

Gestion du patient coronarien âgé  
(haut risque hémorragique)  
Quelle DAPT au décours ?  
Plus c'est long moins c'est bon ...

Pr Gilles LEMESLE

USIC et Centre Hémodynamique, CHRU de Lille

Institut Pasteur de Lille, UMR 1011

Faculté de Médecine de l'Université de Lille



# Déclaration de liens d'intérêts

- Honoraires : Amgen, Astra Zeneca, Bayer, Biopharma, Bristol Myers Squibb, Boehringer Ingelheim, Daiichi Sankyo, Lilly, MSD, Novartis, Pfizer, Sanofi Aventis, Servier, The medicine company

2021 © GRCI, Tous droits réservés - Toute reproduction même partielle est interdite.

2021 © GRCI, Tous droits réservés - Toute reproduction même partielle est interdite.

# Problèmes du sujet âgé

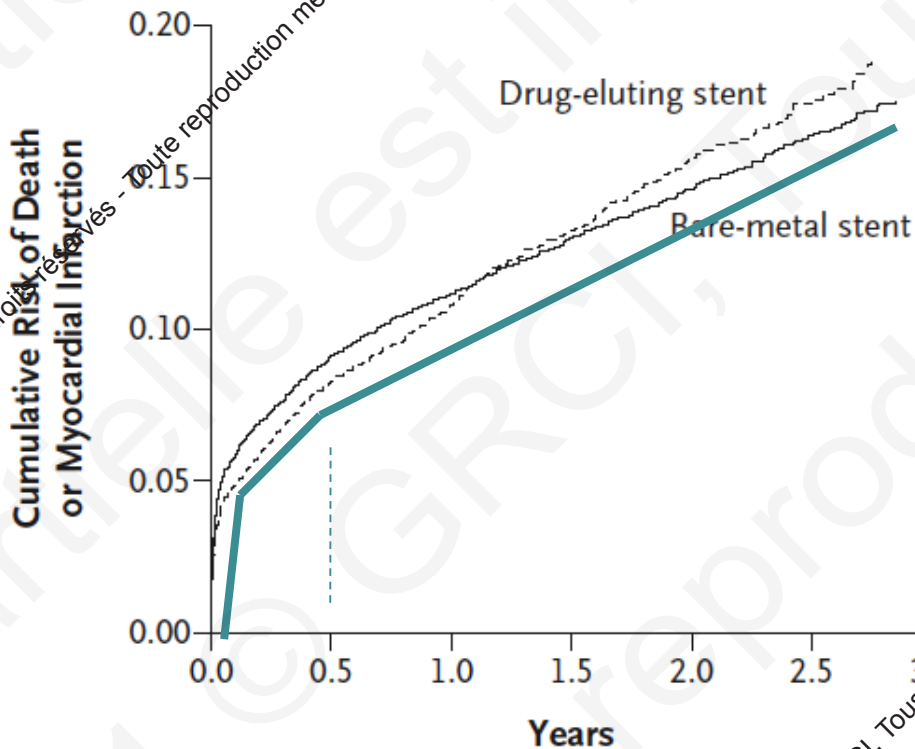
---

- Nombreuses co-morbidités
  - Risque d'événement ischémique accru
  - Risque hémorragique accru
  - Insuffisance rénale => Risque de surdosage/accumulation des traitements
  - Anémie
  - Fragilité vasculaire
  - Forte prévalence de la FA et nécessité d'anticoagulation
- Lésions coronaires plus complexes (calcifications, atteinte diffuse, ...)



