Patients spécifiques: quel stent et pourquoi?

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Patients spécifiques?

Sujets âges+++

Patients sous anticoagulant au long court

- Fibrillation atriale
- Valve mécanique

Patients en attente de chirurgie

Comorbidités: cancer, corticotherapie, Anémie

Problème posé

Patient attente de chirurgie Risque hémorragique ↑

↓ ↓

Nécessité d'une bithérapie antiplaquettaire courte

2 types de DAPT

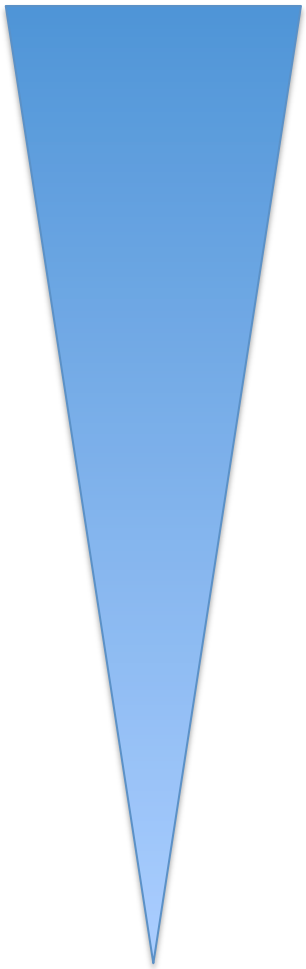
For the stent

What is the mandatory period?= minimal period of DAPT for this stent

For the patient

What is the optimal duration of DAPT for my patient

Quelle durée de DAPT ?



12 mois

6 mois

3 mois

1 mois

Is it possible to reduce this duration?

12 months to 6 months?

EXCELLENT (JACC 2012)

PRODIGY (Circulation 2012)

SECURITY (JACC 2014)

ISAR SAFE (EHJ 2015)

No ischemic risk

6 months : less bleeding

Reduce duration for 1 month?

LEADERS FREE Trial Design

Prospective, double-blind randomized (1:1) trial
2466 High bleeding risk (HBR) PCI patients

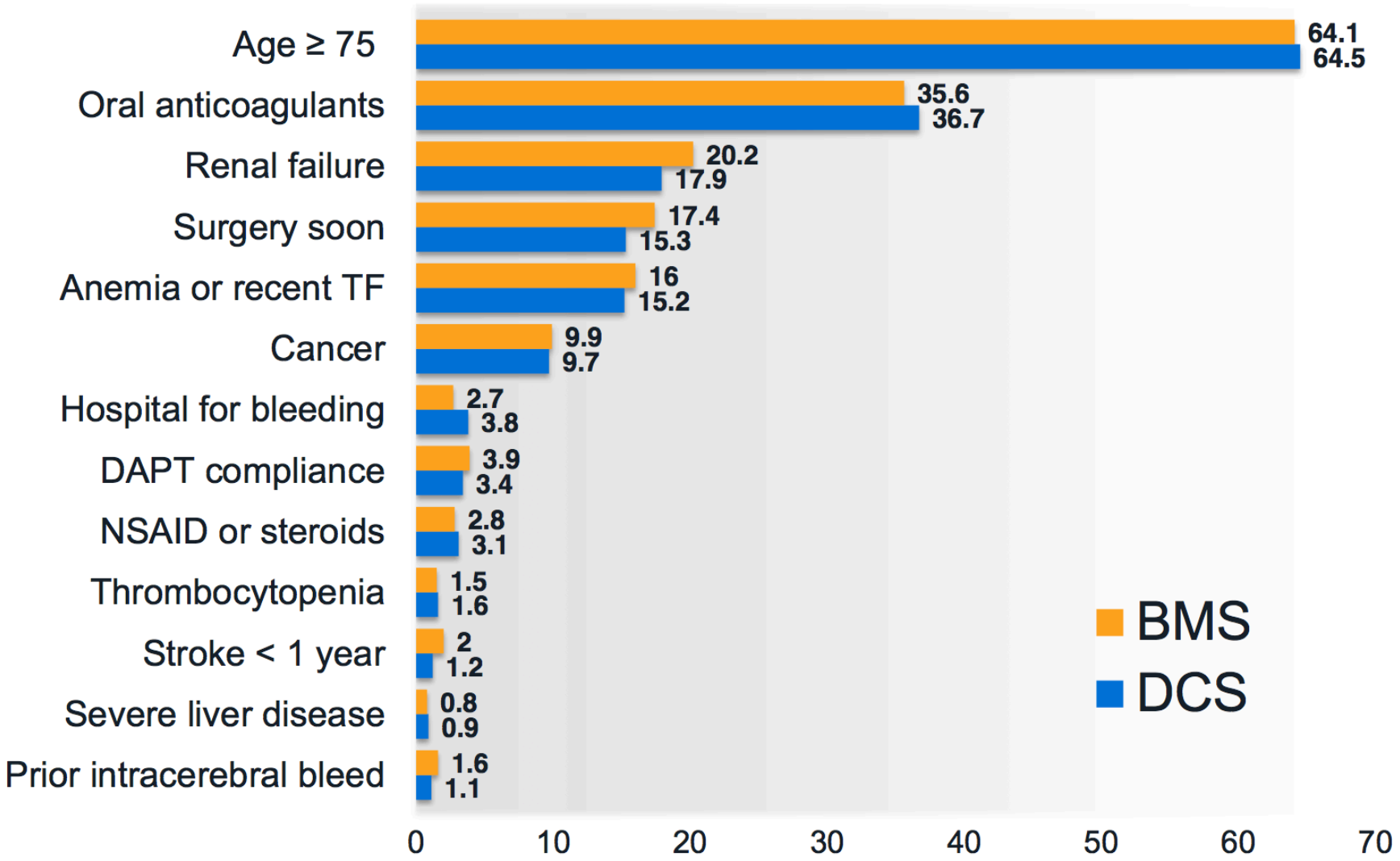
BioFreedom™ DCS **vs.** **Gazelle™ BMS**

