

DIOR-eluting Balloon The Spanish Registry. Focus on Small Vessels

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Potential conflicts of interest

Speakers's name: Antonio SERRA

- I have the following potential conflicts of interest to report:**
 - Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)

- I do not have any potential conflict of interest**

- The limitations of currently available drug eluting stents have renewed interest in new technologies
- Situations in which previous interventions have been associated with a high risk of restenosis and/or stent thrombosis
 - ✓ In- stent restenosis
 - ✓ *De novo* lesions in small vessels (< 2.5mm)
 - ✓ Side branch in bifurcated lesions
 - ✓ Contraindication to prolonged dual antiplatelet therapy

Paclitaxel- Eluting DIOR-Balloon

1. Paclitaxel

+

Solubilizing agent to increase optimal drug delivery

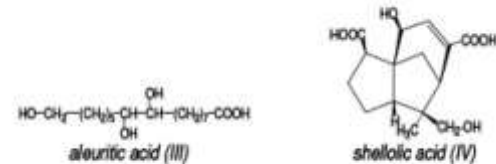
+

Micro-crystals (following dimethylsulfate treatment)

Dior 1st G

Posa et al. CAD 2008

The drug is dissolved in "Shellac" FDA approved substance graded as a food

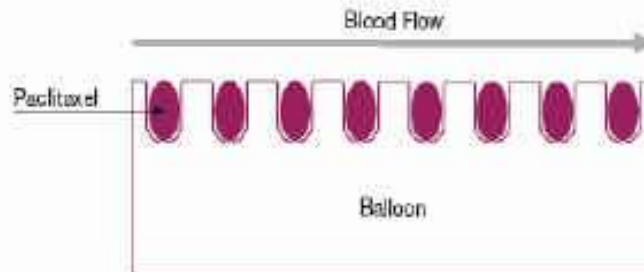


Dior 2nd G

Hemetsberger R, Posa A et al. J. Kardiol 2009

3.-Coating method

3µg/mm² balloon-surface paclitaxel-coating

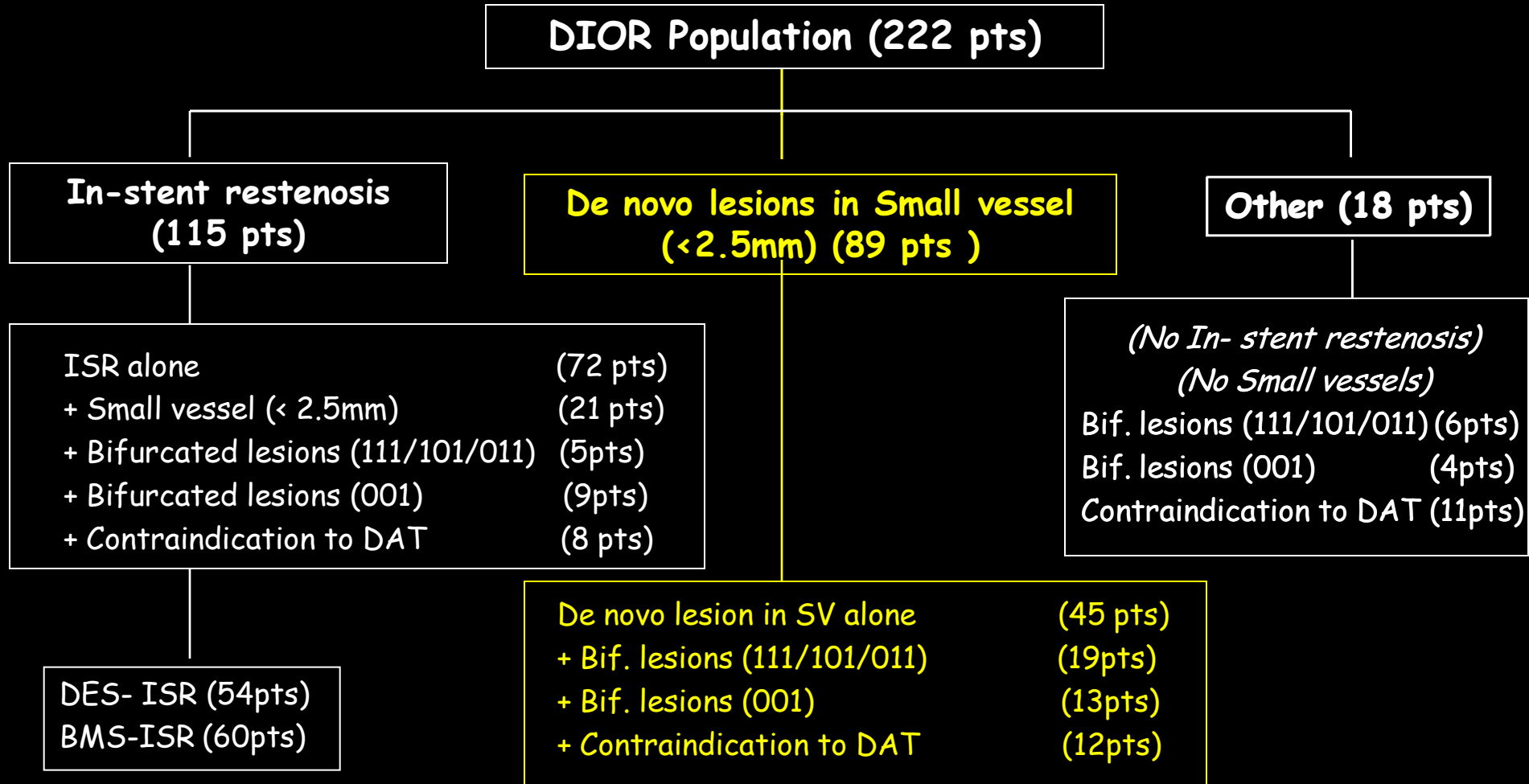


2. Balloon designed with 3 folds of micro-porous surface.

The three-folded balloon protects the loaded drug from the early wash-out effect

Dior™ (EuroCOR, GmbH, Germany)

Population group in whom the use of either BMS or DES may be considered inappropriate or even harmful: Dior population



*Contraindication to prolonged dual antiplatelet therapy**

STUDY'S FLOWCHART

Clinical/Angiographic eligible patient



Target lesion Pre-dilatation (Shorter balloon than the Dior)
Dior dilatation: above nominal pressure + at least during 60sec



Angiographic success: a final residual lesion stenosis <50% in the TL and absence of > type B coronary dissection

Follow-up

No angio success: BMS

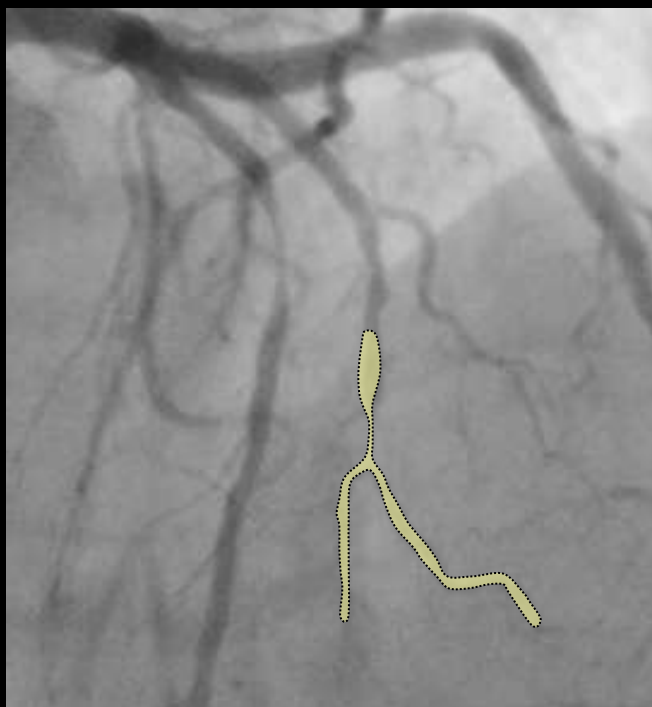
Clinical FU at 1 and 6 months and 1 year after the index procedure

Angiographic FU at 7±2 months in 3 centers (40% of population)

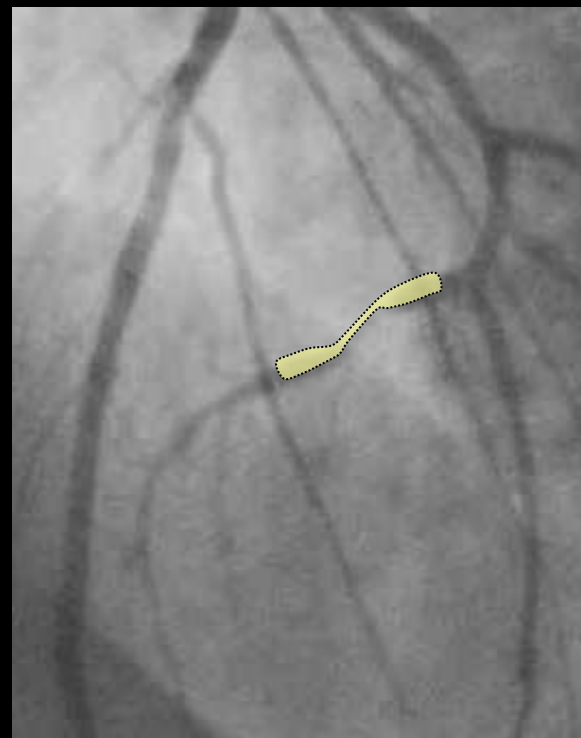
www.registrodior.com

Small vessel disease

Independently of the type of PCI (BMS/DES): small coronary vessel size is a strong predictor of restenosis following angioplasty¹⁻³



1. Elezi S, et al. *Circulation* 1999



2. Moses JW et al. *N Engl J Med* 2003

3. Elezi S et al. *JACC* 2006

Clinical and lesions characteristics (n=89)

Age (years) (mean±SD) **65.6±10.0**

Risc Factors

- ✓ **Diabetes** **38.4 (34)**
- ✓ **Renal impairment (creat >1.3mg/dl)** **12.6 (28)**

Clinical presentation

- ✓ **ACS (%)** **58.4 (52)**

Angiographic data

- ✓ **SMV alone** **50.6 (45)**
 - ✓ **+ Bifurcated lesion (111,011,101)** **21.3 (19)**
 - ✓ **+ Ostial lesion (001)** **14.6 (13)**
 - ✓ **+ Contraindication to prolonged DAT** **13.5 (12)**
- ✓ **Fisrt diagonal branch** **30.3 (27)**
- ✓ **Fisrt Marginal branch** **20.2 (18)**
- ✓ **LVEF (≤ 50%)** **30.4 (21)**
- ✓ **3 vessel disease** **30.3 (27)**

Unless specified otherwise, values are % and (n) of patients

Baseline procedural characteristics (n=89)

• Radial approach	39.3 (35)
• 6F- guide catheter	82.0 (73)
• Pts with stent implanted outside the target lesion	49.4 (44)
✓ DES outside the target lesion	39.3 (35)
• Pre-dilatation (plain balloon)	100 (89)
✓ Diameter, mm (mean±SD)	2.0±0.3
✓ Length, mm (mean±SD)	14.9 ±4.1
• Drug elution with Dior Balloon	
✓ Diameter, mm (mean±SD)	2.2±0.2
✓ Length, mm (mean±SD)	20.1±5.2
✓ Main balloon pressure, mmHg, (mean±SD)	12.9±3.5
✓ Inflation time (sec). (mean±SD)	104.3±53.9
• Post-dilatation	5.6 (5)

