

From LEADERS to LEADERS FREE: A Patient Centric Approach

Clinical Implication of Biofreedom Stent - Review of Real Experiences

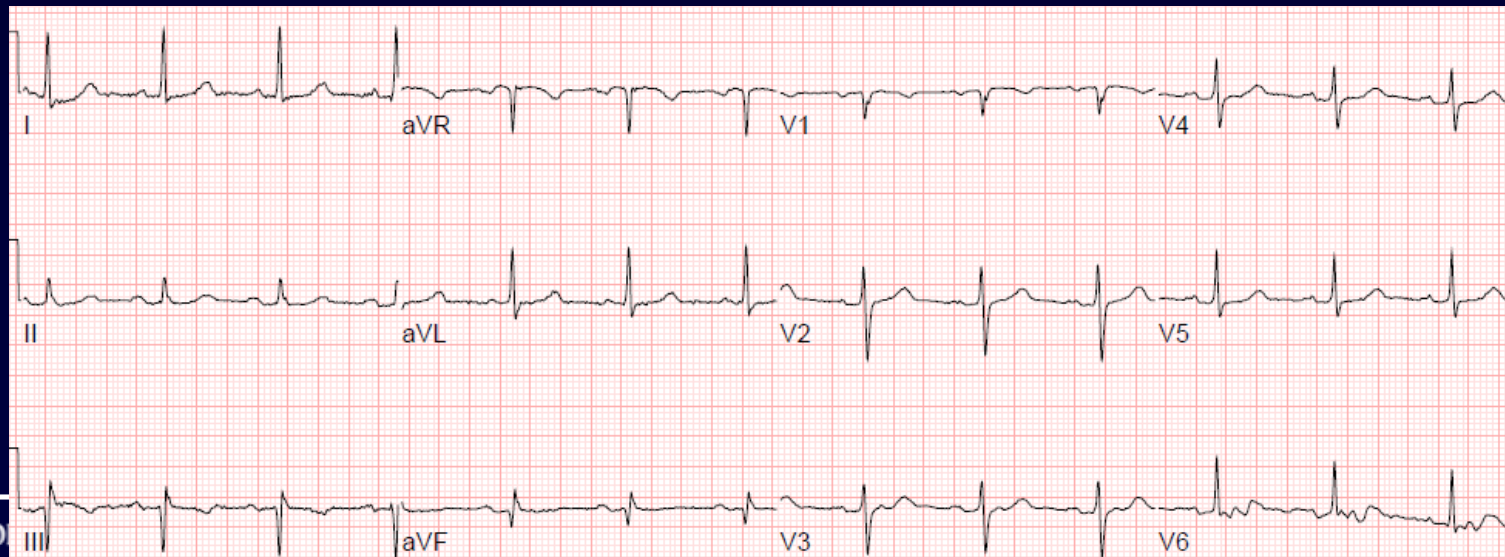
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CASE #1.