DAPT mandated for 1 month only, followed by long-term SAPT

- **Primary safety endpoint:**
  Composite of cardiac death, MI, definite / probable stent thrombosis at 1 year (non-inferiority then superiority)
- **Primary efficacy endpoint:**
  Clinically-driven TLR at 1 year (superiority)

P Urban *et al* NEJM 2016

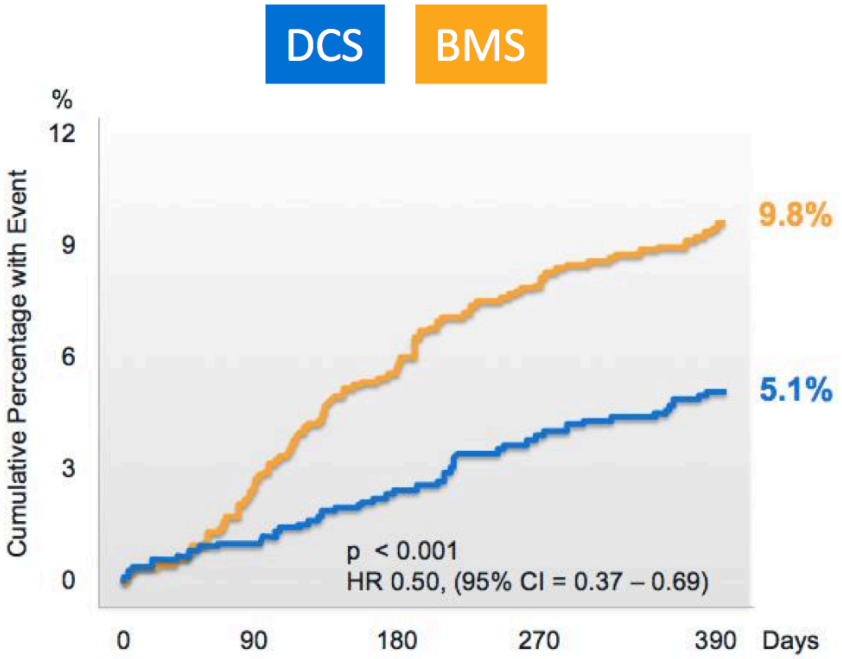
Inclusion Criteria Applied (1.7 criteria / patient)



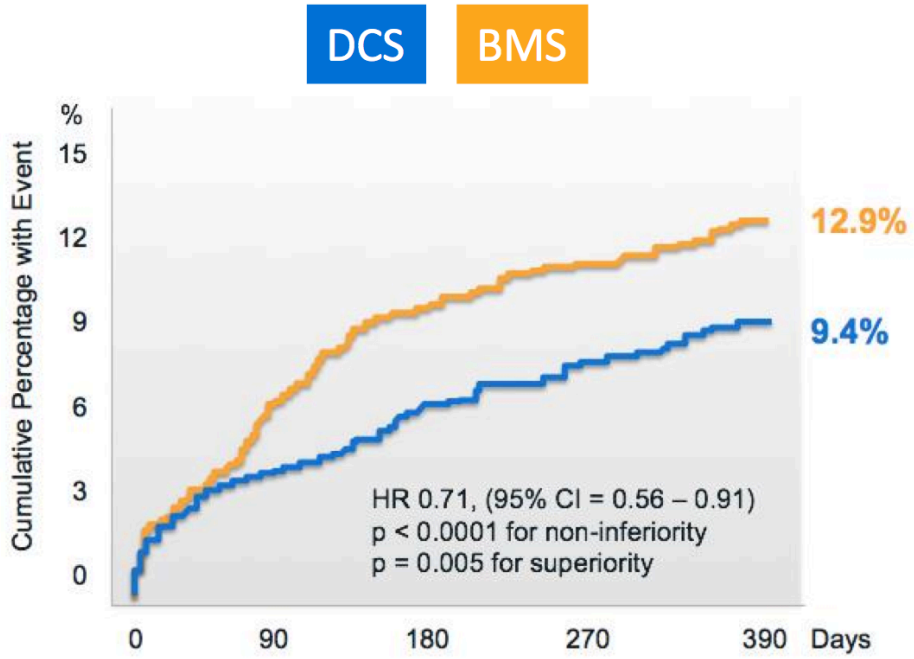
Reduce duration for 1 month?

