

# Angioplasties complexes chez les patients à hauts risques de saignement (HBR)

## Pourquoi adapter son traitement antiagrégant plaquettaire?

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# DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

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**G Cayla has received research grants/consultant fees/lectures fees from Amgen, AstraZeneca, Abbott, Bayer, Biotronik, Bristol-Myers Squibb, Microport, Medtronic, Pfizer, Sanofi-Aventis.**

# Durée de la DAPT: une (très) longue histoire

## BMS

## DES

**DES G 1**

**2006 ESC** 

**DES G2-3**

1995: Ticlid  
2001: CURE

**2003**  
Cypher **2004**  
Taxus

Thrombose de stent tardive

Réduction thrombose de stent+++



Cypher 3 mois

Taxus 6 mois

BMS 1 mois

DAPT 12 mois et plus

Augmentation de la durée

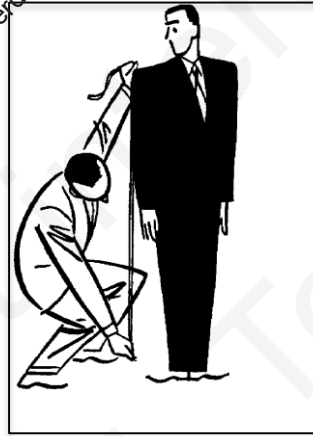
Diminution de la durée  
De escalade

Prise en compte du  
risque hémorragique

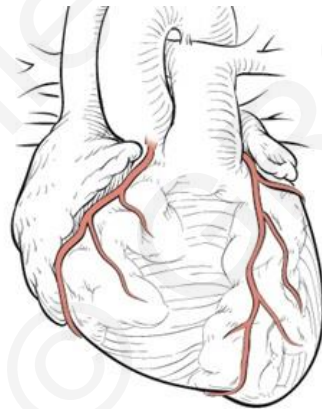
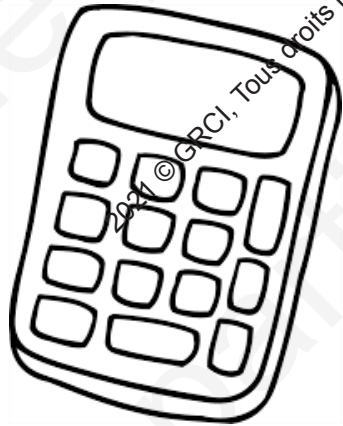
Tout droits réservés - Toute reproduction même partielle est interdite.

# How to individualize the DAPT?

Ischemic risk



Bleeding risk



Score

Evaluation of Anatomic complexity

Evaluation of Bleeding risk

Physician decision

# Individualisation de la durée du traitement antiplaquettaire

6 mois (SCC)-12 mois (SCA)



