

# Clinical Practice of BioFreedom™ and Short Duration DAPT for High Bleeding Risk Patients

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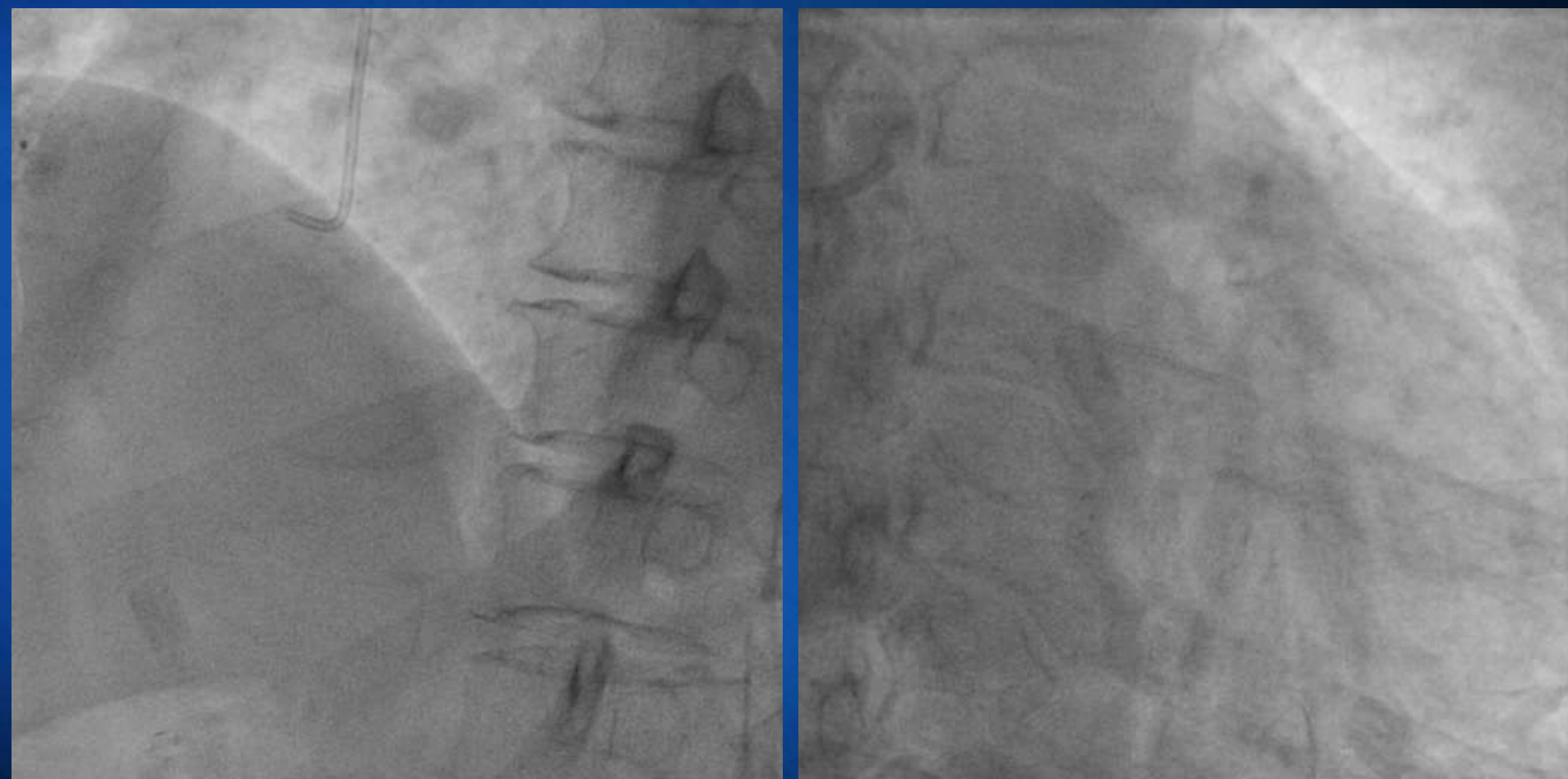
# CASE #1

F / 76

- C.C: Transfer from local clinic due to recently aggravated exertional chest pain & positive TMT
- PHx:
  - **Hypertension / CKD, stage II**
  - No history of general medical check-up including EGD, colono, and dental check-up
- Echo: No RWMA / Normal sized cardiac chambers with normal global LV systolic function (LVEF 74%)
- Height 150 cm/ Weight 38kg .. **BMI 16.9 kg/m<sup>2</sup>**



# Coronary angiography



✓ CAOD (1VD) – LAD ostium lesion



# What to consider for this patient?

PCI of LAD, definitely needed ...

- PCI strategy?
- DES type?
- DAPT duration?



# DAPT score, a clinical decision tool to identify patients expected to derive benefit vs harm from continuing DAPT beyond 1 year after PCI, considering ischemic/ bleeding risks

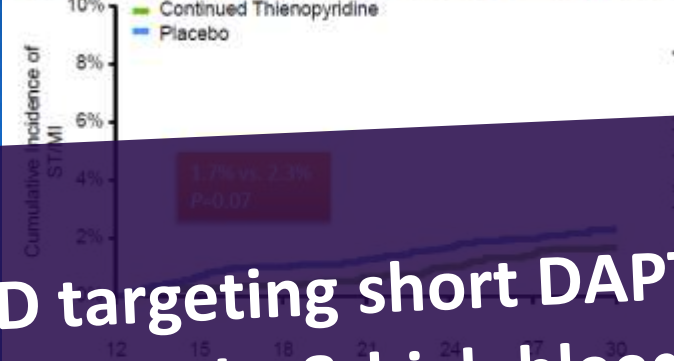


## The DAPT Score

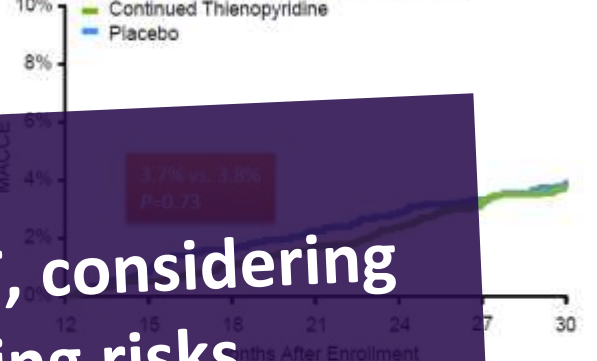
| Variable                              | Points |
|---------------------------------------|--------|
| <b>Patient Characteristic</b>         |        |
| Age                                   |        |
| ≥ 75                                  | -2     |
| 65 - 75                               | -1     |
| < 65                                  | 0      |
| Diabetes Mellitus                     | 1      |
| Current Cigarette Smoker              | 1      |
| Prior PCI or Prior MI                 | 1      |
| CHF or LVEF < 30%                     | 2      |
| <b>Index Procedure Characteristic</b> |        |
| MI at Presentation                    | 1      |
| Vein Graft PCI                        | 2      |
| Stent Diameter < 3mm                  | 1      |

## Continued Thienopyridine vs. Placebo DAPT Score <2 (Low); N=5731

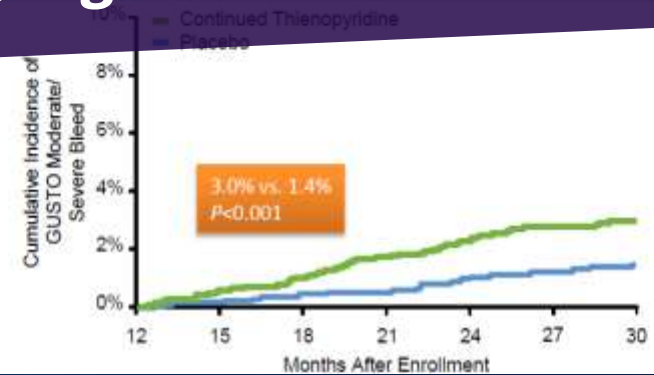
### Myocardial Infarction or Stent Thrombosis



### Death, MI, or Stroke (MACCE)



### GUSTO Moderate/ Severe Bleeding



Plan >

✓ PCI at LAD targeting short DAPT, considering low ischemic risks & high bleeding risks ...

- Patient's DAPT score : - 2

# *First things to do !*

## Considerations from patient's factor

- Female 76 yrs
  - Height 150 cm/ Weight 38kg .. **BMI 16.9 kg/m<sup>2</sup>**
  - CKD, stage II
  - No history of general medical check-up including EGD, colono, and dental check-up
- A lean old-aged CKD person, non-expectable further treatment requiring discontinuation of DAPT.



