TAILored versus COnventional AntithRombotic stratEgy IntenDed for Complex HIgh-Risk PCI Trial : TAILORED-CHIP trial

Hanbit Park, MD.

Division of Cardiology, Gangneung Asan Hospital

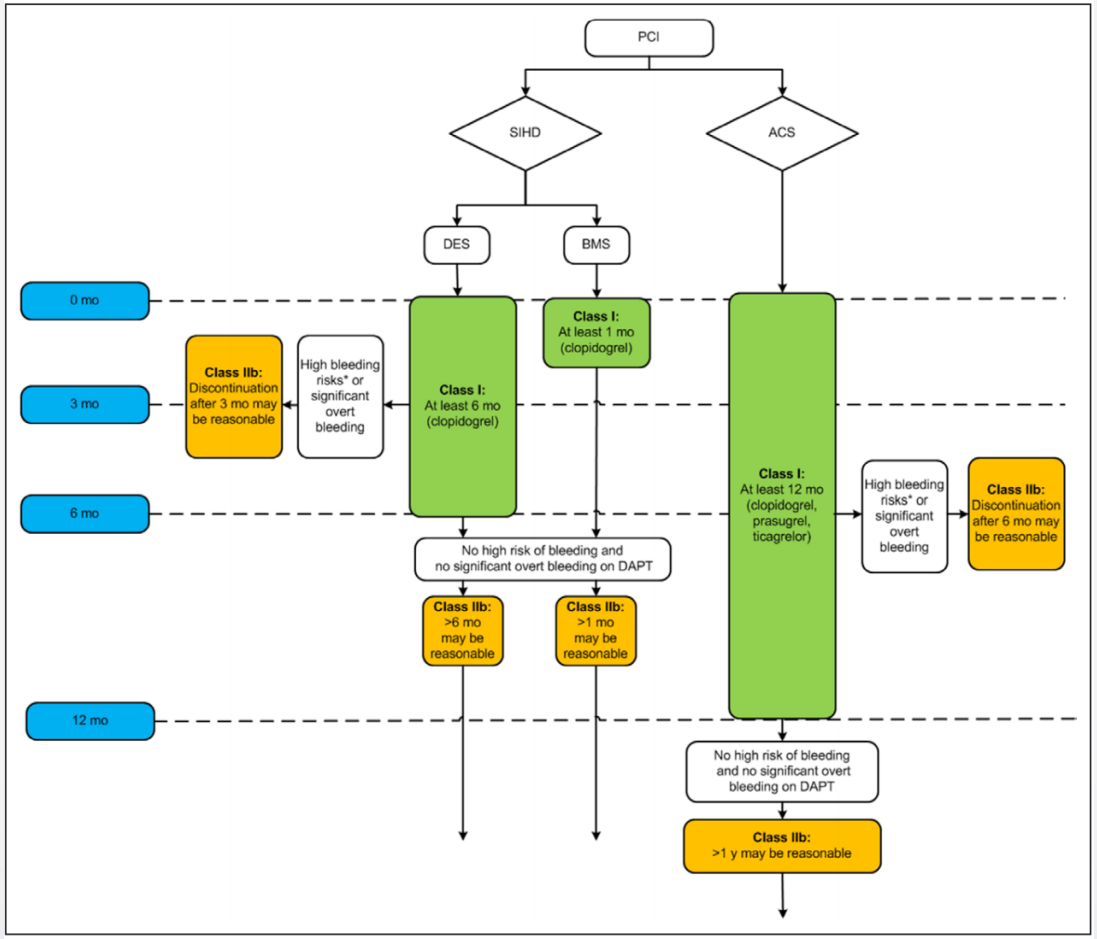
University of Ulsan, College of Medicine