Brief History

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



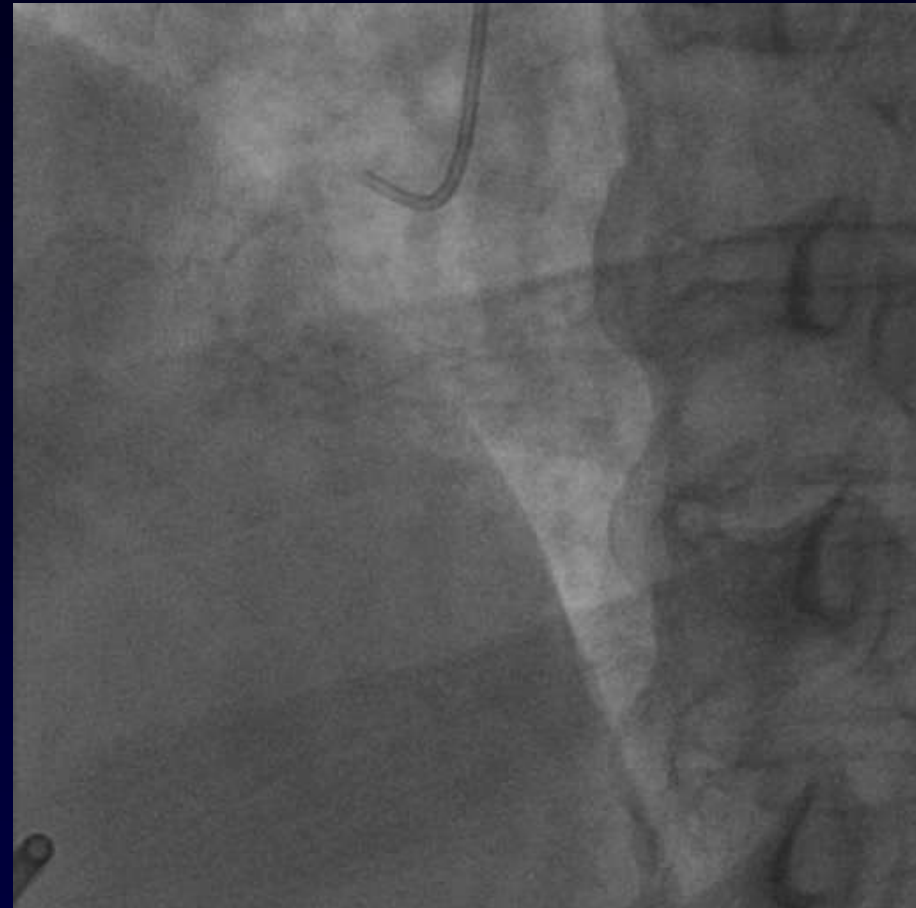
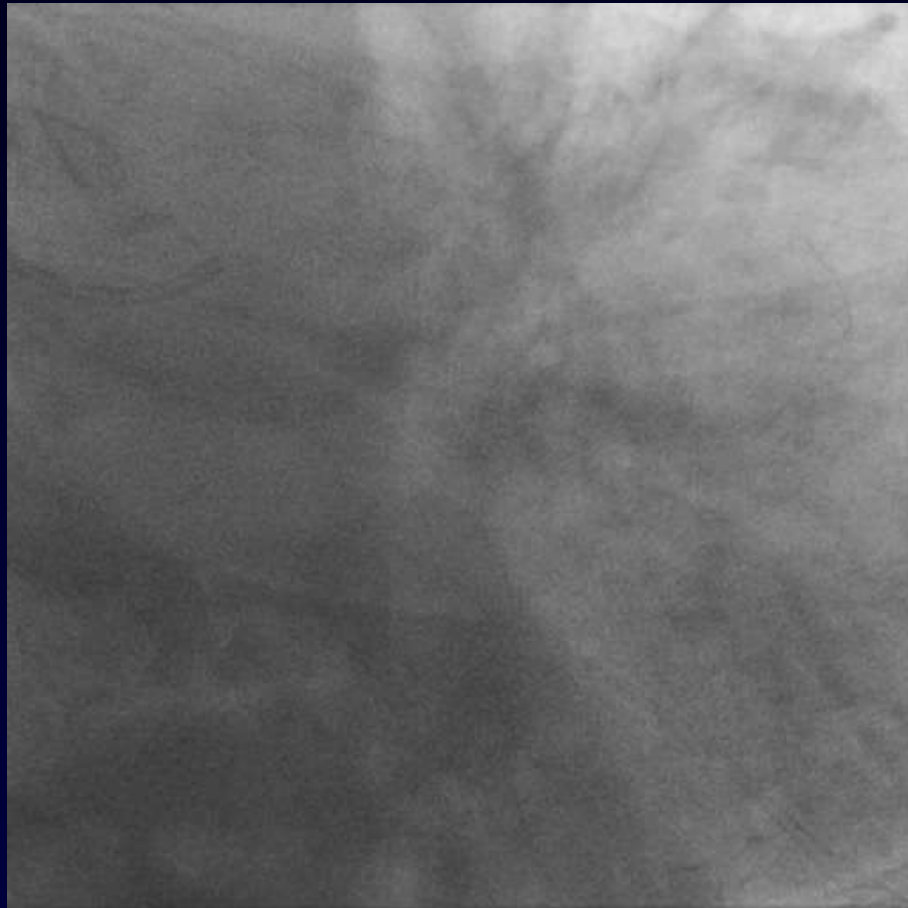
APCT & PET-CT



Imp. R/O Distal CBD cancer
Plan. Operation



Coronary angiography



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

Diagnosis & Plan

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

Cardiologic answer



- *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

1-VD...too healthy coronary arteries to perform bypass surgery...LAD, normal

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

Delayed operation would be risky and patient can not understand.

