

Long lesions, diffuse disease, MVD

What can we do? What should we do?

Bernard Chevalier & Jean Fajadet

Clinique Pasteur & CCN, France

Long lesions, diffuse disease, MVD

What can we do? What should we do?

- **What can we do?**

What is technically feasible, what is doable

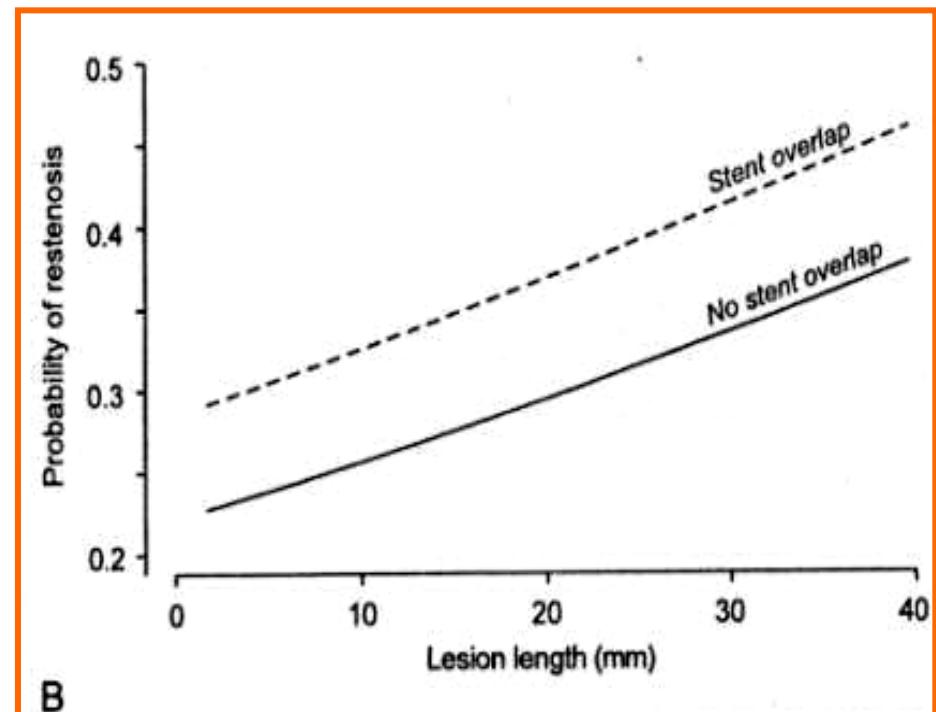
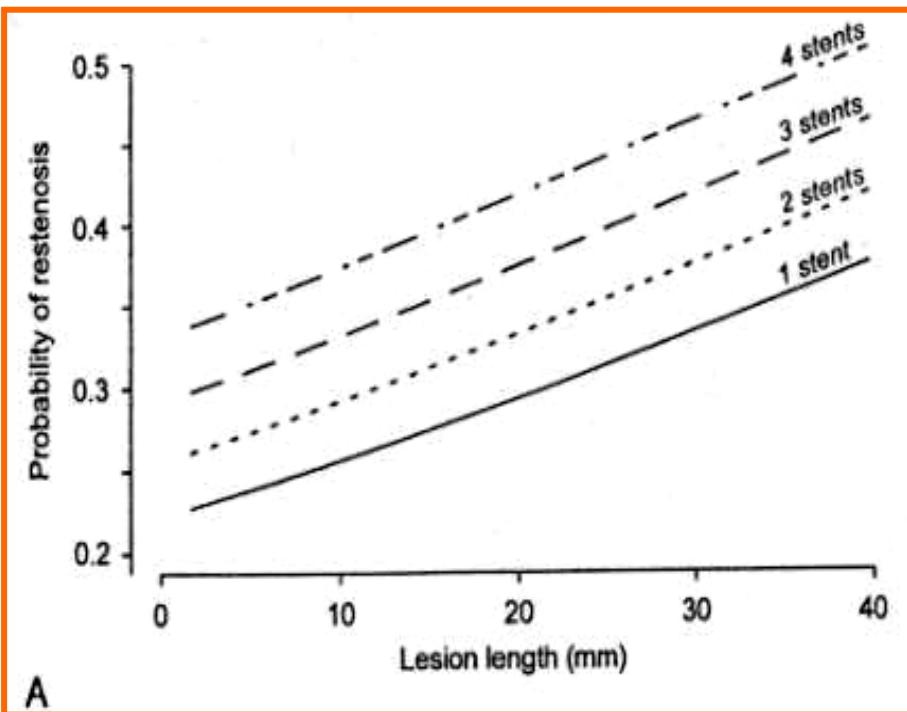
- **What should we do?**

What is reasonable, what is recommended

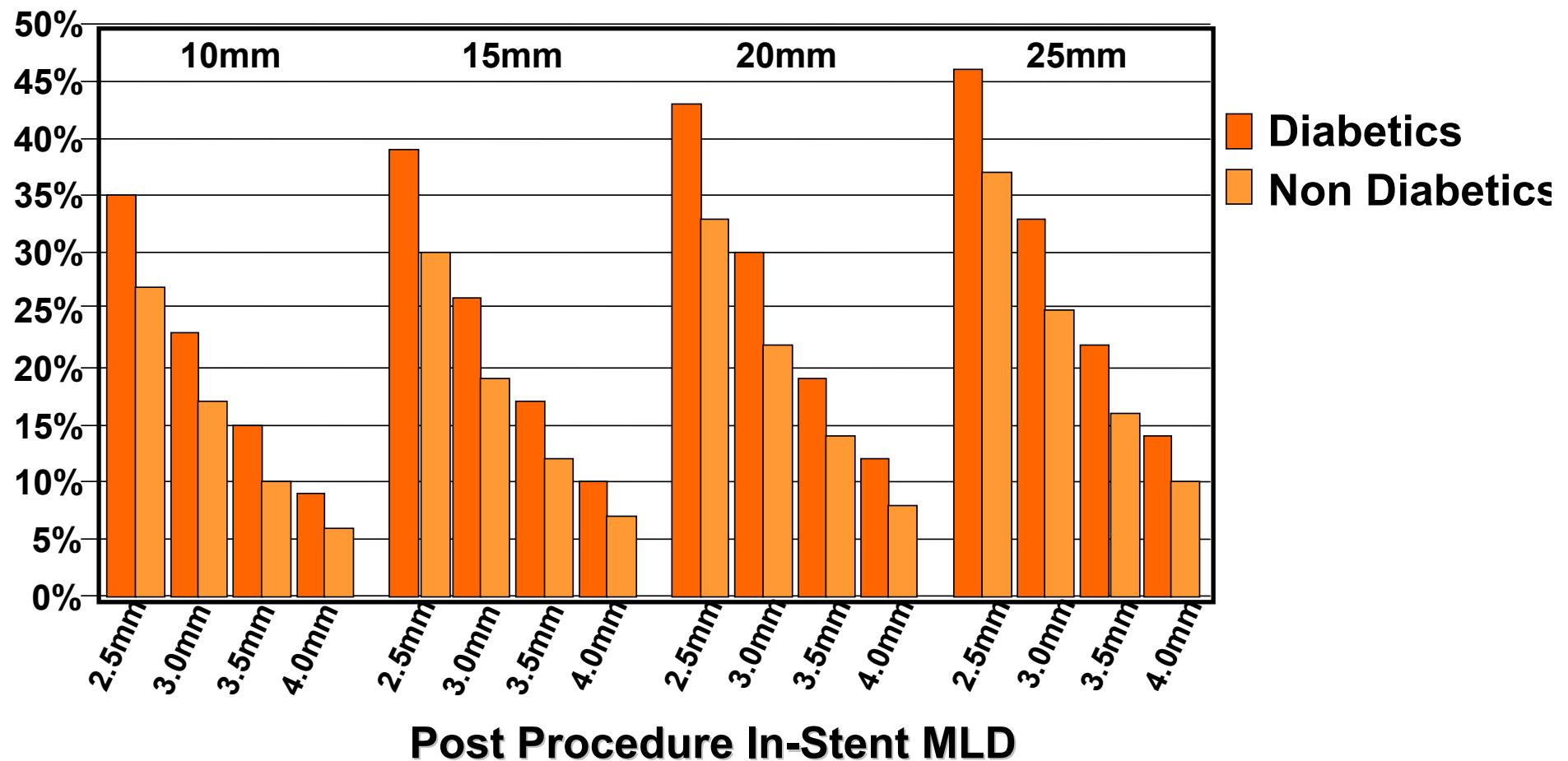
Long lesions

- **What have we learned with BMS ?**

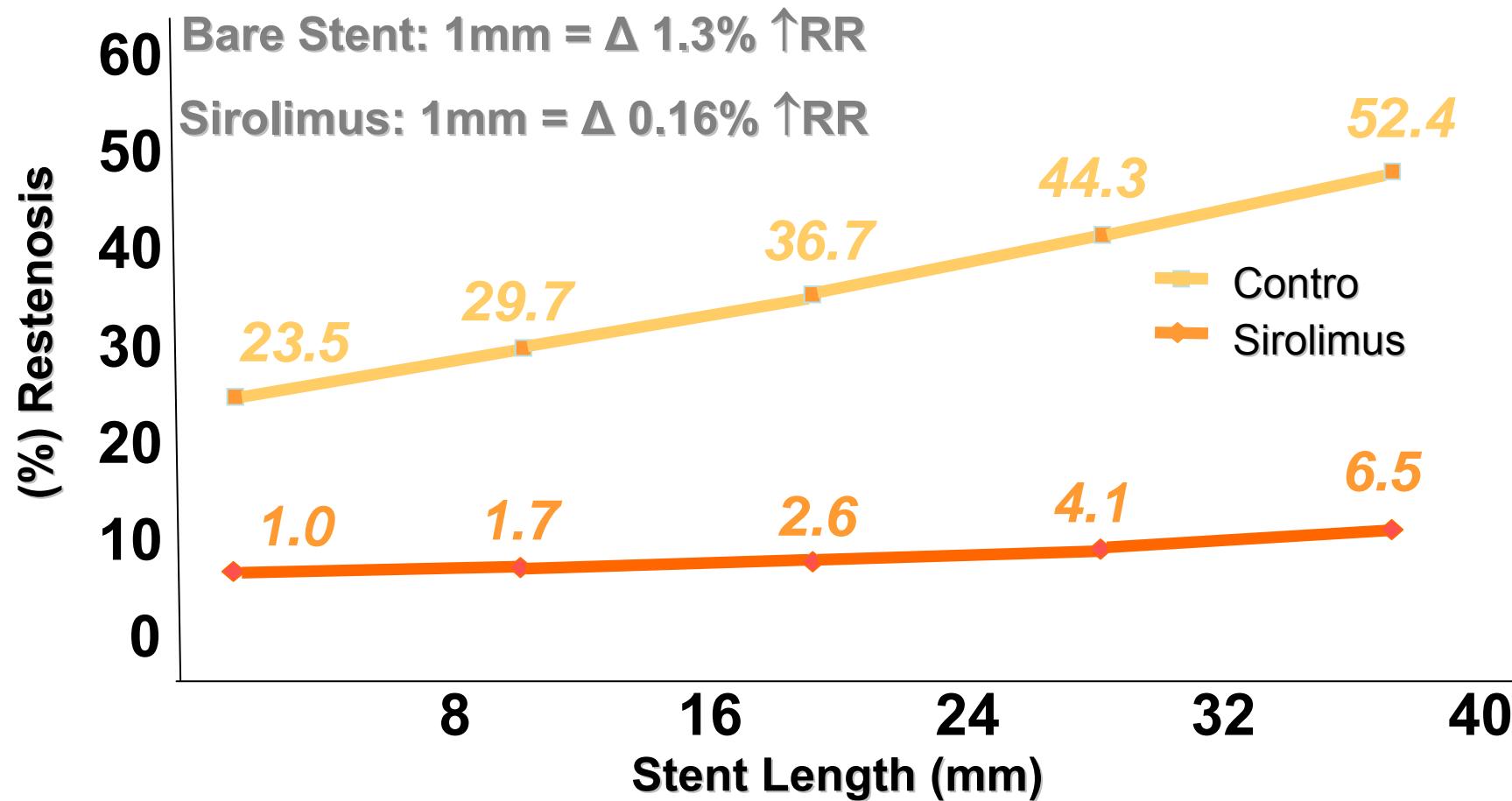
Influence of Lesion Length on Restenosis After Coronary Stent Placement



