

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, corticothérapie, Anémie

Problème posé

Patient attente de chirurgie Risque hémorragique ↑



Nécessité d'une bithérapie antiplaquettaire courte

2 types de DAPT

For the stent



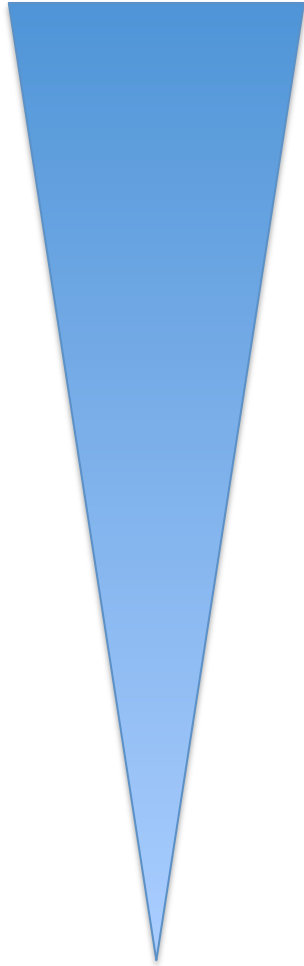
What is the mandatory period? = minimal period of DAPT for this stent

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

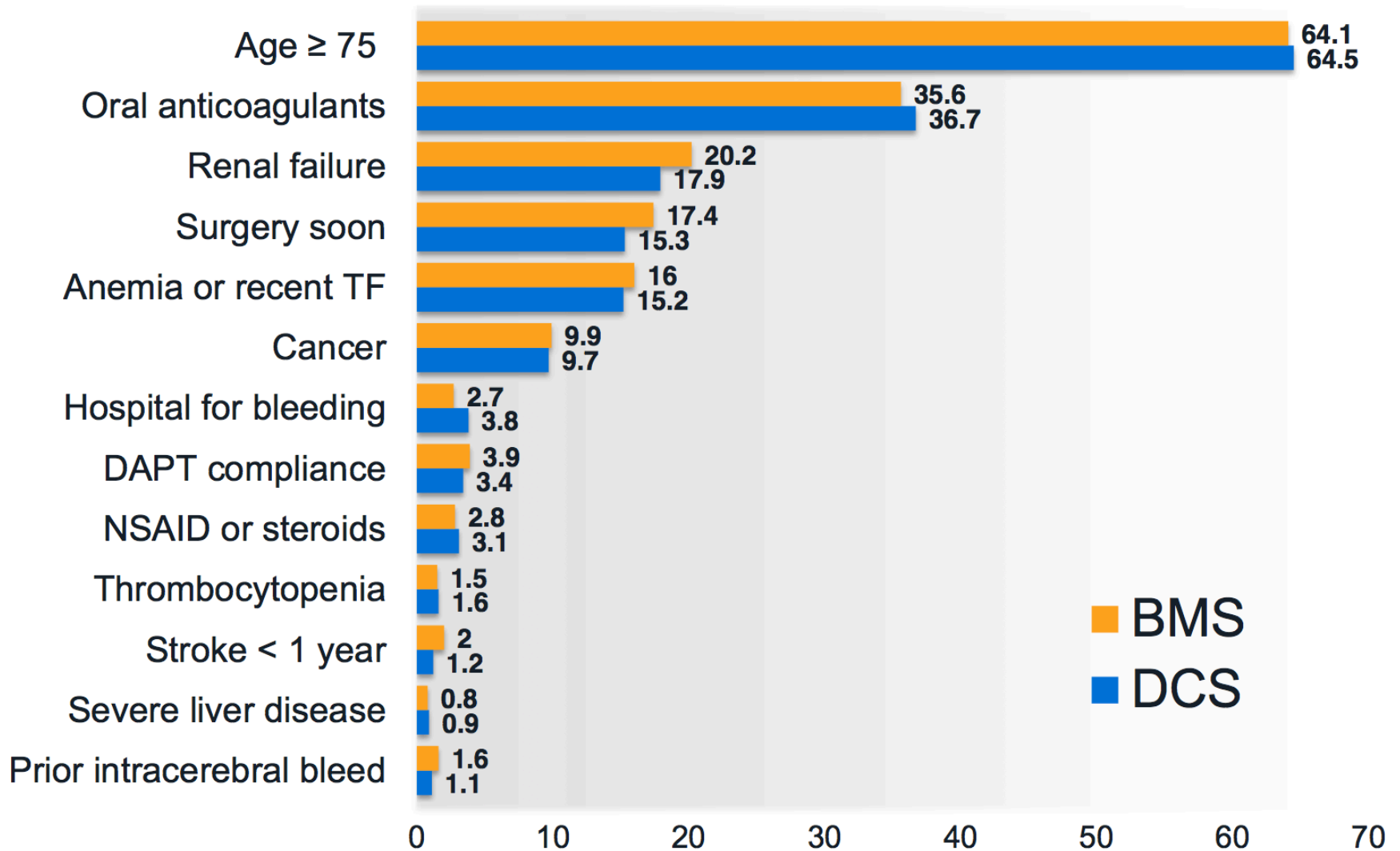
vs.

