LEADERS FREE

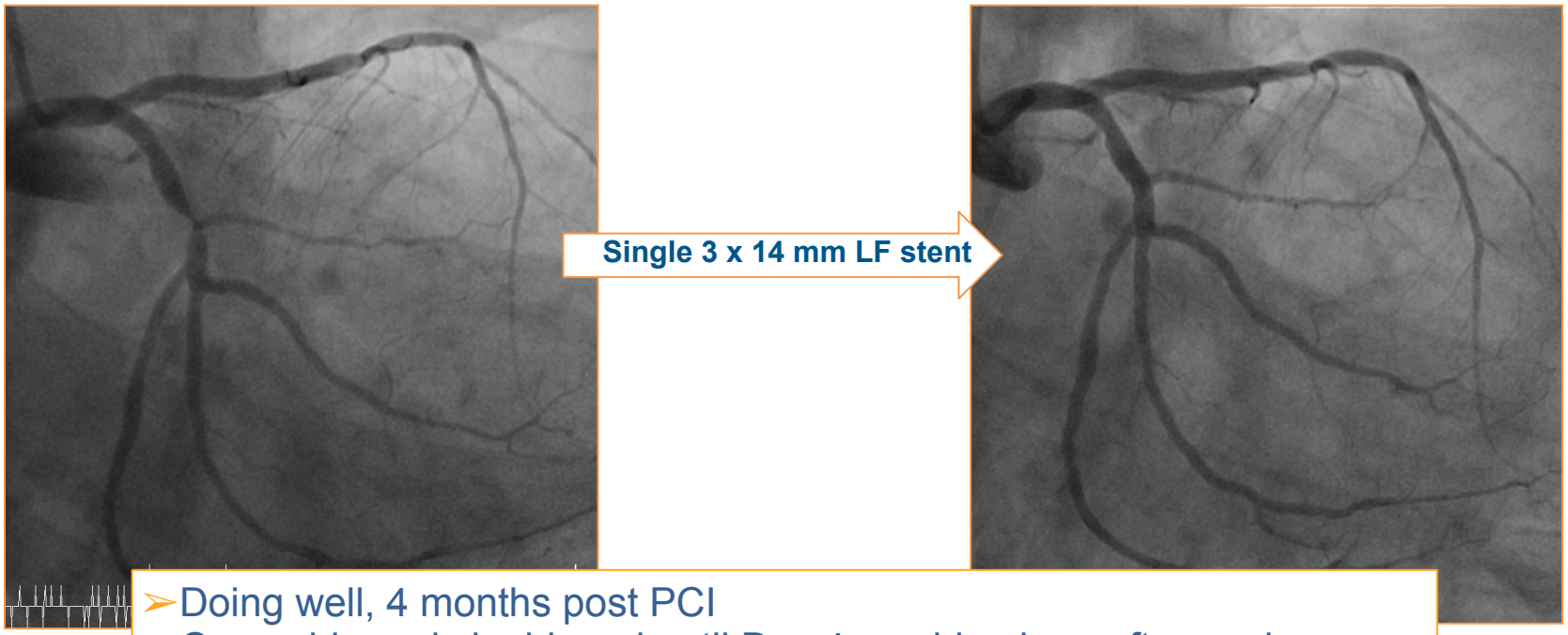
A LIBRARY OF LEADERS FREE CASES

Philip Urban MD

Washington, March 16, 2017

A straight forward case…

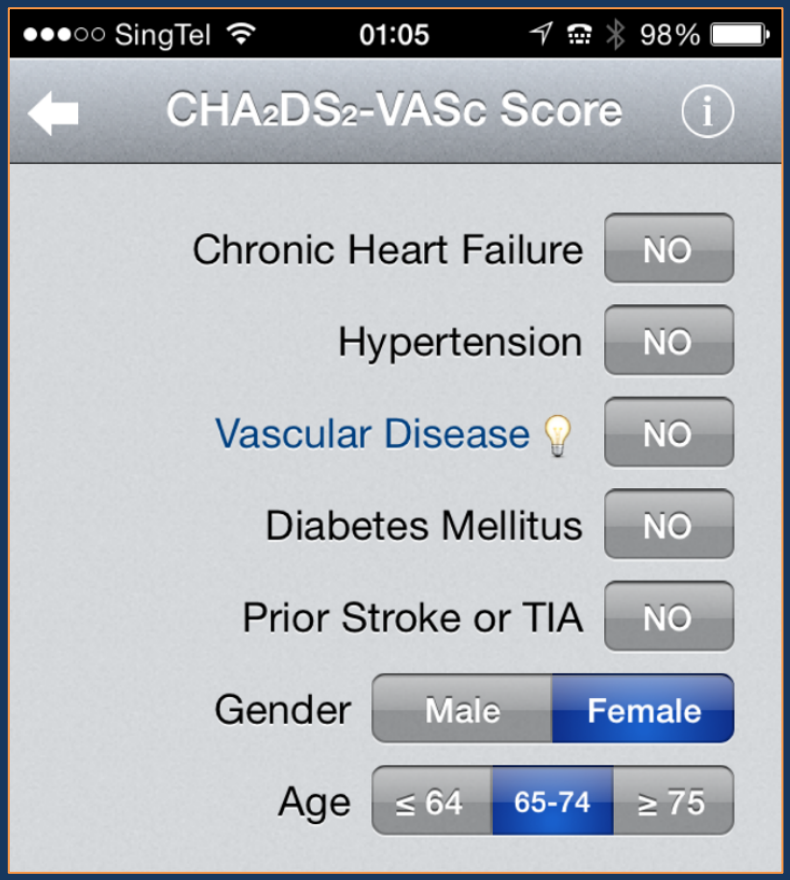
- 66 year old lady with recurrent grade 2 AP in October 2013
- Lobectomy March 2013 for bronchial carcinoma
- Bilateral hip replacement planned ASAP (pain ++ & walking with difficulty)
- Randomized November 5, 2013

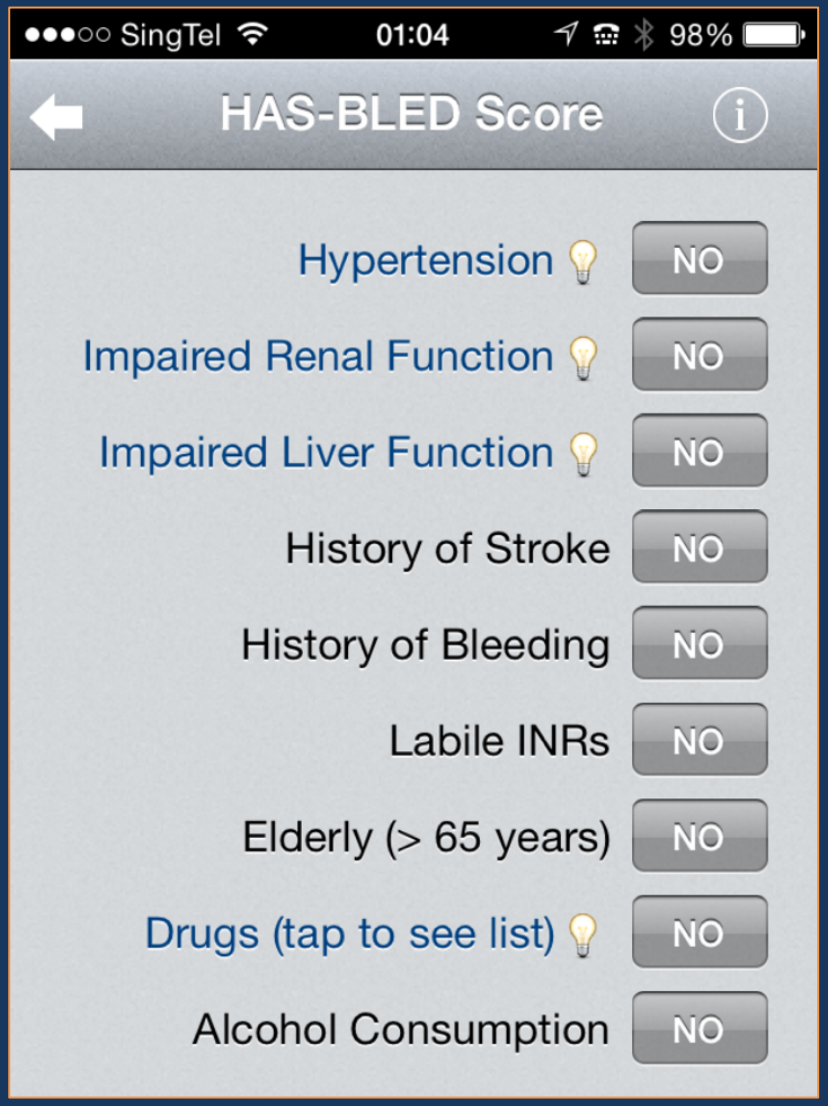


- Doing well, 4 months post PCI
- On aspirin and clopidogrel until Dec 4, aspirin alone afterwards
- hip operations done January and March 2014: no problems (TF 1 unit)

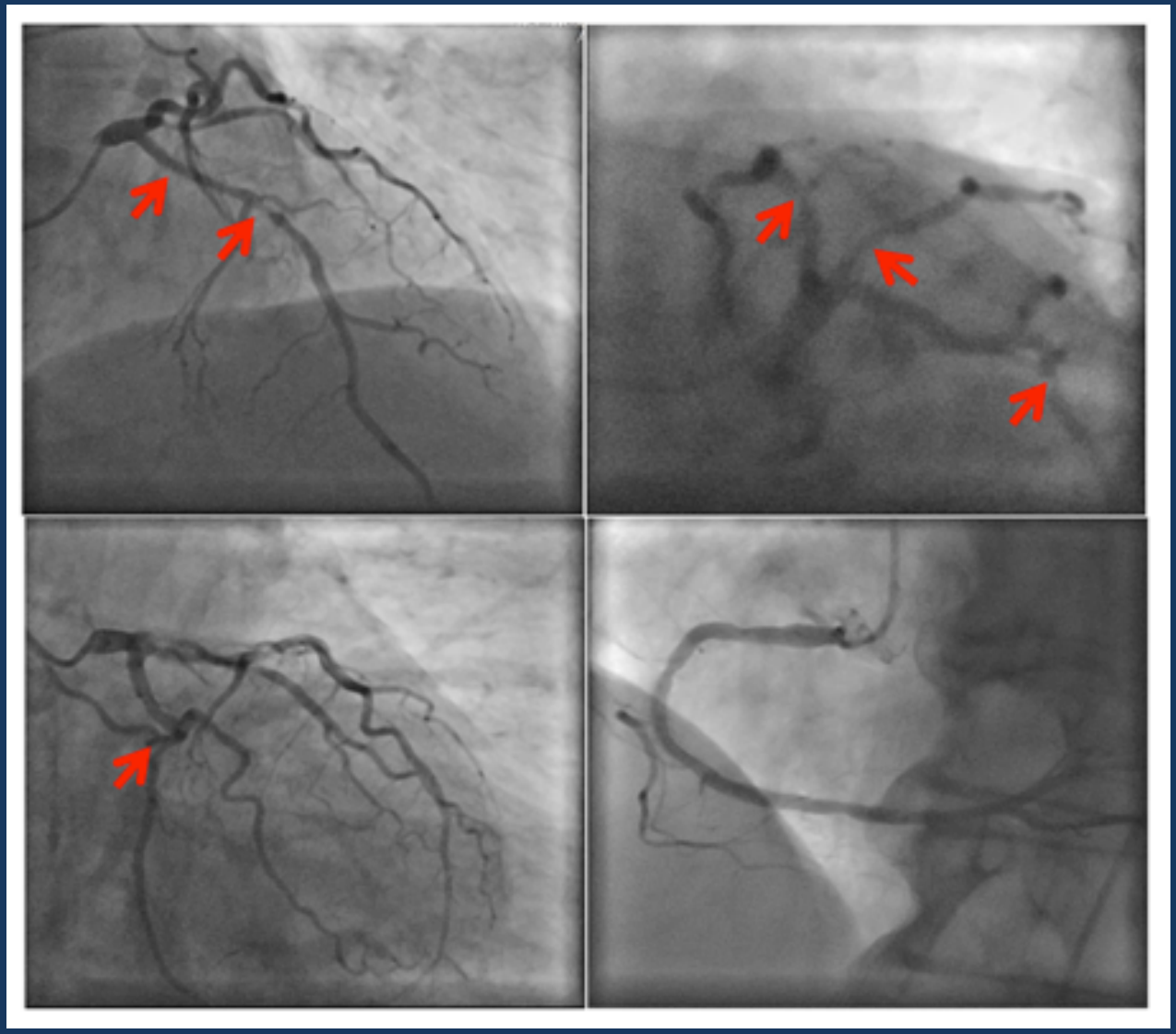
de Waha S, MD; Ludwig D, MD; Abdel-Wahab M, MD; & Richardt G, MD. Bad Segeberger Clinics, Germany

