



XIV Jornadas SOLACI **5º Región Cono Sur**

Stents Coronarios
Cuándo, cómo y por qué
según la situación clínica?



HOSPITAL ITALIANO
de Buenos Aires

*Instituto de Medicina
Cardiovascular*

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Conflicto de intereses

- ❑ *Conferencista*

Boston Scientific, Biosensors, Cordis, Terumo

- ❑ *Asesor*

Cordis

- ❑ *Fondos para investigación*

Cordis, Eurocor

- ❑ *Programas de entrenamiento y educación*

Biosensors, Cordis, Terumo

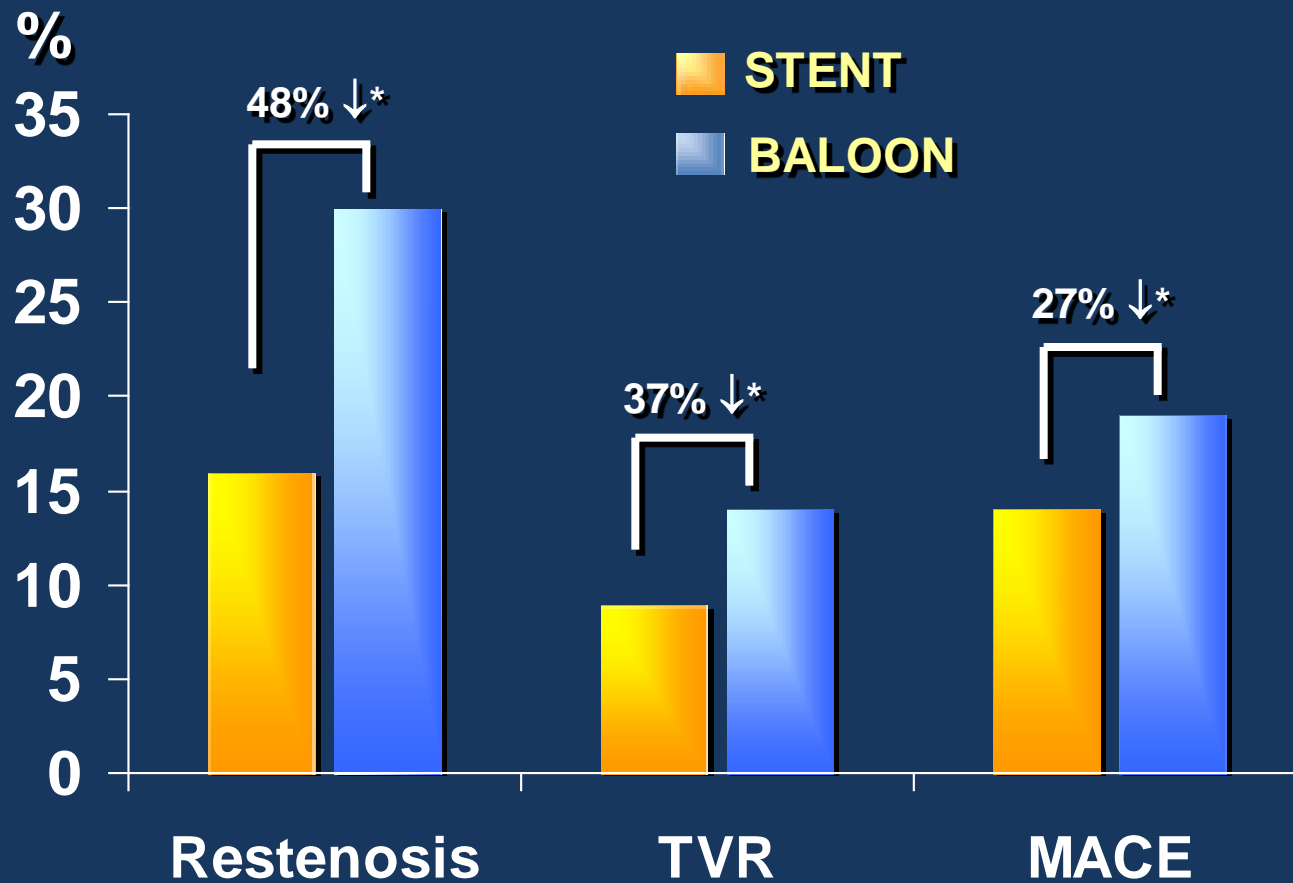
Que problemas queremos resolver con los stents?

- ✓ Cobertura y soporte mecanico de la placa
- ✓ Recrear el lumen mas grande posible
- ✓ Contener disecciones
- ✓ Prevenir oclusiones agudas
- ✓ Reducir la reestenosis