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)

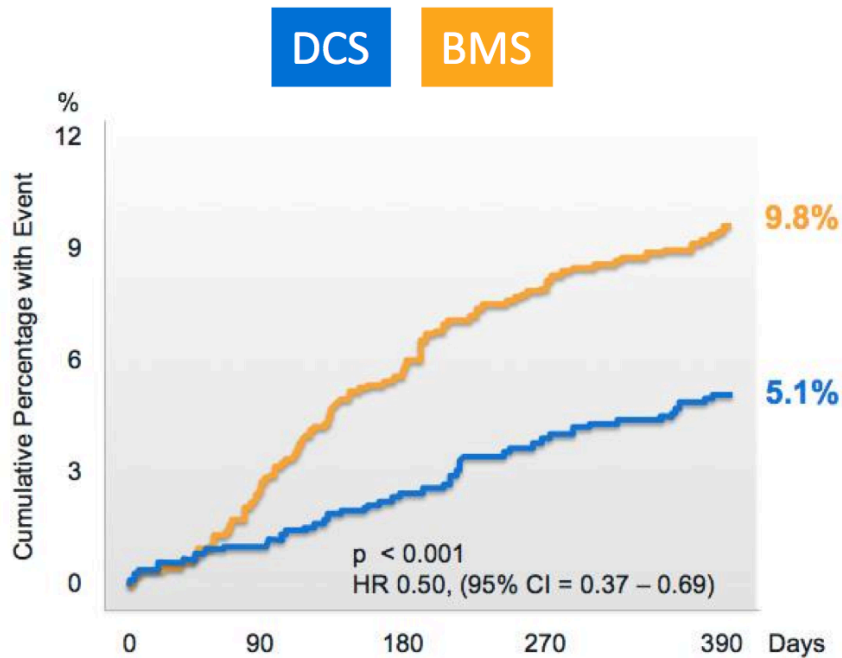
Inclusion Criteria Applied (1.7 criteria / patient)



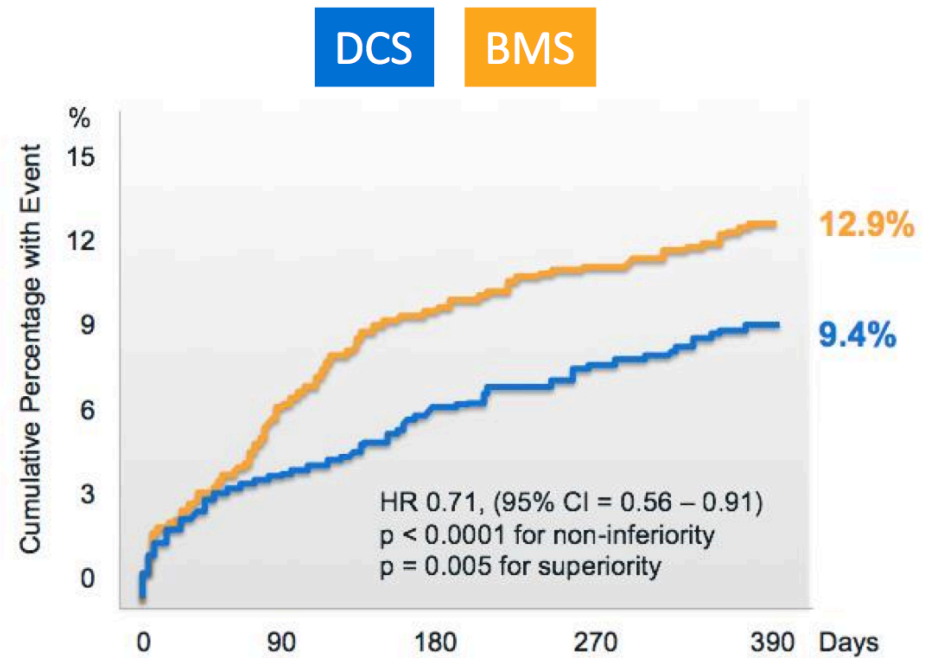
Reduce duration for 1 month?

