Bioabsorbable Polymer DES in high risk patients

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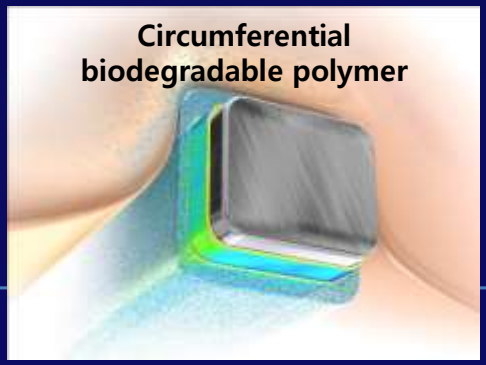
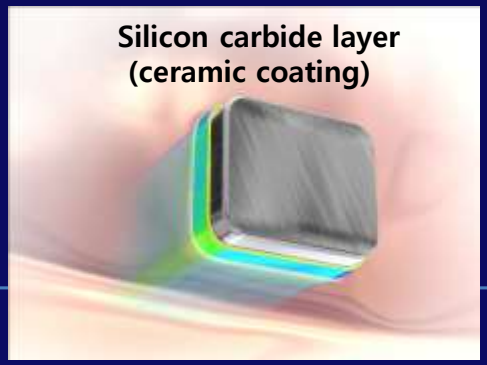
DES and Scaffolds *(Selection)*

Durable Polymer DES		Biodegradable Polymer DES				Bioresorbable Scaffold
Xience/Promus	Resolute Integrity	BioMatrix/Nobori	Ultimaster	Synergy	Orsiro	Absorb (BVS)
CoCr/PtCr-EES	CoCr-ZES	316L-BES	CoCr-SES	PtCr-EES	CoCr-SES	PLLA-EE Scaffold

Thickness (μm) of uncoated strut						
81	91	120 / 125	80	74*	60**	150

Distribution and thickness (μm) of polymer coating, and type of polymer						
Circumferential 7-8/side Fluoro-poymer	Circumfer. 6/side BioLinx™	Abluminal ≥10 PLA	Abluminal 15 PDLLA	Abluminal 4 PLGA, PCL	Cicumfer. 4-7/side PLLA**	Circumferential 3/side PDLLA





Orsiro clinical roadmap is already strong with powerful additions under way (26.5k patients enrolled, 45k planned)

	Study	Study design	Total patients	Primary endpoint	Status
BIOTRONIK initiated	BIOFLOW-I	FIM	30	9 mo LLL	Completed
	BIOFLOW-II	RCT vs. Xience Prime	440	9 mo LLL	Primary endpoint reached
	BIOFLOW-III	International registry	1,356	12 mo TLF	Primary endpoint reached
		Satellite registries (14)	>3,000	12 mo TLF	Enrolling
	BIOFLOW-IV	RCT vs. Xience Prime/Xpedition	579	12 mo TVF	Enrollment completed
	BIOFLOW-V	RCT vs. Xience	1,334	12 mo TLF	Enrollment completed
	BIOFLOW-VI	RCT vs. Xience	440	9 mo LLL	Enrollment completed
	BIOFLOW-INDIA	Indian single-armed trial	120	9 mo LLL	Completed
	BIOLUX RCT	RCT vs. Pantera Lux in ISR	210	6 mo LLL	Primary endpoint reached

Orsiro clinical roadmap is already strong with powerful additions under way (26.5k patients enrolled, 45k planned)

	Study	Comparison	Total patients	Primary endpoint	Status
Investigator initiated	**BIOSCIENCE**	Xience Prime	2,100	12 mo TLF	Primary endpoint reached
	BIO-RESORT	Synergy & Resolute Integrity	3,530	12 mo TVF	Primary endpoint reached
	SORT OUT VII	Nobori	2,525	12 mo TLF	Primary endpoint reached
	BIONYX	Resolute Onyx	2,470	12 mo TVF	Enrolling (1395 enrolled)
	SORT OUT IX	BioFreedom	3,150	12 mo TLF	Enrolling (1650 enrolled)
	BIOSTEMI	Xience Prime	1,250	12 mo TLF	Enrolling (60 enrolled)
	ORIENT	Resolute Integrity	375	9 mo LLL	Primary endpoint reached
	HAT-TRICK-OCT	Endeavor Resolute	40	3 mo Strut coverage	Primary endpoint reached
	ISAR OCT	Xience Prime	87	6 & 24 mo Strut coverage	Primary endpoint reached
	SMART-Choice	Promus and Xience	5,100	3-15 mo Composite	Enrolling (1994 enrolled)
	ESODE	DESyne	600	12 mo MACE	Enrolling (382 enrolled)
	BIODEGRADE	BioMatrix Flex	3,850	18 mo TLF	Enrolling (1653 enrolled)

Safety and clinical performance of Orsiro DES in the treatment of subjects with single de novo coronary artery lesions

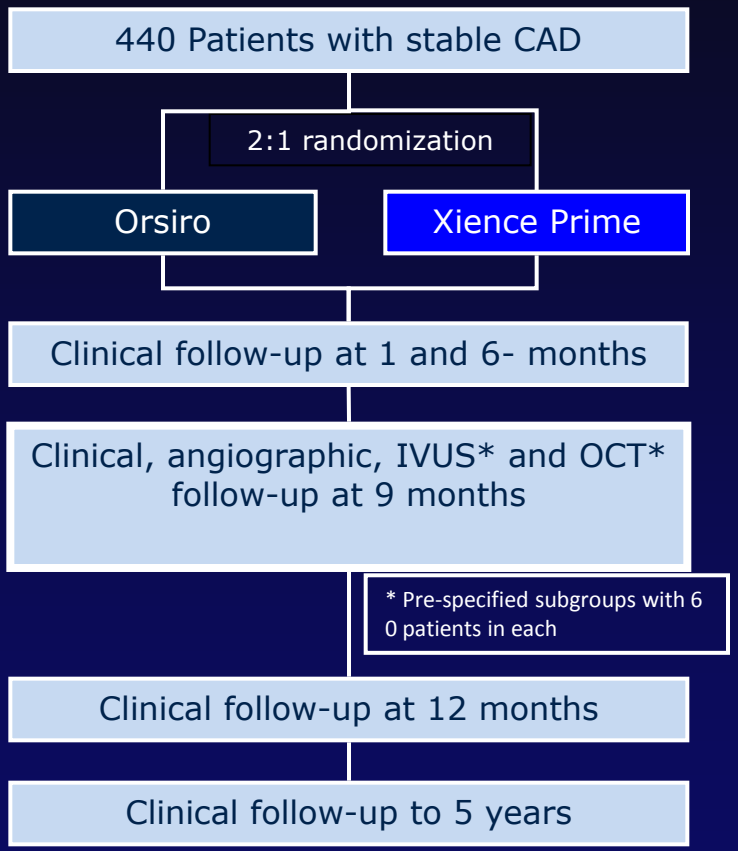
BIOFLOW-II

DESIGN
An international, prospective, multi-center, randomized, controlled trial comparing the Orsiro DES to Xience Prime

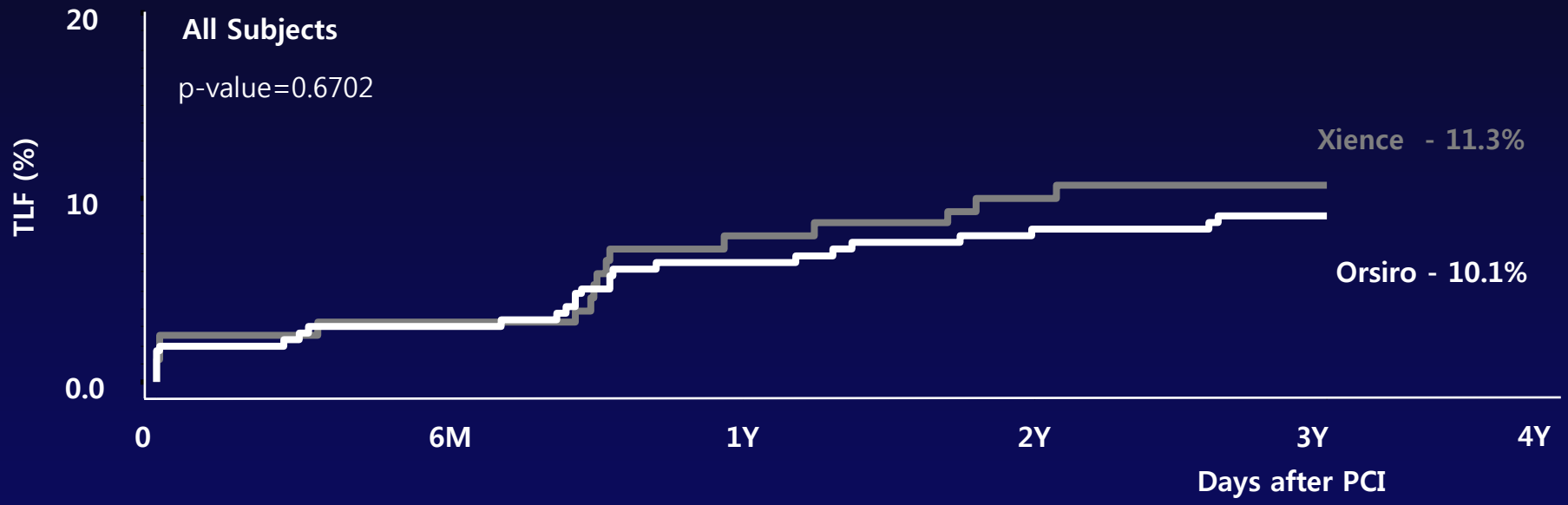
OBJECTIVE
To compare the Orsiro stent with a bioabsorbable polymer to the XIENCE Prime® stent with a durable polymer for the treatment of de novo coronary lesions with respect to non-inferiority for in-stent Late Lumen Loss (LLL) at 9-months

COORDINATING CLINICAL INVESTIGATORS
Prof. Stephan Windecker, Bern, Switzerland
Dr. Thierry Lefèvre, Massy, France

PRIMARY ENDPOINT
In-stent Late Lumen Loss at 9-month



TLF rate at 48 months

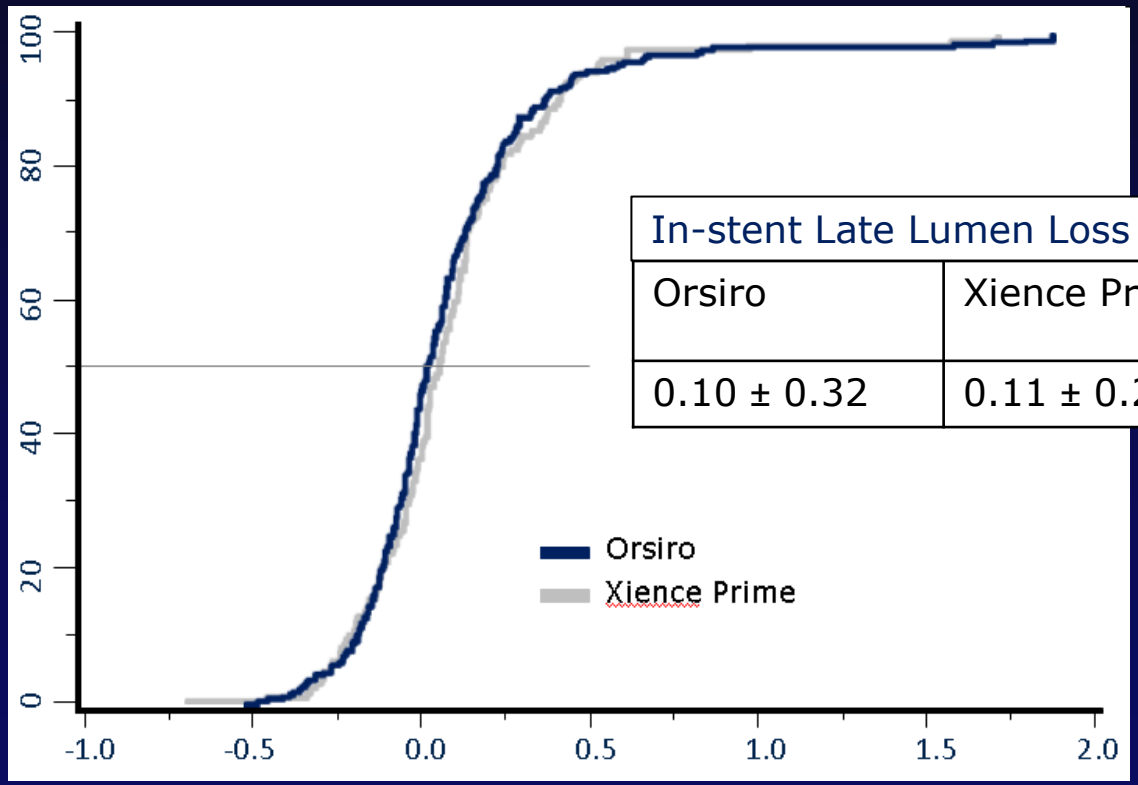


Source: T. Slagboom, oral presentation, TCT 2016

Primary angiographic endpoint
In-stent Late Lumen Loss

BIOFLOW-II

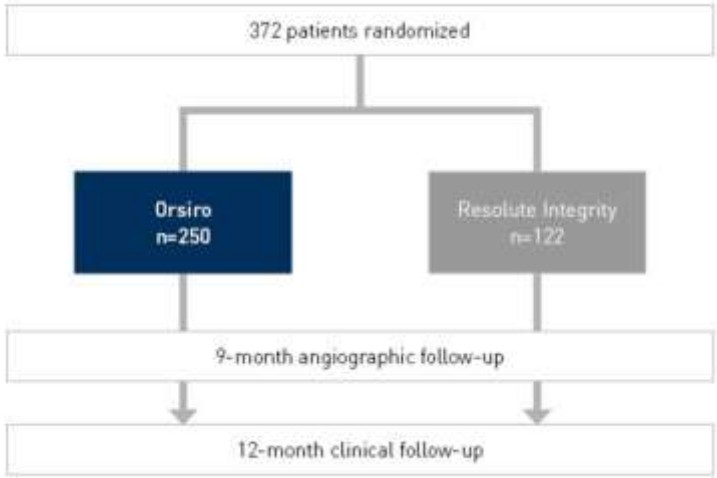
Cumulative frequency of in-stent Late Lumen Loss at 9 months (mm)



In-stent Late Lumen Loss at 9 months (mm)		
Orsiro	Xience Prime	p-value for non-inferiority
0.10 ± 0.32	0.11 ± 0.29	< 0.0001

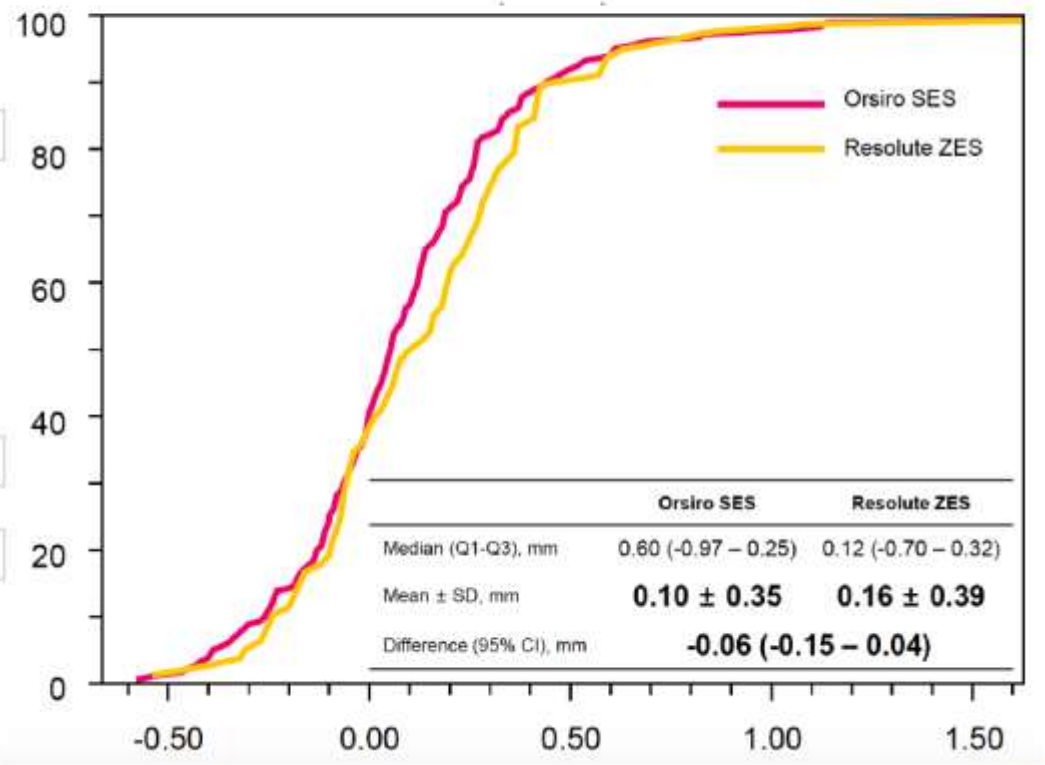
Sources: Windecker S. et al., Comparison of a Novel Biodegradable Polymer Sirolimus-Eluting Stent With a Durable Polymer verolimus-Eluting Stent Results of the Randomized BIOFLOW-II Trial, Circ Cardiovasc Interv, DOI: 10.1161/CIRCINTERVENTIONS.114.001441

Reproducible In-stent Late Lumen Loss



ORIENT: Late Lumen Loss at 9 Months

RCT, 2:1 BP-SES (Orsiro) versus DP-ZES (Resolute Integrity), n=372



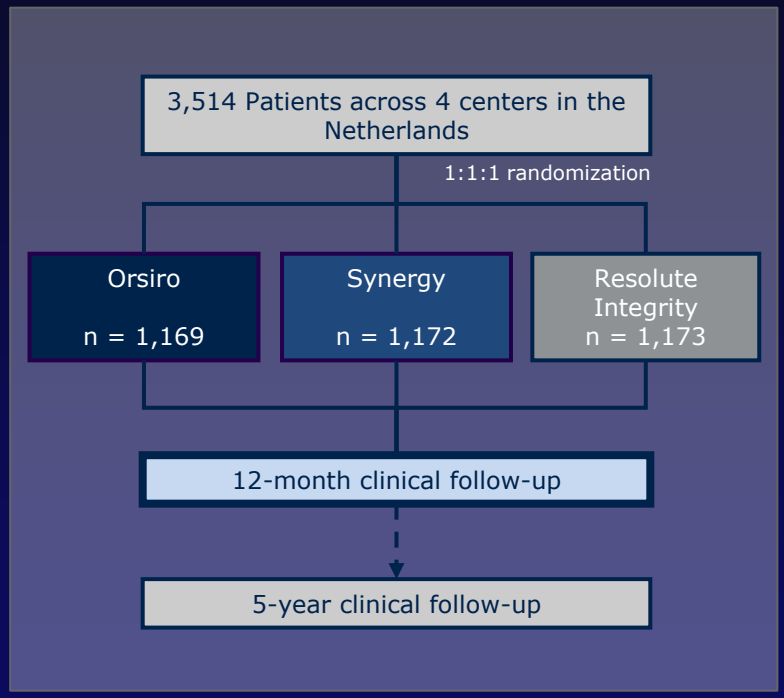
Kang SH, Eurointervention, 2017

The most powerful Orsiro trial yet provides data against the strongest competitors

DESIGN
Large-scale, investigator-initiated, assessor and pati ent-blinded, multicenter, three-arm, randomized co ntrolled trial. 3,514 all-comers patients randomly as signed (1:1:1) to treatment with Orsiro, Synergy or Resolute Integrity

PRINCIPAL INVESTIGATORS
Prof. Clemens von Birgelen,
Thoraxcentrum Twente, Netherlands

PRIMARY ENDPOINT
Target vessel failure (TVF) at 12 months defined as the composite of cardiac death, target vessel-relate d myocardial infarction (MI), or target vessel revasc ularization (TVR)



BIO-RESORT: Study Devices

	Durable Polymer DES	Biodegradable Polymer DES	
	Resolute Integrity CoCr-ZES	Synergy PtCr-EES	Orsiro CoCr-SES
			
Thickness (μm) of uncoated strut	91	74*	60**
Distribution, thickness (μm), and type of polymer	Circumfer. 6/side BioLinx™	Abluminal 4 PLGA, PCL	Cicumfer. 4-7/side PLLA**

BIO-RESORT: Study Devices

	SYNERGY 	RESOLUTE INTEGRITY 	ORSIRO 
Coating characteristics	Biodegradable Abluminal	Durable Circumferential Symmetrical	Biodegradable Circumferential Asymmetrical
Bare strut thickness, µm	74 (3.0 – 3.5 mm: 79, 4.0 mm stent: 81)	91	60 (≥ 3.5 mm stents: 80)
Coating thickness, µm	4	5.6	7.4 / 3.5 (ab-/luminal)
Coated strut thickness, µm *(of smallest stent)*	78	102	71
Metal	Platinum-chromium	Cobalt-chromium	Cobalt-chromium
Polymer	PLGA (poly [lactic-co-glycolic acid] polymer) coating	BioLinx®, a blend of hydrophobic C10, hydrophilic C19, and poly-vinyl pyrrolidone	PLLA (poly [L-lactide] acid) (BIOlute®), on thin amorphous silicon carbide (proBIO®)
Drug	Everolimus	Zotarolimus	Sirolimus
Drug release time, mo.	3	6	3.3
Degradation time, mo.	4	---	< 24

BIO-RESORT

- All-comer patients: any patient who requires a percutaneous coronary intervention with DES implantation
- Patients with any clinical syndrome, number of target lesions or vessels, any lesion length, vessel size, etc.