Unless specified otherwise, values are % and (n) of patients

Results: QCA analysis (n=89)

Variable	Pre-PCI	Post-PCI
Reference diameter	2.0±0.3	
Lesion length	14.6±6.8	
MLD	0.5±0.3	1.6±0.4
Diameter stenosis %	78.1±11.3	23.6±8.5
Acute Gain		1.2±0.4

Unless specified otherwise, values are mm (mean±SD)

• **Bail-out indication of stent (BMS) %, (n)** **7.9% (7)**

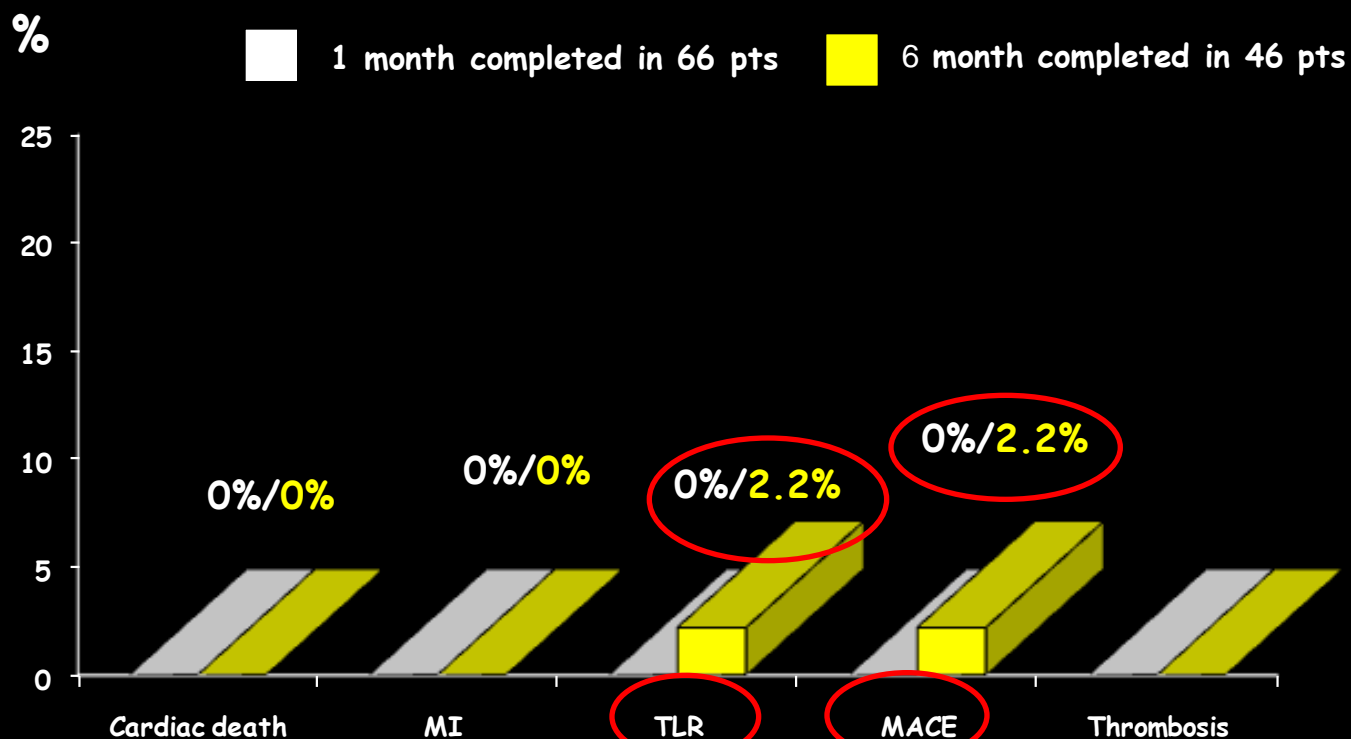
Acute recoil ≥ 50%, (n) **(0)**

Coronary dissection > type B, (n) **(7)**

Other, (n) **(0)**

1 and 6-month Clinical follow-up (89 pts)

92.1% of Angiographic success
(BMS after Dior 7.9% (7): coronary dissection)



Angiographic follow-up

- 1 center with systematic angio FU at 6-7 months
- 89 SMV population_ **Angiographic FU planned in 43 patients (48%)**
- **Currently completed Angio FU in 30 pts (69.7%)**

Variable	Pre-PCI	Post-PCI	6mo FU
Reference diameter	1.9±0.3		
Lesion length	15.3±6.6		
MLD	0.41±0.31	1.55±0.40	1.28±0.47
Diameter stenosis %	81.2±13.4	24.8±14.9	36.6±23.1
Acute Gain		1.14 ±0.12	
In-segment late loss			0.27±0.07
Binary Restenosis, (n) %			4/30 (13.3%)

Unless specified otherwise, values are mm (mean±SD)

DIOR CASES

DIOR IN SMALL VESSEL + LAD

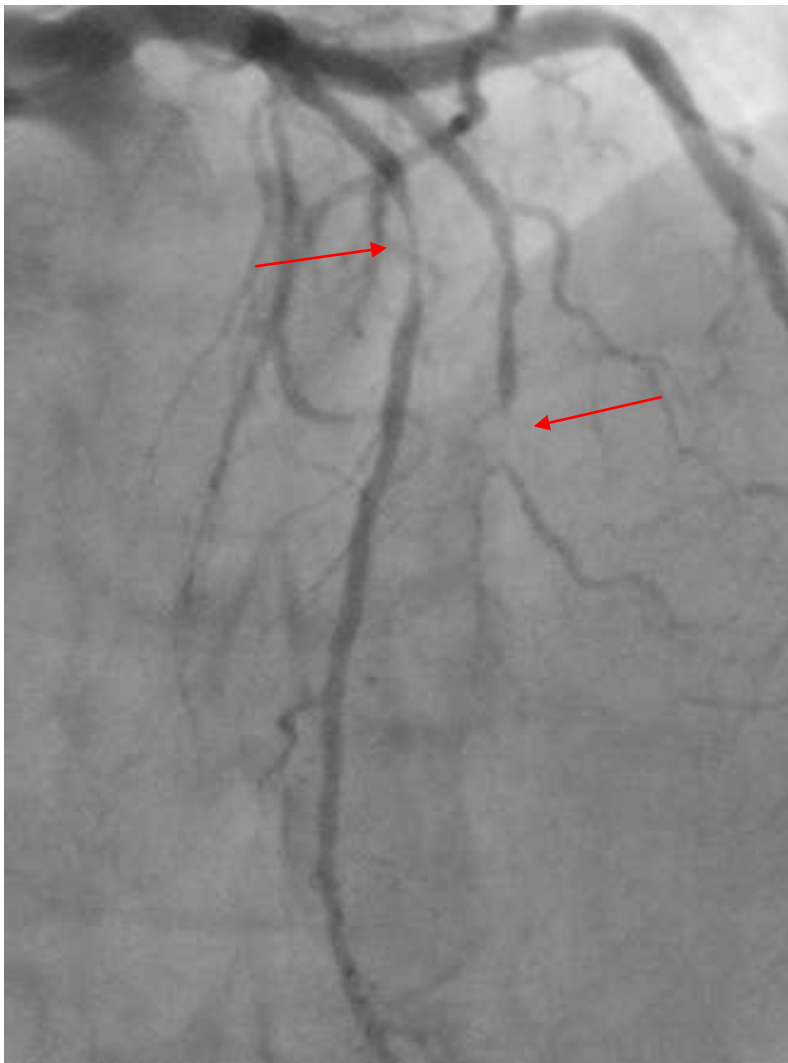
DIOR IN SMALL VESSEL + 001 BIFURCATED LESION

DIOR IN SMALL VESSEL + 111 BIFURCATED LESION

DIOR IN SMALL VESSEL + 3 VESSEL DISEASE

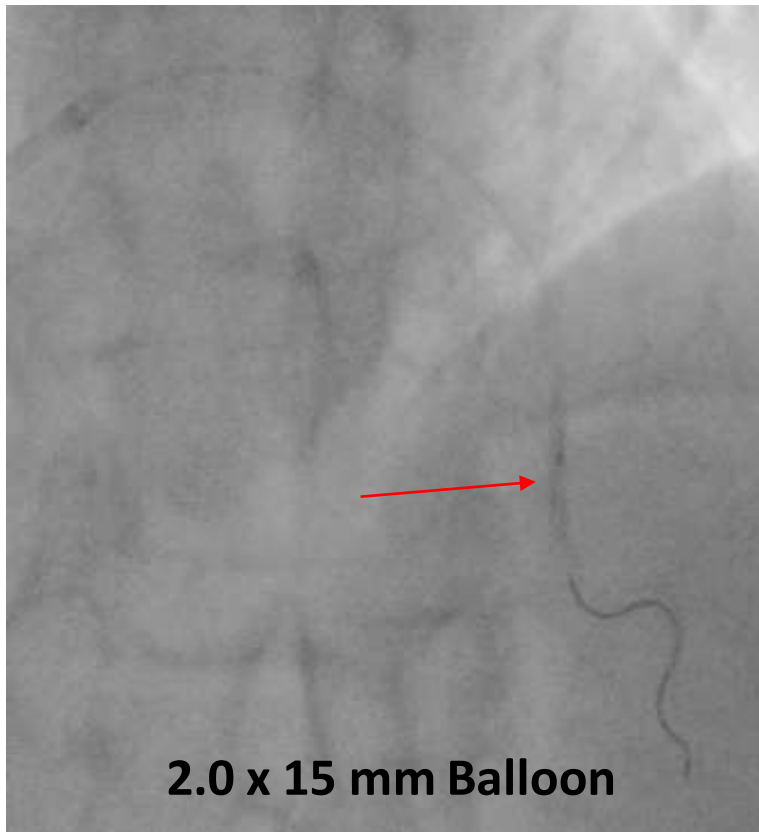
(IN REAL LIFE POPULATION COMBINATION OF DEB AND DES)

Case 1 : Mid LAD stenosis + first diagonal branch stenosis (distal lesion, small vessel)