BIOFREEDOM Stent > BMS

Efficacy (clinically driven TLR)



Safety (cardiac death, MI, ST)

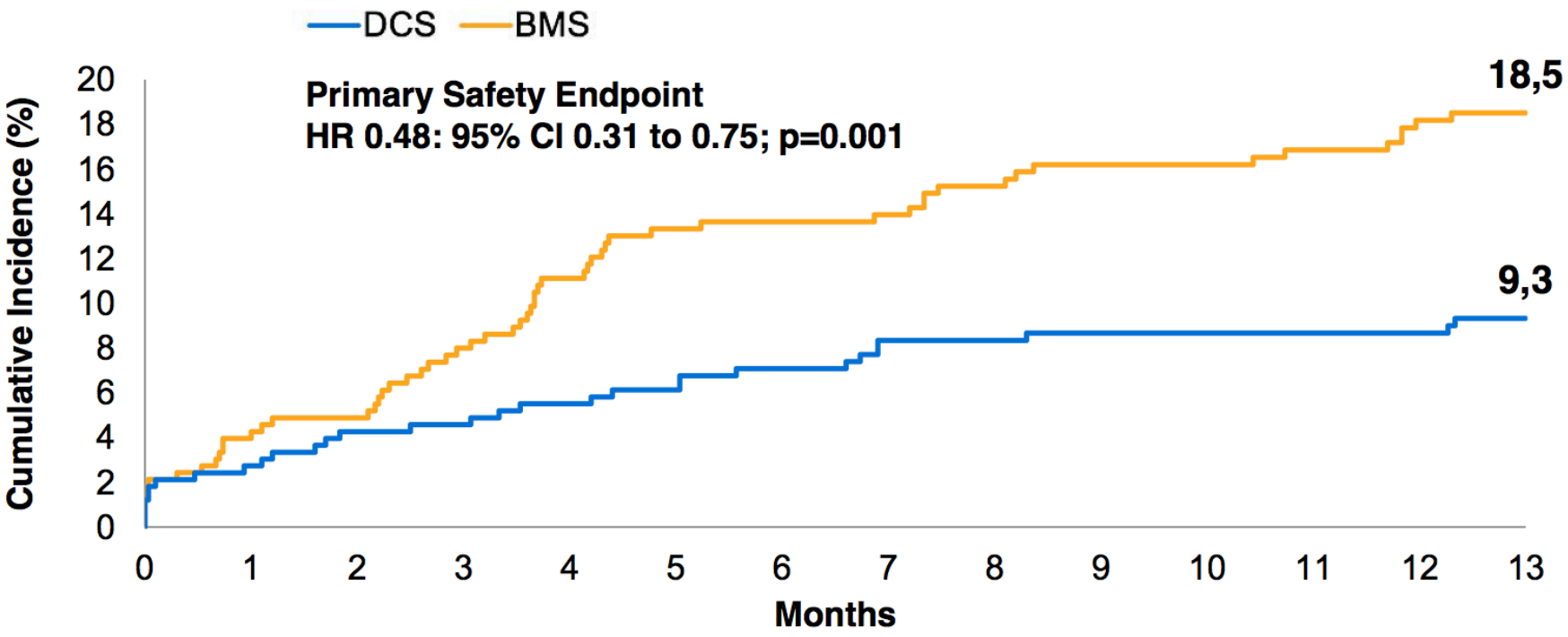


Urban P *et al* NEJM 2015

LEADERS ACS patients

Cardiac Death, MI, or Def / Prob ST- 12 Month FU

N=659 ACS patients



C Naber EHJ 2016

Conclusion LEADERS FREE

Population à haut risque hémorragique