Lesion Length, Vessel Size, and Diabetes

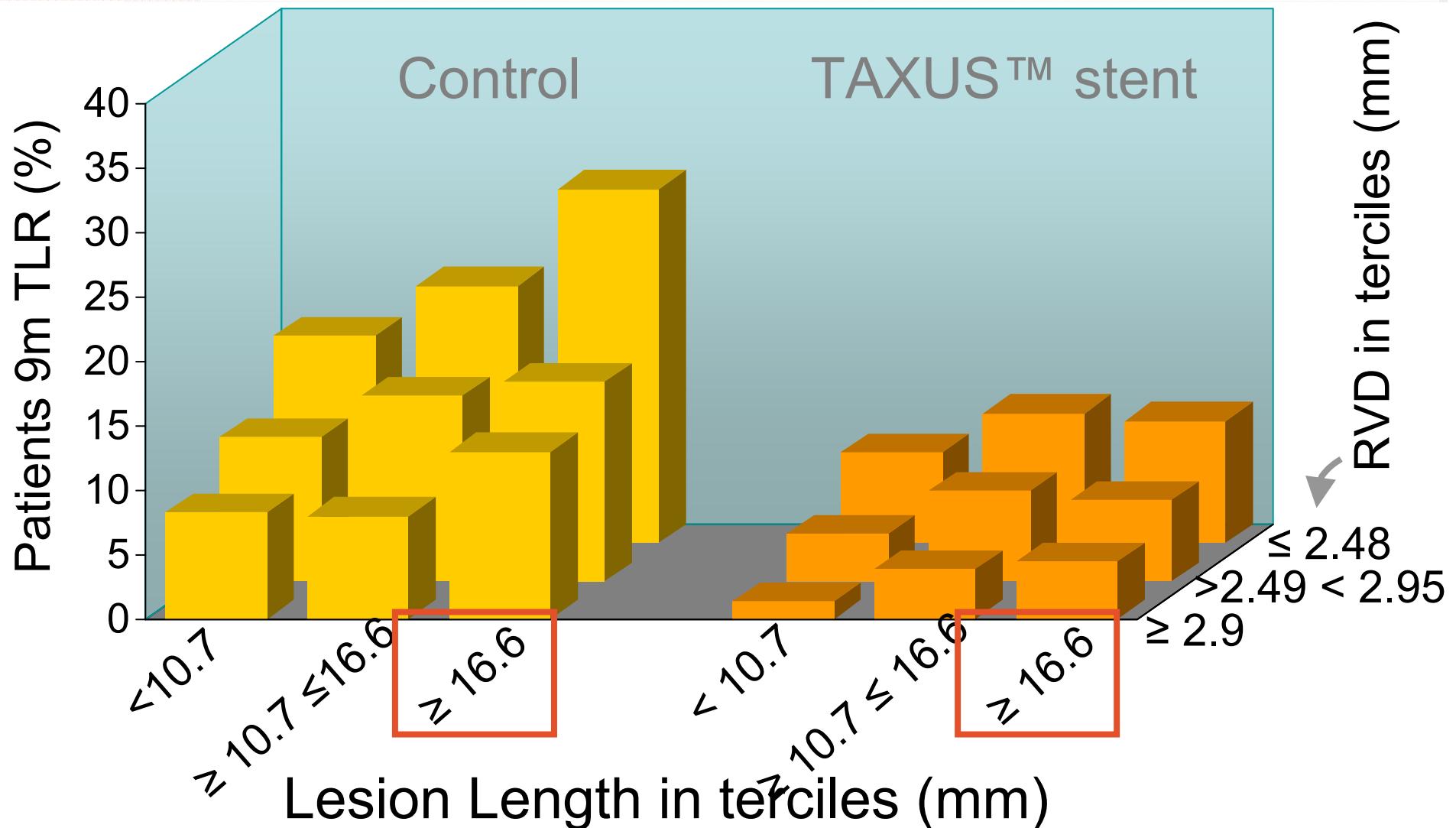


- What have we learned with BMS ?
- **What are we learning with DES ?**

In-Stent Restenosis

Effect of Vessel Size and Lesion Length on 9m TLR

(All Patients, TAXUS II, IV, V, VI trials)



Clinical, Angiographic, and Procedural Predictors of Angiographic Restenosis After Sirolimus-Eluting Stent Implantation in Complex Patients.

An Evaluation From the Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital (RESEARCH) Study

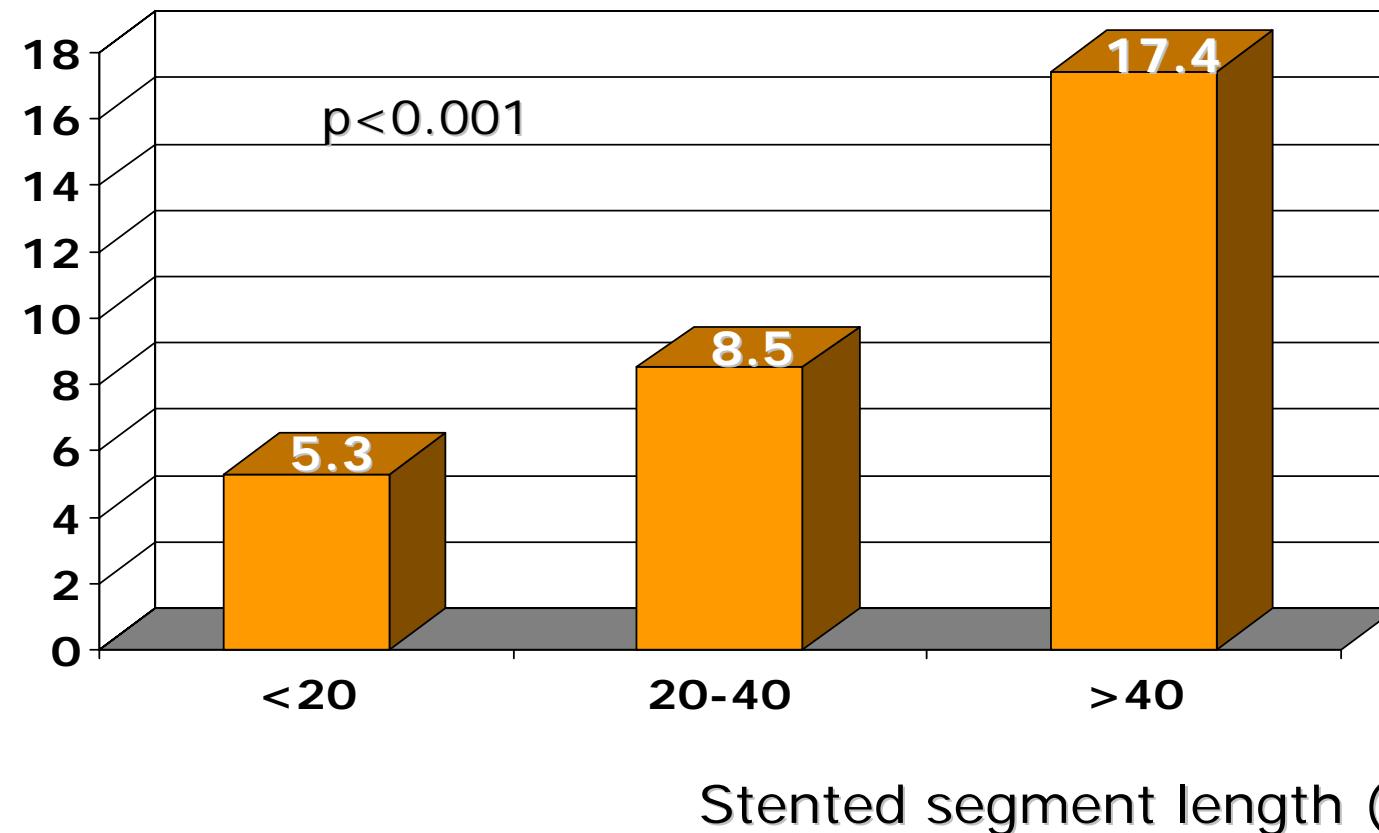
238 patients, 441 lesions, restenosis = 7.9%

TABLE 5. Actual Rates of Post-SES In-Segment Restenosis According to the Presence of High-Risk Characteristics*

| | In-Segment Restenosis Rate, % |
|----------------------------------|-------------------------------------|
| Treatment of in-stent restenosis | 19.6 |
| Ostial location | 14.7 |
| Diabetes mellitus | 14.3 |
| Stented length >26 mm† | 13.9 |
| Reference diameter <2.17 mm‡ | 10.3 |
| Non-LAD location | 10.8 |

Restenosis vs Stented Segment Length

Restenosis (%)



Clinical outcome at 1 year of very long lesions in Research

Stented length=79mm (64-168)

| Events (%) | All n=122 | SES n=81 | PES n=41 | p value |
|---------------|--------------|-------------|-------------|------------|
| Death | 4.1 | 2.5 | 7.3 | 0.2 |
| MI | 10.0 | 11.2 | 5.4 | 0.53 |
| TVR | 7.5 | 7.5 | 7.6 | 0.96 |
| MACE | 18.0 | 18.5 | 17.1 | 0.87 |