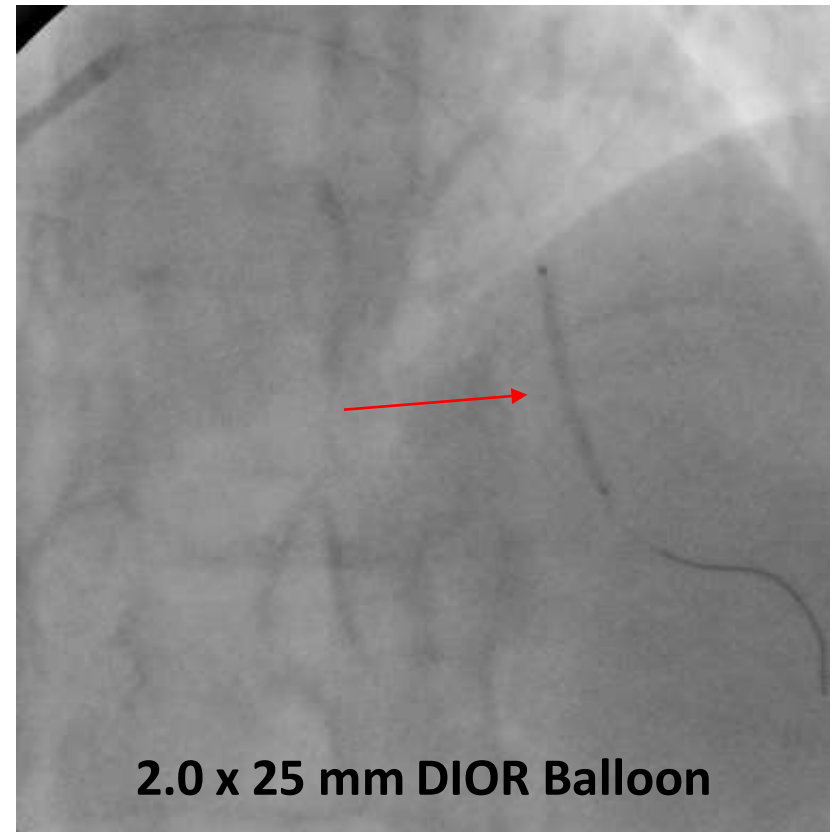


Treatment of First diagonal branch with DIOR Balloon

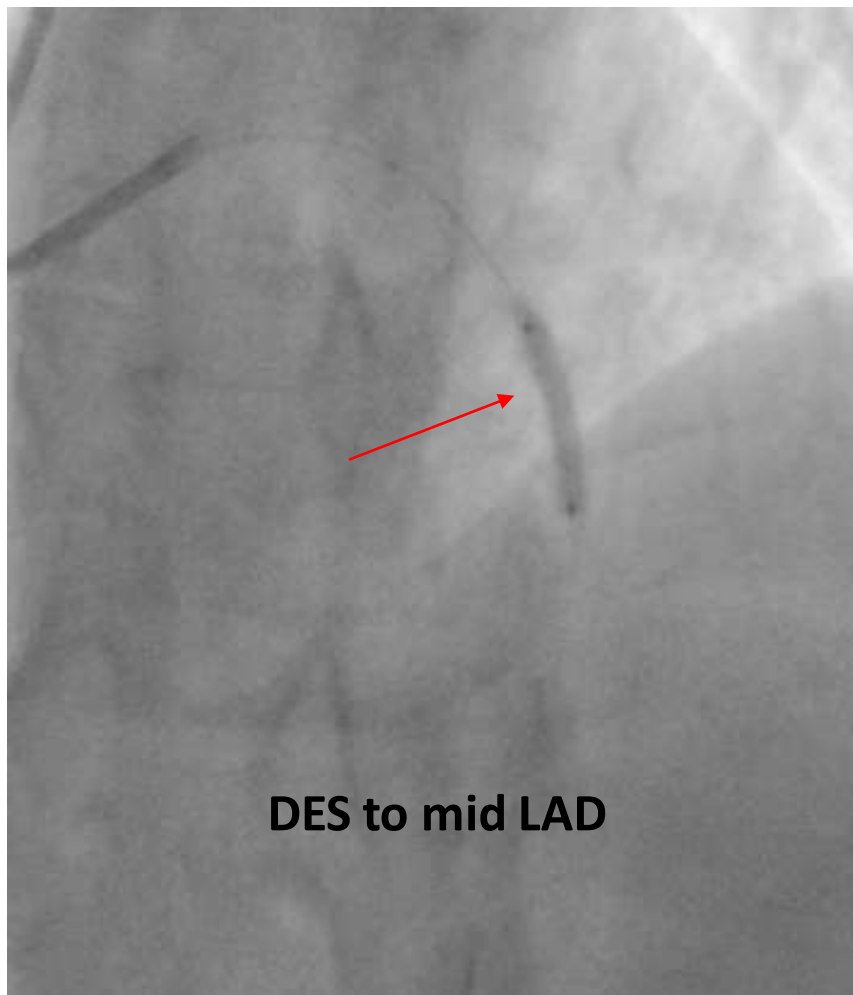
Pre-dilatation with plain balloon
(shorter than Dior balloon)
Low increase in pressure until
14-16 atm in 2-3 minutes



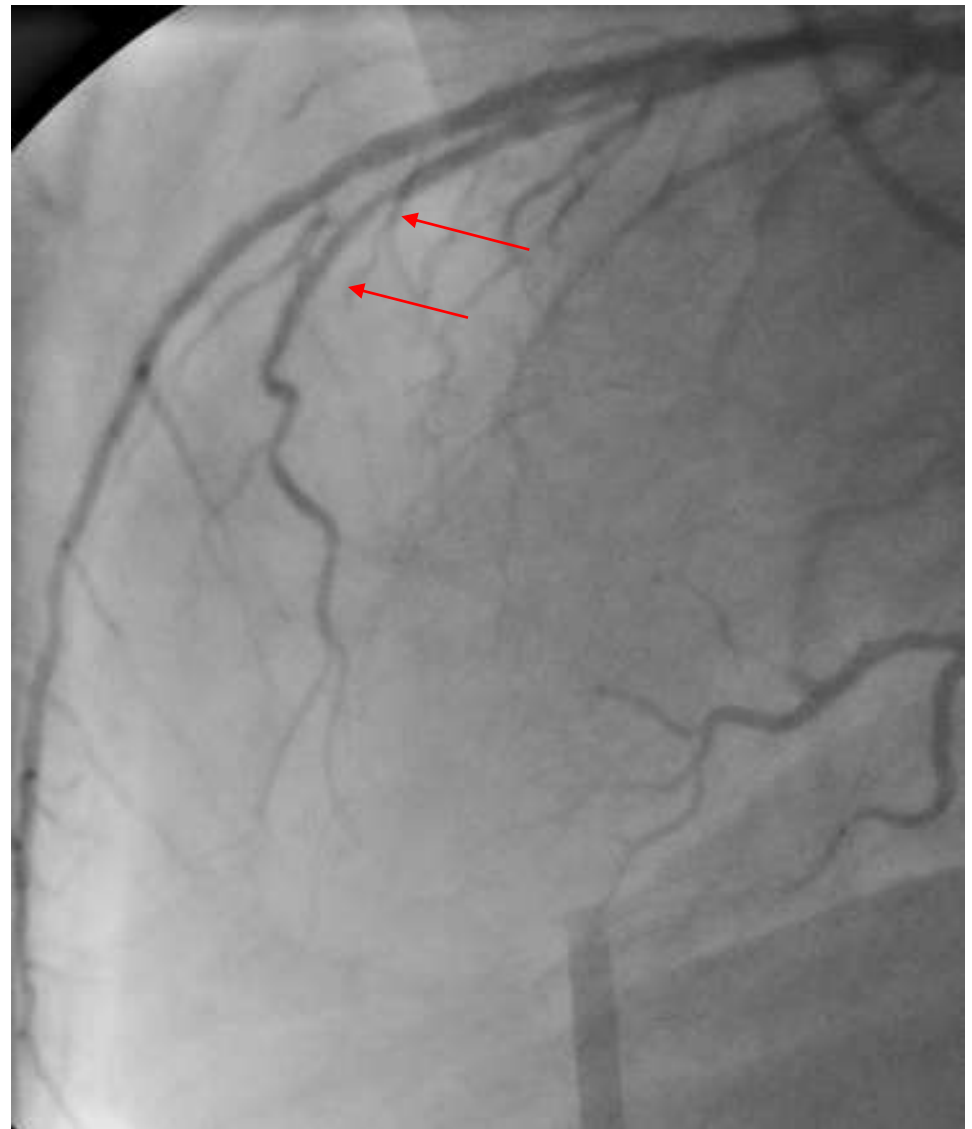
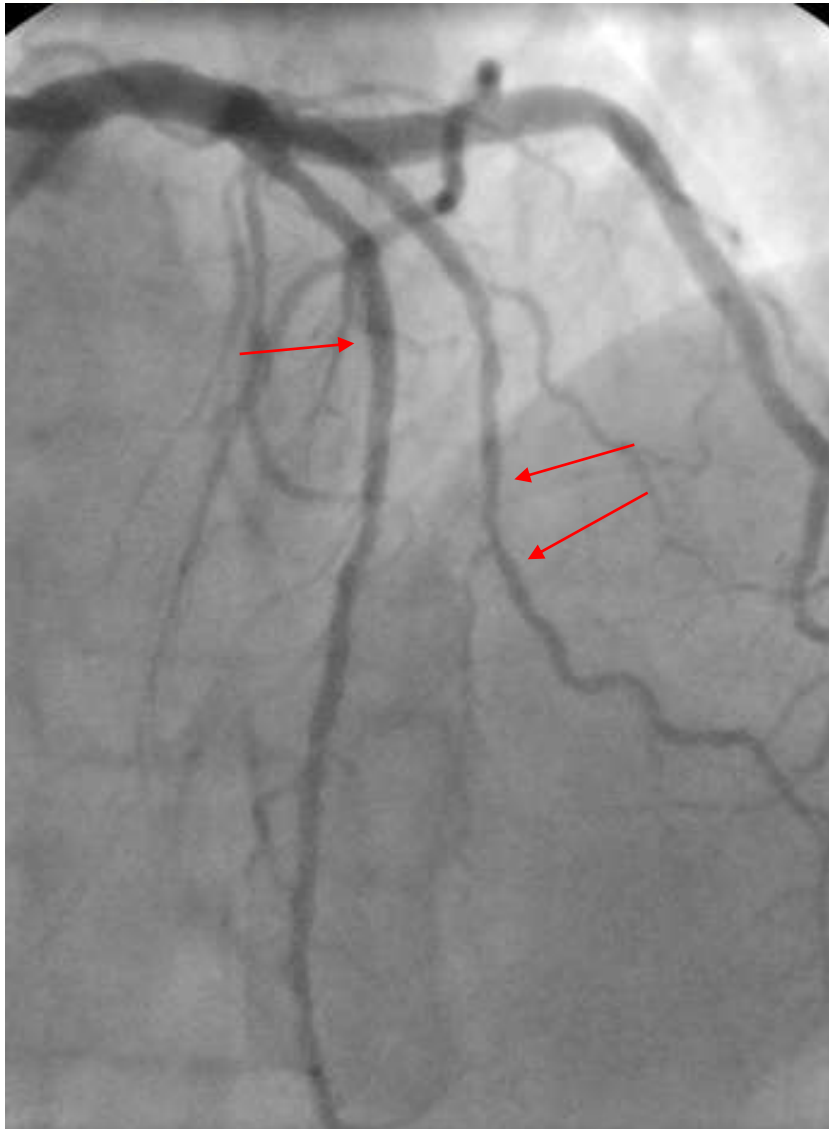
Drug elution to vessel wall with
Dior balloon, at least for 60sec, at
nominal pressure.