- **Inclusion criteria:** Pat. ≥ 18 yrs.; PCI with DES required; informed consent; ability and willingness to comply with study procedures and follow-up
- **Exclusion criteria:** Participation in another drug or device RCT before reaching primary EP; life expectancy < 1 year; planned surgery < 6 mo's unless DAPT maintained; known pregnancy; known intolerance to DES, anticoagulants or antiplatelet drugs preventing DAPT

3,514 all-comers were 1:1:1 randomized to DES type and assessed

Everolimus-eluting	Zotarolimus-eluting	Sirolimus-eluting
SYNERGY	RESOLUTE INTEGRITY	ORSIRO

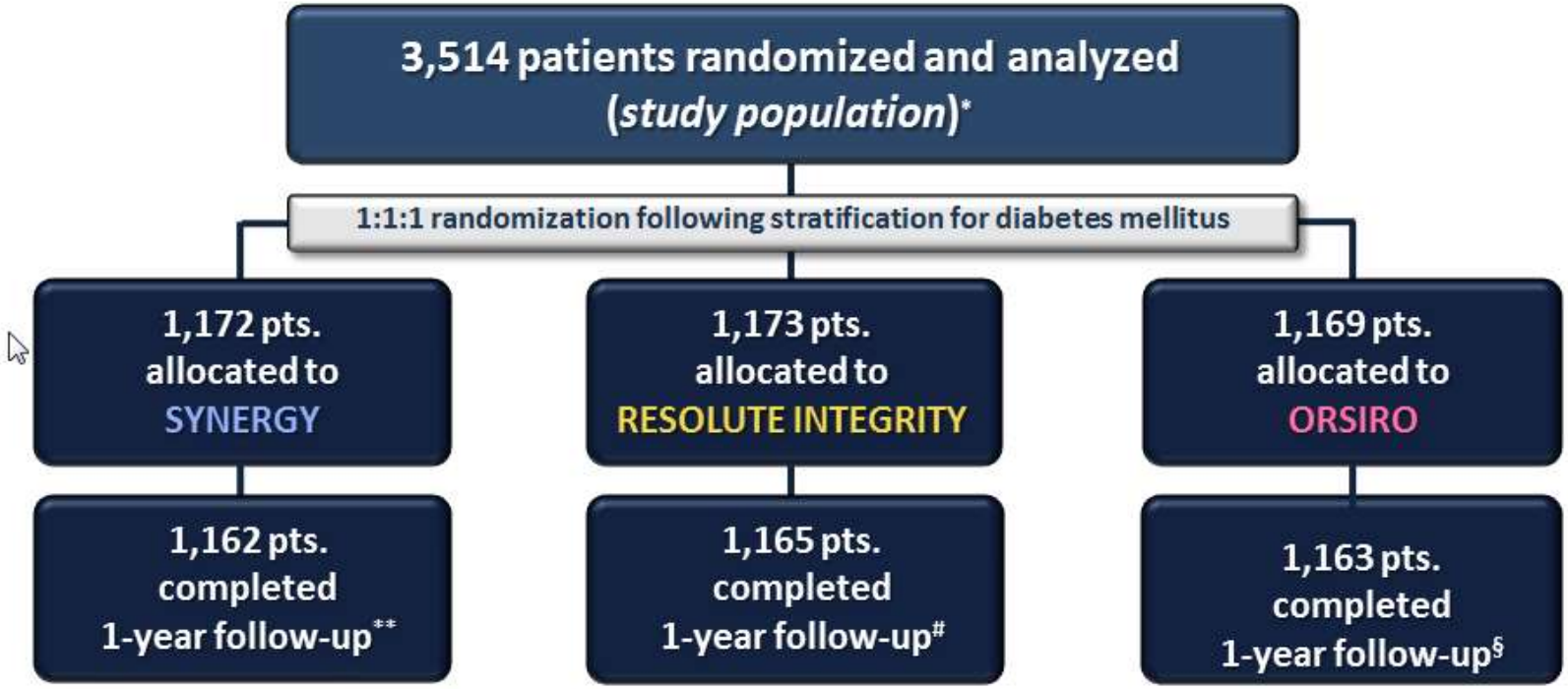
30 days | **1 year** | 2 years | 3 years | 4 years | 5 years

Investigator-initiated, multicenter, assessor and patient-blinded, three-arm, randomized, non-inferiority trial · Visits to outpatient clinic, questionnaire or telephone follow-up · No routine angiographic follow-up · Independent monitoring and clinical event adjudication (CEC) · Supervision by DSMB

- **Primary endpoint** Target Vessel Failure at 1-year (composite of cardiac death, target vessel-related myocardial infarction, or clinically driven target vessel revascularization) to test 2 independent hypotheses that the safety and efficacy of both ORSIRO and SYNERGY is non-inferior to the reference device RESOLUTE INTEGRITY
- **Secondary endpoints** Death · myocardial infarction (MI) · repeat revascularization · stent thrombosis · TLF, MACE, POCE

BIO-RESORT Study Sites: Thoraxcentrum Twente, Medisch Spectrum Twente, Enschede · Rijnstate Hospital, Arnhem · Haga Hospital, The Hague · Albert Schweitzer Hospital, Dordrecht; all in the Netherlands · Enrollment from December 21, 2012 to August 24, 2015 · PI: C. von Birgelen, MD PhD – Thoraxcentrum Twente, MST, Enschede, the Netherlands

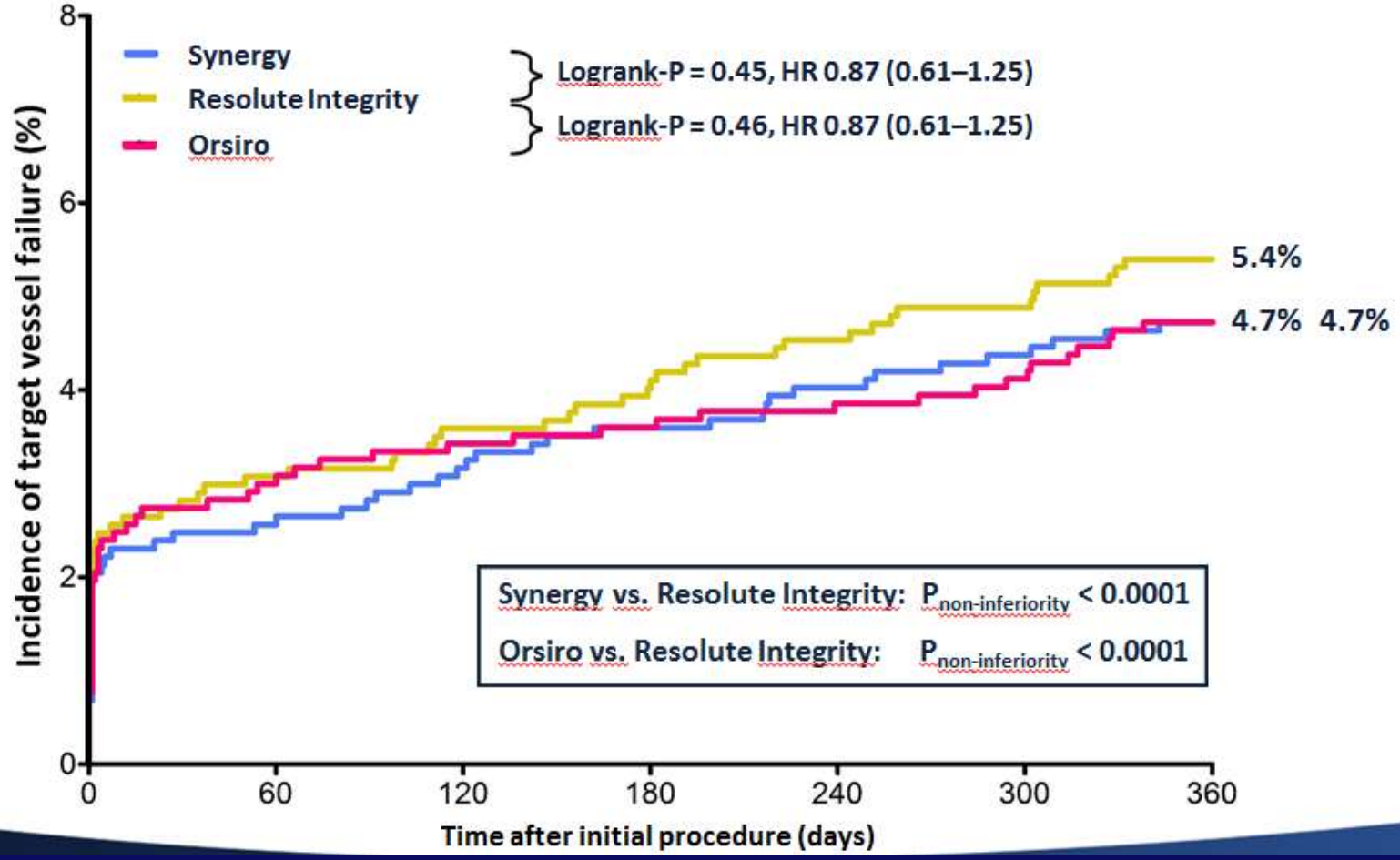
Study Flow Diagram



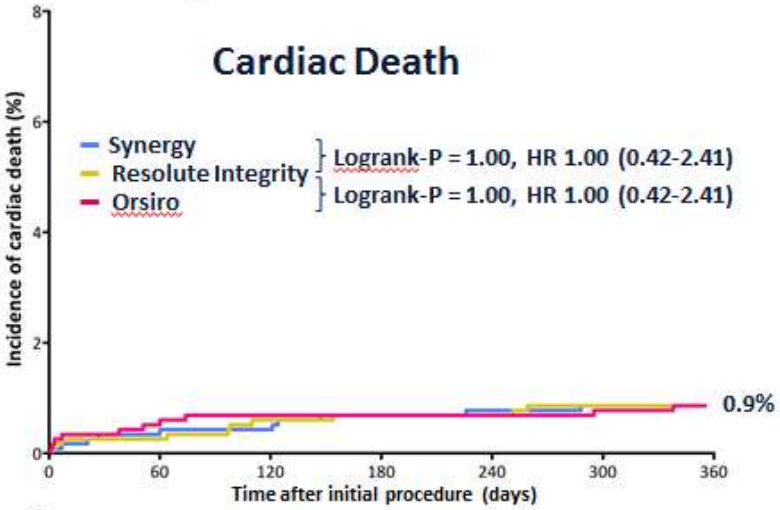
- 1-year follow-up data were obtained from 99.3% of the study population, which represents 99.9% of the patients who still participated in the trial or had died.
- During the first year of follow-up, 21 patients (0.6%) withdrew consent, while only 3 / 3,514 patients (< 1 ‰) were actually "lost" (i.e., could not be contacted).

Primary Endpoint

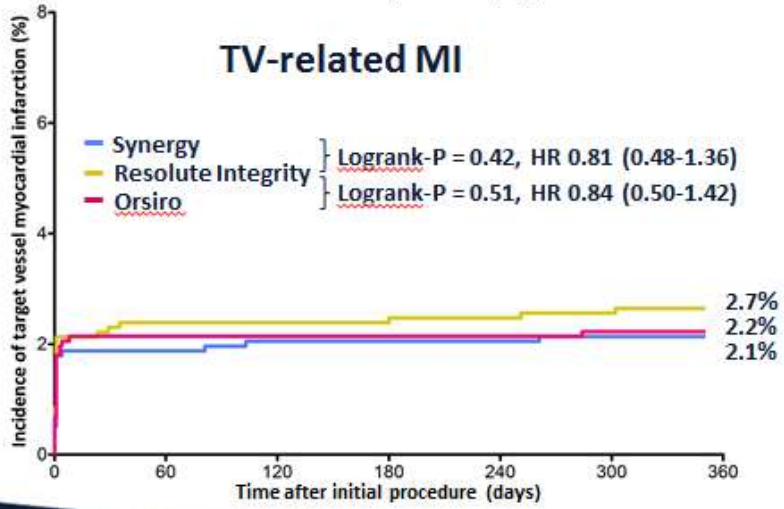
Target Vessel Failure at 1-Year Follow-Up

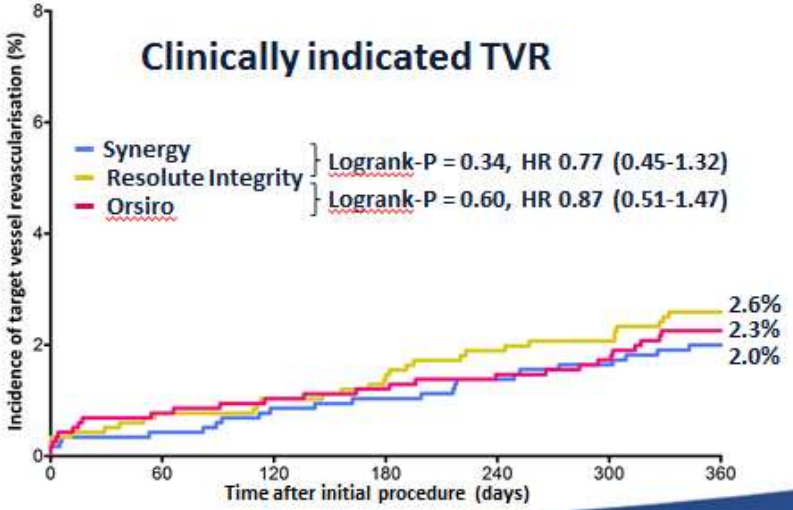


Components of TVF at 1-Year Follow-Up



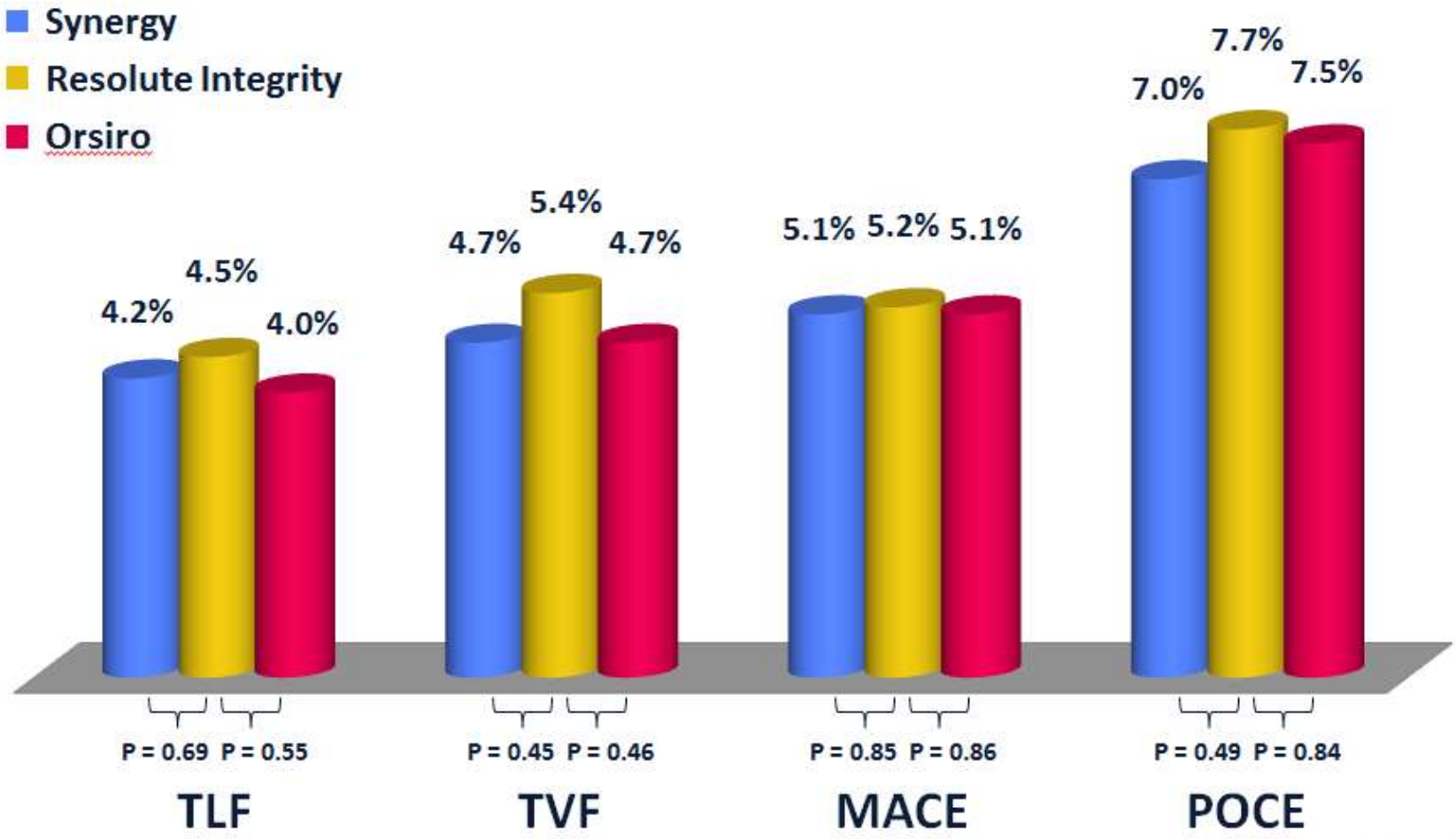
At 1-year follow-up, there was no statistically significant difference between stent groups in the components of Target Vessel Failure (TVF).