short duration of DAPT

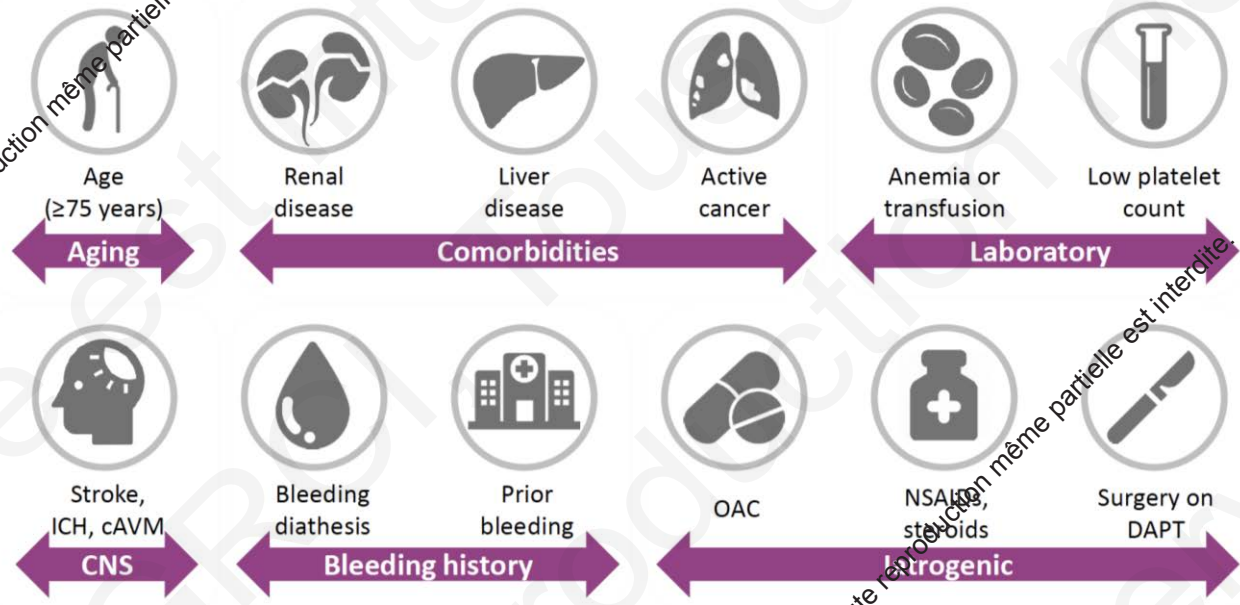
Long duration of DAPT

De escalation of DAPT



# Individualisation de la durée du traitement antiplaquettaire

**HBR**



=35 40% des patients

# Etudes DAPT + HBR

## Population HBR



DAPT 1 mois post PCI  
*DES vs BMS*

DAPT 1 mois post PCI  
*DES 1 vs DES 2*

DAPT 1 mois vs 6 mois post PCI  
*DES 1 – 1mois vs DES 1- 6 mois*



# DAPT for 1 month?

HBR patients

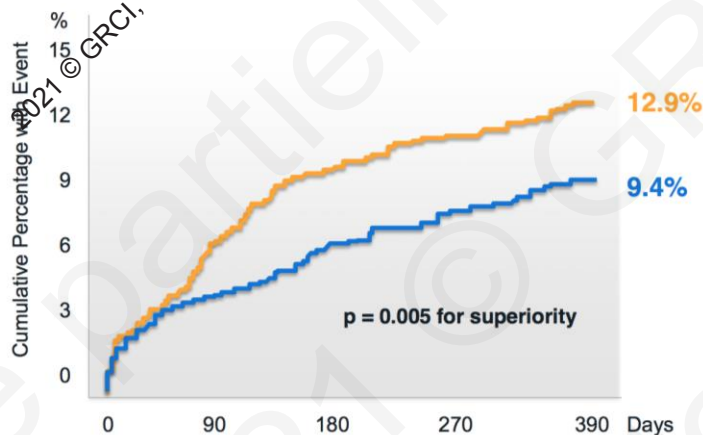
**No Randomisation of 2 durations**

Comparison of DES vs BMS in high risk of bleeding patients using one month DAPT

LEADERS FREE

**BIOFREEDOM Stent > BMS**

**Cardiac Death, MI, ST**



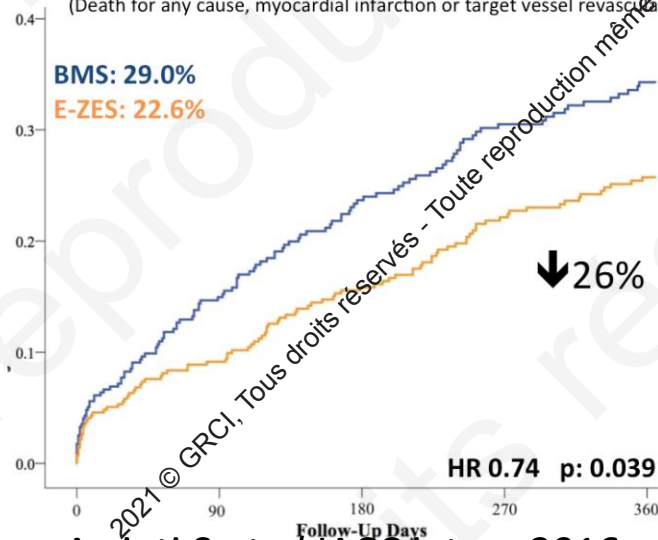
Urban P *et al* NEJM 2015

ZEUS

**ZOTAROLIMUS Eluting endeavor > BMS**

**Major Adverse Cardiovascular Events**

(Death for any cause, myocardial infarction or target vessel revascularization)