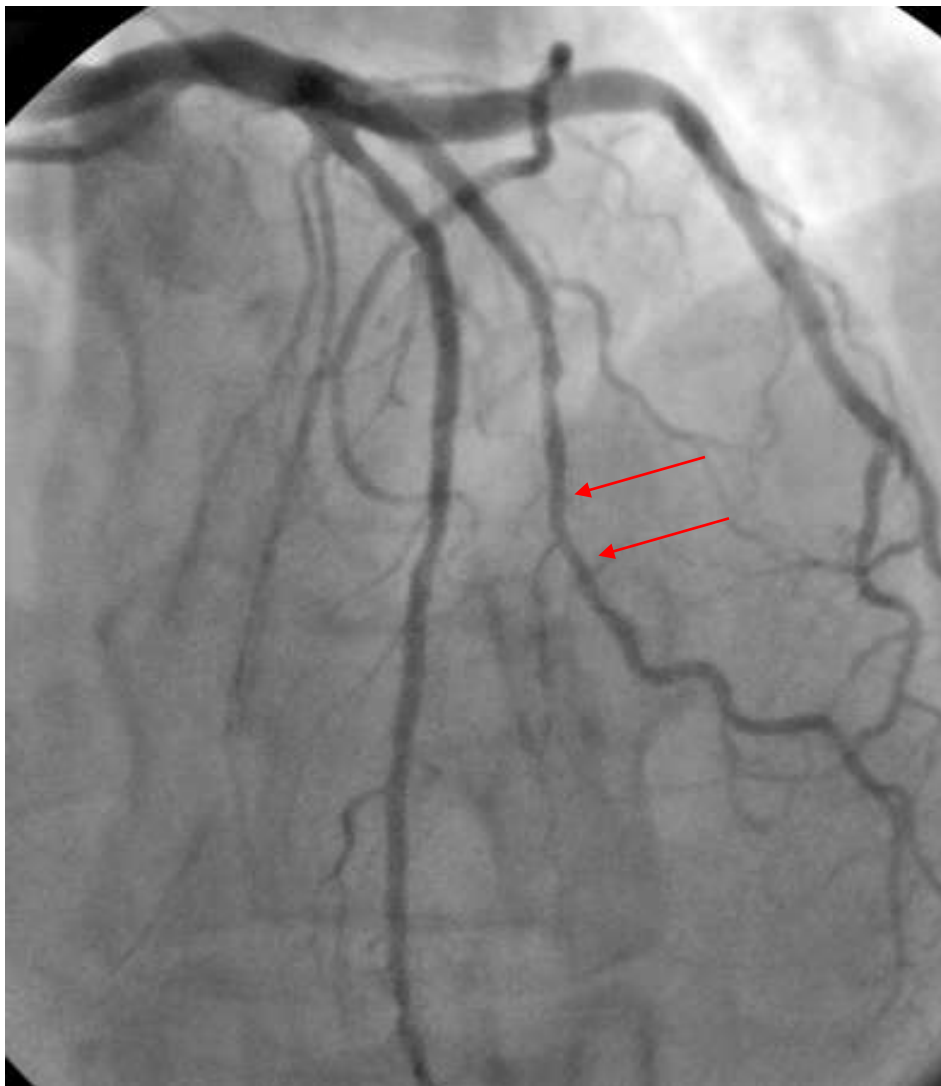
Case 1 : Treatment of LAD lesion



Case 1 : Immediate result

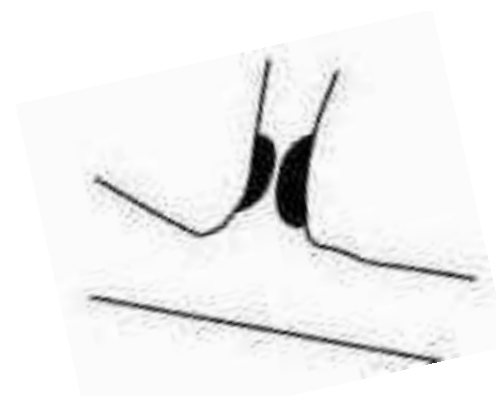
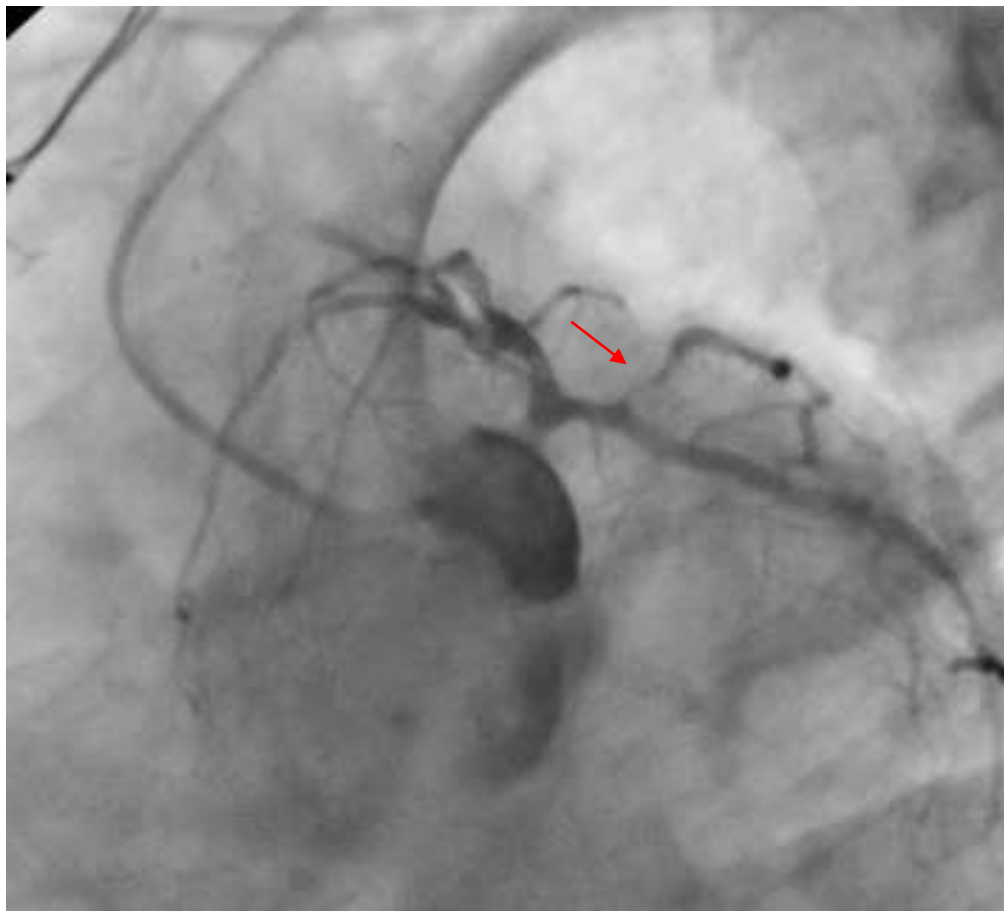


Case 1 : 6-month angiographic follow-up The patient remained asymptomatic



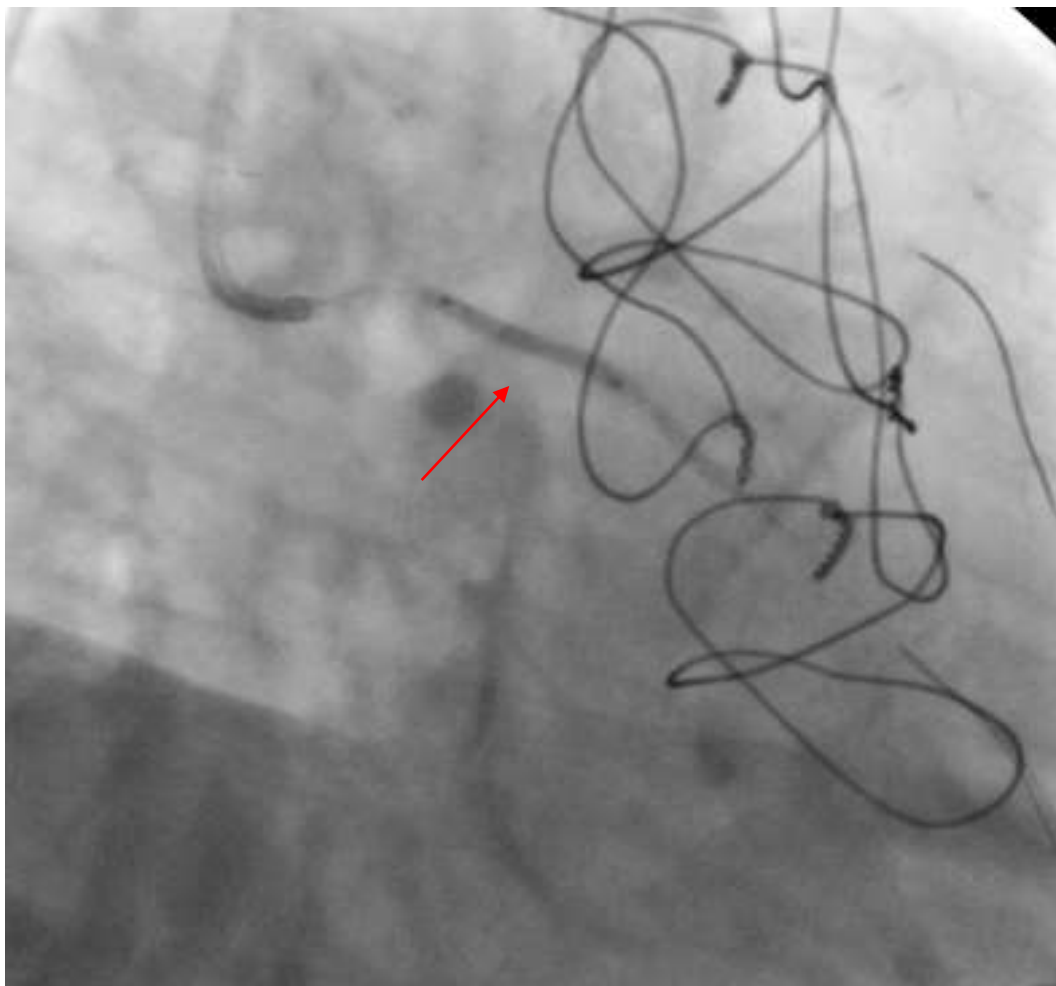
**Combination of DES for LAD +
DEB for small vessel (D1)**

Case 2 : first marginal stenosis (ostial lesion + small vessel)