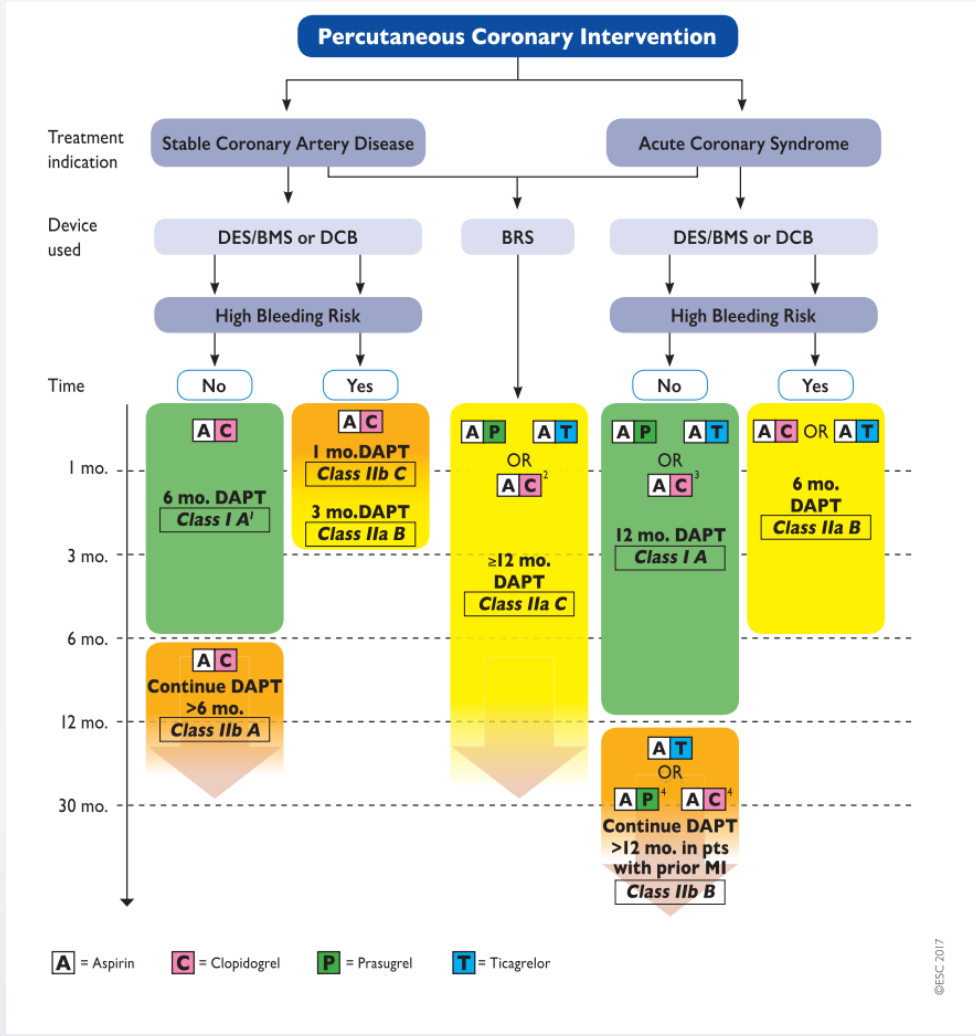
Disclosure

- I have nothing to disclose.