# Natural history after an acute coronary event

Adjusted Composite Event



Stability at 6 months

**No. at Risk**

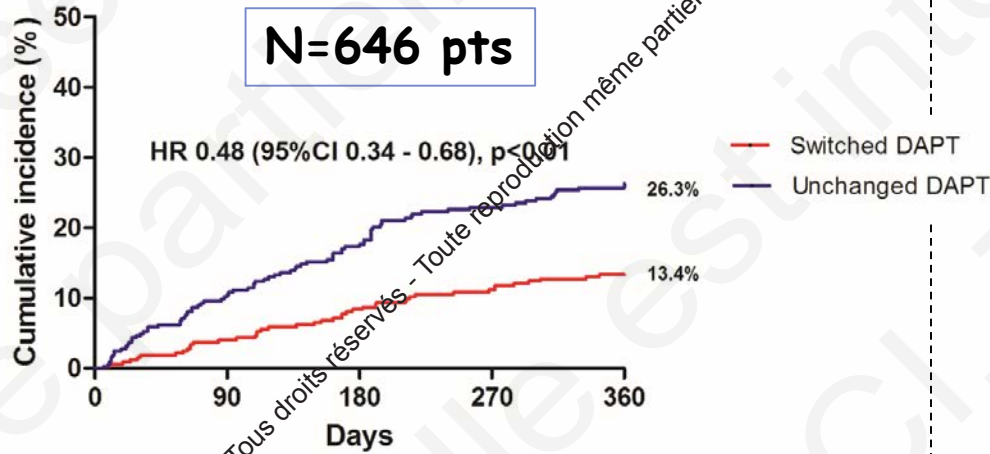
Bare-metal stent	12,880	11,706	11,432	8665	5520	2963	7
Drug-eluting stent	5,770	5,307	5,158	3216	1608	580	0

# La dé-escalation

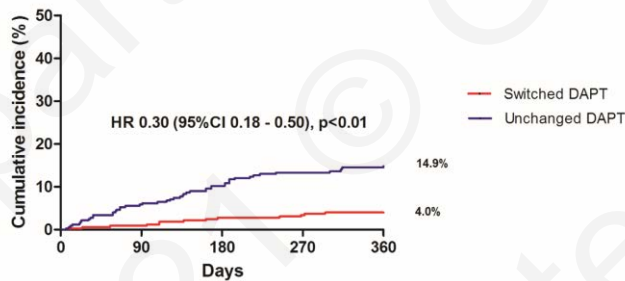
2021 © GRCI, Tous droits réservés - Toute reproduction même partielle est interdite.

2021 © GRCI, Tous droits réservés - Toute reproduction même partielle est interdite.

## Primary Endpoint Death, Urgent revasc., Stroke, BARC $\geq 2$

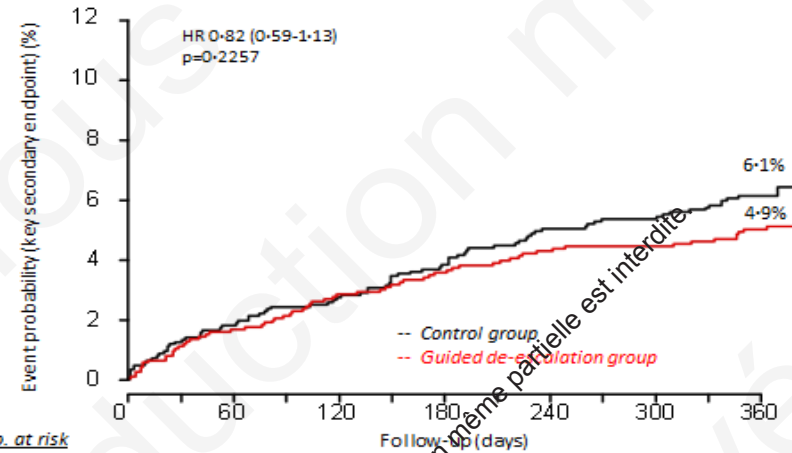


### BARC bleedings $\geq 2$



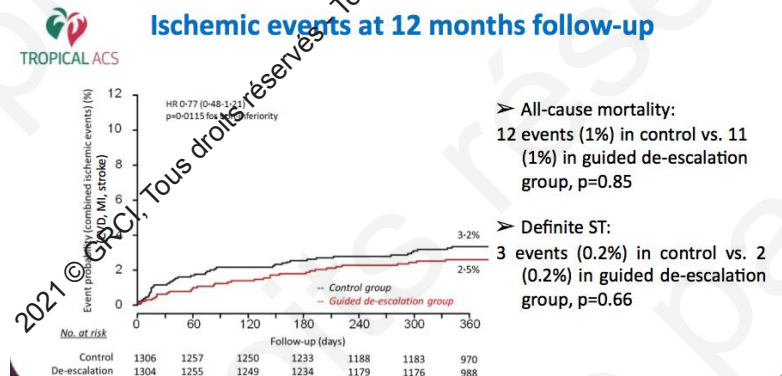
ENDPOINTS	Switched DAPT (n=322)	Unchanged DAPT (n=323)	HR (95%CI)	P-value
TIMI Major	1 (0.3%)	4 (1.2%)	0.30 (0.05 - 1.73)	0.18