**0, 0, 1 Bifurcated lesion
Disease extends > 5 mm
distal to the ostium**

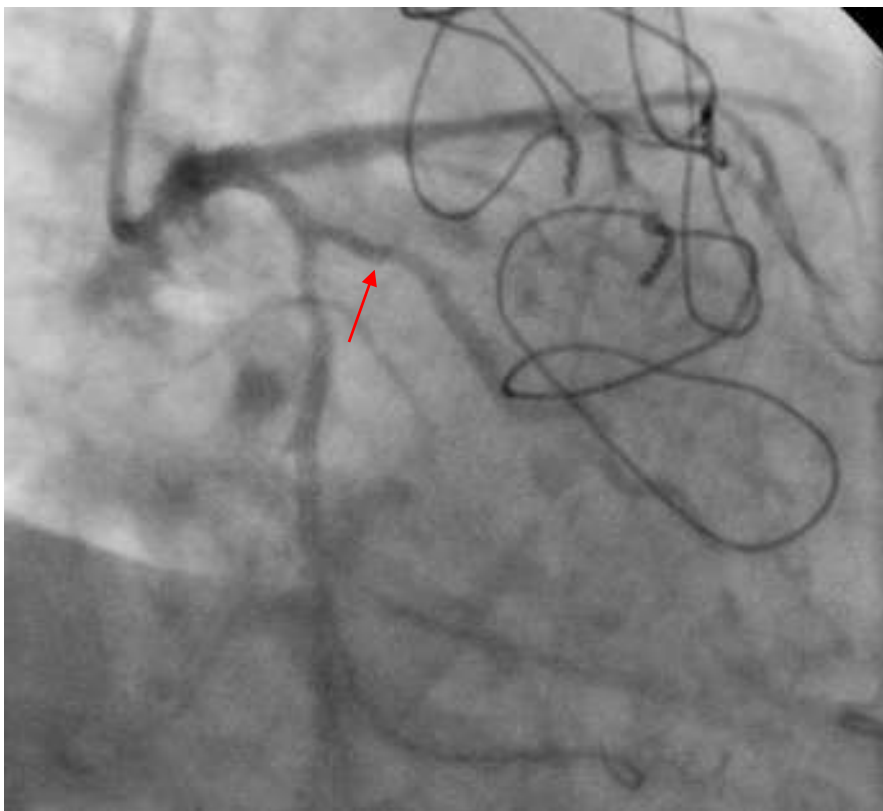
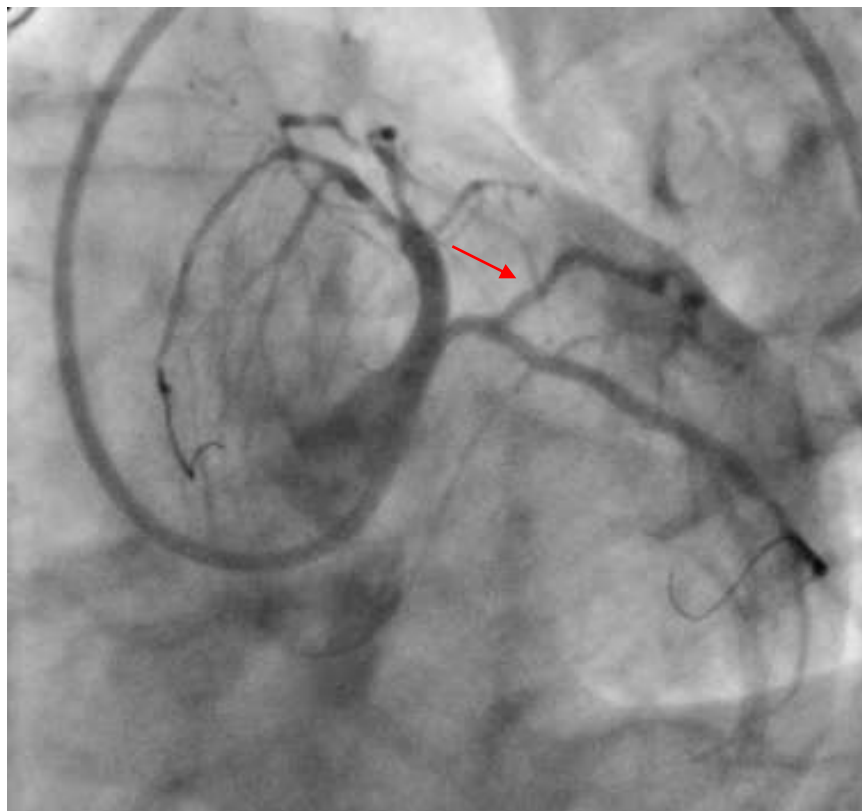
Case 2 : first marginal stenosis (ostial lesion + small vessel)



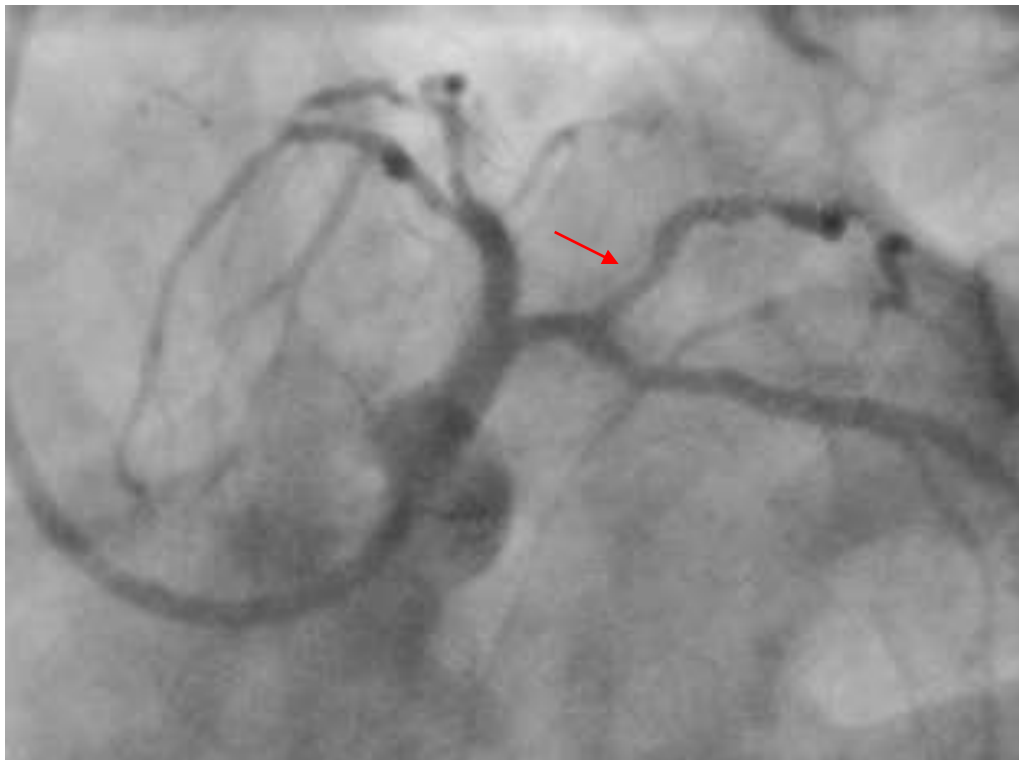
1. Pre-dilatation with balloon
(shorter than Dior balloon)
Cutting 2.0 x 10 mm.
2. Drug elution with DIOR
balloon 2.0 x 25 mm for
at least 60 seconds

Case 2 : first marginal stenosis (ostial lesion + small vessel)

Immediate result



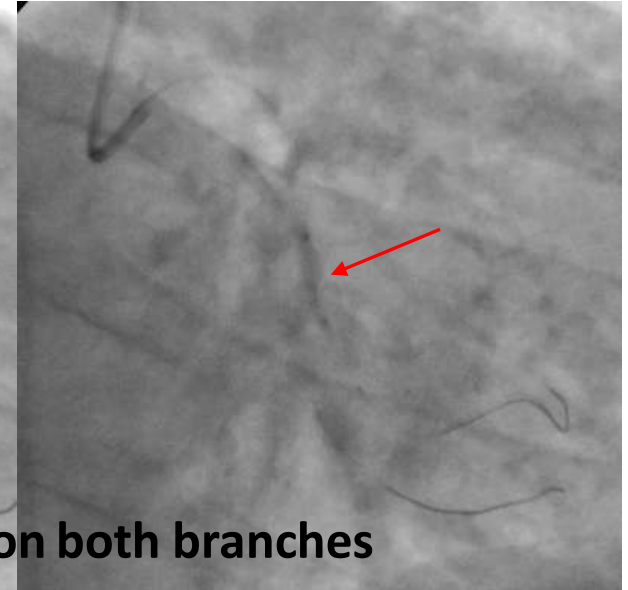
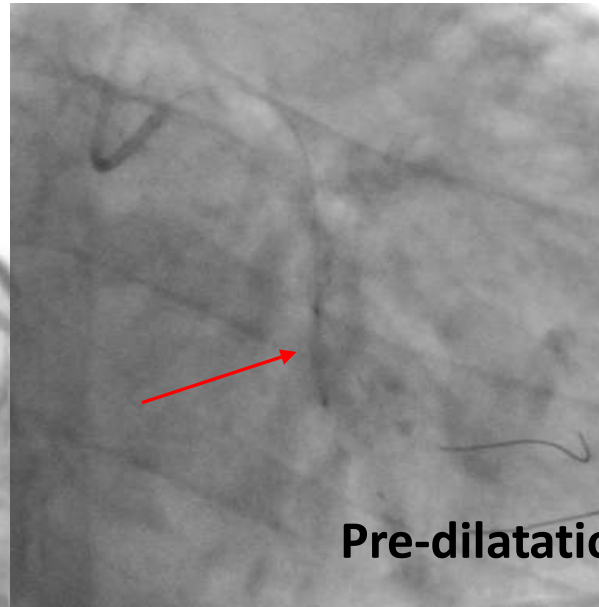
Case 2 : 6-month angiographic follow-up The patient remained asymptomatic



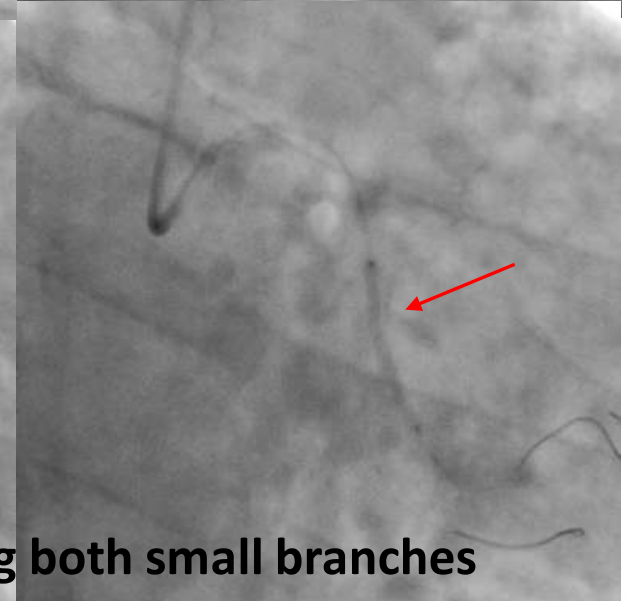
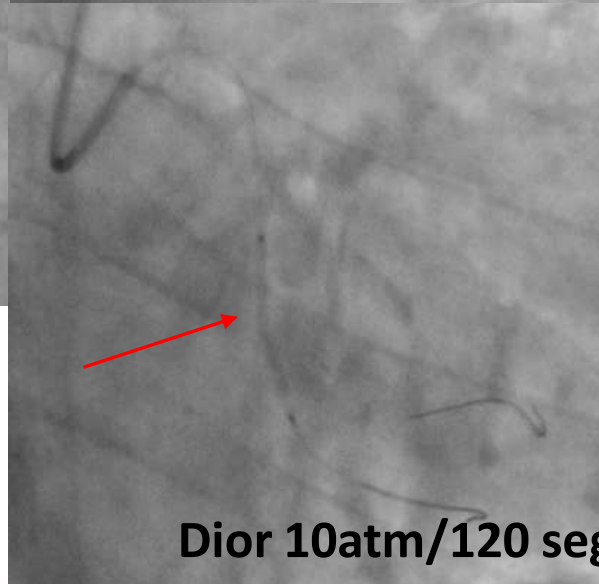
Case 3 : Bifurcated lesion in small vessel disease