# What to consider for this patient?

a lean old-aged person having multiple risks

- **PCI strategy?**

- ✓ LAD ostium → 1-stent technique, LCx cross-over

- **DES type? → Strongly related DAPT duration !**

- **DAPT duration? → A prime consideration**

- ✓ Short-duration DAPT would definitely better! (<12 months / <6 months)

- ✓ If possible, DAPT duration <3 months would good. 1-month DAPT would be the best !



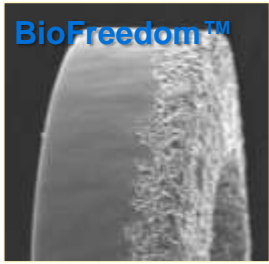
# Determination of DAPT duration according to the DES types?

- Short-duration DES; New-generation DES better than 1<sup>st</sup>-generation DES
- ✓ Data regarding 1-month DAPT after PCI?





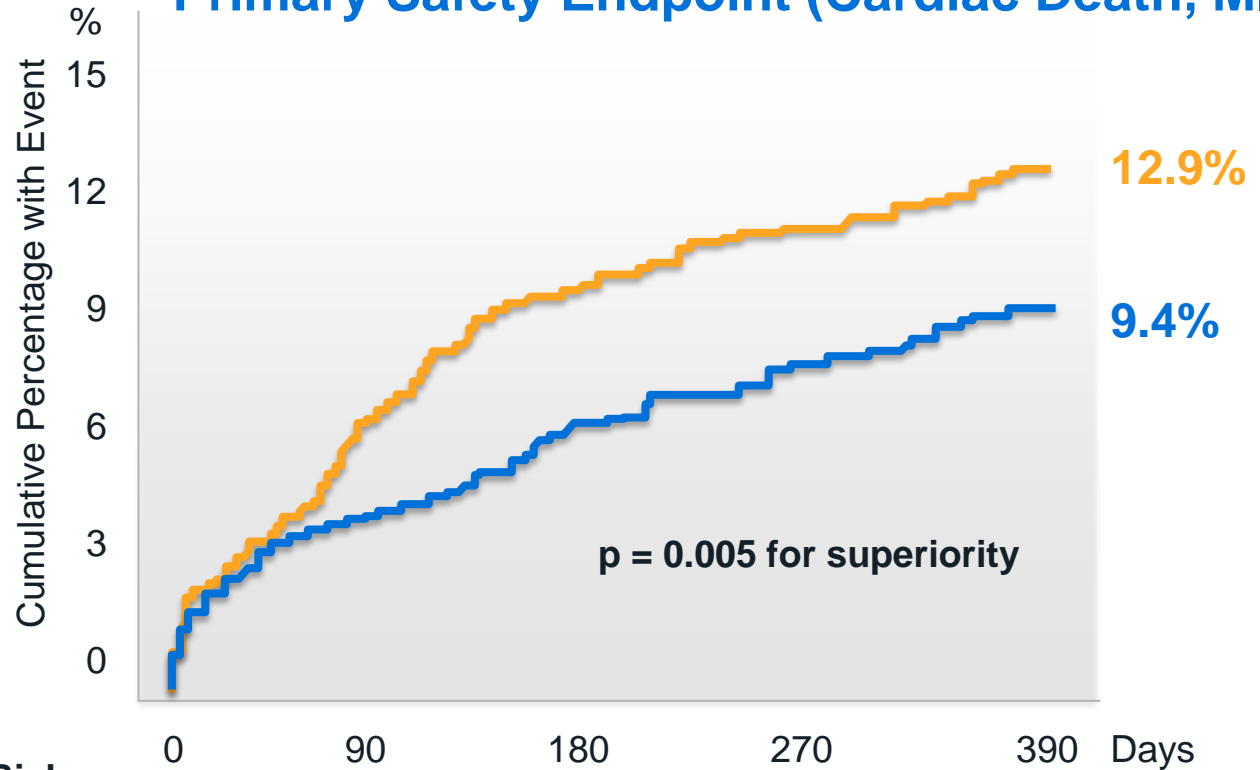
Prospective, double-blind randomized (1:1) trial  
 2,466 High bleeding risk PCI patients with **1-month DAPT**



**Potential Advantages:**

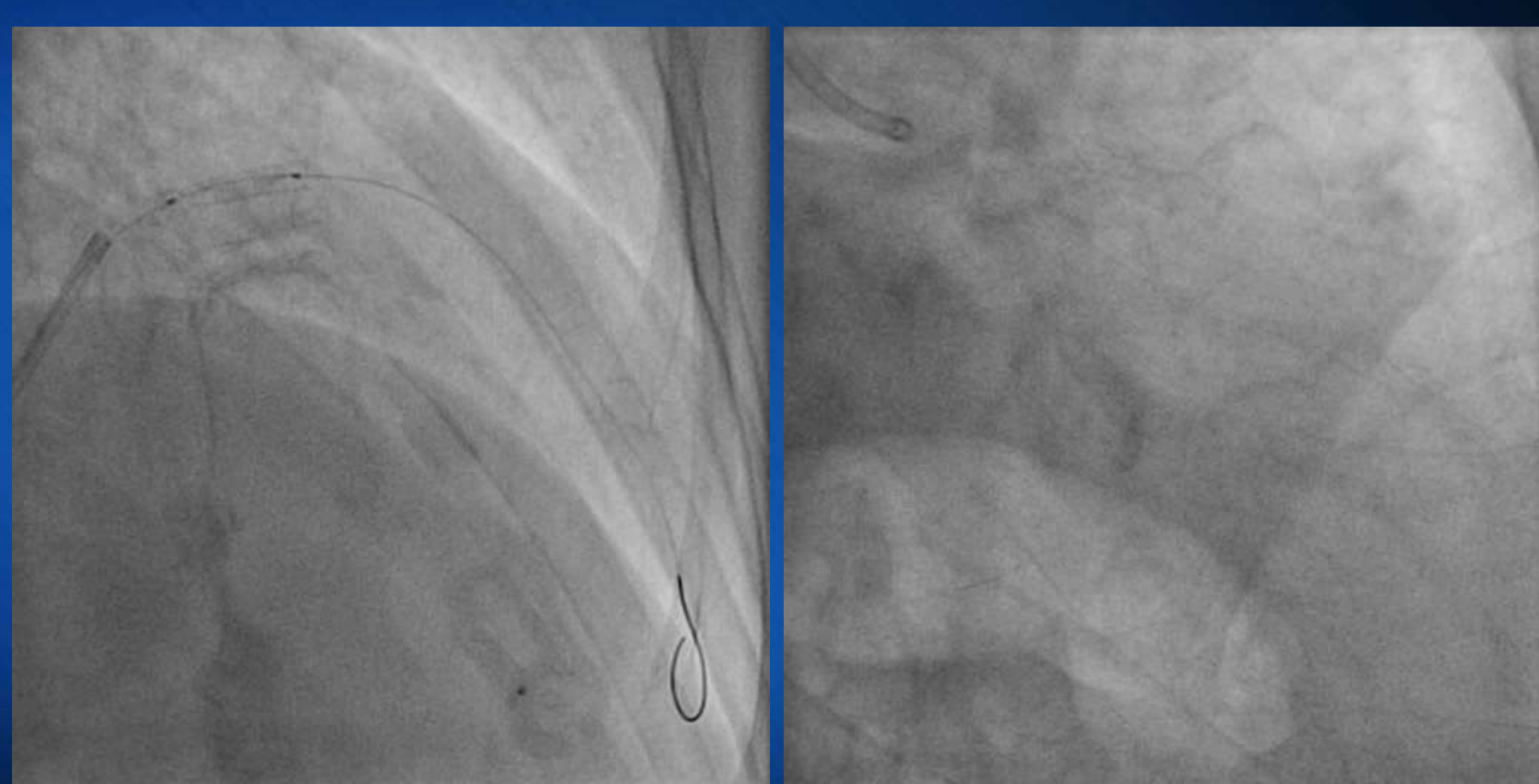
- ✓ Avoid any possible polymer-related adverse effects
- ✓ Rapid drug transfer to vessel wall (98% within one month<sup>2</sup>)
- ✓ Safe to shorten DAPT

**Primary Safety Endpoint (Cardiac Death, MI, ST)**



| Number at Risk         | 0    | 90   | 180  | 270  | 390 Days |
|------------------------|------|------|------|------|----------|
| <b>BioFreedom™ DCS</b> | 1221 | 1146 | 1105 | 1081 | 1045     |
| <b>BMS</b>             | 1211 | 1115 | 1066 | 1037 | 1000     |

# PCI



**Successful PTCA c stent at p-LAD (BioFreedom 3.5 x 18mm)**



# Progress

PTCA c stent at p-LAD  
(BioFreedom 3.5 x 18mm)

