.

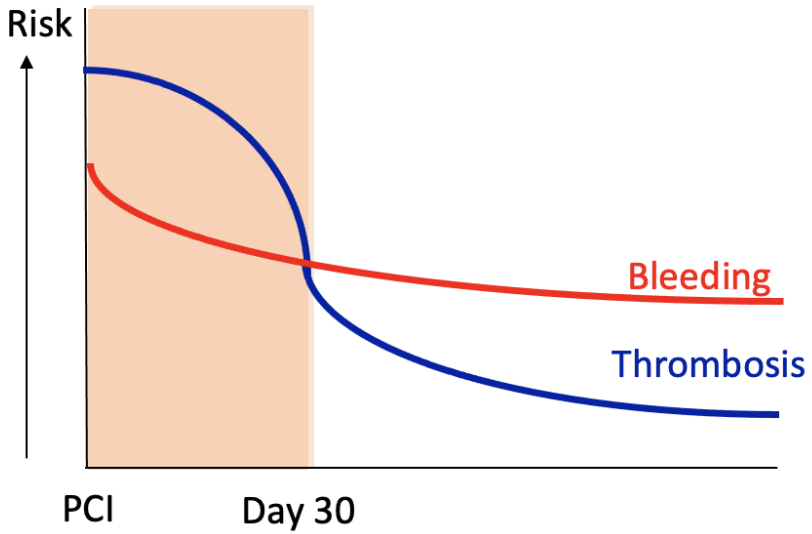
Table 2. Suggested Approaches to Antithrombotic Treatment after an ACS Event.*

Time after ACS Event	Default Strategy	Patients with High Ischemic Risk	Patients with High Bleeding Risk	Patients with Concomitant Atrial Fibrillation†
≤1 mo	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Aspirin, clopidogrel, and DOAC‡
>1 mo to 12 mo	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Any $P2Y_{12}$ inhibitor alone	Clopidogrel and DOAC
>12 mo	Any $P2Y_{12}$ inhibitor alone	Aspirin and newer-generation $P2Y_{12}$ inhibitor, or switch to aspirin and low-dose rivaroxaban	Any $P2Y_{12}$ inhibitor or aspirin	DOAC

N Engl J Med 2021;384:452-60.

Pragmatic Antithrombotic Strategies According to Temporal Bleeding and Ischemic Risk