Before DIOR

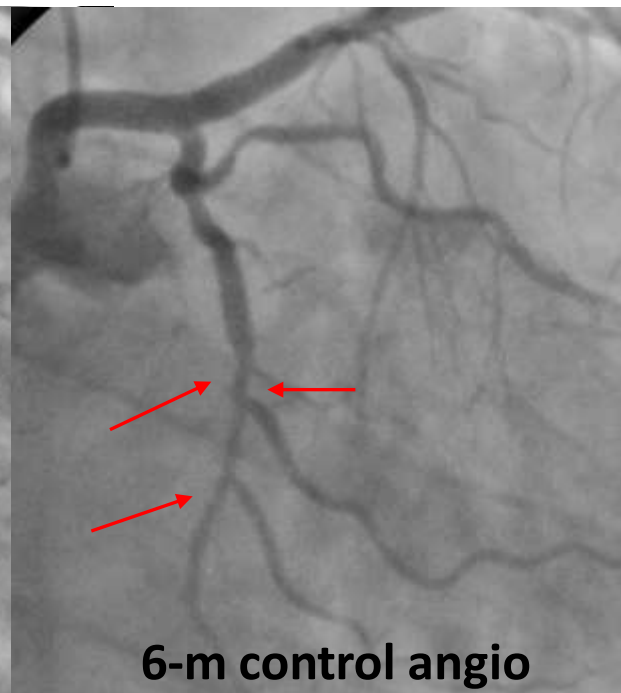
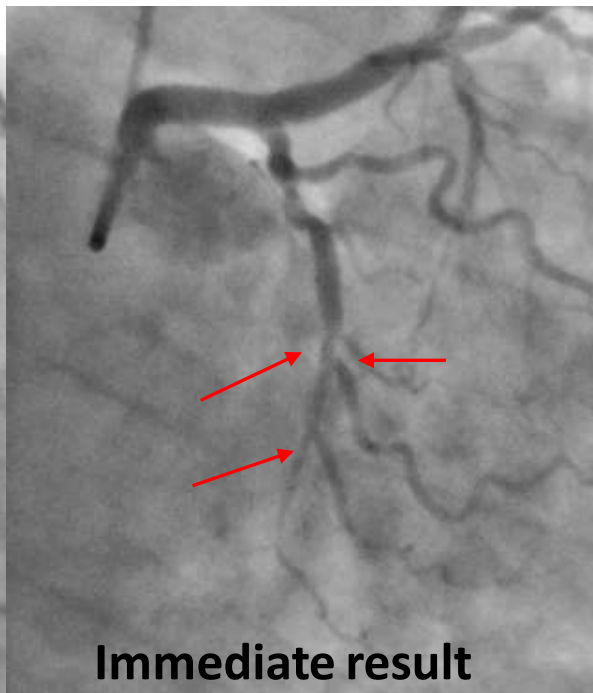
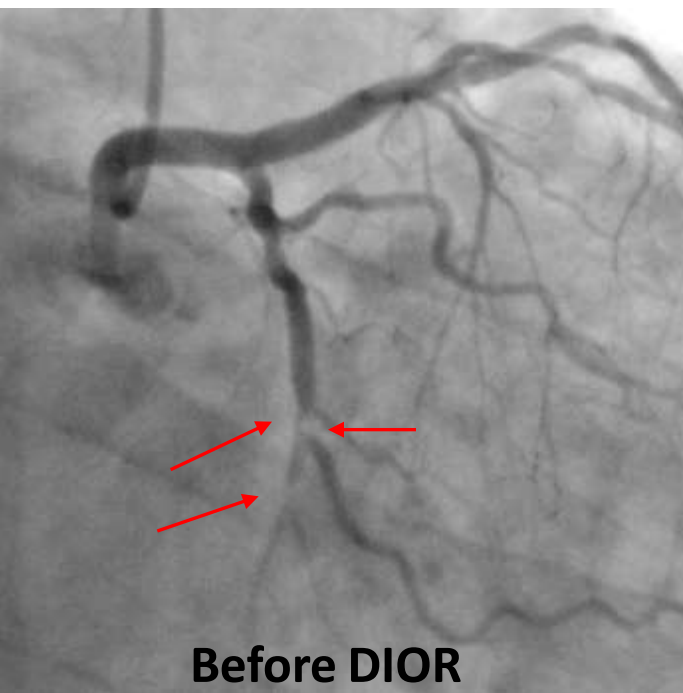


Pre-dilatation both branches

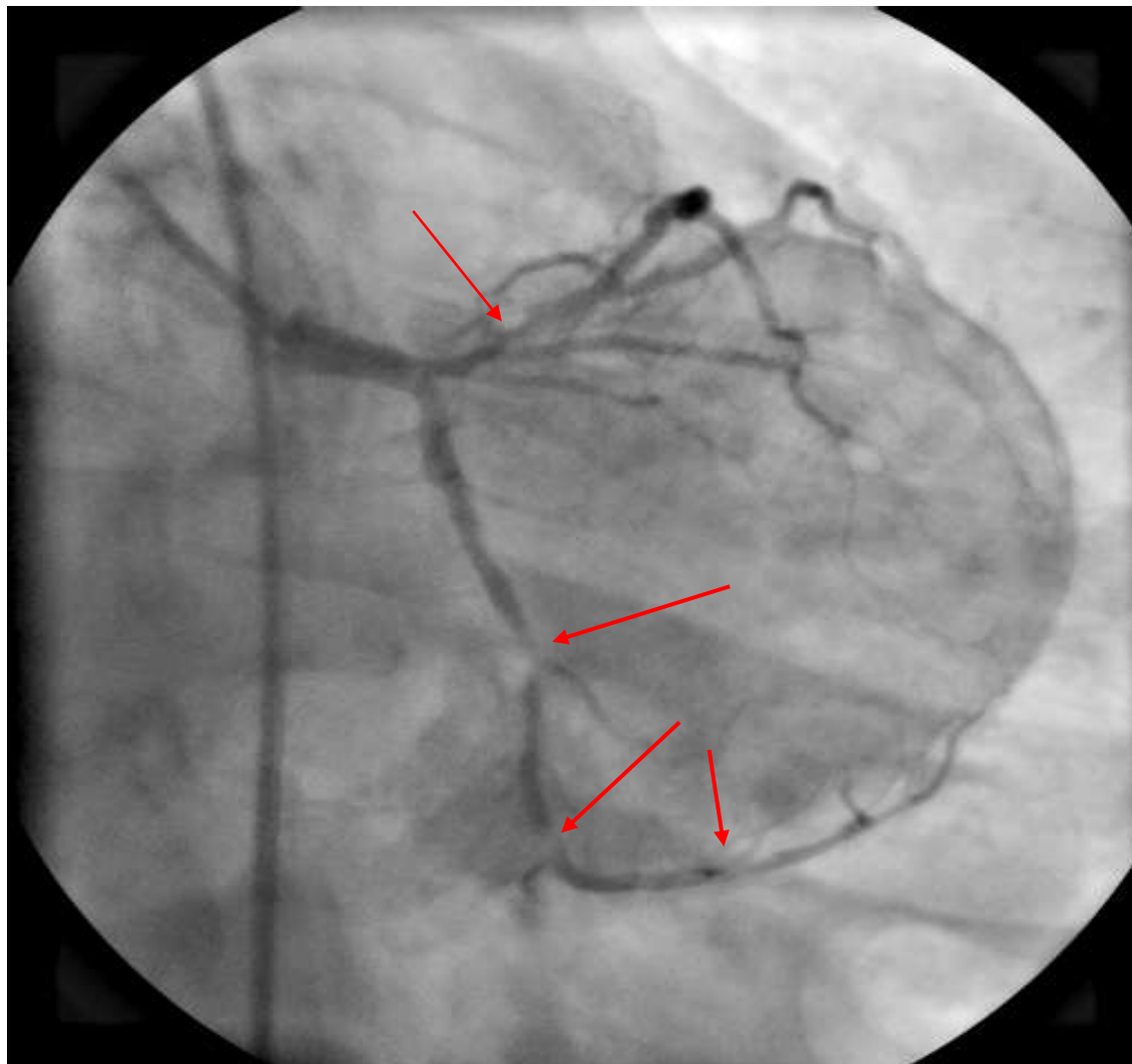


Dior 10atm/120 seg both small branches

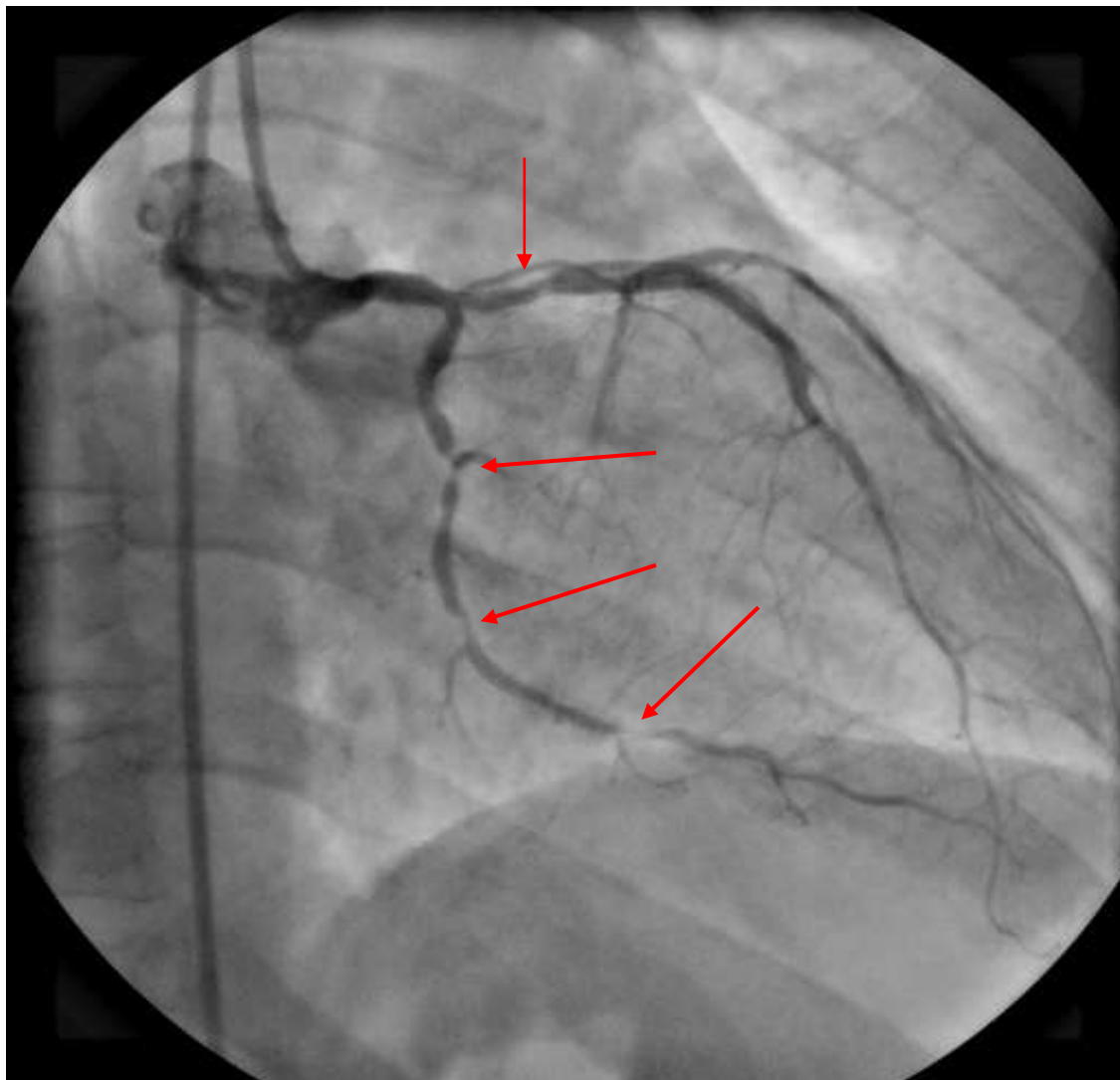
Case 3 : Bifurcated lesion in small vessel disease Angiographic follow-up