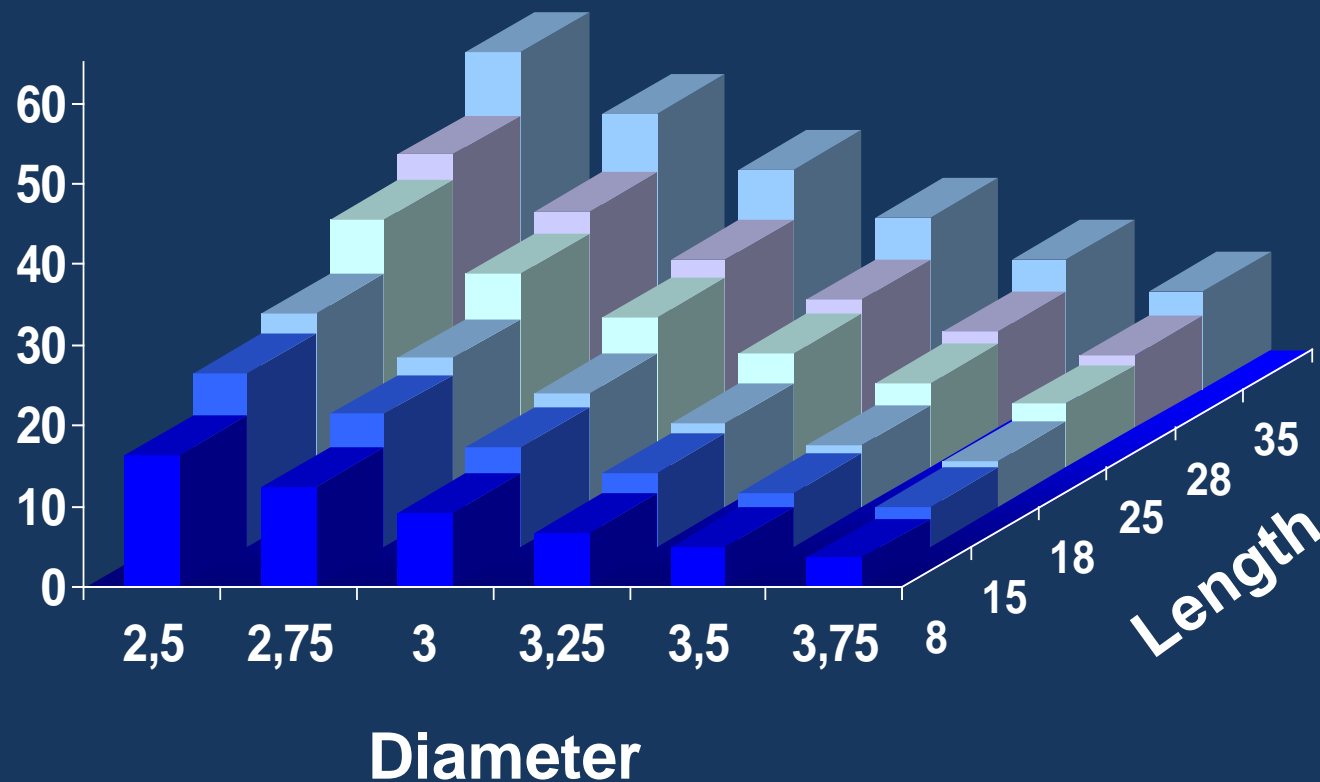
Que problemas podemos provocar con los stents?

- ✓ Trombosis
- ✓ Riesgo hemorragico

BENESTENT II study trial

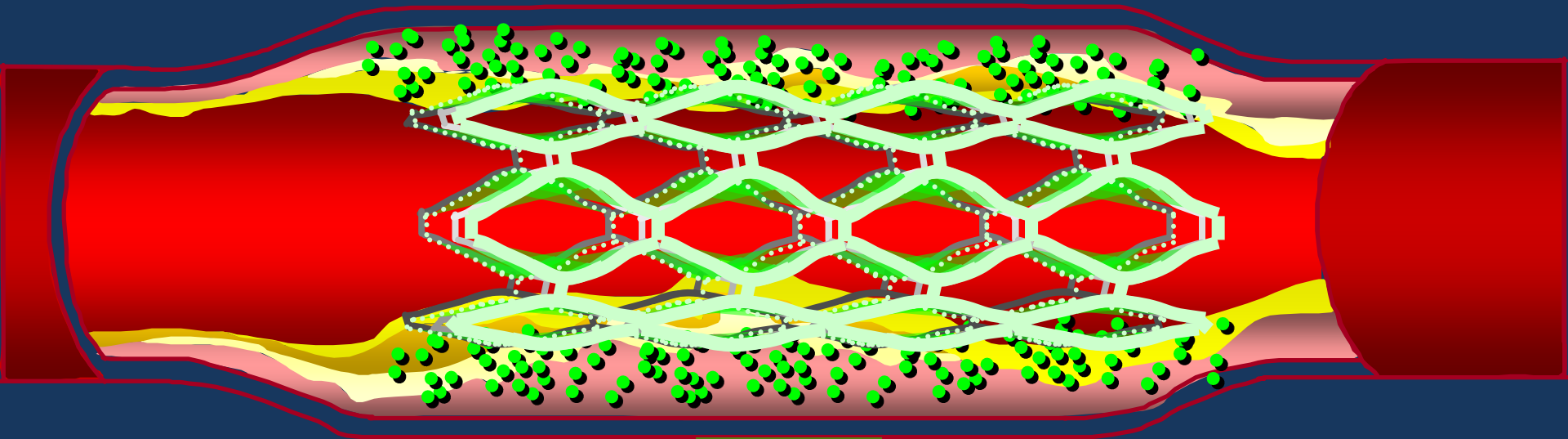


Restenosis prediction



Kereiakes D et al. Usefulness of stent length in predicting in-stent restenosis (the MULTI-LINK stent trials). Am J Cardiol 2000 Aug 1;86(3):336-41

WHAT DOES IT MEANS DRUG ELUTING STENT?