- 73 year old lady admitted for recurrent stable AP
- Previous BMS to mid-LAD and RCA
- AF on OAC
- (CHA2DS2-VASc 5 & HAS-BLED 2)

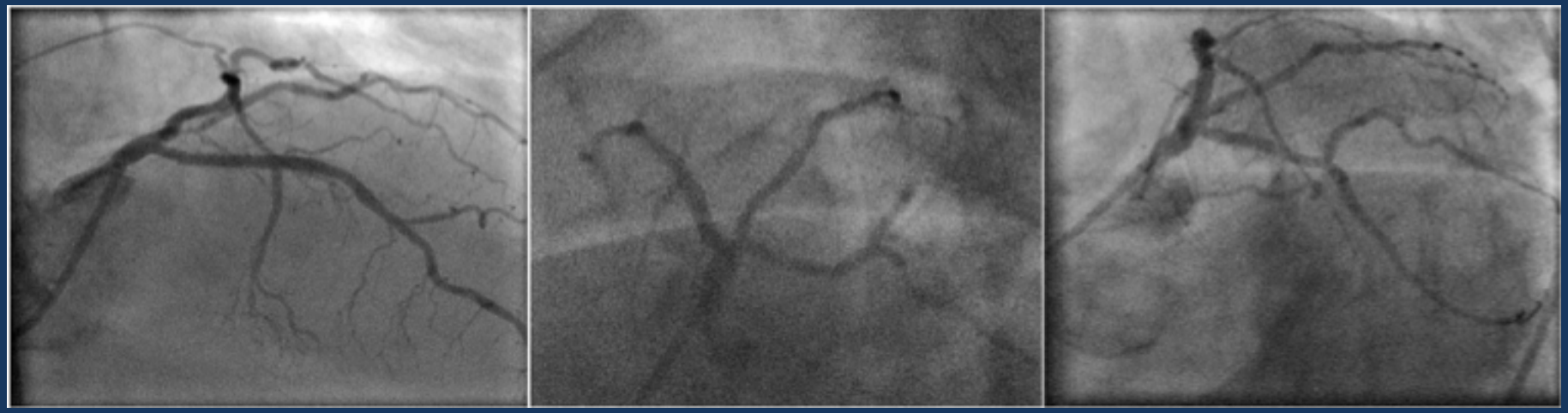

SingTel
01:05
98%
CHA2DS2-VASc Score
Chronic Heart Failure
NO
Hypertension
NO
Vascular Disease
NO
Diabetes Mellitus
NO
Prior Stroke or TIA
NO
Gender
Male
Female
Age
≤ 64
65-74
≥ 75


SingTel
01:04
98%
HAS-BLED Score
Hypertension
NO
Impaired Renal Function
NO
Impaired Liver Function
NO
History of Stroke
NO
History of Bleeding
NO
Labile INRs
NO
Elderly (> 65 years)
NO
Drugs (tap to see list)
NO
Alcohol Consumption
NO

2 VD: ISR of LAD BMS and de novo lesions of intermediate & LCX



4 LF stents to LAD (2), INT (1) LCX (1)

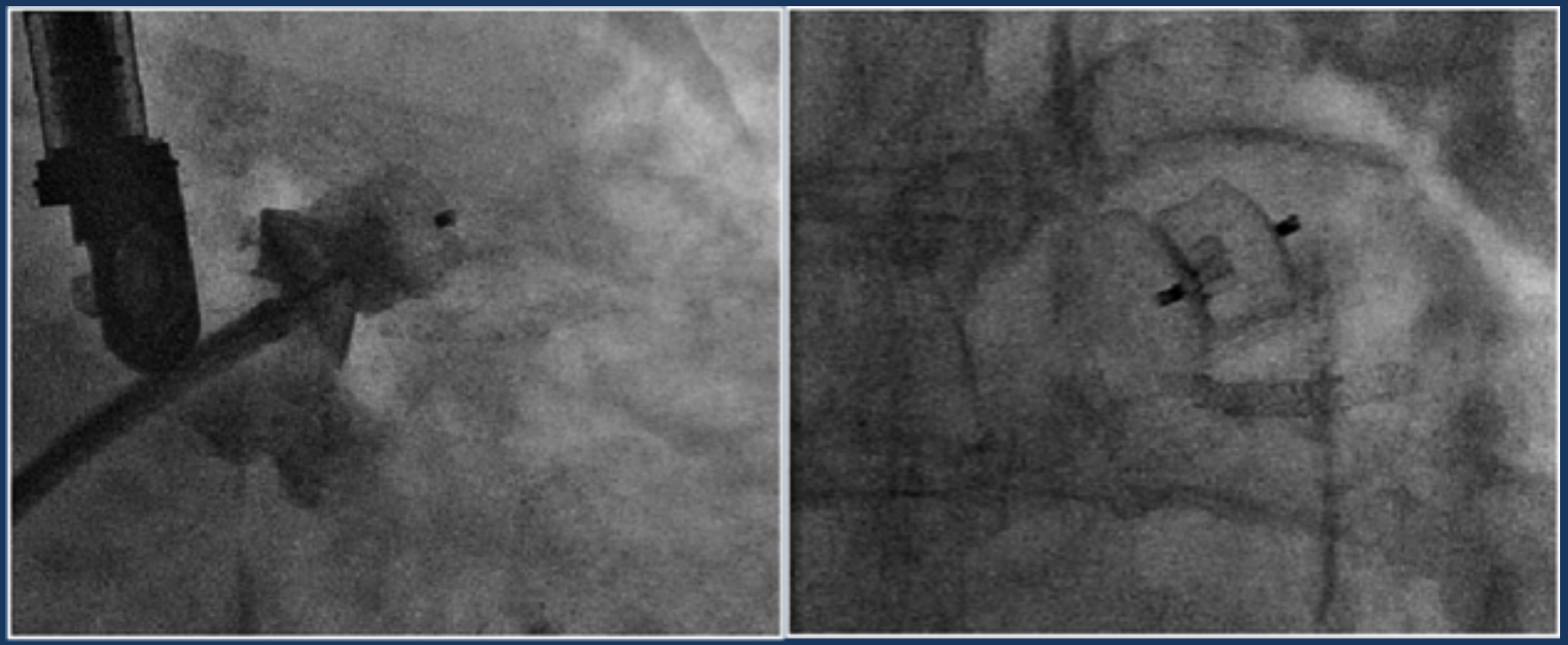


Discharged on triple therapy + PPI
Doing well at 1 month FU visit,
so clopidogrel stopped

GI bleed 2 months post procedure

- Presentation with recurrent meleana
- Source only identified on 2nd gastroscopy (Dieulafoy lesion)
- Clipping of culprit vessel
- Gastroenterologists consider OAC contraindicated

LAA occlusion with Amplatzer device



Discharged on aspirin and clopidogrel

Dr. Paul Ong
TTSH Singapore

- 68 year old Chinese male taxi driver
- Non smoker, no DM
- Presented 6 weeks earlier with NSTEMI and CVA
- ECG showed AF with subtle ST changes inferiorly
- MRI brain showed focal acute infarction in right occipital lobe with no haemorrhagic conversion

- Complete neurological recovery
- Put on aspirin and rivaroxaban
- Elective angiogram 6 weeks later
- Randomized 14/4/2014

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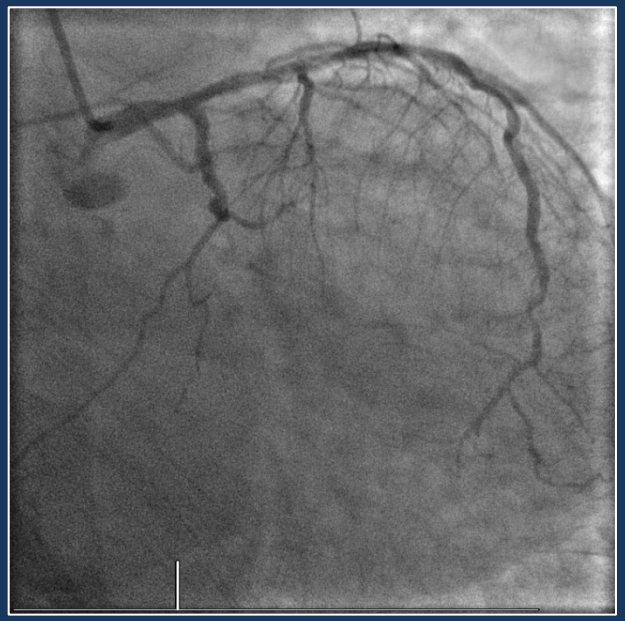
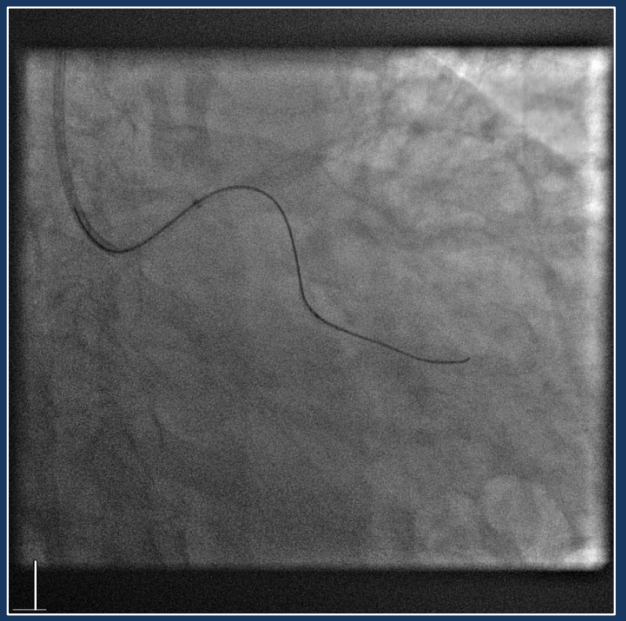
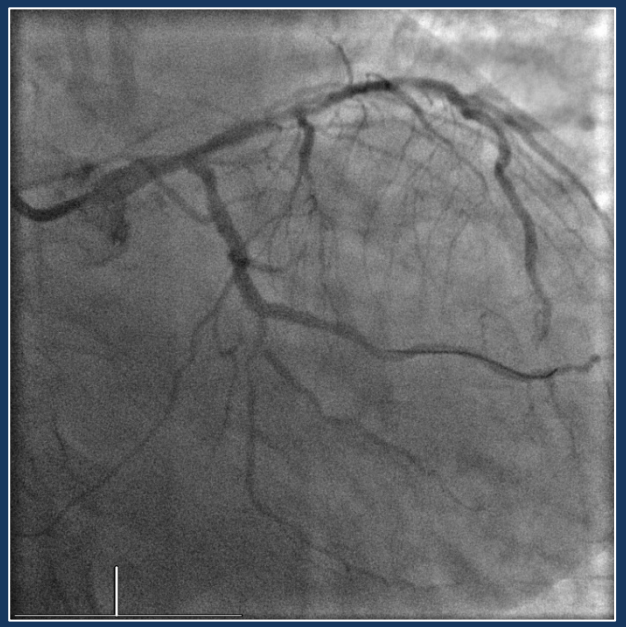


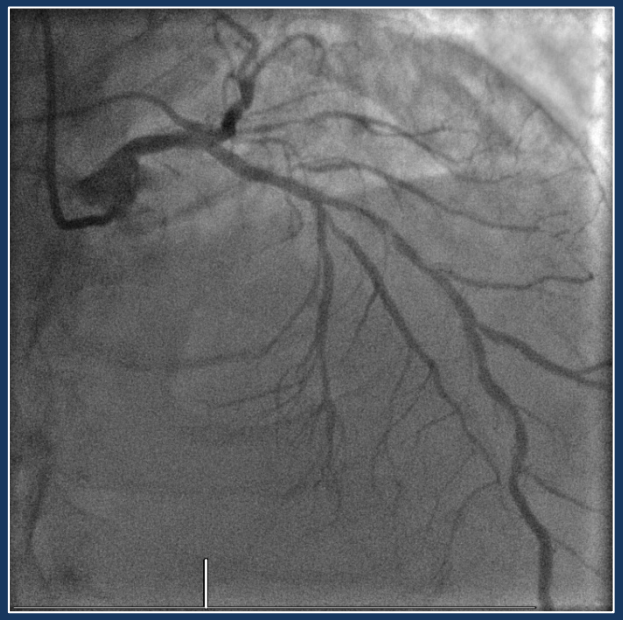


R radial Sheathless PB3.0 guide

CTO Lesion crossed with UltimaBros 3 and predilated with 1.0 and 2.0 balloon with Guideliner support due to tortuosity

Study stent 2.5x28mm deployed with Guideliner support at 12 atm followed by high pressure post dilatation

