

# Potential conflicts of interest

Speaker's name: Layth Mimish

I have the following potential conflicts of interest to report:

- Research contracts
- X 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



## Bioabsorbable-polymer-DES Saudi Registry with 3 year followup

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KAUH, Jeddah



# Objective

To evaluate the short and long term outcome of  
SMT Biodegradable polymer coated

**Infinium** ( Paclitaxel coronary stainless steel DES)  
compared to

**Supralimus** (Sirolimus coronary stainless steel  
DES), and

**Supralimus Core** (Sirolimus coronary cobalt  
chromium DES)

in patients from daily practice.

# Contributing Cardiologists

Dr Abdllatif Khoja

Dr Mohammad Anwar

Dr Taher Hasan

Dr Vitek Reznicek

Dr Husam Ghaitani

Dr Hasan Toukhi

Dr Adil Mazin

Dr Ahmad Nada



# Followup

Home and Work Fixed and Mobile Phone numbers obtained on admission

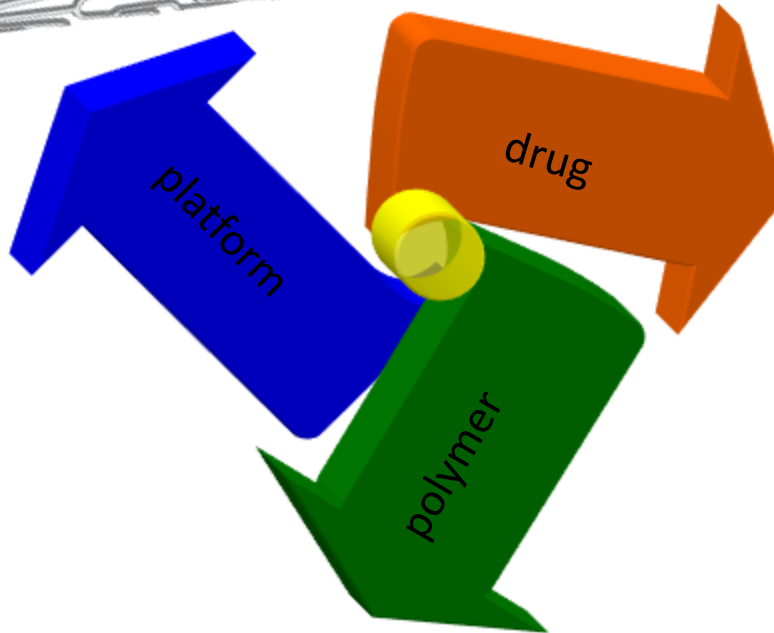
Clinical follow up at 1,3,6,12 months and then Q 6 months

Exercise or nuclear perfusion test at 6 months, then yearly

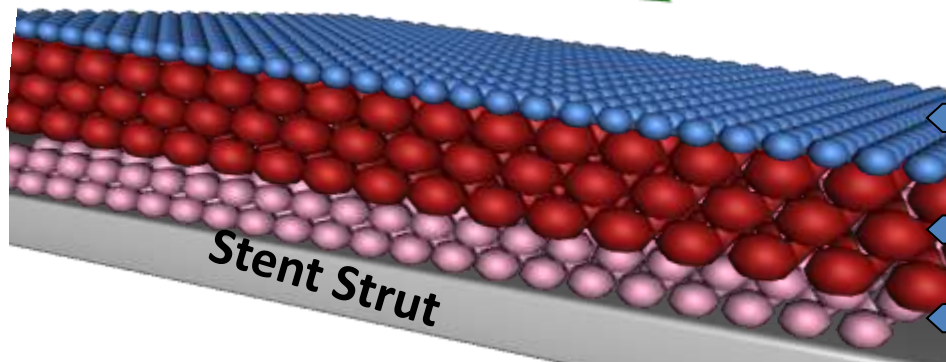
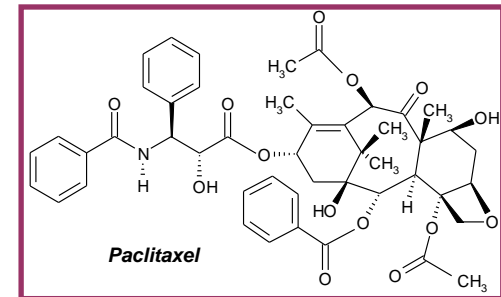
Angiogram is done if the above is positive or patient is symptomatic



millennium  
**Matrix**<sup>®</sup>  
CORONARY STENT SYSTEM CE 0434



## Paclitaxel

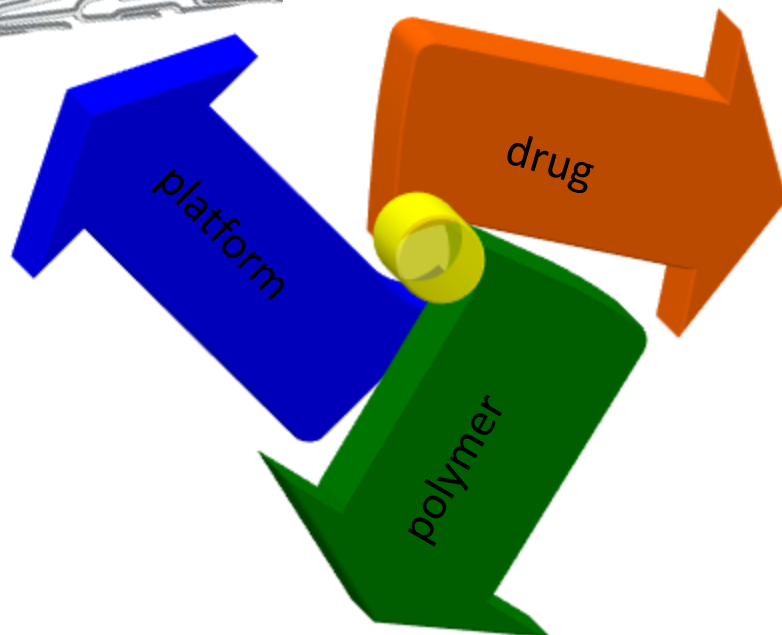


0% Drug- Top Protective layer (Protects from Light, Moisture & Premature Drug Release)