PLATFORM

DRUG

POLYMER

NEW CONCEPT IN ENDOVASCULAR THERAPEUTIS

Inflammation

Thrombosis

Migration

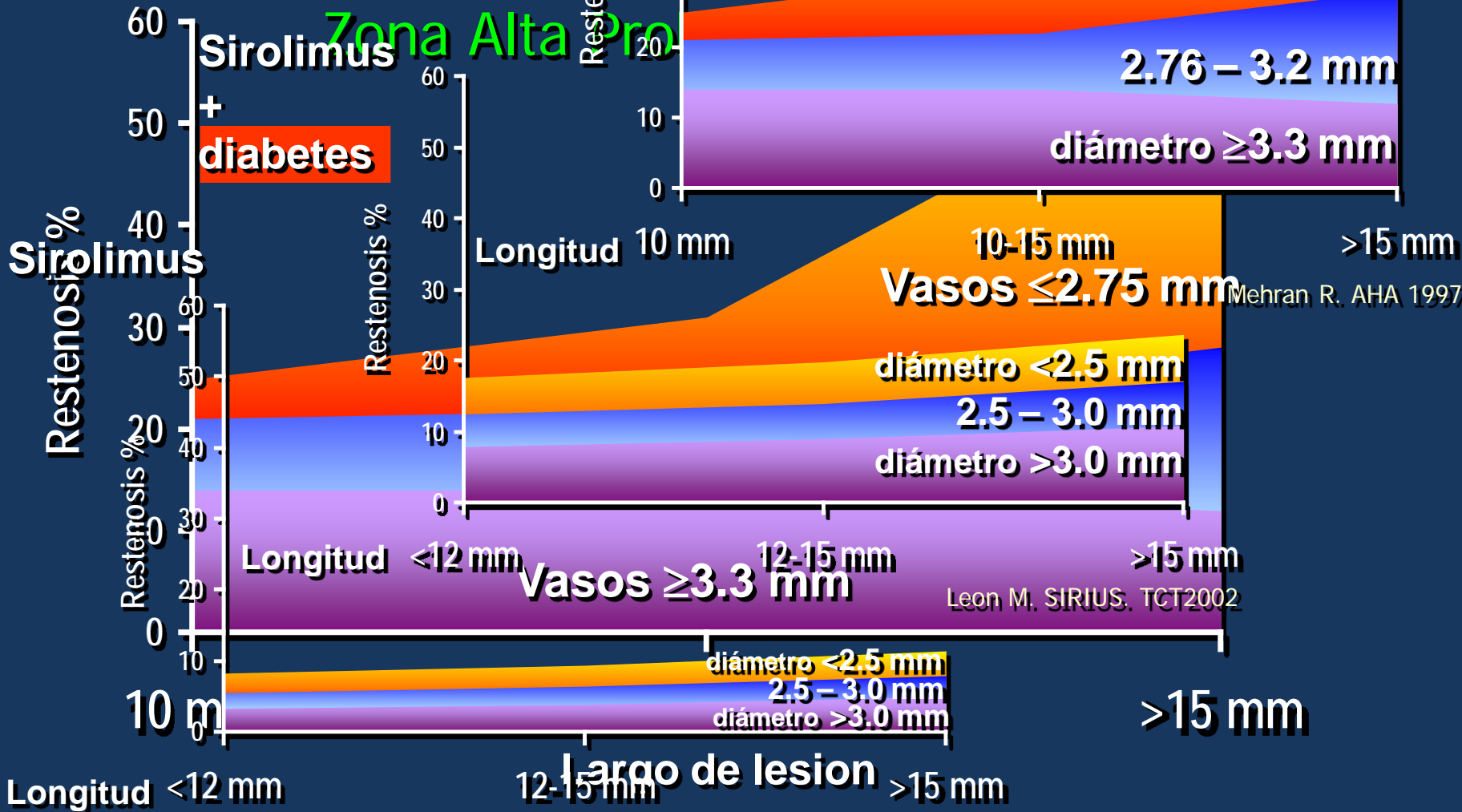
Proliferation

Reestenosis versus tamaño de vaso y largo de lesión

Stent



Zona Alta Pro



Sirolimus

+ diabetes

Sirolimus

Restenosis %

Restenosis %

Restenosis %

Longitud 10 mm

Vasos ≤ 2.75 mm

diámetro < 2.5 mm

2.5 – 3.0 mm

diámetro > 3.0 mm

Longitud < 12 mm

Vasos ≥ 3.3 mm

12-15 mm