BIOFREEDOM Stent > BMS

Efficacy (clinically driven TLR)



Safety (cardiac death, MI, ST)



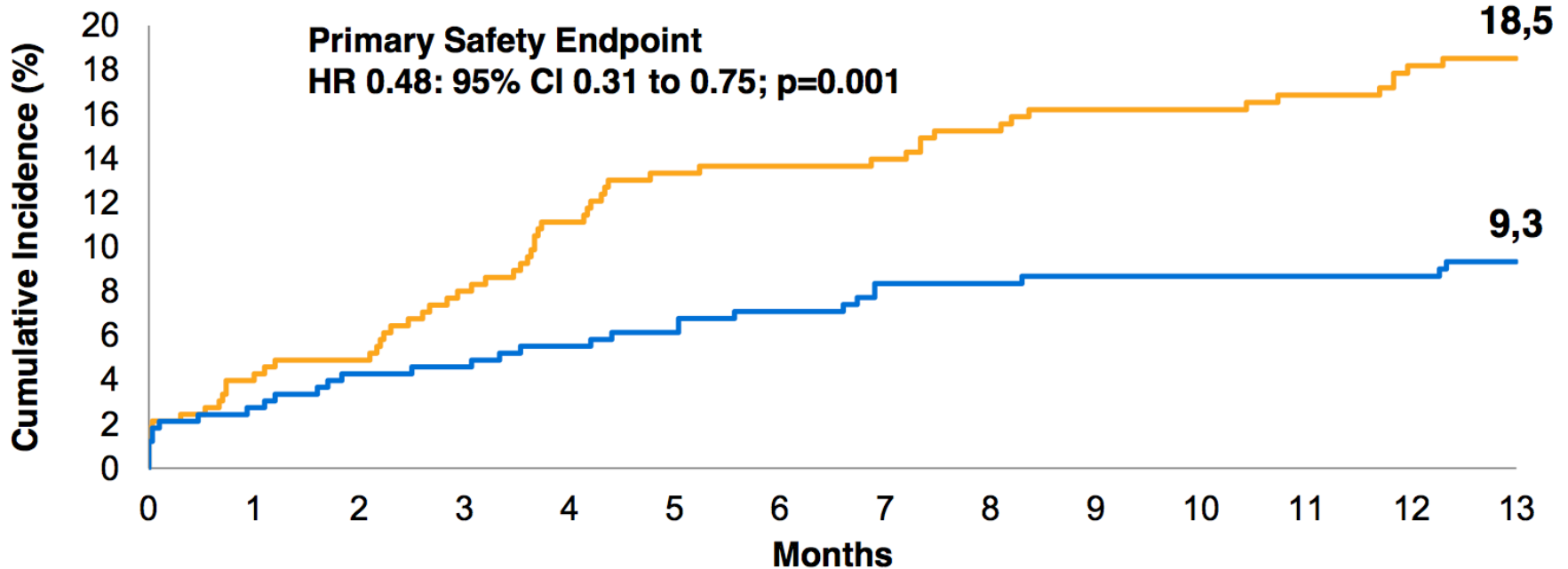
LEADERS ACS patients

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

N=659 ACS patients

— DCS — BMS

Primary Safety Endpoint
HR 0.48: 95% CI 0.31 to 0.75; p=0.001



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?

