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

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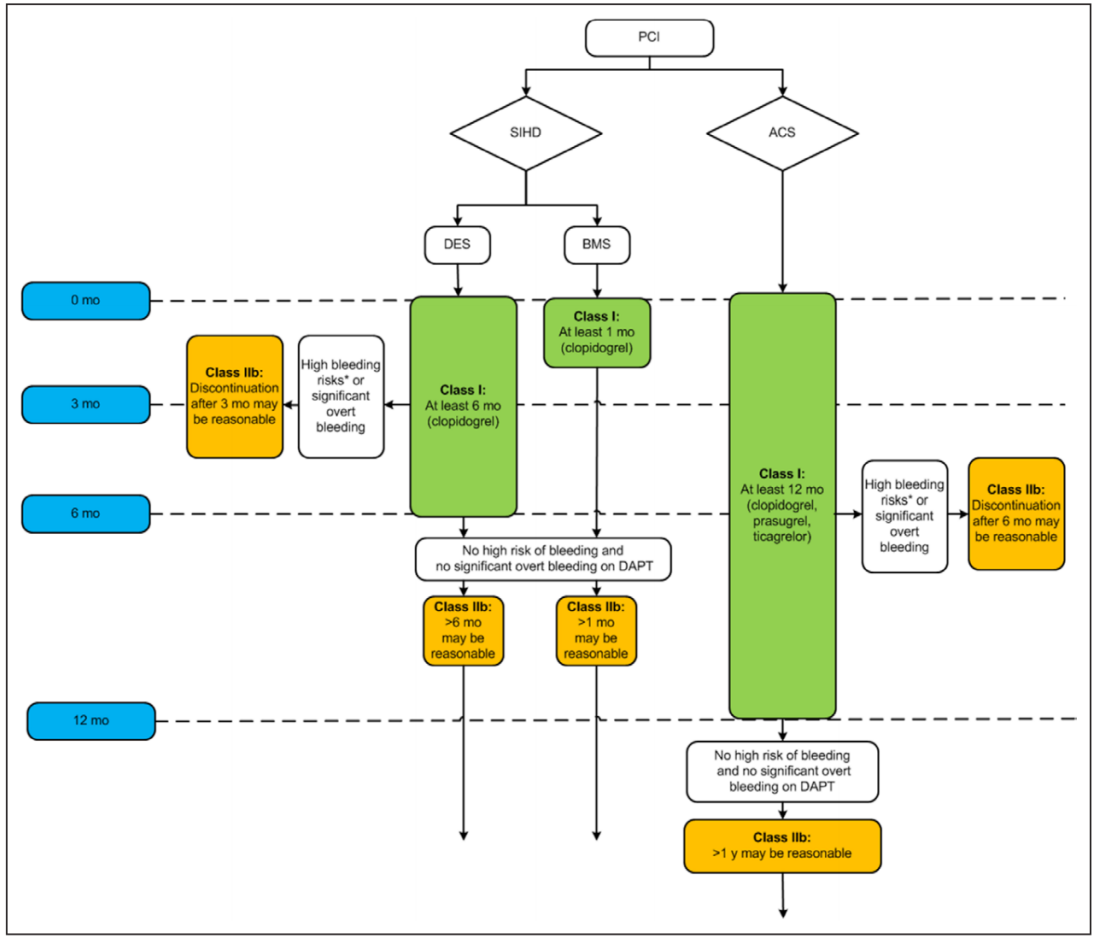
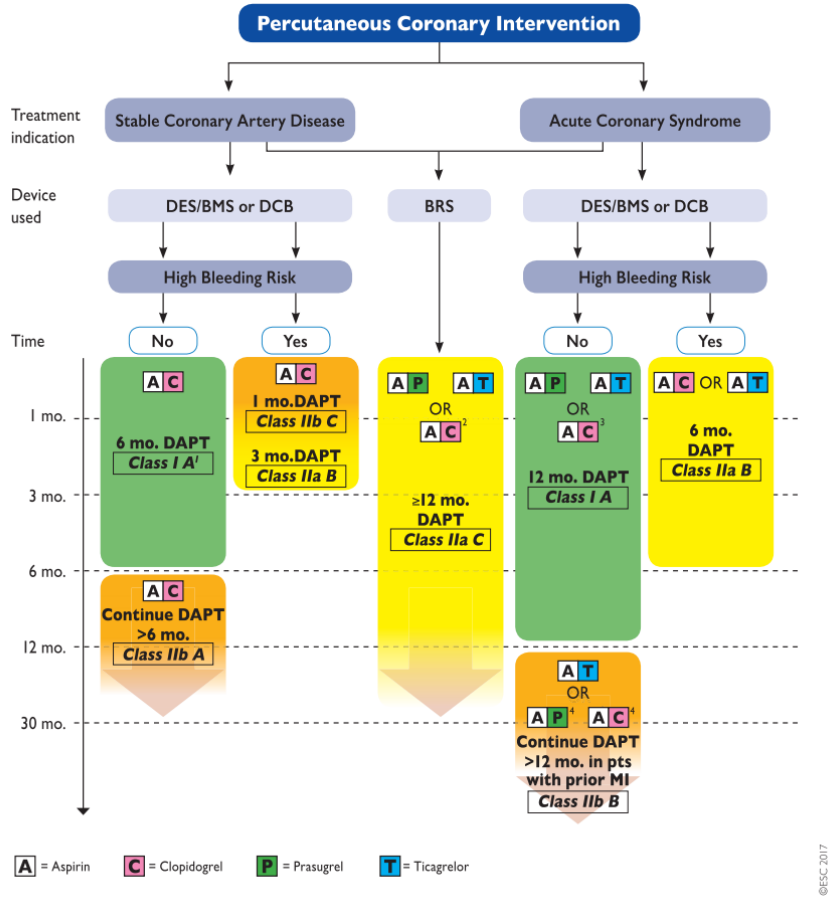
Disclosure