Ce que permet de conclure leaders free

En utilisant 1 mois de DAPT

DCS > BMS

Ce que ne permet pas de conclure leaders free

1 mois DAPT est > à 6/12 mois

Comment réduire mandatory period

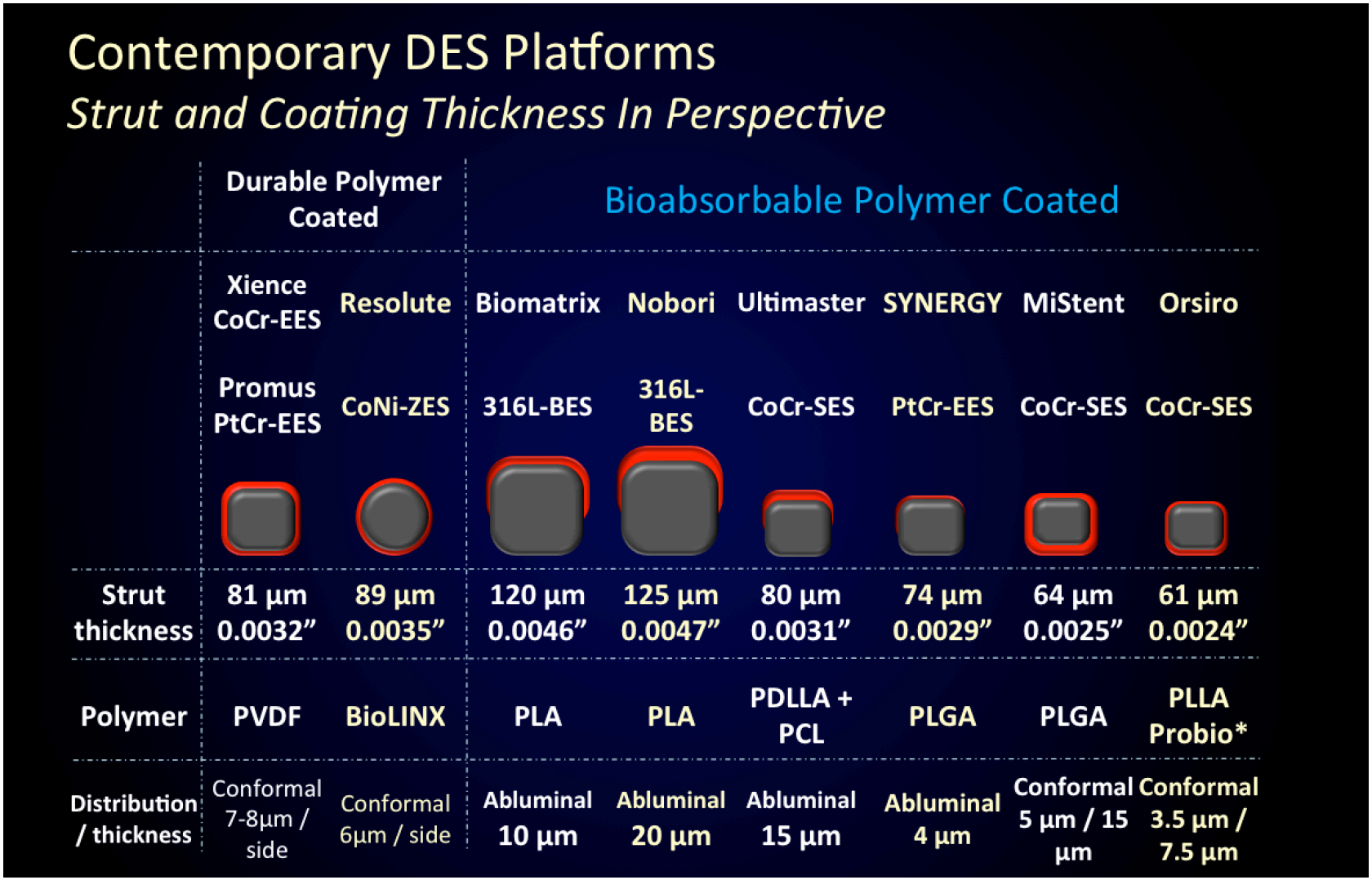
Endothelialisation rapide

Réduction taille maille

Polymère: absence /Biocompatibilité/ biorésorbable

Principe actif: cinétique de relargage?