16.01.05

16.02.08

17. 04.11

## Medication

Aspirin/ Clopidogrel —————> Aspirin —————>

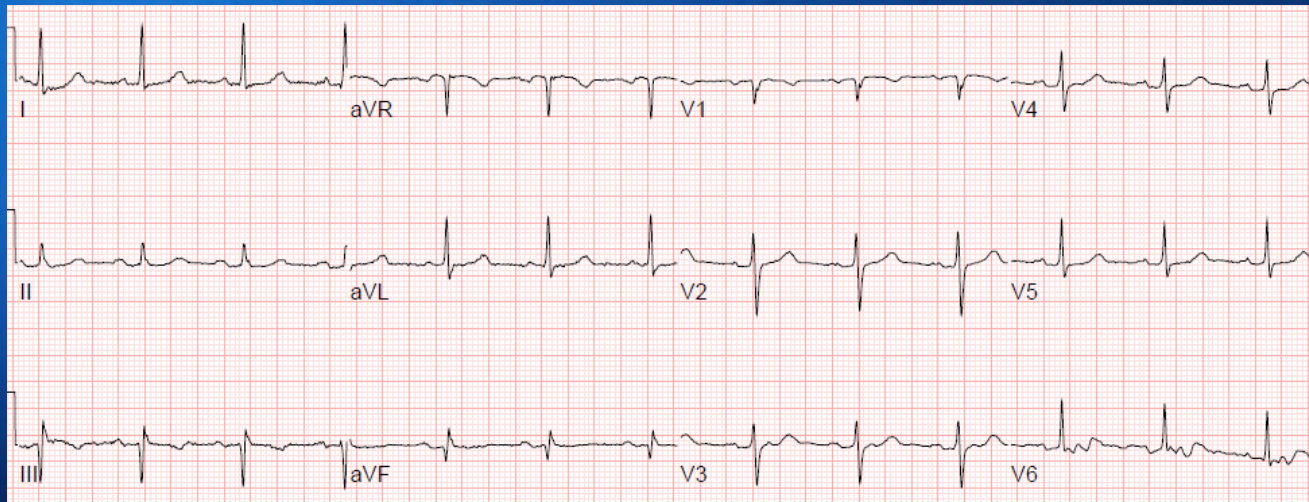
Event - - - - ->

No ischemic or bleeding event occurred.



# CASE # 2

- 65 / M, Pre-op CAG for cancer operation
- Chief complaint
  - Jaundice for 1 month
  - Recently aggravated chest pain for 2 weeks
- Risk factors
  - Hypertension / Ex-smoker (30PYs) / Alcohol : heavy usage
- Echo - RWMA at inferior wall



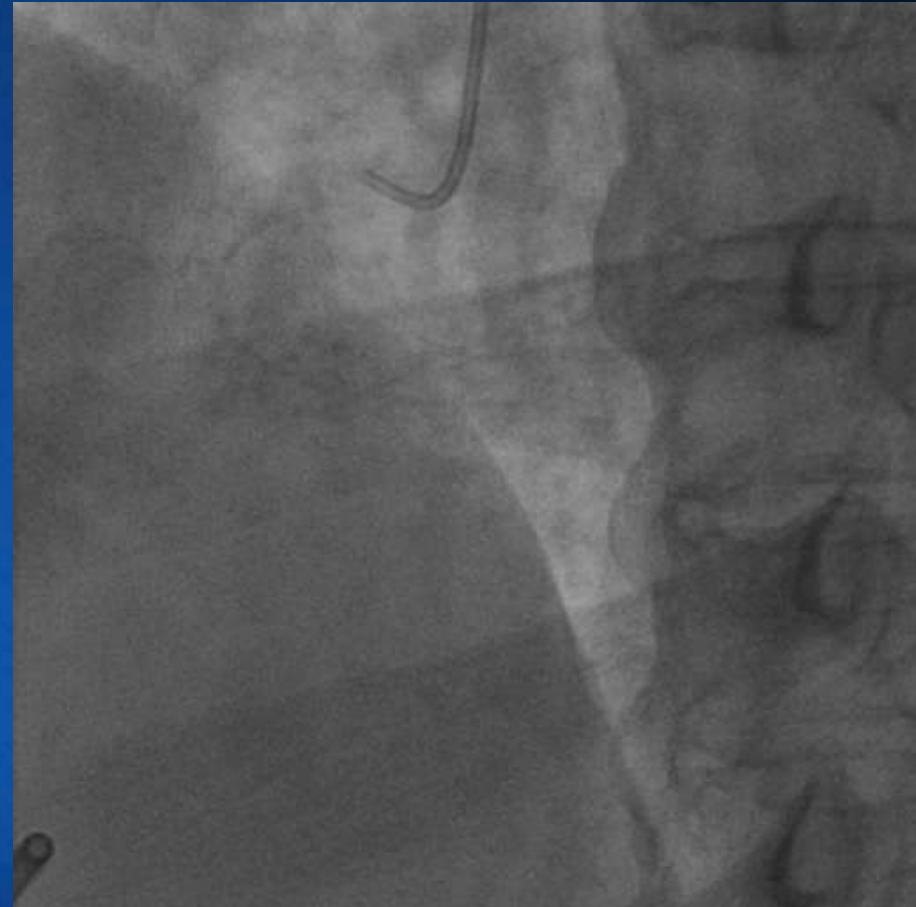
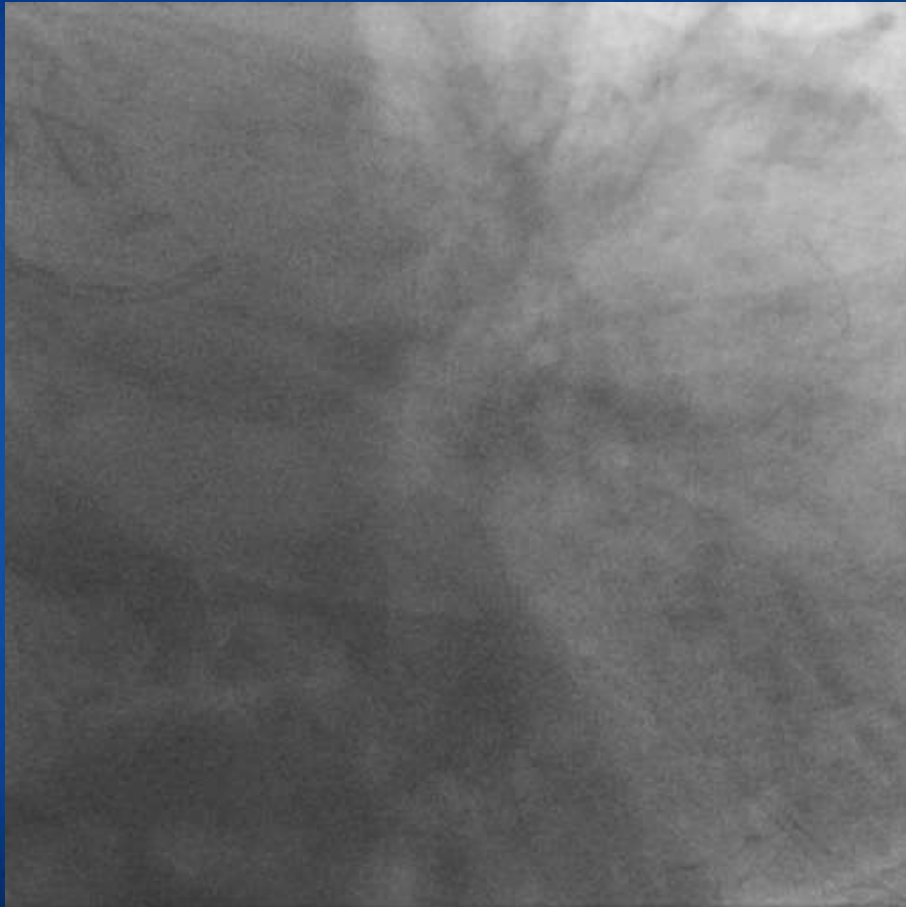
→ Cardiologic answer : recommend CAG

# APCT & PET-CT



Imp. R/O Distal CBD cancer  
Plan. Operation

# Coronary angiography



Tubular eccentric 80% LN of pRCA with hazziness  
→ Suspicious plaque rupture with thrombi



# Diagnosis & Plan

- **Diagnosis** - ACS (UA), 1-VD suspicious of plaque rupture
  - Distal CBD cancer requiring operation

- **Treatment**



**A. CABG first, and then GS Operation**

**1-VD, too healthy coronary arteries to perform bypass Op ... Especially, LAD was normal.**

**B. PCI with BMS, and then GS operation**

**... not easy PCI with BMS in Korea d/t very limited size & length...**

**C. PCI with DES, operation after 6 months (or 3 months) later**

**Delayed operation would be risky and patient could not understand.**



# On Guideline ...

- Coronary artery revascularization before non-cardiac surgery is recommended when indicated by existing clinical practice guideline (Class IC)

- **Current guideline preferred CABG and preoperative PCI is limited.**

- **Timing of surgery after PCI**

Elective noncardiac surgery should be delayed..