Clinical outcome at 1 year (Milan)

Very long lesions

| Events (%) | In-hospital n=66 | Follow-up n=66 |
|------------|---------------------|-------------------|
| Death | 0 | 0 |
| Q MI | 0 | 0 |
| Non Q MI | 16.6 | 1.5 |
| Restenosis | | 19.6 |
| TVR | 0 | 15 |
| CABG | 0 | 1.5 |

Taxus V - Multiple Stent QCA Analysis

Patient Demographics

| | Control n=184 | TAXUS n=188 | P value |
|-------------------------------|------------------|-----------------|---------|
| Diabetes mellitus (%) | 33.7 | 35.1 | 0.83 |
| RVD (mm) | 2.68 ± 0.56 | 2.66 ± 0.55 | 0.77 |
| Lesion Length (mm) | 25.7 ± 10.4 | 24.9 ± 9.5 | 0.44 |
| Calcification, any (%) | 41.5 | 38.3 | 0.60 |
| Type C _{ACC/AHA} (%) | 75.0 | 72.3 | 0.64 |

Taxus V - Multiple Stent QCA Analysis

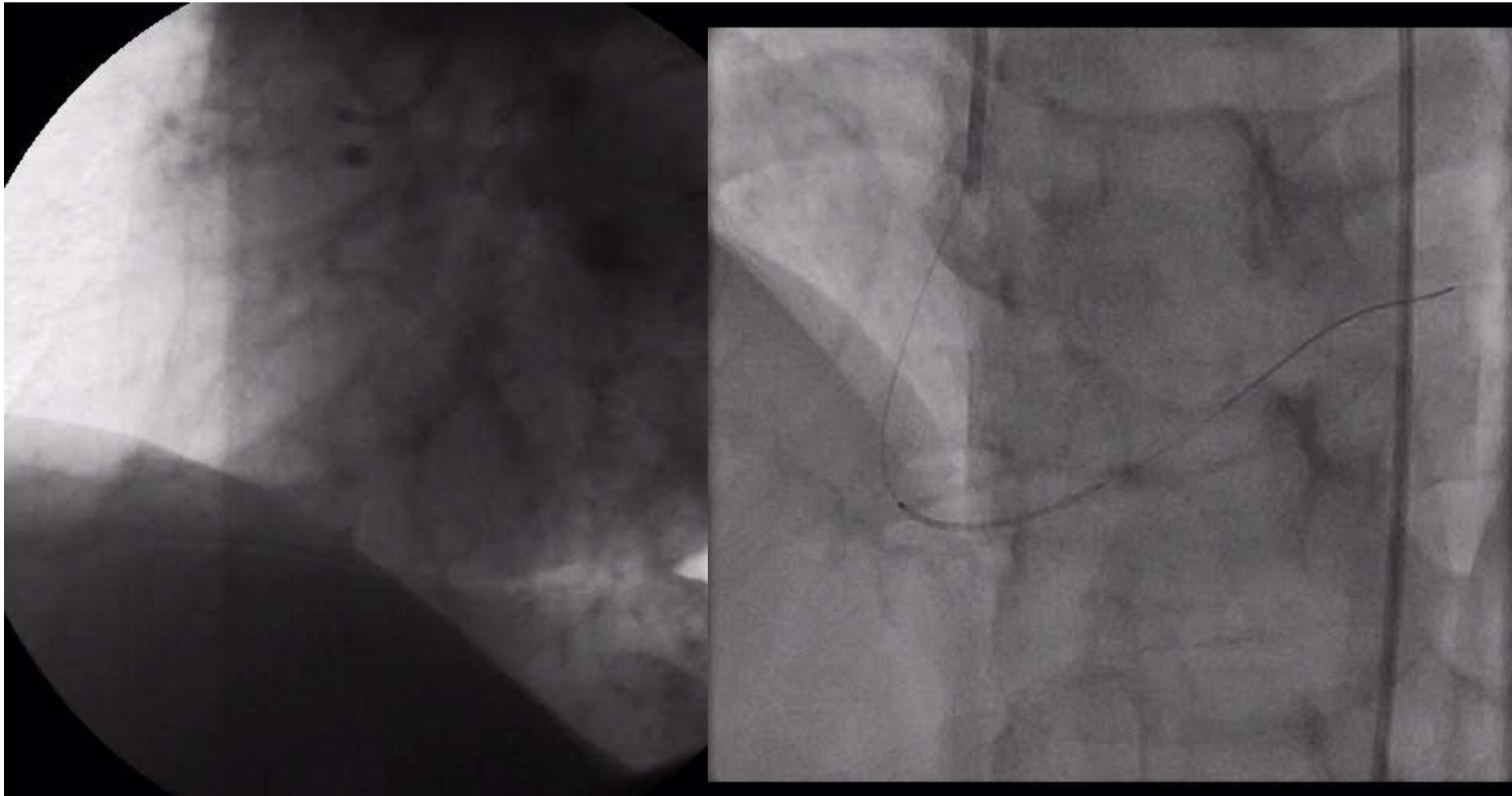
MACE rate

| | Control n=184 | TAXUS n=188 | P value |
|---------------------|------------------|----------------|---------|
| 30-Day MACE | 3.3% | 8.6% | 0.0457 |
| Cardiac Death | 0.0% | 0.0% | |
| MI | 3.3% | 8.6% | 0.0457 |
| TVR | 0.5% | 1.6% | 0.62 |
| 9-Month MACE | 32.0% | 20.7% | 0.0172 |
| Cardiac Death | 0.6% | 0.5% | 1.00 |
| MI | 3.9% | 8.7% | 0.08 |
| TVR | 29.8% | 16.3% | 0.0027 |