Anti-thrombotic strategy after PCI

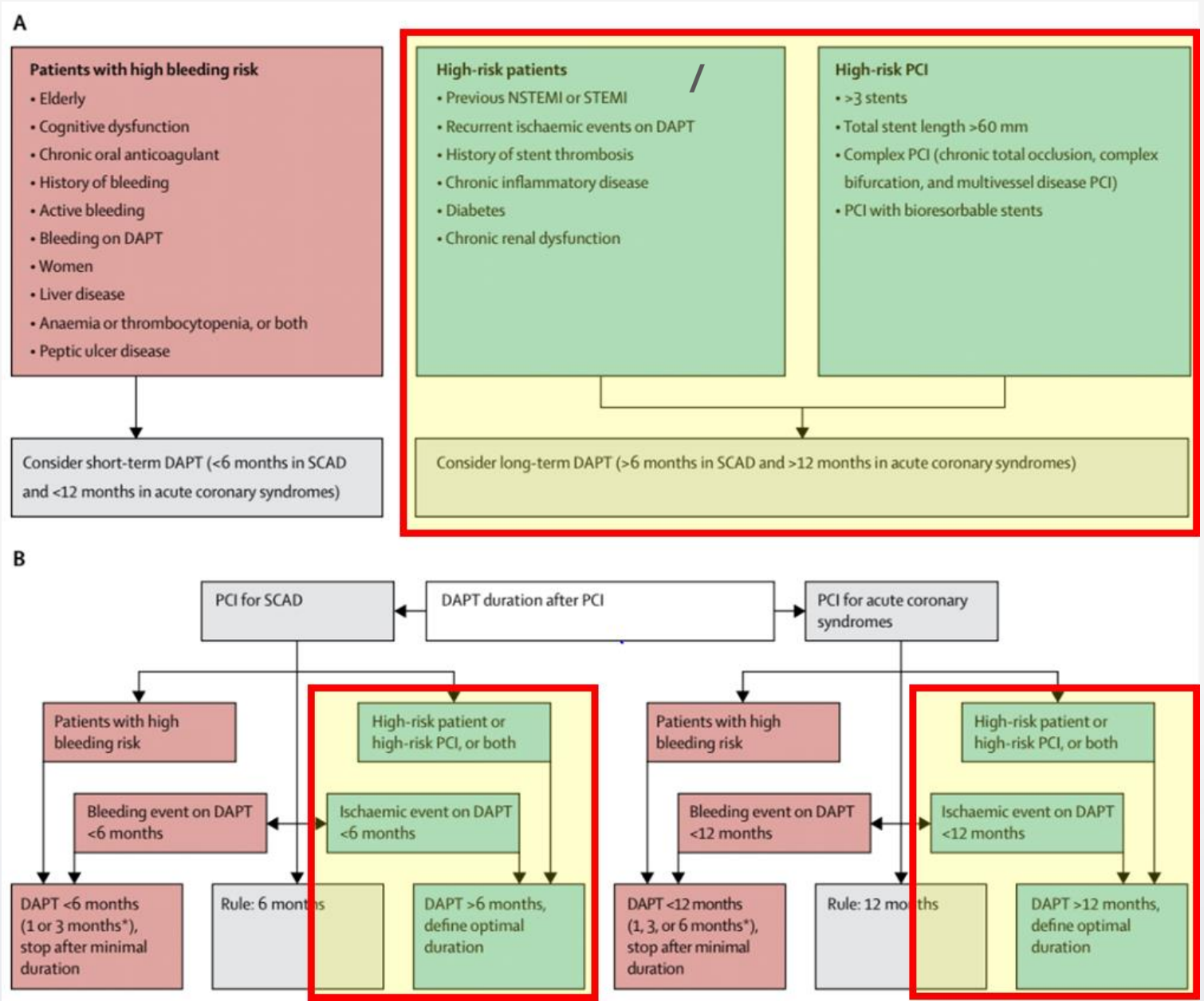
DAPT duration according to clinical manifestation





2107 ESC, 2016 ACC/AHA guideline

Complex High-Risk PCI



Lancet 2017;390:810-20.

Anti-thrombotic in CHIP

Prolonged (i.e. >6 months) DAPT duration[d] may be considered in patients who underwent complex PCI.[247]	IIb	B