Rationale



Adapted from N Engl J Med 2021;384:452-60

Proposed strategy

Standard guideline-directed DAPT

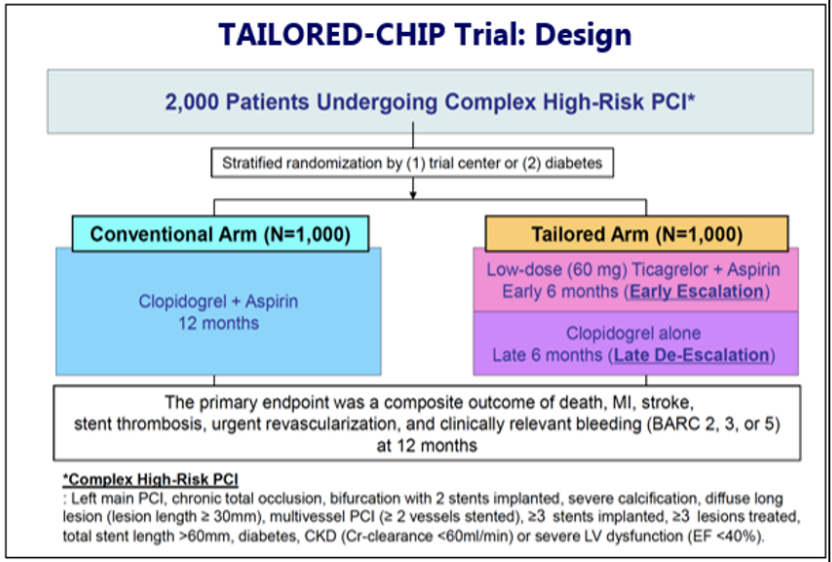
Versus

DAPT escalation with potent P2Y12 inhibitors

DAPT de-escalation
- PFT-guided
- Genotype-guided
- Non-guided

Aspirin or P2Y12 inhibitor monotherapy

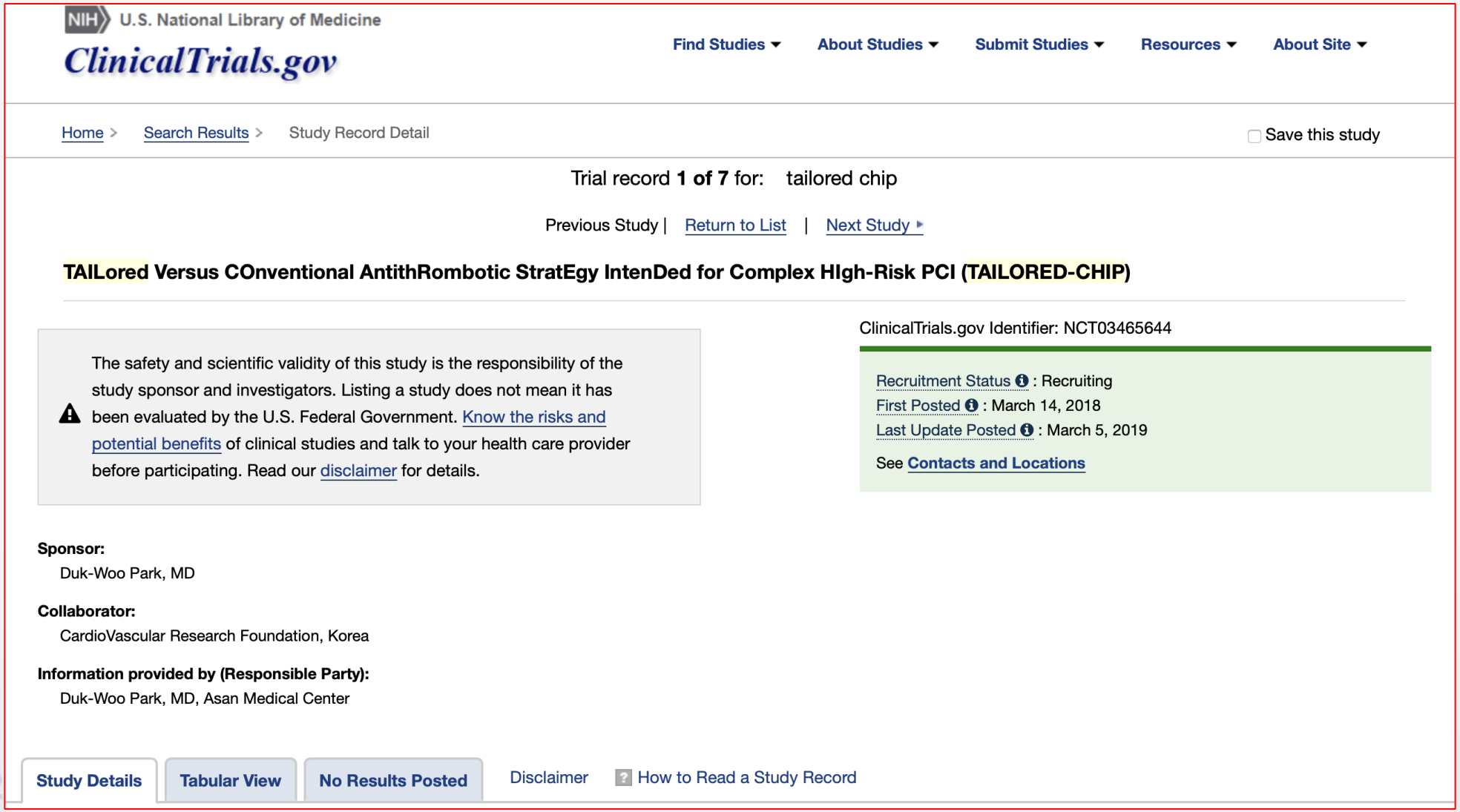
Related ongoing trial



OS Kwon and DW Park. JACC: Asia 2022;2:1–18

Complex CHIP Population

: TAILORED-CHIP Trial (ClinicalTrials.gov: NCT03465644)