Treatment Plan

- Treatment

Surgeon response



A. CABG
Operat

B. PCI with
operati

C. PCI with
months



used two
geries. If
e, he refused

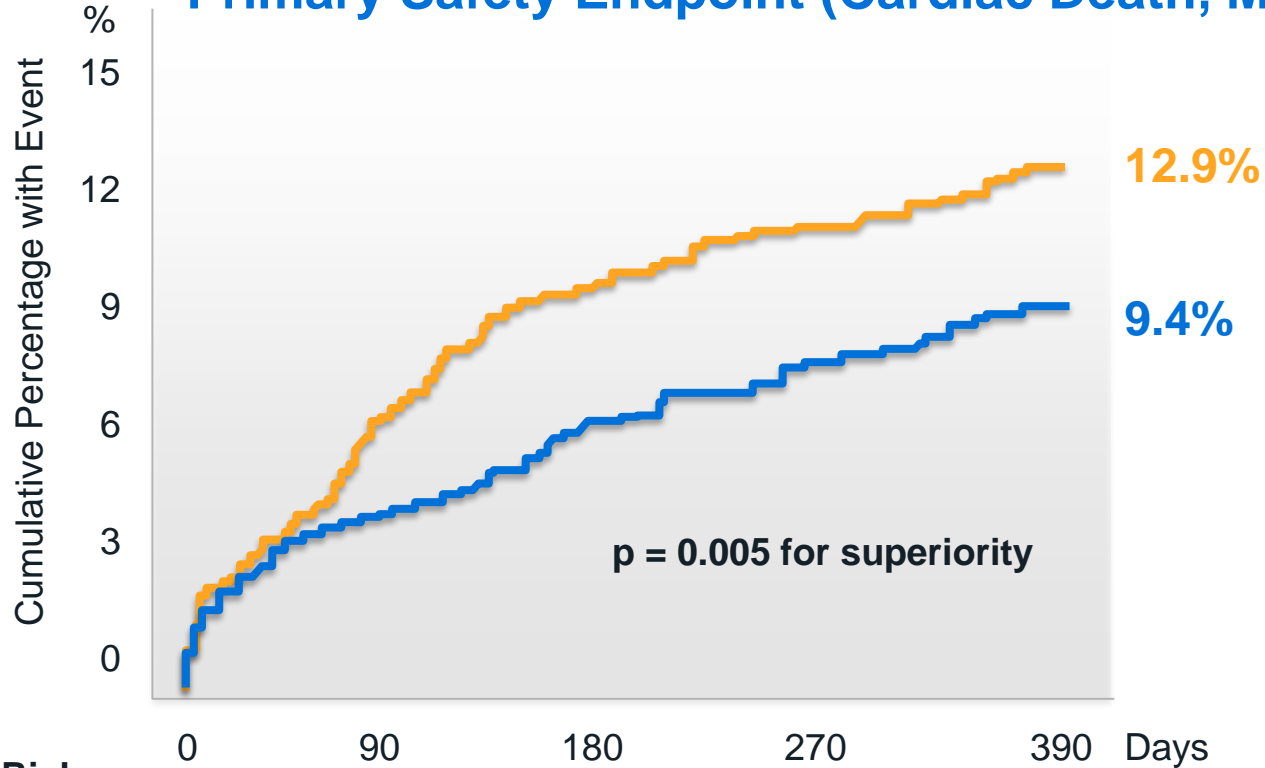
preading,
could not

Treatment Option

- 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 !!!* PCI with DES, operation 1 month later with maintaining aspirin only**