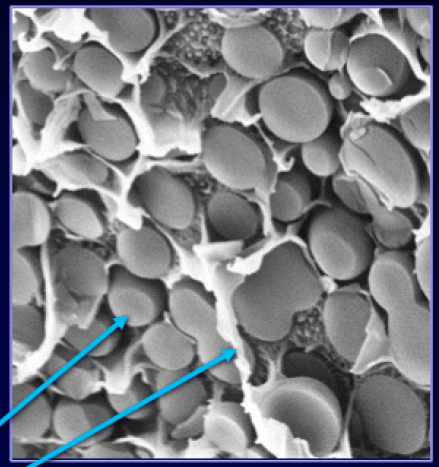
Epaisseur de maille



SYNERGY Stent Technology Design

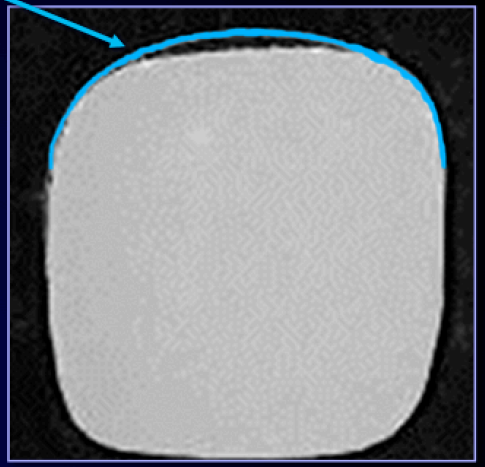
Everolimus Drug
PLGA Polymer

Drug & Polymer Coating



SEM of coating (x5000)

Abluminal (4µm)



Luminal

Platform

Platinum chromium

- 74µm (0.0029in)
- Increased Visibility

Bioabsorbable Polymer Coating

PLGA

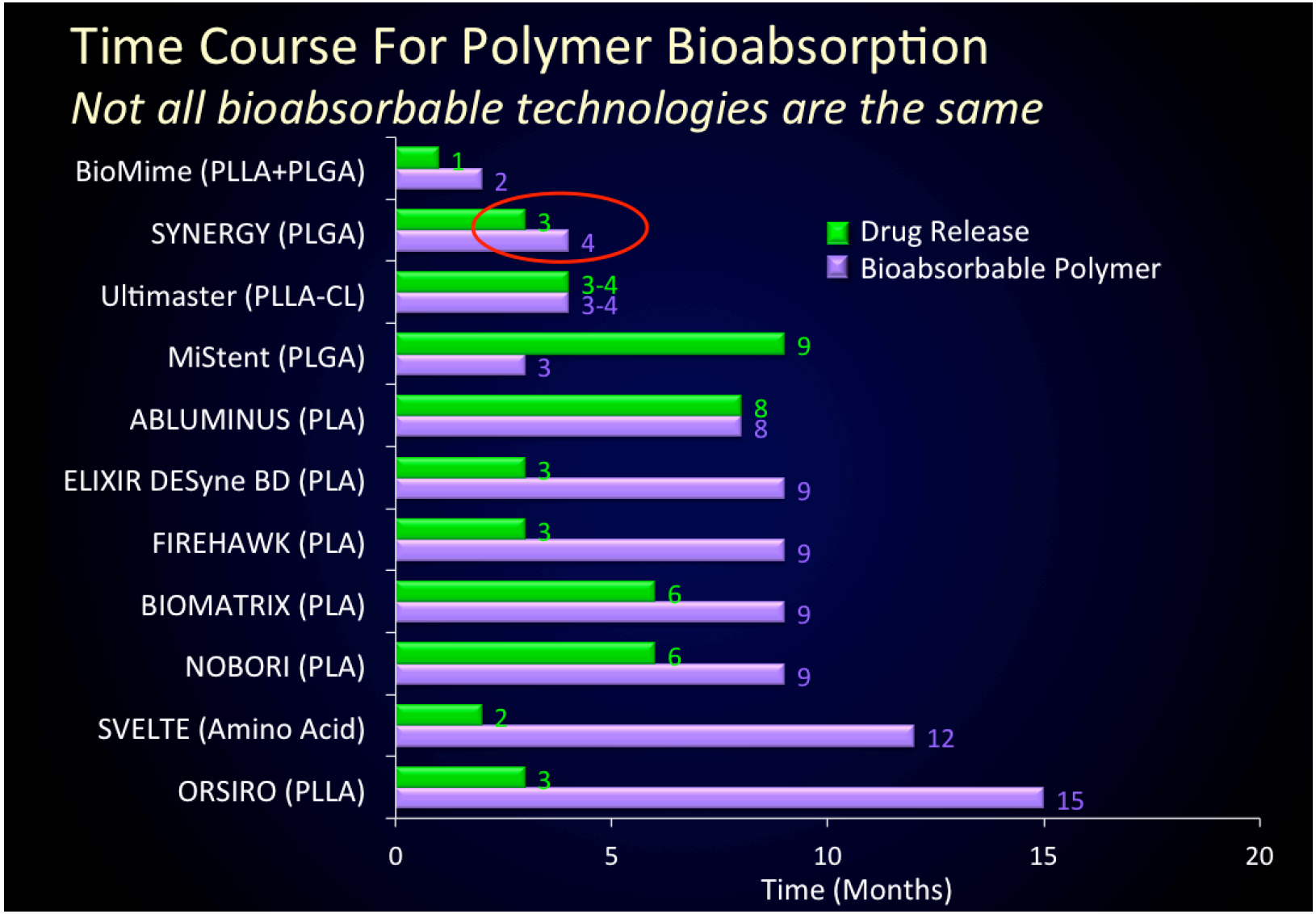
- Abluminal
- 4 µm thick
- 85:15 ratio
- < 4 month absorption time