> 15 mm

Leon M. SIRIUS. TCT2002

Longitud < 12 mm

Largo de lesion

12-15 mm

> 15 mm

> 15 mm

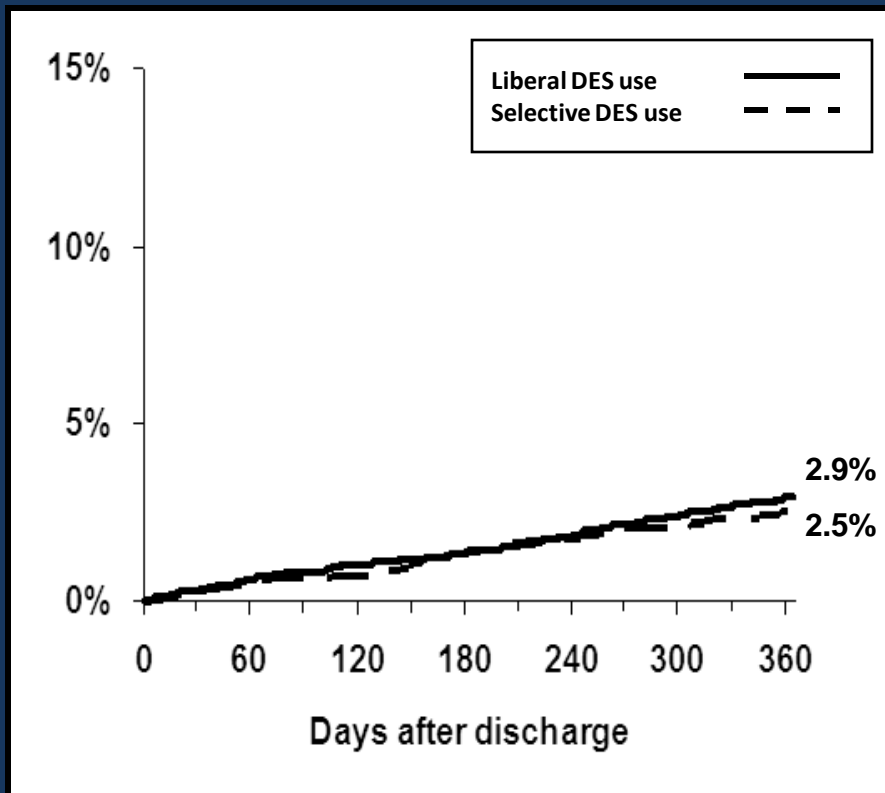
Leon M. SIRIUS. TCT2002

Mehran R. AHA 1997

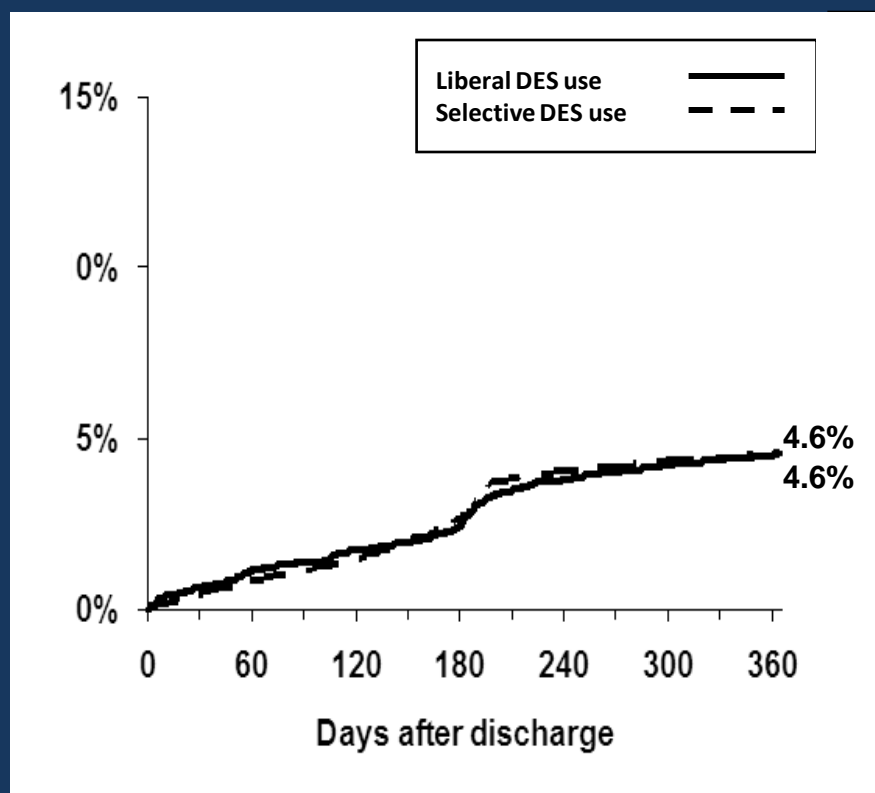


Clinical Outcomes: Death or MI

Death

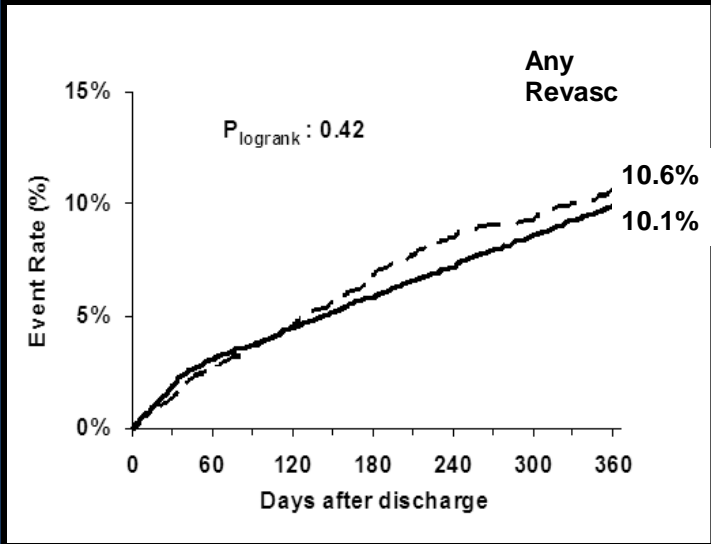
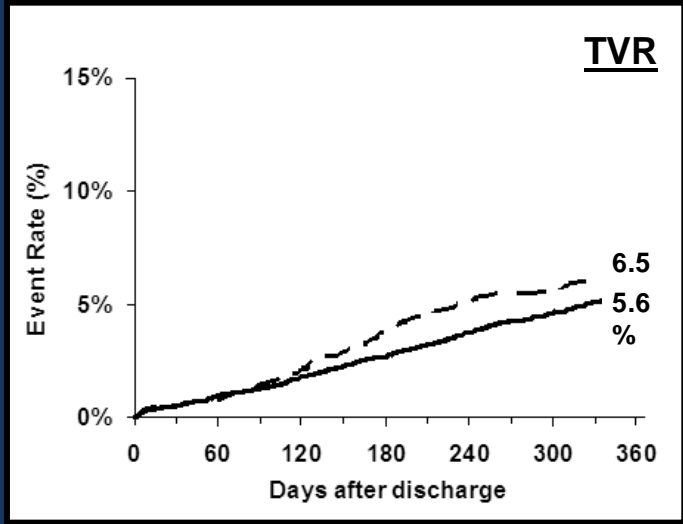
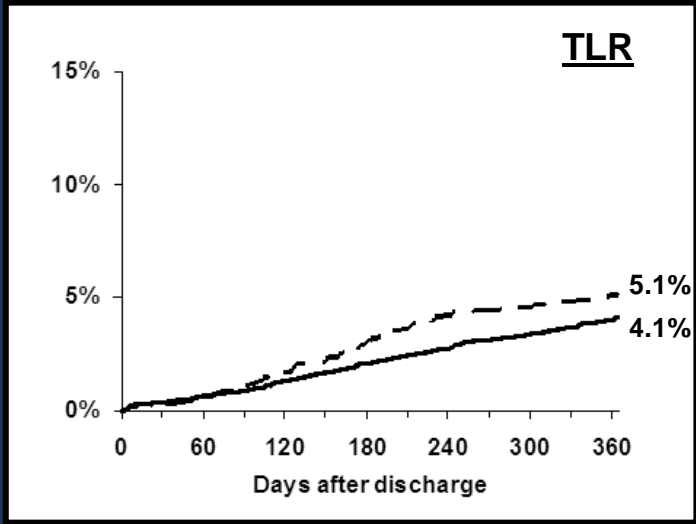


Death or MI





Clinical Outcomes: Repeat Revasc.