- I have nothing to disclose.

Anti-thrombotic strategy after PCI

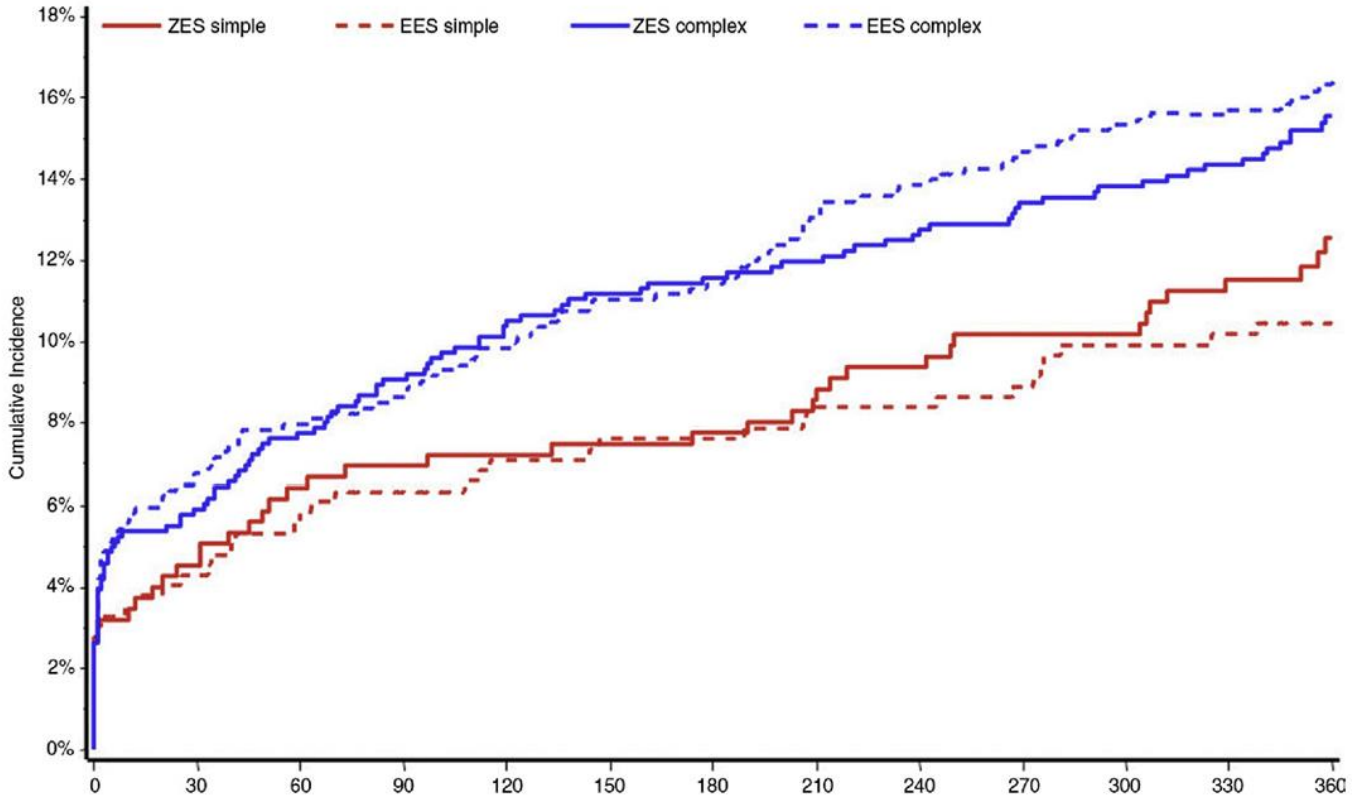




2016 ACC/AHA guideline/2017 ESC guideline

Complex PCI

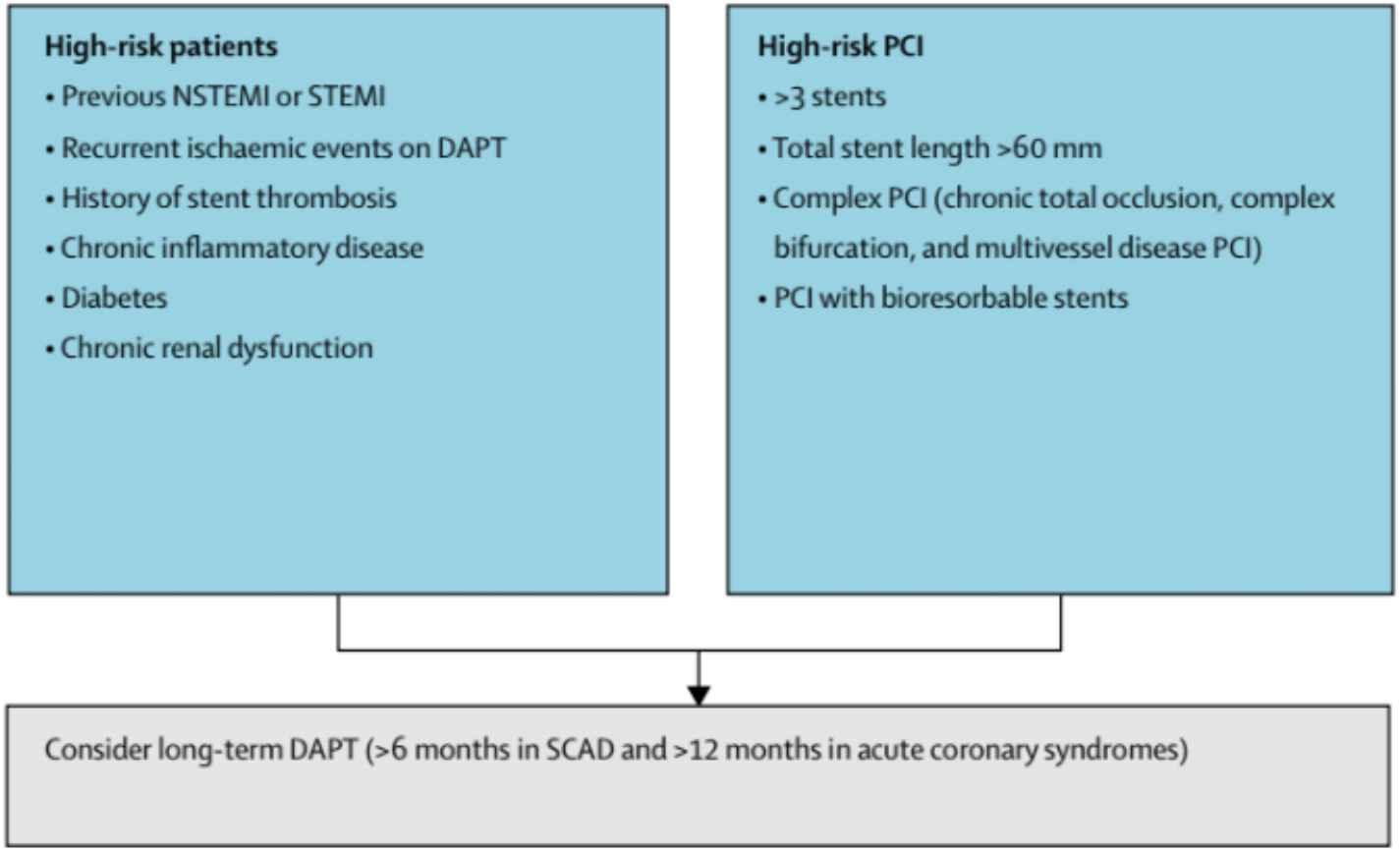
A substudy of RESOLUTE All-comer trial



No. at Risk													
EES Complex	756	734	699	689	683	675	666	661	646	640	633	628	622
ZES Complex	764	743	714	700	690	679	674	671	665	659	654	651	642
EES Simple	396	385	377	370	368	365	363	363	357	356	354	349	341
ZES Simple	376	366	356	349	347	346	345	343	338	336	333	333	324

JACC 2011;57:2221-32.

Complex High-Risk PCI



Lancet 2017;390:810-20.