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ClinicalTrials.gov

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Trial record **1 of 7** for: tailored chip

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TAILored Versus COnventional AntithRombotic StratEgy IntenDed for Complex HIgh-Risk PCI (TAILORED-CHIP)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03465644

Recruitment Status : Recruiting
First Posted : March 14, 2018
Last Update Posted : March 5, 2019

See Contacts and Locations

Sponsor:
Duk-Woo Park, MD

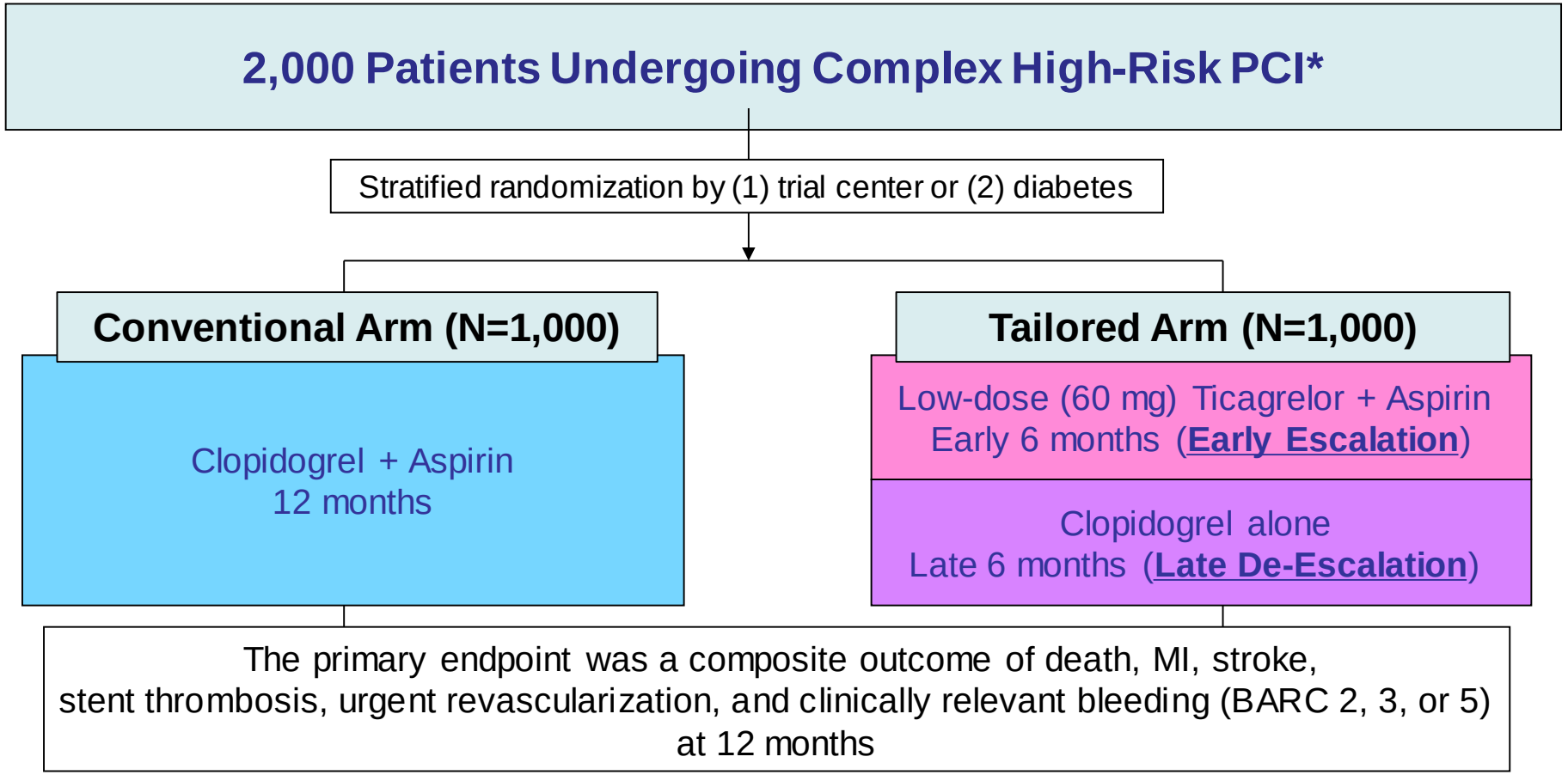
Collaborator:
CardioVascular Research Foundation, Korea

