HIGH TECH MARSEILLE

1·2·3 FÉVRIER 2023

MARSEILLE·PALAIS DU PHARO

Ballon actif et lésion de novo

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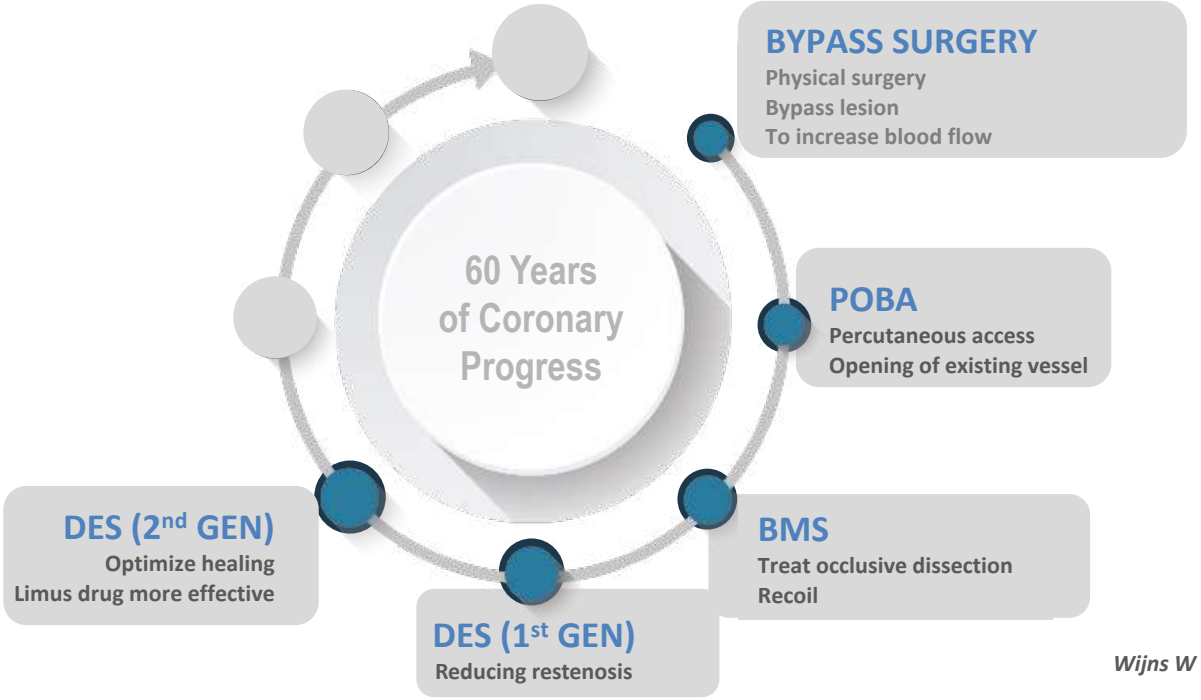
Liens d'intérêts

- **Bourses de recherche :** Abbott, Astra-Zeneca, Bayer
- **Honoraires (orateur ou consultant) :** Abbott, Amgen, Astra-Zeneca, Bayer, Bouchara-Recordati, Biotronik, BMS, Boehringer Ingelheim, Bracco, Daiichi-Sankyo, Lilly, MSD, Novartis, Novo, Organon, Pfizer, Sanofi, Servier, Sunpharm, Vifor Pharma