**Surgeon and patient agree to our suggestion.
We perform PCI first with BioFreedom stent**

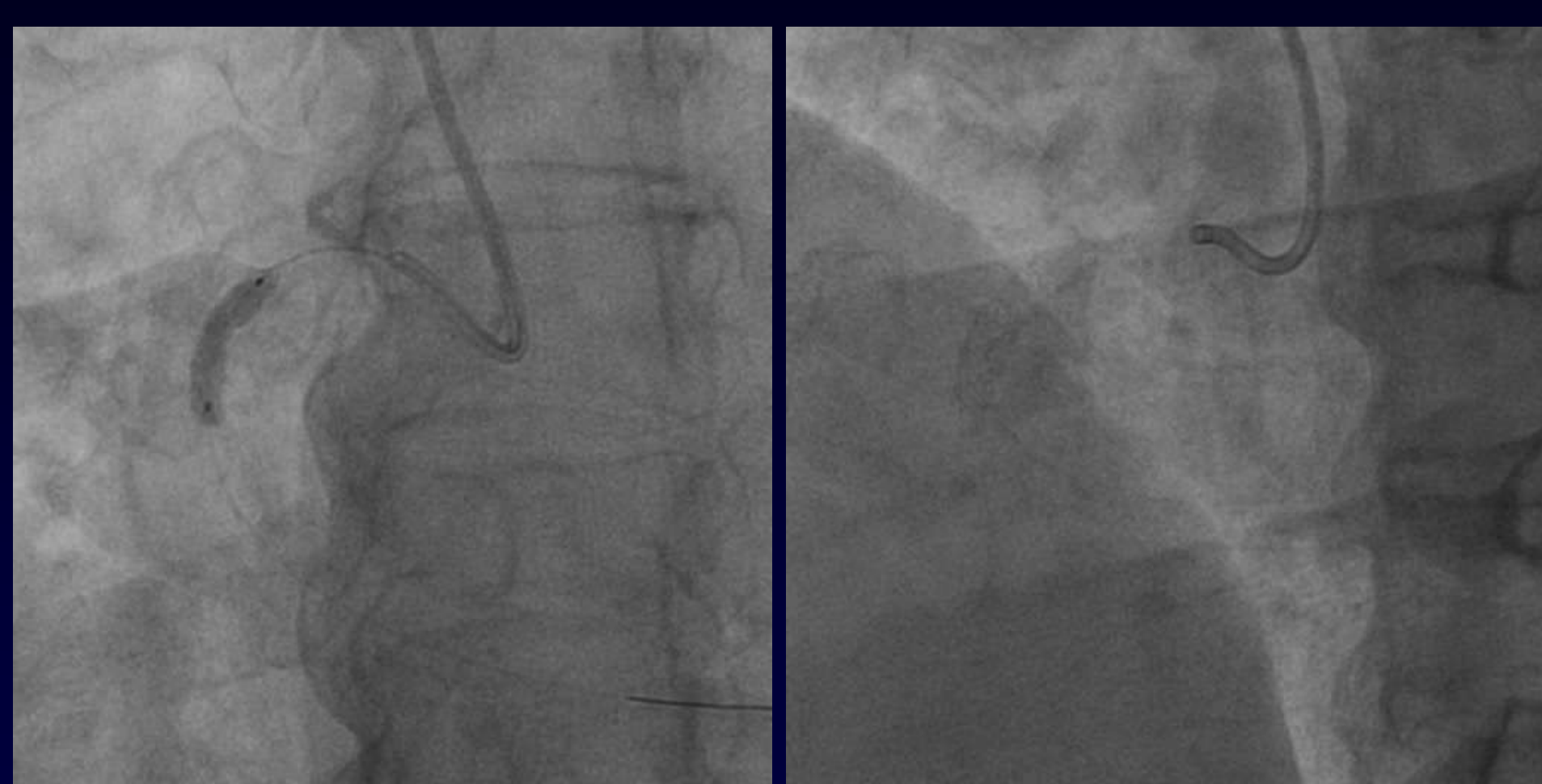
Primary Safety Endpoint (Cardiac Death, MI, ST)



Number at Risk

	0	90	180	270	390 Days
BioFreedom™ DCS	1221	1146	1105	1081	1045
BMS	1211	1115	1066	1037	1000

PCI



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

Progress

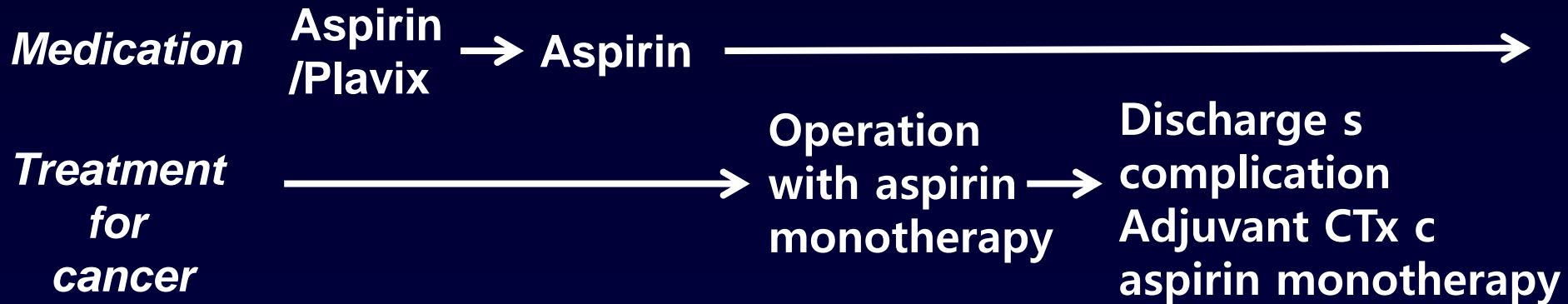
PTCA c stent at p-RCA (BioFreedom 4.0 x 14mm)