Information provided by (Responsible Party):
Duk-Woo Park, MD, Asan Medical Center

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

TAILored versus C***O***nventional Antith***R***ombotic Strat***E***gy
Inten***D***ed for ***C***omplex ***HI***gh-Risk ***P***CI

TAILORED-CHIP Trial

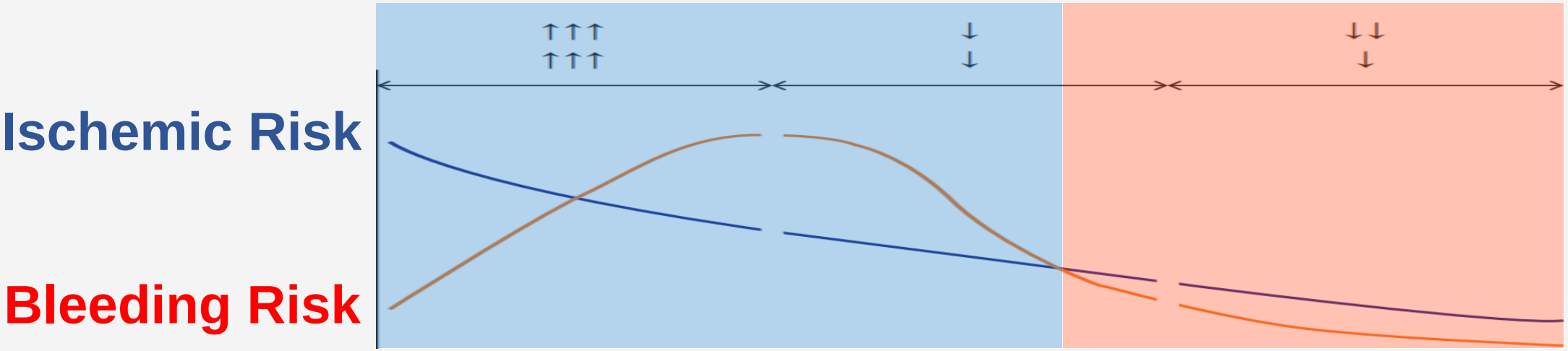


***Complex High-Risk PCI**

: Left main PCI, chronic total occlusion, bifurcation requiring two-stent technique, severe calcification, diffuse long lesion (lesion length ≥ 30mm), multivessel PCI (≥ 2 vessels requiring stent implantation), ≥3 requiring stents implantation, ≥3 lesions will be treated, predicted total stent length for revascularization >60mm, diabetes, CKD (Cr-clearance <60ml/min) or severe LV dysfunction (EF <40%).