Restenosis after long DES implantation

Male 54 y.o. angina III

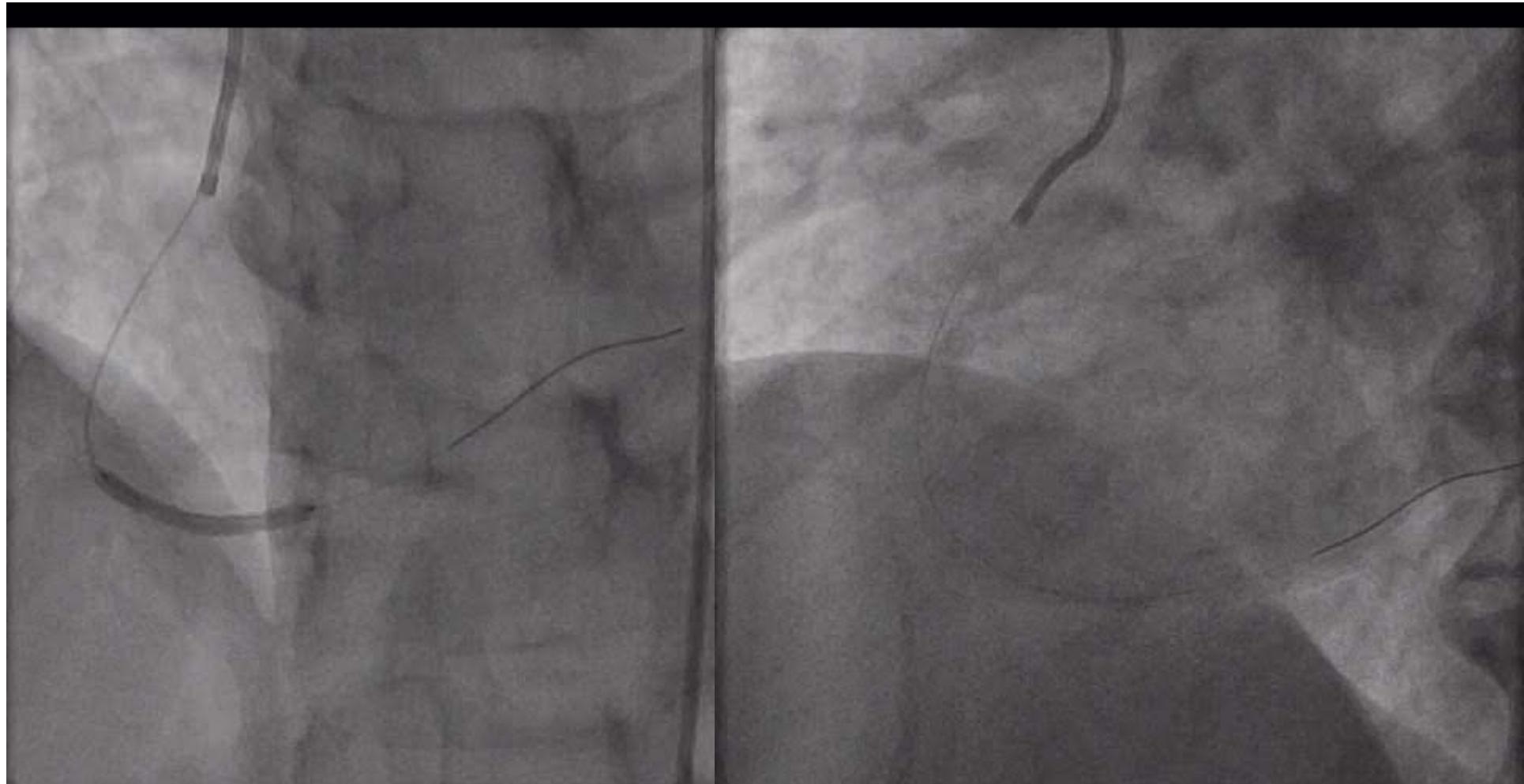
03-2005: EF=70%, 90% long RCA stenosis



Cypher 2.5x33mm

Male 54 y.o. angina III

03-2005: EF=70%, 90% long RCA stenosis

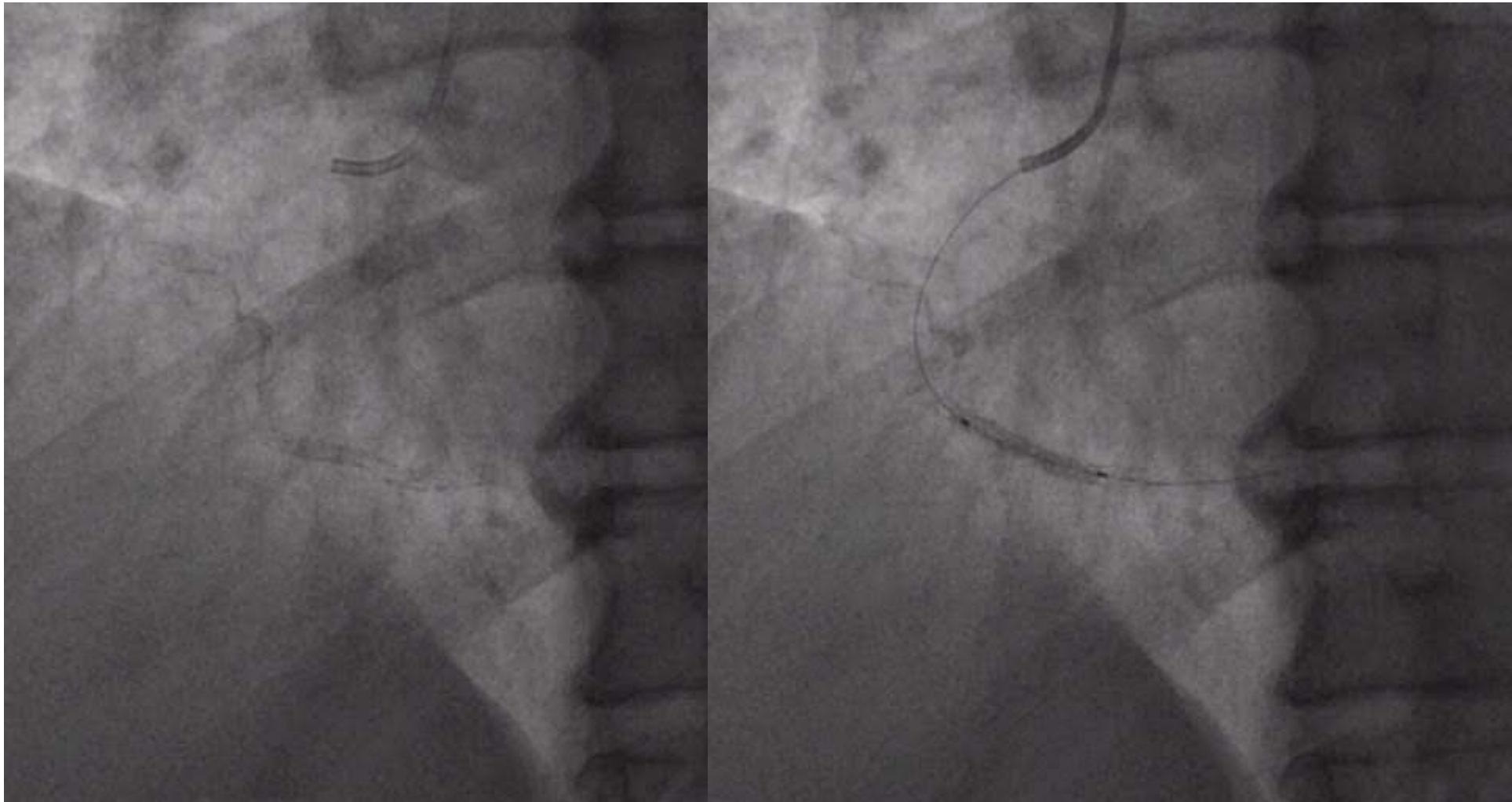


Cypher 2.5x33mm, 18 atm. QCA: diameter post = 2.8mm

Male 54 y.o. angina III

03-2005: Cypher / RCA

01-2006: recurrent angina, restenosis

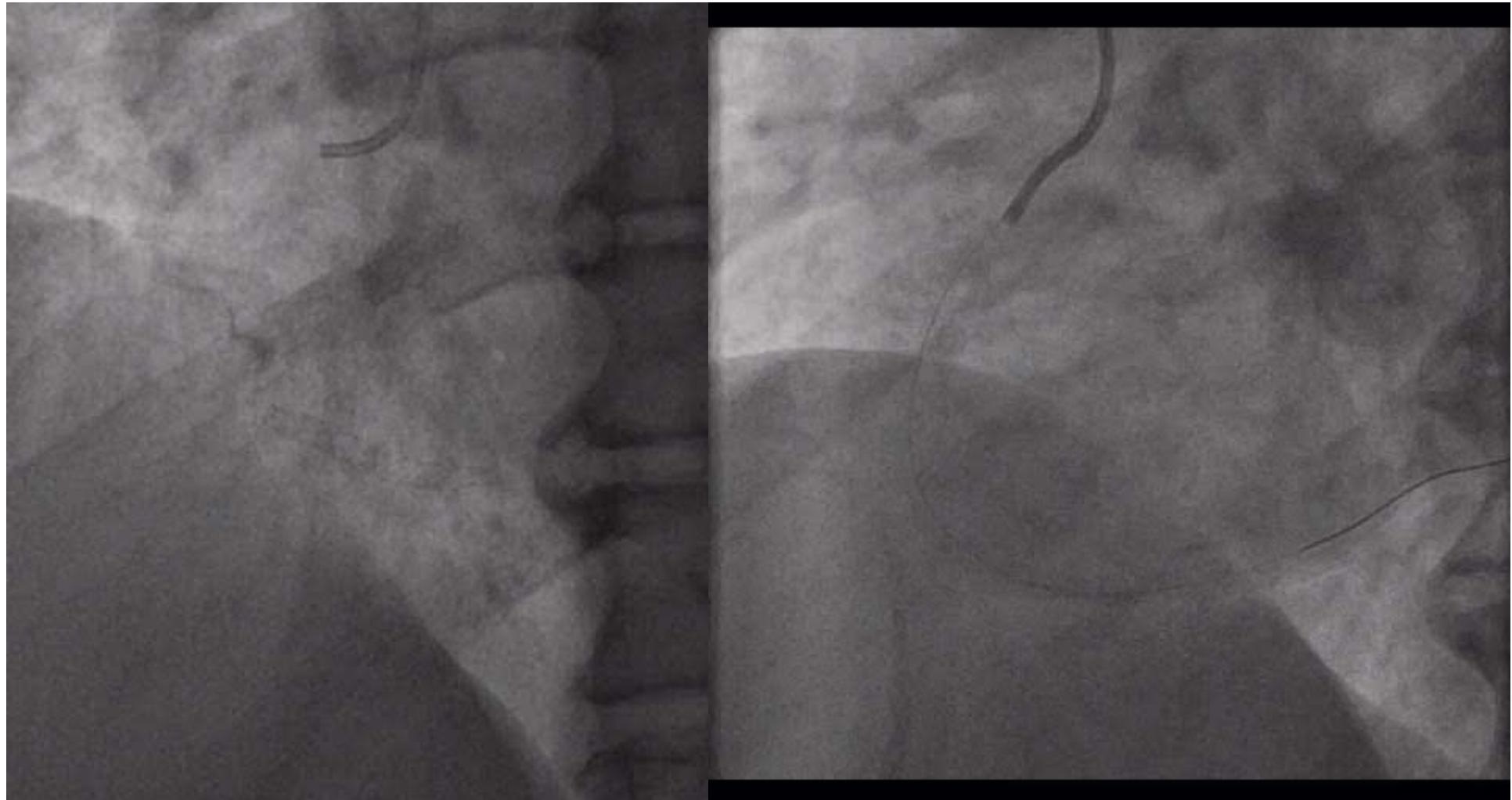


Focal restenosis . 3.0mm balloon (18 atm) & 3.5mm (12atm)

Homme 54 ans, tabac, angor d'effort de novo

03-2005: Cypher / C. Droite

01-2006: Récidive d'angor, resténose



QCA: diameter post=3.4mm

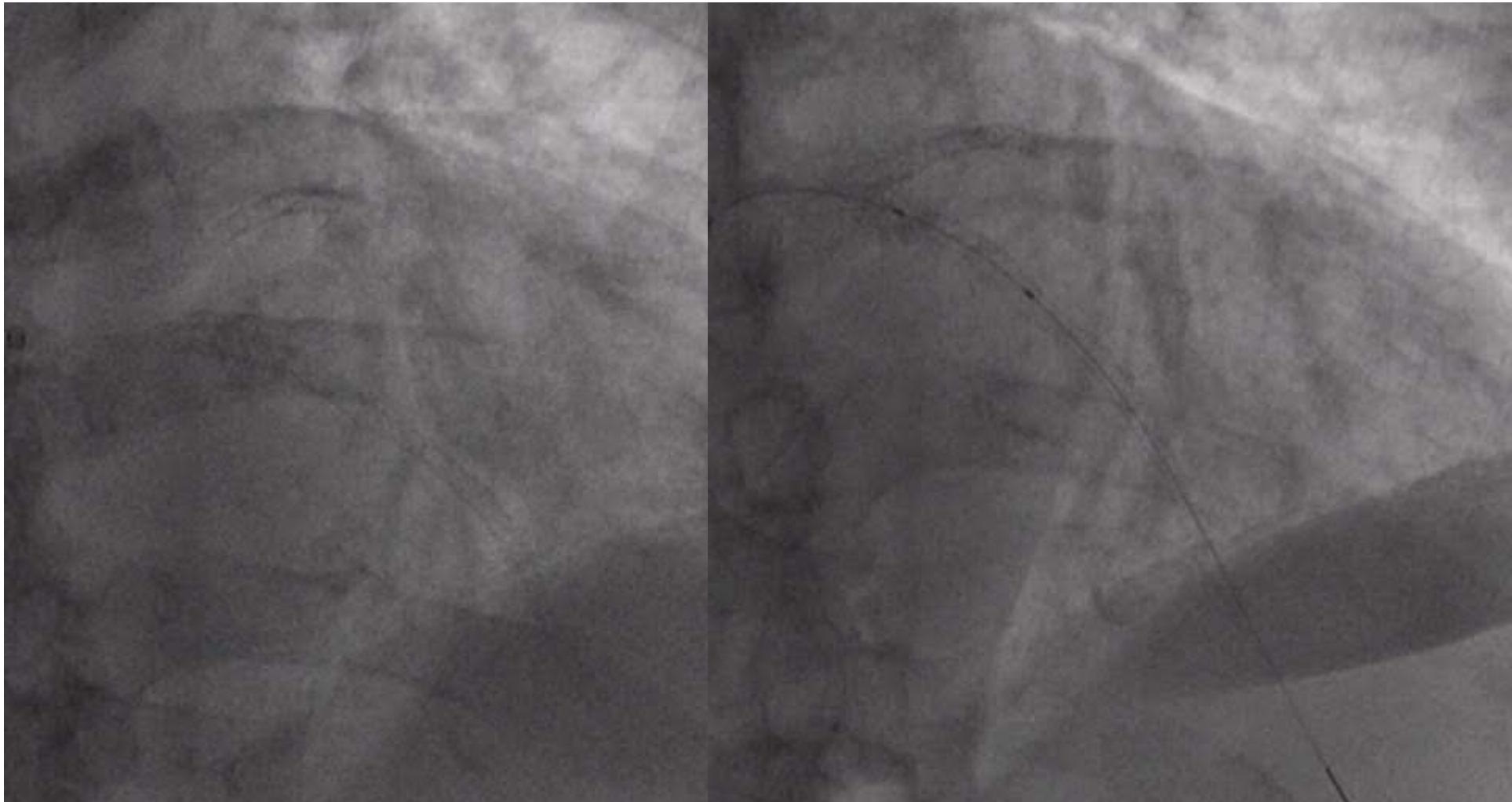
Previous result 03-2005 (2.8mm)

Woman 70 y.o.IDD, Renal Ins. (creat.=22mg/l)

10-2003: PCI / OM (Cypher)

12-2004: PCI / LAD (Taxus)

10-2005:ACS, LAD restenosis



Diffuse restenosis

3.0mm balloon, 18 atm.