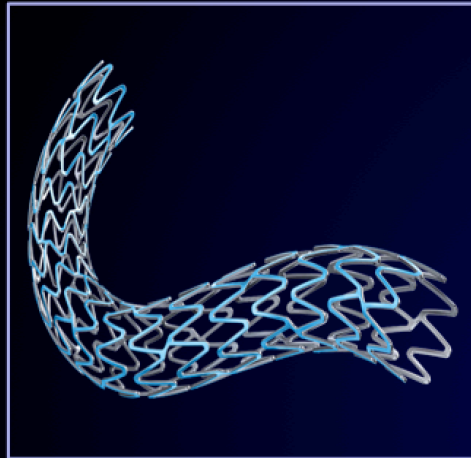
Epaisseur de maille

Contemporary DES Platforms

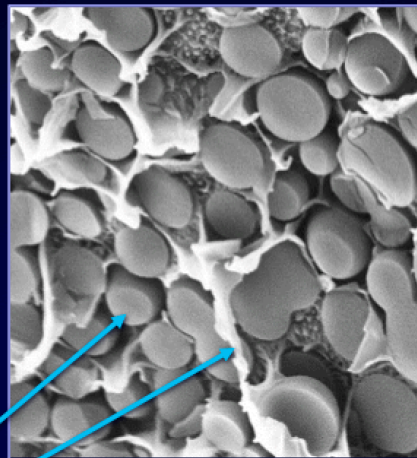
Strut and Coating Thickness In Perspective

	Durable Polymer Coated		Bioabsorbable Polymer Coated					
	Xience CoCr-EES	Resolute	Biomatrix	Nobori	Ultimaster	SYNERGY	MiStent	Orsiro
	Promus PtCr-EES	CoNi-ZES	316L-BES	316L-BES	CoCr-SES	PtCr-EES	CoCr-SES	CoCr-SES
								
Strut thickness	81 μm 0.0032"	89 μm 0.0035"	120 μm 0.0046"	125 μm 0.0047"	80 μm 0.0031"	74 μm 0.0029"	64 μm 0.0025"	61 μm 0.0024"
Polymer	PVDF	BioLINX	PLA	PLA	PDLLA + PCL	PLGA	PLGA	PLLA Probio*
Distribution / thickness	Conformal 7-8 μm / side	Conformal 6 μm / side	Abluminal 10 μm	Abluminal 20 μm	Abluminal 15 μm	Abluminal 4 μm	Conformal 5 μm / 15 μm	Conformal 3.5 μm / 7.5 μm

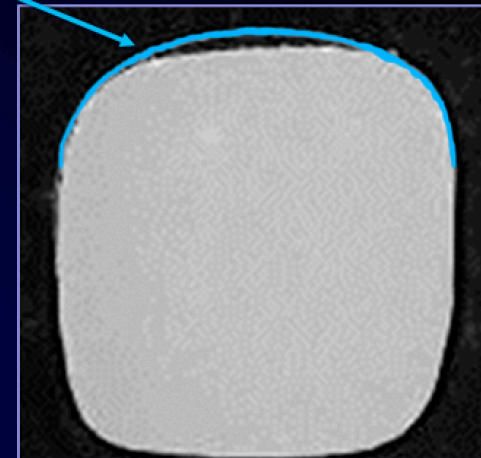
SYNERGY Stent Technology Design



Everolimus Drug
PLGA Polymer



SEM of coating (x5000)



Abluminal (4 μ m)