TAILORED-CHIP Trial:
Study Rationale

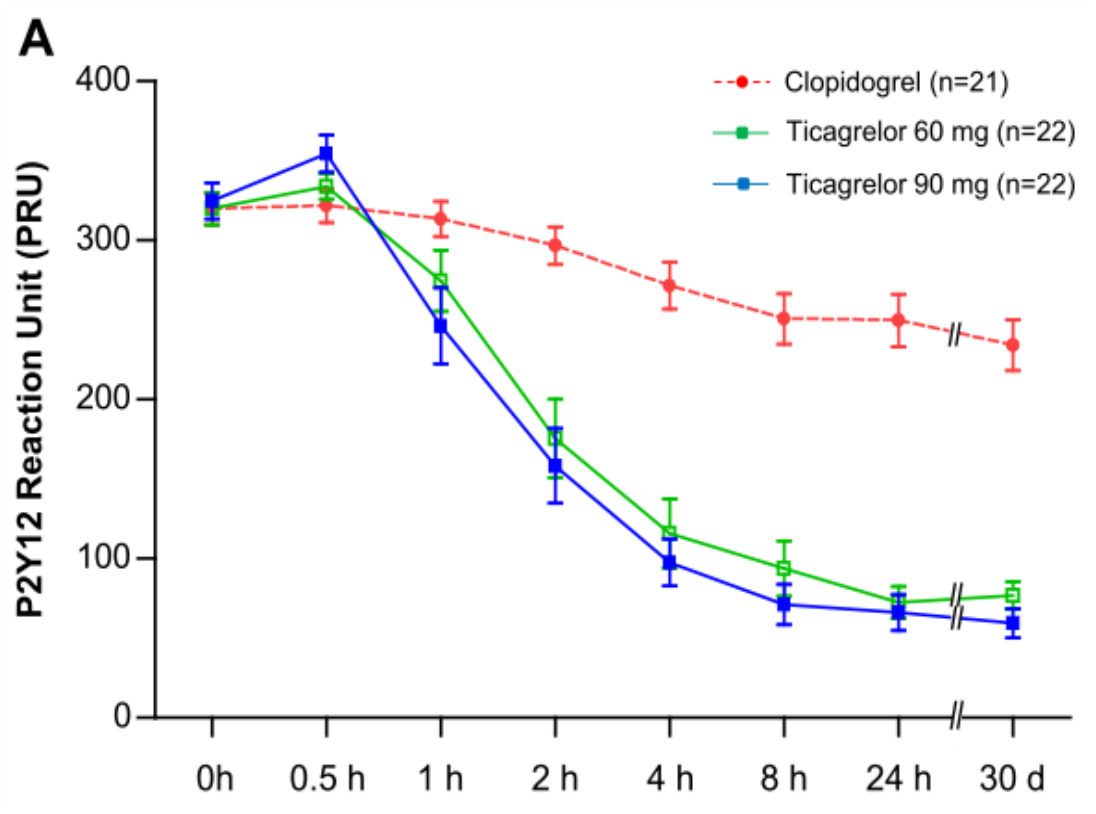
Complex High-risk PCI (CHIP Patients)