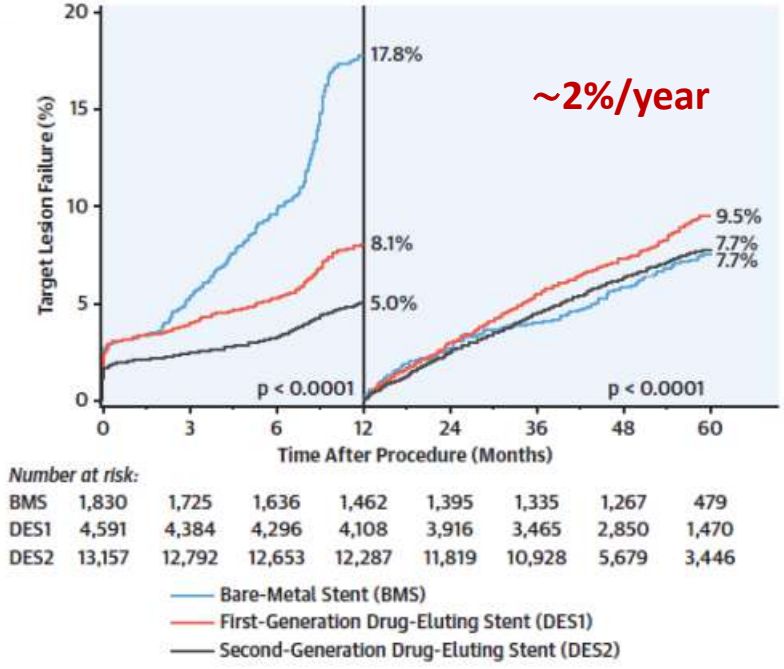
Progress in Coronary Revascularisation



Wijns W et al. European Heart Journal 2010
Jeger RV et al. Lancet 2020

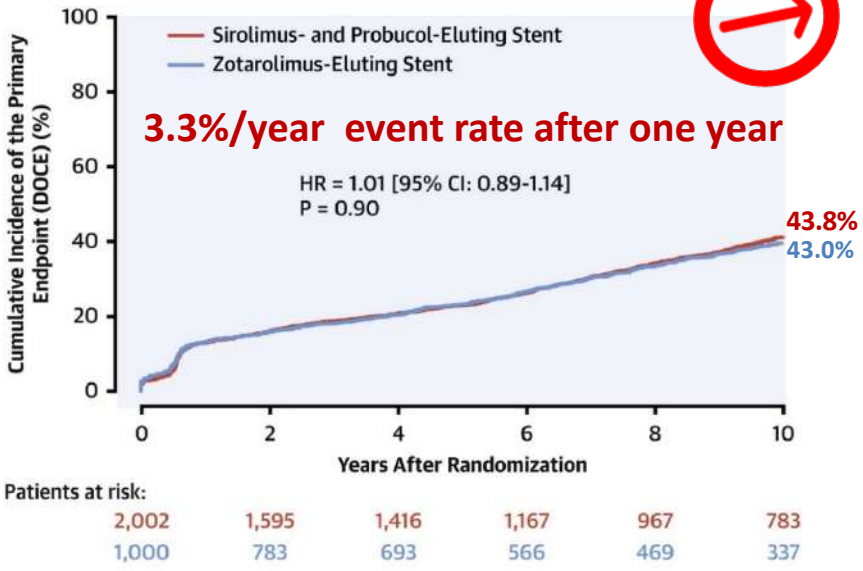
2-3%/year stent-related event rate with no plateau beyond 1 year

Meta-analysis of 19 trials
25,032 patients (5-years follow up)