## Key Secondary endpoint Bleeding BARC $\geq 2$



No. at risk	0	60	120	180	240	300	360
Control	1306	1253	1240	1214	1158	1152	950
De-escalation	1304	1244	1226	1205	1148	1145	960

### Ischemic events at 12 months follow-up



- All-cause mortality:  
12 events (1%) in control vs. 11 (1%) in guided de-escalation group,  $p=0.85$
- Definite ST:  
3 events (0.2%) in control vs. 2 (0.2%) in guided de-escalation group,  $p=0.66$

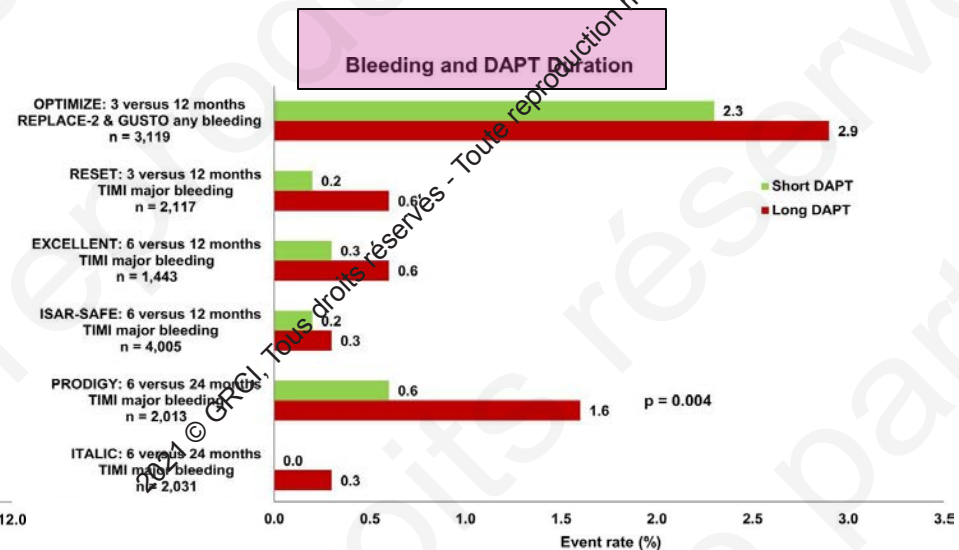
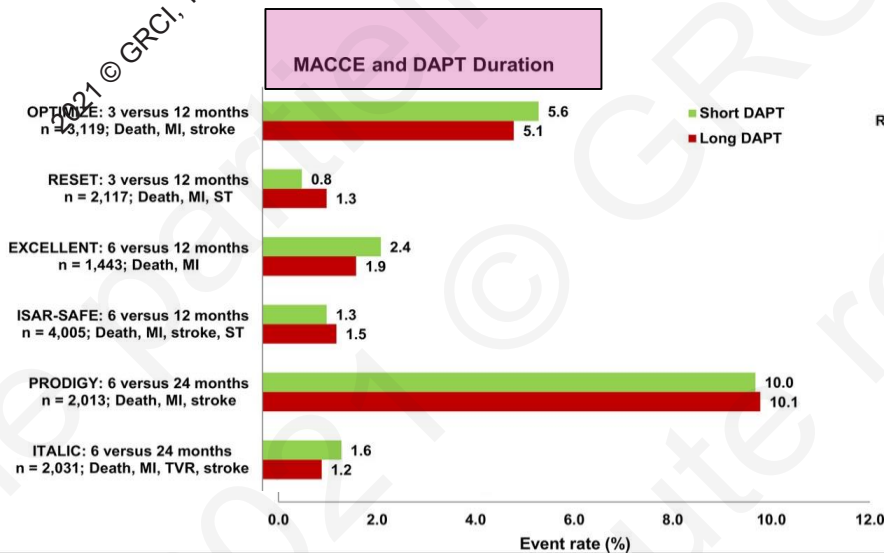
# L'arrêt précoce de la DAPT

2021 © GRCI, Tous droits réservés - Toute reproduction même partielle est interdite.

2021 © GRCI, Tous droits réservés - Toute reproduction même partielle est interdite.