15.12.08

16.01.08

16.01.13

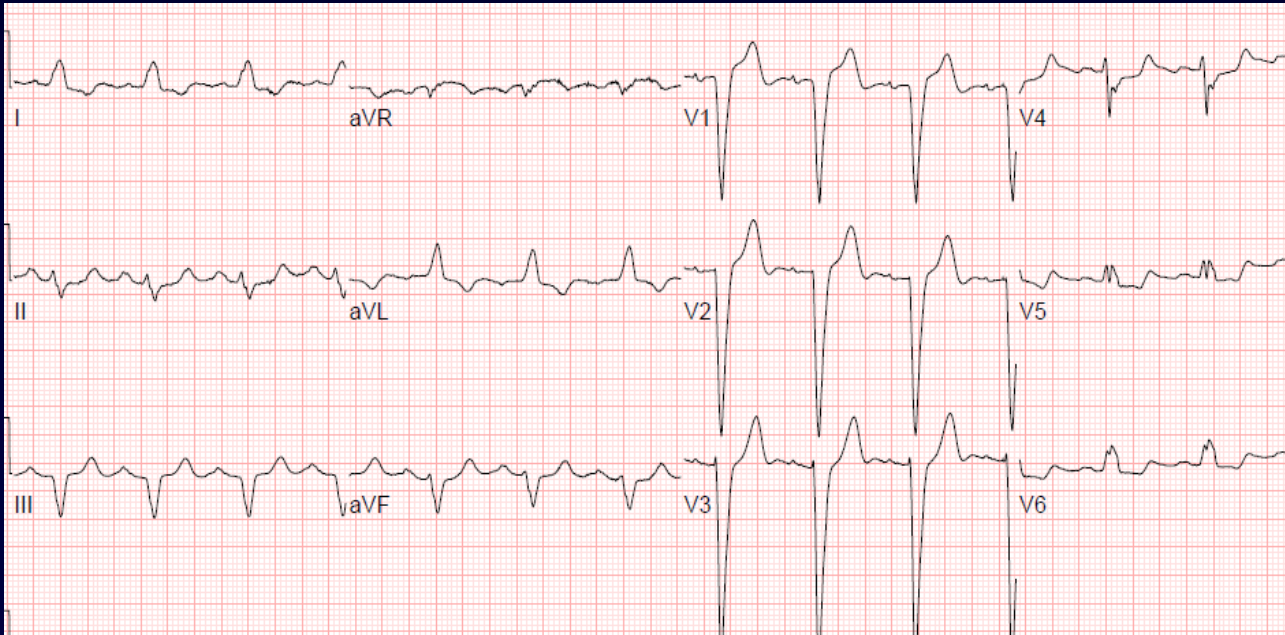
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