Drug

Everolimus

- 100µg/cm^2
- 3 month release time

Polymère


Time Course For Polymer Bioabsorption
Not all bioabsorbable technologies are the same
BioMime (PLLA+PLGA)
SYNERGY (PLGA)
Ultimaster (PLLA-CL)
MiStent (PLGA)
ABLUMINUS (PLA)
ELIXIR DESyne BD (PLA)
FIREHAWK (PLA)
BIOMATRIX (PLA)
NOBORI (PLA)
SVELTE (Amino Acid)
ORSIRO (PLLA)
1
2
3
4
3-4
3-4
9
3
8
8
3
9
3
9
6
9
6
9
2
12
3
15
Drug Release
Bioabsorbable Polymer
0
5
10
15
20
Time (Months)

Etudes cliniques nécessaires?

2 types

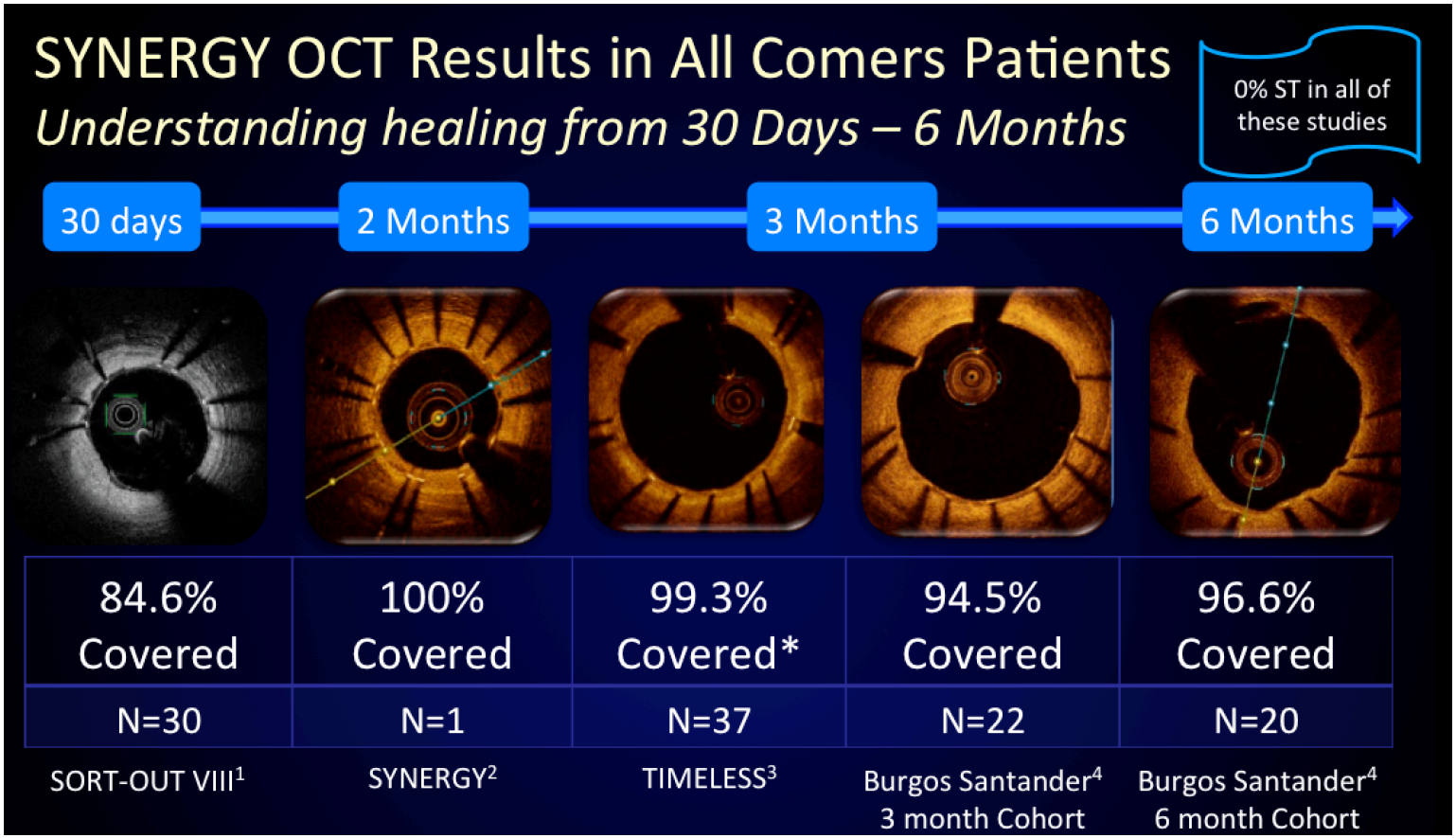
Critères intermediaires

Critères cliniques

Etudes OCT sur endothélialisation

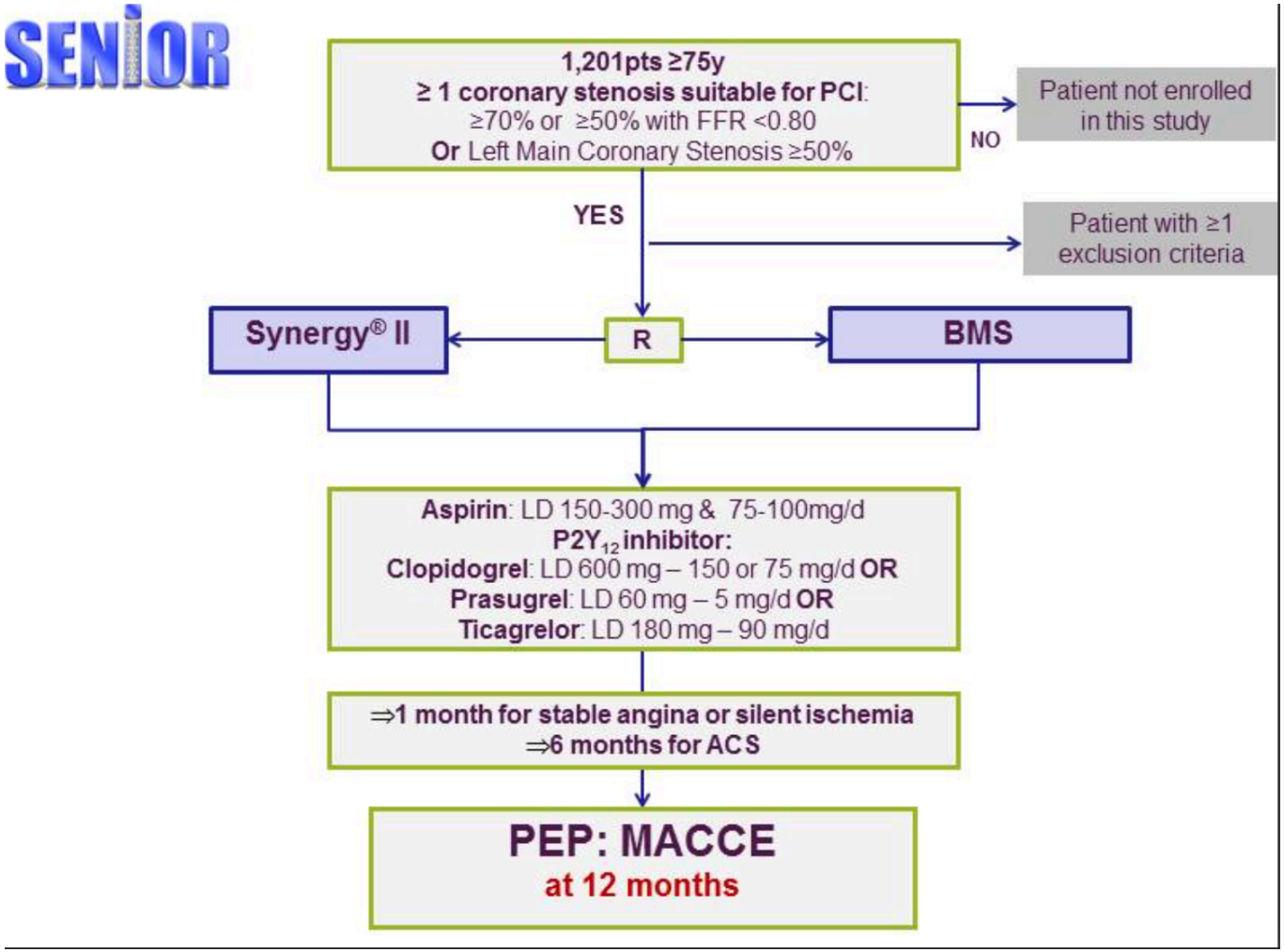
Comparaison 2 durées TT avec même device