Luminal

Platform

Platinum chromium

- 74 μ m (0.0029in)
- Increased Visibility

Bioabsorbable Polymer Coating

PLGA

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

Drug

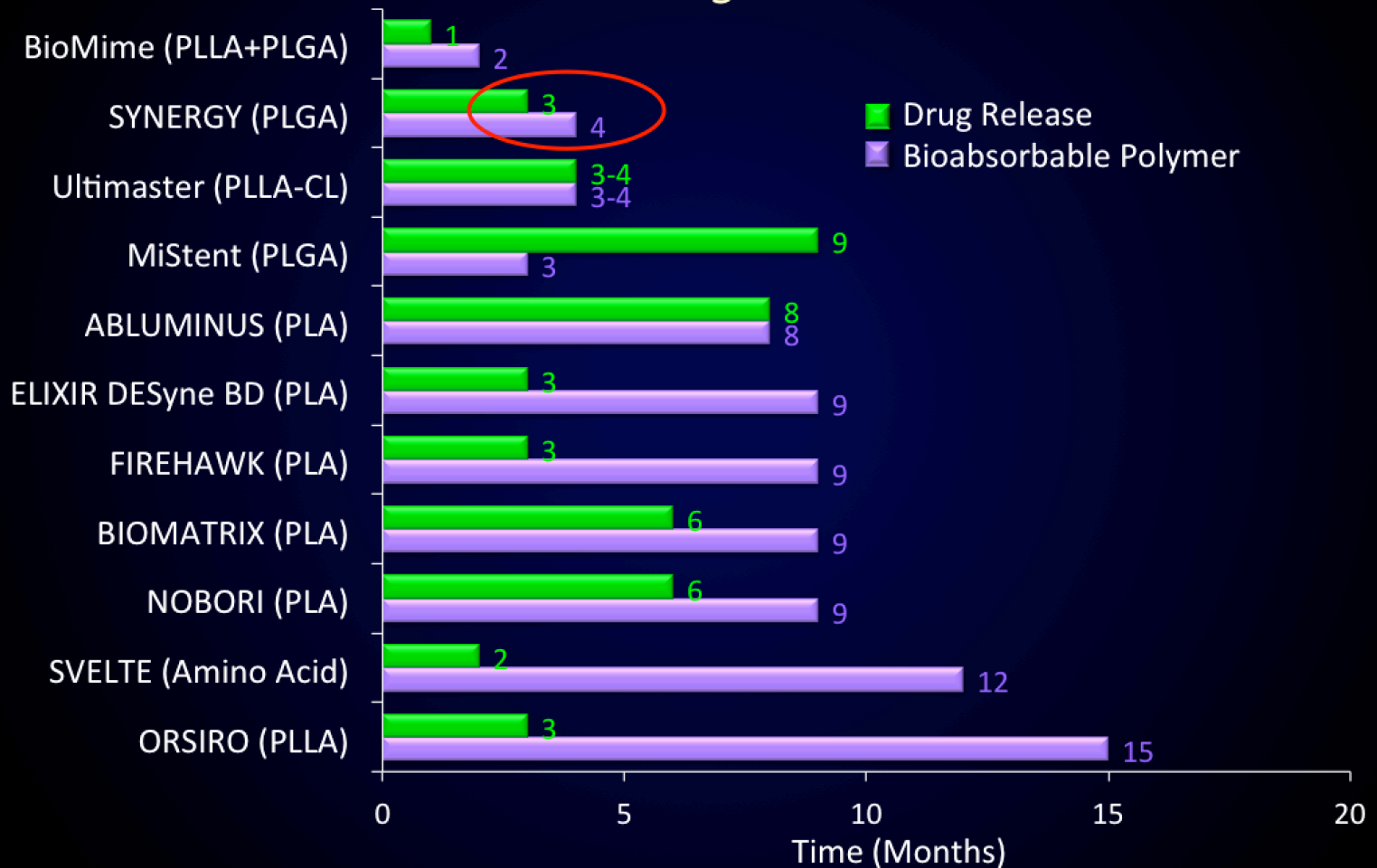
Everolimus

- 100 μ g/cm²
- 3 month release time

Polymère

Time Course For Polymer Bioabsorption

Not all bioabsorbable technologies are the same



Etudes cliniques nécessaires?

2 types

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graph TD; A[2 types] --> B[Critères intermediaires]; A --> C[Critères cliniques];
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Critères intermediaires

Critères cliniques

Etudes OCT sur endothélialisation

Comparaison 2 durées TT avec
même device

Etudes OCT

SYNERGY OCT Results in All Comers Patients *Understanding healing from 30 Days – 6 Months*

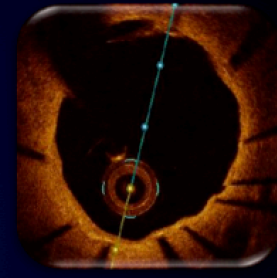
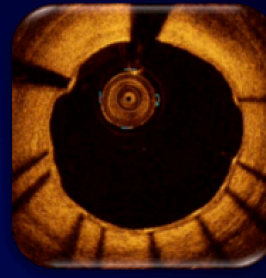
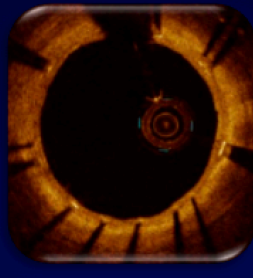
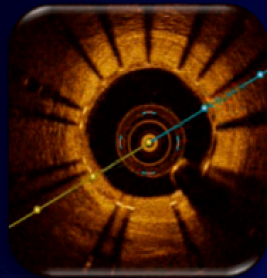
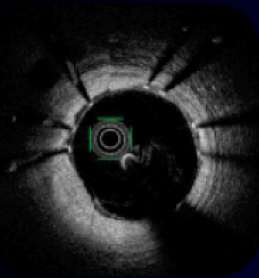
0% ST in all of these studies