- ✓ 14 days after balloon angioplasty (Class I\_C)
- ✓ 30 days after BMS implantation (Class I\_B)
- ✓ 365 days after DES implantation (Class I\_B)
- ✓ 180 days after DES if the risk of delay is greater than the expected risk of ischemia and stent thrombosis (Class IIb\_B)



# Treatment Plan

- Treatment



A. CABG first, and then GS Operation

B. PCI with BMS, and then GS operation

C. PCI with DES, operation after 6 months or 3 months later

- Patient definitely refused two consecutive major surgeries.
- The patient said; "If operation must be done, I will refuse all therapies."
- Because of cancer-spreading, delay over 1 month could not be allowed.



# Treatment Option

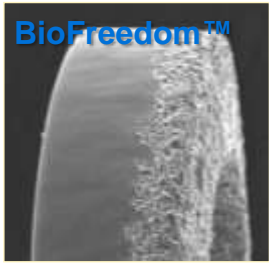
## Prior classical option for the treatment

- A. CABG first, and then GS Operation
- B. PCI with BMS, and then GS operation
- C. PCI with DES, operation after 6 months later

*All these options were not good for this patient !!!*



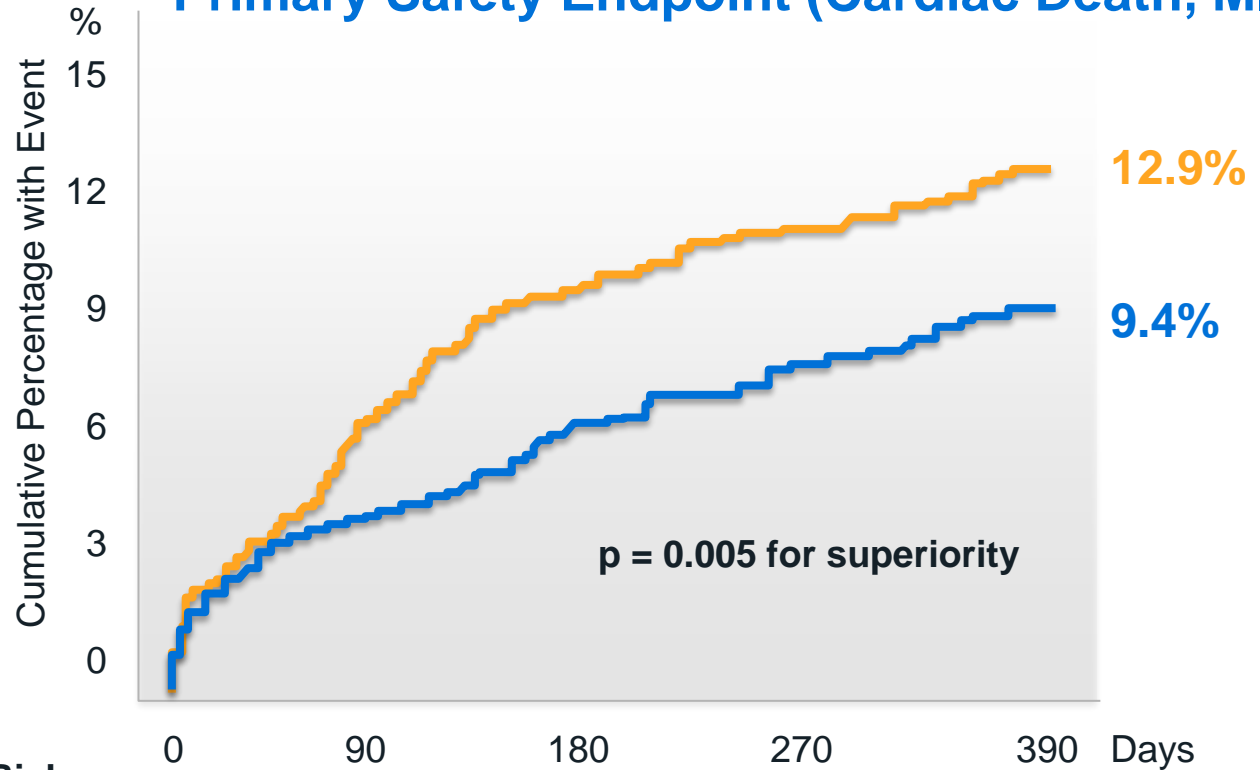
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# Treatment Option

## Prior classical option for the treatment

- A. CABG first, and then GS Operation
- B. PCI with BMS, and then GS operation
- C. PCI with DES, operation after 6 months or 3 months later

## **D. *New option*** (based on the results of LEADES Free trial) !

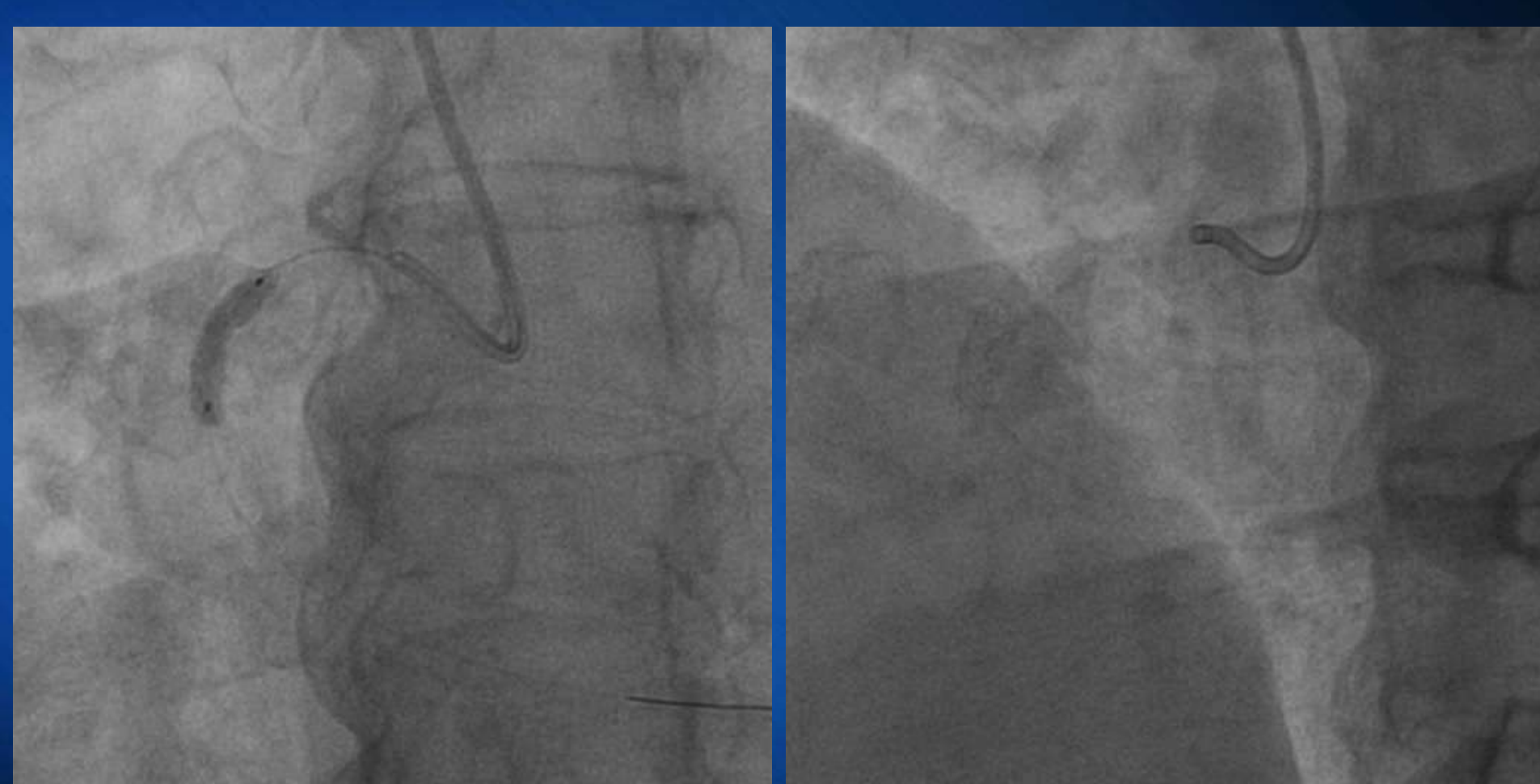
PCI with DES first, and then operation 1 month later  
with maintaining aspirin only

Surgeon and patient agree to our suggestion.