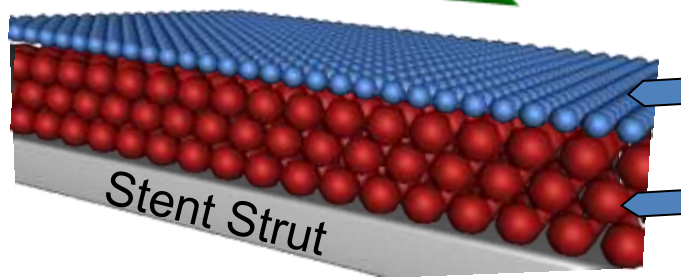
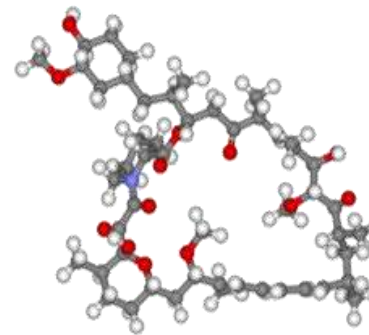
31% Drug- Middle layer (Programmed for Moderate Drug Release)

69% Drug- Base layer (Programmed for Slow Drug Release)

# Supralimus Stent



Sirolimus



0% Drug- Top layer  
(Protective layer)

100% Drug- Base  
layer (Slow Release)