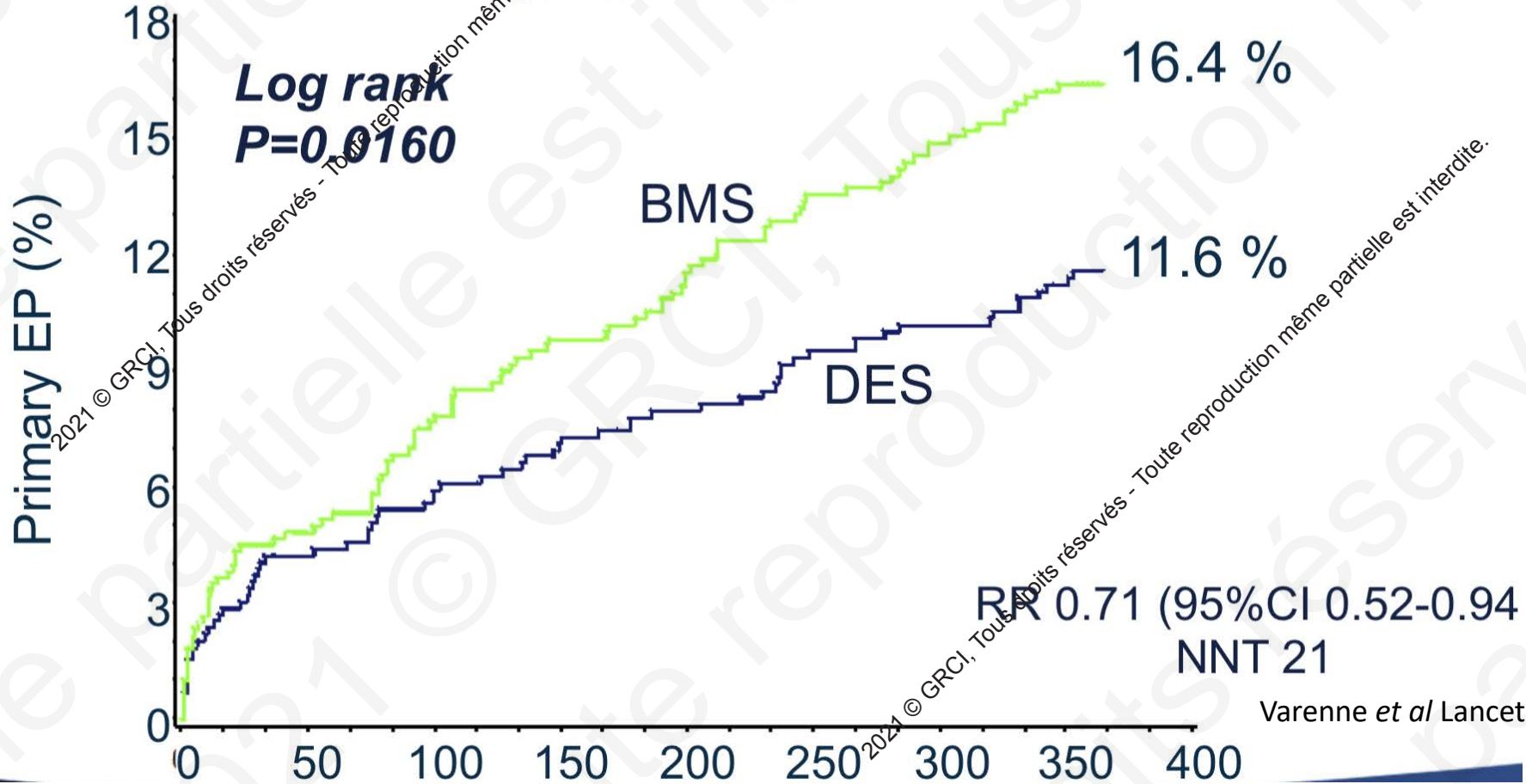
Arriotti S *et al* JACC interv 2016



Tailored DAPT: 1 mo in stable and 6 mo in ACS pts  
Prespecified by the investigator prior to randomization

# SENIOR Trial Primary End Point

All-cause mortality, MI, stroke, ischemia-driven TLR



Varenne et al Lancet 2017

# Etudes DAPT + HBR

Population HBR



DAPT 1 mois post PCI  
*DES vs BMS*

DAPT 1 mois post PCI  
*DES 1 vs DES 2*

DAPT 1 mois vs 6 mois post PCI  
*DES 1 – 1mois vs DES 1- 6 mois*

# DEVICE: SHORT DAPT/HBR

## Onyx ONE Global Study Design

Prospective, Multicenter, Single-blind Randomized Trial

High Bleeding Risk patients undergoing PCI  
(no lesion, vessel limitations)