→ We perform PCI first with BioFreedom stent



# PCI



**Successful PTCA c stent at p-RCA (BioFreedom 4.0 x 14mm)**



# Progress

**Pre-op CAG**  
**PTCA c stent at p-RCA**  
**(BioFreedom 4.0x14mm)**

16.03.07

16.04.06

16.04.13

2017.04

*Med* Aspirin /Clopidogrel → Aspirin →

*Cancer Treatment* ● → Operation with aspirin monotherapy → Discharge s Cx And finished final CTx c aspirin monotherapy



# If CABG chosen, what happened ?

Pre-op CAG:  
PTCA c stent at p-RCA  
(BioFreedom 4.0x14mm)

16.03.07



16.04.13



Recommend CABG.

→ Family discussion

→ Meeting @ OPD 1week later → CS consultation & scheduling 1 week later → CABG & discharge 2 weeks later

- New treatment strategy, "PCI with BioFreedom & operation 1-month later with aspirin monotherapy" would be faster than other pre-op treatment including bypass surgery.



# Severance Experience of 1-month DAPT after BioFreedom implantation before surgery

- Duration: Feb 2016 ~ Mar 2017
- Indicated patients: N = 19





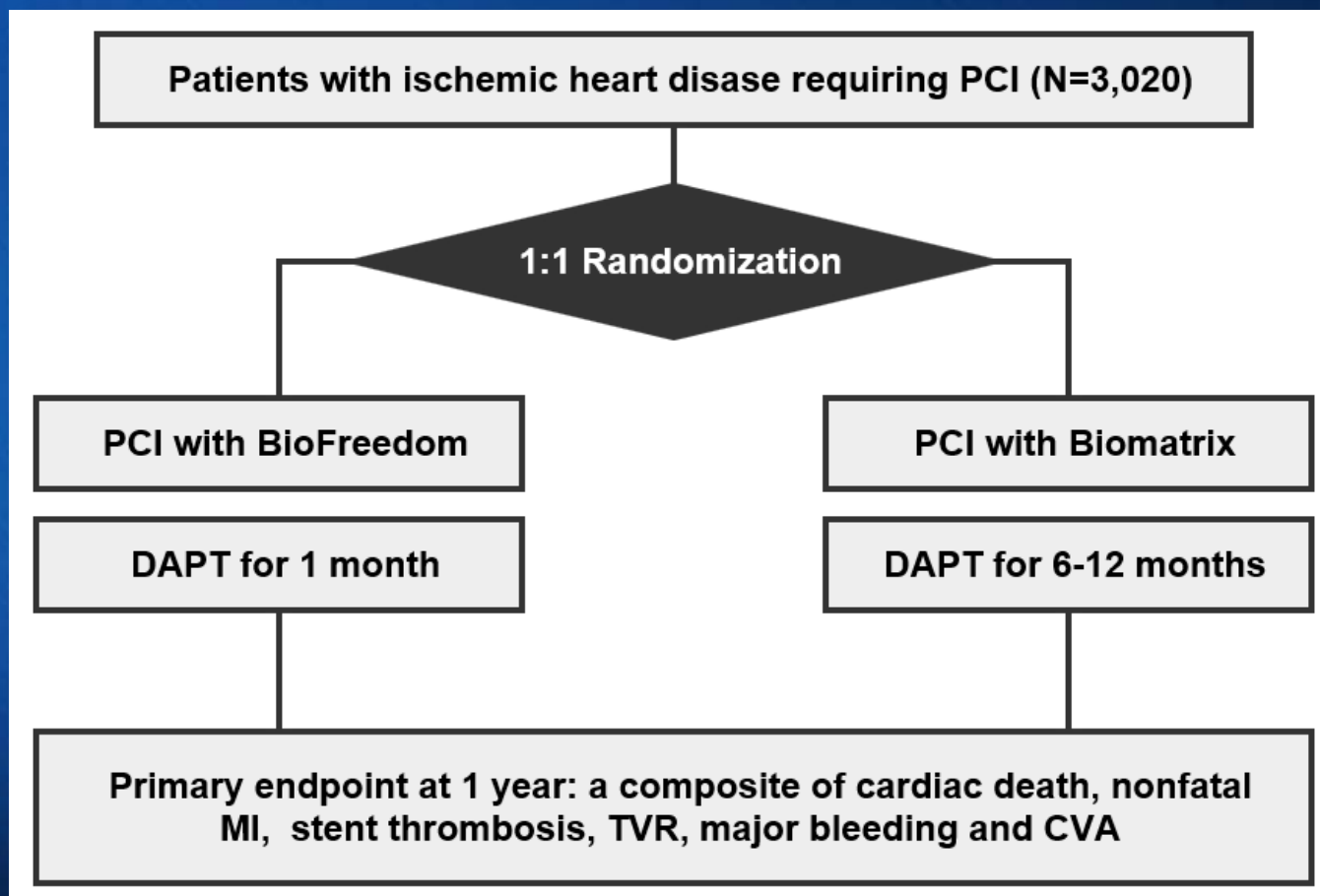
# Baseline characteristics

|                                    | Biofreedom<br>(N =19) |
|------------------------------------|-----------------------|
| Age, Mean $\pm$ SD                 | 70.2 $\pm$ 7.4        |
| Gender, Male                       | 16 (84.2)             |
| Hypertension                       | 11 (57.9)             |
| Diabetes                           | 6 (31.6)              |
| CKD                                | 4 (21.1)              |
| COPD                               | 2 (10.5)              |
| Current smoker                     | 8 (42.1)              |
| Coronary artery disease            |                       |
| one-vessel disease                 | 6 (31.6)              |
| two-vessel disease                 | 9 (47.4)              |
| three-vessel disease               | 4 (21.1)              |
| Target vessel revascularization, % | 77.2 $\pm$ 28.4       |
| Cancer surgery, %                  | 16 (84.2)             |

# Outcomes

|  | <b>Biofreedom<br/>(N = 19)</b> |
|--|--------------------------------|
| <b>Proceeding to surgery</b>           | <b>19 (100.0)</b>              |
| <b>All cause of Death</b>              | <b>0 (0)</b>                   |
| <b>Adverse event</b>                   |                                |
| <b>Peri-revascularization period</b>   | <b>0 (0)</b>                   |
| <b>Perioperative period</b>            | <b>2 (10.5)</b>                |
| <b>Maintain DAPT days, Median, IQR</b> | <b>31 (29, 37.5)</b>           |

# A Randomized Controlled Comparison Between One vs. More Than Six Months of DAPT After Biolimus A9-eluting Stent Implantation



ClinicalTrials.gov Identifier: NCT02513810

P.I. Prof Myeongi-Ki Hong



## Lesson from these experiences (1)

- ✓ *Considering the current / future results of “**BioFreedom with 1-month DAPT**”, treatment range might be extended to the more general uses as below.*

### BioFreedom stent implantation with short duration DAPT (<3 month)

- PCI in patients having **high potentials for elective surgery within 12 months**
- PCI in patients with **high bleeding risks**
- PCI for **old-age group**
- or PCI for **all general population**



## *Lesson from these experiences (2)*

A polymer-free and carrier-free drug-coated stent, the **BioFreedom stent** implantation would be the “**new**” **treatment option.**

- **PCI using DES (with 1-month DAPT) before major surgery** (except brain surgery)