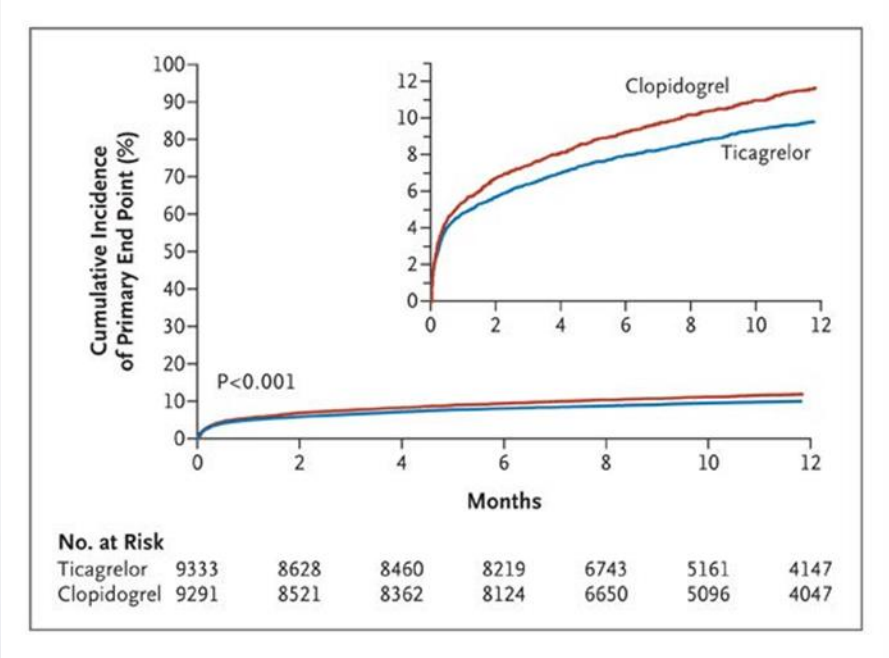
"Optimal DAPT treatment of complex high-risk PCI is still unknown."

2017 ESC guideline

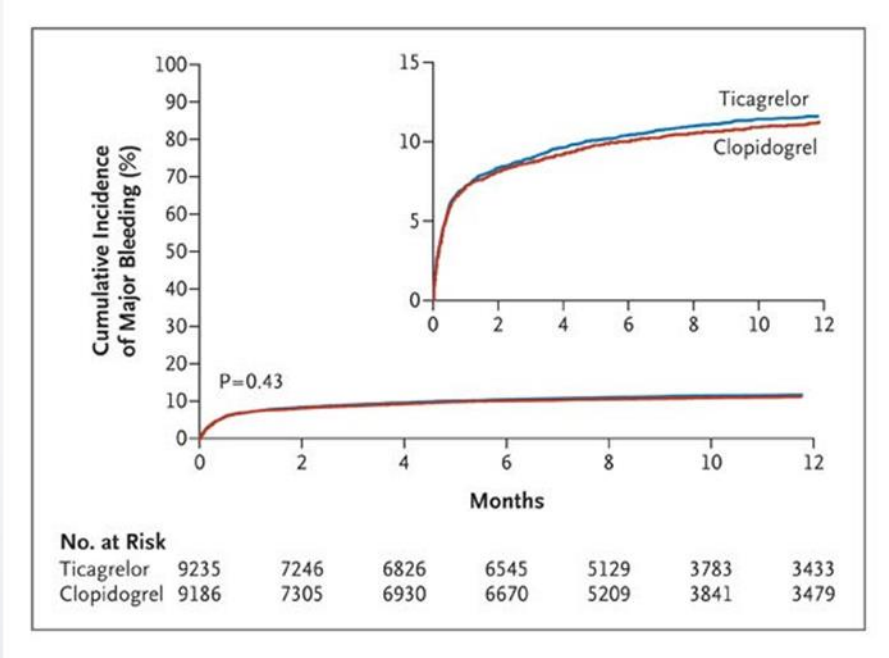
Ticagrelor (Brillinta®)

- A reversible and direct-acting oral antagonist of the adenosine diphosphate receptor P2Y12, provides faster, greater, and more consistent P2Y12 inhibition than clopidogrel.