# Supralimus Core

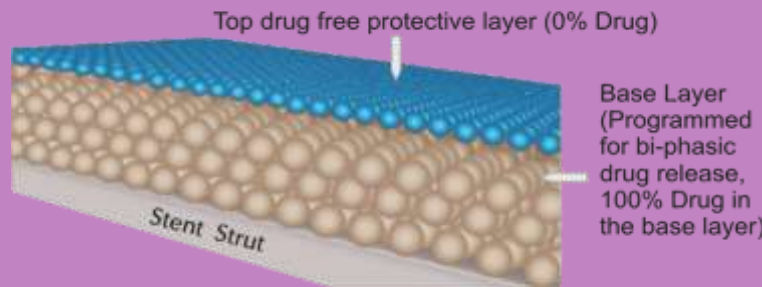
Platform

Coronnum<sup>®</sup>  
Cobalt Chromium Coronary Stent System CE



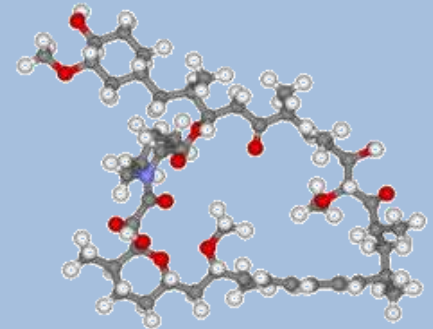
Polymers Biodegradable

The drug-polymer average coating thickness is 5-6  $\mu\text{m}$

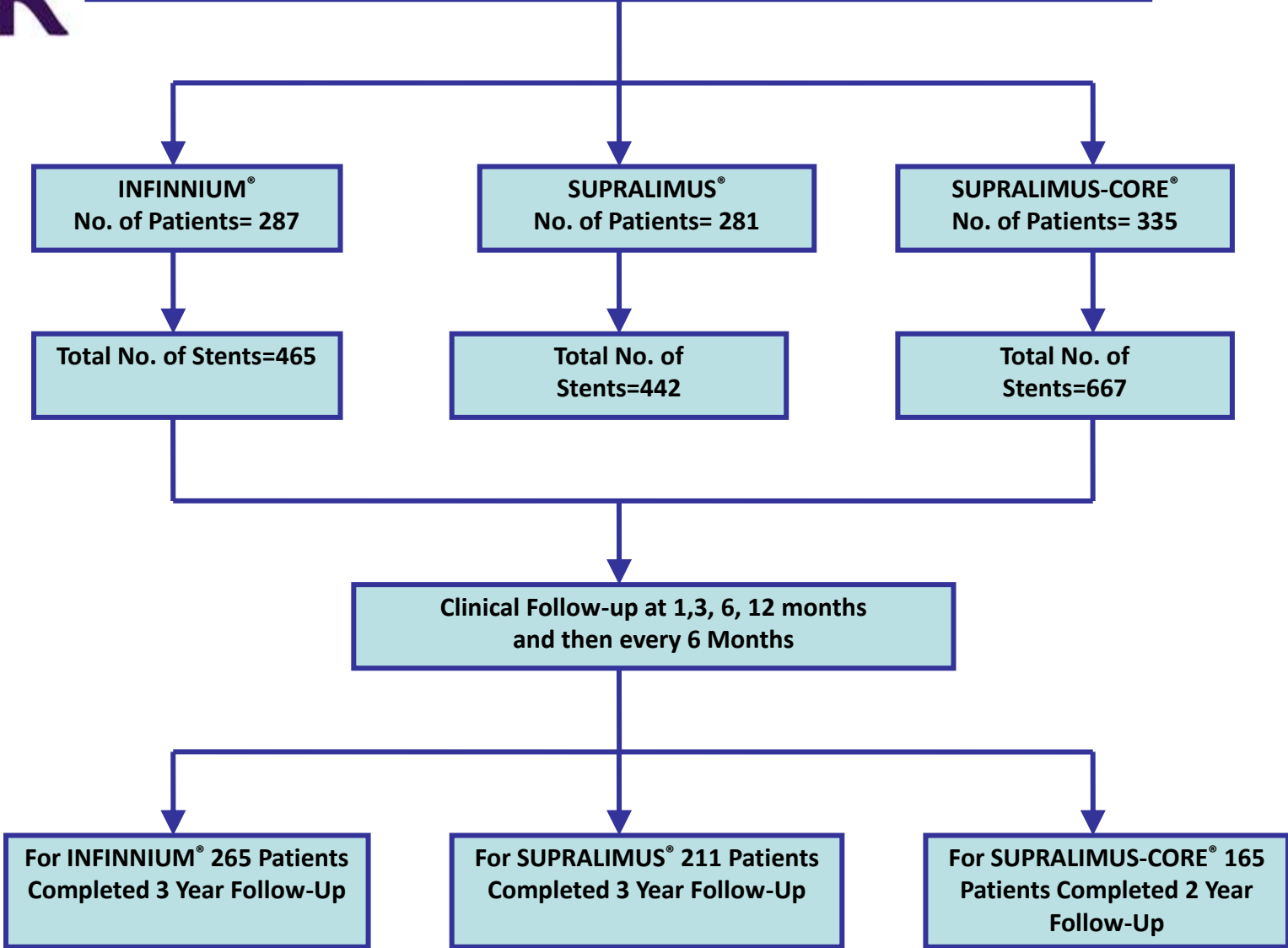


Drug

Sirolimus



**Saudi Registry total 903 Patients**



# Medications

- ASA 81mg BID or 300-500 for patients not on ASA before
- Plavix 300-600mg
- IV bolus of Heparin
- Reopro or Aggrastat Bolus , and infusion for
  - Patients with ACS
  - Diabetics with diffuse disease and small vessels
  - Complex lesions and multi-vessel Intervention

**(66% for Infinnium, & 68% for Supralimus, and 81% for Supralimus Core Group)**

# Demographic Data

Implant Period 7/2004, 5/2005, and 4/2008-Dec 2010

	INFINIUM	SUPRALIMUS	SUPRALIMUS CORE	TOTAL
No. of Stents	465	442	667	1574
No. of Patients (n)	287	281	335	903
Stent/Pt	1.9±1	1.9±1	2.2±1	2±1
(Range)	(1-9)	(1-9)	(1-6)	(1-9)
Mean Age	56±11	55±11	54±10	55±10
(Range)	(31-85)	(32-83)	(32-88)	(31-88)
Males (%)	231 (80.5%)	236 (84%)	270 (80.6%)	737 (81.6%)
Females (%)	56 (19.5%)	45 (16%)	65 (19.4%)	166 (18.4%)

# CAD Risk Factors

	INFINIUM	SUPRALIMUS	SUPRALIMUS CORE	TOTAL
No. of Patients	287	281	335	903
Diabetes (%)	150 (52%)	152 (54%)	181 (54%)	483 (53.5%)
Hyperlipidemia (%)	190 (66%)	185 (66%)	202 (60%)	577 (64%)
Hypertension (%)	179 (62%)	166 (59%)	180 (54%)	525 (58%)
Smoking (%)	152 (53%)	149 (53%)	172 (51%)	473 (52%)

# Clinical Presentation

	INFINIUM	SUPRALIMUS	SUPRALIMUS CORE	TOTAL
No. of Patients	287	281	335	903
Mean CCS Class	3±1	3±1	3±1	3±1
UAP (%)	110 (38%)	110 (39%)	129 (39%)	349 (39%)
NSTEMI (%)	37 (13%)	37 (13%)	54 (16%)	128 (14%)
STEMI (%)	32 (11%)	35 (12%)	68 (20%)	135 (15%)
Shock	2	1	1	4

# Number of Vessels Rx/ Case

	INFINIUM	SUPRALIMUS	SUPRALIMUS CORE	TOTAL
No. of Patients	287	281	335	903
Single vessel (%)	153 (53%)	147 (52%)	173 (52%)	473 (52%)
Double Vessel (%)	2(32%)	79 (28%)	117 (35%)	288 (32%)
Tripple Vessel (%)	42 (15%)	55 (20%)	45 (13%)	142 (16%)

# Lesion Characteristics

	INFINNIUM	SUPRALIMUS	SUPRALIMUS CORE	TOTAL
No. of Stents	465	442	667	1574
Small Vessel (%)	172 (37%)	157 (35%)	241 (36%)	570 (36%)
Long Lesion (%)	212 (45%)	204 (46%)	321 (48%)	737 (47%)
Calcified (%)	96 (21%)	92 (21%)	142 (21%)	330 (21%)
Restenotic Lesion (%)	29 (6%)	31 (7%)	47 (7%)	107 (7%)
Mean RVD	3±0.5	3±0.5	2.9±0.4	3±0.5
Mean Lesion Length	18.6±9	19±8	20±8	19±8

Small Vessel 2.5mm  
Long Lesion > 22mm

# Stenting

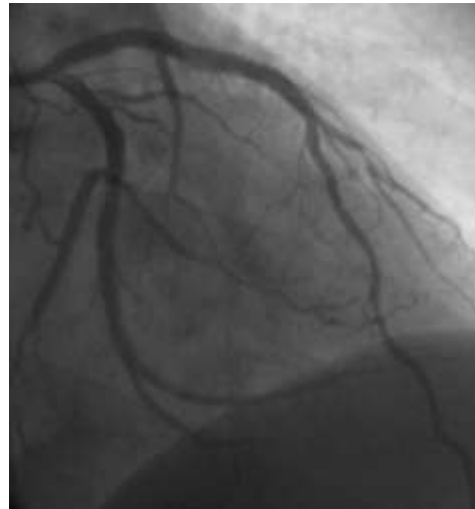
	INFINNIUM	SUPRALIMUS	SUPRALIMUS CORE	TOTAL
No. of Stents	465	442	667	1574
Direct Stenting	10	31	15	56
Mean Stent Diameter (mm)	3±0.5	3±0.5	3±0.4	3±0.5
Mean Stent Length (mm)	22±7.5 (11-39)	22±7 (9-39)	23±7 (12-36)	22±7 (9-39)