*... comparable with bypass surgery before major surgery*

*... could be better than PCI using BMS*

**We need more data regarding theses ....**



*Thank you for your attention*

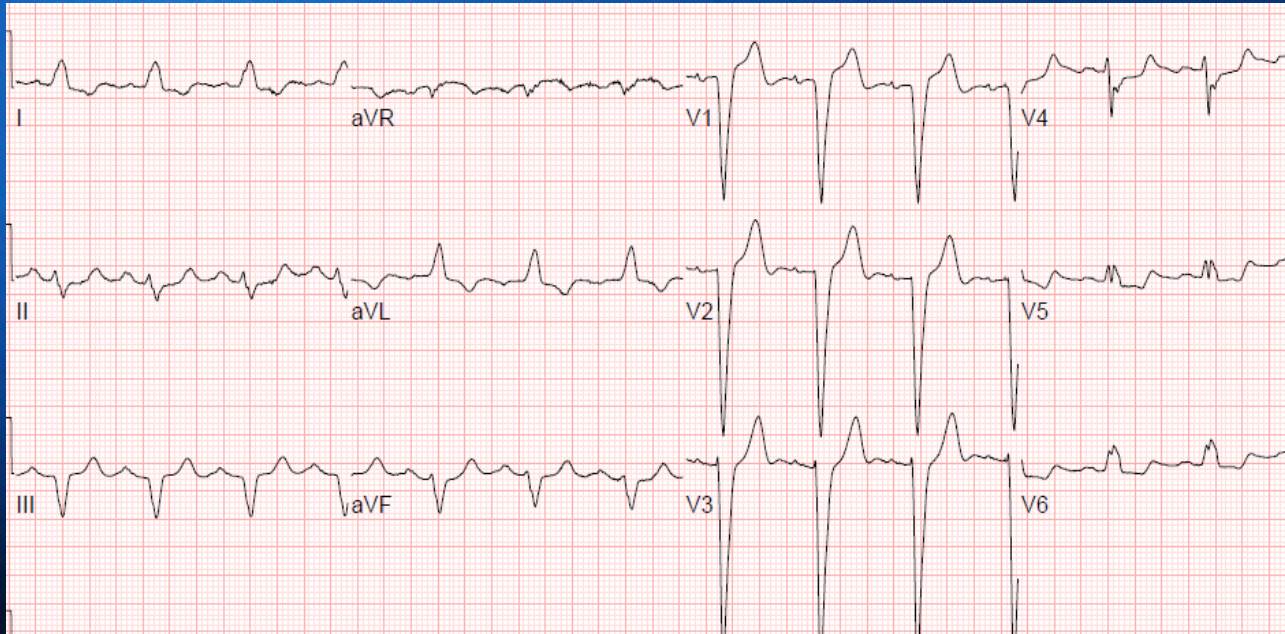
*The Gma*

*Severance Cath room at 1996*

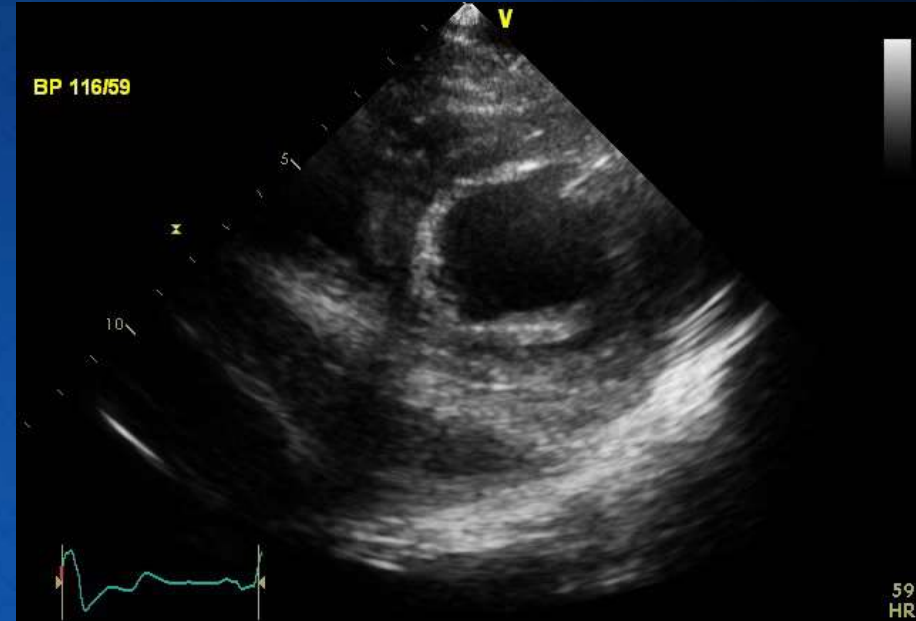
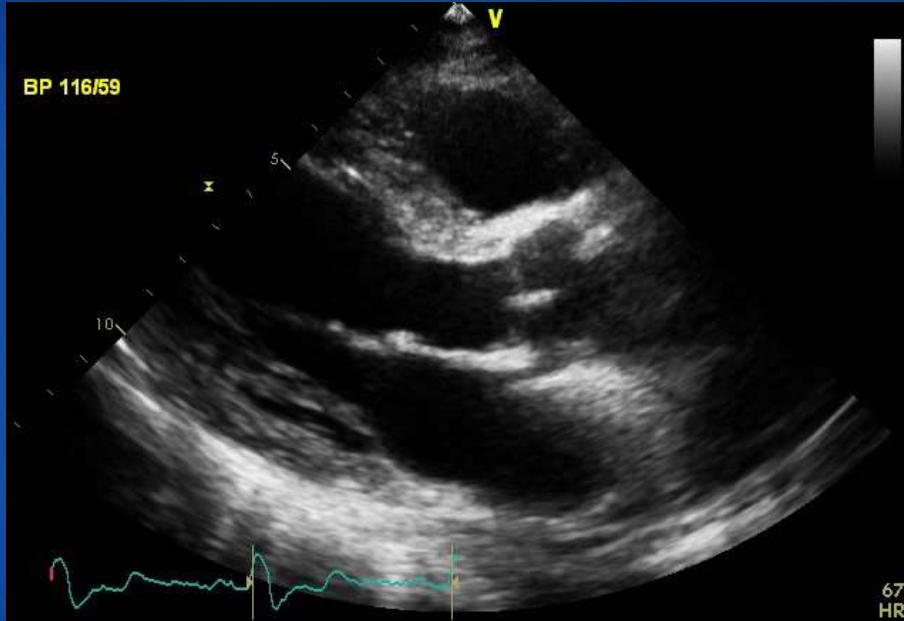


# Brief History

- 73 / M
- Consult for : abnL ECG & Echo, pre-op evaluation of pancreatic Ca
- Past Hx
  - Pancreatic cancer, cT4N0M0  
s/p 5 cycles of chemotherapy (15.10.22~16.2.18)
  - => Planning of Curative resection
- Risk factors
  - Smoking: Current smoker (50PYs) / Alcohol : non-drinker