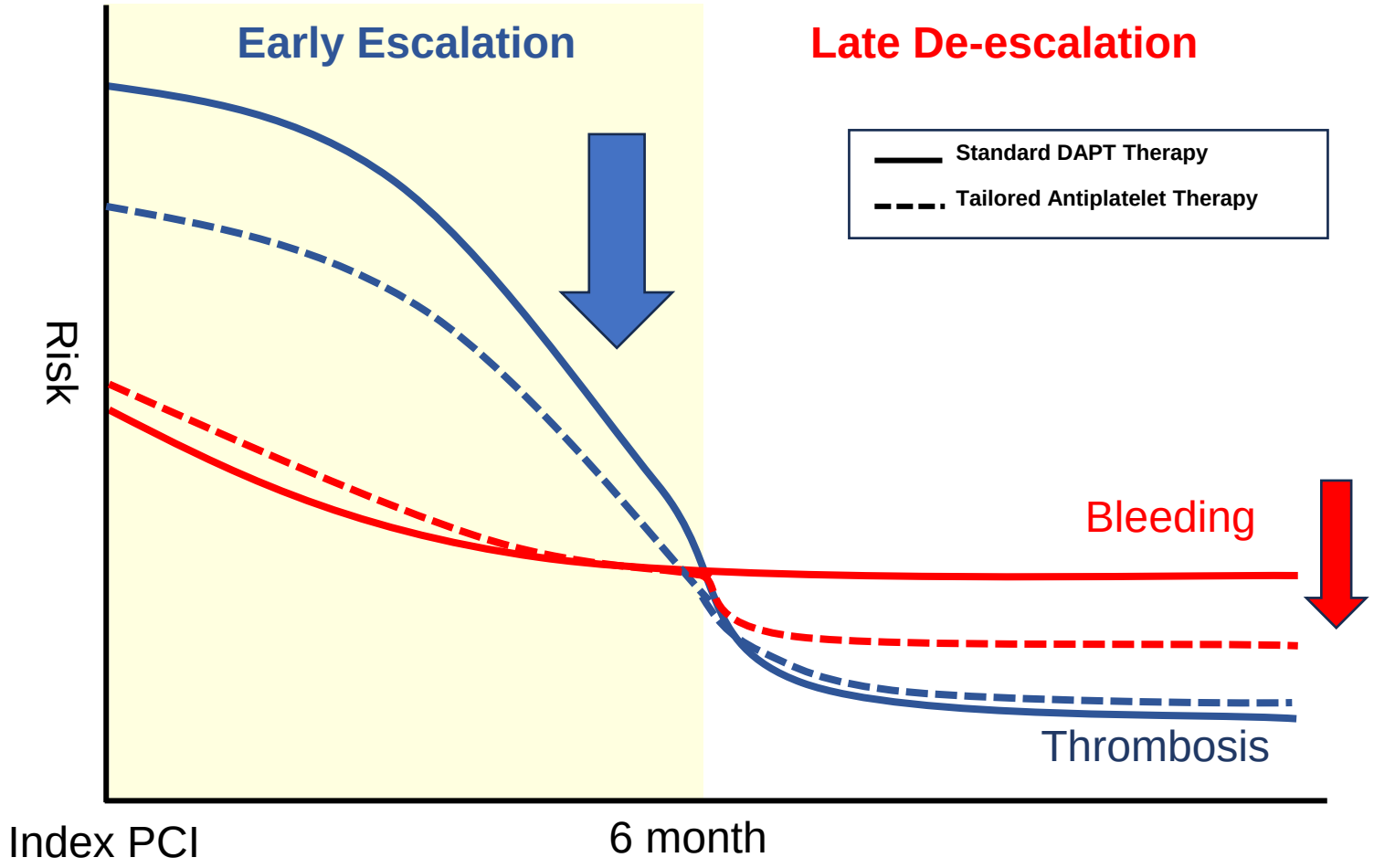
Anti-thrombotic in CHIP

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

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