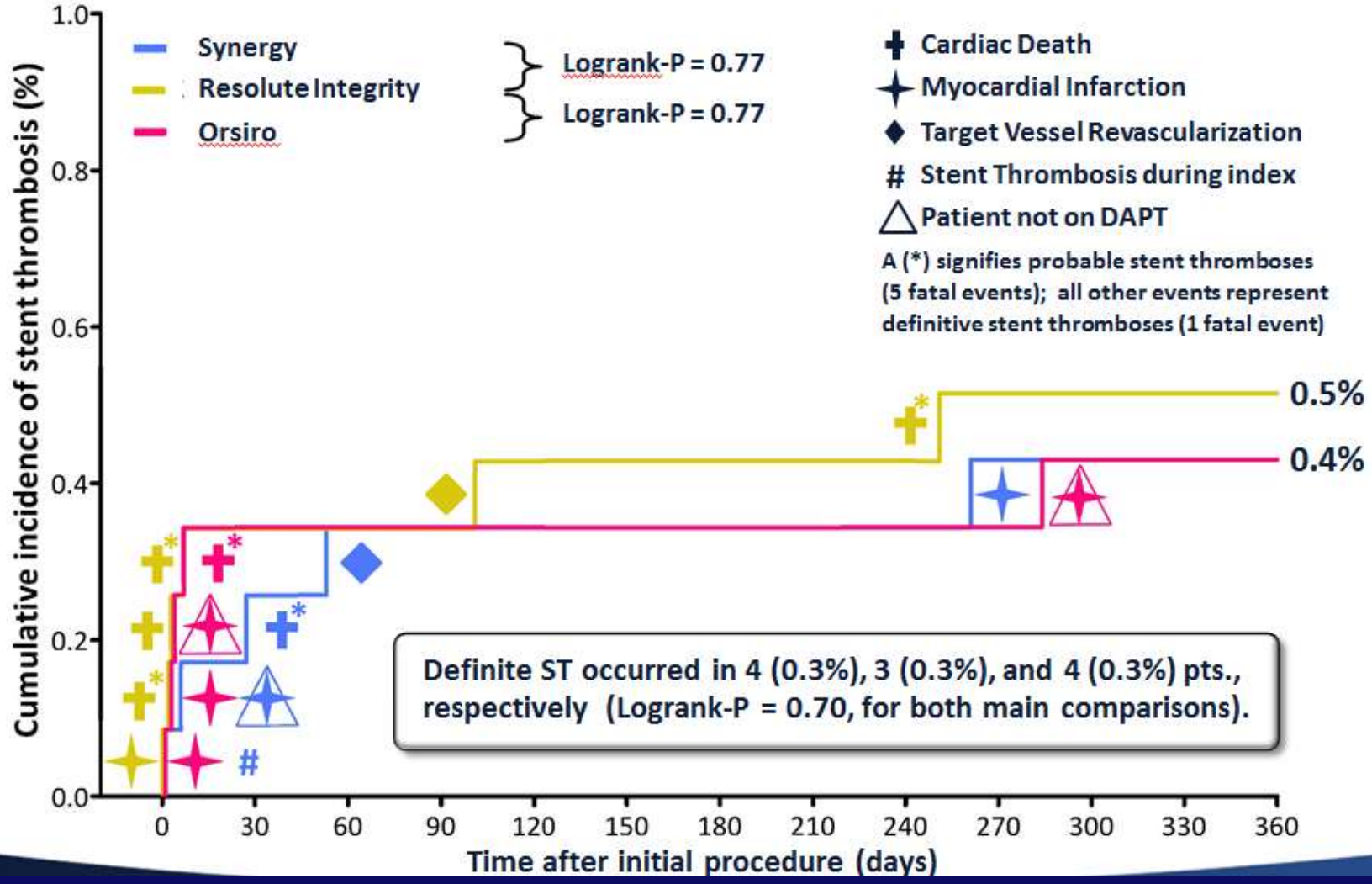


Composite Clinical Endpoints

At 1-Year Follow-Up

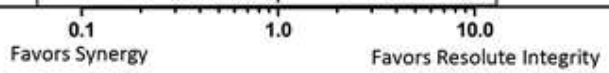


Definite or Probable Stent Thrombosis



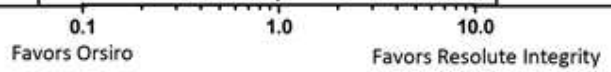
TVF Subgroup Analysis at 1-Year

	Synergy n = 1,172	Resolute Integrity n = 1,173	Forestplot	Hazard ration (95% CI)	*P*
All	55/1172 (4.7)	63/1173 (5.4)		0.87 (0.61-1.25)	0.45
Men	40/845 (4.7)	49/848 (5.8)		0.82 (0.54-1.24)	0.34
Acute coronary syndrome	37/816 (4.5)	39/815 (4.7)		0.97 (0.62-1.53)	0.90
Multivessel PCI	12/201 (6.0)	16/220 (7.3)		0.82 (0.39-1.73)	0.59
Diabetes	12/203 (5.9)	17/210 (8.1)		0.73 (0.35-1.52)	0.39
RVD < 2.75mm	33/680 (4.9)	42/667 (6.3)		0.77 (0.49-1.21)	0.25
Bifurcation lesion	23/415 (5.5)	30/409 (7.3)		0.75 (0.43-1.28)	0.29
Lesion length > 27 mm	17/353 (4.8)	30/369 (8.1)		0.58 (0.32-1.06)	0.07
In-stent restenosis	2/28 (7.1)	2/31 (6.5)		1.06 (0.15-7.55)	1.00
Renal insufficiency	2/29 (6.9)	6/33 (18.2)		0.37 (0.07-1.81)	0.26
Bypass graft treated	3/18 (16.7)	2/30 (6.7)		2.61 (0.44-15.66)	0.35
Left main treated	2/25 (8.0)	5/28 (17.9)		0.45 (0.09-2.29)	0.43



TVF Subgroup Analysis at 1-Year

	Orsiro n = 1,169	Resolute Integrity n = 1,173	Forestplot	Hazard ration (95% CI)	P
All	55/1169 (4.7)	63/1173 (5.4)		0.87 (0.61-1.25)	0.46
Men	38/854 (4.4)	49/848 (5.8)		0.76 (0.50-1.17)	0.21
Acute coronary syndrome	37/818 (4.5)	39/815 (4.7)		0.97 (0.62-1.53)	0.89
Multivessel PCI	14/219 (6.4)	16/220 (7.3)		0.87 (0.43-1.79)	0.72
Diabetes	12/211 (5.7)	17/210 (8.1)		0.70 (0.33-1.46)	0.33
RVD < 2.75mm	35/731 (4.8)	42/667 (6.3)		0.76 (0.49-1.19)	0.22
Bifurcation lesion	25/412 (6.1)	30/409 (7.3)		0.82 (0.48-1.39)	0.47
Lesion length > 27 mm	21/351 (6.0)	30/369 (8.1)		0.73 (0.42-1.27)	0.26
In-stent restenosis	0/30 (0.0)	2/31 (6.5)		-	0.49
Renal insufficiency	4/46 (8.7)	6/33 (18.2)		0.47 (0.13-1.65)	0.31
Bypass graft treated	3/22 (13.6)	2/30 (6.7)		2.08 (0.35-12.46)	0.64
Left main treated	2/23 (8.7)	5/28 (17.9)		0.43 (0.08-2.23)	0.44



Clemens von Birgelen, Lancet, 2016

Conclusion

- Use of all three drug-eluting stents for the treatment of a complex all-comers population resulted in favorable clinical outcomes.
- Very thin strut everolimus-eluting Synergy and sirolimus-eluting Orsiro stents, which have dissimilar biodegradable polymer coatings, were non-inferior to the thin strut durable polymer zotarolimus-eluting Resolute Integrity stent.
- The absence of a loss of 1-year safety and efficacy with the use of the novel stents is a prerequisite before assessing potential benefits at longer term follow-up.

Registry for an all-comers patient population with the sirolimus eluting Orsiro stent system in daily clinical practice

BIOFLOW-III

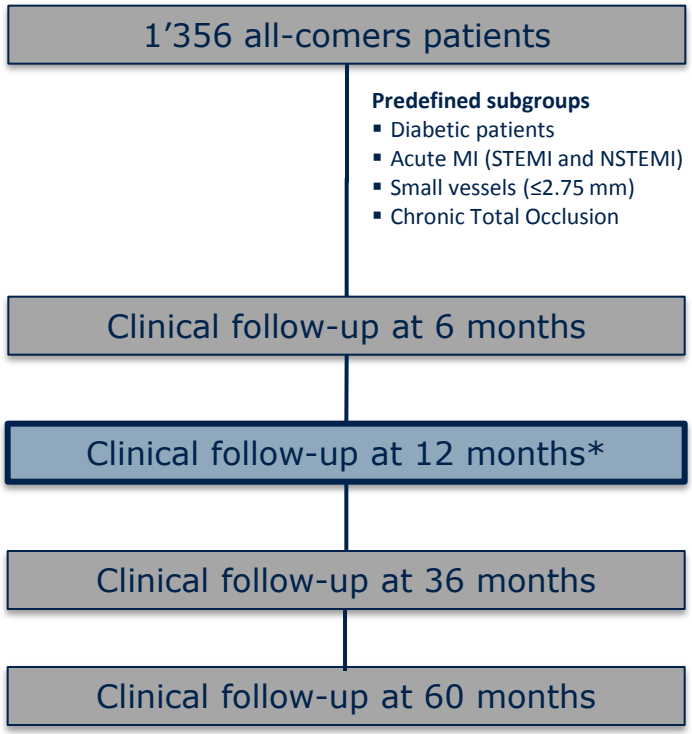
NCT01553526

DESIGN
An international, prospective, multi-center open-label, registry of the Orsiro hybrid DES in daily clinical practice

OBJECTIVE
Evaluate safety and clinical performance of the Orsiro drug eluting stent with a bioabsorbable polymer in a large patient population in standard clinical care

COORDINATING INVESTIGATOR
Prof. Dr. Johannes Waltenberger,
Universitätsklinikum Münster, Germany

PRIMARY ENDPOINT
Target Lesion Failure (TLF) at 12 months



* 97.4 % FUP compliance

Source: Waltenberger et al. EuroIntervention 2015; 10-online publish-ahead-of-print March 2015

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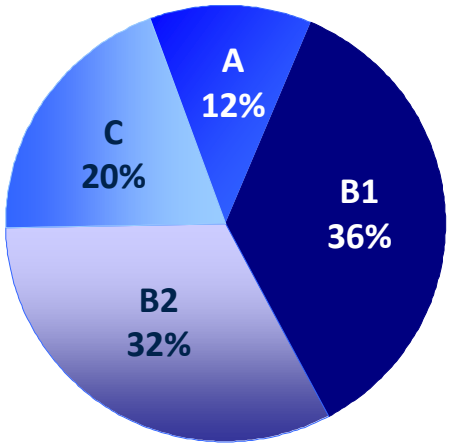
Patient Characteristics

BIOFLOW-III

Patients	N = 1,356
Age (mean ± SD)	66.1 ± 10.7 yrs
Male % (N)	71.6 % (971)
Hypertension	75.9 % (1,029)
Hypercholesteremia	60.1 % (815)
Smoking	54.6 % (741)
Diabetes mellitus	29.6 % (402)
Insulin dependent	34.1 % (137)
Non-Insulin dependent	65.9 % (265)
History of MI	27.7 % (376)
Stable angina	47.3 % (641)
Previous PCI	39.6 % (537)
Acute MI	32.6 % (442)
Lesion	**N = 1,738**
Small vessels (≤2.75mm)	48% (828)
Chronic Total Occlusion	4% (65)

ACC/AHA Lesion Classification



Lesion length (mm ± SD)	15.8 ± 9.1
Ref. vess. diameter (mm ± SD)	3.0 ± 0.4
Diameter stenosis (% ± SD)	86.3 ± 11.1
Moderate calcification	23.6 %
Severe calcification	7.0 %
Bifurcation	16.2 %

Source: Waltenberger et al. EuroIntervention 2015; 10-online publish-ahead-of-print March 2015.

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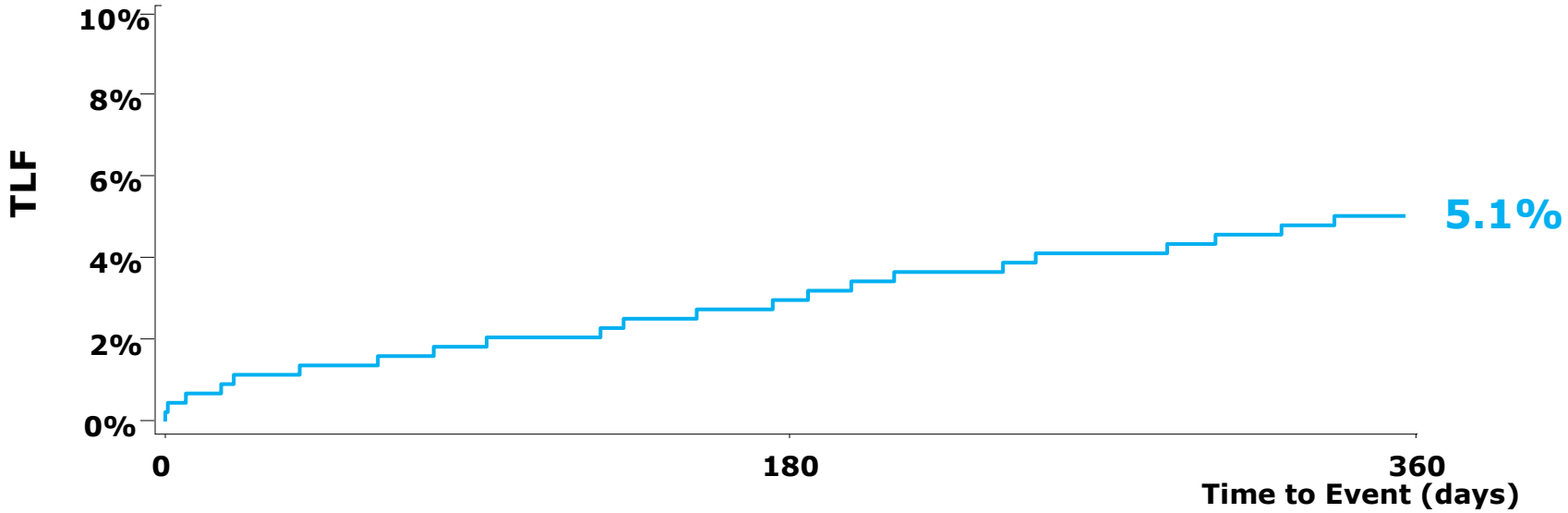
Primary & Major Secondary Endpoint Results at 12 months

BIOFLOW-III

TLF at 12 Months – All Subjects



Major Secondary Endpoints

Devices	N = 1,738
Device success	**98.8%**
Procedures	**N = 1,356**
Procedure success	**98.2%**

Target Lesion Failure Composites (%)	Orsiro N=298
Cardiac Death	**1.3**
Target vessel MI	**2.3**
TLR (Clinically driven)	**3.0**
CABG (Emergent)	**0.0**

Source: Waltenberger et al. EuroIntervention 2015; 10-online publish-ahead-of-print March 2015.

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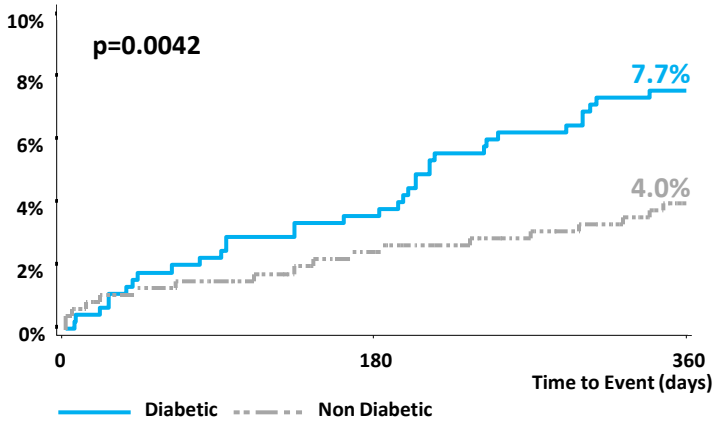
Diabetic subgroup analysis

BIOFLOW-III

Patient Characteristics

	Diabetics N = 402	Non-diabetics N = 953	P-value
Age (mean yrs ± SD yrs)	68.6 ± 10	65.1 ± 11	< 0.0001
Hypertension	88% (352)	71% (677)	< 0.0001
Hypercholesteremia	64% (256)	59% (559)	0.0844
Insulin dependent	34% (137)	0% (0)	n/a
Non-Insulin dependent	66% (265)	0% (0)	n/a

12-month TLF Results



Lesion and Stent Characteristics

	Diabetics N = 517	Non-diabetics N = 1,220	P-value
B2/C type lesions	49% (253)	53% (651)	0.0915
Mean stent length (mm)	18 ± 6	18 ± 6	0.9335
Mean stent diameter (mm)	3.0 ± 0.4	3.0 ± 0.4	0.4096

Device and procedural success

	Diabetics	Non-diabetics
Device success	99.0%	98.7%
Procedure success	98.0%	98.3%

Source: Data on file at BIOTRONIK

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Small vessel subgroup analysis

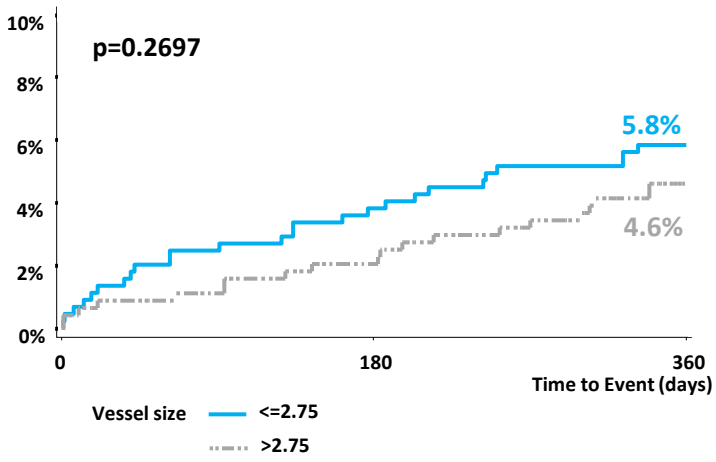
BIOFLOW-III

Patient Characteristics

	≤ 2.75mm[1] N = 575	>2.75mm N = 766	P-value
Age (mean yrs ± SD yrs)	67.2 ± 11	65.3 ± 11	0.0012
Hypertension	79% (454)	74% (567)	0.0359
Hypercholesteremia	61% (351)	59% (454)	0.5115
Diabetes	33% (188)	28% (210)	0.0376
Non-Insulin dependent	60% (113)	71% (149)	0.0228
Insulin dependent	40% (75)	29% (61)	

[1]Reference vessel diameter (RVD) ≤2.75mm

12-month TLF Results



Lesion and Stent Characteristics

	≤ 2.75mm N = 828	>2.75mm N = 896	P-value
B2/C type lesions	50% (413)	55% (490)	0.0458
Mean stent length (mm SD)	18 ± 6	19 ± 6	0.0011
Mean stent diameter (mm)	2.7 ± 0.3	3.2 ± 0.4	< 0.0001

Device and procedural success

	Small Vessels	Non-small Vessels
Device success	99.3%	98.3%
Procedure success	98.3%	98.2%

Source: Data on file at BIOTRONIK

BIOTRONIK excellence for life

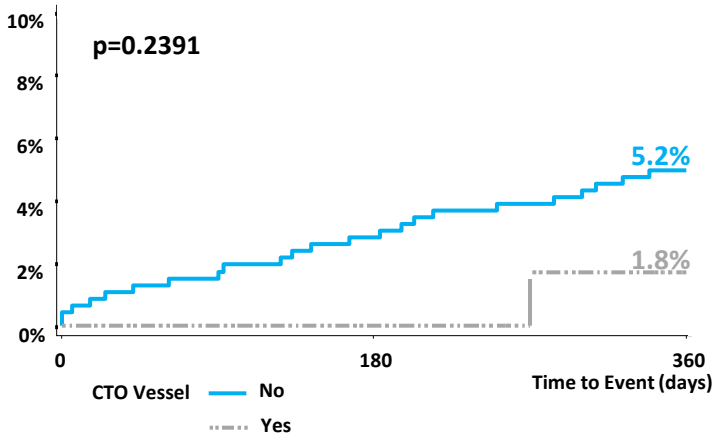
CTO subgroup analysis

BIOFLOW-III

Patient Characteristics

	CTO N = 58	Non-CTO N = 1,207	P-value
Age (mean yrs ± SD yrs)	64.7 ± 10	66.1 ± 11	0.3212
Hypertension	81% (47)	76% (919)	0.3914
Hypercholesteremia	60% (35)	60% (722)	0.9362
Diabetes	28% (16)	29% (345)	0.8665
Non-Insulin dependent	63% (10)	67% (230)	0.7300
Insulin dependent	38% (6)	33% (115)	

12-month TLF Results



Lesion and Stent Characteristics

	CTO N = 83	Non-CTO N = 1,530	P-value
B2/C type lesions	81% (67)	51% (785)	< 0.0001
Mean stent length (mm)	20 ± 7	18 ± 6	< 0.0001
Mean stent diameter (mm)	2.9 ± 0.4	3.0 ± 0.4	0.0043

Device and procedural success

	CTO	Non-CTO
Device success	100.0%	98.6%
Procedure success	100.0%	98.0%

Source: Data on file at BIOTRONIK

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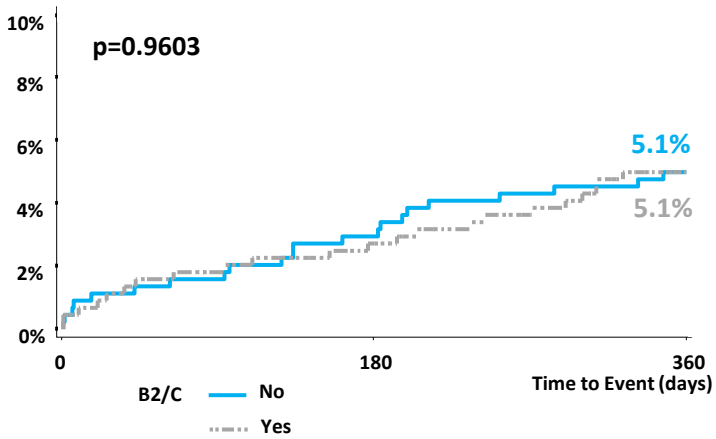
B2/C lesion subgroup analysis