Liberal DES use 
 Selective DES use 

Proposed Guidelines for DES Use

Washington State

Any one of the following

- Stent diameter ≤ 3.0 mm
- Stent length ≥ 15 mm
- Treatment of in-stent restenosis
- Diabetes
- Unprotected LM stenosis

NICE (UK)

Any one of the following

- Vessel diameter < 3.0 mm
- Lesion length > 15 mm

Ontario

Diabetes plus

- Lesion length > 20 mm
- OR
- Vessel diam ≤ 2.75 mm

Implications of Guidelines for DES Utilization: *Ontario Tech Assessment*

Characteristic	Proportion of Lesions
Diabetes	35.2%
(A) Vessel diameter ≤ 2.75 mm	39.1%
(B) Lesion length > 20 mm	18.9%
Diabetes + (A or B)	18.7%

n = 3310 lesions

Implications of Guidelines for DES Utilization: *NICE Guidance*

Characteristic	Proportion of Lesions
Vessel diameter <3.0 mm	42.1%
Lesion length >15 mm	36.4%
Either of the above	61.8%

Implications of Guidelines for DES Utilization: *Washington State*

Characteristic	Proportion of Lesions
Stent diameter <3.0 mm	74.0%
Stent length >15 mm	70.2%
Treatment of ISR	6.6%
Diabetes	34.6%
Treatment of unprotected LM	0.8%
Any characteristic	93.4%

n=13,945 lesions

MEGAMETANALYSIS

Target-vessel revascularization

Study type	Patients, n	Trials, n	Relative risk	P*
RCT: all	7291	16	0.45	<0.001
RCT: on-label	4618	9	0.53	<0.001
RCT: off-label	2673	8	0.38	<0.001
Registries	73 819	17	0.53	<0.001

* Random-effects model

↓ 47 to 62%

MEGAMETANALYSIS

MI

Study type	Patients, n	Trials, n	Relative risk	p	
RCT: all	8850	20	0.94	0.54 ^a	
RCT: on-label	4318	9	1.03	0.82 ^a	
RCT: off-label	4532	12	0.77	0.19 ^b	↓ 23%
Registries	129 955	24	0.89	0.023 ^b	↓ 11%

a. Fixed-effects model
b. Random-effects model

Kirtane AJ, Stone GW. Comprehensive meta-analysis of DES vs BMS randomized trials and registries; March 28, 2008; Chicago, IL.