Woman 70 y.o.IDD, Renal Ins. (creat.=22mg/l)

10-2003: PCI / OM (Cypher)

12-2004: PCI / LAD (Taxus)

10-2005:ACS, LAD restenosis



Final result – Diagonal occlusion

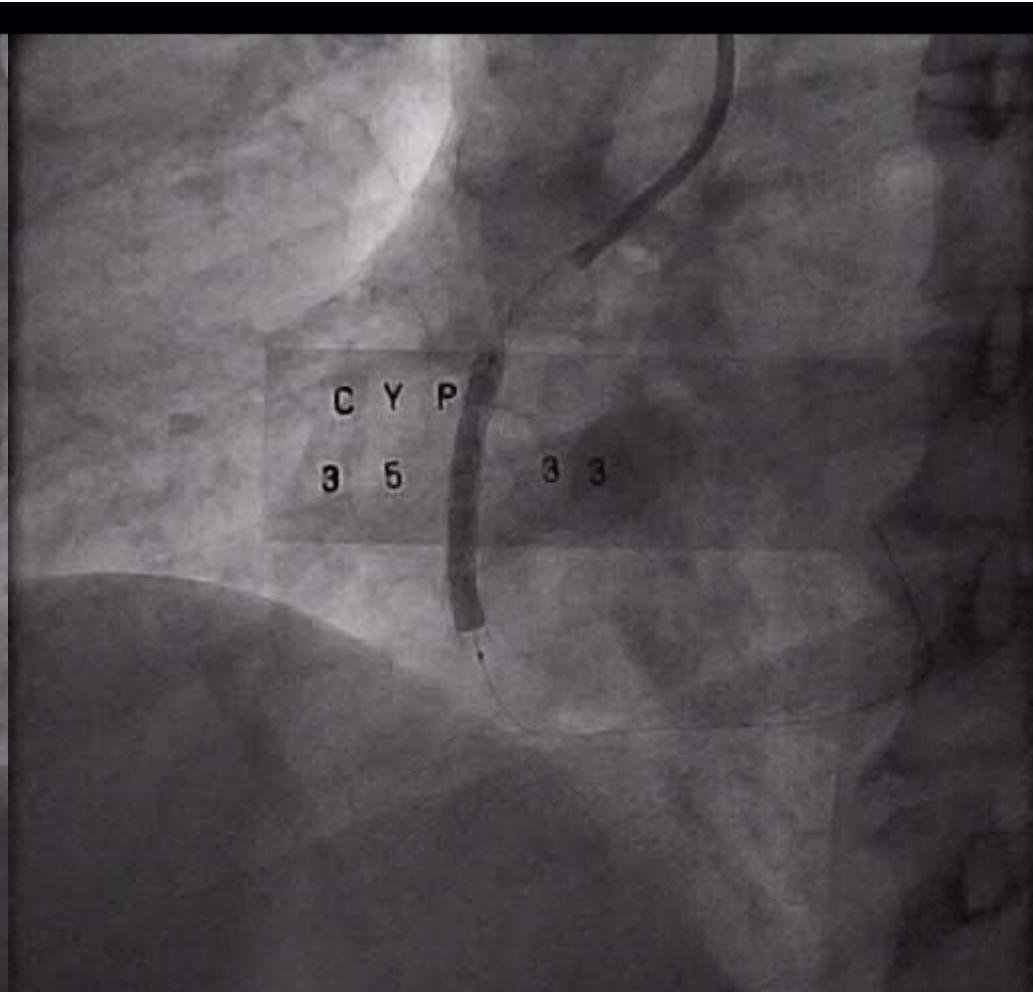
Male 68 y.o. , NIDD

05-2005: Recanalisation of RCA + 2 Taxus stents

10-2005: Silent inferior ischemia



Diffuse restenosis

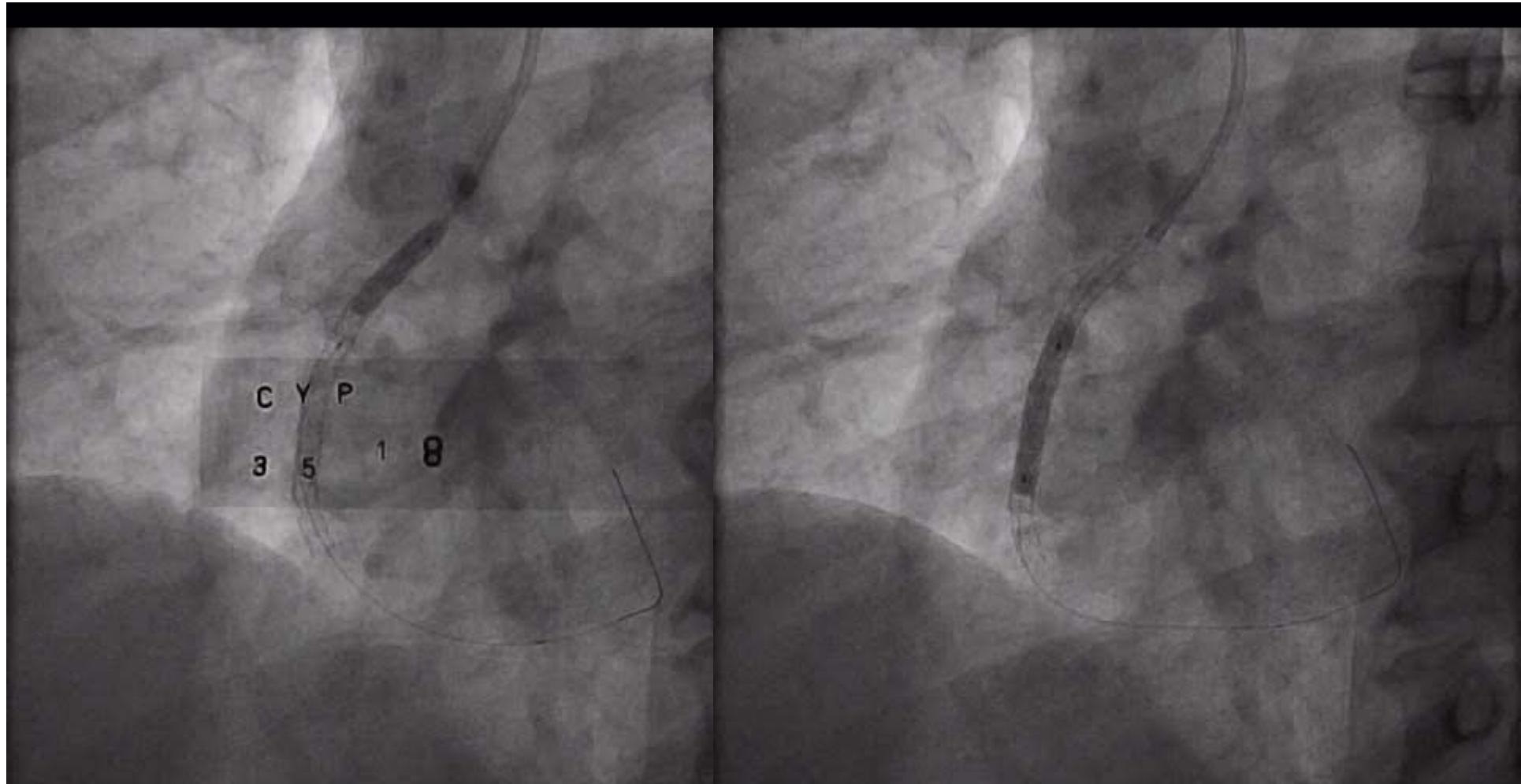


3.5x33mm Cypher

Male 68 y.o. , NIDD

05-2005: Recanalisation of RCA + 2 Taxus stents

10-2005: Silent inferior ischemia



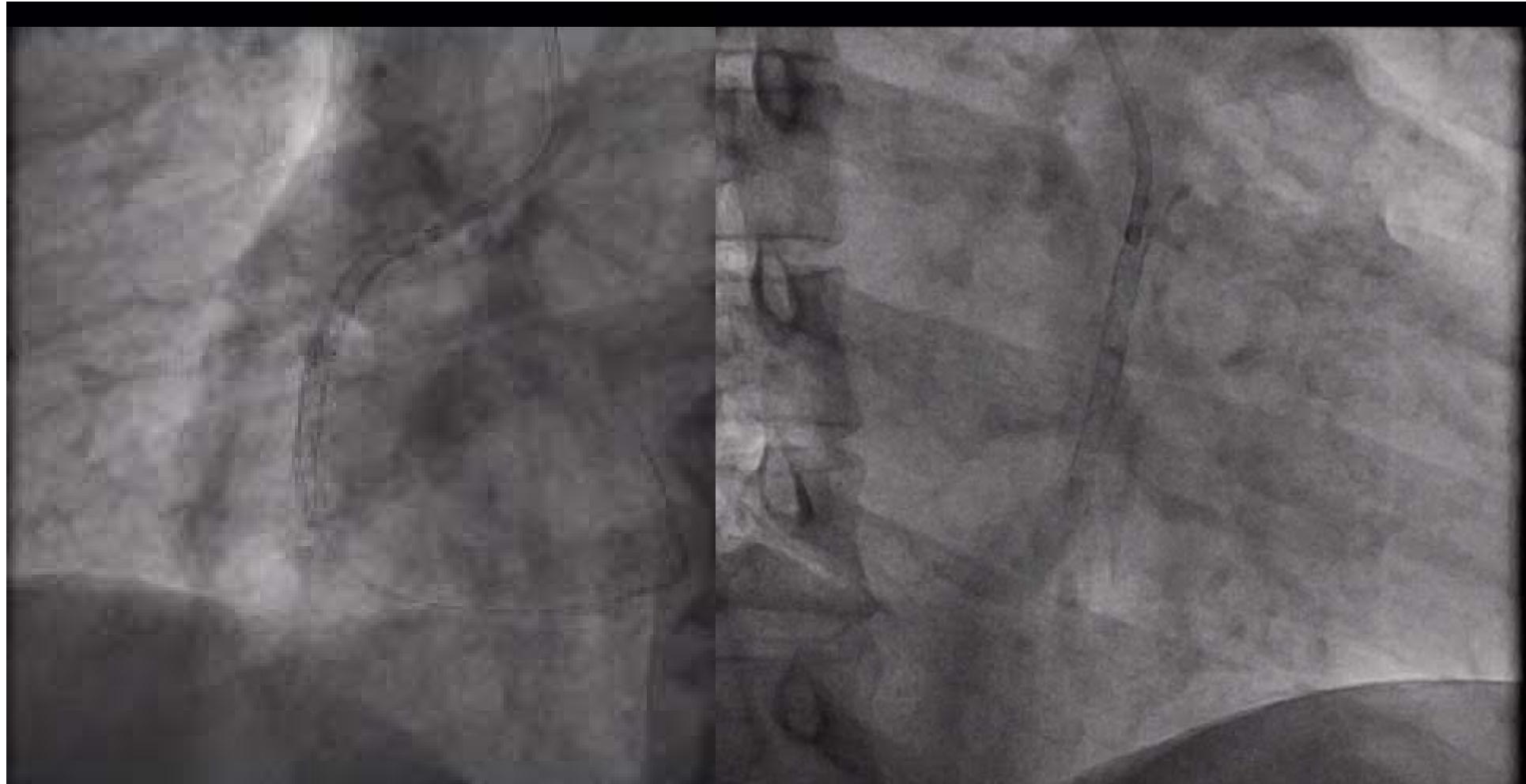
3.5x18mm Cypher

Post dilatation

Male 68 y.o. , NIDD

05-2005: Recanalisation of RCA + 2 Taxus stents

10-2005: Silent inferior ischemia



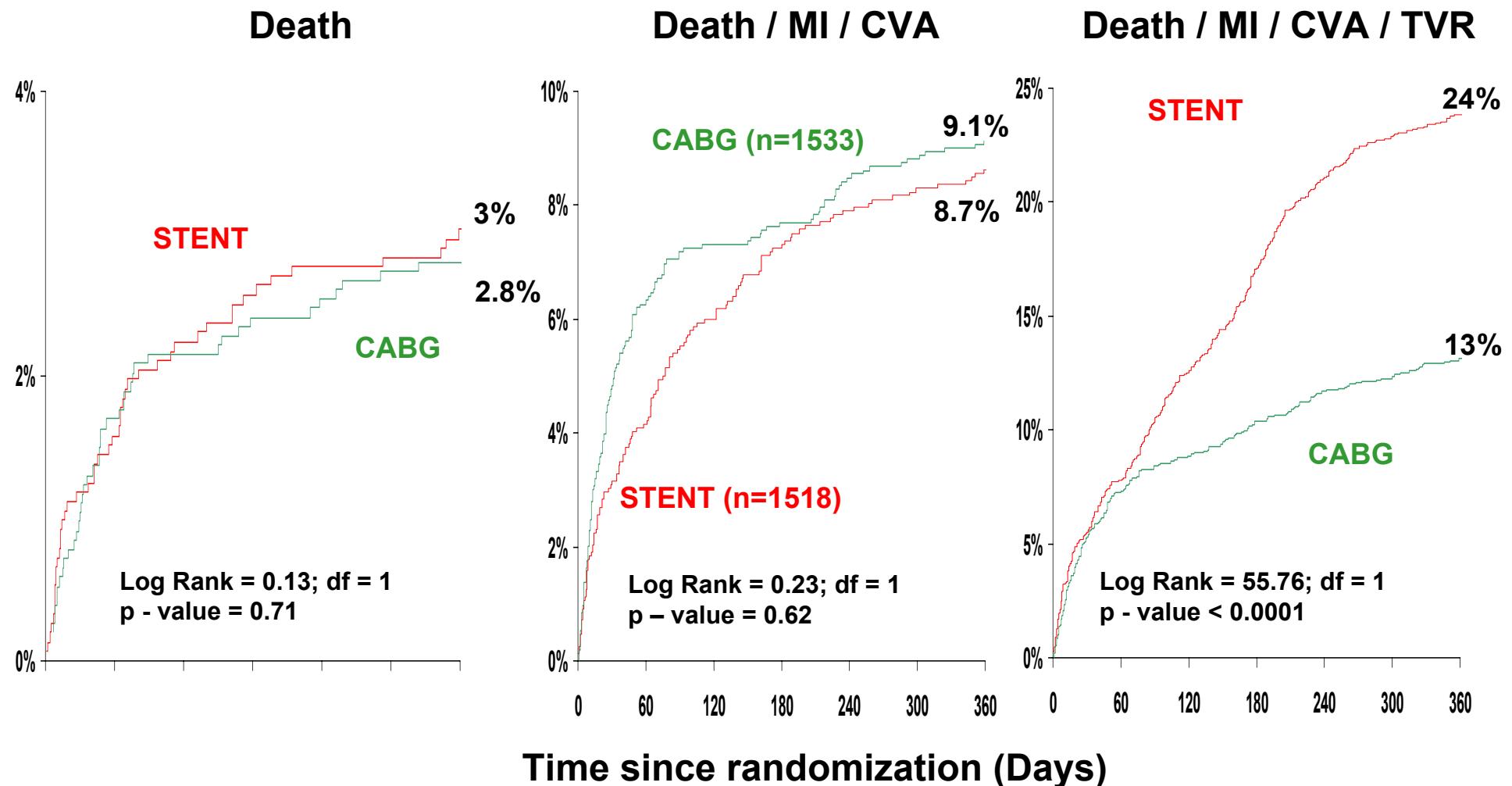
Final result – Side branch occlusion

- Almost all long lesions can technically be treated with implantation of long stents.
- Vessel calcification and tortuosity can make the procedure more difficult.
- The use of debulking or buddy wire technique can facilitate stent positioning.
- Restenosis and TLR rates are lower with DES
- Treatment of ISR can lead to side branch occlusion

- While clinical results are favourable in «standard» lengths (<30mm), they are less encouraging in very long stenosis.
- The expected clinical outcome after stenting of long lesions will be influenced by the other predictors of restenosis (vessel size, diabetes) and MACE (diabetes, renal insufficiency...)