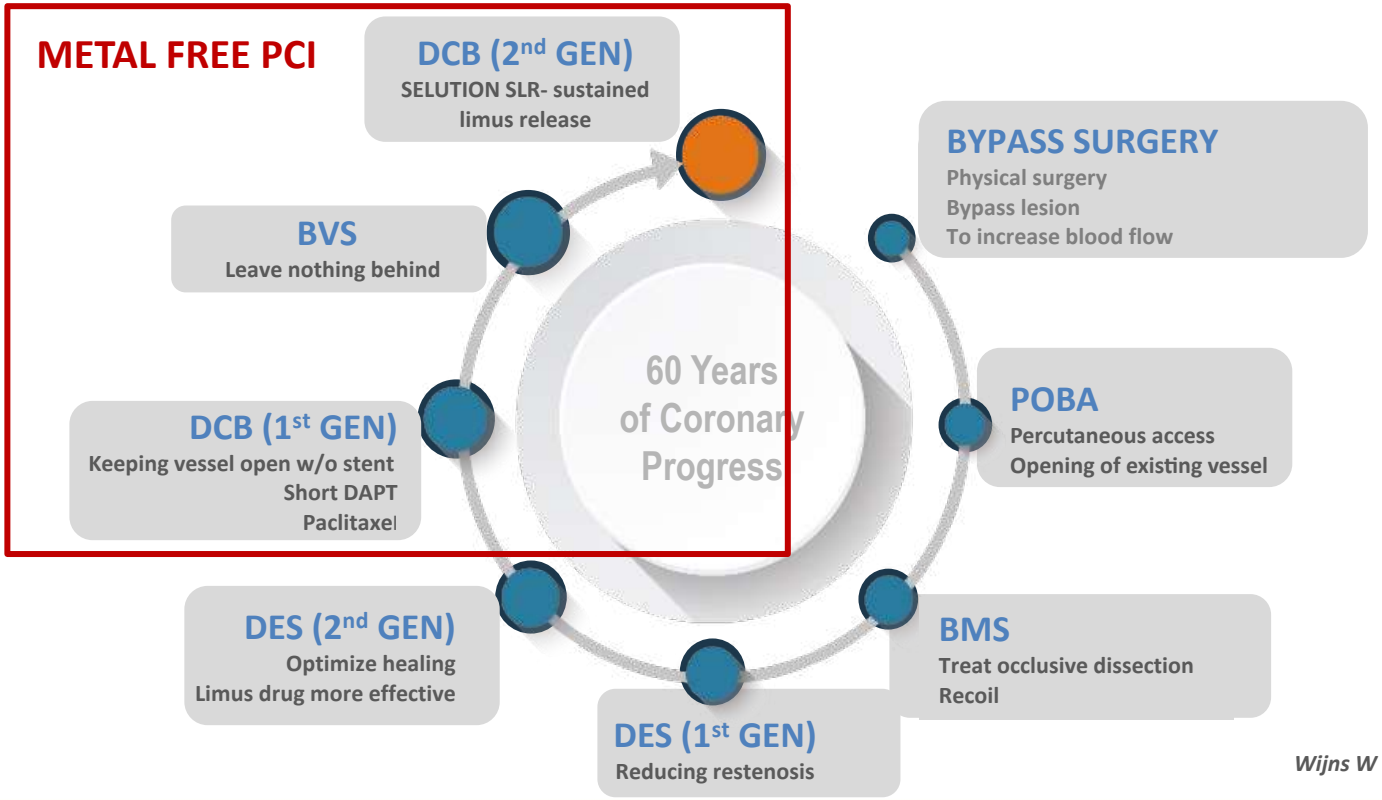
Madhavan et al. J Am Coll Cardiol. 2020

ISAR Test 5
3,002 patients



Kufner S et al. JACC 2020

Progress in Coronary Revascularisation



Wijns W et al. European Heart Journal 2010
Jeger RV et al. Lancet 2020

Recommandations and (Dis)Advantages of DCB

Advantages	• Metal free PCI • Short DAPT
Disadvantages	• Complications related to procedure
Unknow	• Long terme clinical outcomes in patients with de novo lesion (> 3mm)

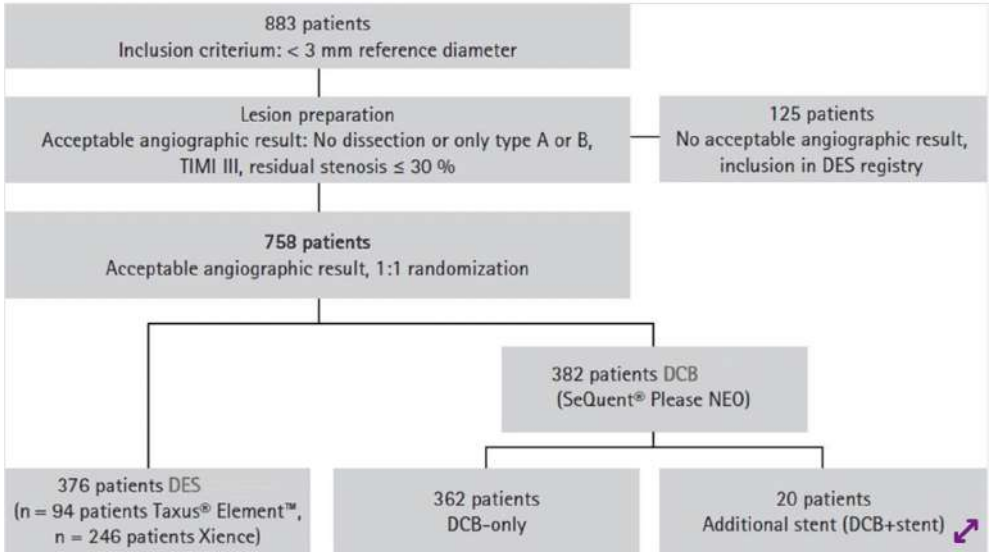
Restenosis		
Drug-coated balloons for the treatment of in-stent restenosis of BMS or DES	**I**	**A**