Vascular death, MI, or stroke



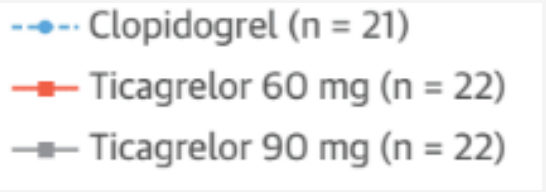
Major bleeding



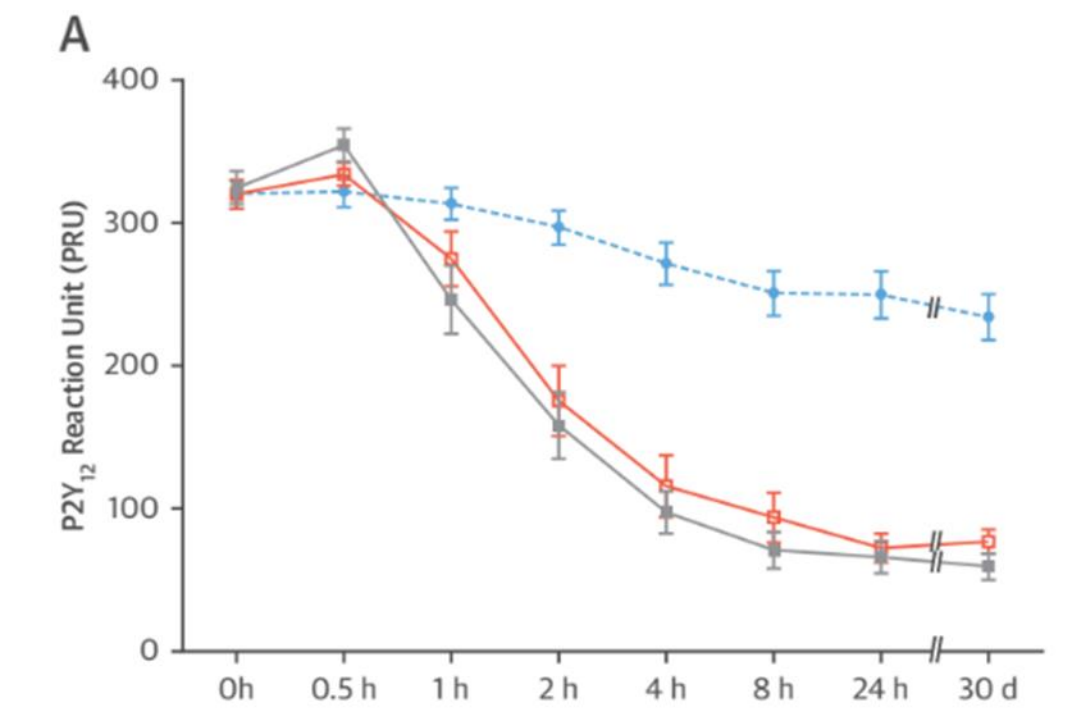
PLATO trial. NEJM 2009;361:1045-57.

OPTIMA trial

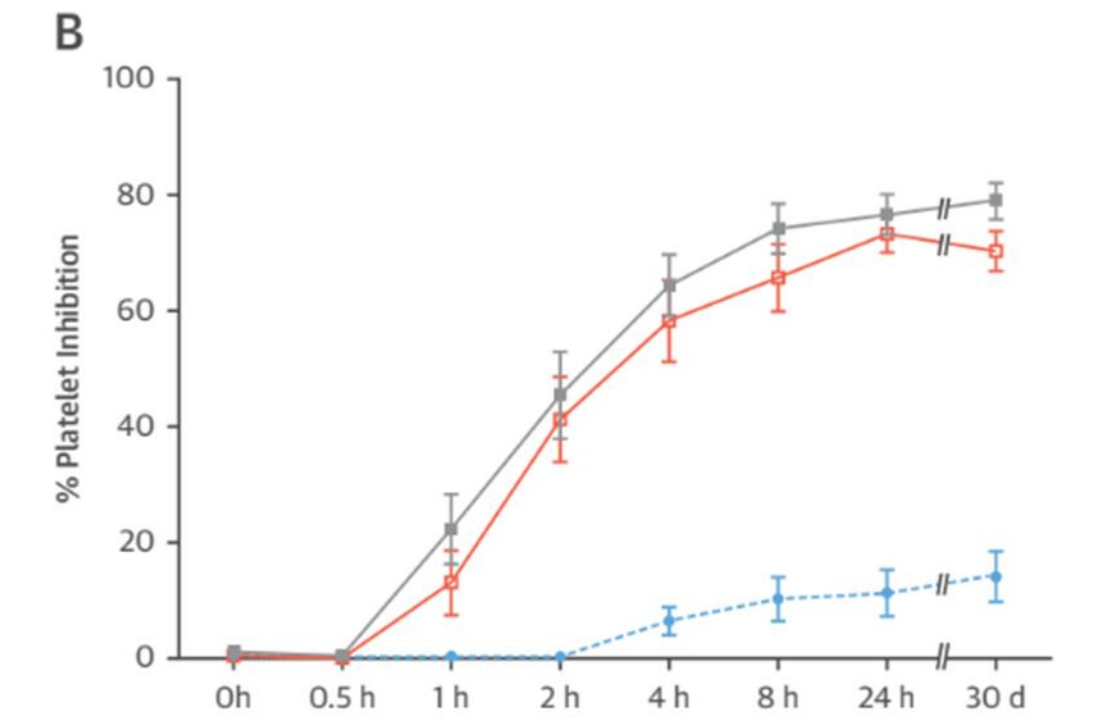
Clopidogrel vs. Ticagrelor 60mg vs. Ticagrelor 90mg