Resolute Onyx™ ZES  
with 1 Month DAPT  
(N=1000)

1:1 randomization   
84 global sites  
Enrollment Nov 2017 – Sep 2018

BioFreedom™ DCS  
with 1 Month DAPT  
(N=1000)

Clinical Follow-up

1mo 2mo 6mo 1yr 2yr

**Primary safety endpoint:** Cardiac death, MI or stent thrombosis (def/prob) at 1 year

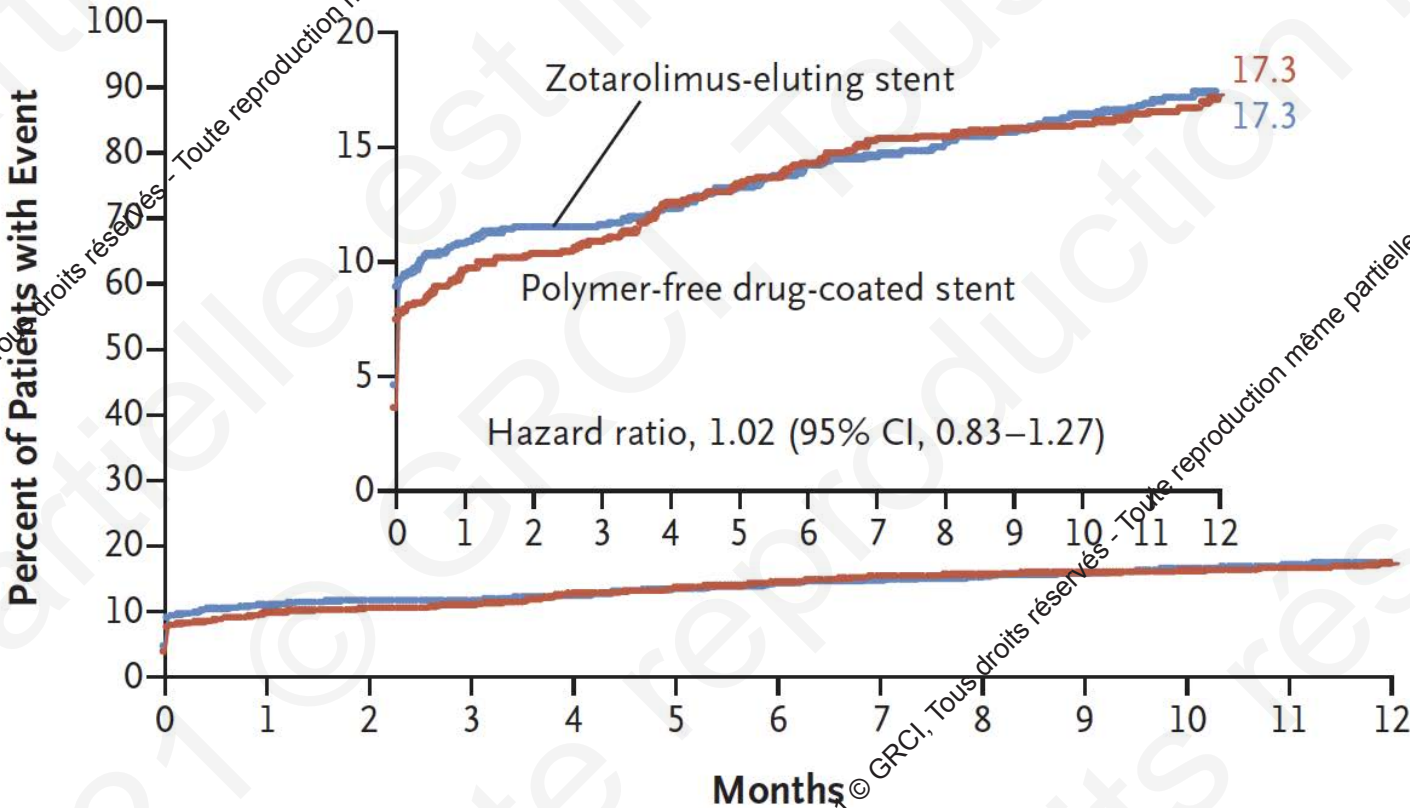
**2° Efficacy endpoint (powered):** Target Lesion Failure (TLF; cardiac death, TV-MI or CD-TLR) at 1 year