30 days

2 Months

3 Months

6 Months



84.6%
Covered

N=30

SORT-OUT VIII¹

100%
Covered

N=1

SYNERGY²

99.3%
Covered*

N=37

TIMELESS³

94.5%
Covered

N=22

Burgos Santander⁴
3 month Cohort

96.6%
Covered

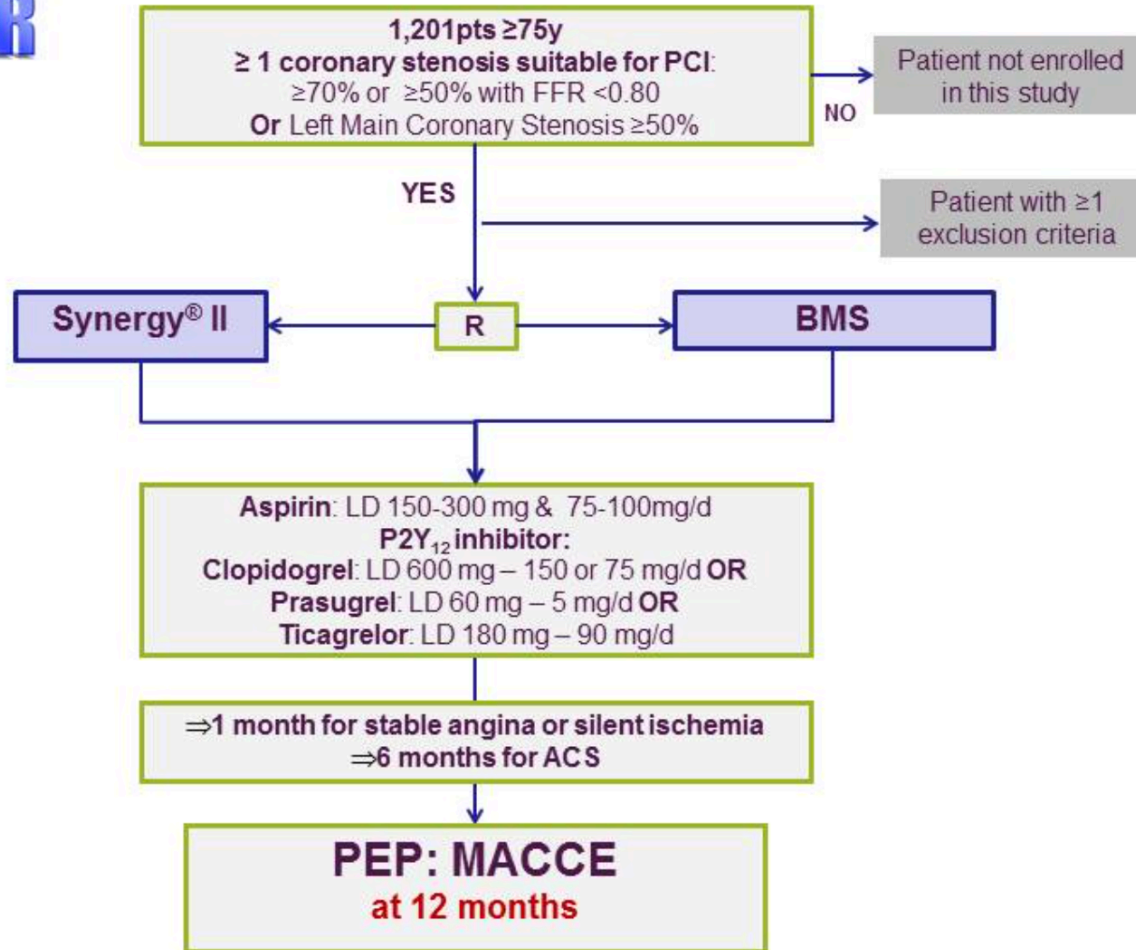
N=20

Burgos Santander⁴
6 month Cohort

Petites études, en faveur bonne endothelialisation précoce

Etudes clinique

SENIOR



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)