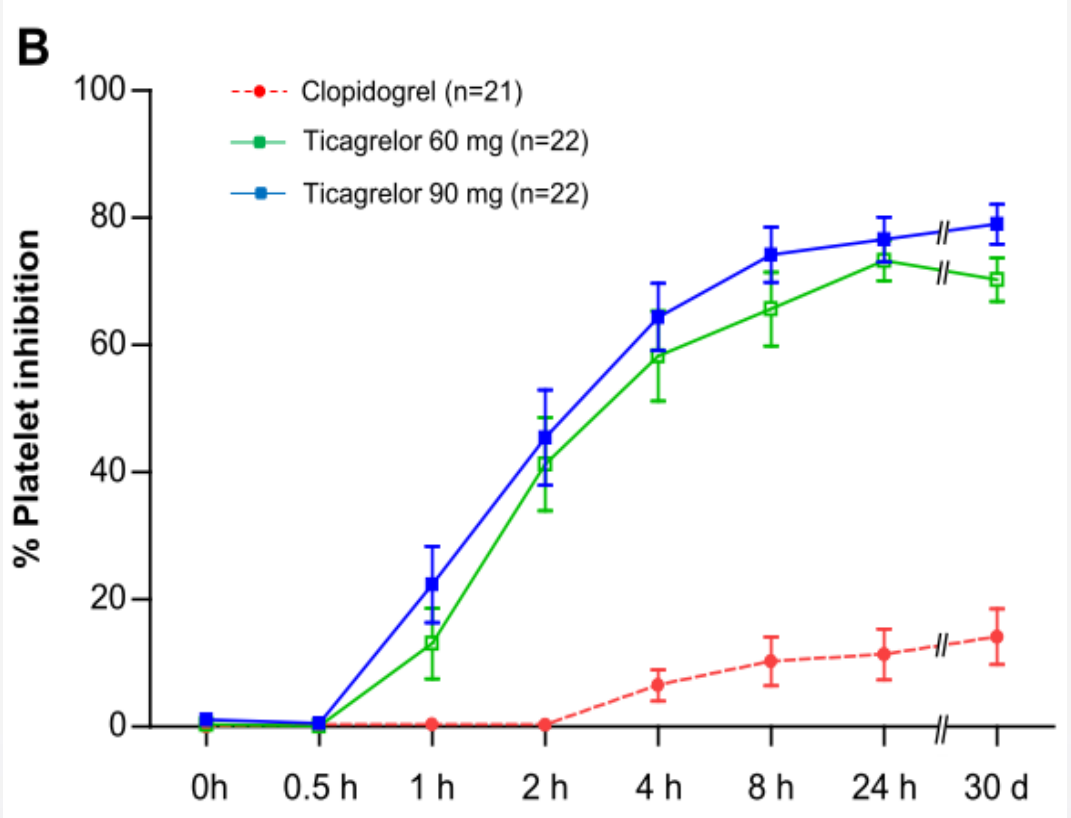


More Potent Strategy
For Early Ischemic Risk
"Low-dose Ticagrelor (60mg) + ASA"

Less Potent Strategy
For Late Bleeding Risk
"Clopidogrel Only (Aspirin-free strategy)"

Rationale for Low-Dose Ticagrelor Based on OPTIMA trial





Low-dose Ticagrelor > Clopidogrel

Low-dose Ticagrelor ≈ Standard-dose Ticagrelor

DW Park, SJ Park et al, JACC 2018;71:1594-1595.

Inclusion criteria

- Men or women aged ≥18 years
- Patients undergoing PCI with contemporary newer-generation DES.
- Patients must have at least one of any features of complex high-risk anatomic, procedural and clinical-related factors.
  - ✓**Lesion- or procedure-related factors**; *Left main* lesion, bifurcation lesion requiring *two stent technique*, *CTO* lesion, severe *calcification*, *diffuse long* lesion (lesion length ≥ at least 30mm), multi-vessel PCI (≥ *2 vessels requiring stent implantation*), ≥*3 requiring stent* implantation, ≥*3 lesions* will be treated, or predicted *total stent length > 60 mm*

  Or

  - ✓**Clinical factors**; *Diabetes, chronic kidney disease* (CrCl <60 mL/min), severe LV dysfunction (*LVEF<40%*)

Exclusion criteria

- ***Enzyme-positive ACS*** *(NSTEMI or STEMI)*
- Contraindication to aspirin or P2Y12 inhibitors (ticagrelor or clopidogrel)
- Cardiogenic shock at index admission
- Patients treated with only BMS or balloon angioplasty during index procedure
- ***Need for chronic oral anticoagulation*** (warfarin or NOAC)
- ***Active bleeding or extreme-risk for major bleeding*** (e.g. active PUD, GI pathology with high risk for bleeding, malignancy with high risk for bleeding)