16.1.4 Drug-coated balloons

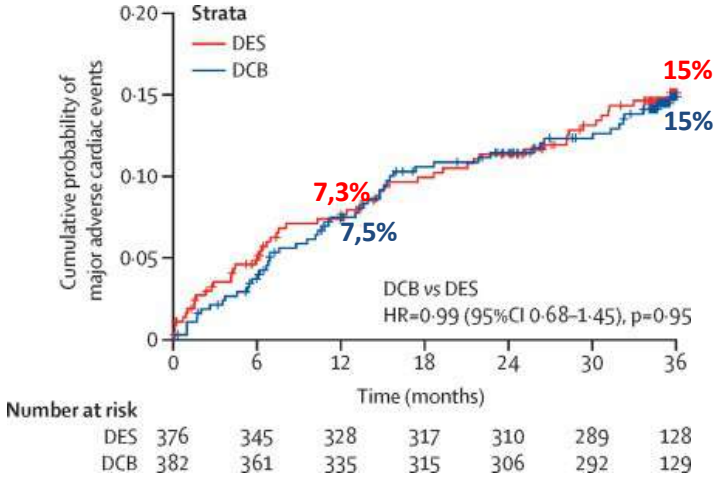
The rationale for using DCBs is based on the concept that with highly lipophilic drugs, even short contact times between the balloon surface and the vessel wall are sufficient for effective drug delivery. There are various types of DCB that are approved for use in Europe and their main characteristics are listed in Supplementary *Table 8*. Although specifically designed comparative randomized trials are lacking, a class effect for all DCBs cannot be assumed.[598] Randomized trial data supporting the use of DCB angioplasty are limited to the treatment of in-stent restenosis (see section 13.4). In terms of the use of DCB angioplasty for *de novo* disease, a number of small randomized trials have been reported with somewhat conflicting results.[599–601] At present, there are no convincing data to support the use of DCB angioplasty for this indication.

Neumann JF et al. EHJ 2018

BASKET – Small 2



Primary Endpoint: Non-inferiority for MACE (cardiac death, non-fatal MI, and target vessel revascularization) @ 12 months

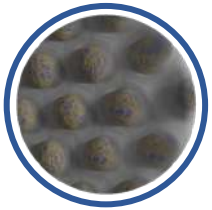


In small native coronary artery disease :

- DCB was non-inferior to DES regarding MACE up to 12 months, with similar event rates for both treatment groups;
- There is maintained efficacy and safety of DCB versus DES up to 3 years.

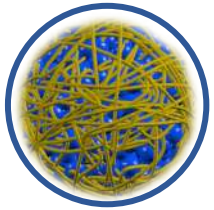
Jeger RV et al. Lancet 2020
Jeger RV et al. Lancet 2018

SELUTION SLR™
Sirolimus-Eluting Balloon with Sustained Release



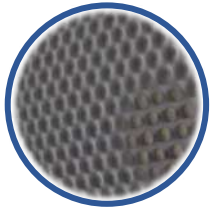
Proprietary MicroReservoir Technology

- Creation of MicroReservoirs combining sirolimus & biodegradable polymer
- Sirolimus - a proven safe & effective cytostatic drug
- Offering a wider therapeutic range



MicroReservoirs: Miniature Drug-Delivery

- Optimal size MicroReservoirs to achieve pharmaco- kinetic release profile comparable to best in class DES
- Consistent and predictable drug release
- Sustained therapeutic effect for up to 90 days[1]



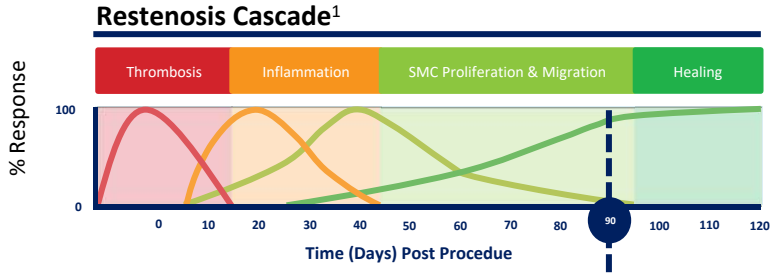
Cell Adherent Technology (CAT™)