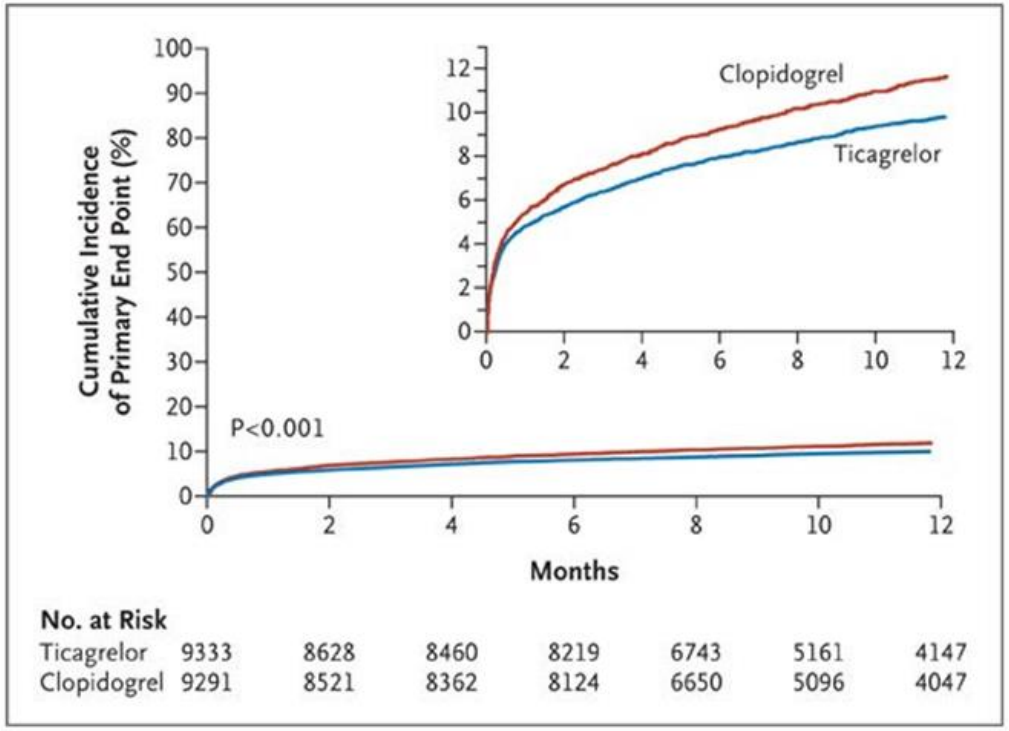
2017 ESC guideline

Optimal Antiplatelet Strategy for CHIP
Temporal Modulation of DAPT

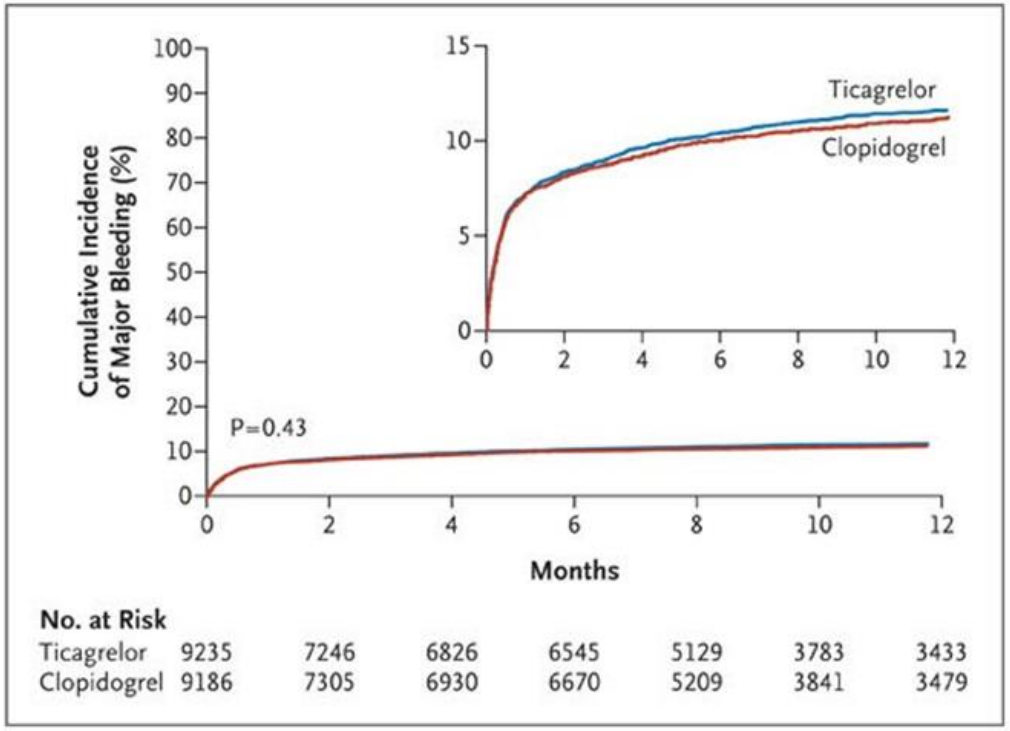


Ticagrelor (Brillinta®)