Analysis done per Stent

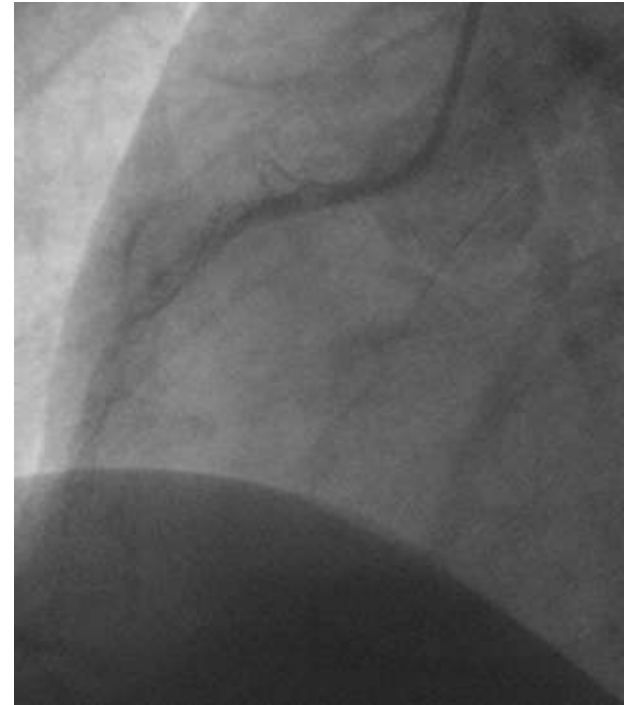
# Outcome

	INFINIUM	SUPRALIMUS	SUPRALIMUS CORE **(2Yrs only)	TOTAL
No. of Stents	465	442	667	1574
No. of Patients	287	281	335	903
Success (%)	461 (99%)	433 (98%)	663 (99%)	1557 (99%)
Acute MACCE (%)	3 (1%)	2 (0.7%)	3 (0.9%)	8 (0.9%)
Completed 3 Yrs FUP	265 (92.3%)	211 (75.1 %)	165 (49.2%)	
MACE upto 3Yrs Followup (%)	15 (6%)	6 (2.2%)	10 (3.1%)	31 (3.6%)
Restenosis documented	31 (11.7%)	14 (5%)	14 (4.3%)	59 (6.8%)
CABGS	8	7	1	16

# T.B Dr V Acute Inf MI

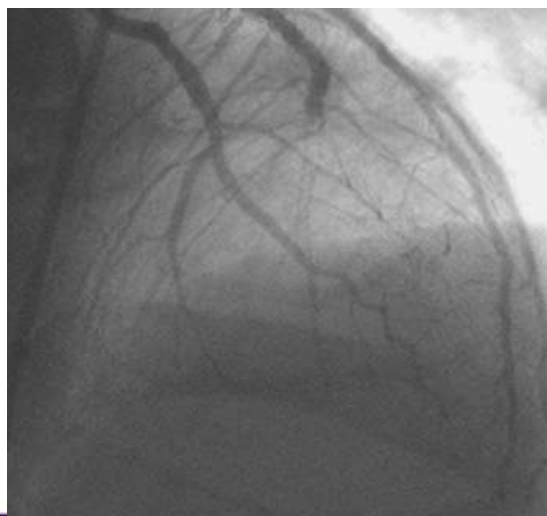
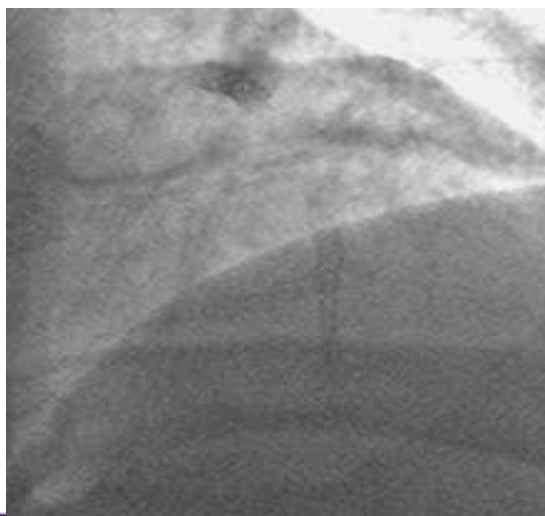
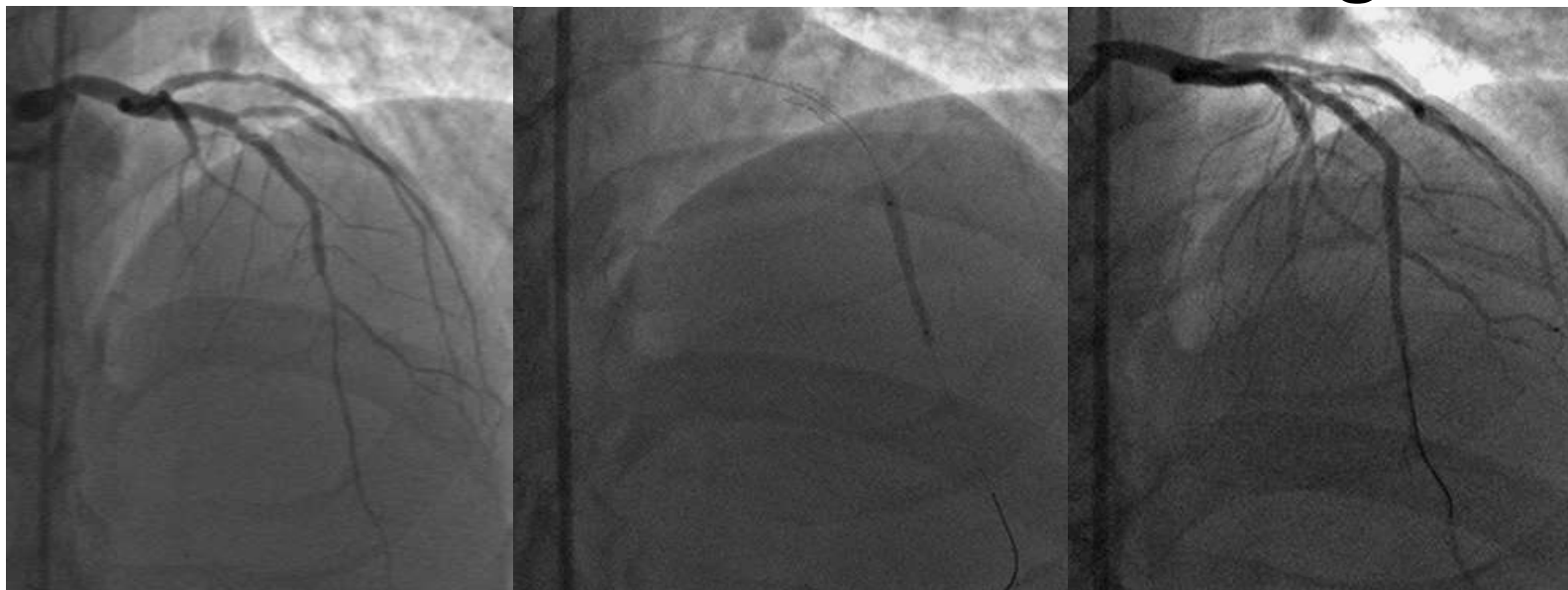