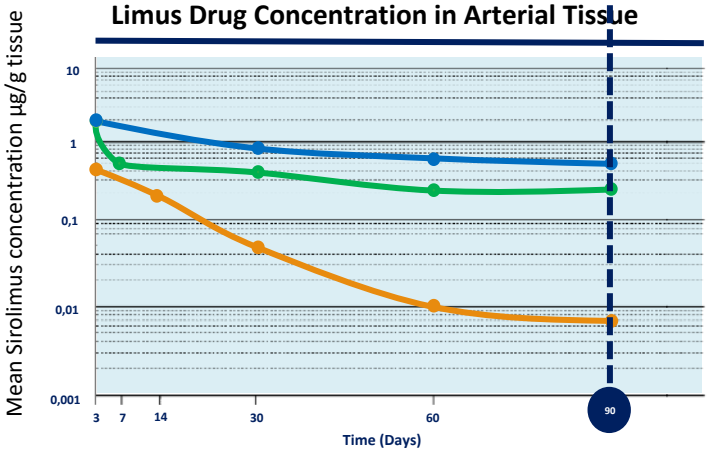
Proprietary amphipathic lipid technology which binds MicroReservoirs to the balloon surface

- Contains and protects micro-reservoirs during insertion and inflation
- Enhances drug retention and bioavailability, allowing for a lower drug dose concentration on the balloon surface (1 µg/mm²)
- Optimizes transfer of MicroReservoirs to the tissue and maximizes the cellular uptake of sirolimus

Drug concentration evident in MicroReservoirs and tissue - Data on file at M.A. Med Alliance SA

SELUTION SLR™
Sirolimus-Eluting Balloon with Sustained Release





Stent-like elution profile of SELUTION SLR

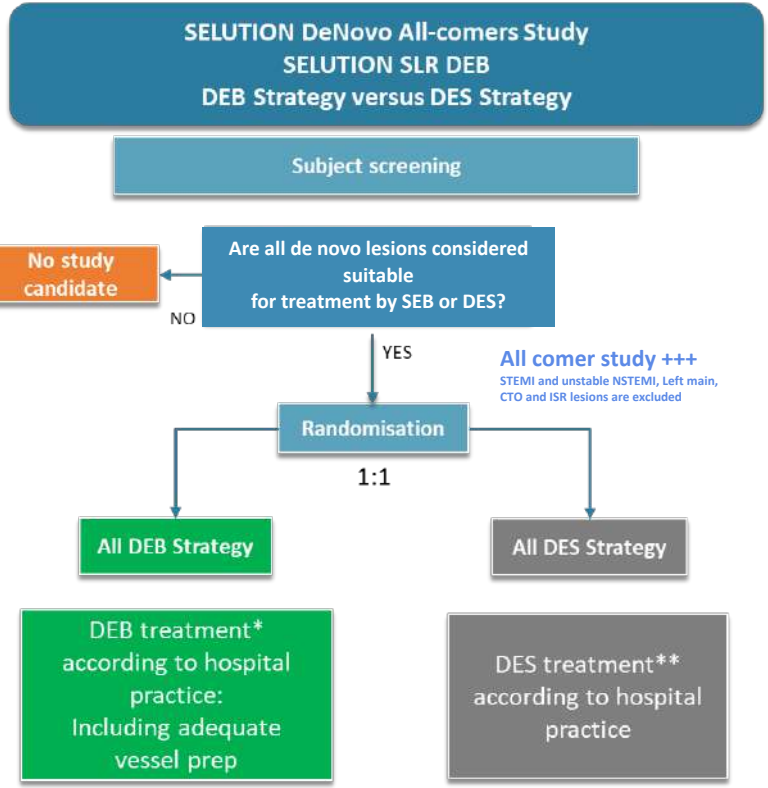
90 Days Sustained Limus Drug Release to cover SMC proliferation & migration period

- SELUTION SLR™
- Everolimus eluting stent (2nd gen)
- Crystaline Sirolimus DEB

1. XienceV -Perkins et al JIC 22 S26 2009.
2. SELUTION SLR - Data on file at M.A. Med Alliance SA.
3. Competitor Sirolimus DEB (MagicTouch) - Aloke Finn LINC 2021.