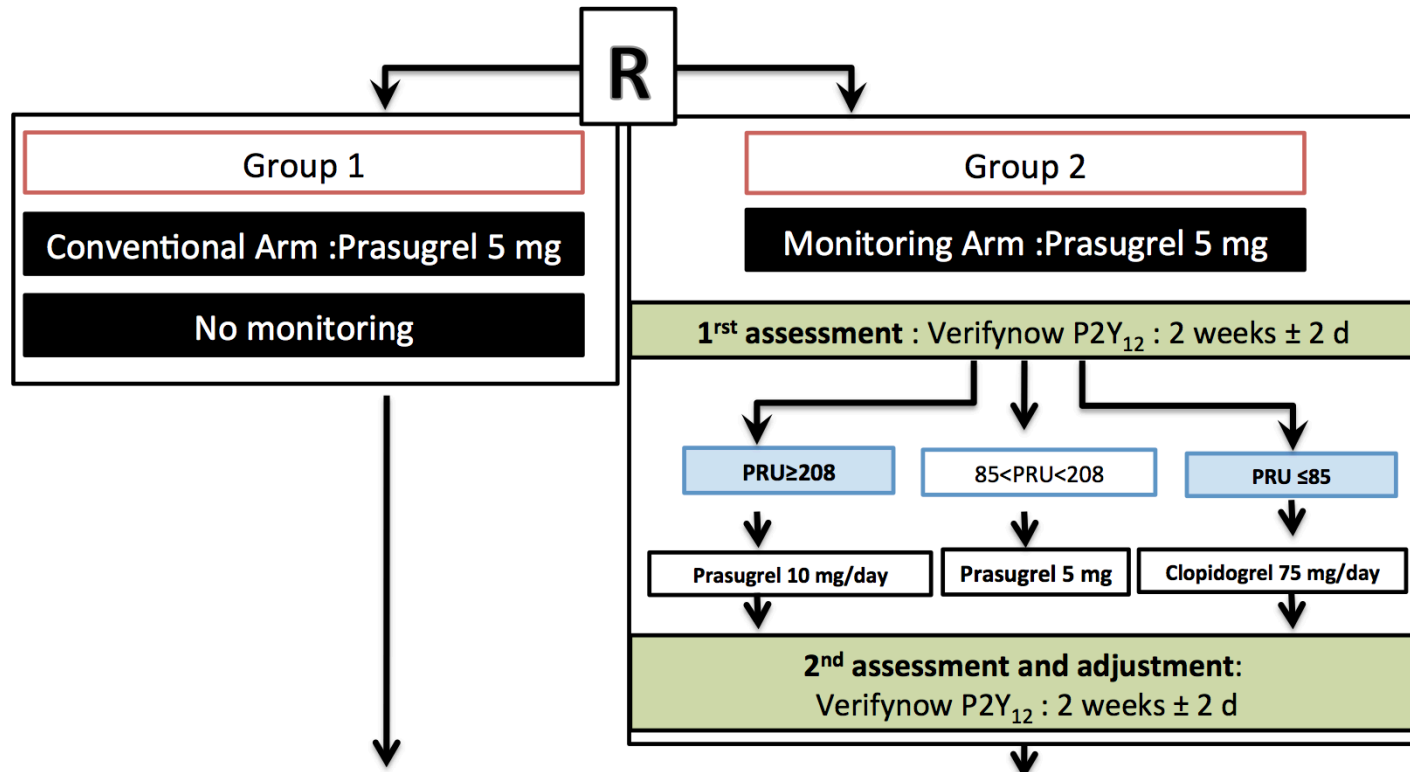


- Primary Endpoint: Death and MI, ARC definite/probable ST
- Secondary Endpoint: Rate of major bleeding (GUSTO severe/life-threatening + moderate)

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

Autres questions: ajuster intensité tt AAP, ANTARCTIC ?

ACS patients treated by PCI (BMS or DES) ≥ 75 years



Assessment of the primary end point (net clinical benefit) over 12 months
Bleeding type 2,3,5 of the BARC definition and
MACE : CV death, MI, urgent revascularisation, stent thrombosis, stroke

Conclusion

Patients à haut risque hémorragique

Sujets âgés+++ et patients sous anticoagulant

Quel stent? DES/DCS > BMS

Amélioration stent: ↓ période minimale

Vers une durée minimale 1 mois post DES?