# T.B Dr V FUP 1/12

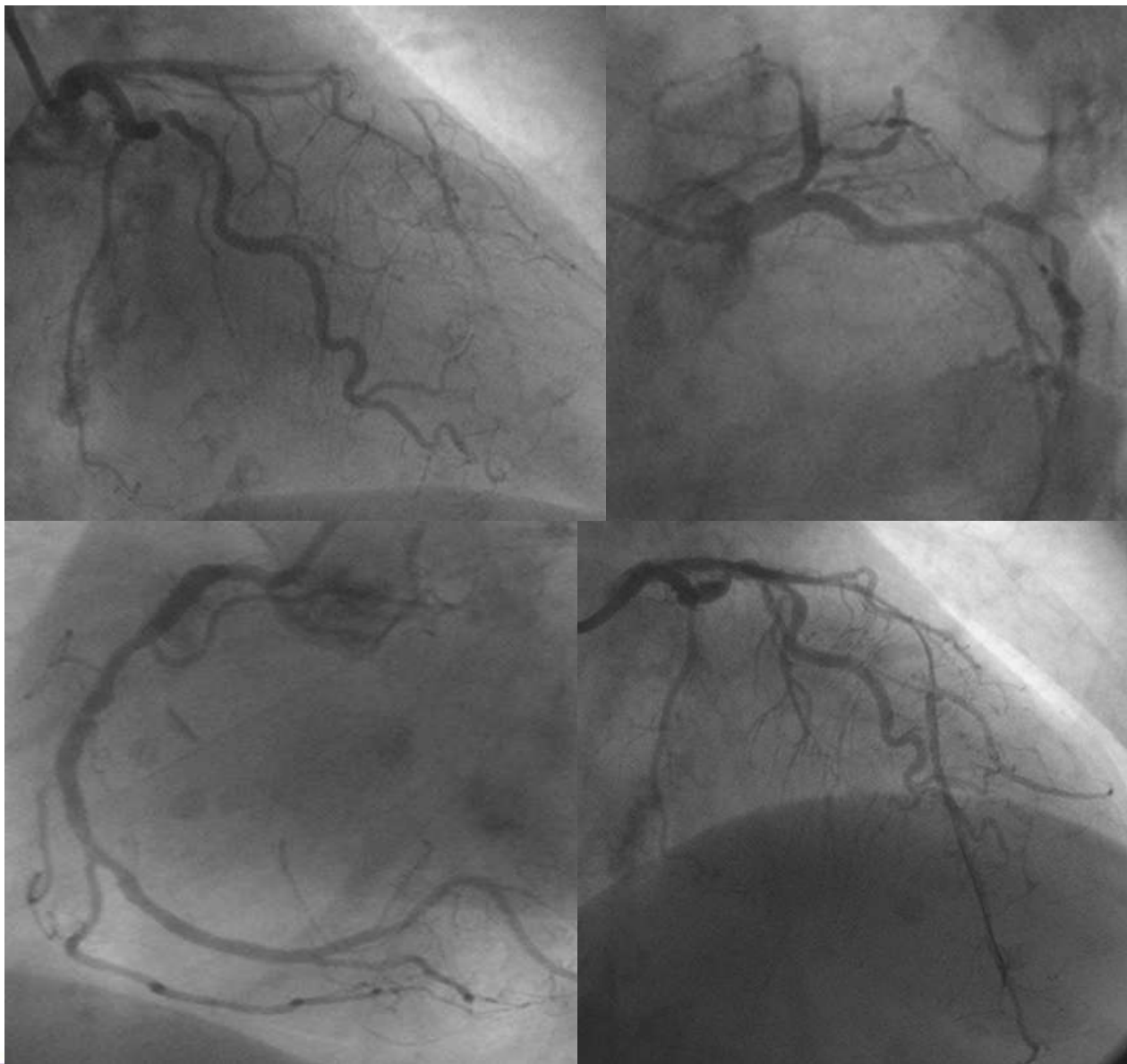


Mr E

# New Lesion S/P LAD Stenting



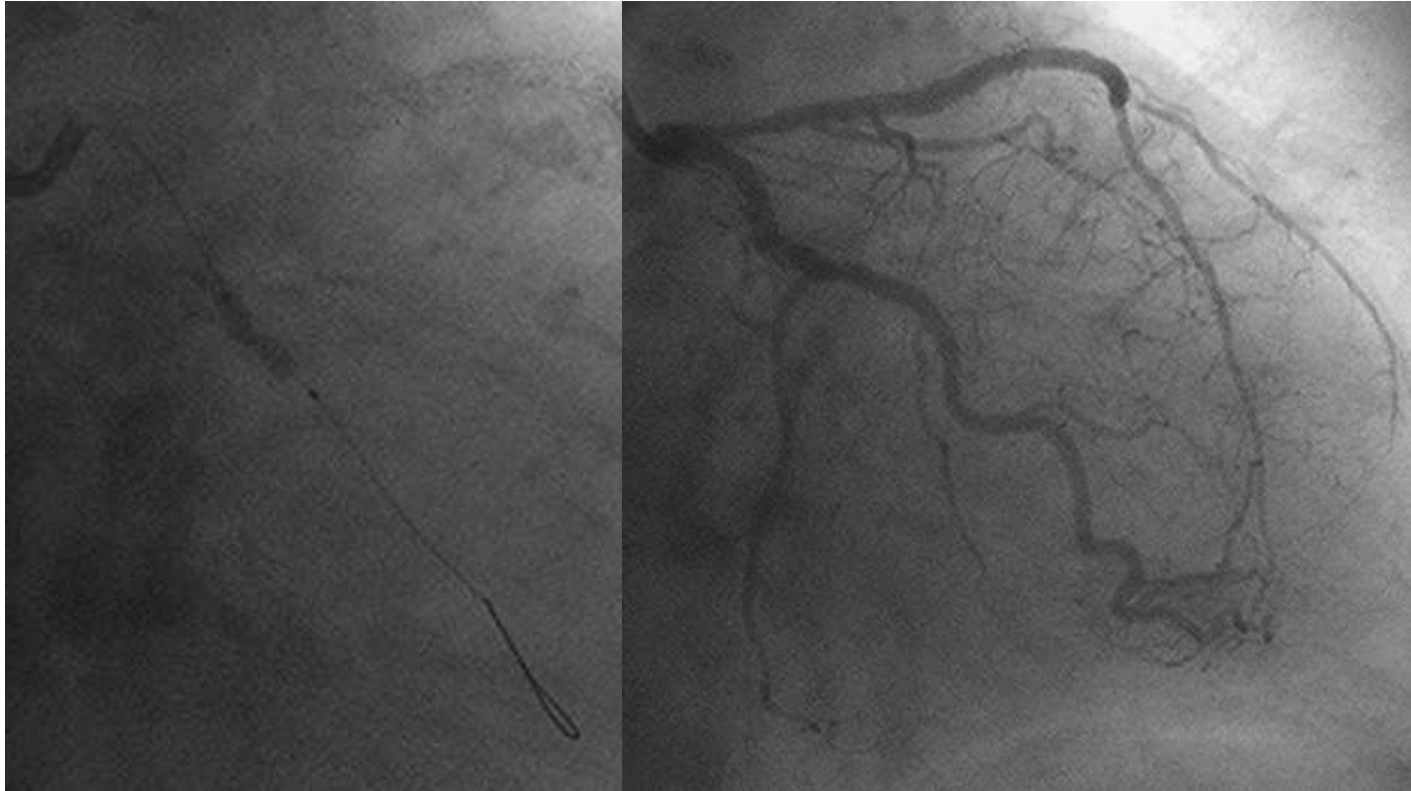
# S.T. 76 Yr old Female, Post ASMI UAP



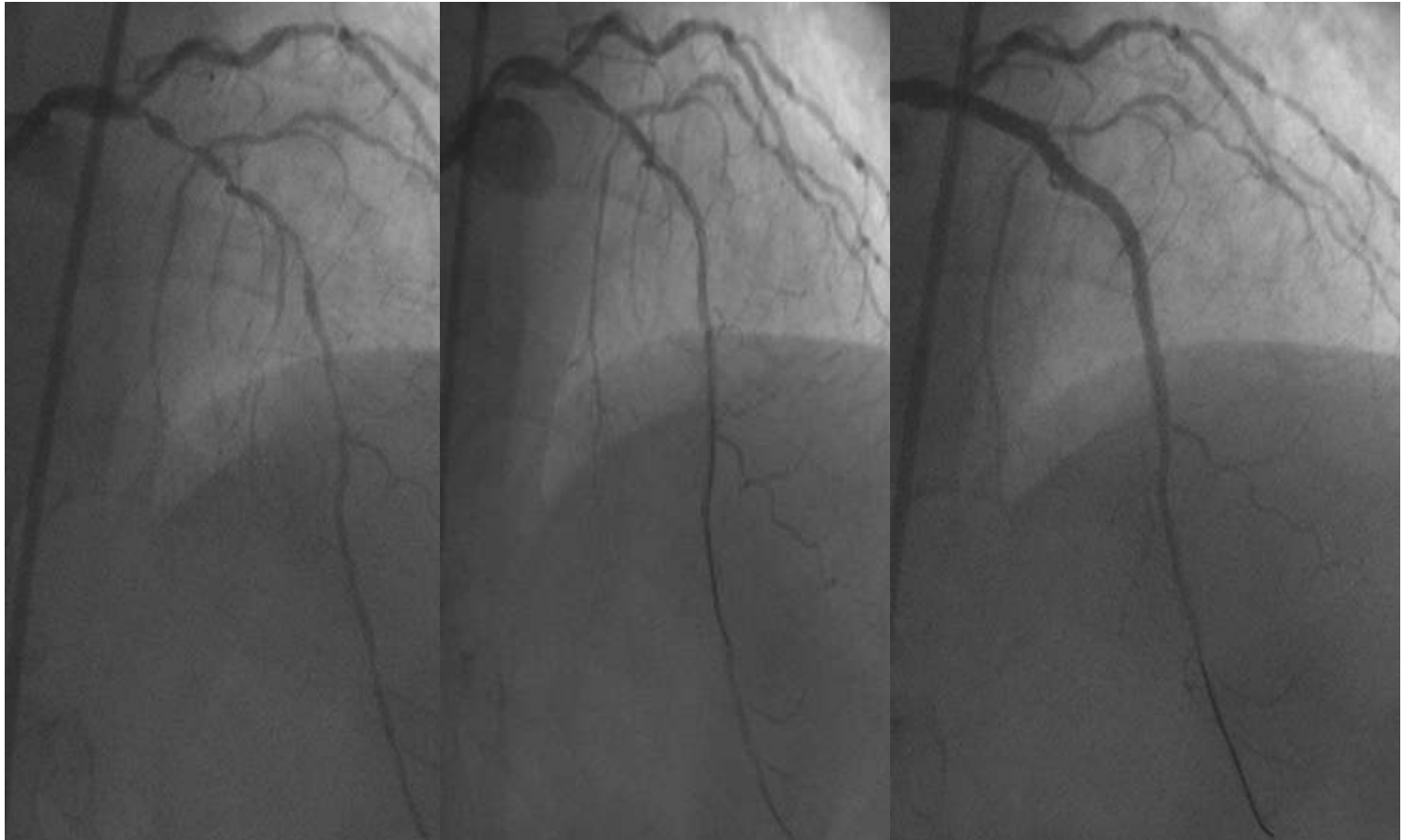
# S.T. 76 Yr old Female, Post ASMI UAP



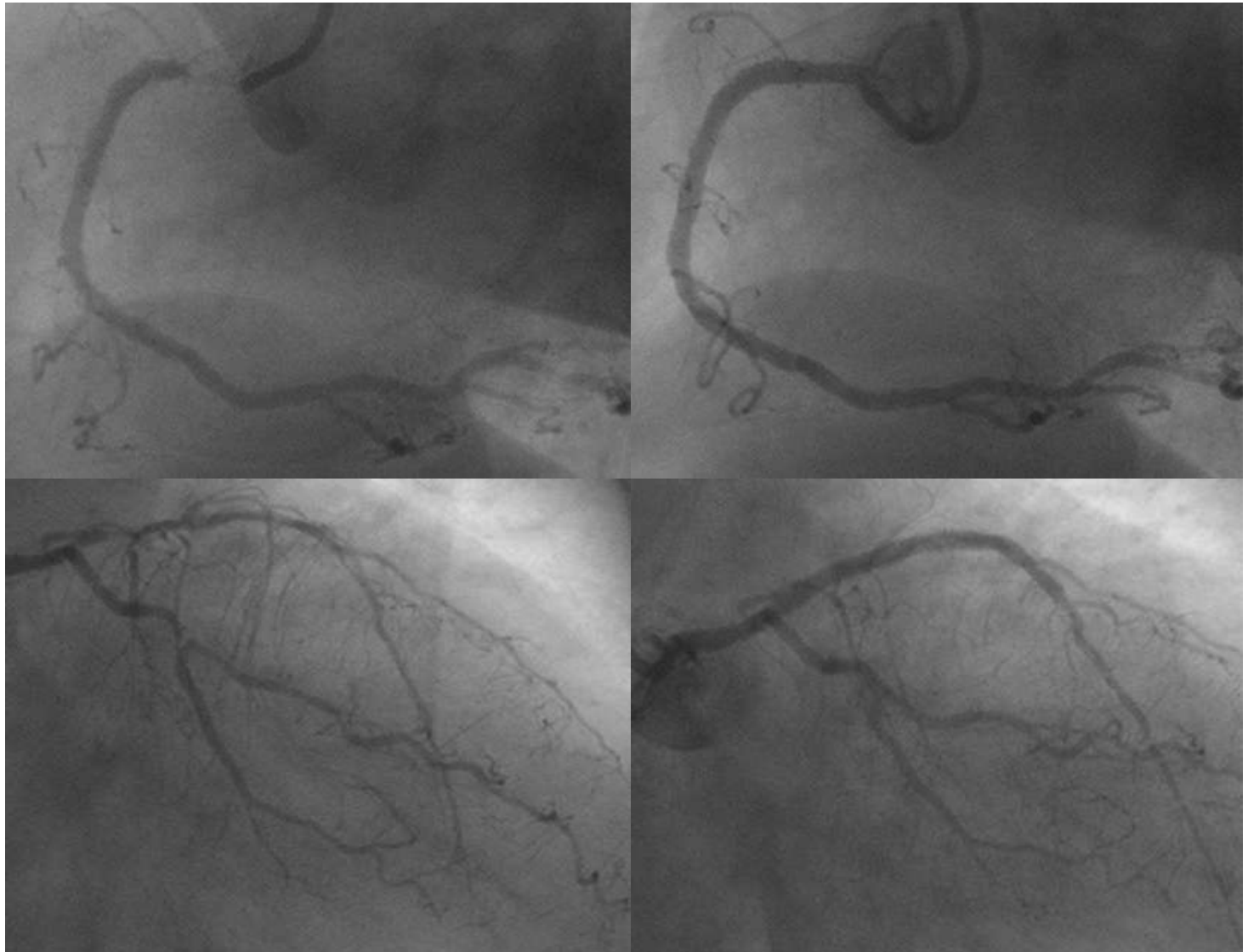