Vascular death, MI, or stroke



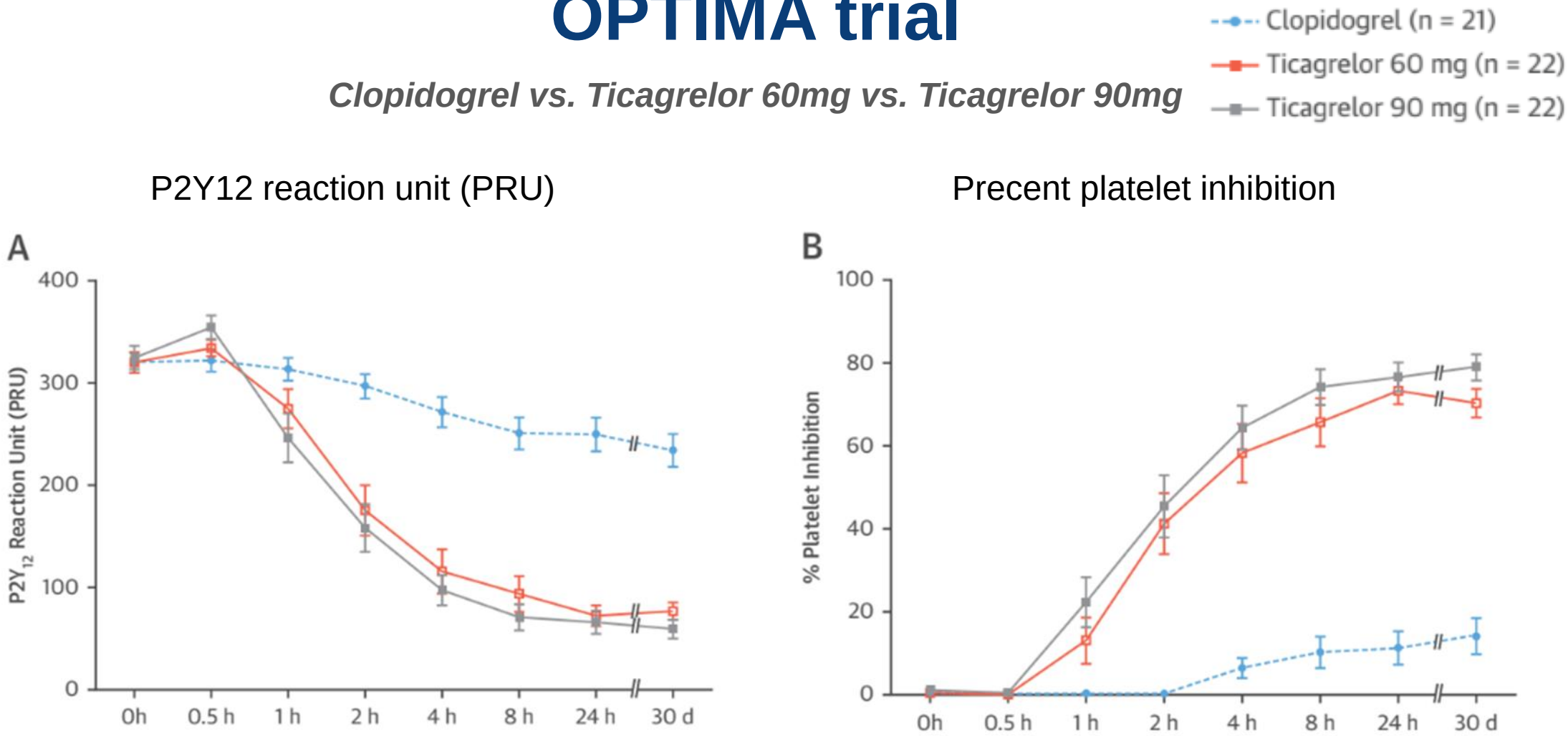
Major bleeding



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

OPTIMA trial

Clopidogrel vs. Ticagrelor 60mg vs. Ticagrelor 90mg



"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.