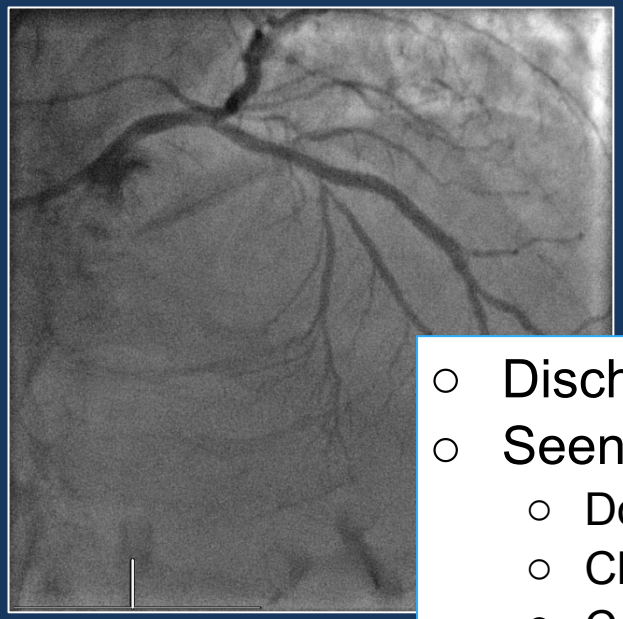


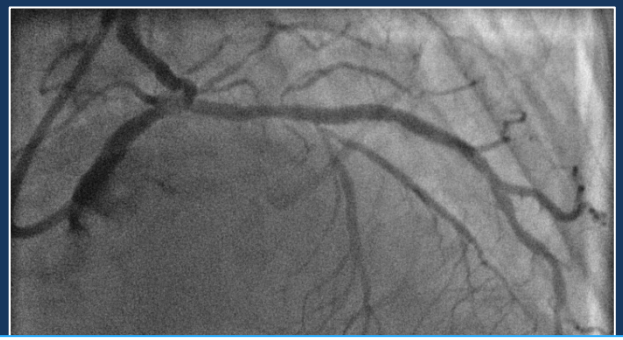


Long diffuse LAD lesion predilated with 2.0*13mm scoring balloon at 14 atm

Lesion stented with 2.75x18mm and 3.0x11mm

Study stent followed by high pressure post dilatation





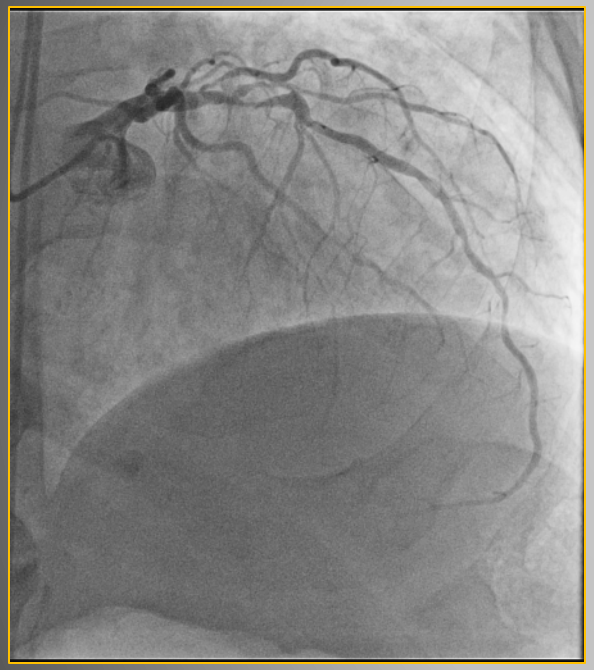
- Discharged on DAPT+NOAC
- Seen at 1 month:
  - Doing well, no angina
  - Clopidogrel stopped
  - Continued on aspirin + rivaroxaban
- At 4 months: no bleeding, angina or CVA

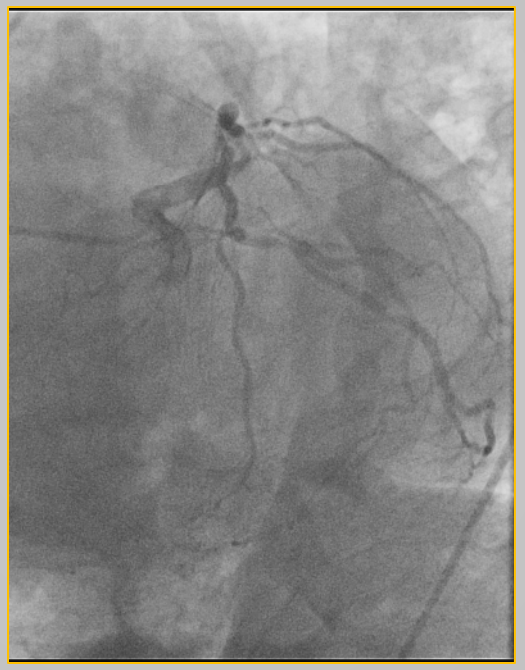
Christoph Dubois MD

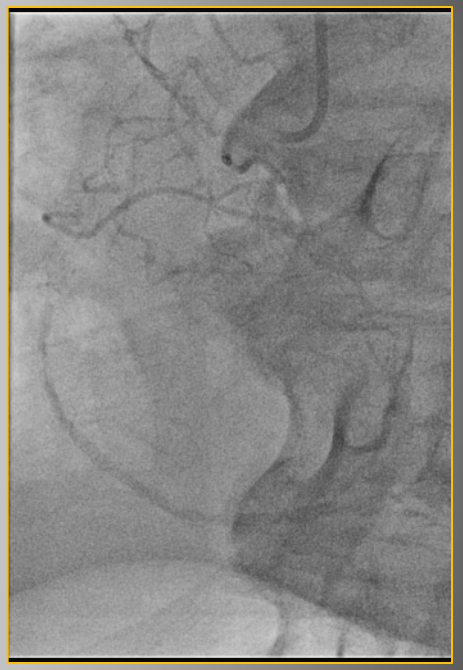
- 84 years old man
- NIDD, high BP, hyperlipidemia
- Hx gastric ulcer
- AF on Pradaxa (110 mg BD)
- Creatinine clearance 52 ml/min
- Hb 10.7 g/dl

- Admitted for CHF, preserved LVEF, inferior hypokinesia, biopsies negative for amyloidosis

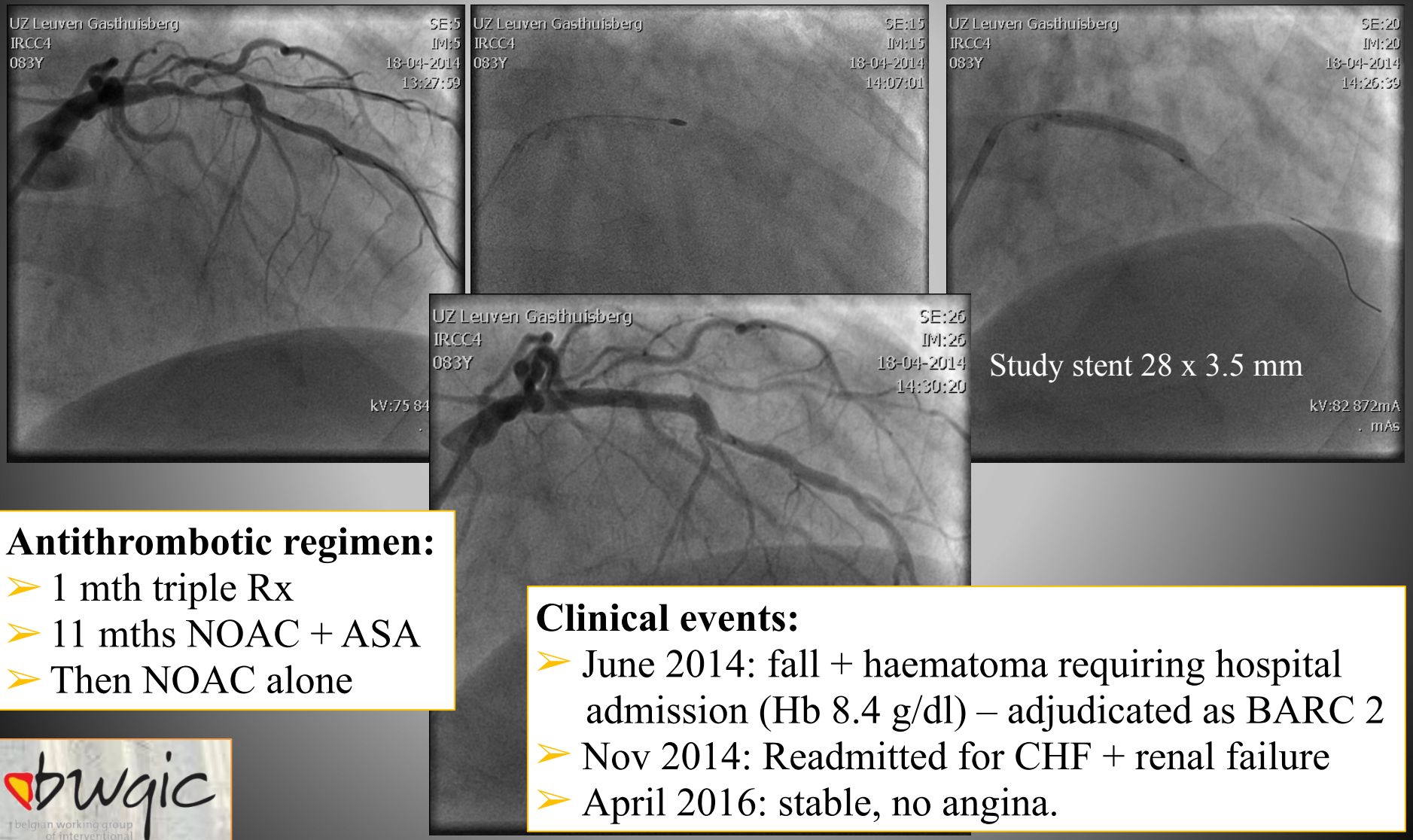
Diagnostic angiogram







PCI - April 2014



Antithrombotic regimen:

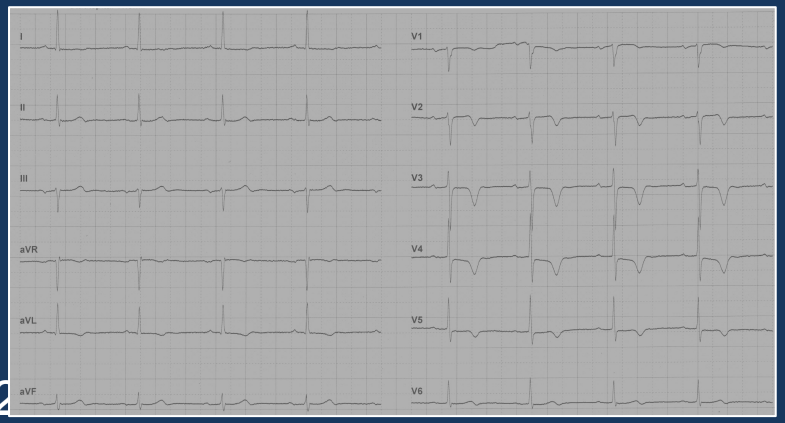
- 1 mth triple Rx
- 11 mths NOAC + ASA
- Then NOAC alone

Clinical events:

- June 2014: fall + haematoma requiring hospital admission (Hb 8.4 g/dl) – adjudicated as BARC 2
- Nov 2014: Readmitted for CHF + renal failure
- April 2016: stable, no angina.