Study endpoints

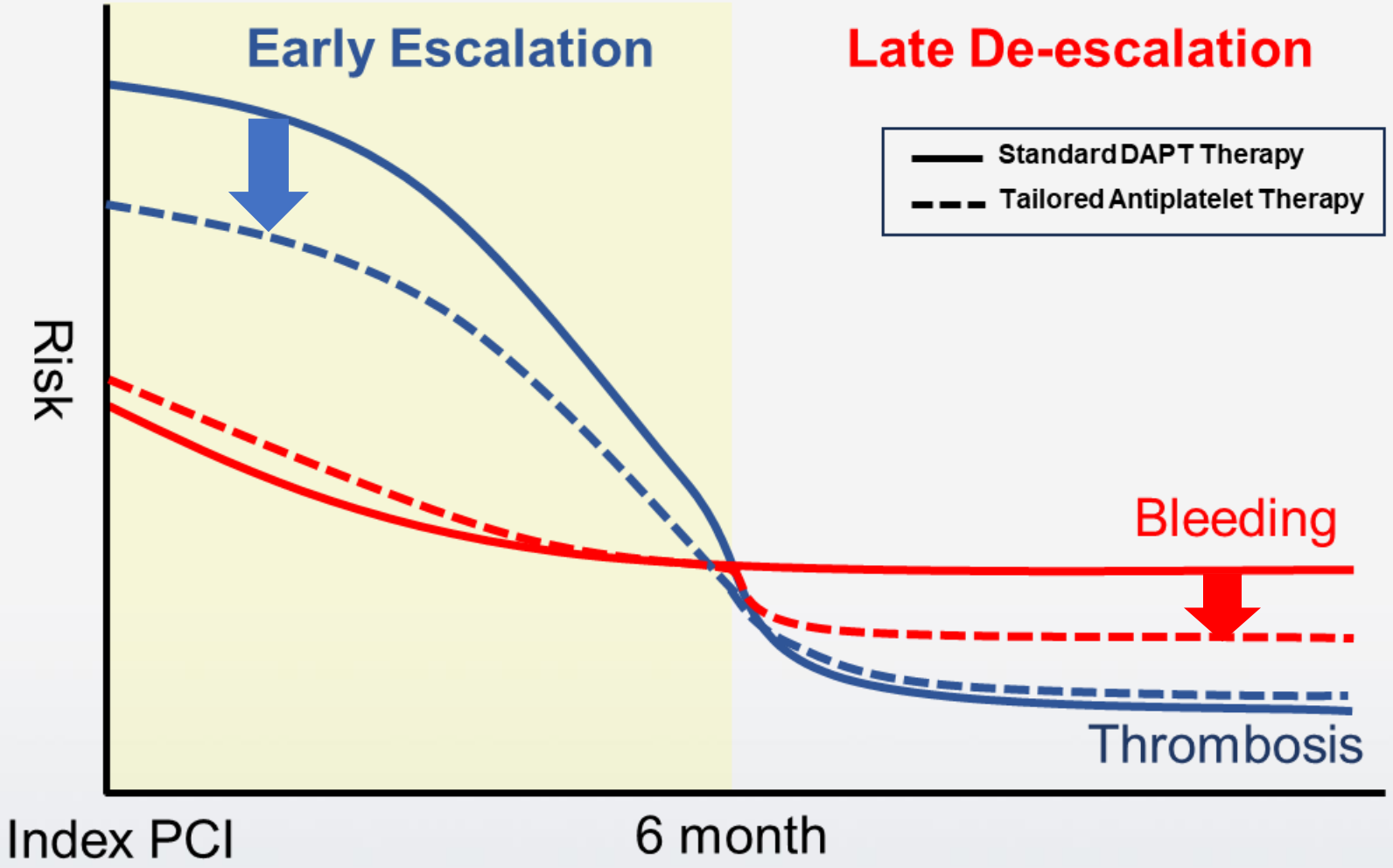
Primary

A **net clinical outcome** of all-cause death, MI, stroke, stent thrombosis, urgent revascularization and clinically relevant bleeding (BARC 2,3, or 5) at 12 months post-PCI

Secondary

- Each component of primary outcome
- Composite of death (all or CV), MI, stroke, stent thrombosis or urgent revascularization
- Composite of death (all or CV), MI, or stroke
- Composite of death (all or CV) or MI
- Any revascularization
- BARC 3 or 5 bleeding
- Major or minor bleeding according to definition from TIMI
- Major or minor bleeding to definition from ISTH