# Cx Also



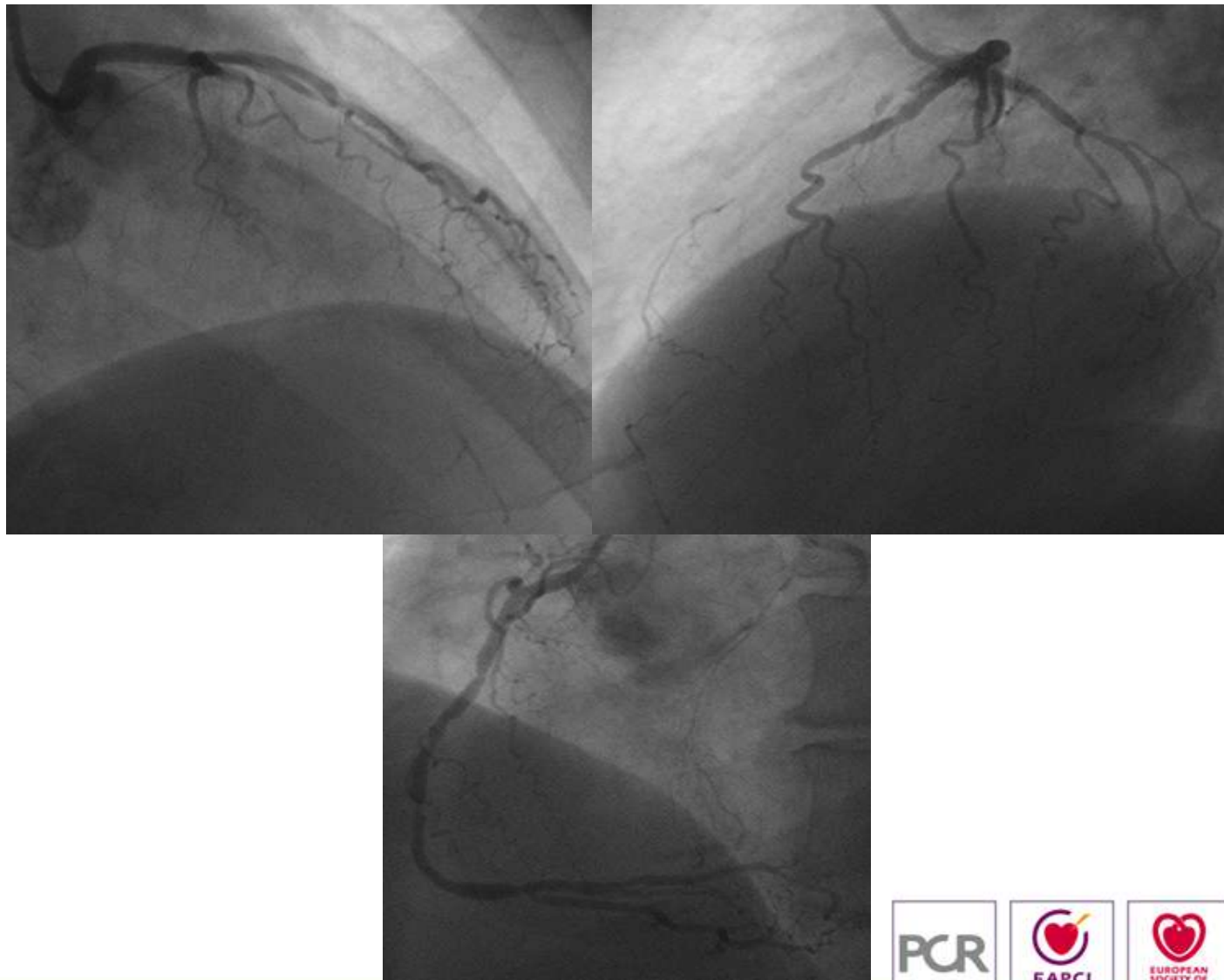
S. O. 80 YRS, UAP



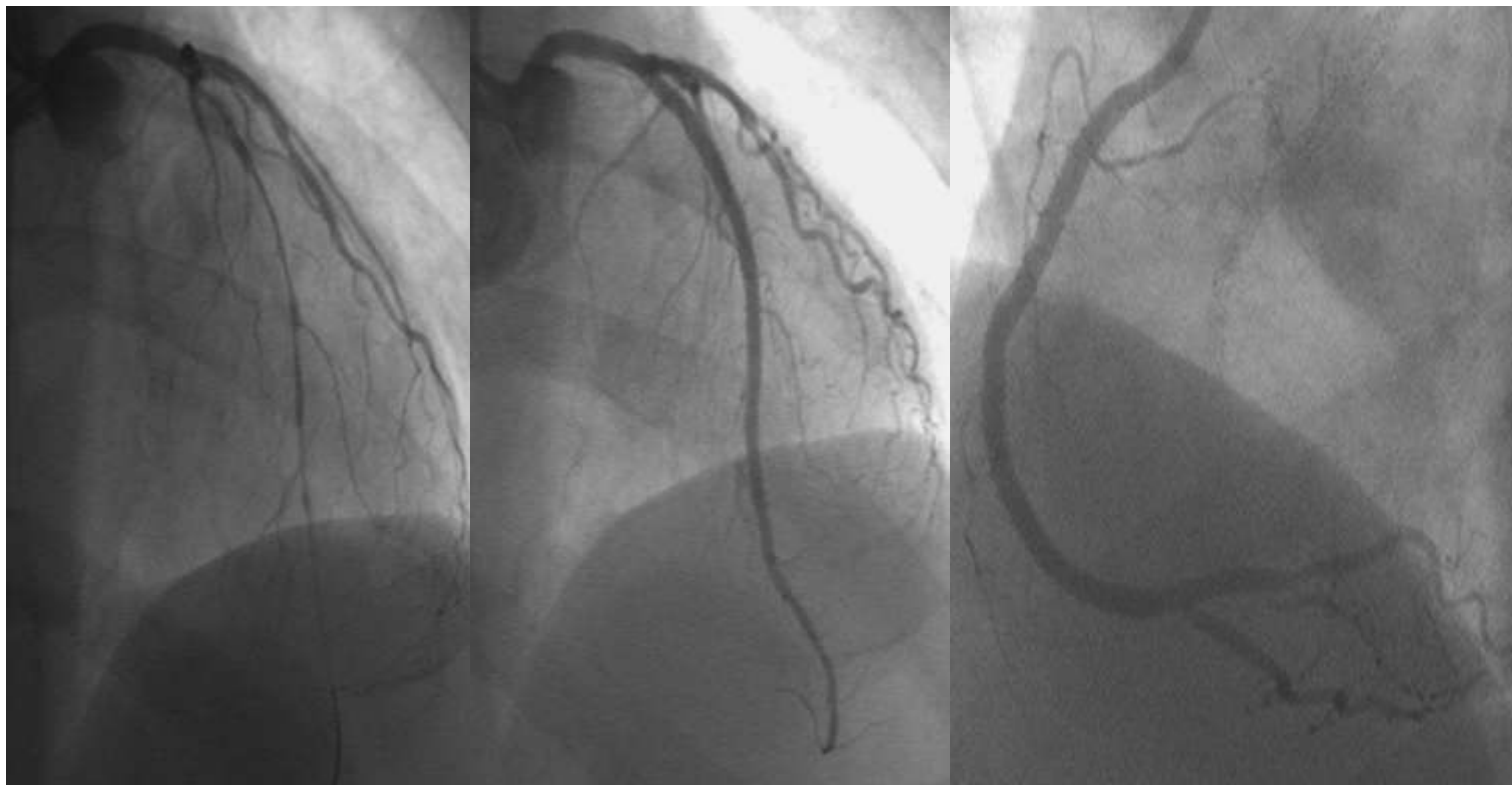
# S. O. 80 YRS, UAP



Mr J. A. 39 Yrs UAP  
Strong +ve GXT



# Mr J. A. 39 Yrs UAP Strong +ve GXT



# Conclusion

- The acute and up to 3 years follow up data clearly shows the safety of the stents, both on short and long term periods .
- Despite the non-selectivity of the patients, complexity of the lesions treated, and high prevalence of Diabetes, small vessels and long lesions treated, hyperlipidemia, and patients with acute coronary syndrome , the follow up data prove efficacy and non inferiority compared to available data from the literature on similar DES .
- Comparative studies with long term FUP are required to prove non inferiority in the same patient population