Dr. Franz Eberli
Triemli Spital Zurich

- 74 year old male, 5 weeks crescendo angina (August 2013).
- First episode during a mountain hike, now with minimal exertion



- 2
  - Radical prostatectomy & radiation therapy
  - Radiation proctitis complicated by infrequent bleeding
- 2013 Bladder cancer: partial surgical resection of bladder

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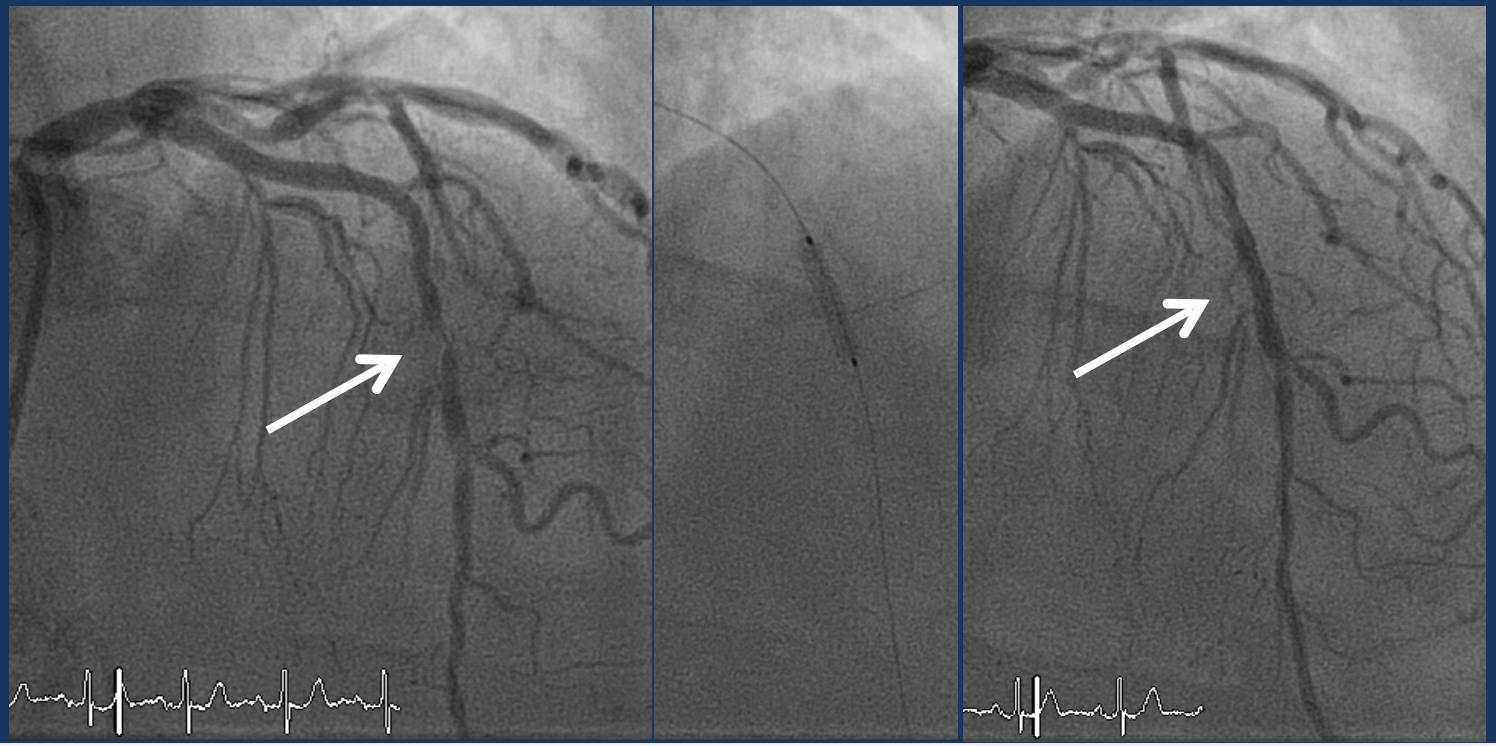
74 Year Old Man with Crescendo Angina
PCI on August 14, 2013

Stenosis mid LAD | Stent 2.75x14mm | Result post Stent



- Stopped Clopidogrel mid-September 2013
- May 2014: macrohematuria + reintervention (on ASA) for bladder ca.
- August 2014 (1 year FU): doing well, no angina, no further bleeding.

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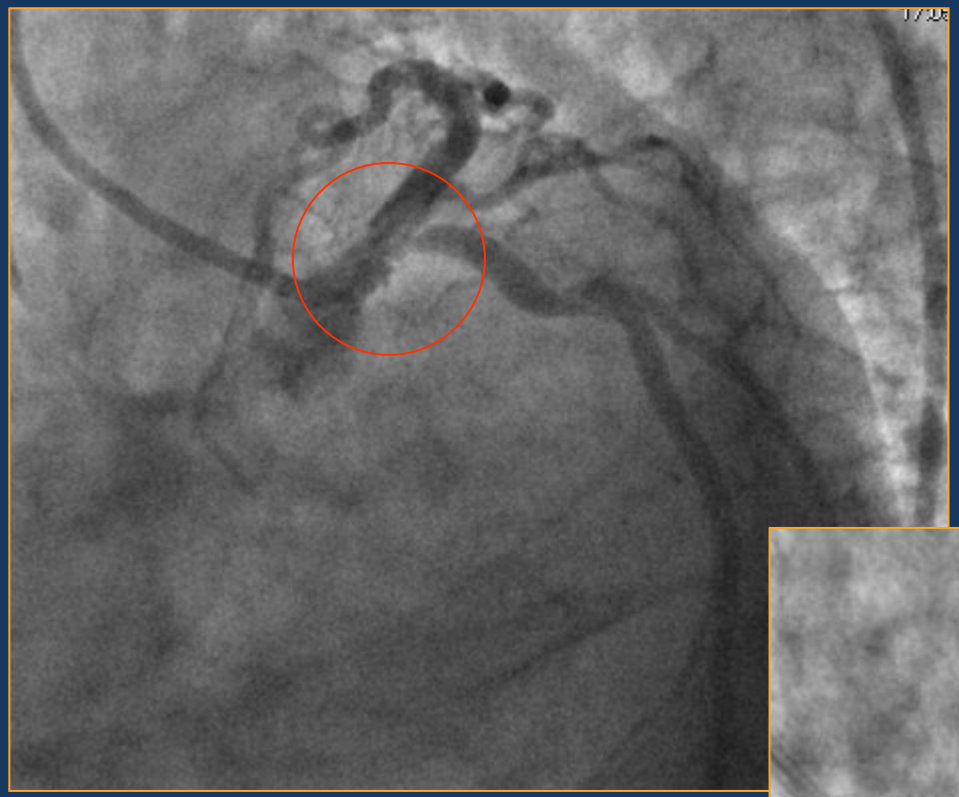
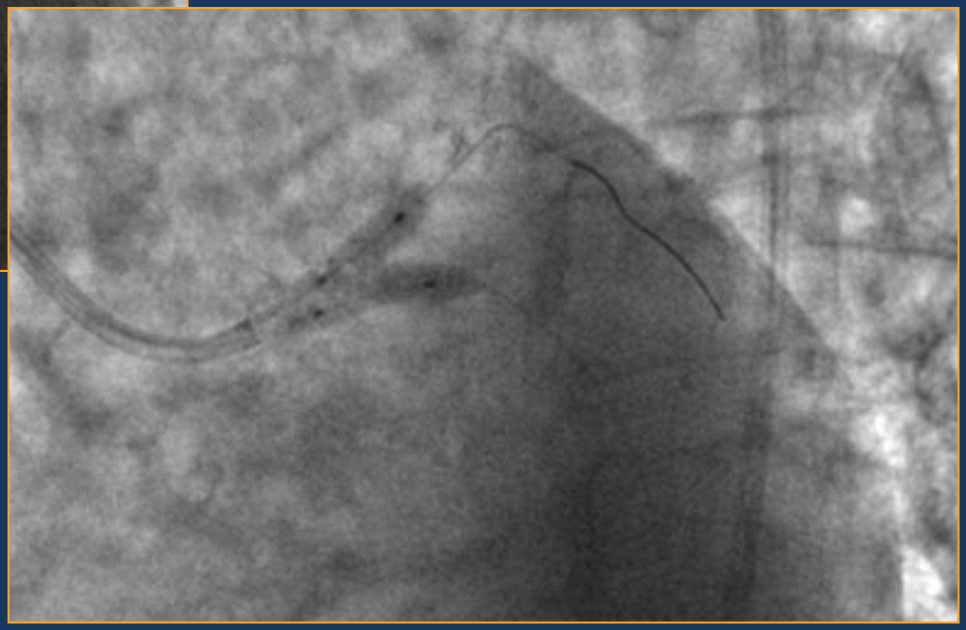
Dr. Keith Oldroyd

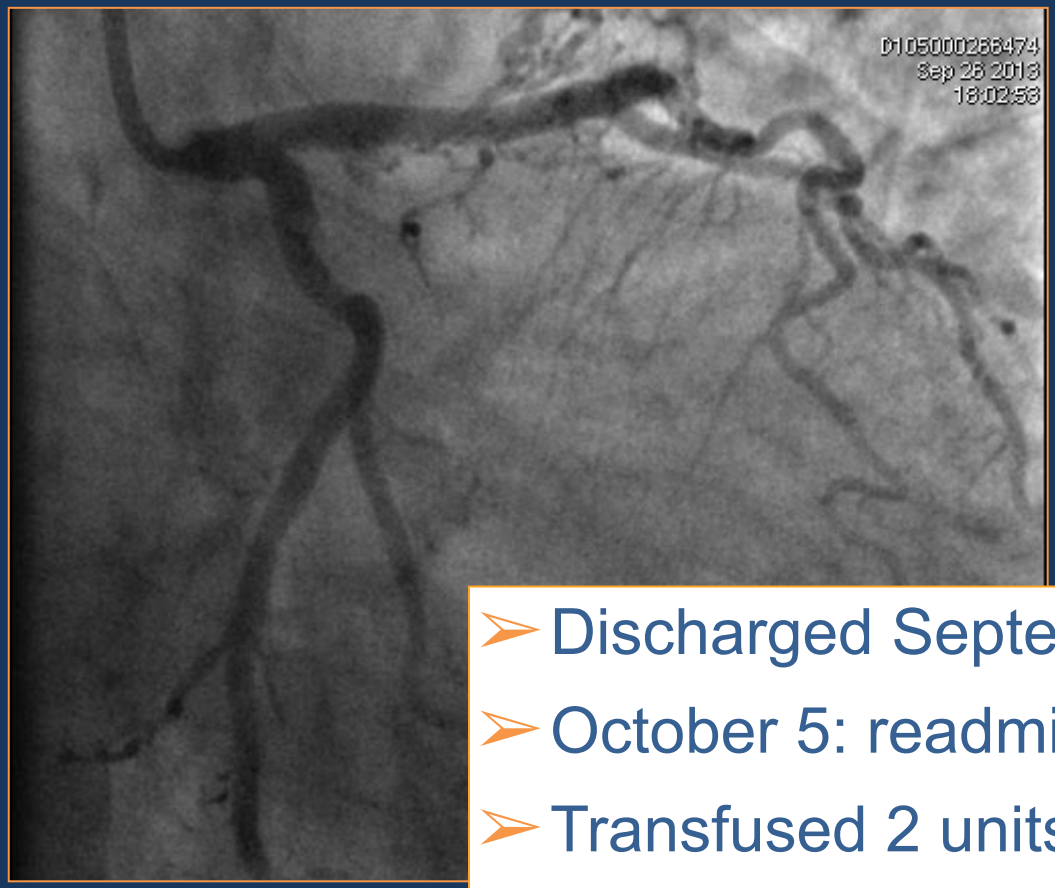
Golden Jubilee National Hospital, Glasgow

- 75 year old lady
- Recurrent GI bleeding due to colonic angiodysplasia
  - 2 blood transfusions in previous 2 months
- Moderate aortic stenosis
- Multi-vessel CHD
- Recurrent NSTEMIs with acute severe pulmonary oedema
- Hb 95-100g/l for 2 weeks in hospital on DAPT
- Randomised



September 26, 2013
LM bifurcation Culotte stenting



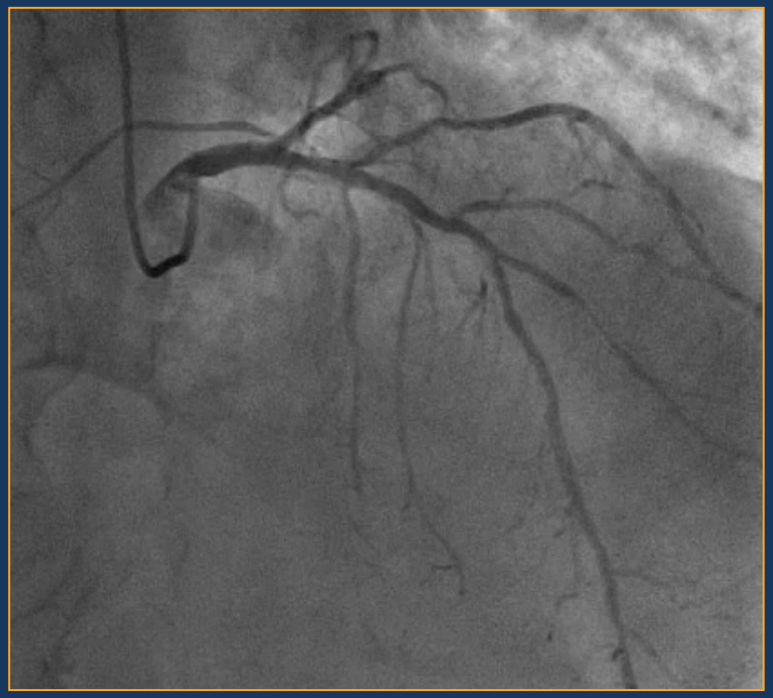


- Discharged September 28
- October 5: readmitted for Hb 70g/l
- Transfused 2 units & DAPT continued
- October 25: doing well, no angina.
  ASA stopped, clopidogrel continued.