P2Y12 reaction unit (PRU)



Precent platelet inhibition



"Low dose Ticagrelor (60mg) > Clopidogrel

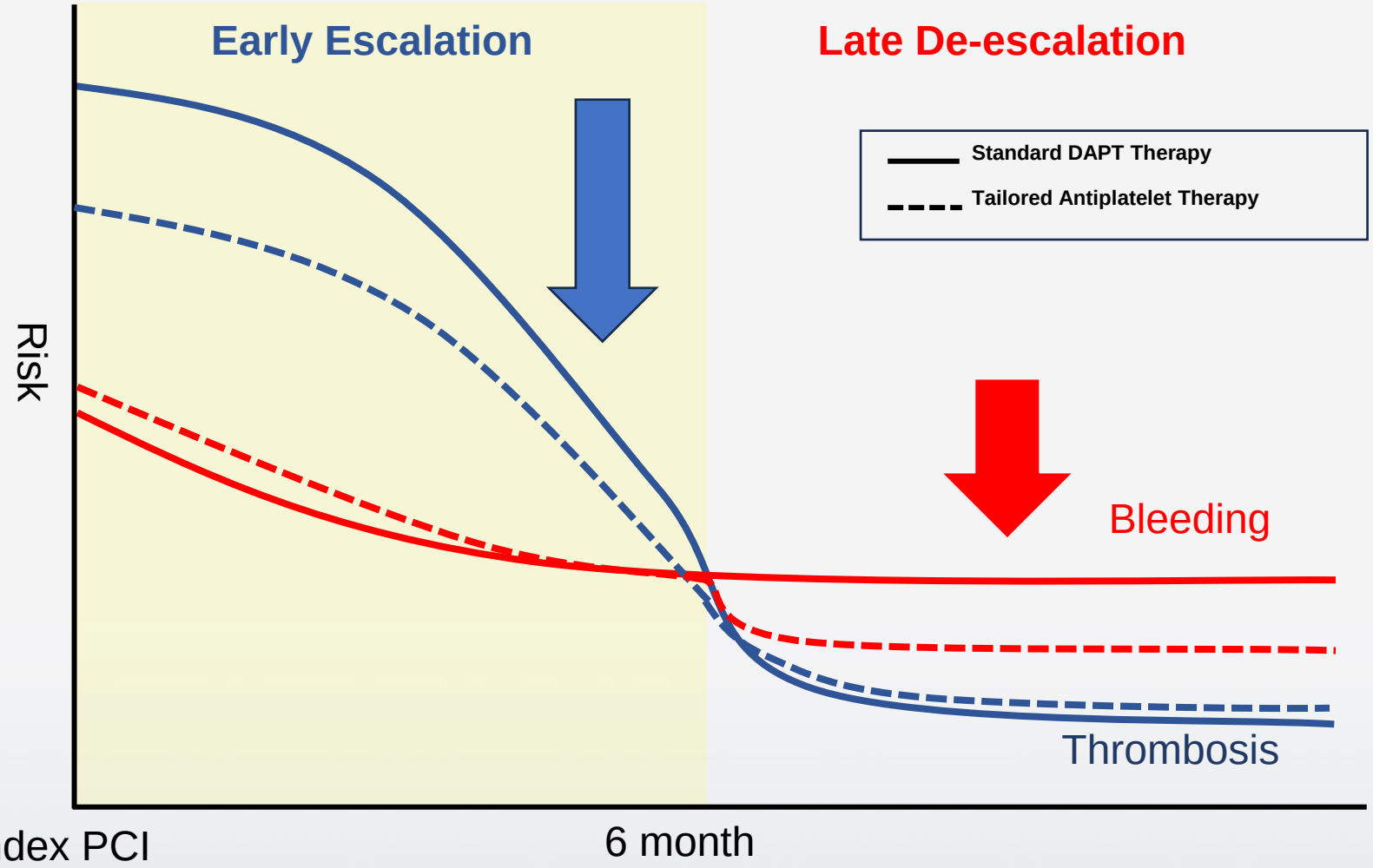
Low dose Ticagrelor (60mg) ≈ Standard dose Ticagrelor (90mg)"