Forrester et al. JAAC 1991; J Am Coll Cardiol 2004

SELUTION DeNovo Study



Co-PI: S. Eccleshall, UK & C. Spaulding, France

OBJECTIVE
- To demonstrate non-inferiority for TVF of a treatment strategy with first line SELUTION SLR™ DEB plus provisional DES vs. systematic treatment with DES for the treatment of de novo coronary lesions.

DESIGN
- Prospective RCT, open label, comparing the SELUTION DEB strategy versus DES strategy
- 3326 patients
- 50 sites in Europe, Asia

PRIMARY ENDPOINTS
- TVF (cardiac death, target-vessel related MI or cdTVR) at 1 year
- TVF at 5 years

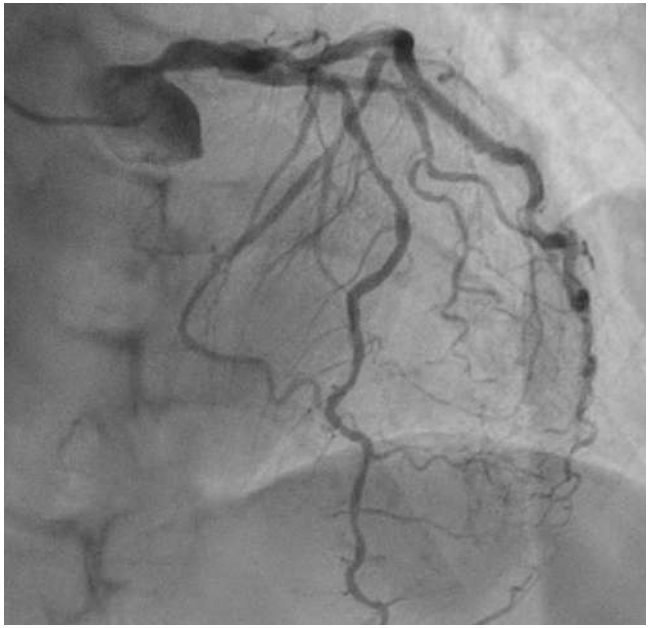
SECONDARY ENDPOINTS
- TVF at 2, 3 and 4 years
- Other secondary endpoints at 30 days, 6 months, 1, 2, 3, 4 and 5 years
  - TLR & TVR: any and clinically driven, non-target lesion TVR, non-TVR
  - Myocardial Infarction
  - All-cause mortality (composite of cardiac & non-cardiac mortality)
  - Patient-oriented ARC-2 composite endpoint:
  - Site-reported BARC 3-5 Bleeding
  - Cost-effectiveness of DEB vs. DES after 1 year in selected countries
  - Net clinical benefit: freedom from TVF and/or BARC 3-5 bleeding

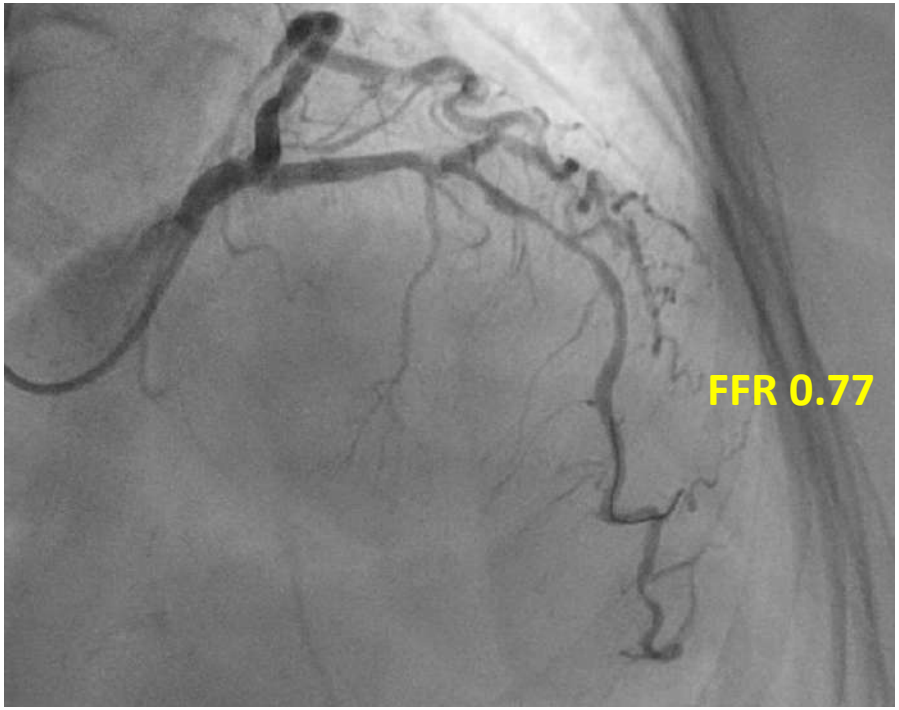
FOLLOW-UP
- Follow-up: 30 days, 6M, 1, 2, 3, 4 and 5 years