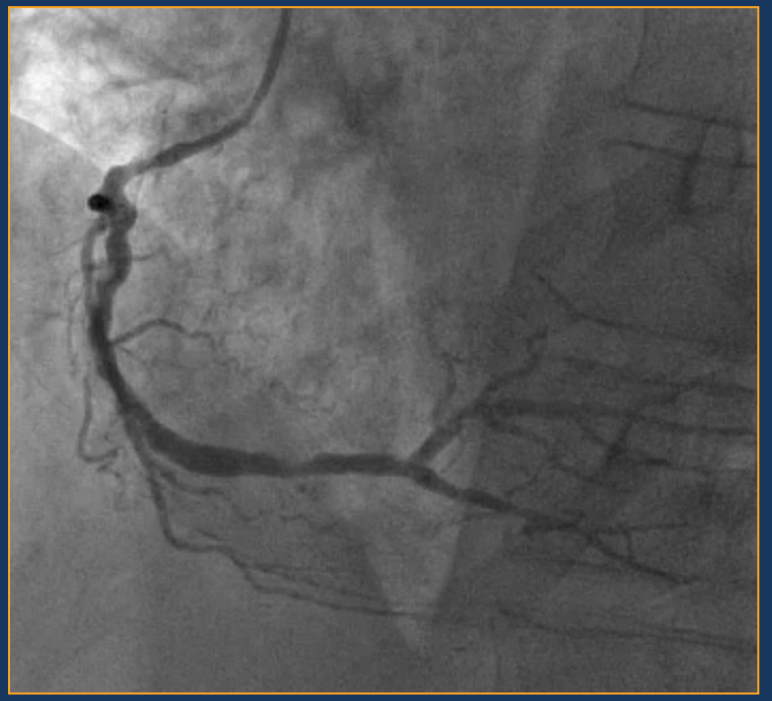
Dr. Philippe Garot
ICPS, Paris, France

- 91 year old hypertensive patient
- Pulmonary edema+NSTEMI
  - Troponin + & ST depression inferior leads
- CrCl= 30 ml/min
- Echo: LVEF 60%, AS=0.6 cm2, mean AG: 62mm Hg
- Invasive evaluation

Coronary angiogram

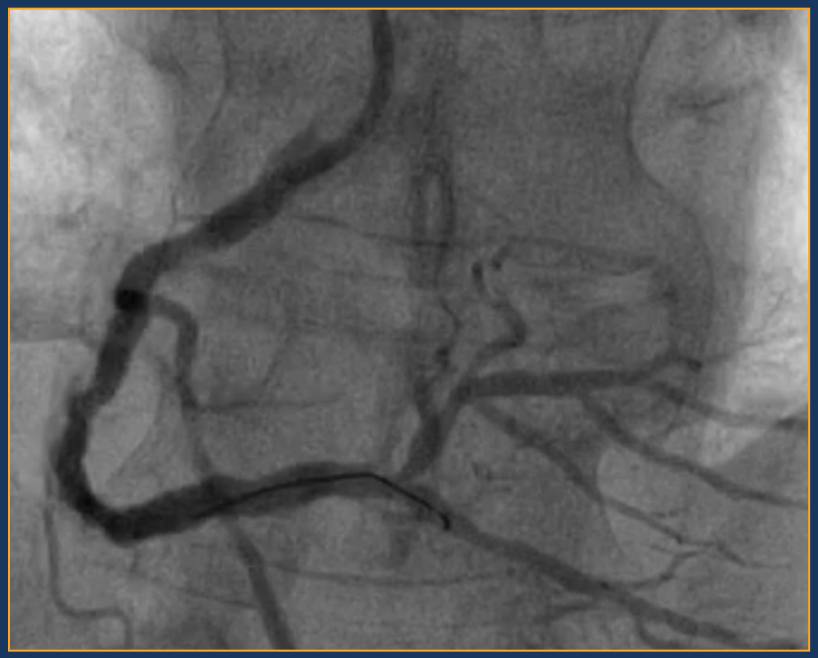


Distal LAD and 3rd Diag. 70%

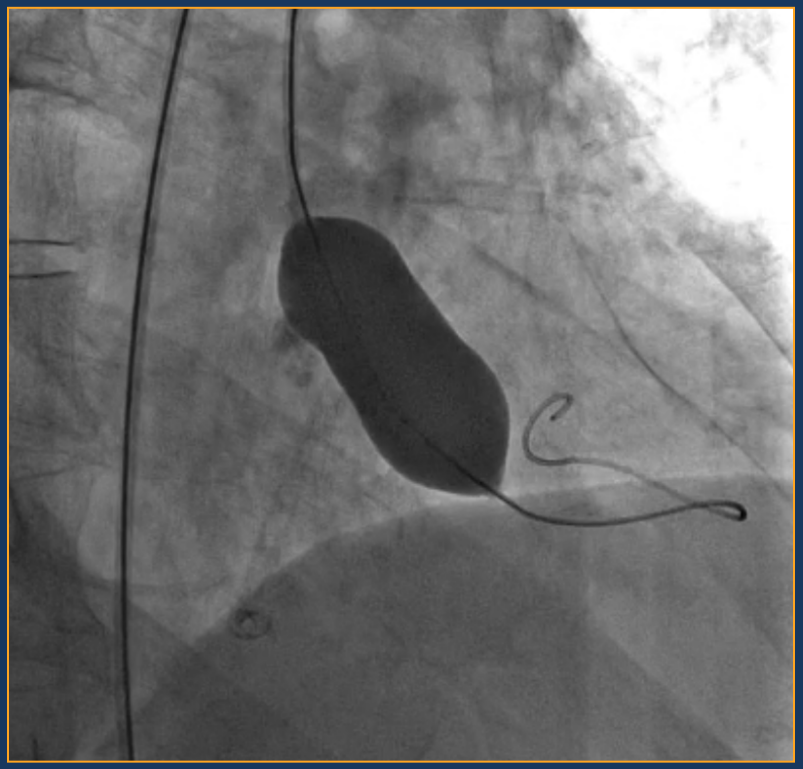


Prox and Distal RCA>70%

RCA PCI + Aortic Valvuloplasty



Stent Leaders Free 14x3.5 (prox)
28x3.5 (dist)



Aortic valvuloplasty (Mean aortic Gradient decrease 62 to 28 mmHg)

- Now doing well, 2 months post PCI
- On aspirin alone
- TAVI planned in a few weeks time

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Dr. Jacques Berland

Clinique St Hilaire, Rouen, France

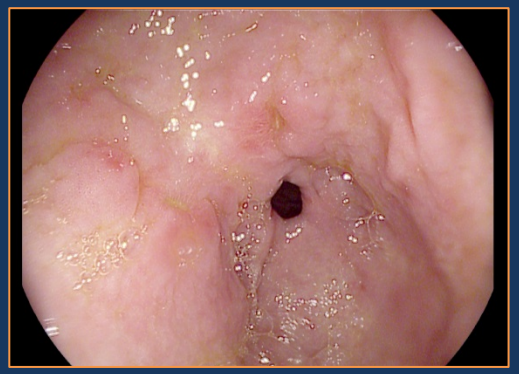
67 year old lady
Hepatic cirrhosis CHILD A6
Chronic AF (Chads2vasc = 3) on OAC

- October 6, 2013 admitted for:
  - major GI bleed (8 blood unit)
  - concomitant ACS (Troponine +)

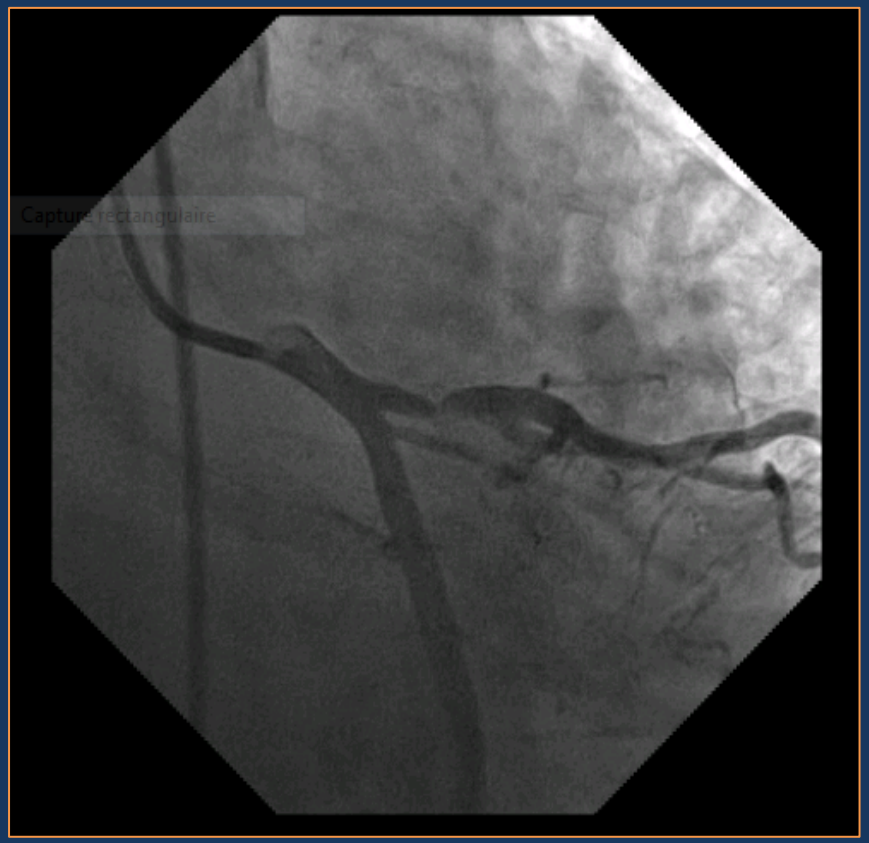
    OAC stopped, clopidogrel started 75 mg OD

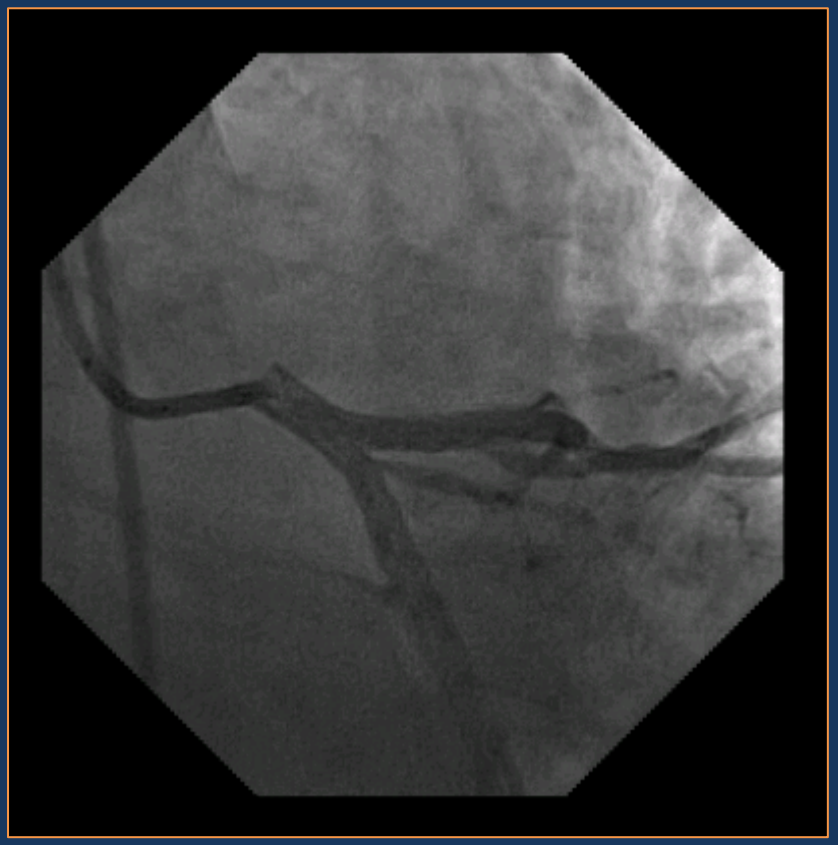
- October 9: Fibroscopy: 2 pre pyloric ulcers Forrest III.
- October 17: Transfert for coronary angio: severe LAD stenosis
- October 21: Control fibroscopy : 2 healed prepyloric ulcers

  Aspirin 75 mg OD added



October 22, 2013 : LAD STENTING Leaders Free Protocol





For FU at 1 month: stop aspirin and restart OAC? (HAS-BLED score = 5*)

JB2

* 12.5% risk of major bleeding/year

Challenging cases in Leaders Free Protocol

75 year old French Lady

Francesca SANGUINETI MD; Philippe GAROT MD, FESC
From the Hôpital Privé Jacques Cartier, Hopital Privé Claude Galien, ICPS, Générale de Santé, MASSY, QUINCY, FRANCE.