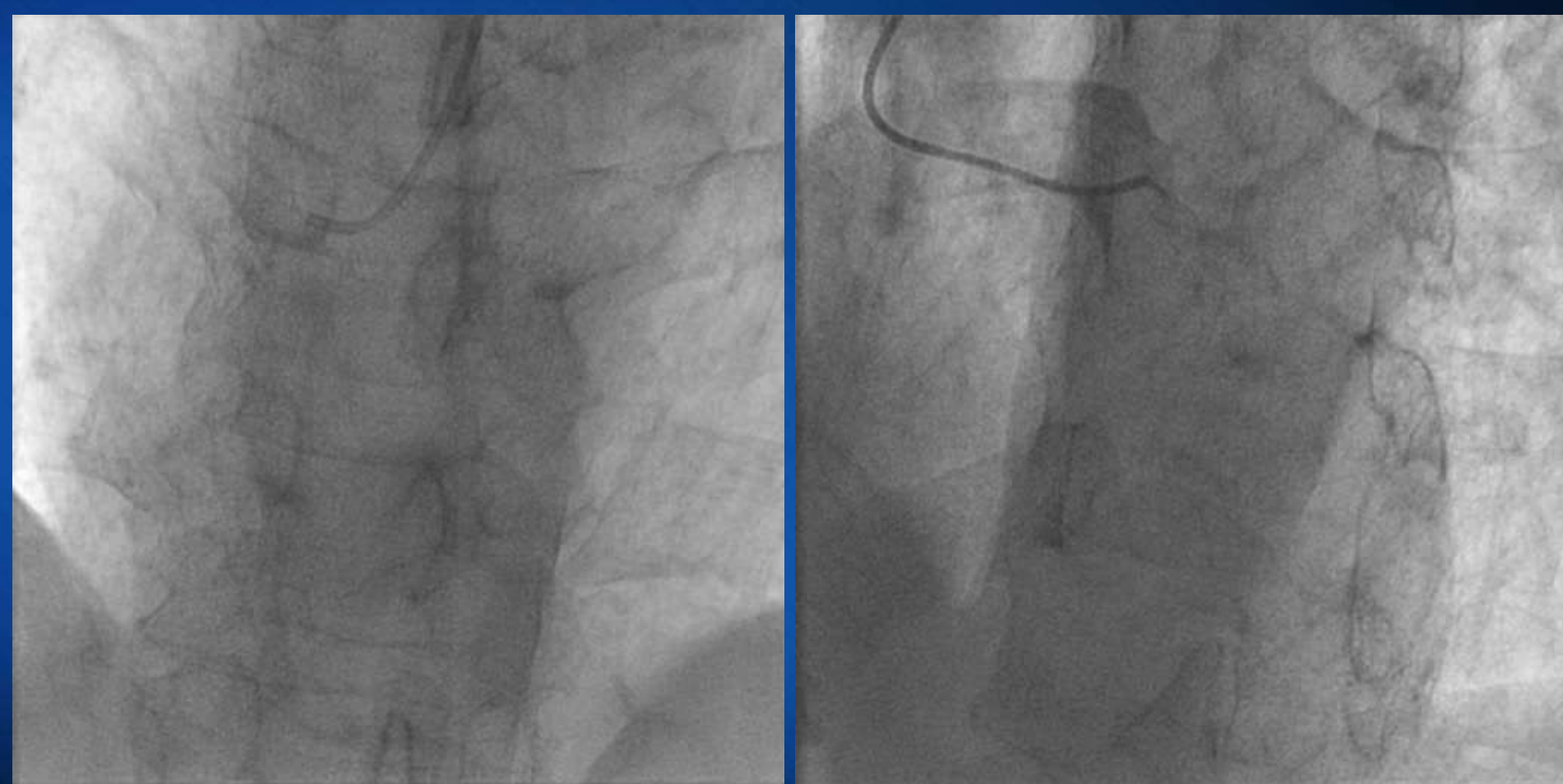
# TTE



- Moderate hypokinesia at inferior apex.
- LV ejection fraction : 68%



# Coronary angiography



**CAOD (2VD), significant stenosis at RCA & LAD**



# Diagnosis

- **Pancreatic cancer**  
s/p 5 cycles of chemotherapy (15.10.22~16.2.18)  
  
=> scheduled to undergo curative operation
  
- **Stable angina, CAD 2-VD**  
→ requiring Pre-Op revascularization



# Revascularization plan

- Treatment PCI with BioFreedom stent

16.03.07  
CAG + PCI

16.04.07  
Discontinue of  
clopidogrel

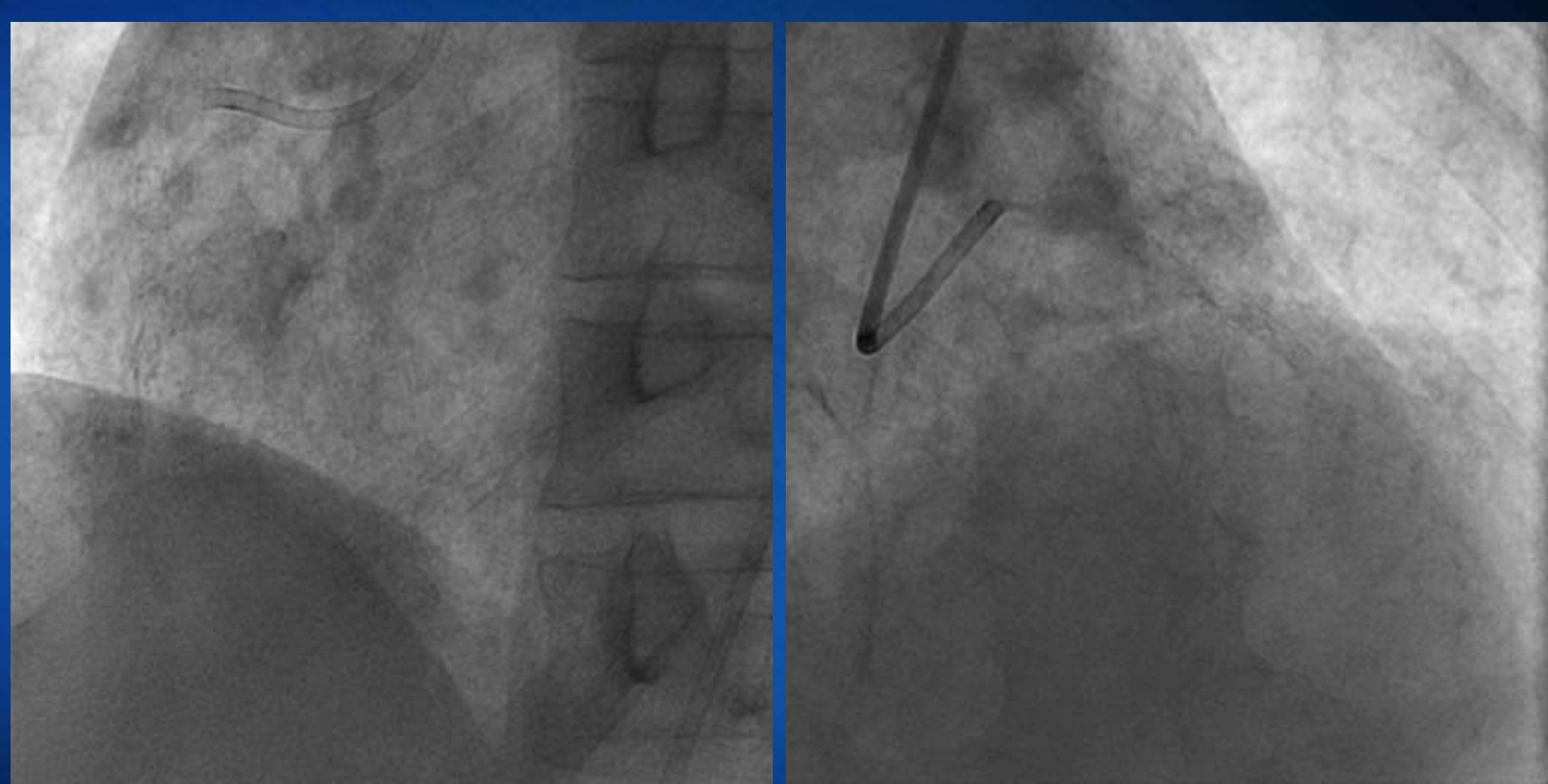
16.04.14  
Pancreas op with Aspirin  
monotherapy ... Discharge at 04. 22

- Sometimes, New treatment strategy, “PCI with BioFreedom & operation 1-month later with aspirin monotherapy” would be faster than other pre-op treatment including bypass surgery.

→ Waiting for Op  
→ After confirmation of Op date, discontinue aspirin and clopidogrel consecutively ..