BIOFLOW-III

Patient Characteristics

	A/B1 N = 611	B2/C N = 743	P-value
Age (mean yrs)	66.0	66.3	0.6256
Hypertension	76% (466)	76% (561)	0.7769
Hypercholesteremia	59% (359)	61% (454)	0.3477
Diabetes	32% (195)	28% (207)	0.1076
Insulin dependent	33% (65)	35% (72)	0.7593
Non-Insulin dependent	67% (130)	65% (135)	

12-month TLF Results



Lesion Characteristics

	A/B1 N = 715	B2/C N = 1,012	P-value
Lesion Length (mm)	13.1 ± 5.8	17.6 ± 10.4	<0.0001
RVD (mm)	3.0 ± 0.4	3.0 ± 0.4	0.0070
Calcification – Moderate (%)	20.7	26.0	0.0102
Calcification – Severe (%)	2.0	10.7	<0.0001
CTO (%)	1.2	6.0	<0.0001
Tortuosity – Excessive (%)	0.8	4.1	<0.0001

Device and procedural success

	A/B1	B2/C
Device success	99.3%	98.4%
Procedure success	99.0%	97.6%

Source: Data on file at BIOTRONIK

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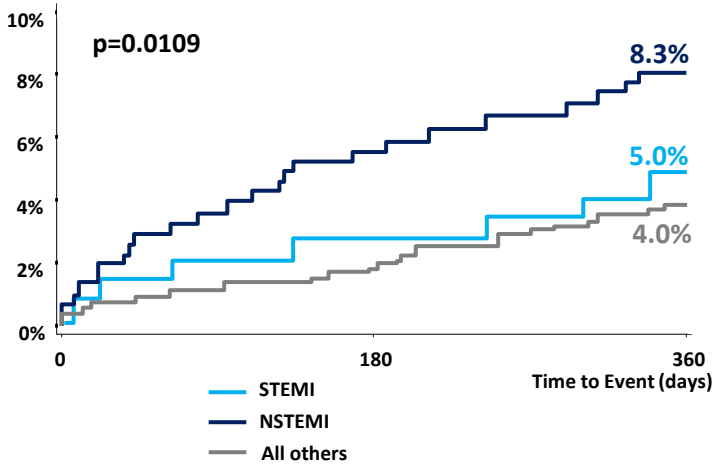
STEMI subgroup analysis

BIOFLOW-III

Patient Characteristics

	STEMI N = 144	NSTEMI N = 293	All others N = 919	P-value
Age in years (mean ± SD)	61.5 ± 11.0	66.7 ± 11.8	66.7 ± 10.2	<0.0001
Hypertension	57.6% (83)	71.0% (208)	80.3% (738)	<0.0001
Hypercholesteremia	45.8% (66)	52.6% (154)	64.7% (595)	<0.0001
Diabetes	23.6% (34)	27.0% (79)	31.4% (289)	0.0839
Non-Insulin dependent	64.7% (22)	60.8% (48)	67.5% (195)	0.5301
Insulin dependent	35.3% (12)	39.2% (31)	32.5% (94)	
Previous MI	11.1% (16)	23.9% (70)	31.6% (290)	<0.0001
Renal disease	5.6% (8)	15.0% (44)	11.6% (107)	0.0651
CHF	7.6% (11)	7.5% (22)	12.5% (115)	0.0235
Previous TIA	5.6% (8)	7.8% (23)	4.7% (43)	0.1146

12-month TLF Results



Lesion & Stent Characteristics

	STEMI N = 144	NSTEMI N = 293	All others N = 919	P-value
B2/C type lesions	66.3% (110)	54.0% (204)	49.5% (591)	0.0002
Mean stent length (mm)	18.6 ± 5.5	17.8 ± 5.8	18.2 ± 5.8	0.2820
Mean stent diameter (mm)	3.1 ± 0.4	3.0 ± 0.4	3.0 ± 0.4	0.0048

Device and procedural success

	STEMI N = 144	NSTEMI N = 293	All Others N = 919	P-value
Device success	95.8%	99.5%	99.0%	0.0007
Procedure success	96.5%	97.6%	98.7%	0.1234

Source: Waltenberger J. Oral presentation EuroPCR 2015.

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HATTRICK OCT

NEOINTIMAL STRUT COVERAGE AND VASODILATOR RESPONSE AT 3 MONTHS

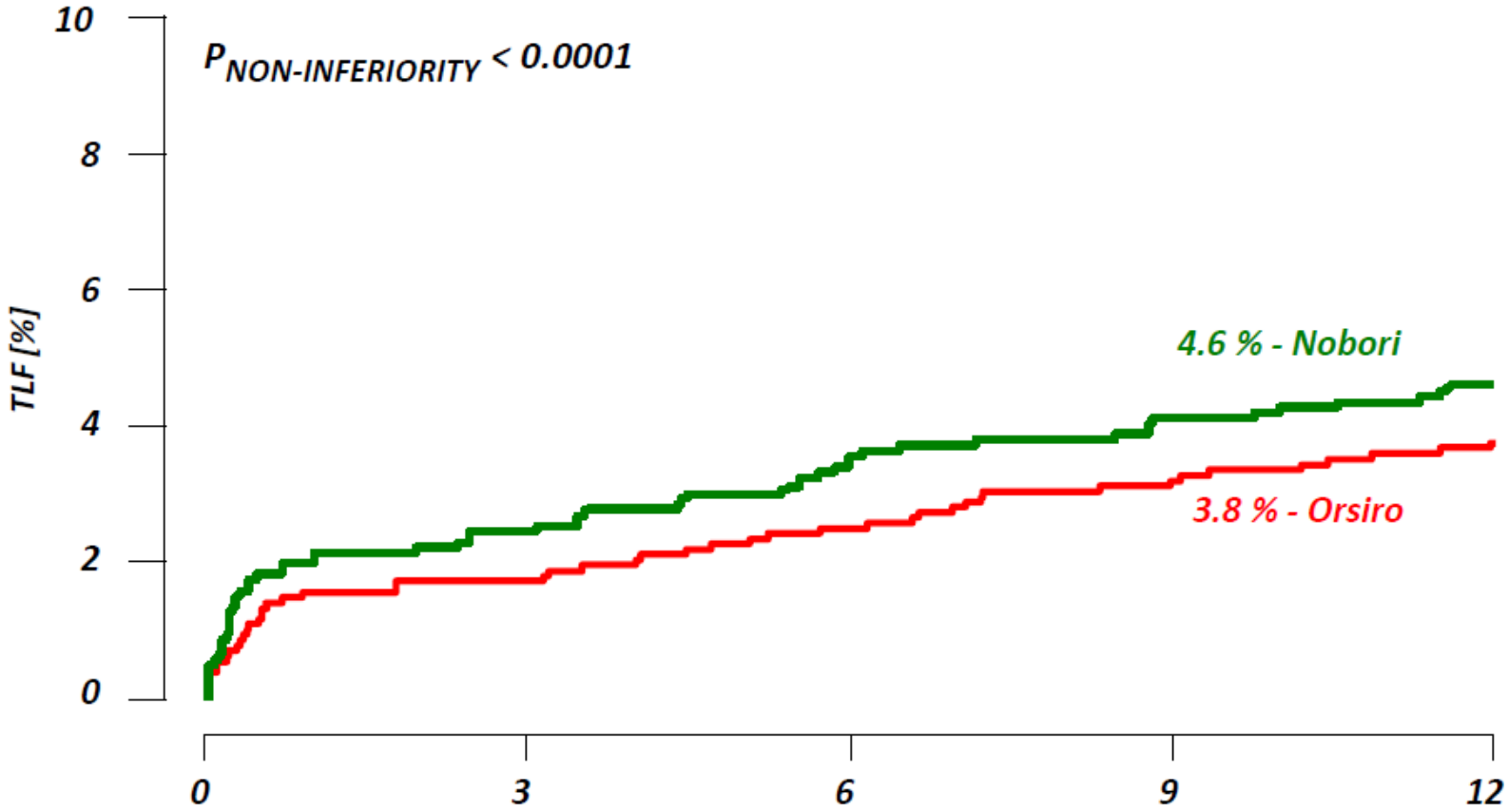
RCT, 1:1 BP-SES (Orsiro) versus DP-ZES (Resolute Integrity) in ACS, n=44

	Orsiro 4897 struts	Resolute Integrity 5467 struts	P
Uncovered stent struts			
- Strut level	3.9%	8.9%	<0.001
- Stent level	3.9 ± 3.2%	8.9 ± 6.9%	0.019
Coronary Flow Reserve (CFR)	3.0±1.3	3.2±1.0	ns

"Sirolimus-eluting stents with bioabsorbable polymer were more completely covered compared to zotarolimus-eluting stents with durable polymer at 3 months after PCI for ACS"

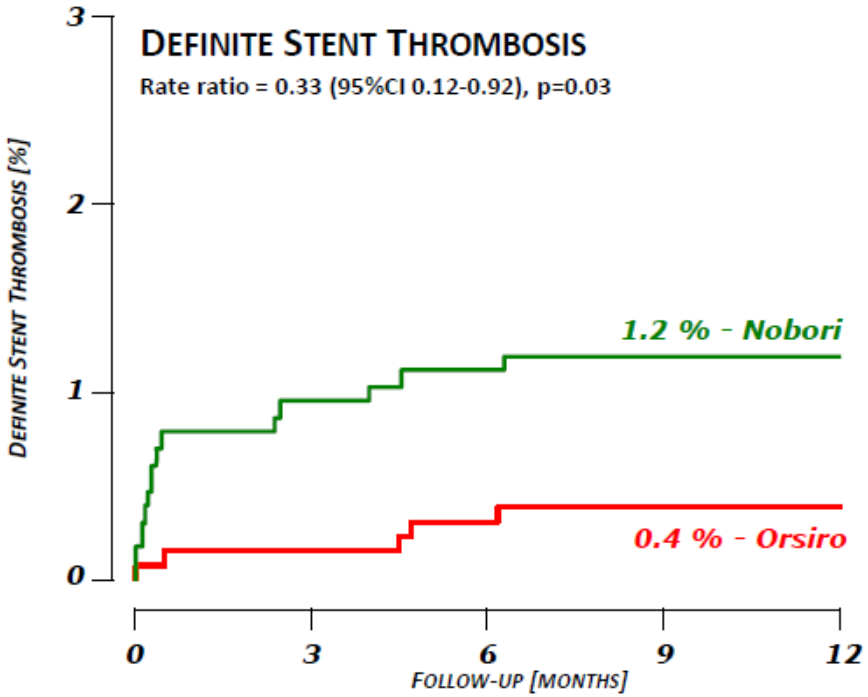
SORT-OUT VII: TLF AT 12 MONTHS

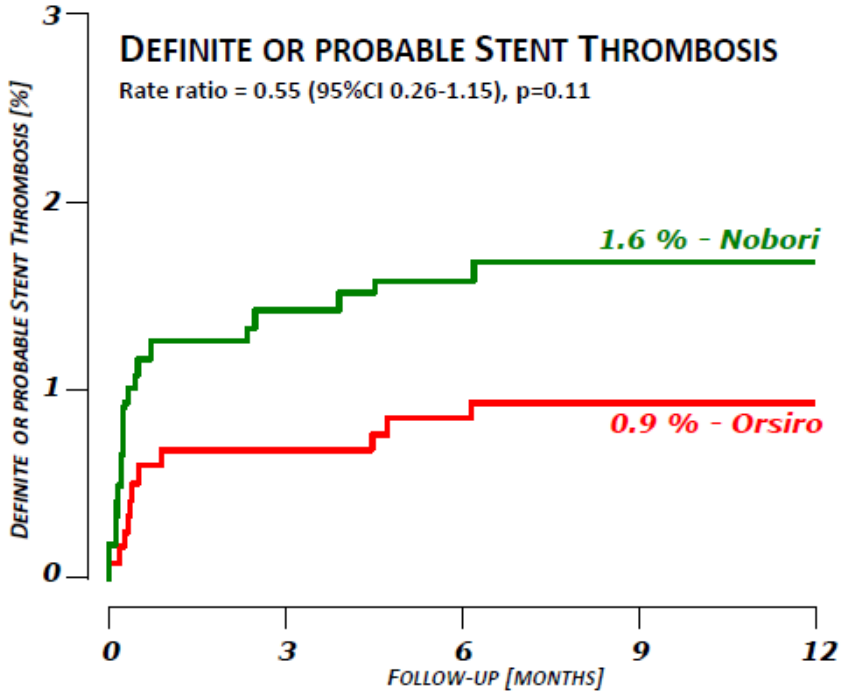
RCT, 1:1 Orsiro versus Nobori, n=2,525 across 3 centers in Denmark



SORT-OUT VII: STENT THROMBOSIS AT 12 MONTHS

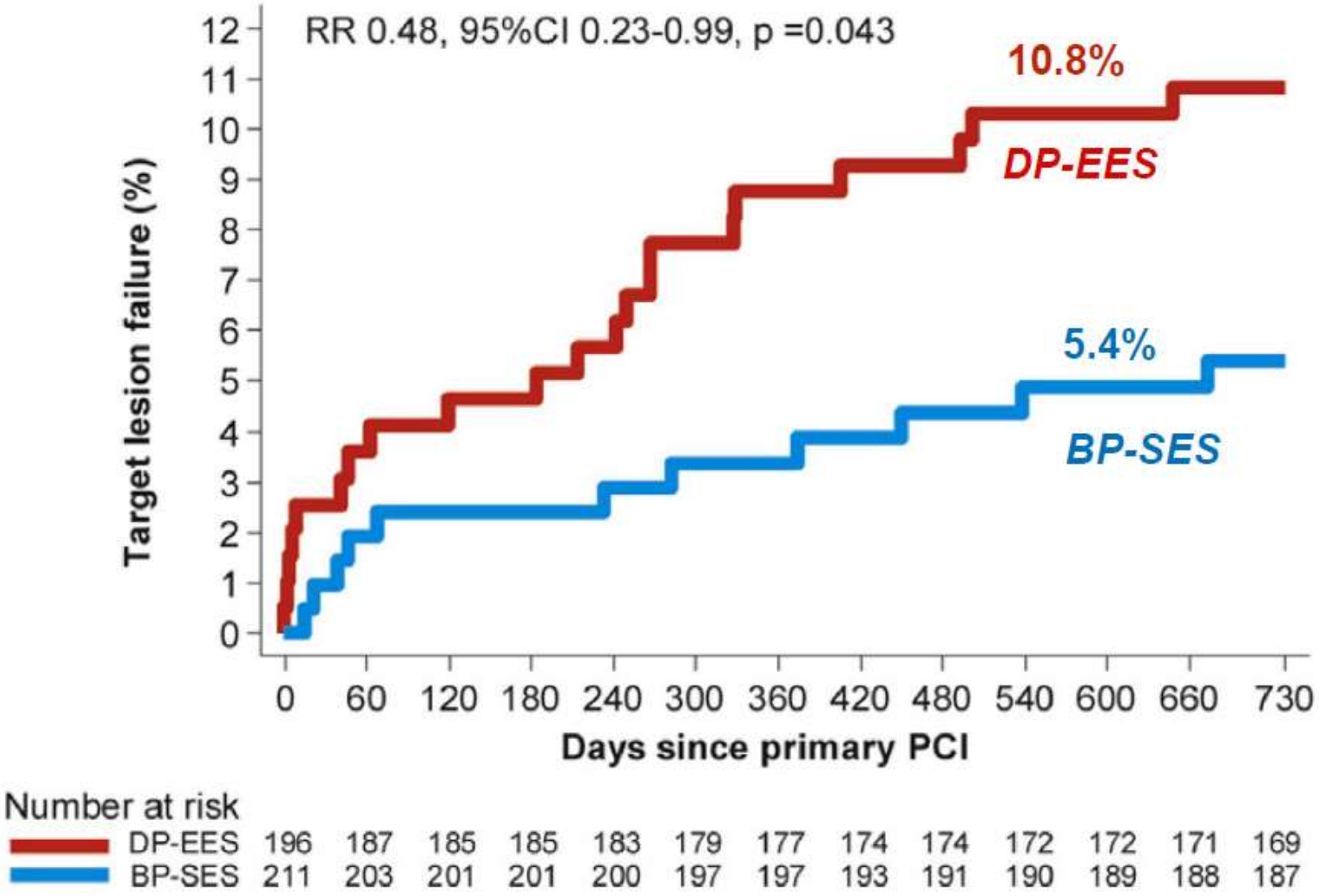
RCT, 1:1 Orsiro versus Nobori, n=2,525 across 3 centers in Denmark





BIOSCIENCE STEMI: TLF AT 2 YEARS

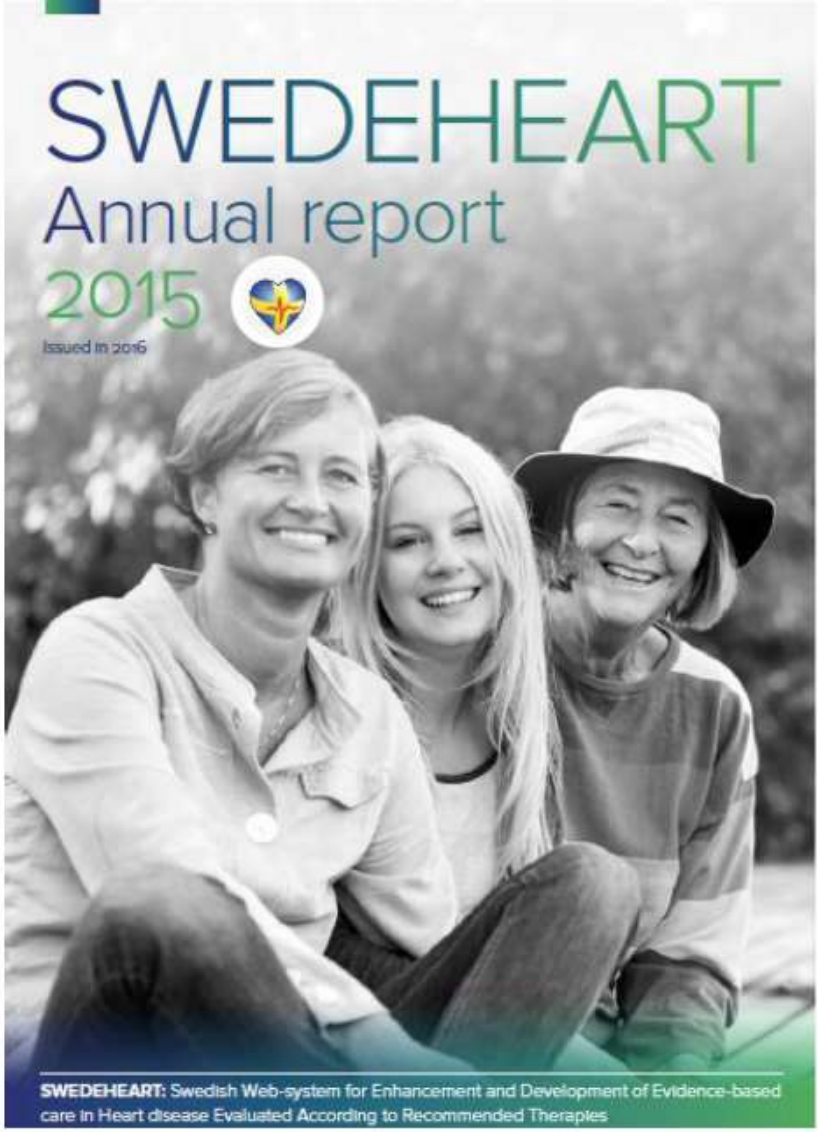
Stratified Randomization, 1:1 BP-SES (Orsiro) versus DP-EES (Xience), n=407



SWEDE HEART

Number of cases annually: 80 000

RIKS-HIA	73 CCU hospitals, 100%
SCAAR	30 PCI hospitals, 100%
Percutaneous valves	7 hospitals, 100%
Heart surgery	7 hospitals, 100%
Secondary prevention	65 hospitals, 85%
Cardiogenetic registry	New