Risk factors

Dyslipidemia (statin therapy)

Hypertension

Medical History

1988 Colectomy for colon cancer

Hypothyroidism requiring substitution therapy

Cardiac History

Permanent atrial fibrillation on OAC

December 2013: proximal RCA PCI (2 **BMS**) for ACS NSTEMI

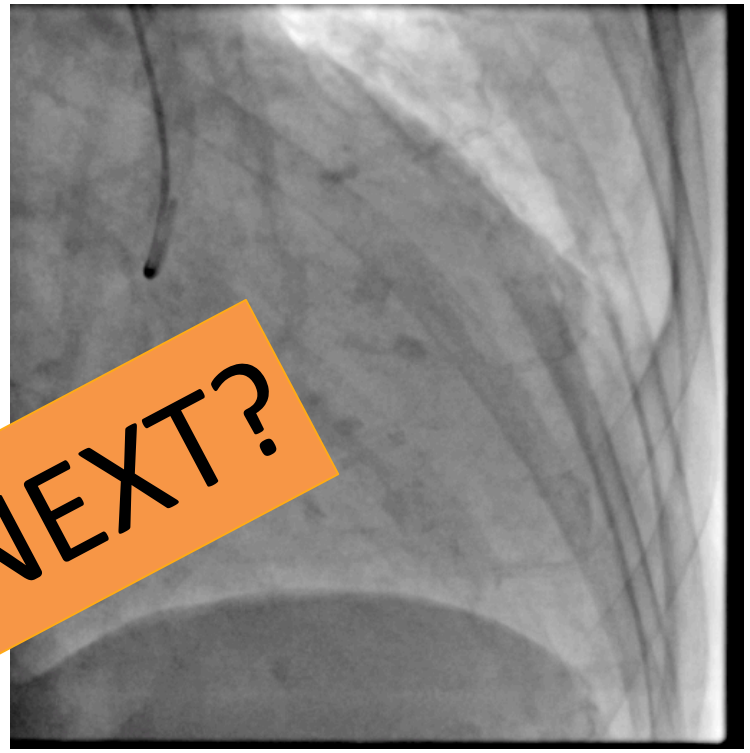
Referred in April 2014 with recurrence typical angina during effort (CCS Class II) for the last month.

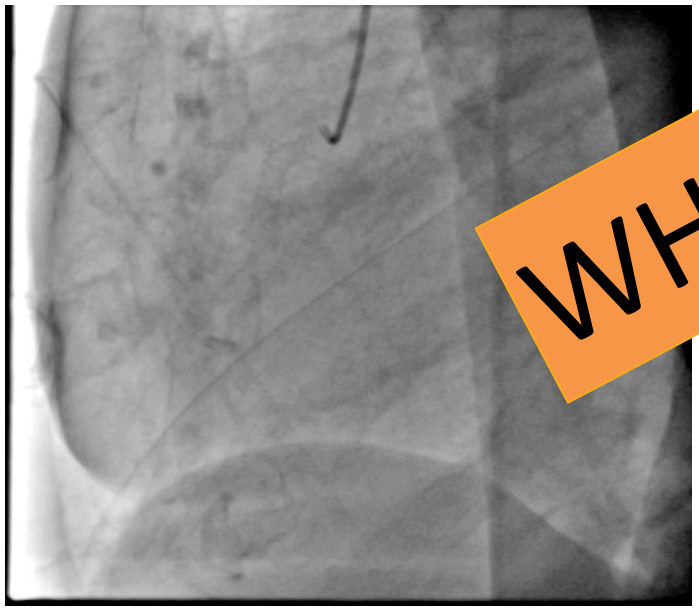
Laboratory investigations

Hb = 14,5 g/dL
Creatinine = 83 µmol/L
Creatinine clearance = **35 ml/min**
CRP = 3.7 mg/l
INR: **2.34**

Baseline angiography

No LCA lesion





WHAT NEXT?

RCA:
Ostial CTO In-stent restenosis with good collateral flow (Rentrop 3)

Strategy

- ✓ Need for new PCI (symptomatic patient with dominant RCA, single vessel disease)
- ✓ Need for DES (BMS restenosis)

BUT

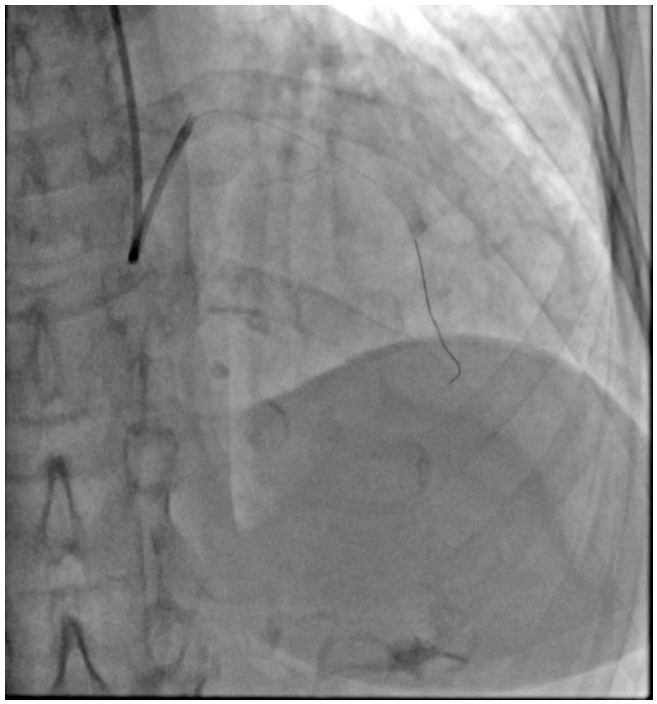
- ✓ High bleeding risk (OAT; age > 75 y.o, impaired renal function)
- ✓ Need for short DAPT

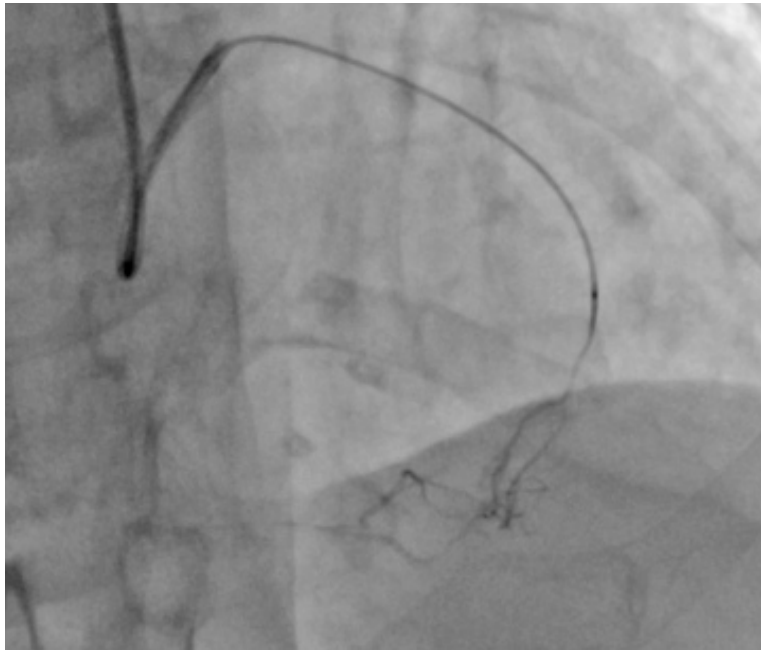
Patient enrolled in the Leaders Free Trial, and randomized to receive, in a double blinded manner, either a Gazelle BMS or a BioFreedom DCS, followed by a 1 month course of DAPT only.

Inclusion Criteria

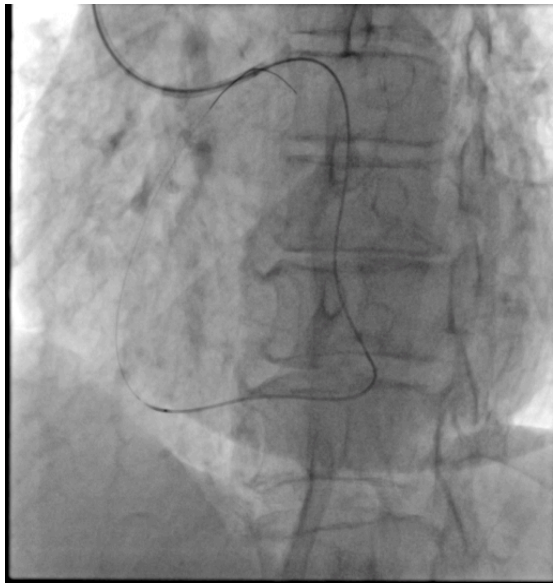
✓ Oral Anticoagulant Therapy (OAT)
✓ Age > 75 years
✓ Creatinine clearance < 40 ml/min

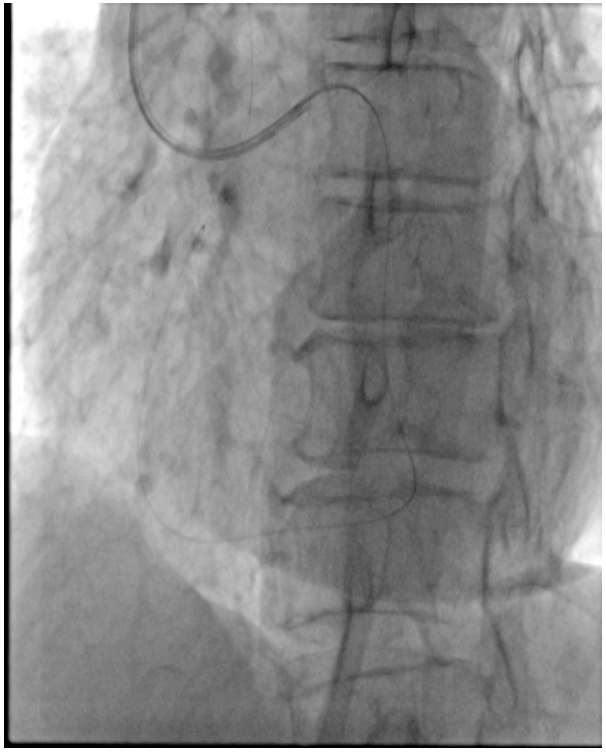
Plan: 1 month Aspirin + Clopidogrel + OAT then Aspirin + OAT





Double radial approach 6F
Anterograde approach failure
Retrograde approach by septal branch
EBU 3.5
Corsair microcatheter
ASAHI Fielder FS
Successful retrograde CTO wiring





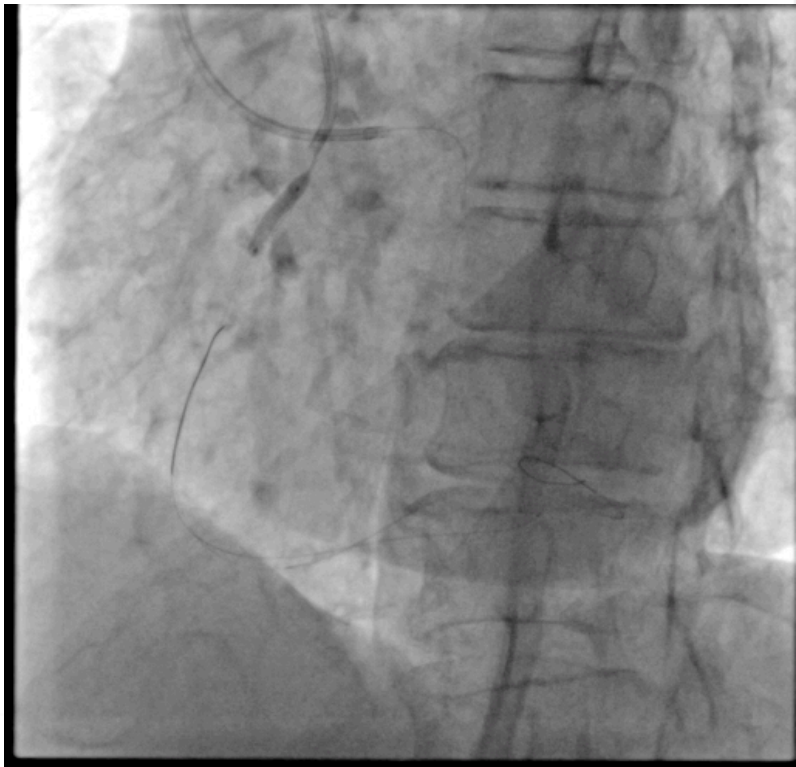
Retrograde PCI with balloon 1,25/15

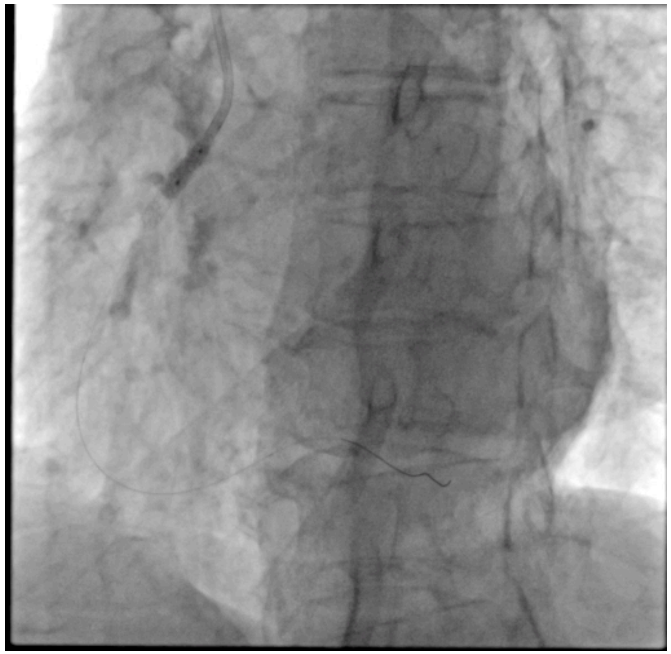
JR 3.5 guiding catheter

Anterograde RCA wiring (Asahi Miracle 3)