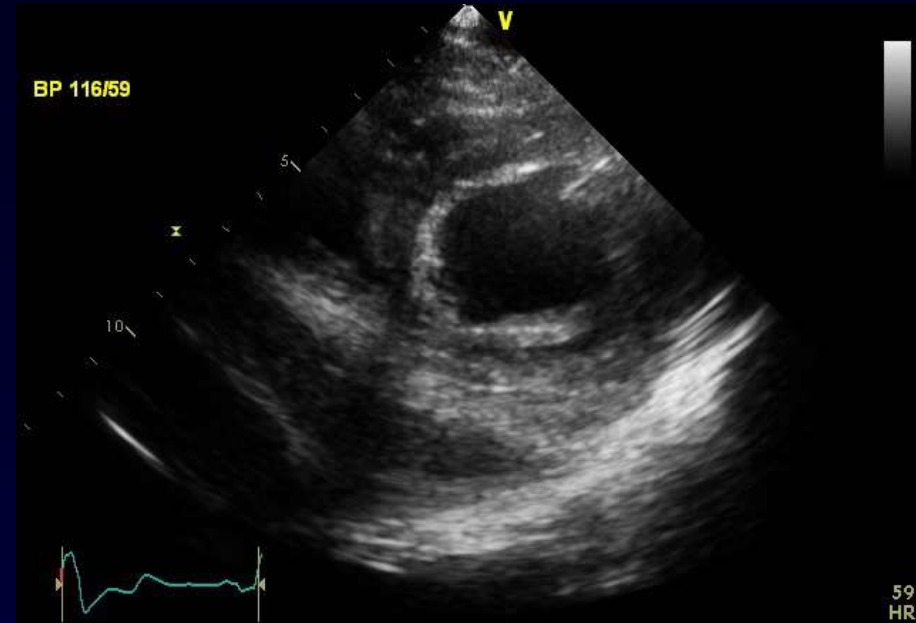
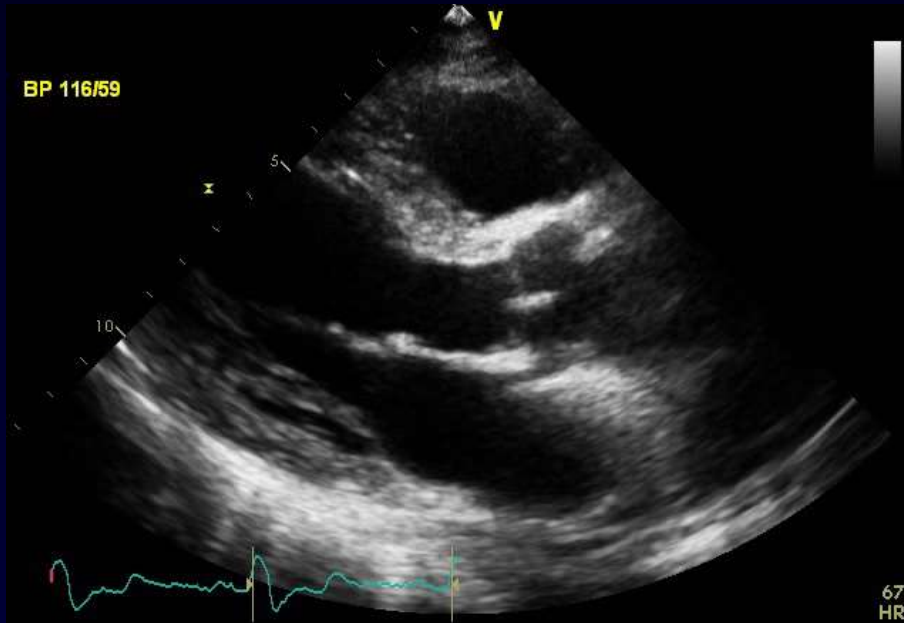
CASE #2.