- Safety concerns:
 - Risk of stent thrombosis after placement of multiple long or overlapped DES
 - Premature interruption of dual antiplatelet therapy

Multi-Vessel Disease

Meta-analysis of BMS vs CABG RCT's



ARTS II

Baseline Demographics

| | ARTS II N=607 | ARTS I (CABG) N=605 | ARTS I (PCI) N=600 |
|--------------------------------------|------------------|------------------------|-----------------------|
| Male (%) | 77 | 76 | 77 |
| Age (years) | 63 | 61 | 61 |
| Body mass index (kg/m ²) | 28 | 27 | 27 |
| Previous MI (Q-wave) | 34 (18) | 42 (24) | 44 (26) |
| Diabetes (IDDM) | 26 (5) | 16 (3) | 19 (4) |
| Hypertension | 67 | 45 | 45 |
| Hypercholesterolemia | 74 | 58 | 58 |
| Family history | 36 | 42 | 39 |
| Current smokers | 19 | 26 | 28 |
| Ejection fraction | 60 | 60 | 61 |
| Unstable angina | 37 | 35 | 37 |

ARTS II - Lesion Characteristics

| | ARTS II N=607 pts N=2160 les. | ARTS I (CABG) N=605 pts N=1638 les. | ARTS I (PCI) N=600 pts N=1606 les. |
|-------------------------|-------------------------------------|---|--|
| % of patients | | | |
| 2-VD | 46 | 66 | 69 |
| 3-VD | 54 | 30 | 27 |
| % of lesions | | | |
| LAD location | 42 | 41 | 39 |
| LCx location | 29 | 29 | 29 |
| RCA location | 29 | 30 | 31 |
| Discrete (<10mm) | 61 | 68 | 66 |
| Tubular (10-20mm) | 27 | 25 | 27 |
| Diffuse (>20mm) | 12 | 7 | 7 |
| Type C lesion | 14 | 8 | 8 |
| Side branch involvement | 34 | 32 | 35 |