Case 4 : Three vessel disease + Small vessel



Case 4 : Three vessel disease + Small vessel

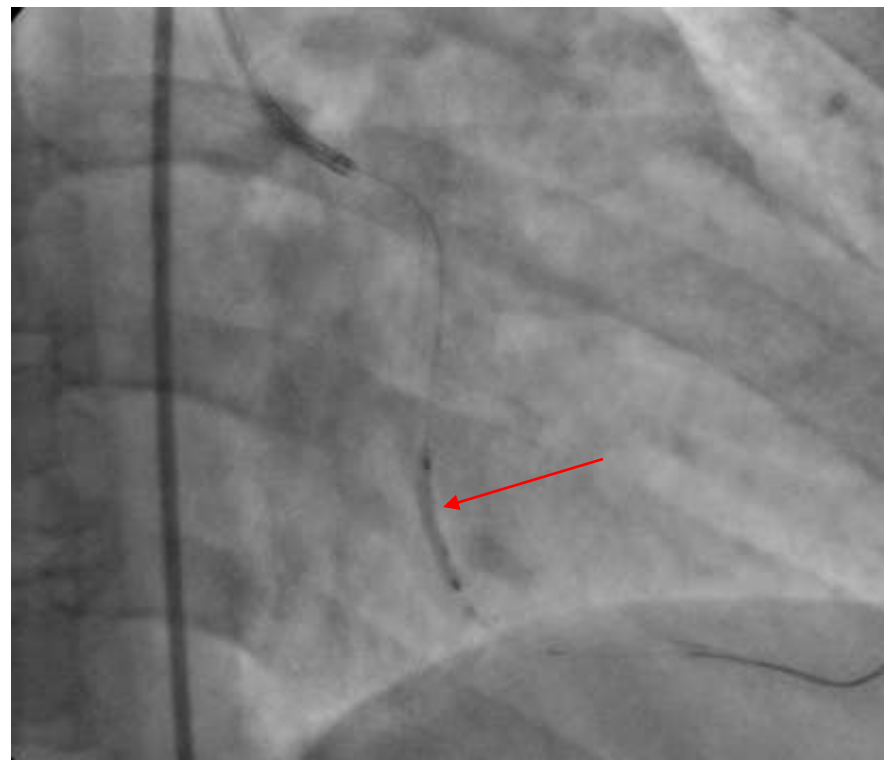
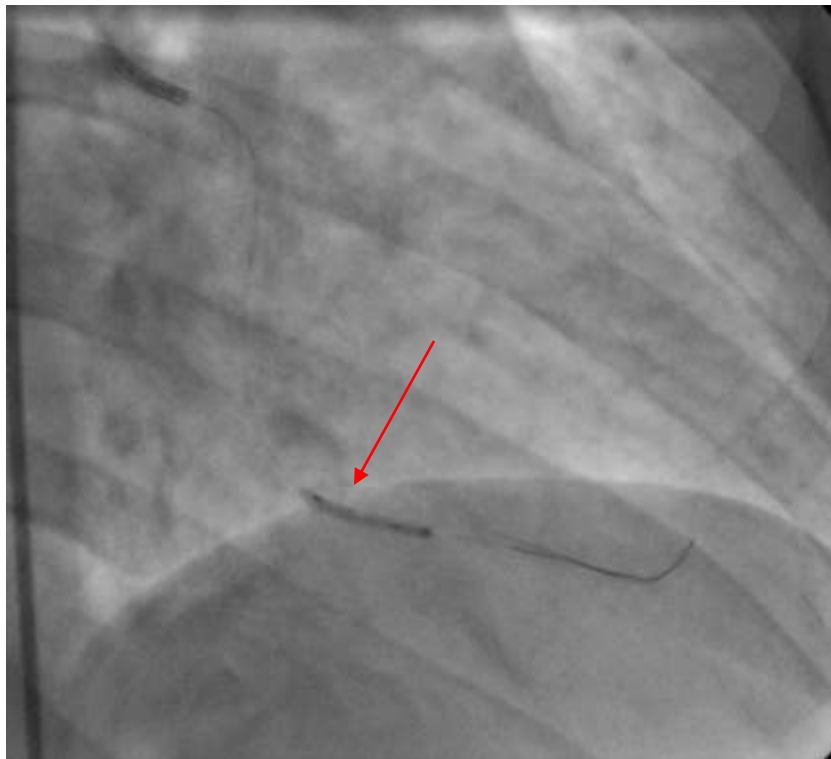


Case 4 : Three vessel disease + Small vessel



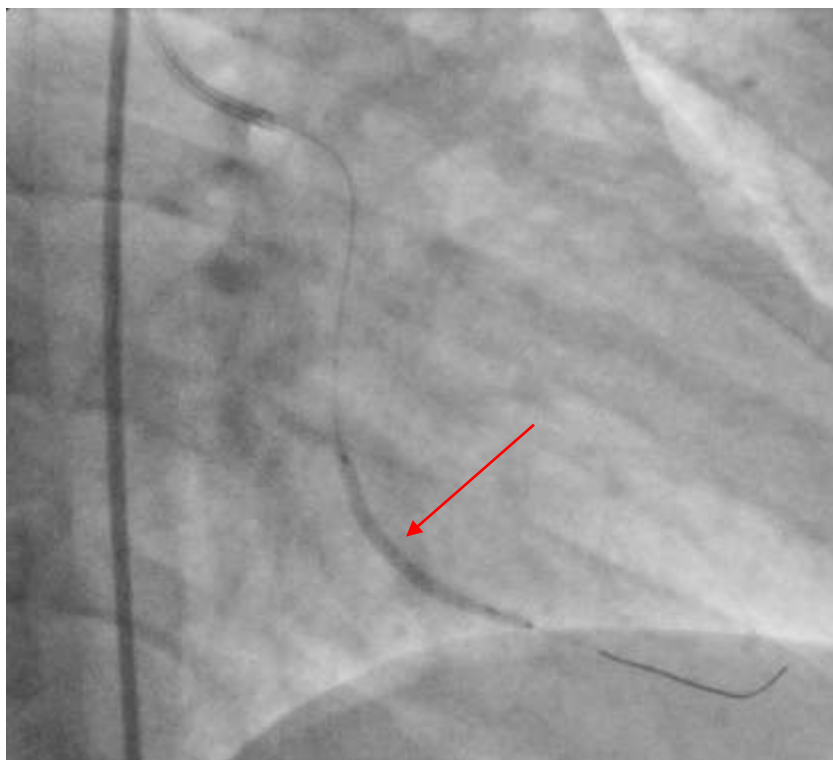
Case 4 : Three vessel disease + Small vessel

Balloon 2x15, 12atm / 120sec each inflation

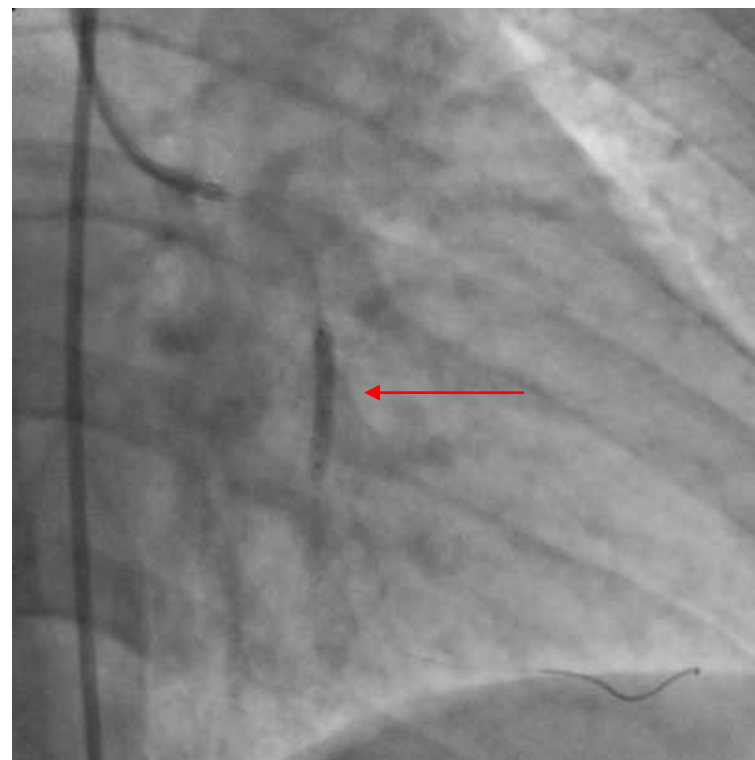


Case 4 : Three vessel disease + Small vessel

Dior balloon 2.0x30, 12atm / 93sec



Xience V 2.25x18, 16atm.