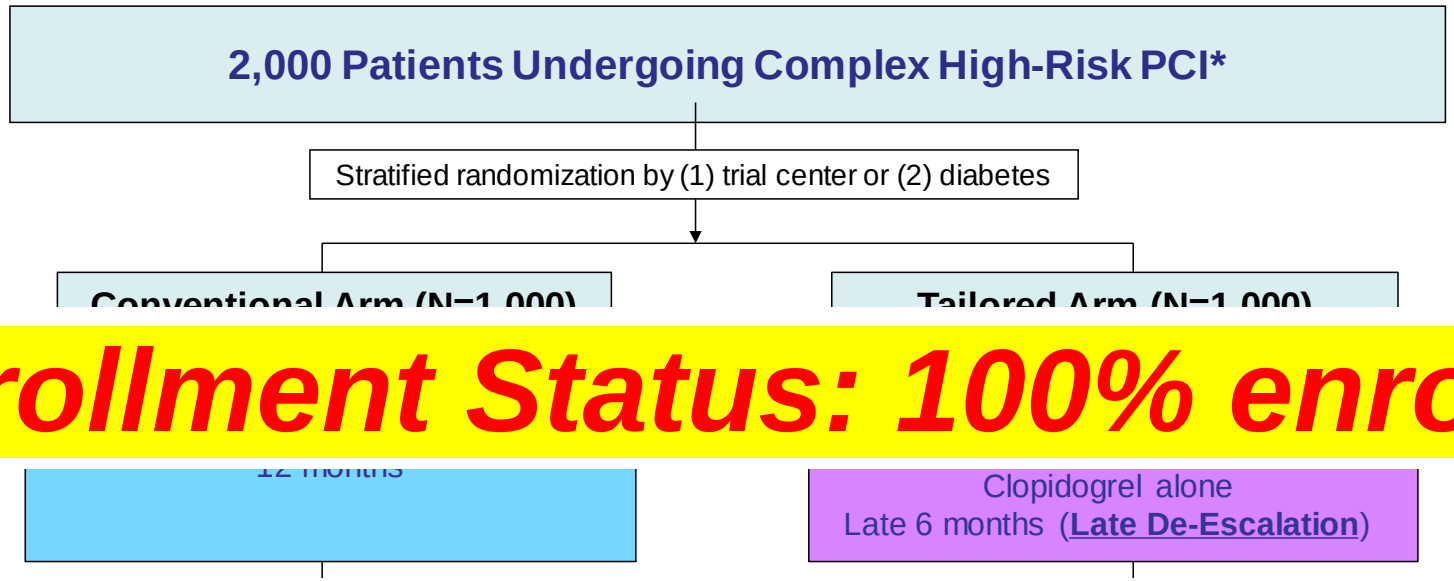
Temporal, Dynamic Treatment Benefit after Complex CHIP PCI



High-Ischemic Risk and Complex PCI Patients

TAILored versus C***O***nventional Antith***R***ombotic Strat***E***gy
Inten***D***ed for ***C***omplex ***HI***gh-Risk ***P***CI

TAILORED-CHIP Trial



Enrollment Status: 100% enrolled

Final Results Will Be Presented the Next-Year ESC 2025 in Madrid!!

Trial P.I.: DW Park and SJ Park

Key Messages

- Optimal antithrombotic strategies are a cornerstone of the management of ACS or PCI and have constantly evolving to balance ischemia and bleeding risk.
- Modulation of antiplatelet therapy is frequently performed, considering the risk of ischemic or bleeding events, with the optimal intensity of platelet inhibition varying according to the stage, clinical presentation, or individual patient factors.
- This strategy can be achieved by reducing (ie, de-escalation) or increasing (ie, escalation) the intensity of platelet inhibition in different ways, including by changing the type, dose, or number of antiplatelet drugs.
- **TAILORED-CHIP trial** will provide important clinical insights on temporal antiplatelet modulation with early escalation and late de-escalation in high-risk patients undergoing CHIP-PCI procedures.