**Other secondary endpoints:** Lesion, device and procedure success rates, BARC bleeding, individual components of primary endpoints

# ONYX ONE

Mean age 74 y, ACS 50%

Primary Outcome of Death from Cardiac Causes, Myocardial Infarction, or Stent Thrombosis



S. Windecker et al NEJM 2020

# Etudes DAPT + HBR

## Population HBR



DAPT 1 mois post PCI  
*DES vs BMS*

DAPT 1 mois post PCI  
*DES 1 vs DES 2*

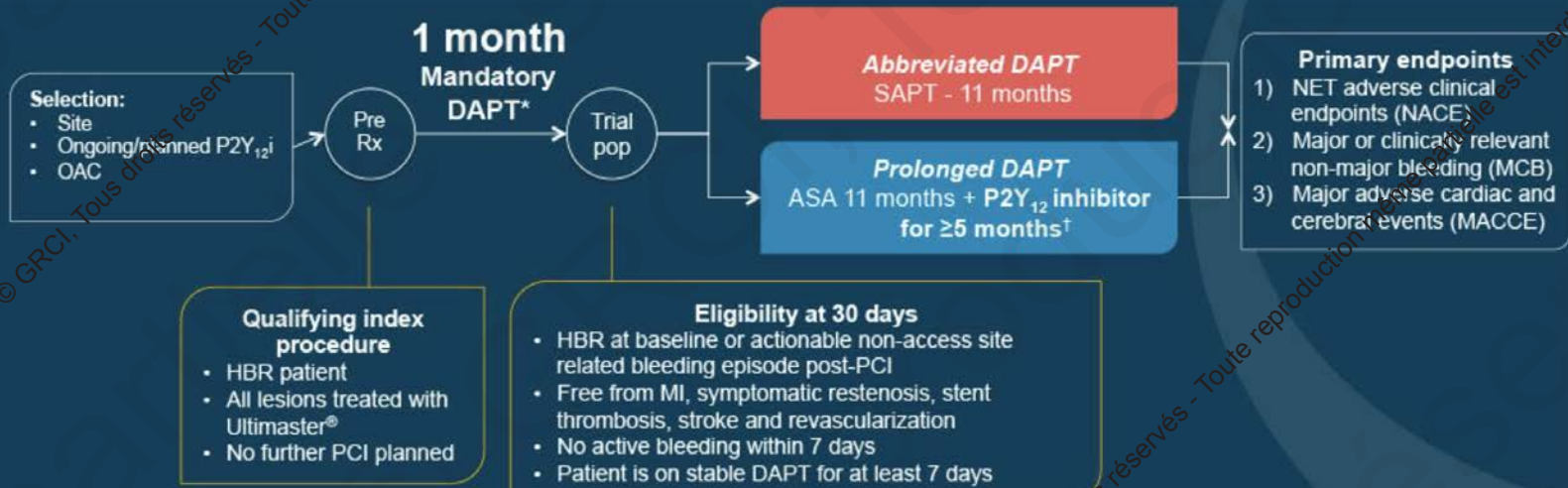
DAPT 1 mois vs 6 mois post PCI  
*DES 1 – 1mois vs DES 1- 6 mois*