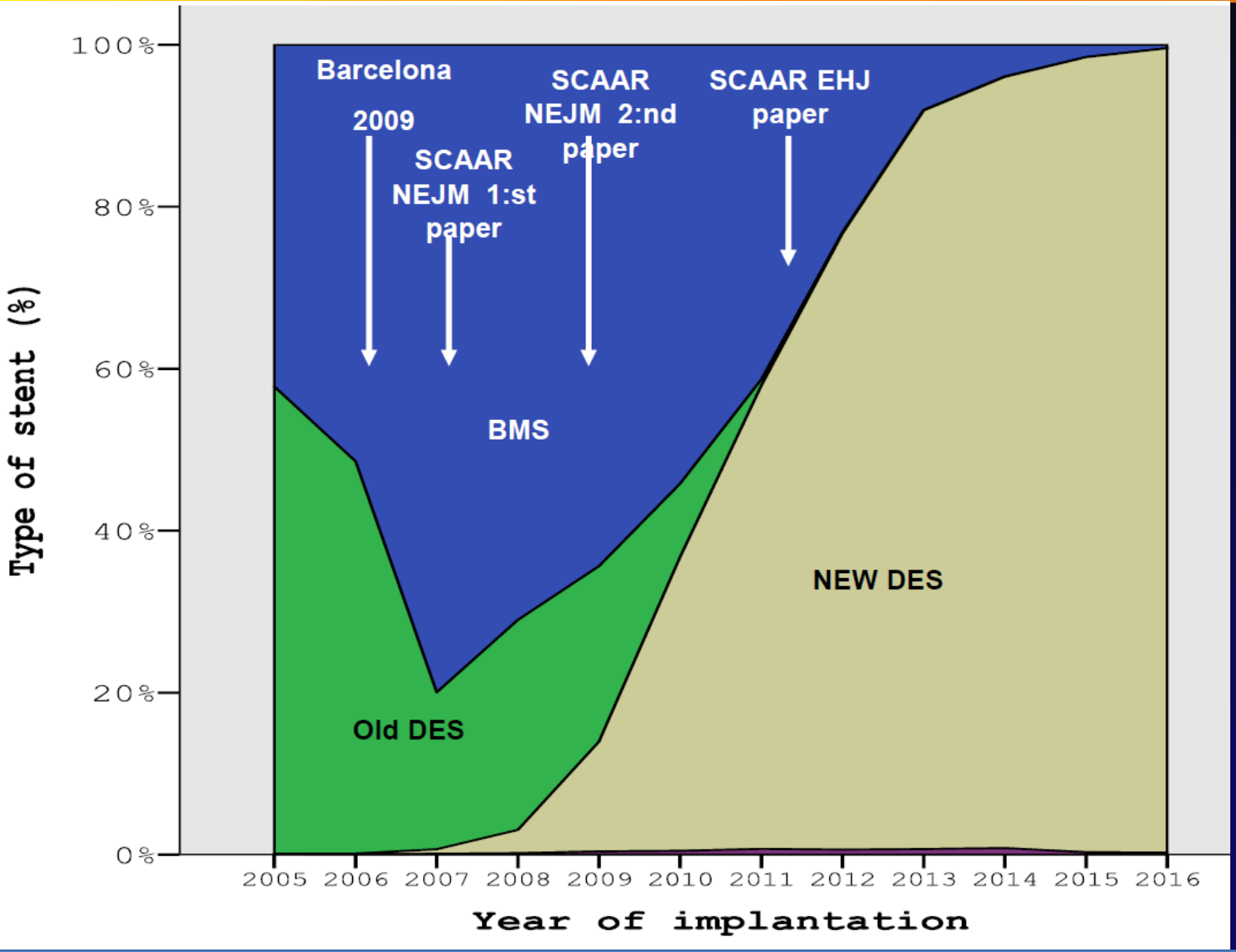


>300 variables (Baseline data, procedural and outcome measures)

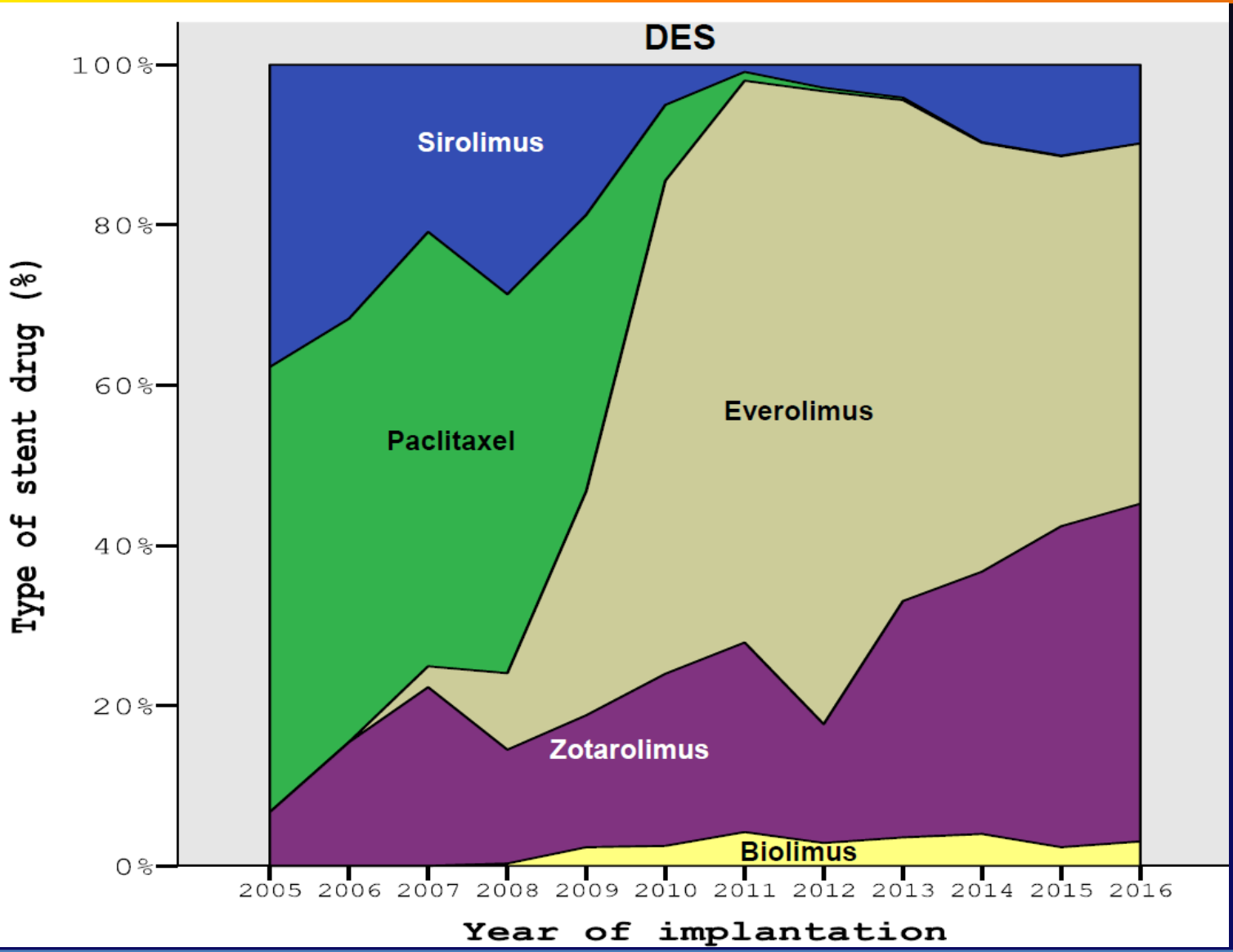
At monitoring: 95-96% agreement between files and registry.

UCR

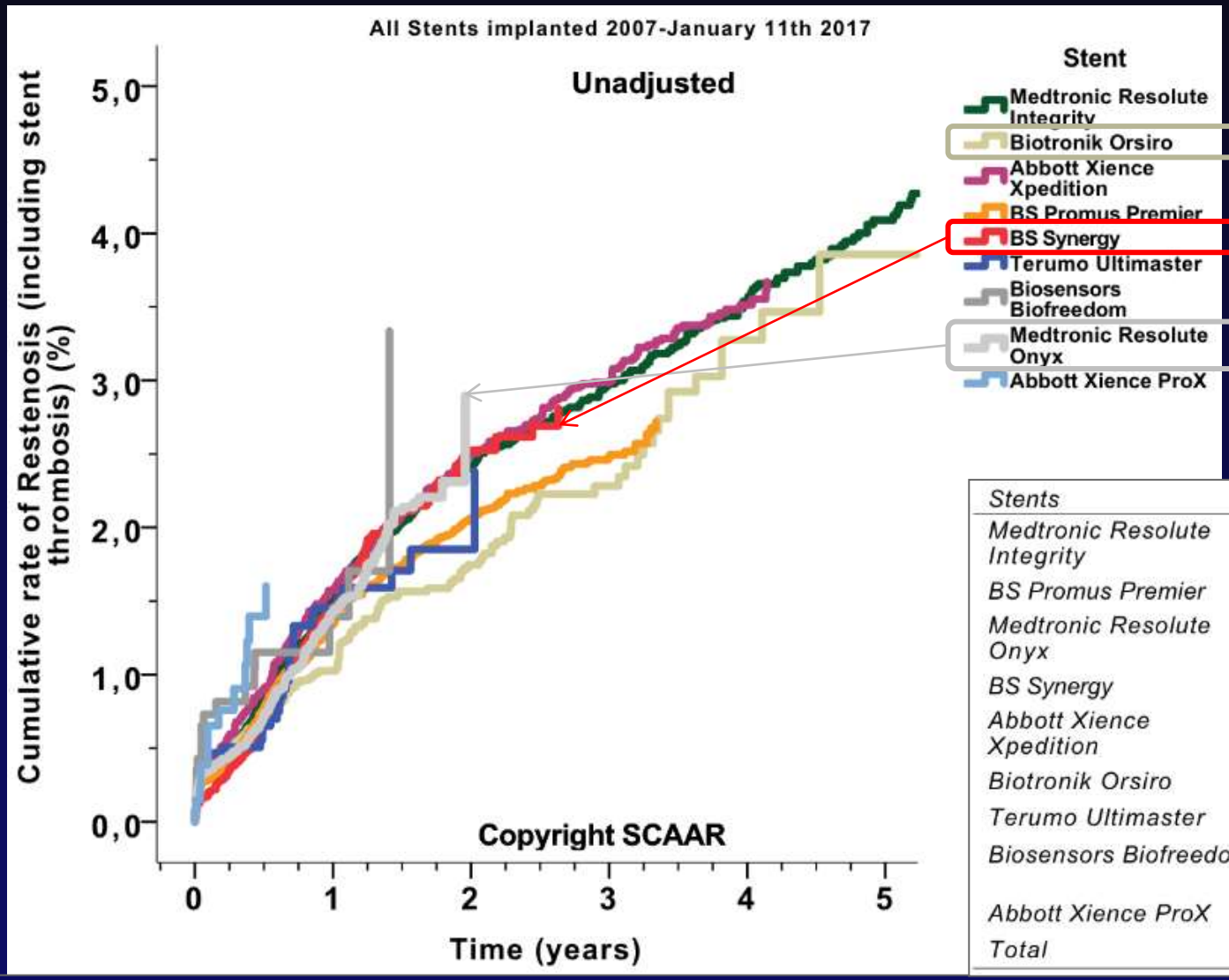
SWEDEHEART – SCAAR



SWEDEHEART – SCAAR

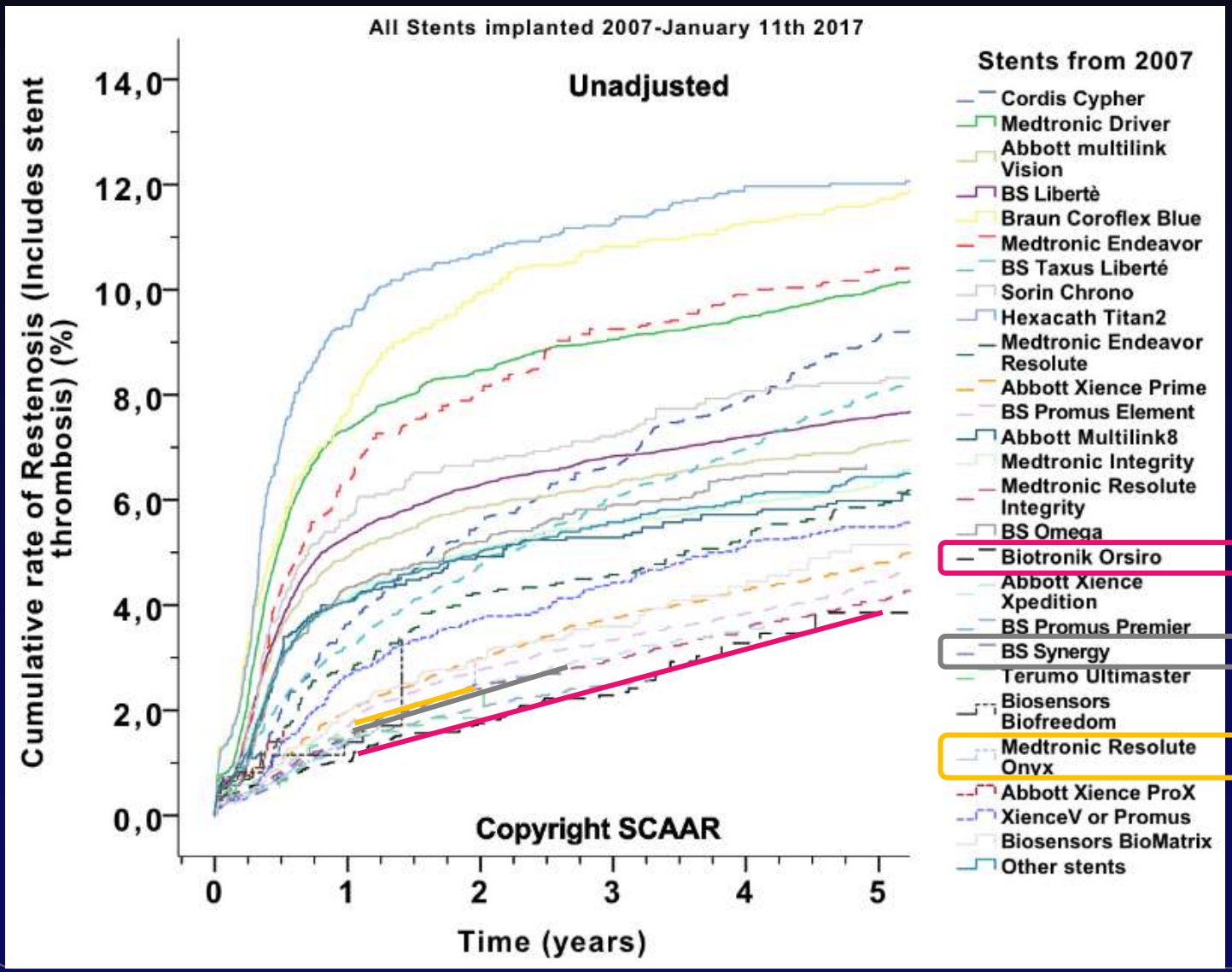


SCAAR data confirms Orsiro's outstanding performance compared to main competitors



Stents	N
Medtronic Resolute Integrity	26825
BS Promus Premier	26759
Medtronic Resolute Onyx	23665
BS Synergy	18521
Abbott Xience Xpedition	13377
Biotronik Orsiro	8482
Terumo Ultimaster	2628
Biosensors Biofreedom	1444
Abbott Xience ProX	1358
Total	123059

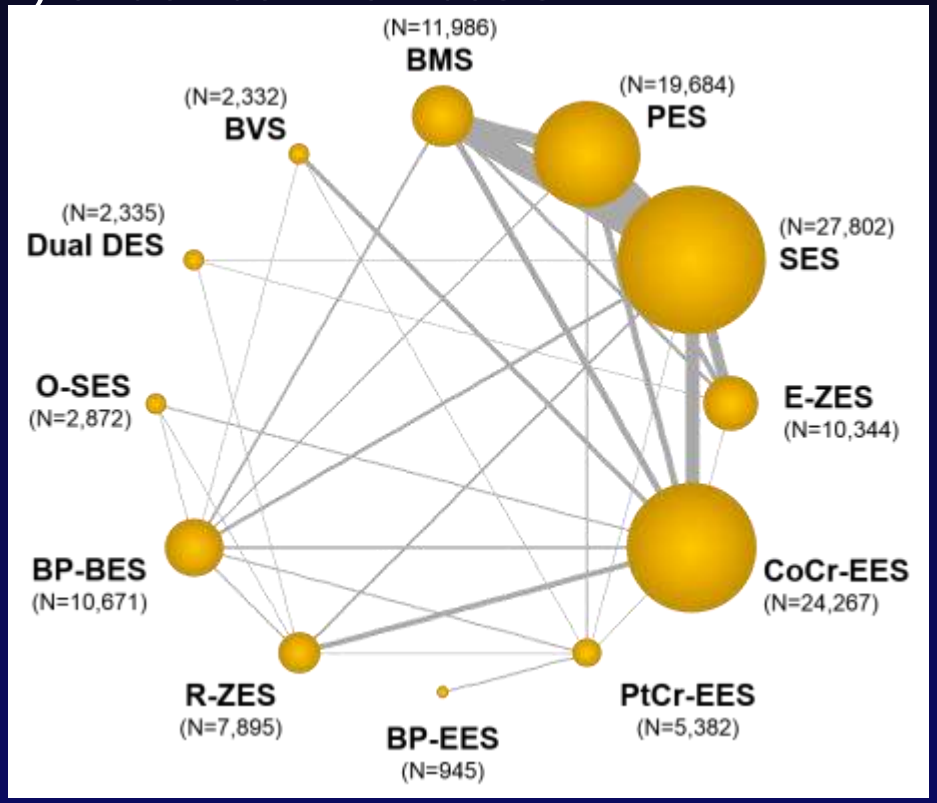
Real world data (SCAAR) even suggest that Orsiro is the best stent there ever was



Study Aim

- To compare the safety of contemporary DES including BVS in terms of the risk of stent thrombosis (ST) or device thrombosis.

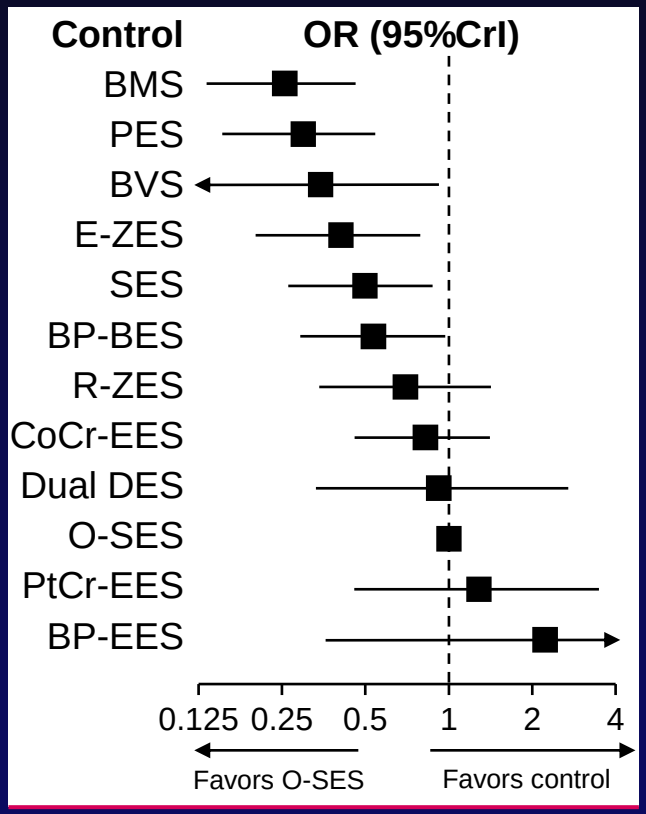
- Due to the low incidence rates of ST, a very large sample size is required to detect the differences in a single trial setting.
- A network meta-analysis has the advantage of providing comprehensive information by combining data from a complex network of multiple trials.