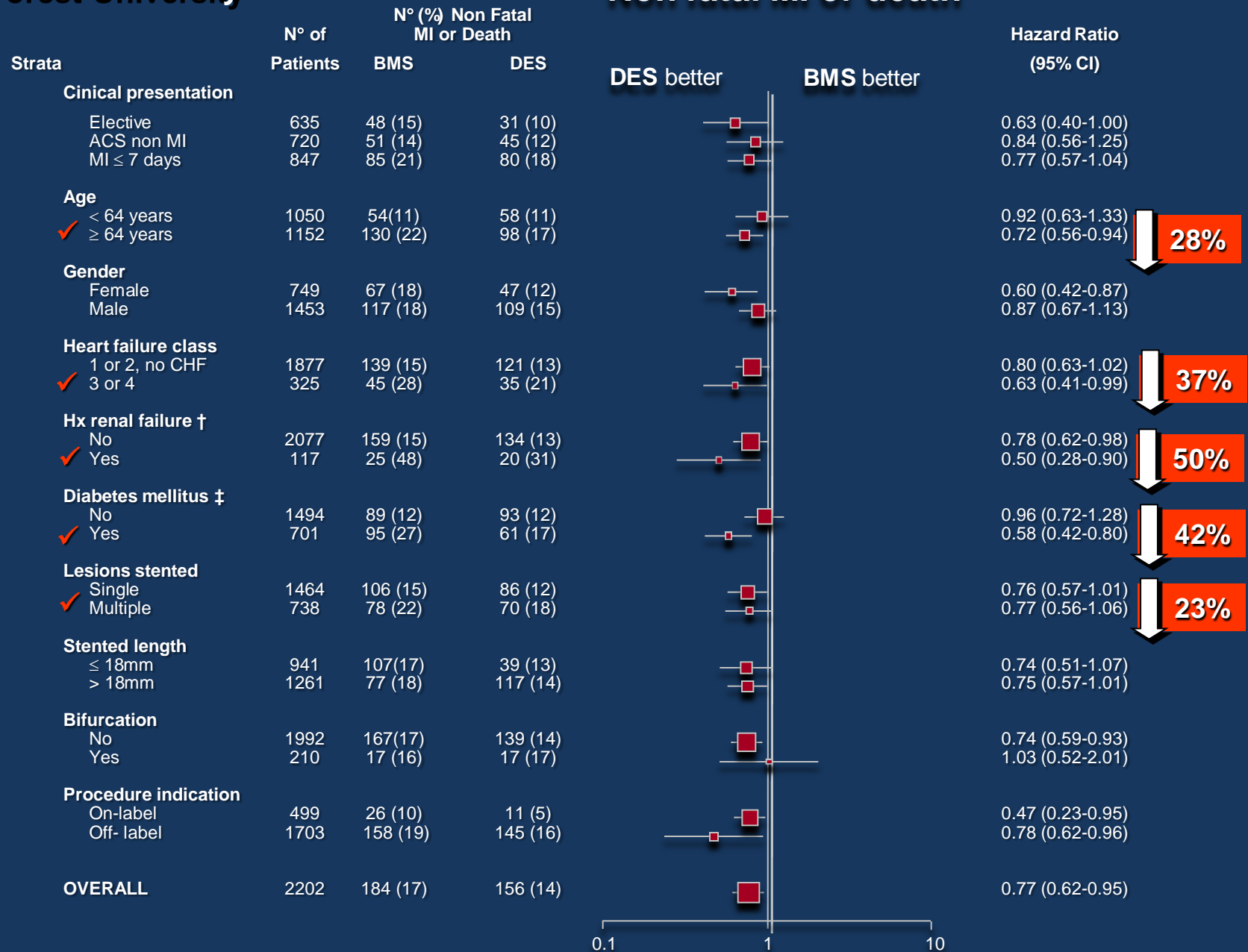
MEGAMETANALYSIS

All-cause mortality

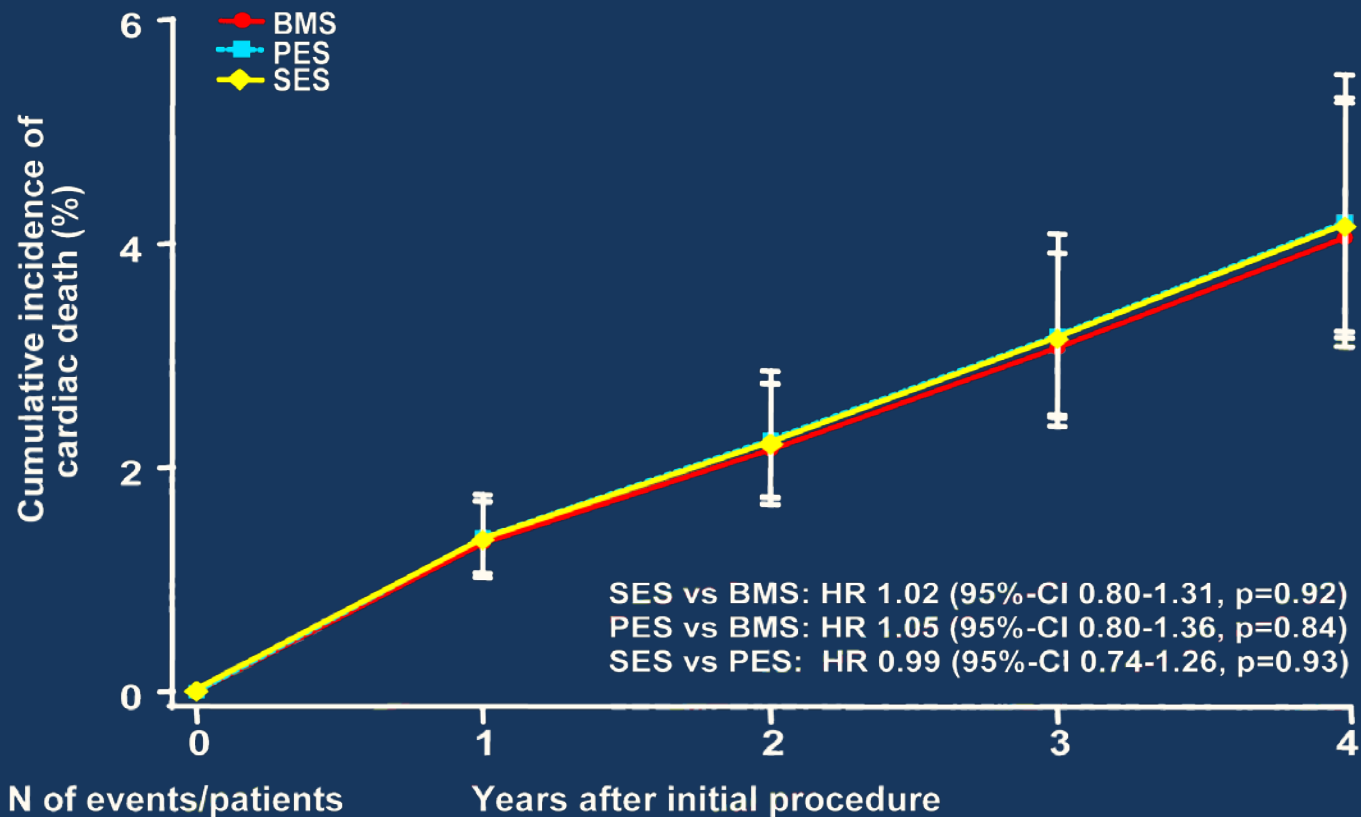
Study type	Patients, n	Trials, n	Relative risk	p
RCT: all	8867	21	0.97	0.72 ^a
RCT: on-label	4818	10	1.05	0.69 ^a
RCT: off-label	4049	12	0.84	0.24 ^a
Registries	161 232	28	0.80	<0.001 ^b ↓ 20%