# MASTER DAPT

## Study design and key features

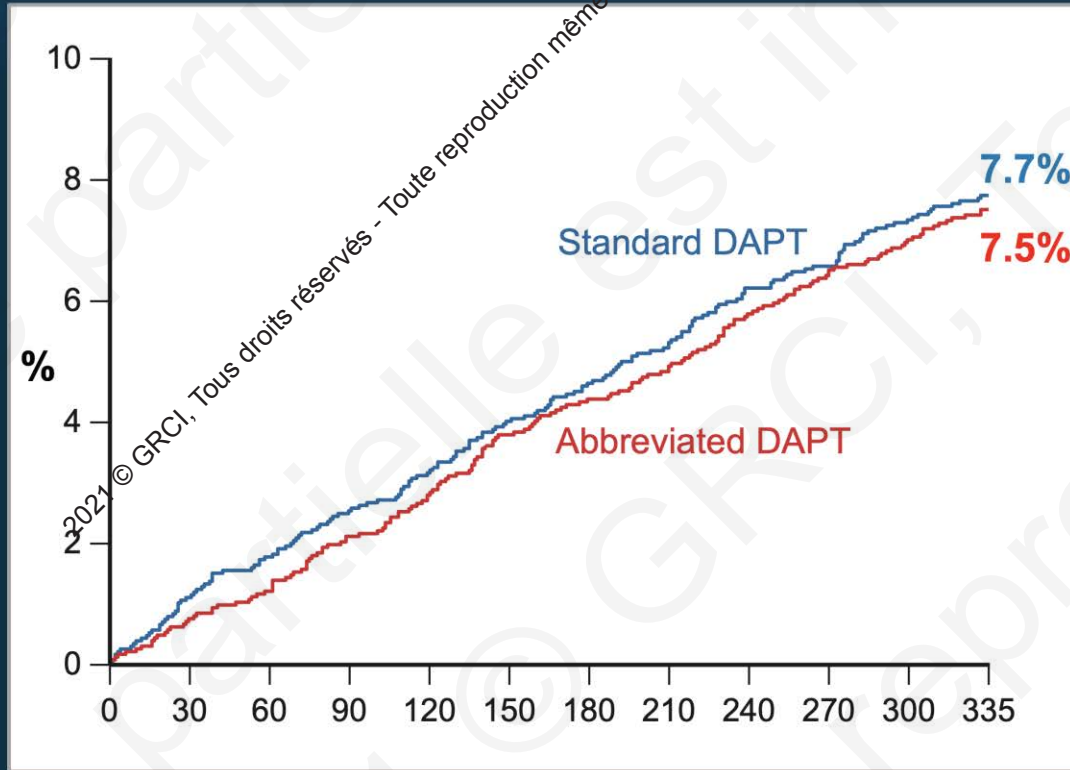
4300 patients, 150 international sites



Valgimigli et al NEJM 2021

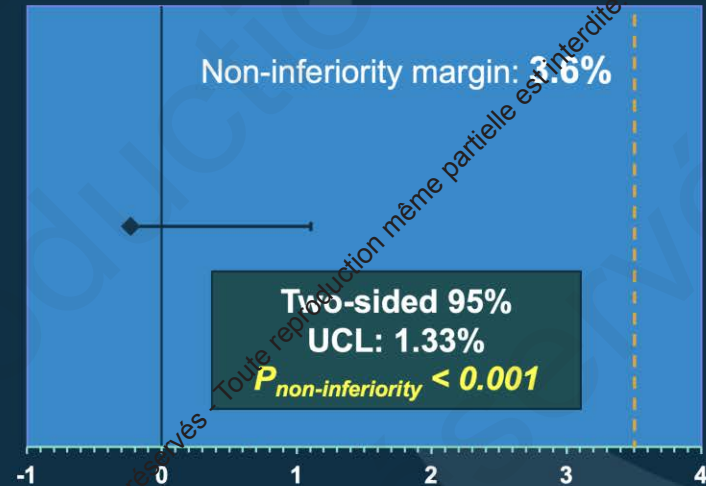
# Net adverse clinical events (NACE)

Per protocol population



## Non-inferiority Analysis

Difference in cumulative incidence, -0.23



**NACE:** All-cause death, MI, stroke, and major bleeding events defined as BARC 3 or 5

Valgimigli et al NEJM 2021



**Bleeding risk > Ischemic risk**

## short duration of DAPT

Chronic coronary syndrome



**1 (IIb)- 3 month (IIa)**

Actute coronary syndrome



**6 month (IIa)**

ESC guidelines

# De escalade

De escalation : **intense P2Y<sub>12</sub> inhibitor** → **Clopidogrel**

TOPIC, ANTARCTIC, TROPICAL, POPULAR AGE, POPULAR GENETIC

“De escalation” : retrait aspirine, **P2Y<sub>12</sub> monothérapie**

- Clopidogrel après 1 mois (STOP DAPT 2/STOP DAPT 2 ACS) 3 mois (SMART CHOICE)
- Ticagrelor after 1-3 months (GLOBAL LEADERS/TWILIGHT/TICO)
- P2Y12 1 mois après ACS (TARGET FIRST)

# Conclusion

**Les progrès techniques des stents actifs permettent d'envisager une durée minimale très courte de bithérapie ( 1mois)**

**Les patients à haut risque hémorragique bénéficient de cette stratégie sans prix à payer sur les événements ischémiques**

**Le type de traitement (Clopi/ Tica-prasu) et sa durée doivent être adaptés à chaque patient**