Etudes OCT



Petites études, en faveur bonne endothelialisation précoce

Etudes clinique



EVOLVE DAPT

EVOLVE Short DAPT Study Design

Prospective, N~2000,
Up to 110 global sites

Patients considered by the treating physician to be at high risk for bleeding

i) ≥75 years of age with bleeding risk

ii) History of major bleeding

iii) Long term anticoagulation therapy

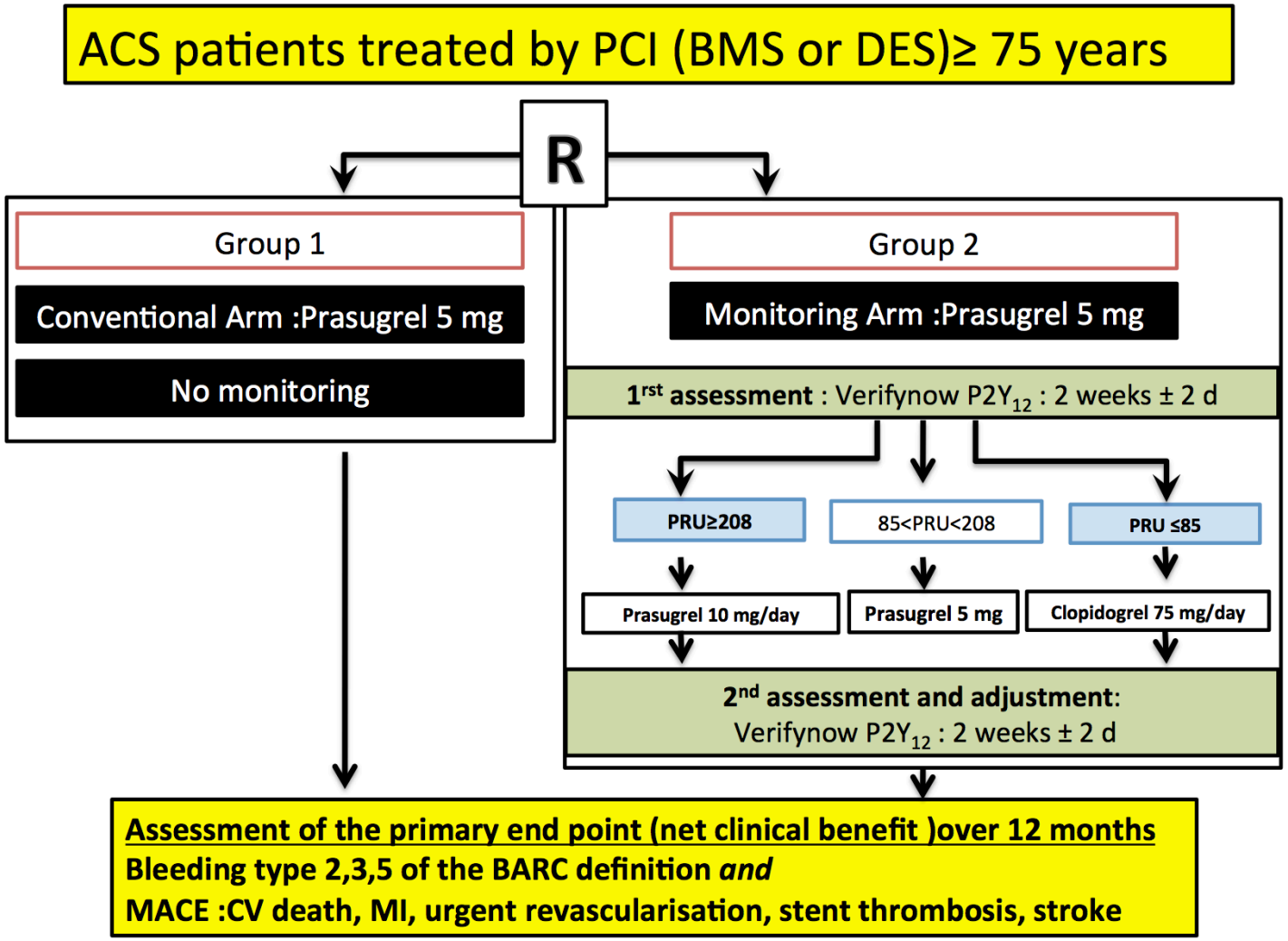
iv) Stroke or renal insufficiency/failure

(excluded LM disease, ostial lesions, >2 lesions, CTO, SVG, ISR, NSTEMI, or STEMI)

- Primary Endpoint: Death and MI, ARC definite/probable ST
- Secondary Endpoint: Rate of major bleeding (GUSTO severe/life-threatening + moderate)

Propensity adjusted comparison to historical control patients treated with standard DAPT will be performed

Autres questions: ajuster intensité tt AAP, ANTARCTIC ?



Conclusion

Patients à haut risque hémorragique

Sujets agés+++ et patients sous anticoagulant

Quel stent? DES/DCS > BMS

Amelioration stent: ↓ periode minimale

Vers une durée minimale 1 mois post DES?