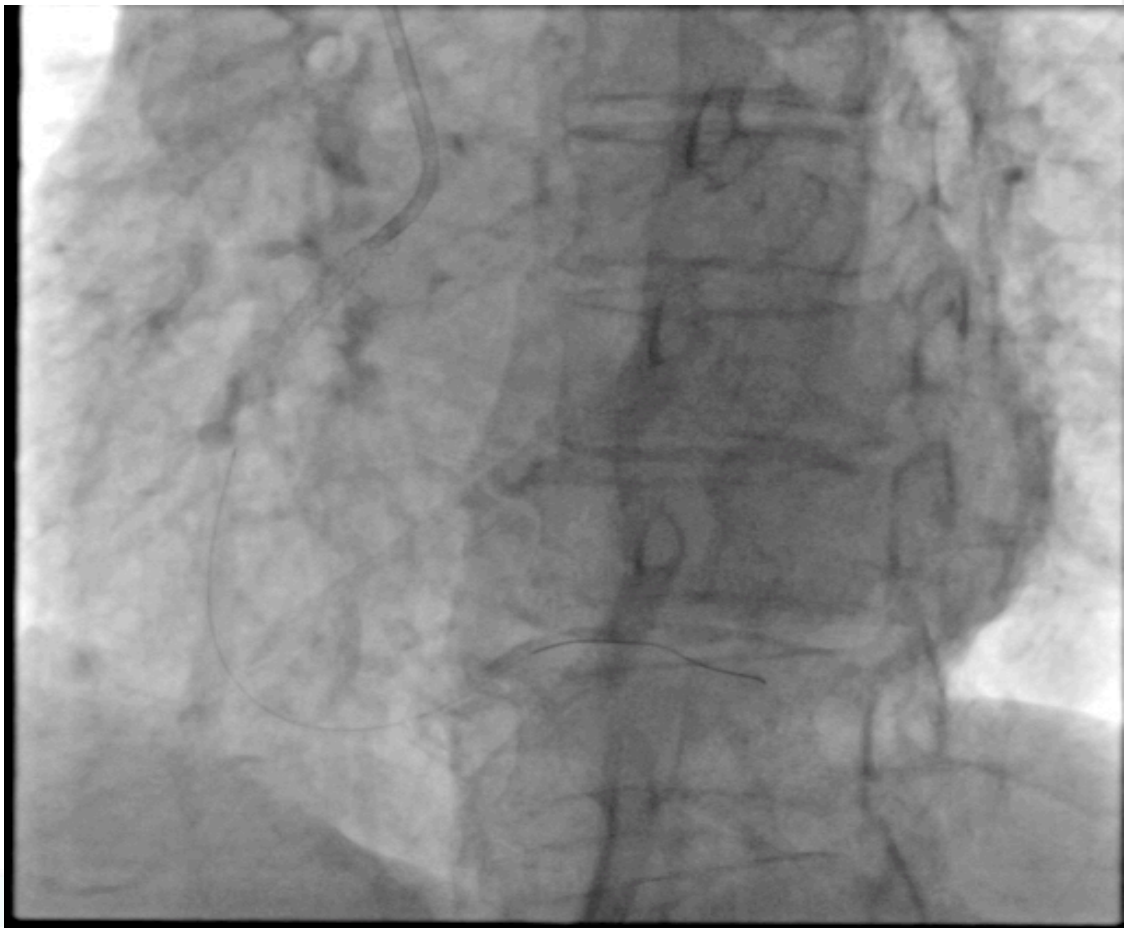
Anterograde dilatation by 3.0/15 balloon

Trial Stent 3.0/24





Postdilatation: NC balloon 3.5/10



Final result

Discharged on triple Rx

1 month follow up:

- **no event**
- **stop Clopidogrel**

LEADERS FREE
Challenging cases and lesions

Dr. Victor Jiménez Díaz

Hospital Meixoeiro

University Hospital of Vigo, Spain

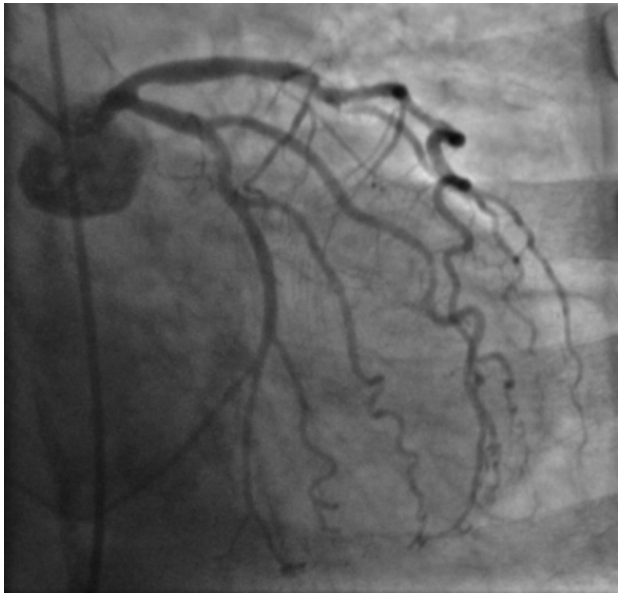
June 15, 2014

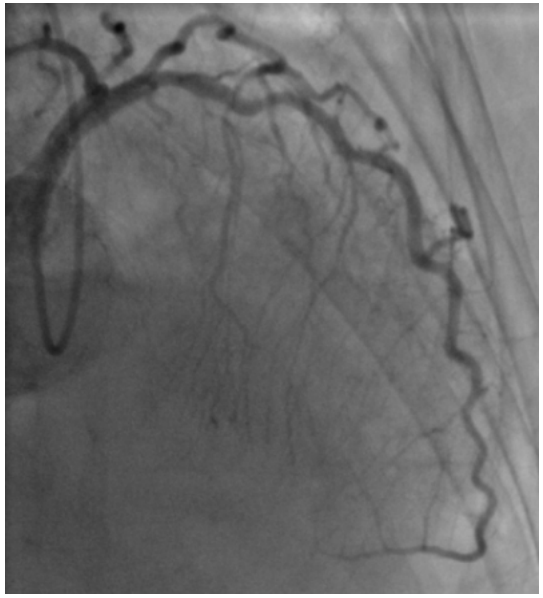
71 year old Spanish lady

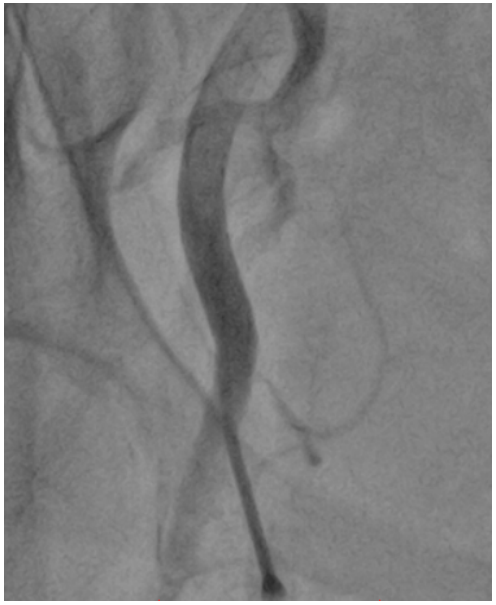
- DM insulin-dependent
- Chronic kidney disease (stage 3)
- Atrial fibrillation + OAC
- Severe aortic stenosis
- Pulmonary fibrosis
- Moderate pulmonary hypertension
- Angiodysplasia and colonic ulcers.

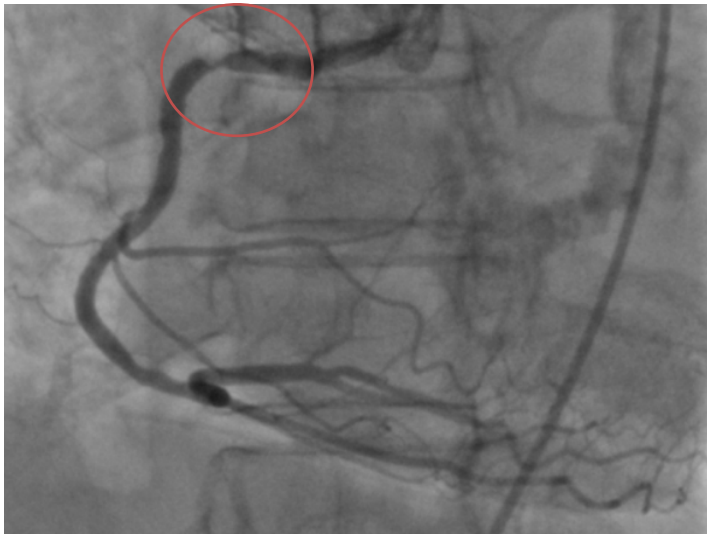
- Episodes of lower gastrointestinal bleeding
- Multifactorial anemia
- History of progressive dyspnea NYHA III-IV and several hospitalizations due to heart failure. Currently admitted for respiratory failure.
- ECG: atrial fibrillation
- TTE: normal LVEF, severe AS (Vmax 4.1 m/s, max/mean gradient 68/35mmHg, AVA 0.5 cm2), moderate PAH (46mmHg), moderate mitral and tricuspid insufficiency.

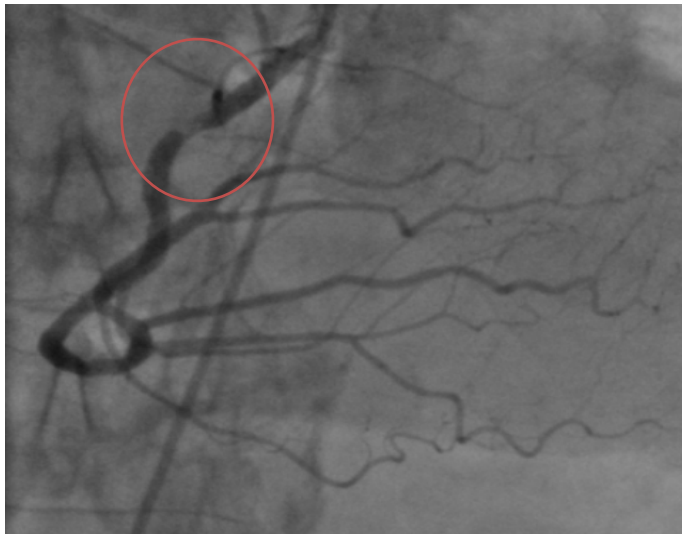
Coronary angiography







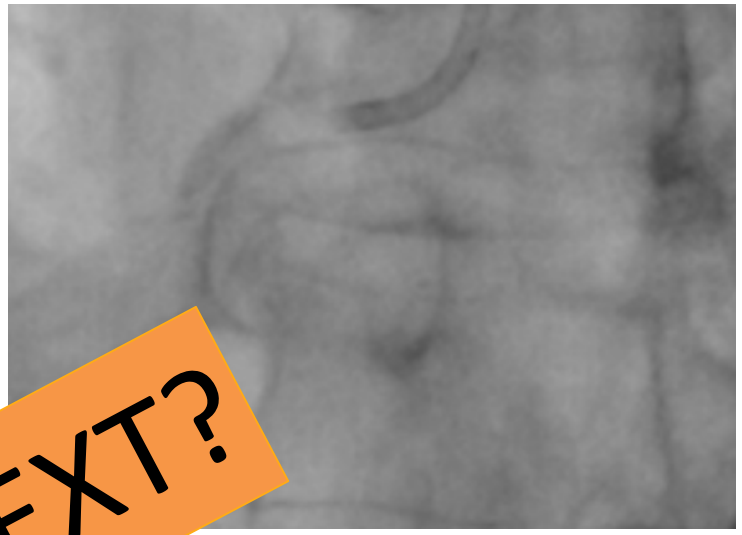


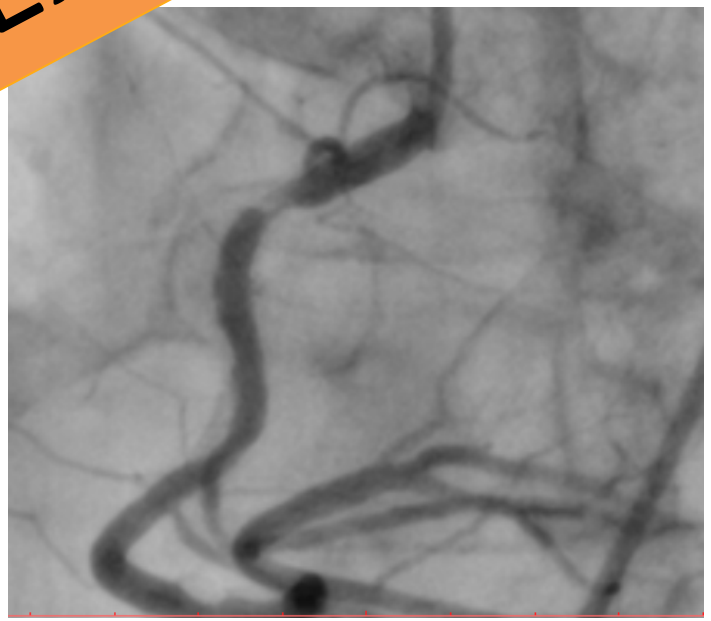


Coronary angiography

- LM: no lesions
- LAD : moderate lesion, mid segment (1ºDiagonal, small vessel)
- Left Circunflex: no lesions
- RCA: **critical and sev**
  calcified lesion,
  segment