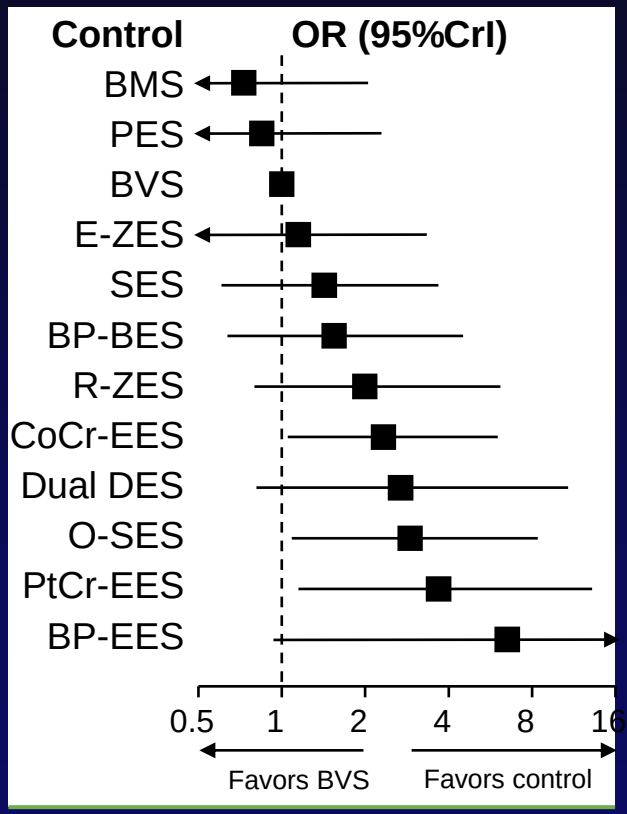
- We performed a systematic literature review of randomized controlled trials and updated a multiple-treatment network meta-analysis using a Bayesian framework.

Stent Thrombosis (definite or probable)

(C) O-SES *vs.* comparators



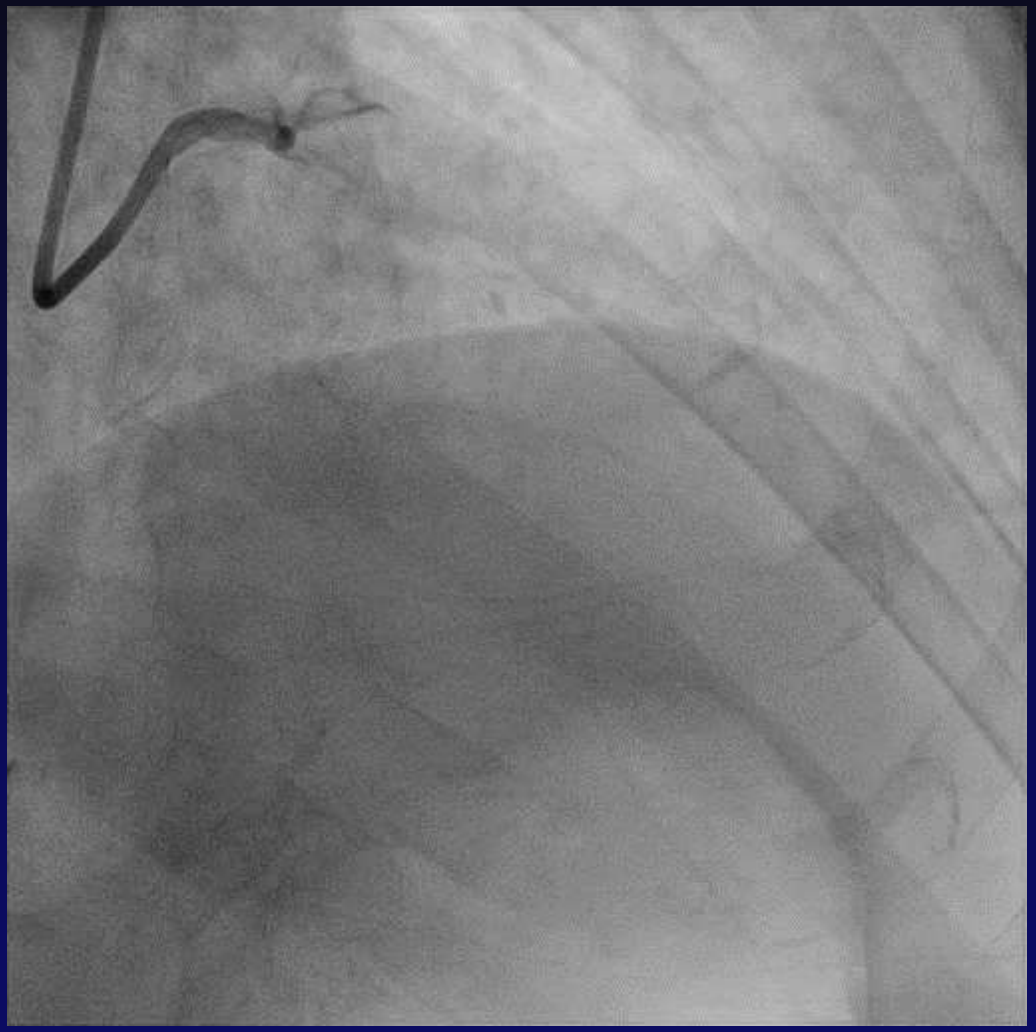
(D) BVS *vs.* comparators



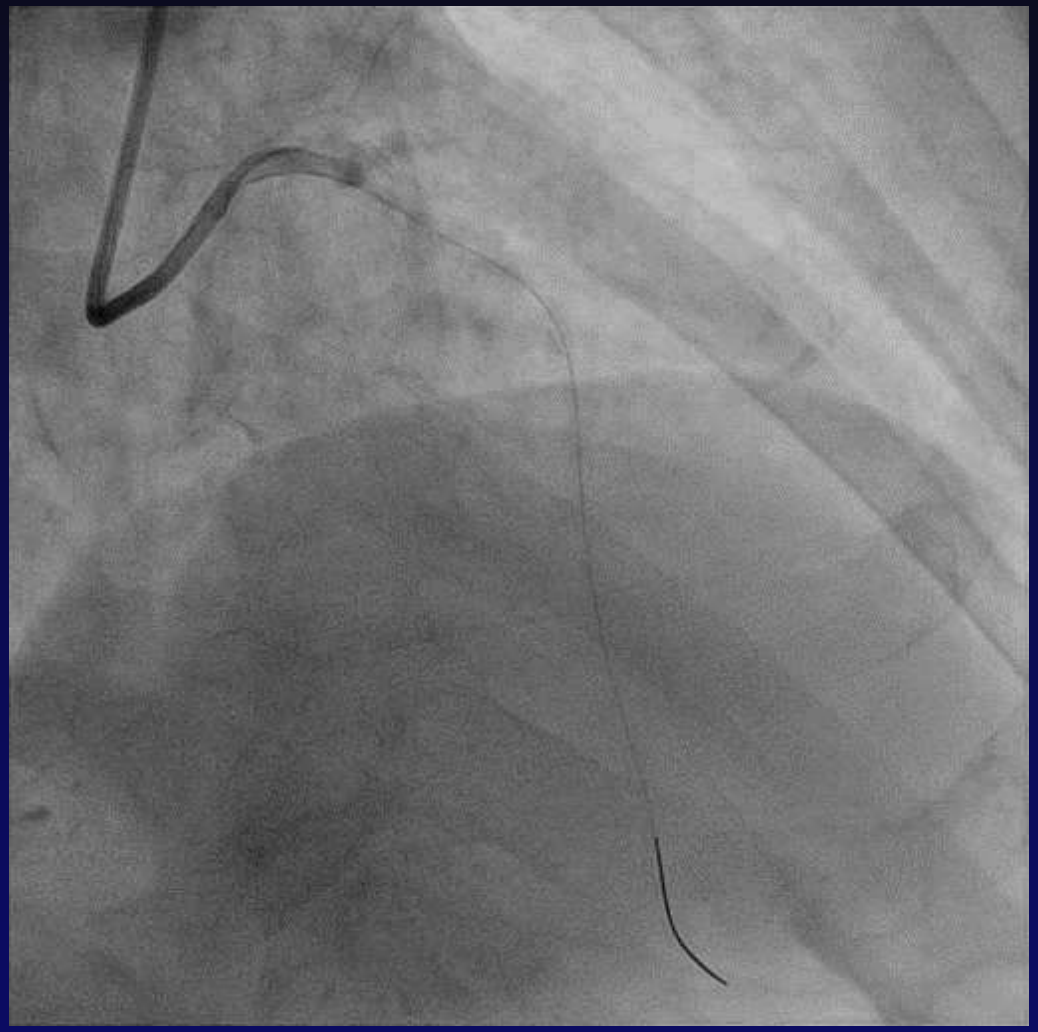
(BP-EES ≒ PtCr-EES ≒ O-SES ≒ Dual DES ≒ CoCr-EES)
> (ZES-R ≥ BP-BES ≥ SES) > (E-ZES) > (BVS ≥ PES ≥ BMS)