Selution DeNovo PTCA Study

- Dyspnea (NYHA 3) and palpitations during effort
- CV risk factors : HTA, obesity
- No past medical history
- Heart TDM : stenosis of LAD

63 years old female





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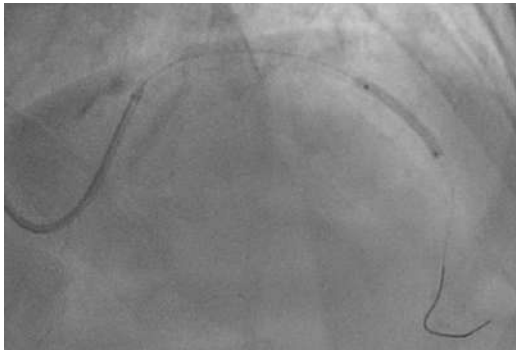
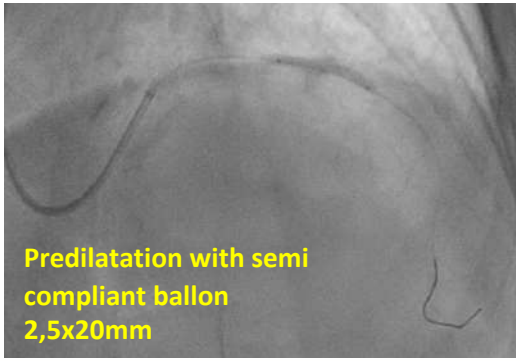
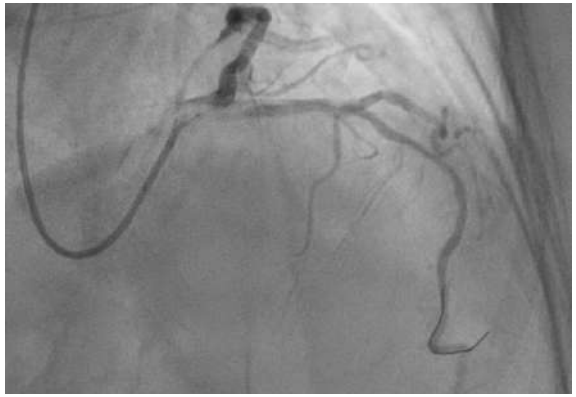
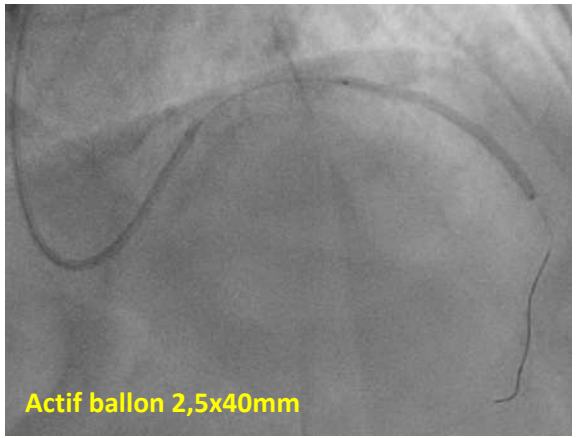