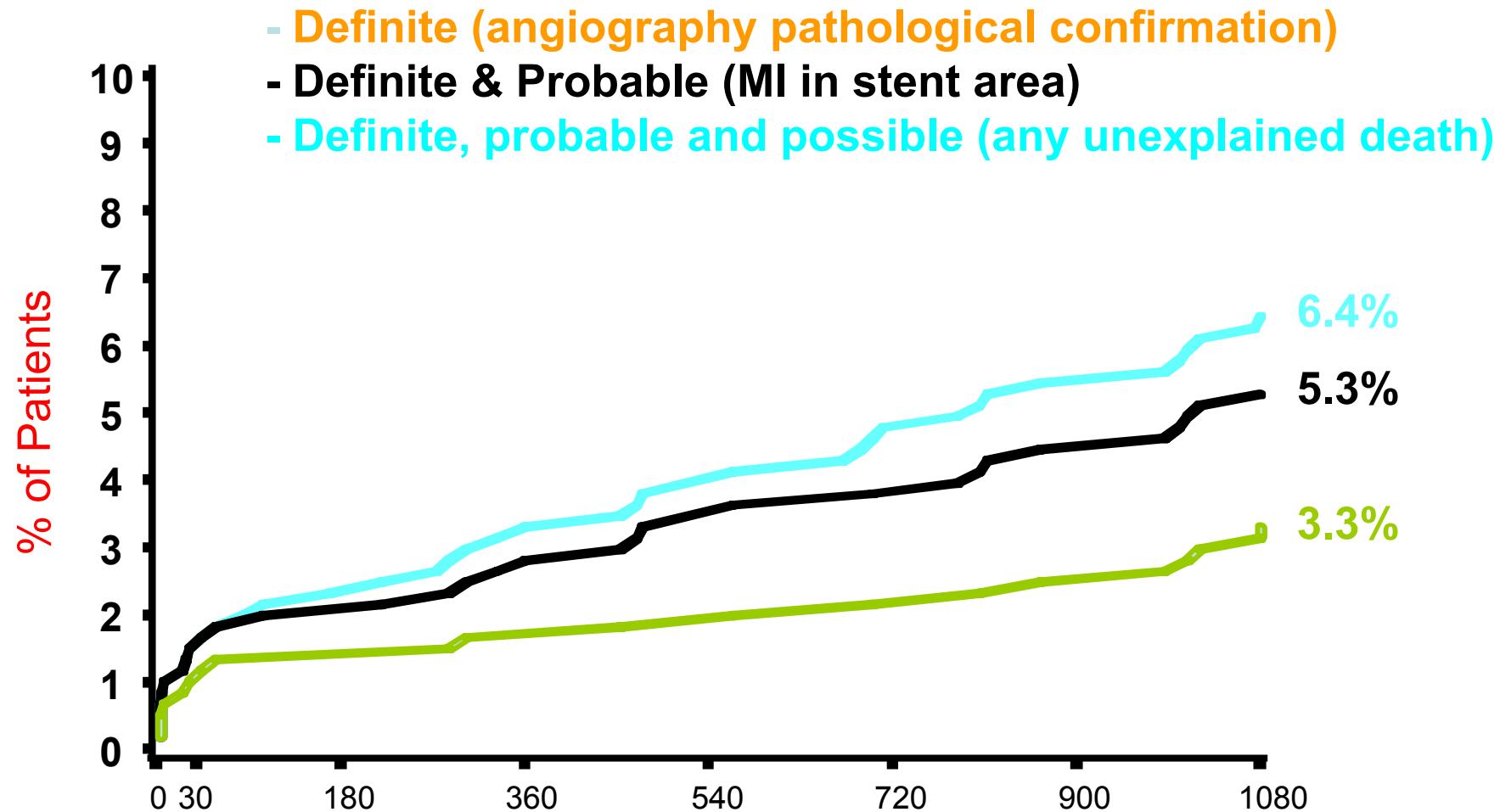
ARTS II

Procedural Characteristics

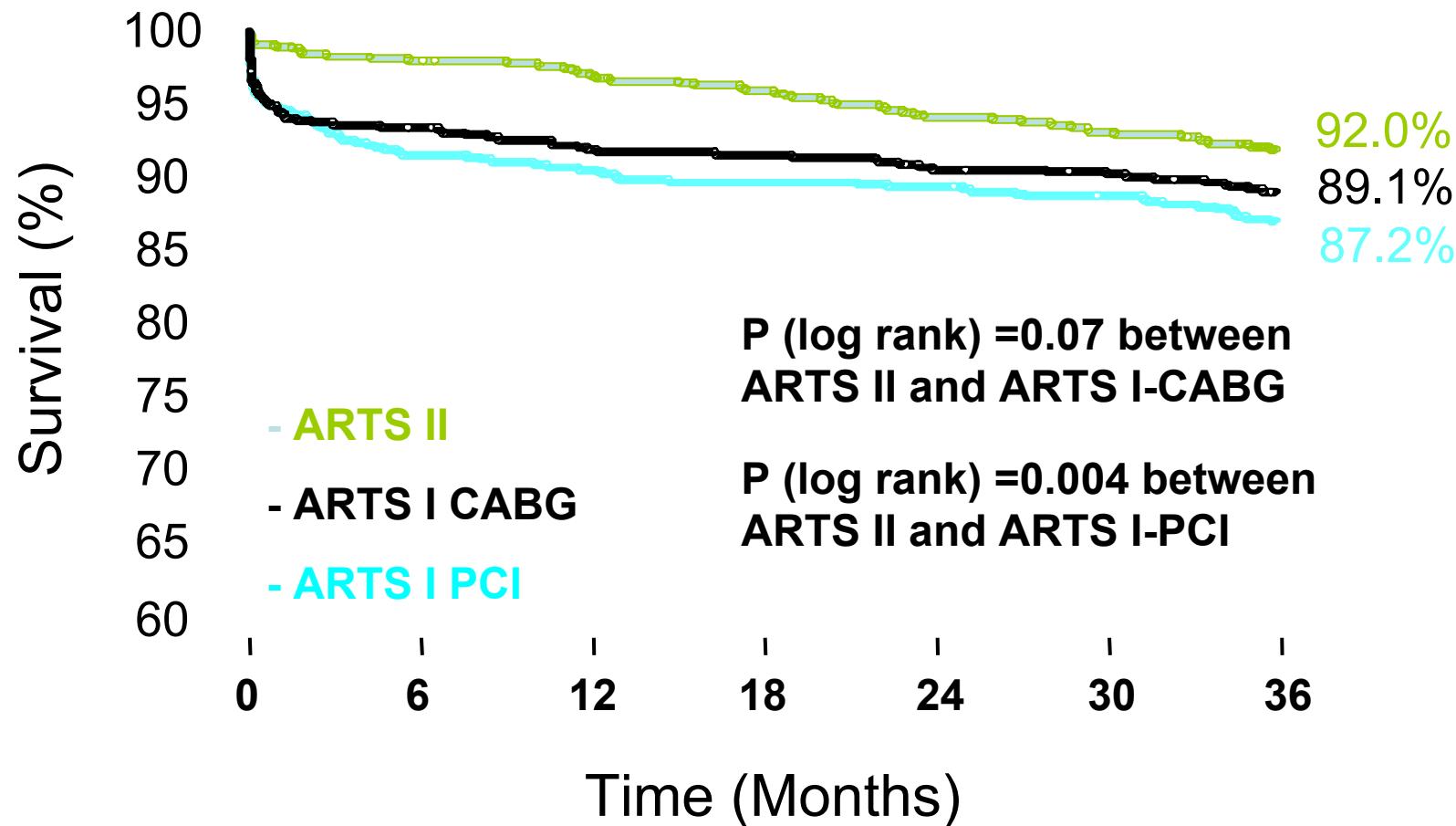
| | ARTS II N=607 pts N=2160 les. | ARTS I (CABG) N=605 pts N=1638 les. | ARTS I (PCI) N=600 pts N=1606 les. |
|-----------------------------------|-------------------------------------|---|--|
| Lesions, # | 3.6 | 2.8 | 2.8 |
| Stented les. / anast. seg., # | 3.2 | 2.6 | 2.5 |
| Stents, # | 3.7 | - | 2.8 |
| Direct stenting, % | 35 | - | 3 |
| Max. inflation pressure, atm | 16.4 | - | 14.6 |
| Total stent length, mm (range) | 73 12-253 | - | 48 8-165 |
| Gp IIb/IIIa inhibitor use, % | 33 | - | - |
| Use of arterial conduit, % | - | 93 | - |
| Duration of procedure, mins | 85 | 193 | 99 |
| Hospital stay, days | 3.4 | 9.6 | 3.9 |

ARTS II – Stent thrombosis up to 3 years *

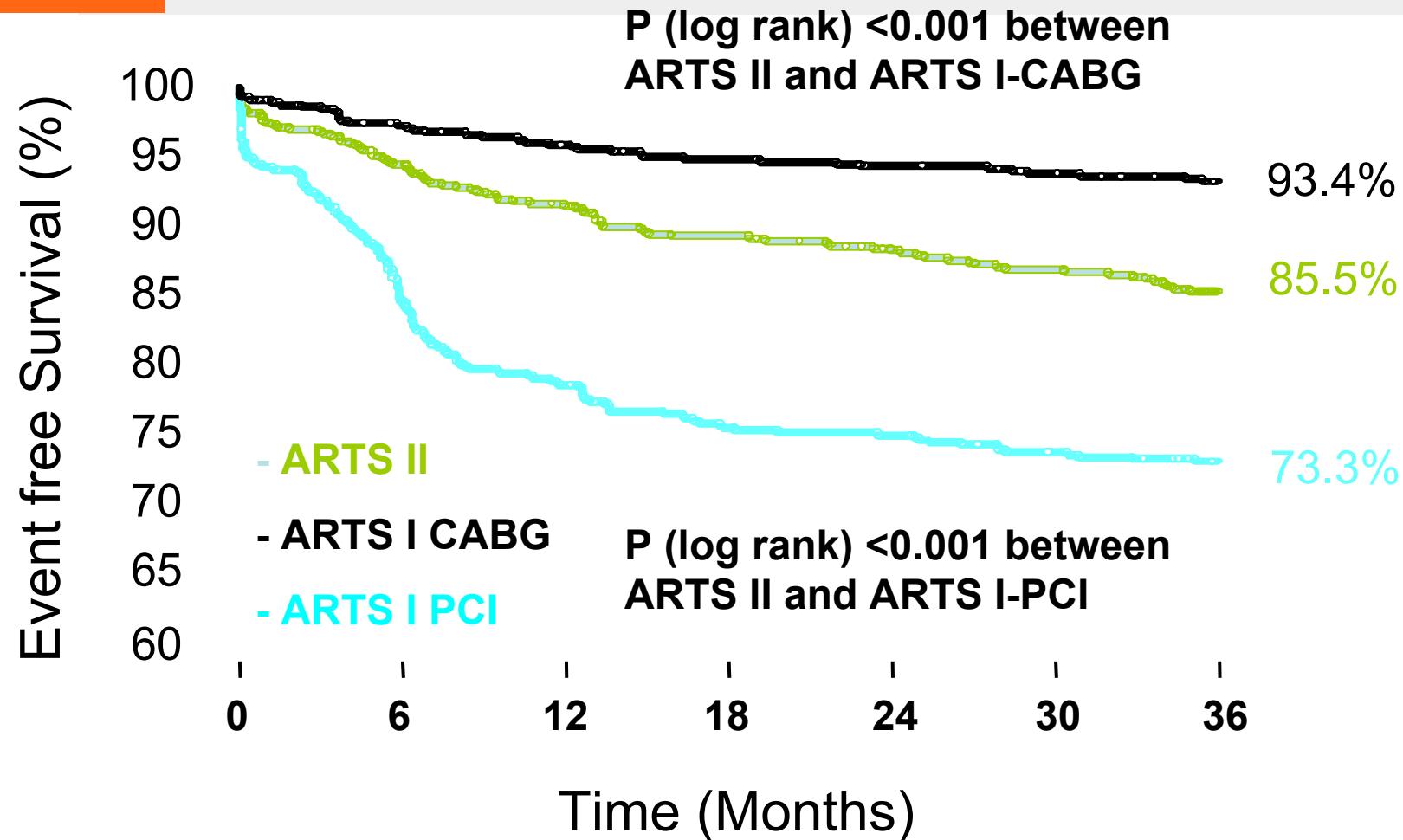
* Re-adjudication according to Dublin definitions