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

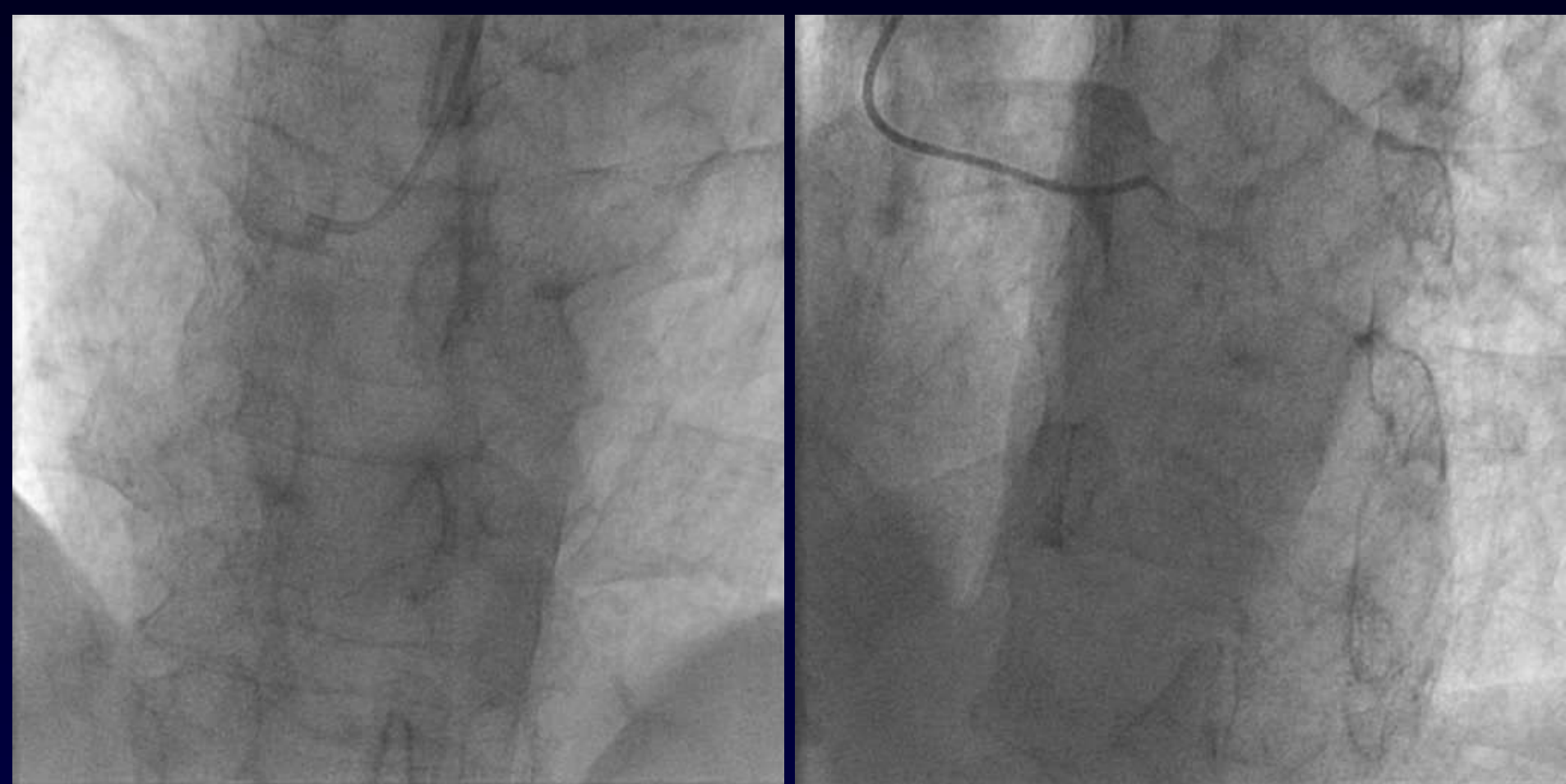


TTE



- 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

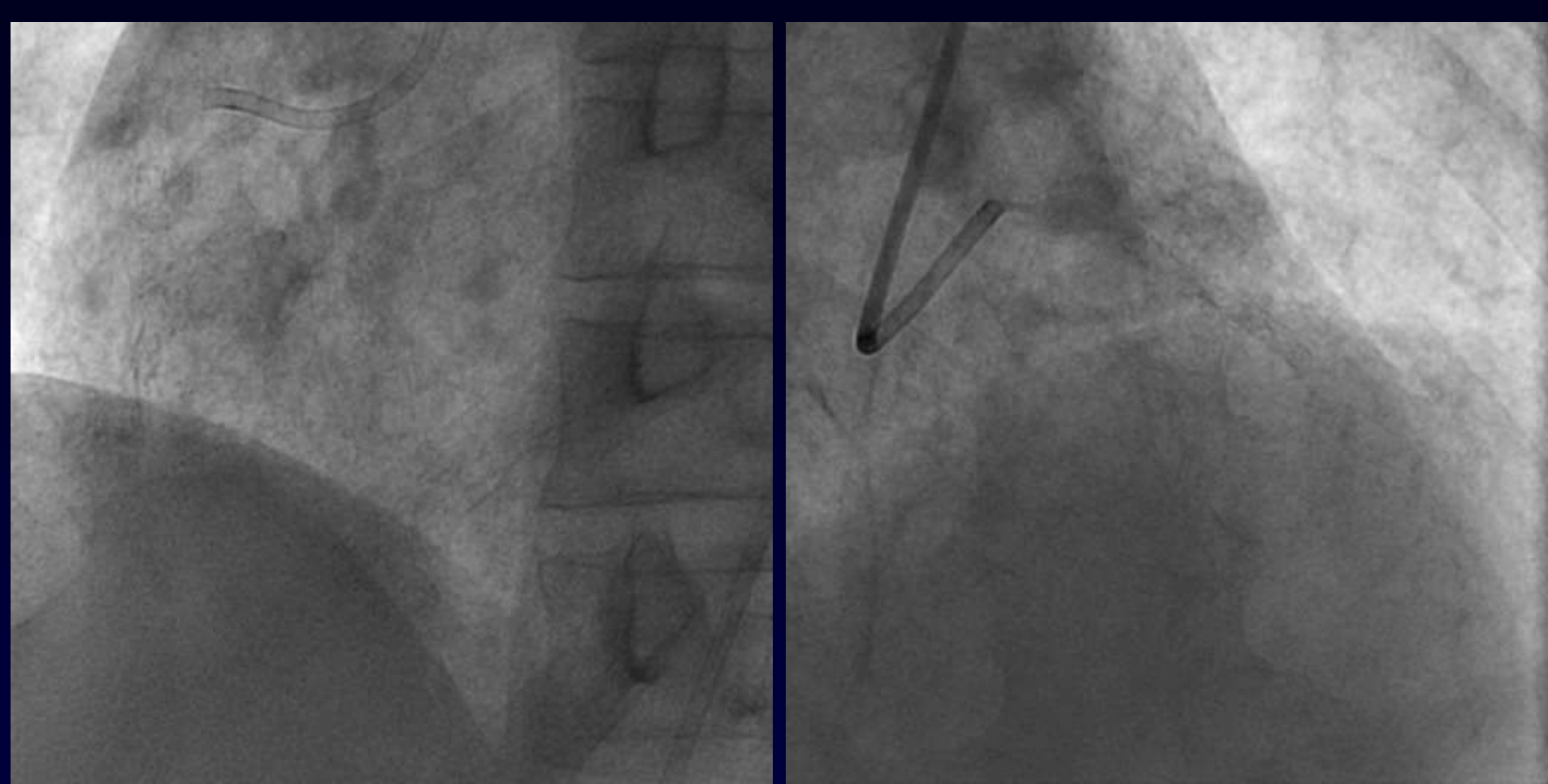
16.04.07
Discontinue of
clopidogrel

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.

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.

Brief History

- **76 / F ... Height 150 cm / Weight 38kg .. BMI 16.9 kg/m²**
- **Chief complaint**
 - **Transfer from local clinic with positive TMT & recently aggravated exertional chest pain**
- **Past Hx**
 - **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%)**

Coronary angiography

Plan>

- Definitely PCI of LAD needed,
which DES ? and how long DAPT?

CONCERNS

- ✓ Old age with low body weight
- ✓ Many future procedures or operations requiring discontinuation of DAPT
- ✓ Low ischemic risks?

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

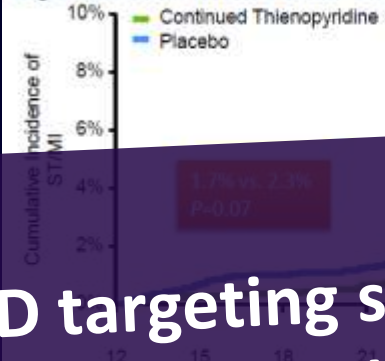


The DAPT Score

Variable	Points