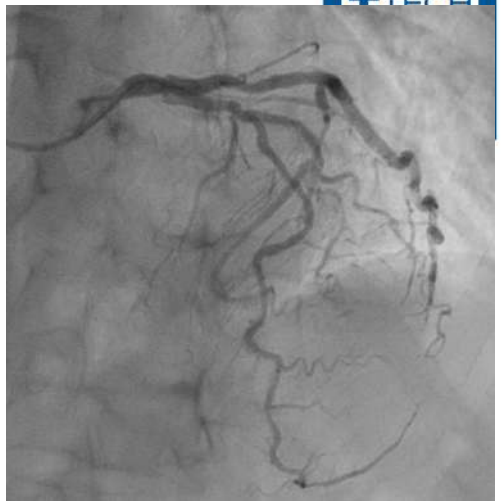


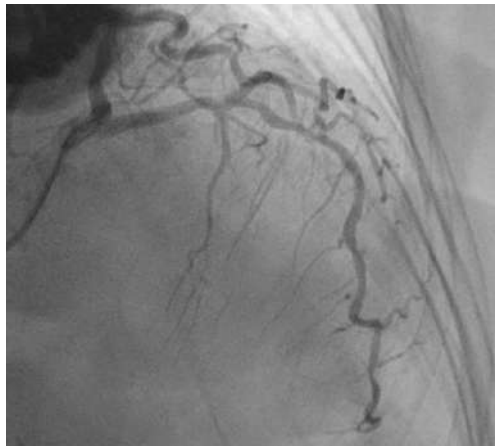
Predilatation with semi compliant ballon 2,5x20mm





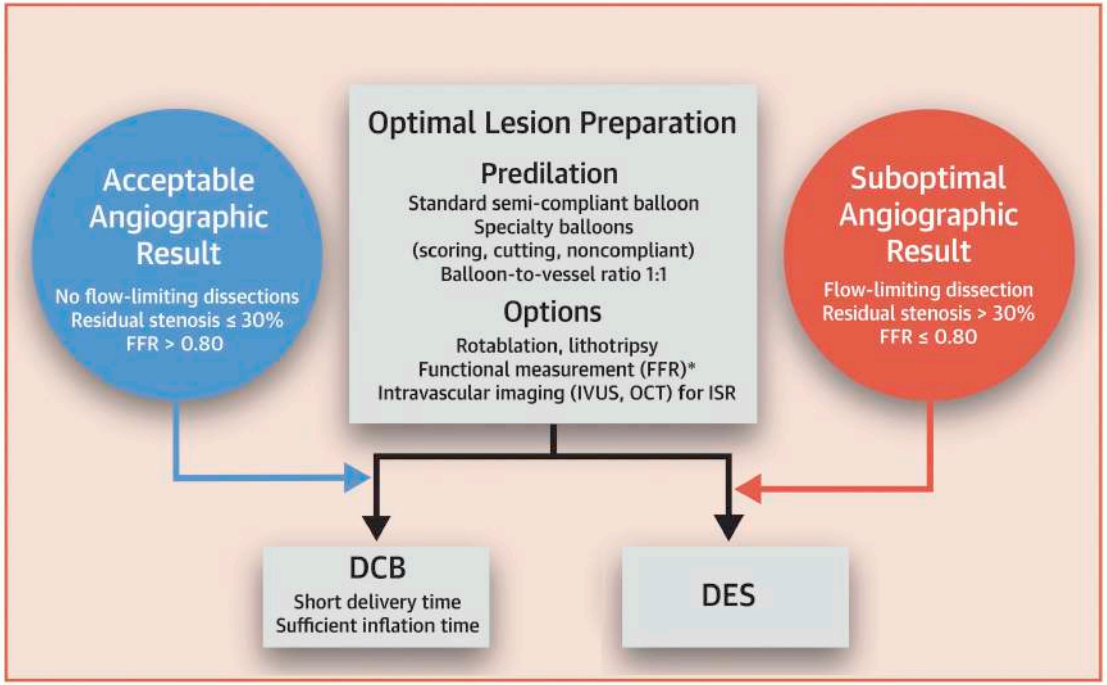
Actif ballon 2,5x40mm





Conclusions

DCB-Only Strategy for PCI in Coronary Artery Disease



Jeger RV et al. JACC interv 2020