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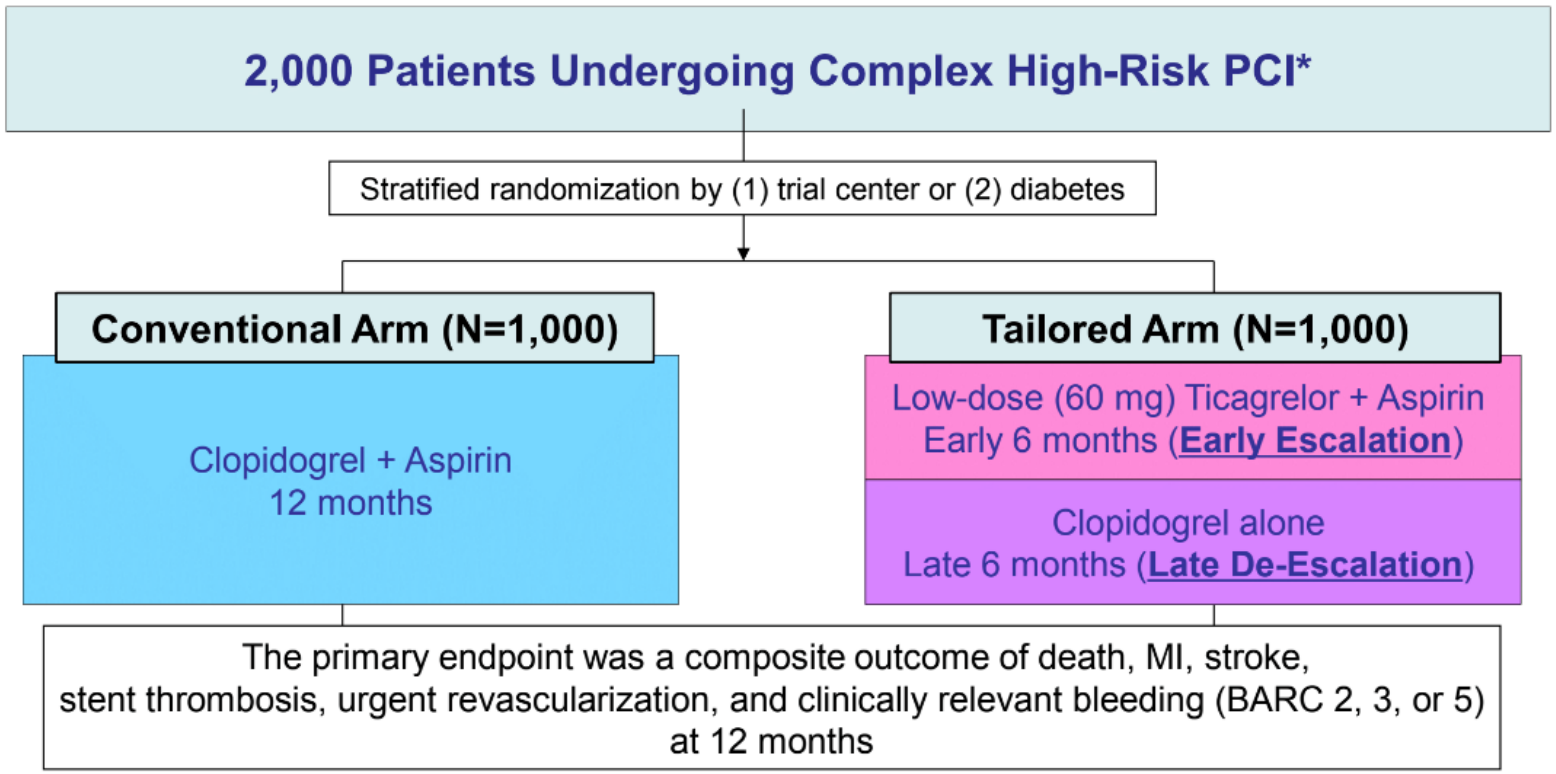
Inten***D***ed for ***C***omplex ***HI***gh-Risk ***P***CI

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%).

Antiplatelet regimens

- Tailored(temporal modulated) antithrombotic strategy
  - First 6 months, Aspirin 100mg 1T QD + Ticagrelor 60mg 1T bid
  - Last 6 months, Clopidogrel 75mg 1T QD

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

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

Complex High-Risk PCI

Lesion and procedural characteristics	Clinical factors
Left main PCI	Diabetes
Chronic total occlusion	Chronic kidney disease (CrCl <60 mL/min)
Bifurcation lesion requiring two stenting technique	Severe LV dysfunction (LV EF <40%)
Severe calcification	
Diffuse long lesion (lesion length > 30mm)	
Multivessel PCI (>2 vessel)	
>3 requiring stent implantation	
>3 lesion to be treated	
>60mm predicted total stent length	

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.

- This year, the primary results will be available.