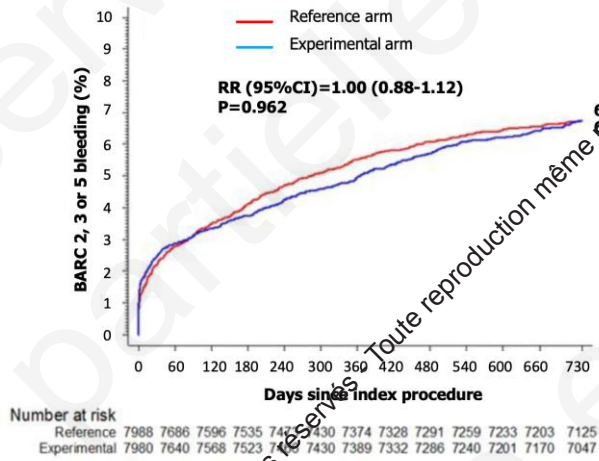
# Randomized studies

- EXCELLENT (1443 patients – 6 mois vs 12 mois) ≈50% IDM
- OPTIMIZE (3119 patients – 3 mois vs 12 mois) ≈ 5% IDM
- RESET (2148 patients – 3 mois vs 12 mois) ≈15% IDM
- PRODIGY (2013 patients – 6 vs 24 mois) ≈50% IDM
- ISAR-SAFE (4005 patients – 6 mois vs 9<sub>/12</sub> mois) ≈20% IDM
- ITALIC (2031 patients – 6 mois vs 12<sub>/24</sub> mois) ≈7% IDM
- SECURITY (1404 patients – 6 mois vs 12 mois) => Aucun IDM
- I-LOVE-2 (1829 patients – 6 mois vs 12 mois) ≈25% IDM
- IVUS-XPL (1400 patients – 6 mois vs 12 mois) ≈15% IDM
- HIPPO (3773 patients – 6 mois vs 18 mois) ≈15% IDM
- SMART-DATE (2712 patients – 6 mois vs 12 mois) ≈70% IDM
- MASTER-DAPT (2913 patients in the no-OAC group – 1 mois vs 12 mois) ≈30% IDM

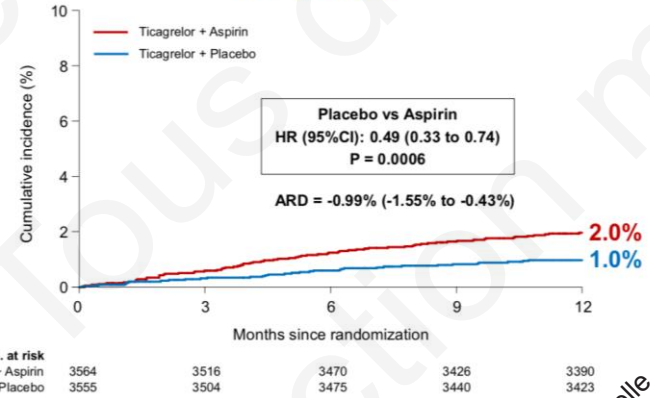




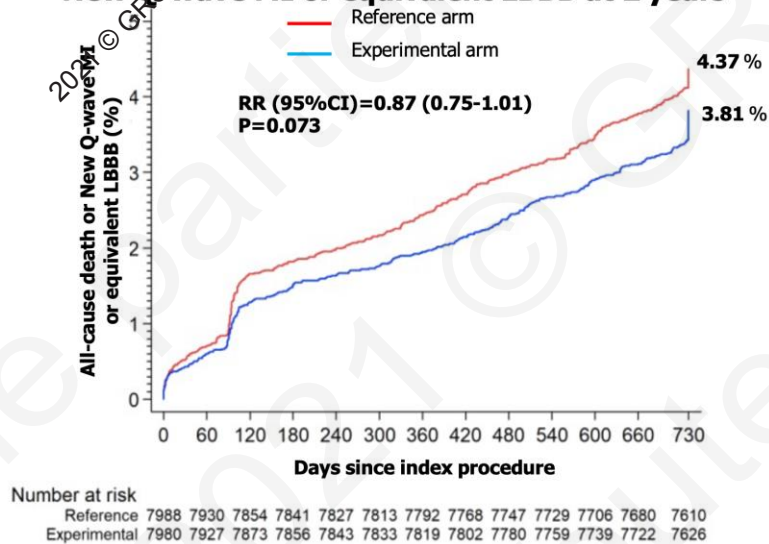
## Kaplan Meier estimate of BARC 2, 3 or 5 bleeding at 2 years