Kang SH, JACC Cardiovasc Interv. 2016

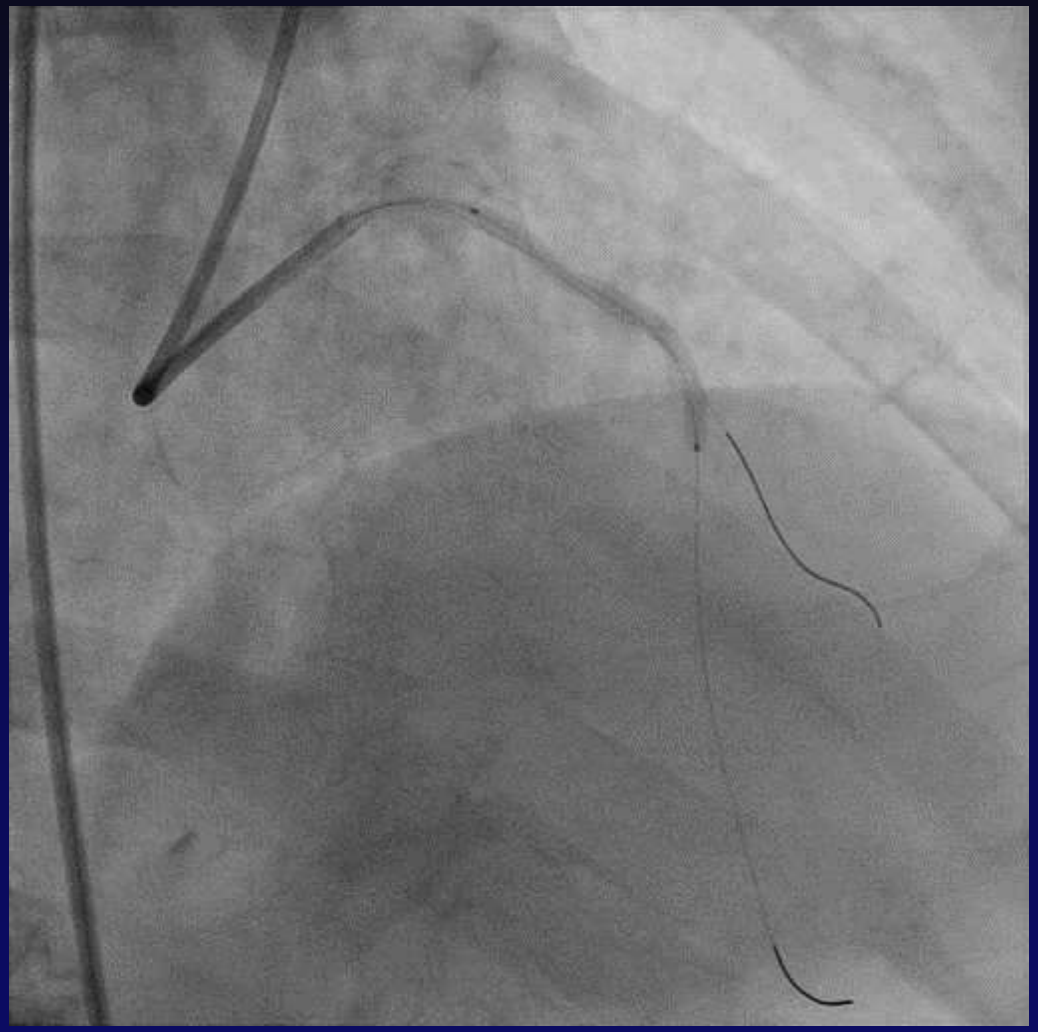
Case 1 – STEMI



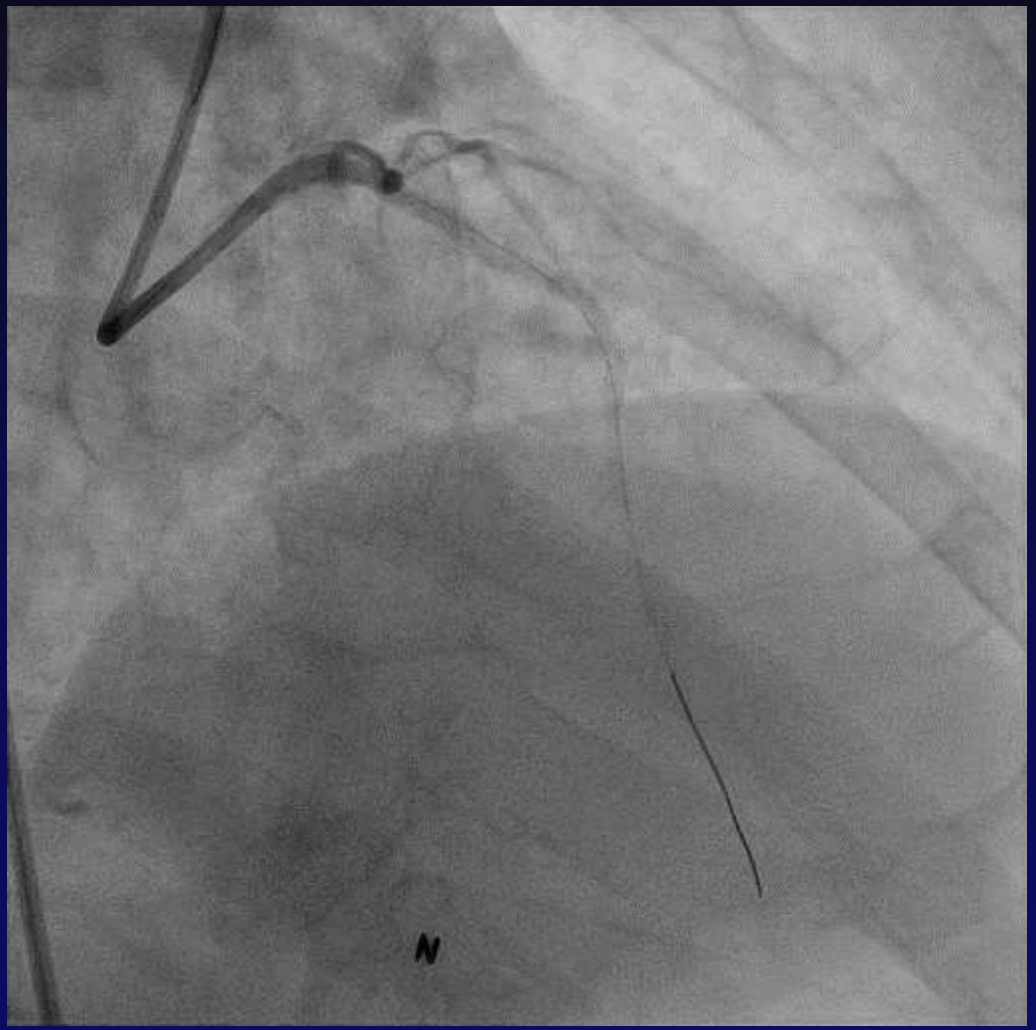
Case 1 – diffuse long lesion



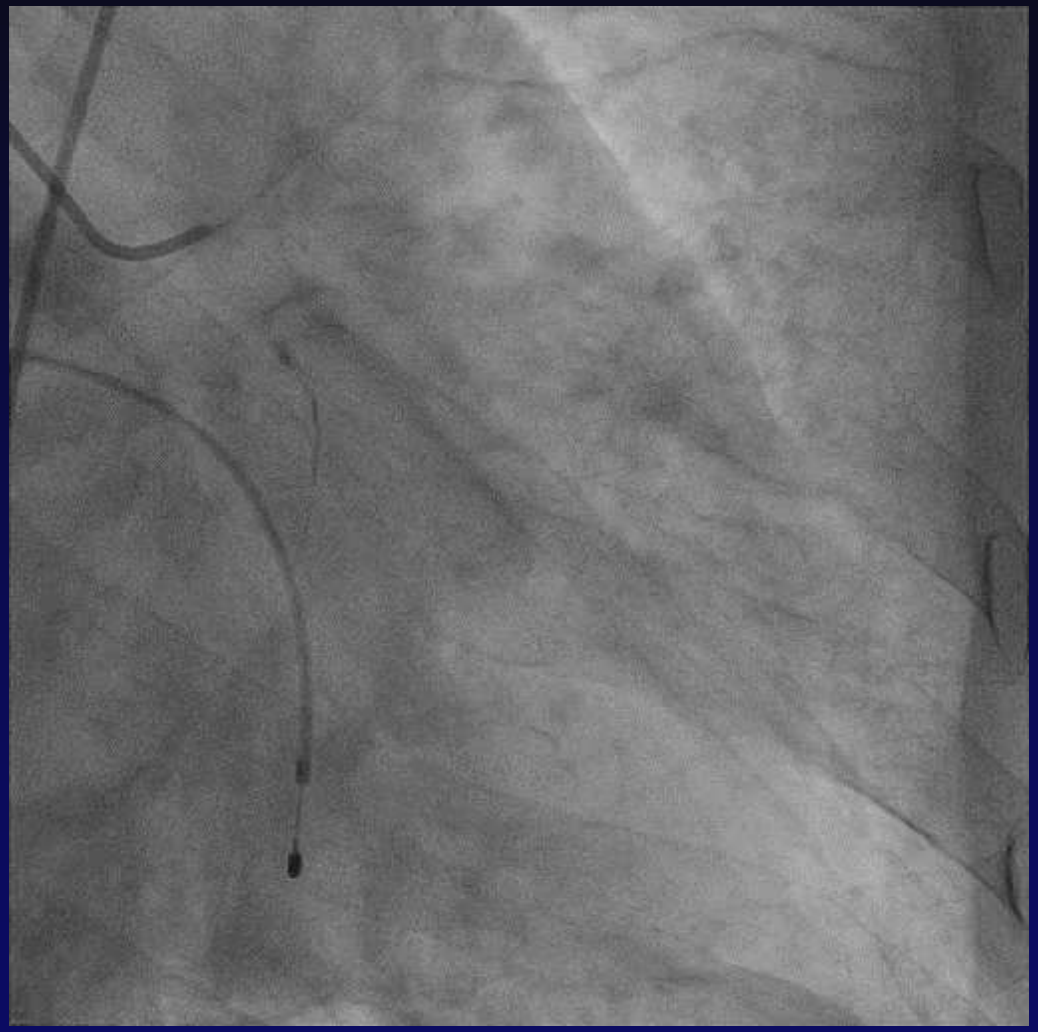
Case 1 – Stenting with Orsiro 2.75x40mm



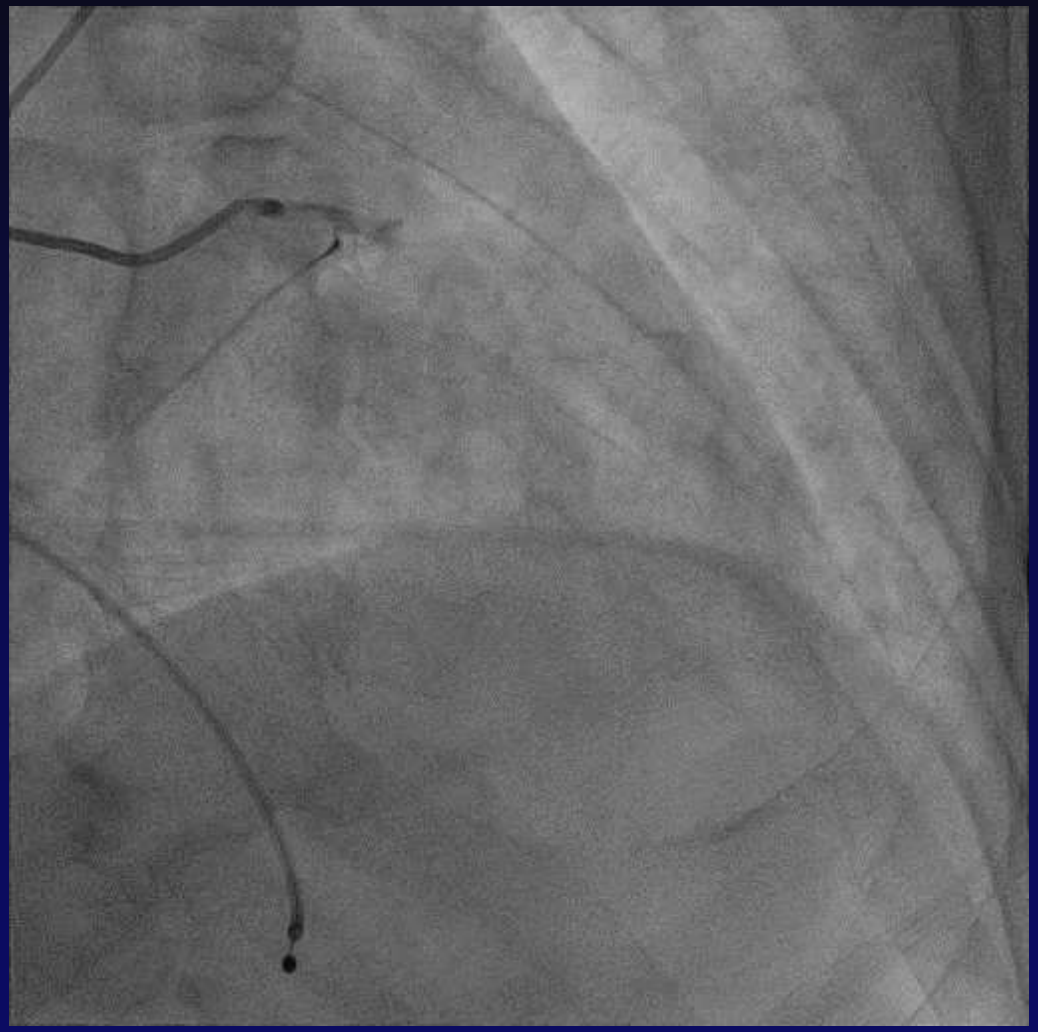
Case 1 – Good acute gain and flow



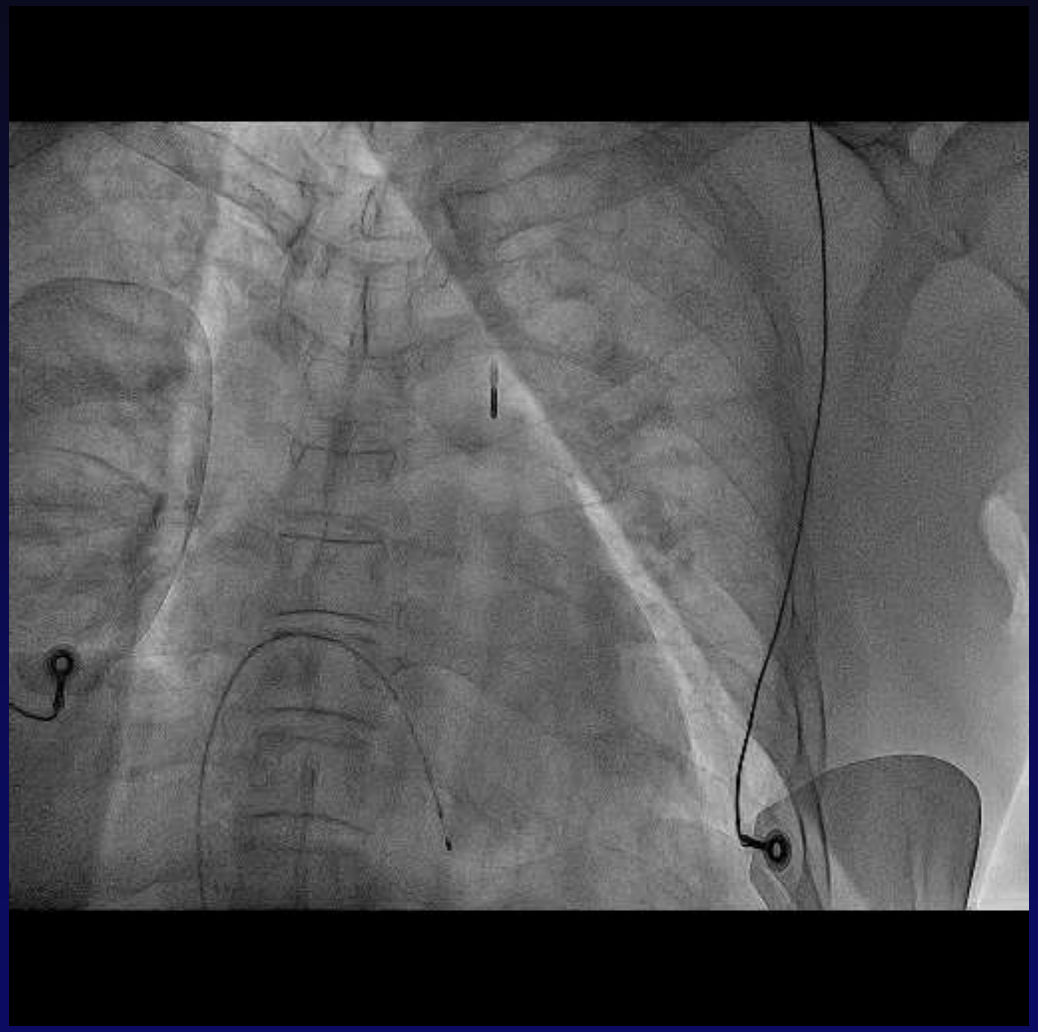
Case 2 – Cardiogenic shock, multivessel disease



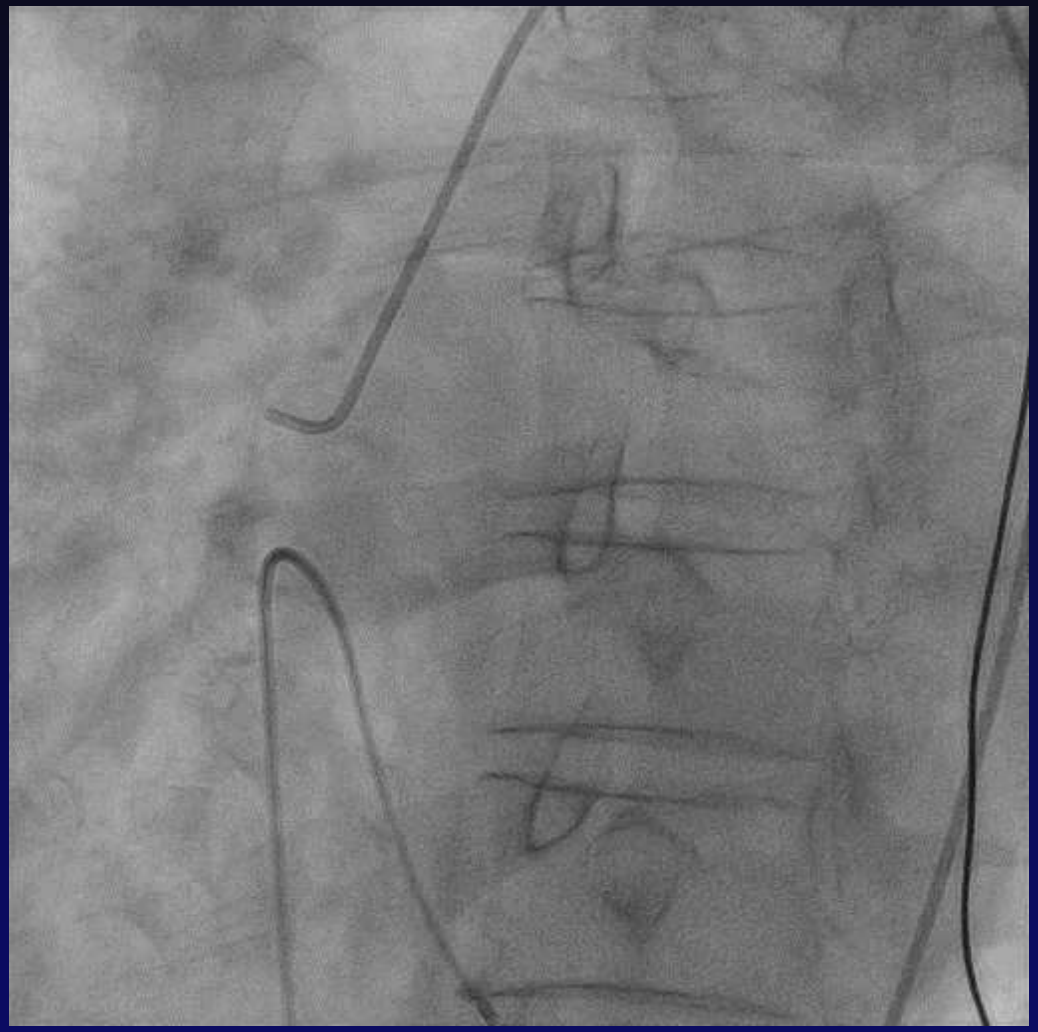
Case 2 – occlusion of dominant LCX and critical stenosis in LAD



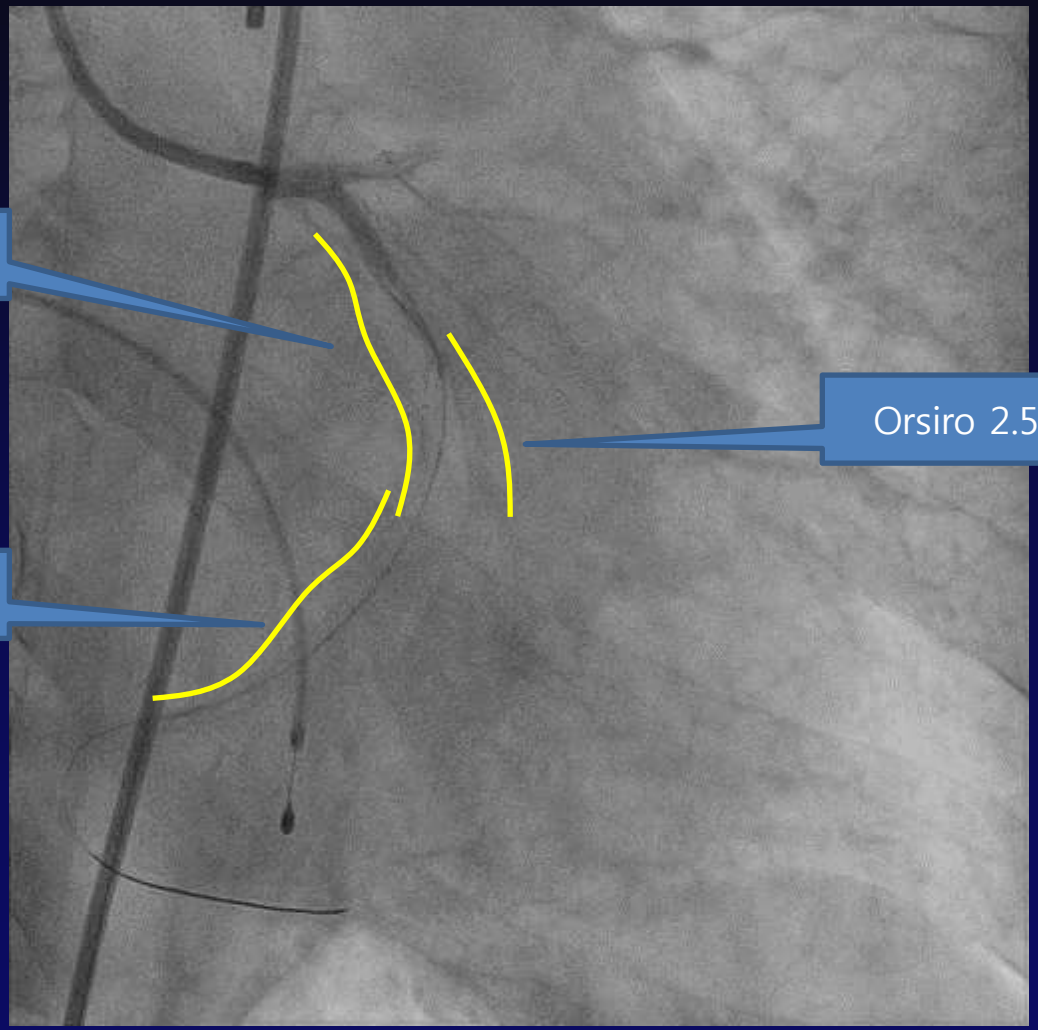
Case 2 – Unstable patient's hemodynamic status



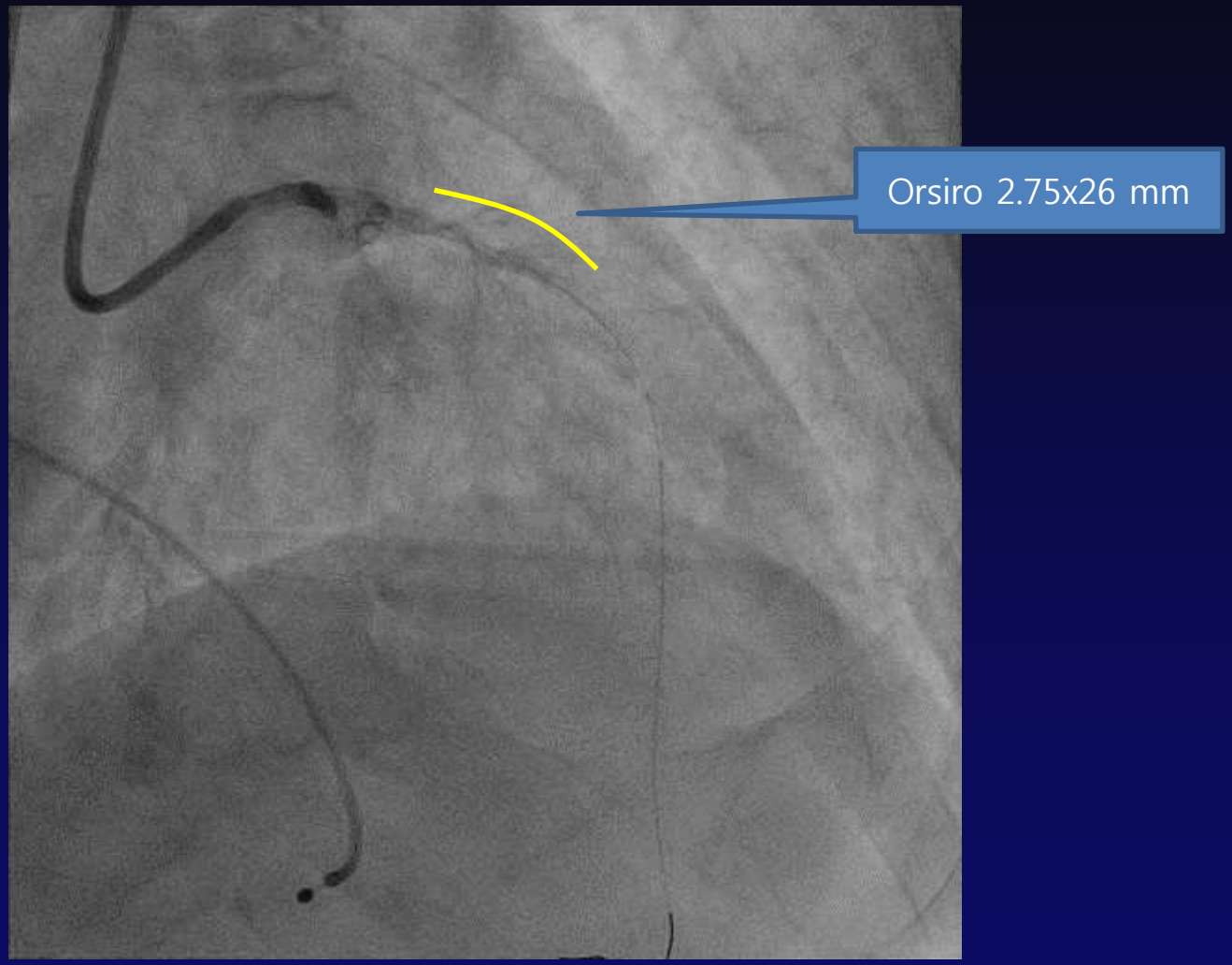
Case 2 – hypoplastic RCA



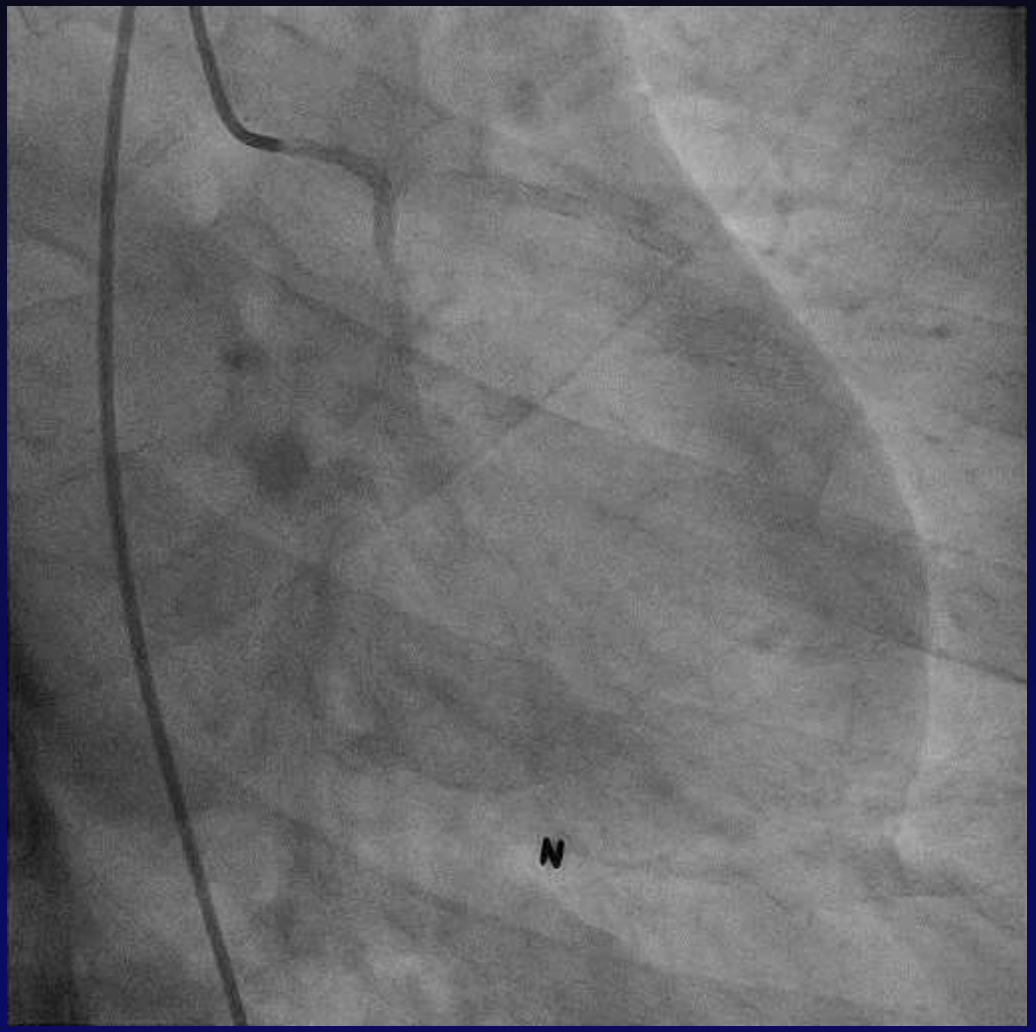
Case 2 – Three stenting to the large LCX