a. Fixed-effects model

b. Random-effects model



Cumulative Incidence of Cardiac Death

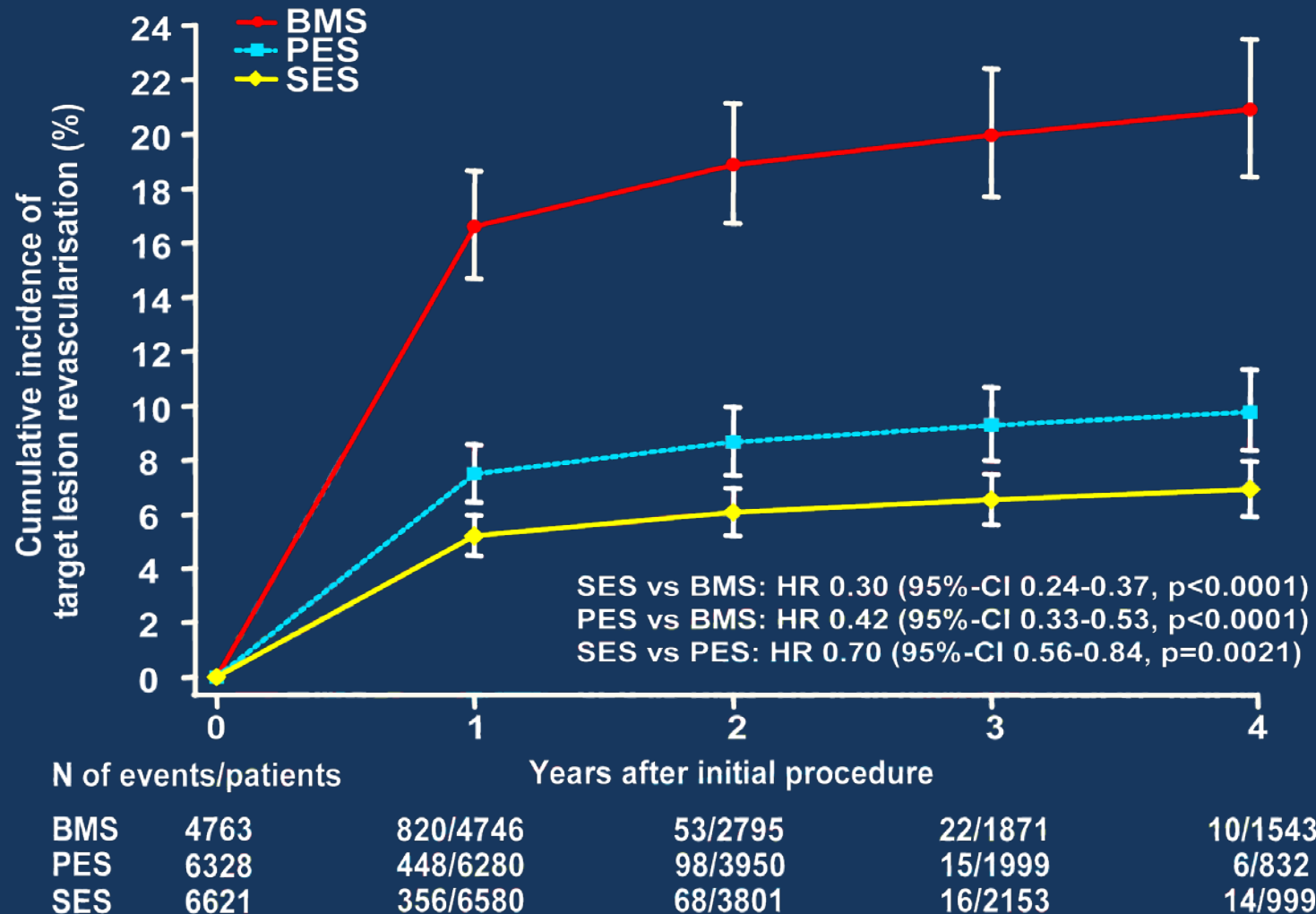


N of events/patients

Years after initial procedure

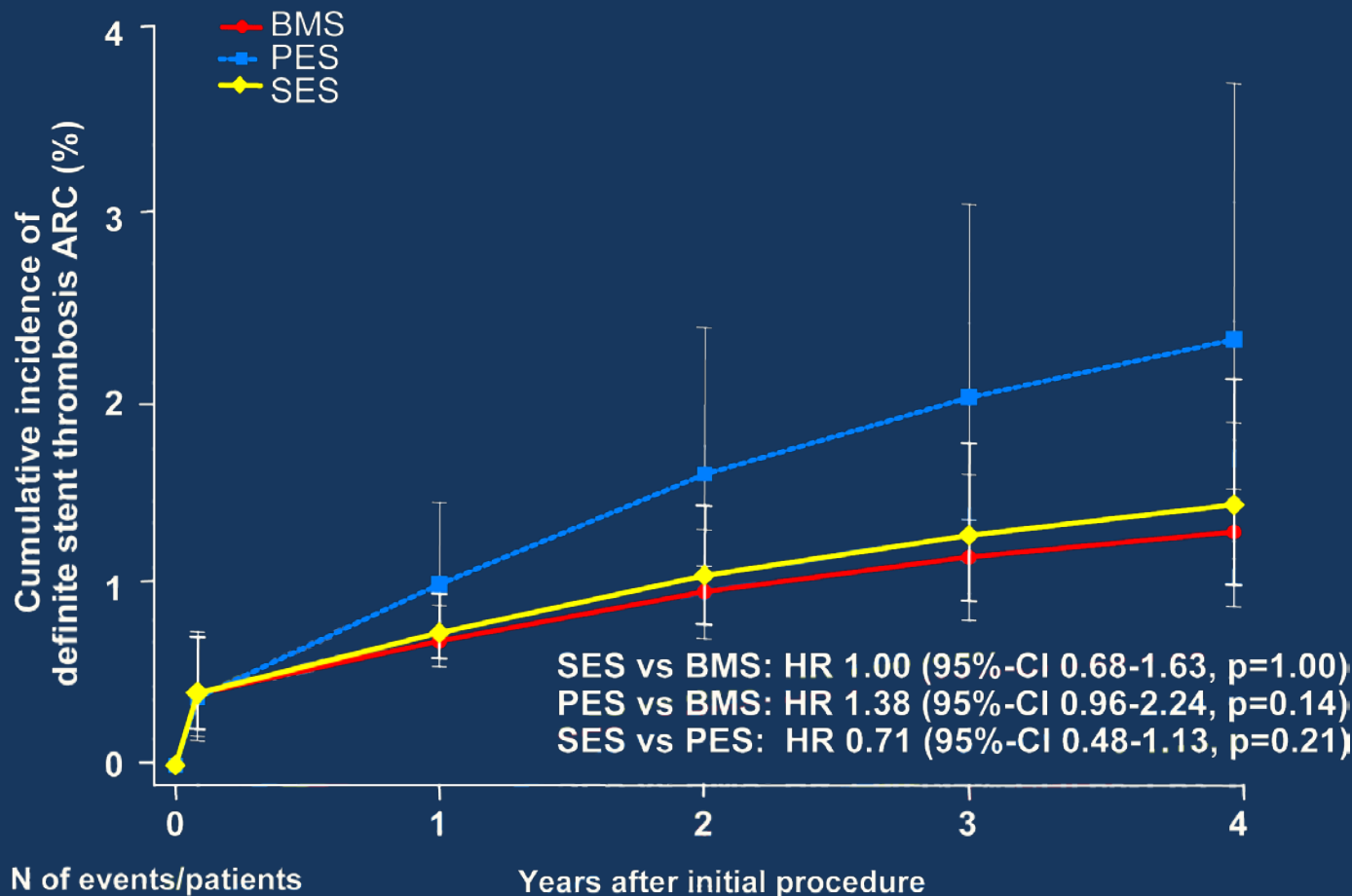
BMS	4763	78/4746	23/3310	13/2234	16/1845
PES	6300	97/6252	41/4232	13/2157	3/841
SES	6642	91/6601	34/4041	24/2340	14/1081