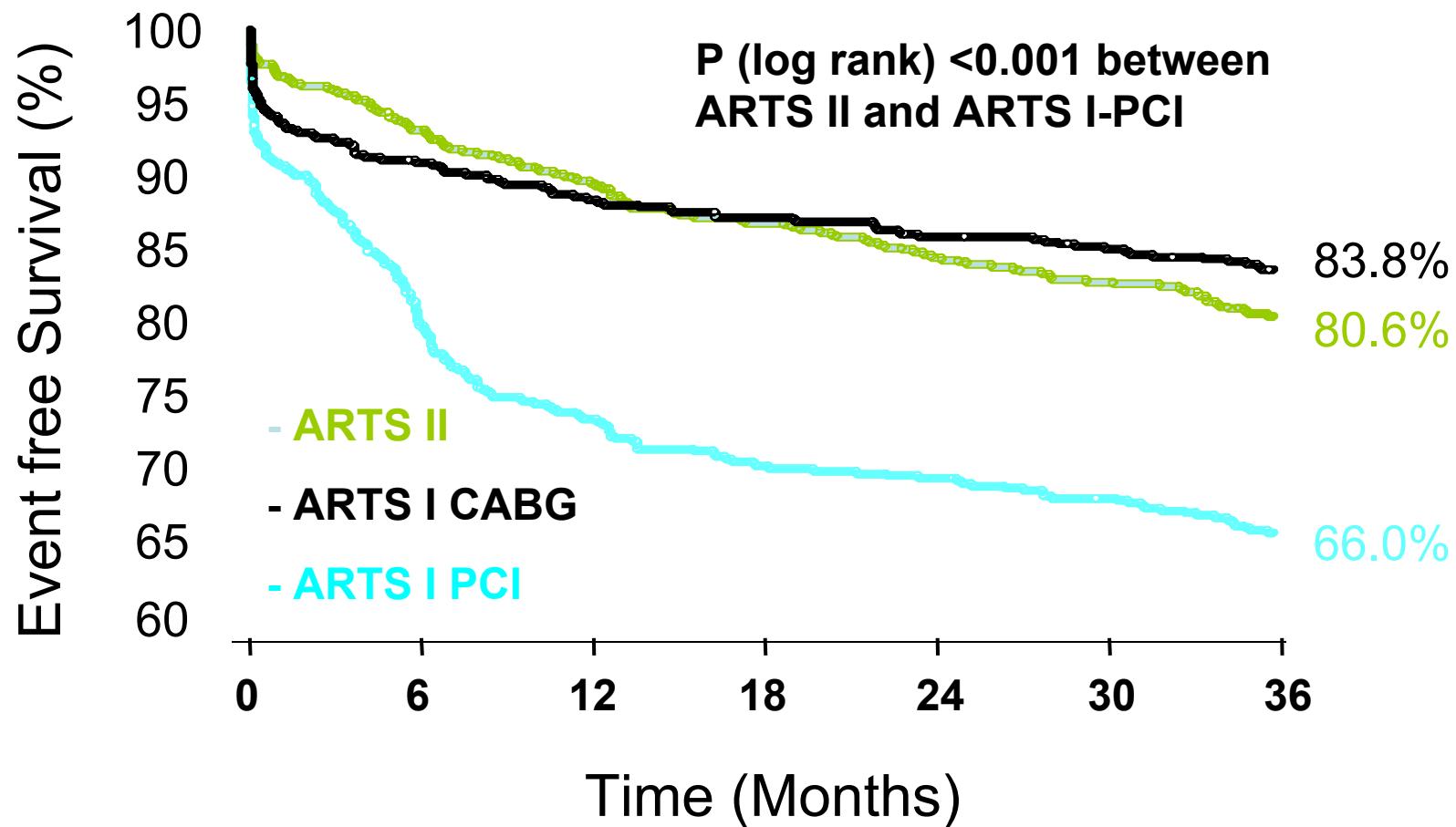
ARTS II - Death/CVA/MIs up to 3 years



ARTS II - Re-Intervention up to 3 years



ARTS II - MACCE up to 3 years



ARTS II – Diabetic population (3 years)

Hierarchical MACCE
up to 3 years
N=112

ARTS II
N=159

ARTS I (CABG)

ARTS I (PCI)
N=96

| | | | |
|-------------------------|-------------------|-------------------|-------------------|
| Death | 8 (5.0%) | 5 (5.2%) | 8 (7.1%) |
| Stroke* | 4 (2.5%) | 5 (5.2%) | 5 (4.5%) |
| MI ** | 3 (1.9%) | 3 (3.1%) | 8 (7.1%) |
| CABG*** | 6 (3.8%) | 0 (0.0%) | 11 (9.8%) |
| Repeat PCI**** | 23 (14.5%) | 4 (4.2%) | 21 (18.8%) |
| MACCE | 44 (27.7%) | 17 (17.7%) | 53 (47.3%) |
| Stent thrombosis | 2 (1.3%) | - | 8 (7.1%) |

* Without death

** Without death and stroke

*** Without death, stroke and MI

**** Without death, stroke, MI or CABG

Figures in Orange indicate statistical difference (95% CI) between ARTS II and ARTS I groups

SYNTAX: Study Design

All Patients with 3VD/LM

Heart Team (surgeon and interventionalist)

amenable for both treatments options

amenable for one treatment approach

Randomized Arm

N=1500 (1:1)

TAXUS VS CABG

- reasonable doubt
- follow-up: 30d, 6m, 1-5 yrs
- Goal: **to define the most appropriate treatment through randomized trial methods**

Two Registry Arms

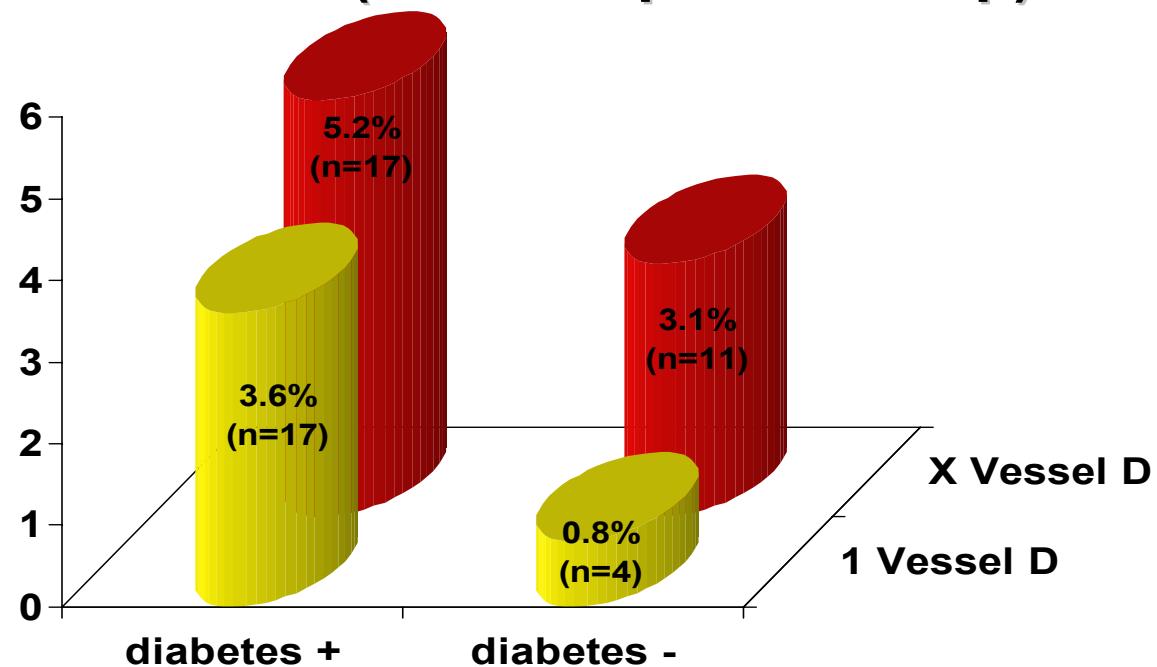
CABG
2750 captured
(750 followed)

PCI
All captured and followed

- consensus exists that only one treatment option (CABG vs PCI) is appropriate
- Goal: **to profile larger pool of non randomizable patients and their subsequent outcomes**

EVASTENT

Global mortality
2.9% (50/ 1662 pts with Fup)

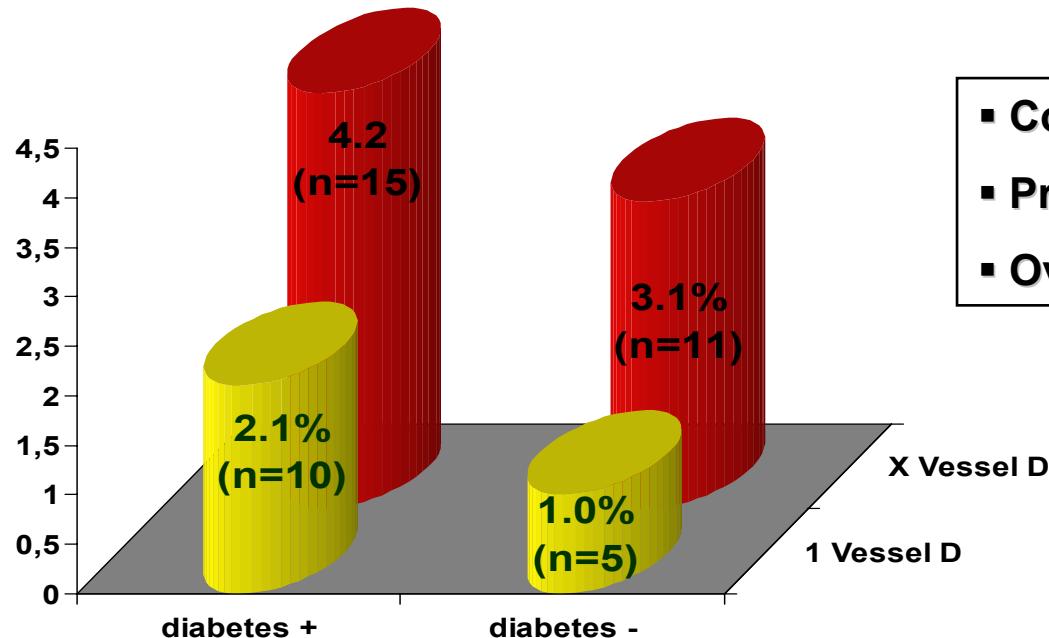


db+ 4.2% vs. db- 1.7% p<.002

MVD 4.1% vs. 1VD 2.1% p< .017

EVASTENT

Stent thrombosis



- Confirmed : 1.6% (27 pts)
- Probable : 0.8% (14 pts)
- Overall : 2.4% (41 pts)

db+ 3% vs. db- 1.7% $p=.07$

Ins+ DM 3.7% vs. db- 1.7% $p=.001$

XVD 3.7% vs. 1VD 1.5% $p<004$

FREEDOM: Study Design

Diabetes Mellitus with 2-3VD

surgeon and interventionalist

amenable for both treatments options

amenable for one treatment approach

Randomized Arm
N=2400 (1:1)

DES VS CABG

- follow-up: 30d, 6m, 1-5 yrs
- Goal: **to define the most appropriate treatment *for diabetic patients* through randomized trial methods**

Two Registry Arms
N=2000

CABG
All captured and followed

PCI
All captured and followed

- consensus exists that only one treatment option (CABG vs PCI) is appropriate
- Goal: **to compare outcomes with randomized group**

Multi-Vessel Disease

Discussion PCI vs CABG:

Age,

Diabetes

Previous cardiac surgery

Comorbidities (previous stroke, COPD, renal insufficiency)

LV function

2 or 3VD

Type of lesions (length, vessel size, calcifications, CTO)

Complete or incomplete revascularisation

Dual antiplatelet therapy

EUROSCORE ++

*« The deepest sin against the human mind is
to believe things without evidence »*

Thomas H. Huxley (1825-1895)

EUROPCR06