# PCI



**Successful PTCA c stent at p ~ mRCA (Biofreedom 3.0 x 28mm)  
p ~ mLAD (Biofreedom 3.0 x 24mm)**

**→ A month later, he underwent pancreas Op & discharged without complications.**

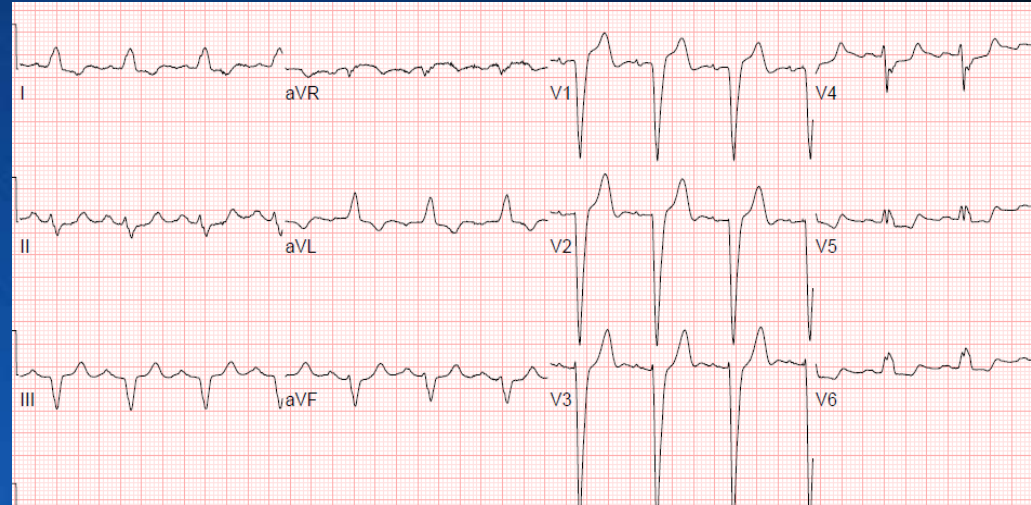


# CASE #3.



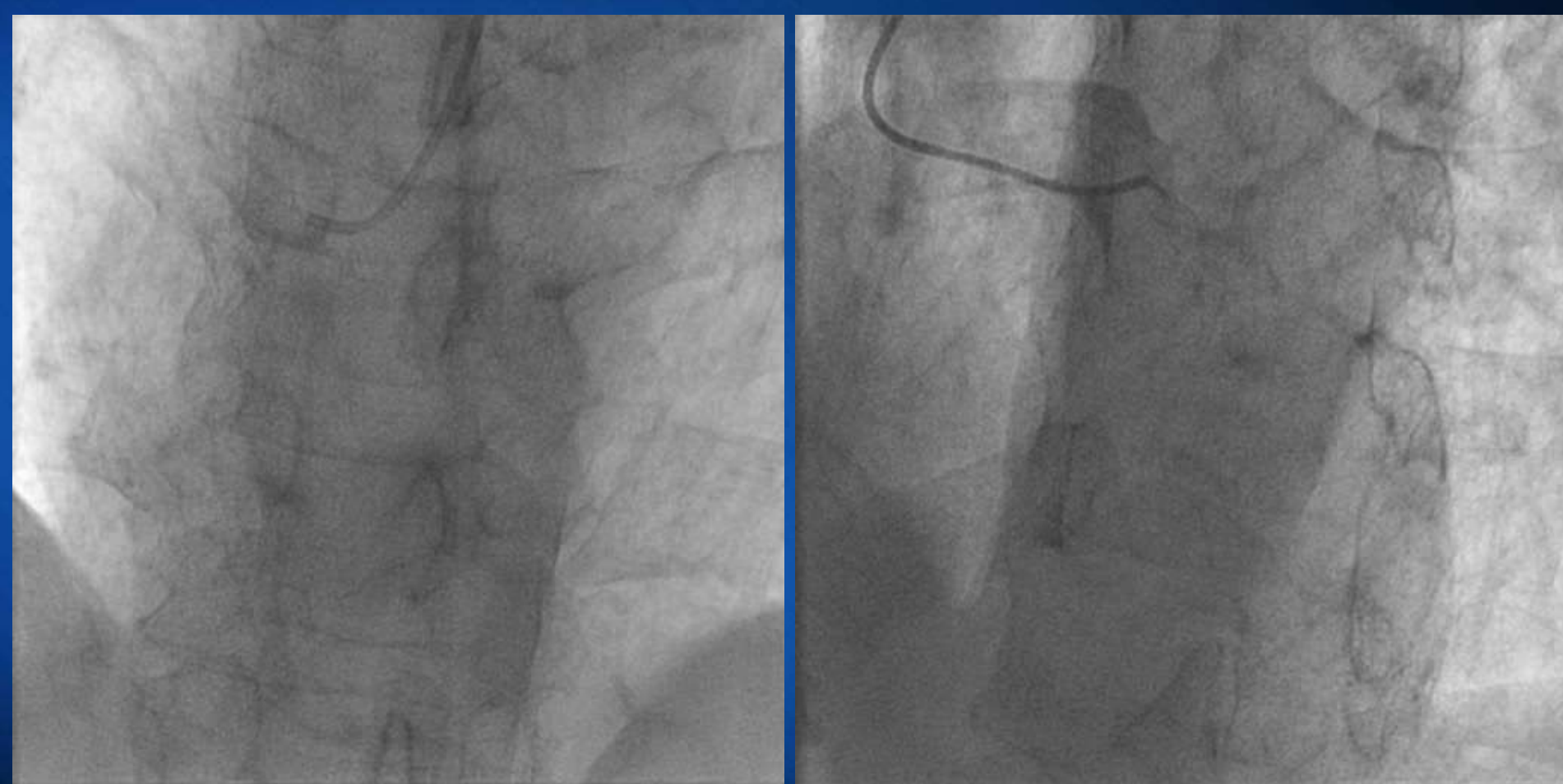
73 / M

- Consult for ... abnL ECG & Echo on pre-op evaluation of pancreatic Cancer
- Past Hx.
  - Pancreatic cancer, cT4N0M0 s/p 5 cycles of chemotherapy (15.10.22~16.2.18) => Planning of Curative resection
- Risk factors
  - Smoking: Current smoker (50PYs)
- Echo : Moderate hypokinesia at inferior apex. LVEF = 68%



→ **Cardiologic answer : recommend CAG**

# Coronary angiography



**CAOD (2VD), significant stenosis at RCA & LAD**



# Diagnosis

- Pancreatic cancer
  - s/p 5 cycles of chemotherapy (15.10.22~16.2.18)
  - **scheduled to undergo curative operation**
- Stable angina, CAD 2-VD
  - **requiring Pre-Op revascularization**
- ✓ **Treatment Plan :**
  - **We suggested two options (CABG vs. PCI) for the treatment and discussed with the patient.**
  - **Patient definitely chose the PCI (cancer op 1 months later)!**





# Revascularization plan

- Treatment PCI with BioFreedom stent

16.03.07  
CAG + PCI

16.04.07  
Discontinue of  
clopidogrel

16.04.14  
Pancreas op with Aspirin  
monotherapy ... Discharge at 04. 22

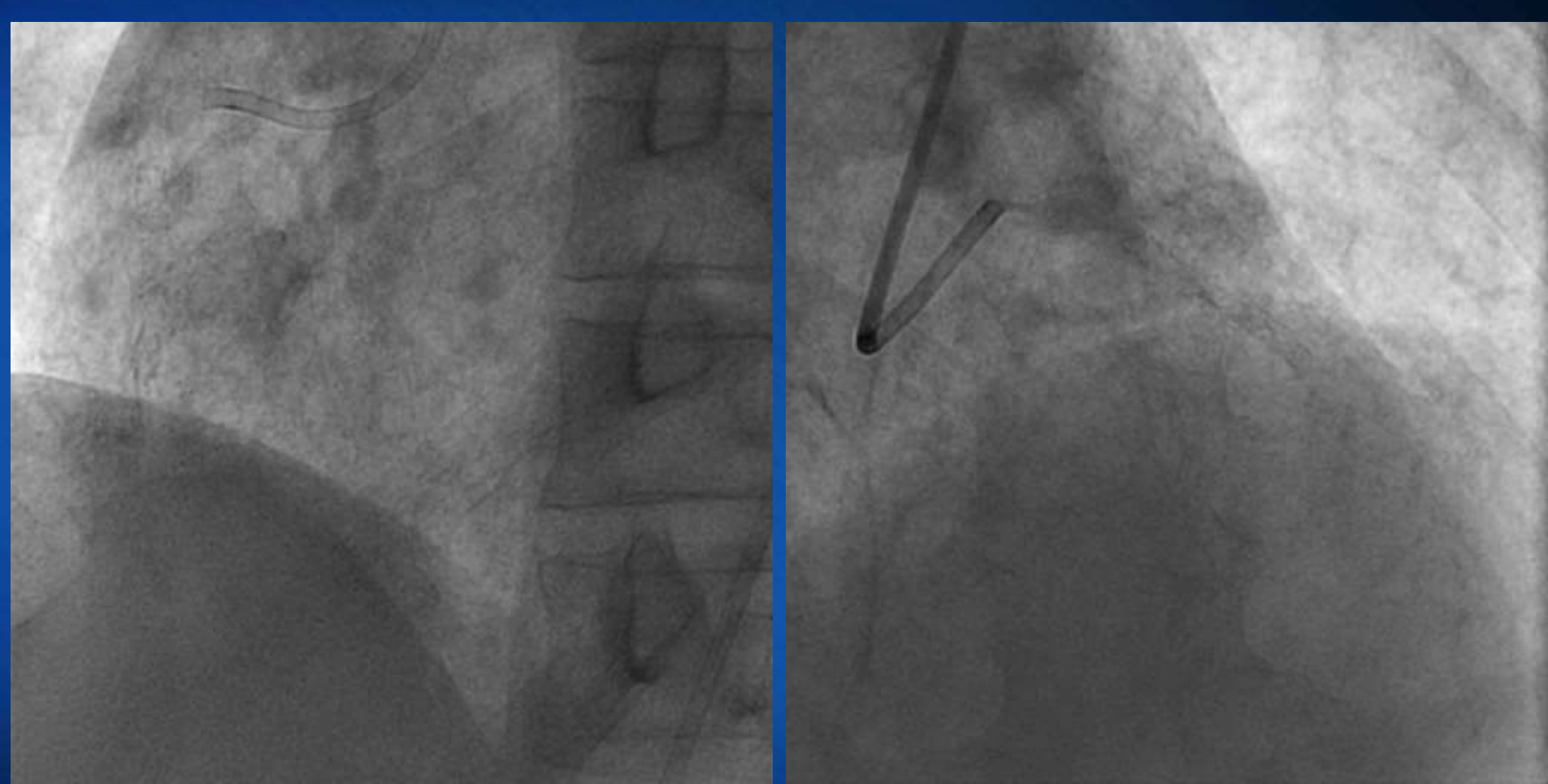
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16.03.24-27  
→ Discharge

- Waiting for Op
- After confirmation of Op date, discontinue aspirin and clopidogrel consecutively ..



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