JACC 2018.

TAILORED-CHIP trial

- A multi-center, open-labeled, randomized controlled trial comparing two different antiplatelet strategies in high-risk PCI patients with complex clinical, lesion, and procedural characteristics.

Concept of study



Conventional DAPT
Aspirin + Clopidogrel

Tailored DAPT
Early 6 mo: Aspirin + ticagrelor 60mg bid
Late 6 mo: Clopidogrel

Antiplatelet regimens

- Experimental regimen: Tailored antithrombotic strategy
  - First 6 months, Aspirin 100mg 1T QD + Ticagrelor 60mg 1T bid
  - Last 6 months, Clopidogrel 75mg 1T QD

- Control regimen: Conventional antithrombotic strategy
  - For 12 months, Aspirin 100mg 1T QD + Clopidogrel 75mg 1T QD

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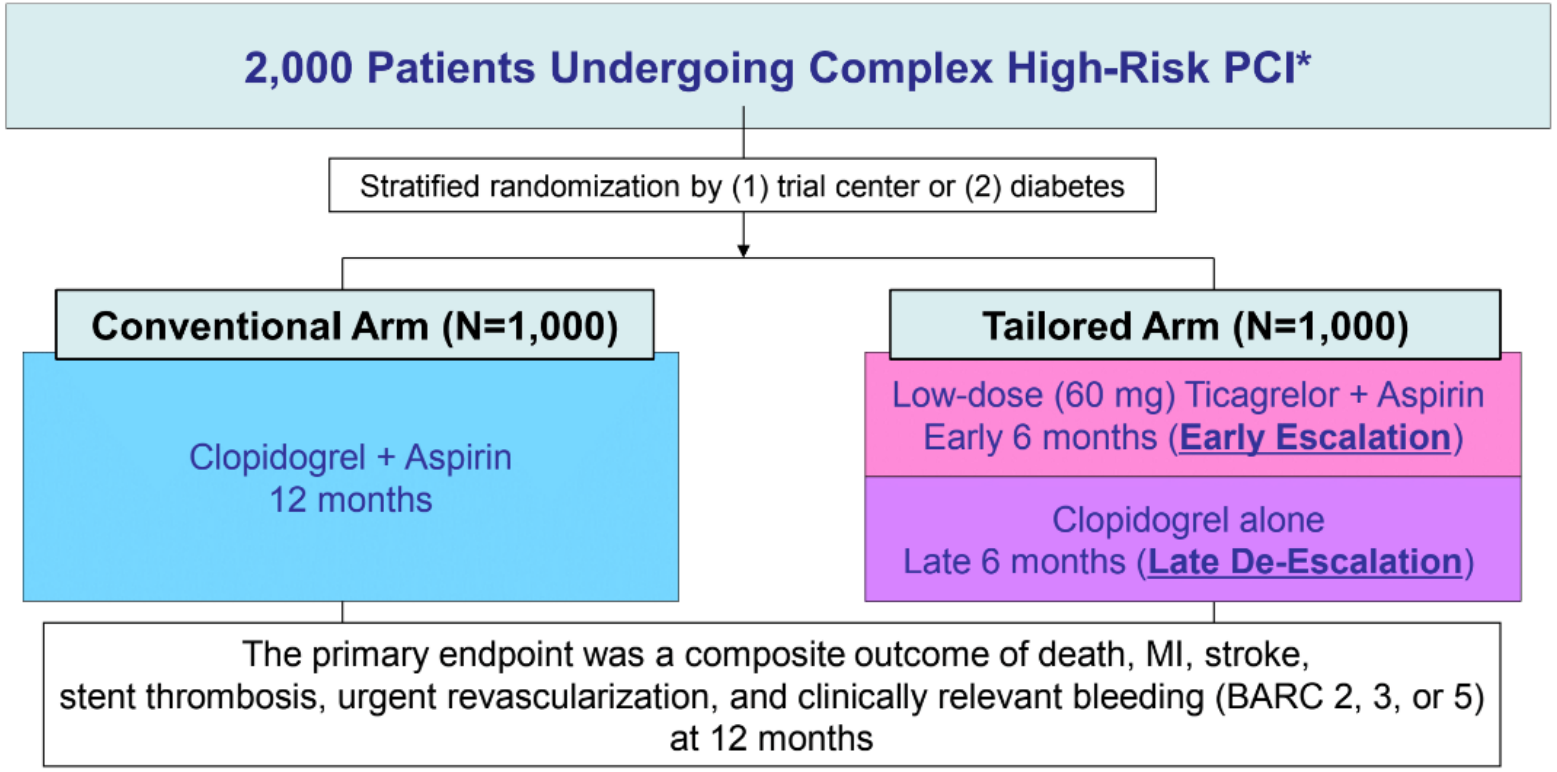
Inten***D***ed for ***C***omplex ***HI***gh-Risk ***P***CI

TAILORED-CHIP Trial



***Complex High-Risk PCI**

: Left main PCI, chronic total occlusion, bifurcation with 2 stents implanted, severe calcification, diffuse long lesion (lesion length ≥ 30mm), multivessel PCI (≥ 2 vessels stented), ≥3 stents implanted, ≥3 lesions treated, total stent length >60mm, diabetes, CKD (Cr-clearance <60ml/min) or severe LV dysfunction (EF <40%).

Study endpoints

- Primary endpoint

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

Study Endpoints

- Secondary endpoints
  - 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

Inclusion criteria