Case 4 : Three vessel disease + Small vessel

Xience V 2.75x15mm

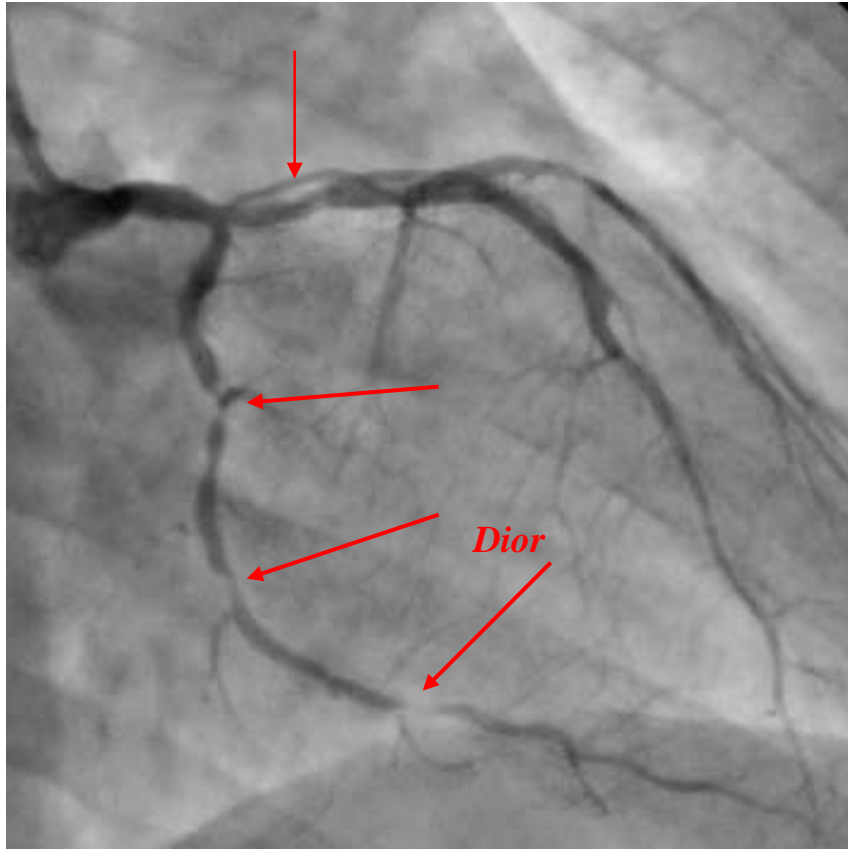


Xience V 3x23mm

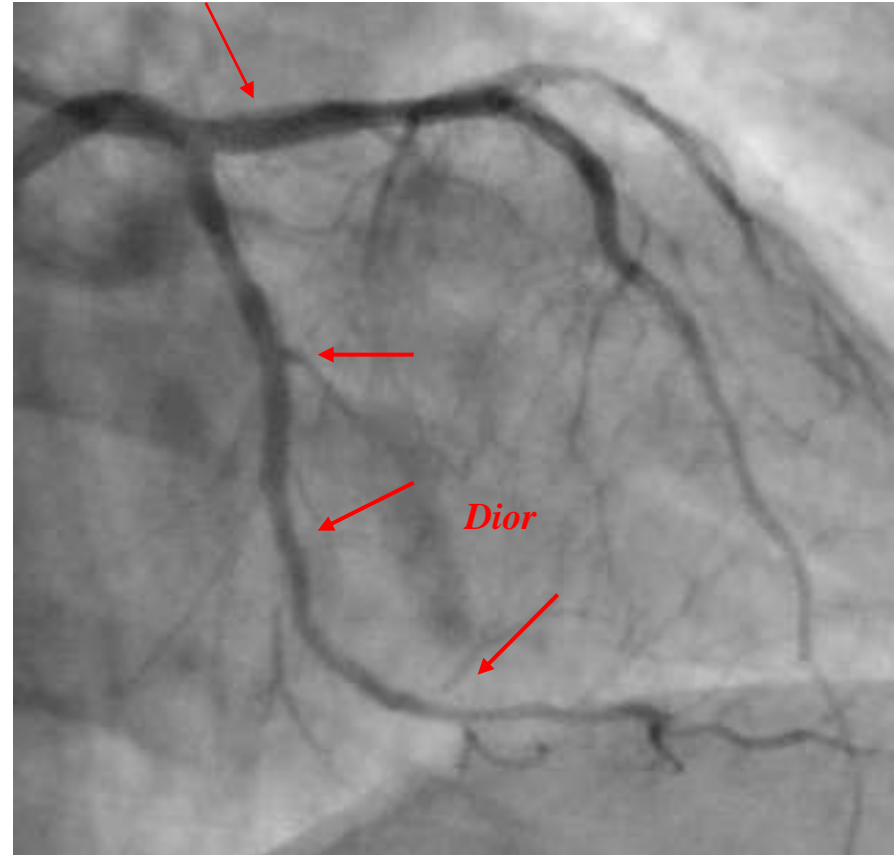


Case 4 : Three vessel disease + Small vessel

Pre-PCI

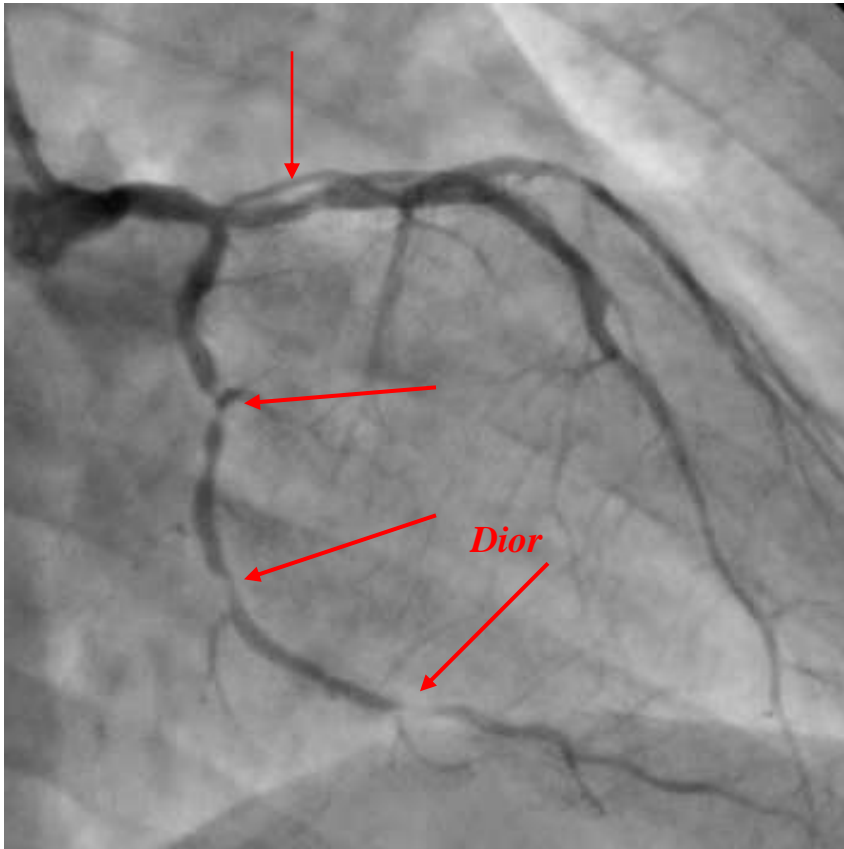


Immediate result

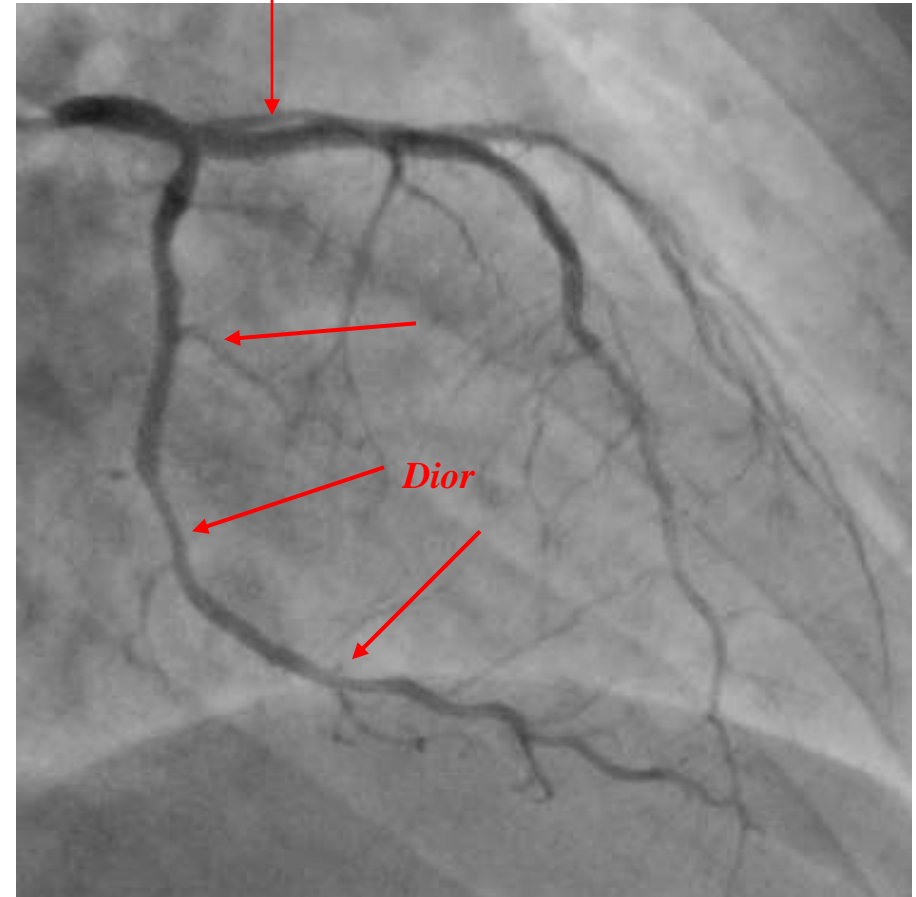


Case 4 : Three vessel disease + Small vessel

Pre-PCI

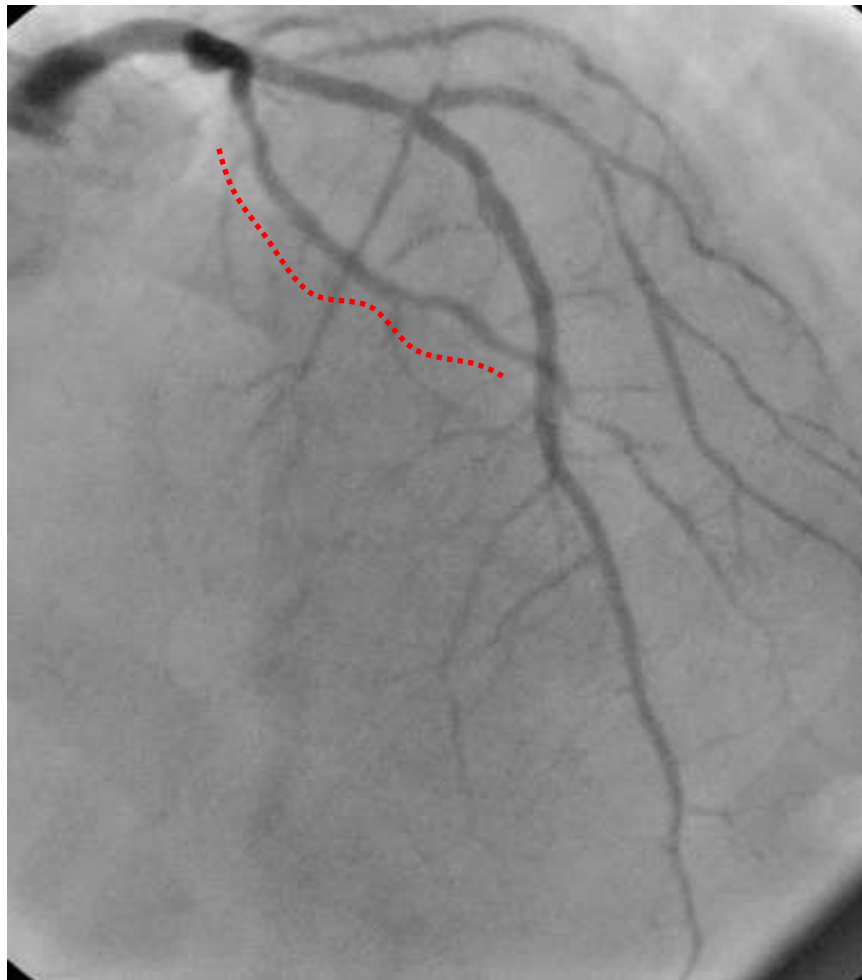


7 months after PCI



3 Vessel Disease: Combination of DES + DEB to treat SMV

Case 4 : Three vessel disease + Small vessel



7 months after PCI. Patient remained asymptomatic

Treatment of small vessel disease with paclitaxel-eluting balloon (Dior^{MT} balloon), according to the strategy described, provides excellent immediate and 6-month results with :

- 0.27 mm of late loss
- 13.3% of binary restenosis
- 2.2% TLR

- Remarkable results in a real world population
 - Really small vessel, including SB of true bifurcated lesions (111, 101, 011) and ostial lesions (001)