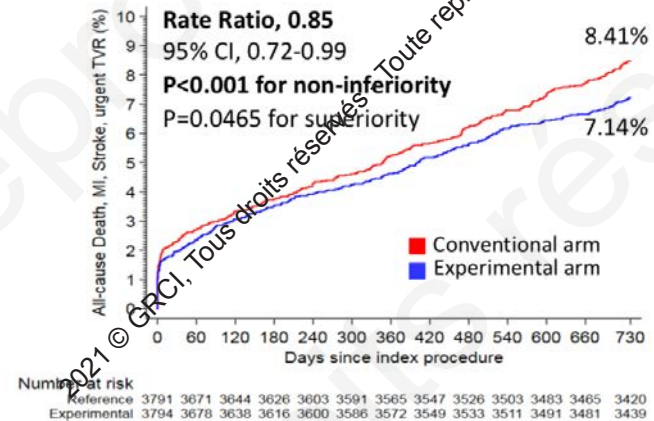
## BARC 3 or 5 Bleeding ITT Cohort



## Kaplan Meier estimate of all-cause death or New Q-wave MI or equivalent LBBB at 2 years



## ISCHAEMIC ENDPOINT



# Conclusion

- The discharge letter must mention the initial strategy that relies on the **interventional cardiologist** decision
  - 3-6 months for scheduled PCI
  - 12 months in case of ACS } The default strategy => Bof !!!
- If there is a necessity to **shorten** (in case of high risk bleeding)
  - It should be mentioned why in the discharge letter, and when stop DAPT
  - In case of long-term oral anticoagulation, the discharge letter should precise what would be the strategy in the early following months
- DAPT duration must be **re-evaluated at each visit (Tolerance)**
- Encore des études à venir ...

# TARGET DAPT Trial Update

## Clinical Trial Design

Study Chair: Junbo Ge

Open label, non-inferiority trial  
Near real world-like patients with symptomatic CAD  
eligible for DES implantation  
(no lesion/vessel limitations excluding STEMI)

Firehawk DAPT 3mo  
n = 1223

1:1 randomization 2,446 patients,  
40 sites (China), Risk-based monitoring

Firehawk DAPT 12 mo  
n = 1223

Clinical/TLF

30d 3mo 6mo 12mo 18mo 2yr

Angio/OCT

Primary Endpoint: NACCE (Death / MI / Stroke / Major Bleeding (ARC 2,3or5)) at 18 months  
Secondary Endpoints: ARC defined ST, TVR, TLR, MACE, DAPT compliance,  
and major bleeding (ARC & TIMI definitions)  
Others Endpoint: Cost/effectiveness @18 months

1815 patients were enrolled at the end of Q3 2021

# TARGET SAFE Trial Update

## Clinical Trial Design

Study Chair: Yaling Han

Double blind, non-inferiority trial  
High bleeding risk PCI patients with symptomatic CAD  
eligible for DES implantation and with  
treatment of a maximum of 4 study stents

Firehawk DAPT 1mo  
n = 860

1:1 randomization 1,720 patients,  
40 sites (China), Risk-based monitoring

Firehawk DAPT 6 mo  
n = 860

Clinical/TLF

30d 3mo 6mo 12mo 18mo 2yr

Angio/OCT

Primary Endpoint: NACCE (Death / MI / Stroke / Major Bleeding (ARC 2,3or5)) at 12 months  
Secondary Endpoints: ARC defined ST, TVR, TLR, MACE, DAPT compliance,  
and major bleeding (ARC & TIMI definitions)  
Others Endpoint: Cost/effectiveness @12 months

731 patients were enrolled at the end of Q3 2021

# TARGET FIRST Trial Update

## Clinical Trial Design

Study Chair: Giuseppe Tarantini

Prospective, multicenter, open-label, randomized  
non-inferiority trial for AMI patients treated with modified  
DAPT and complete revascularization strategy  
(no lesion/vessel limitations)

Firehawk DAPT 1mo+Mono  
n = 1123

1:1 randomization 2,246 patients,  
50 sites (Europe), Risk-based monitoring

Firehawk DAPT 12 mo  
n = 1123

Clinical/TLF

30d 3mo 6mo 12mo

Angio/OCT

Primary Endpoint: NACCE (Death / non-fatal MI / Stroke / ST/ Major Bleeding (ARC 3or5)) at 11 months  
post randomization (12 months post index procedure).  
Secondary Endpoints: ARC defined ST, TVR, TLR, MACE, DAPT compliance,  
and major bleeding (ARC & TIMI definitions)

The First Patient was enrolled on March 27, 2021