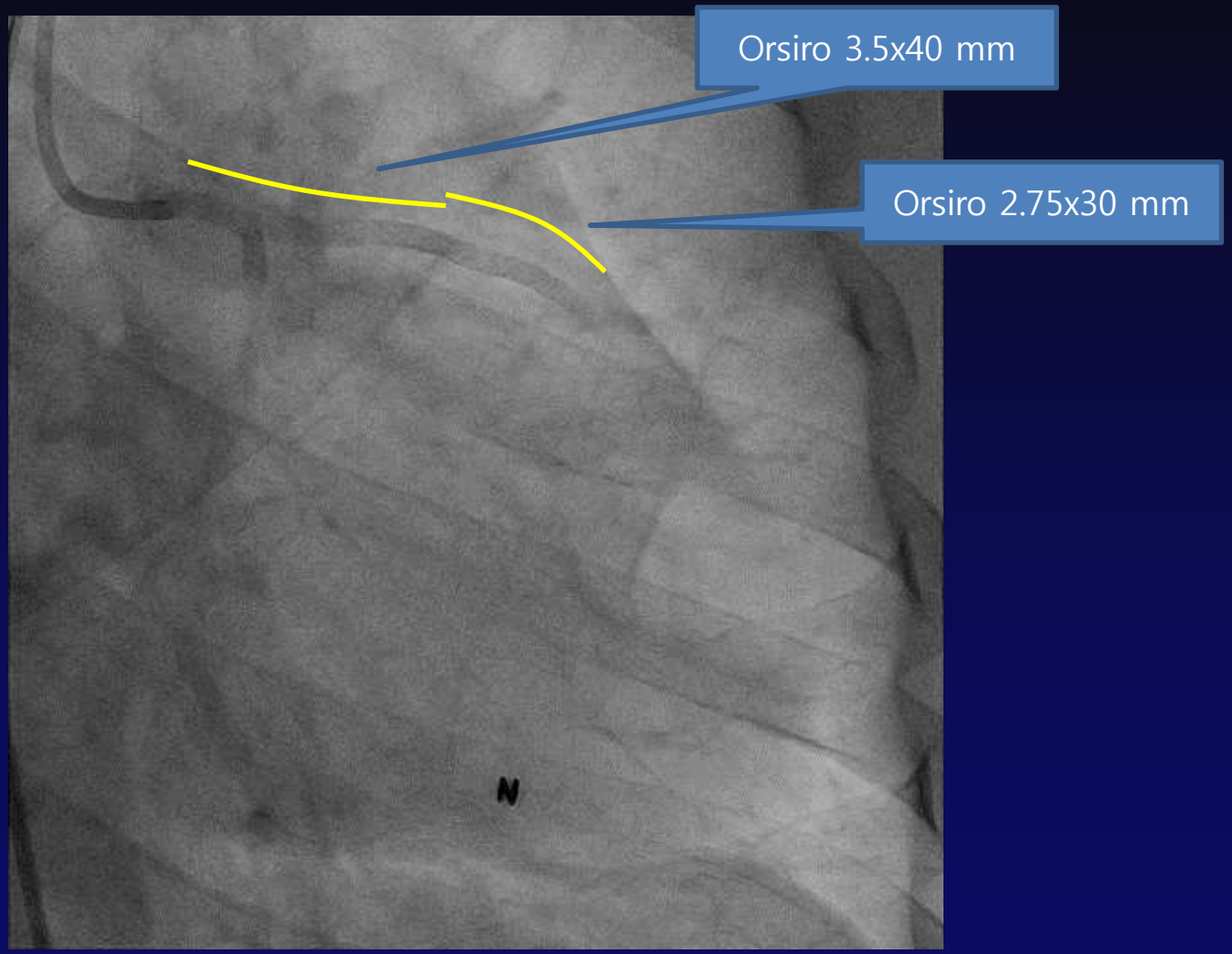
Case 2 – Reliable technical & procedural success rate → Reliable PCI device in high risk PCI casese



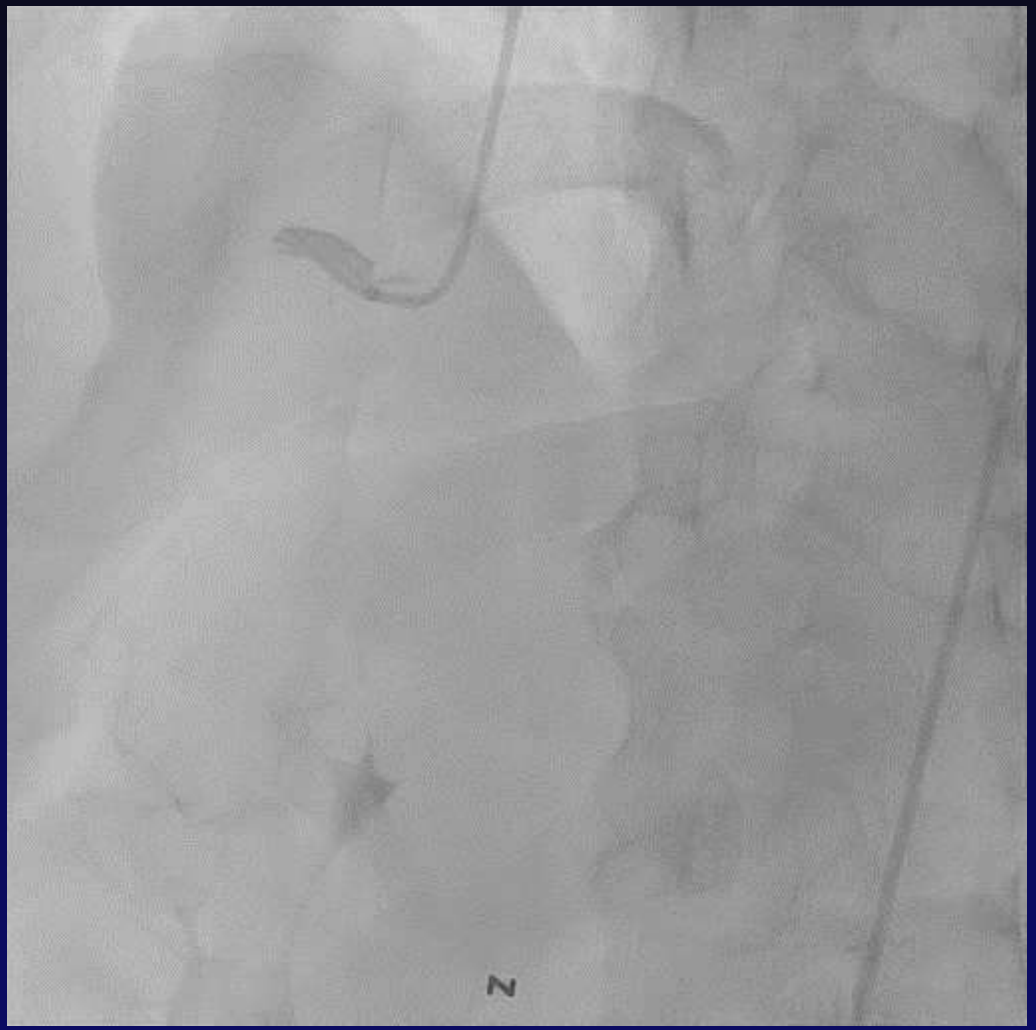
Case 3 – CTO, in-stent occlusion involving LM bifurcation



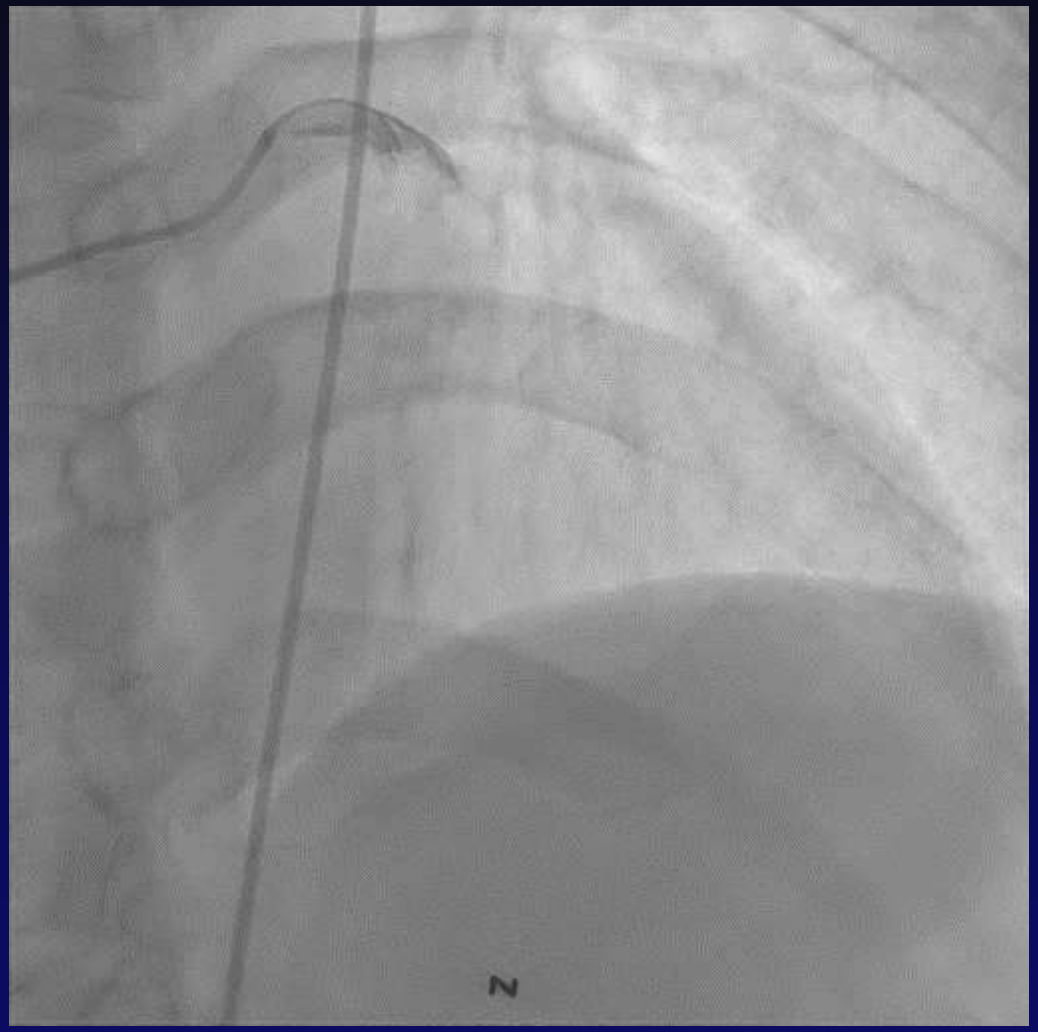
Case 3 – Reliable procedural success rate in complex PCI



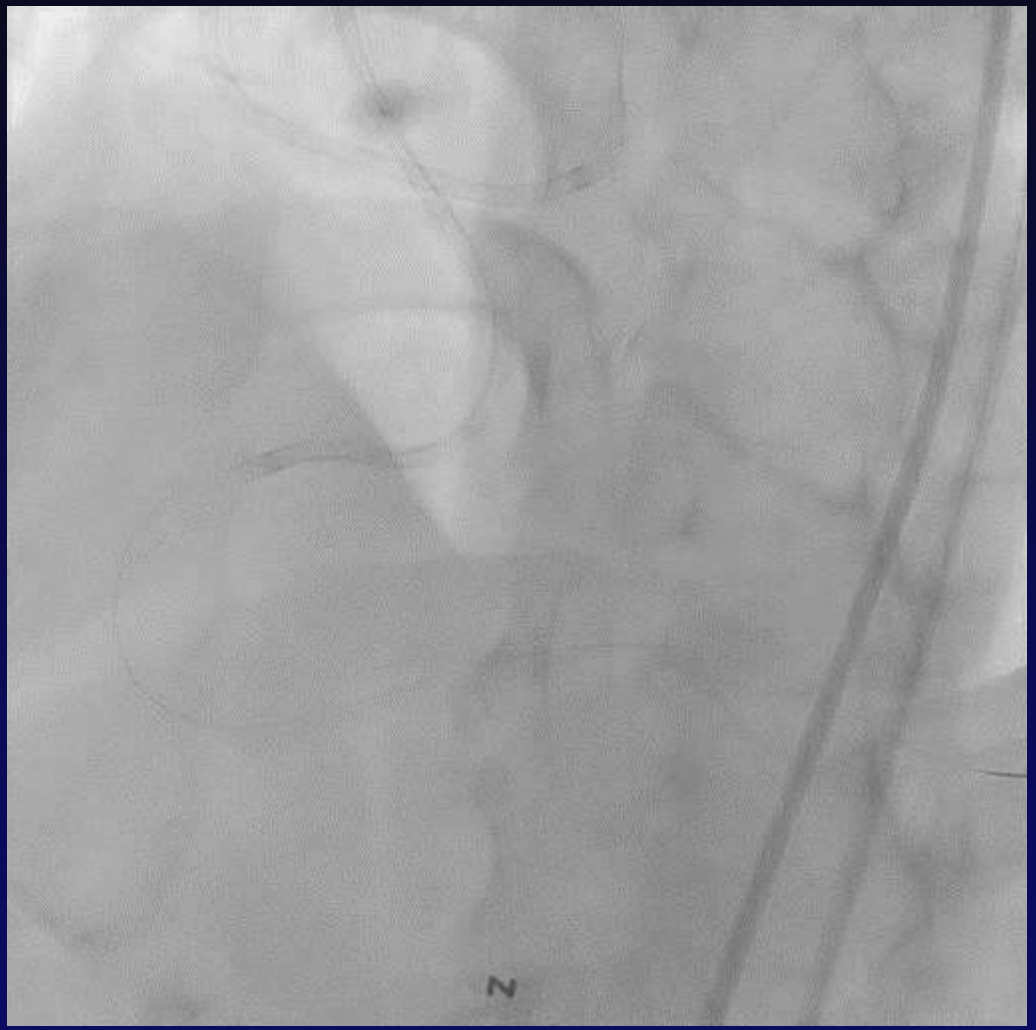
Case 4 – diffuse long thrombotic lesion



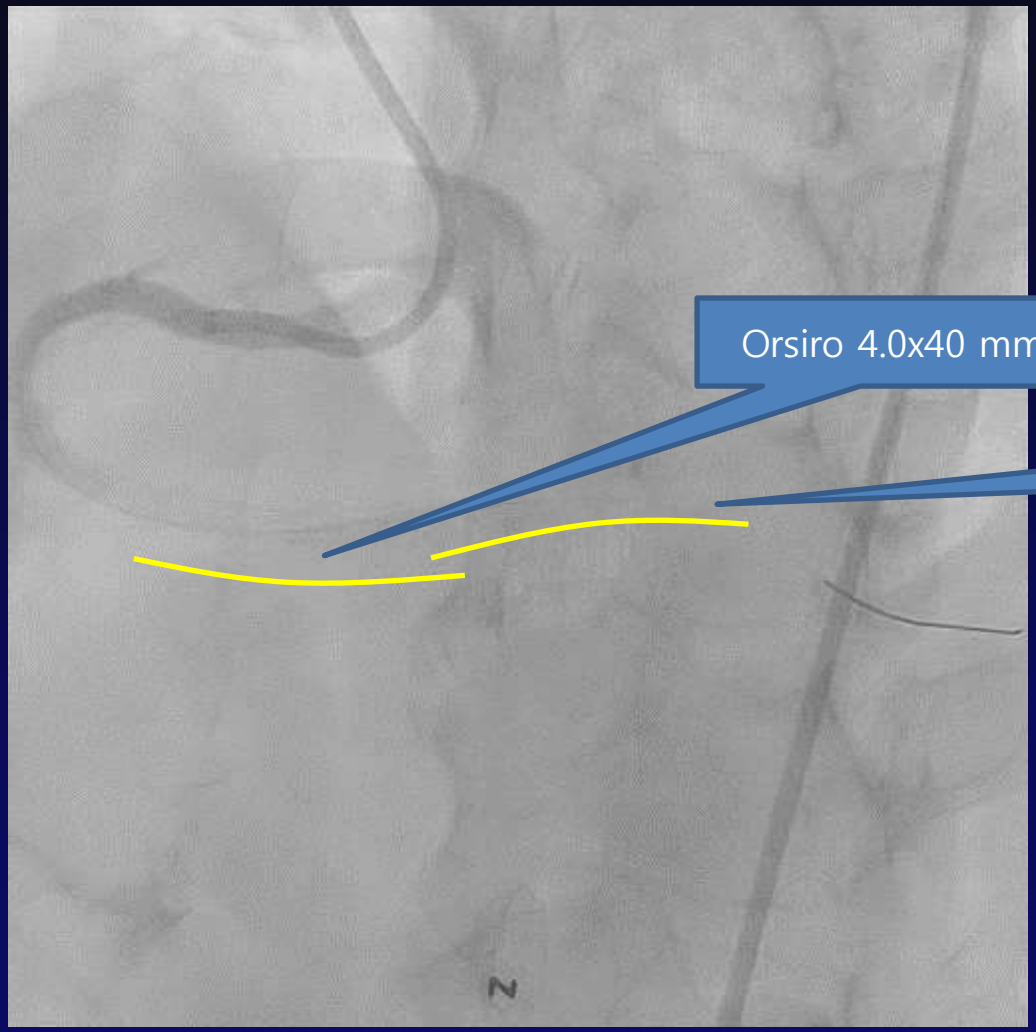
Case 4 – chronic total occlusion with a large distal bed



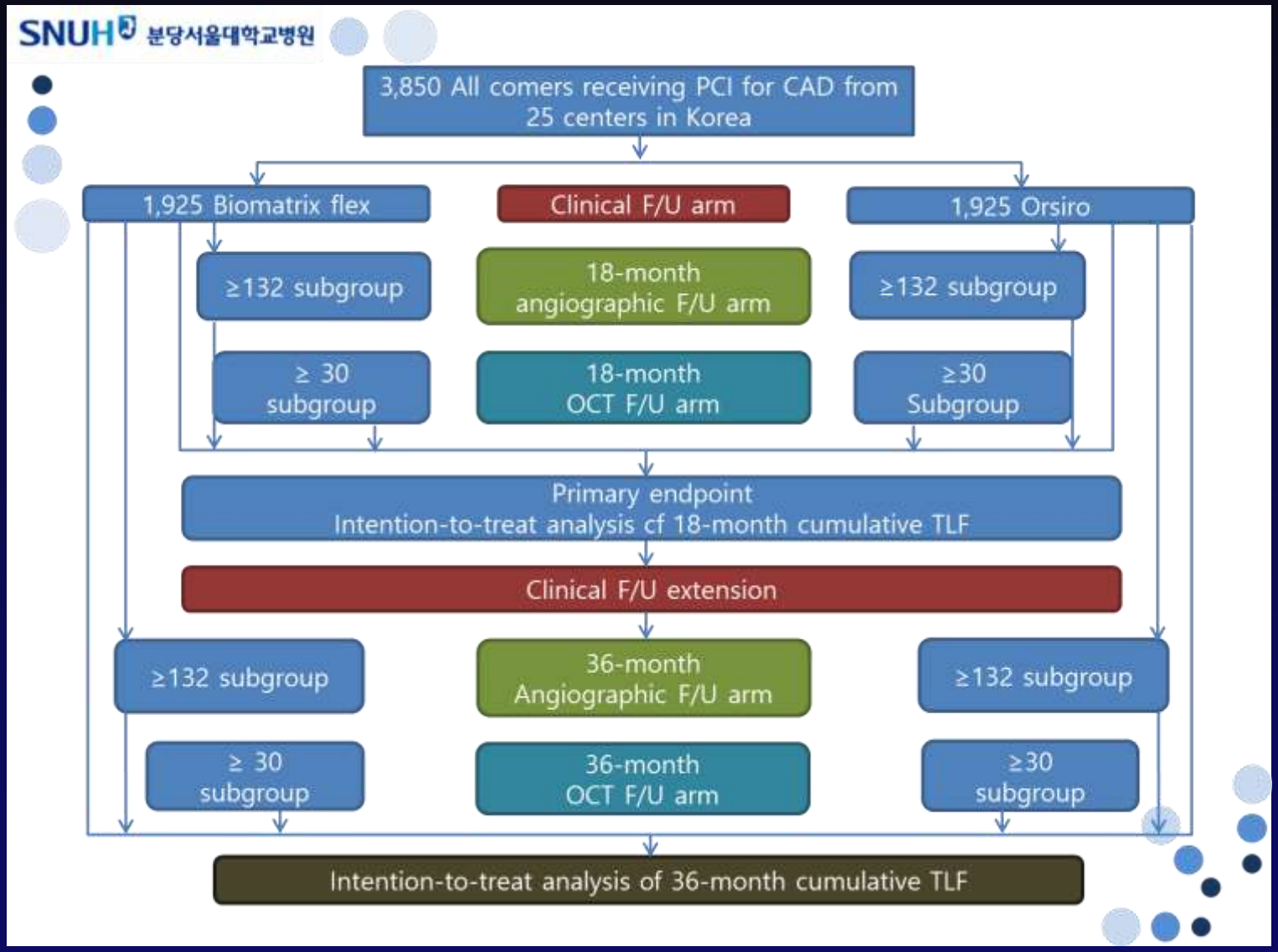
Case 4 – diffuse, long lesion with a large diameter



Case 4 – Just stent it ! With Orsiro



Ongoing RCT – BIODEGRADE



Current enrollment 2,120

Thank you for your attention