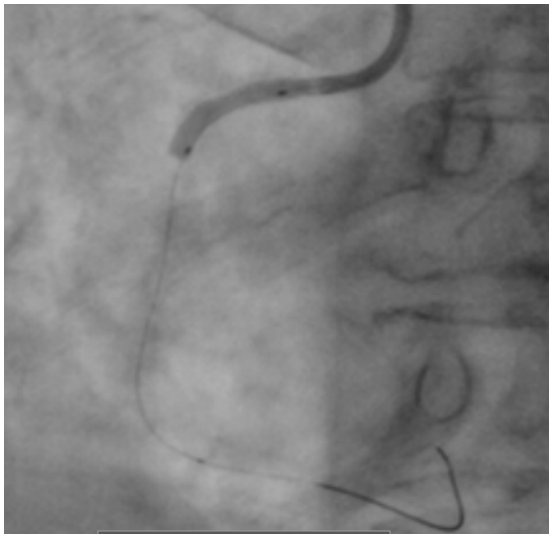
***Poor tolerance to decubitus position

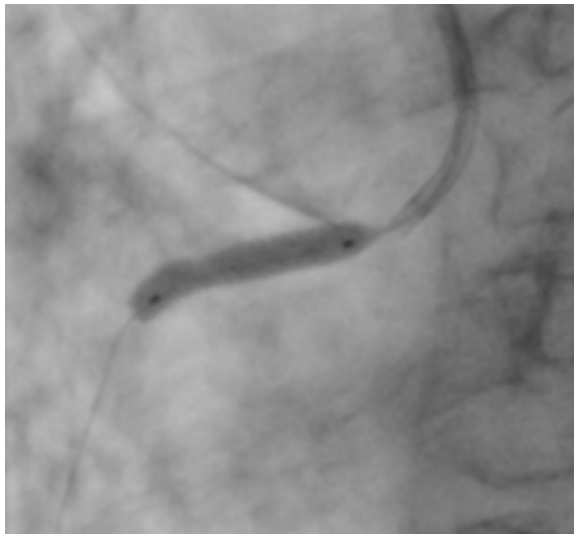


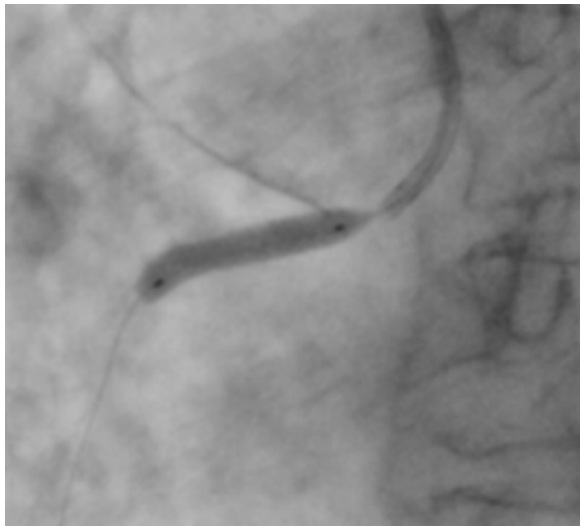


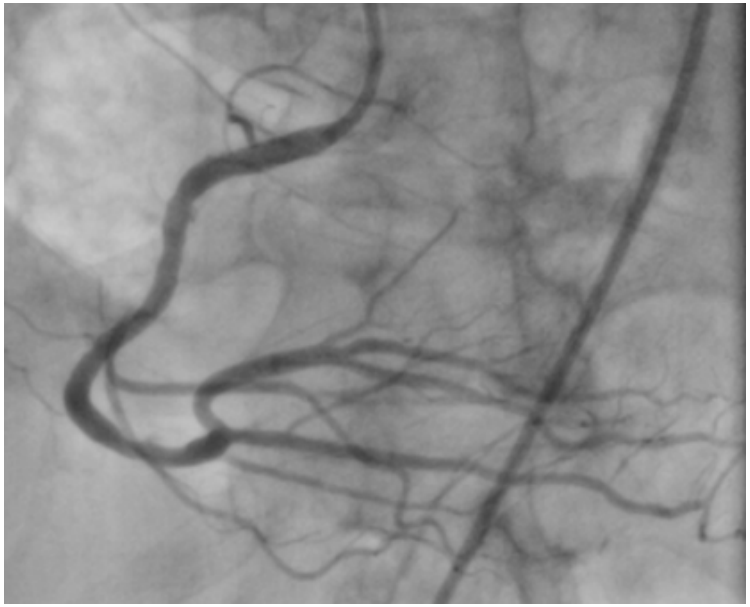
WHAT NEXT?

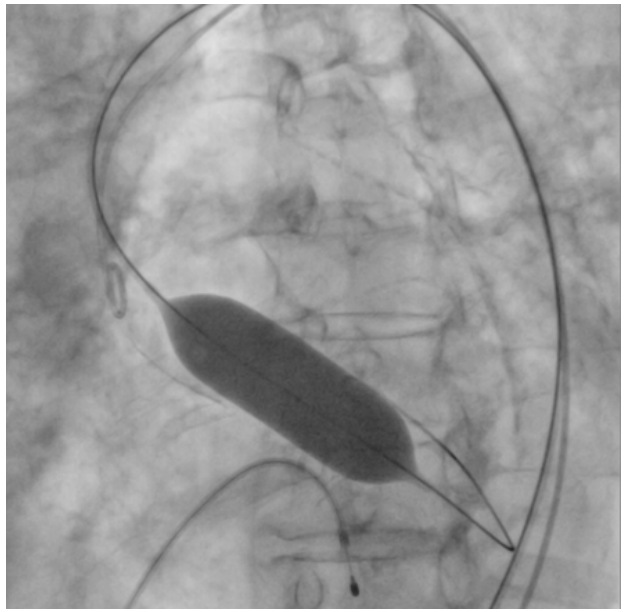
Coronary angioplasty











Procedural data & Hospital outcome

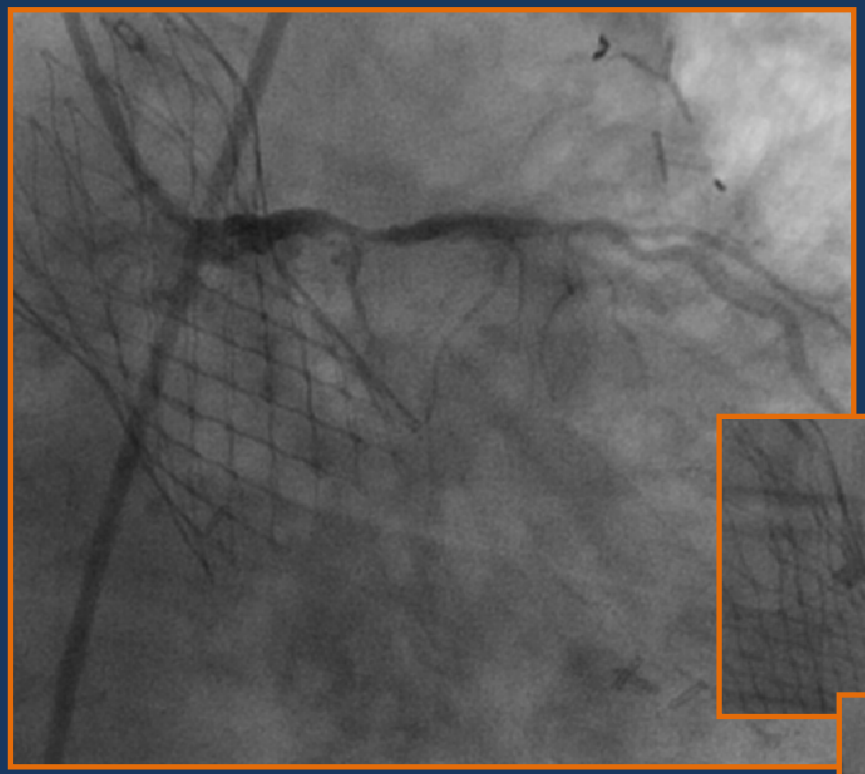
- Procedure *"as fast as possible"*
- Predilation: NC 2.5/15mm balloon
- Stent Leaders Free 3.5/18mm
- DAPT: 1 month
- Vascular access bleeding: blood transfusion

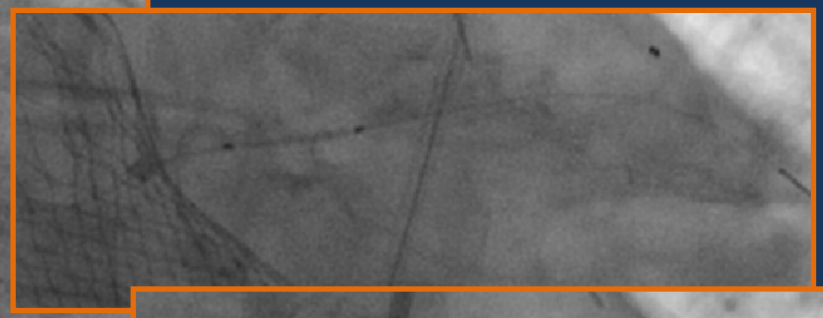
- New episode of acute respiratory failure
- Balloon aortic valvuloplast as a bridge procedure to TAVI
- Improvement of dyspnea
- No vascular complications
- No hospital readmission for cardiovascular causes at 6 months follow-up

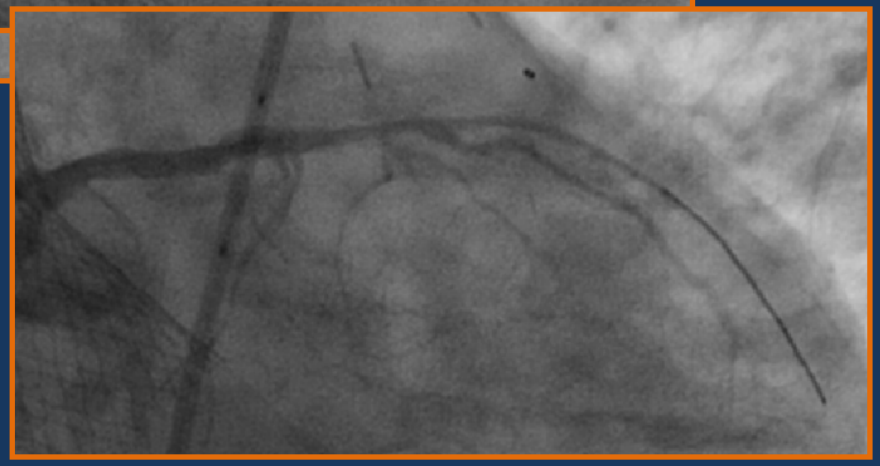
First patient included

HÔPITAL DE LA TOUR

- 89 year old
  - Prior CABG x 3 1994
  - Prior left carotid endarterectomy 2003
  - Prior BMS to RCA 2003
  - Prior TAVI (Corevalve) in 2010
  - Creatinin clearance 19 ml/min
  - Epistaxis 2 weeks ago
- Admitted for ACS with + troponin, Dec 8
- Stabilized on Med Rx
- LEADERS FREE PIC signed Dec 11







12/12/12

single 3 x 11 mm stent
study group « 100 »