- Men or women aged ≥18 years
- Patients underwent successful PCI with contemporary DES.
- Patients must have at least one of any features of complex high-risk anatomic, procedural and clinical-related factors.
- Clinical factors; diabetes, chronic kidney disease (CrCl <60 mL/min), severe LV dysfunction (LVEF<40%)
- Lesion- or procedure-related factors; left main lesion, bifurcation lesion with 2 stents implanted, CTO lesion, severe calcification, diffuse long lesion (lesion length ≥ at least 30mm), multi-vessel PCI (≥2 vessels stented), ≥3 stents implanted, ≥3 lesions treated, or total stent length > 60 mm

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)

Exclusion criteria

- History of ICH or intracranial aneurysm
- Planned surgery within 180 days
- Liver cirrhosis
- Dialysis-dependent renal failure
- Pregnant and/or lactating women
- Concurrent medical condition with a life expectancy of less than 1 year
- Patients who are actively participating in another drug or device investigational study, which have not completed the primary endpoint follow-up period.

Current status

- From February 2019 through January 2024, a total of 2,000 patients were enrolled.

- Next year, the primary results will be available.

In future guideline

Recommendation	Class	Level	Ref
Complex high-risk PCI			
Early escalation and late de-escalation DAPT strategy should be considered in patients who underwent complex high-risk PCI.	I	A	