Patient Characteristic	
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
Index Procedure Characteristic	
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

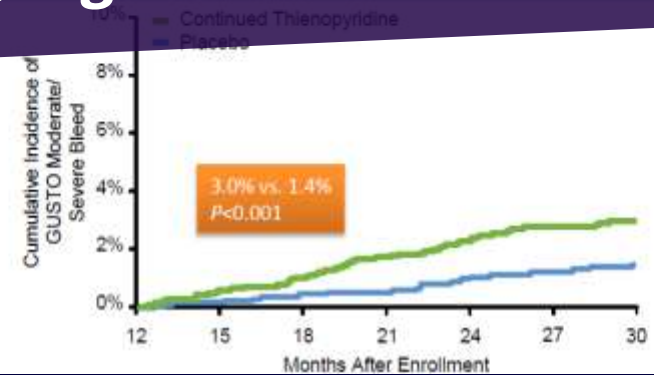


Death, MI, or Stroke (MACCE)



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

GUSTO Moderate/ Severe Bleeding



- Patient's DAPT score : - 2



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

Medication Aspirin/Plavix → Aspirin →

Event → No ischemic or bleeding event occurred.

Lesson from these experiences (1)

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

- **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

Lesson from these experiences (2)

If treatment ranges extended to the more general uses ...

BioFreedom stent implantation with short duration DAPT (1 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**

→ .. We need data.

We are currently doing this study for proving.

Thank you for your attention

The Gma

Severance Cath room at 1996