Cumulative Incidence of TLR



TVR was used as a proxy for 3 studies

Cumulative Incidence of ARC Definite Stent Thrombosis



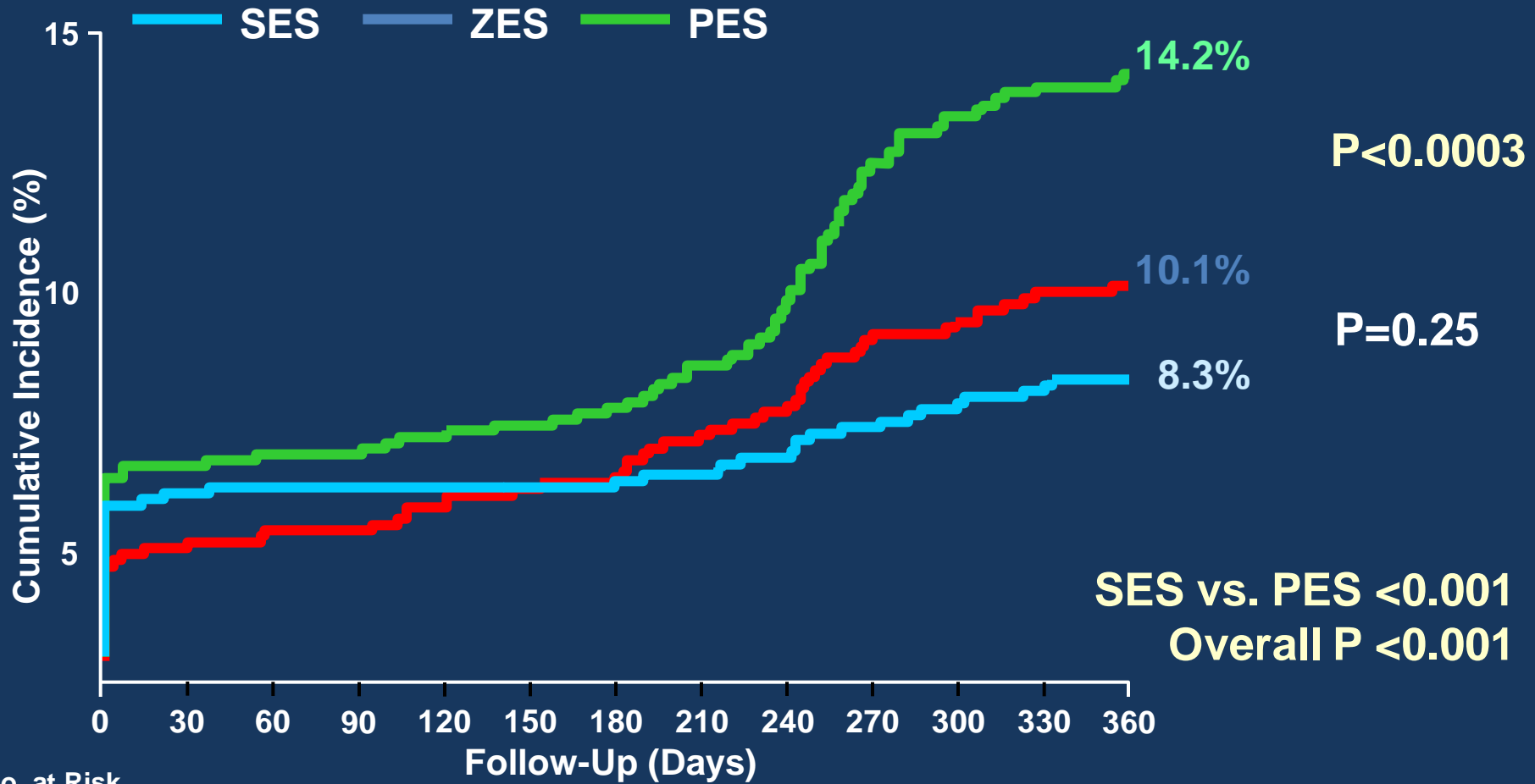
N of events/patients

Years after initial procedure

BMS	4003	42/4000	4/3048	3/1928	1/1806
PES	4327	46/4321	20/3711	5/1853	1/762
SES	4643	52/4642	9/3804	3/2257	2/1070

Death, MI, Ischemia-driven TVR

Primary End Point at 12 month

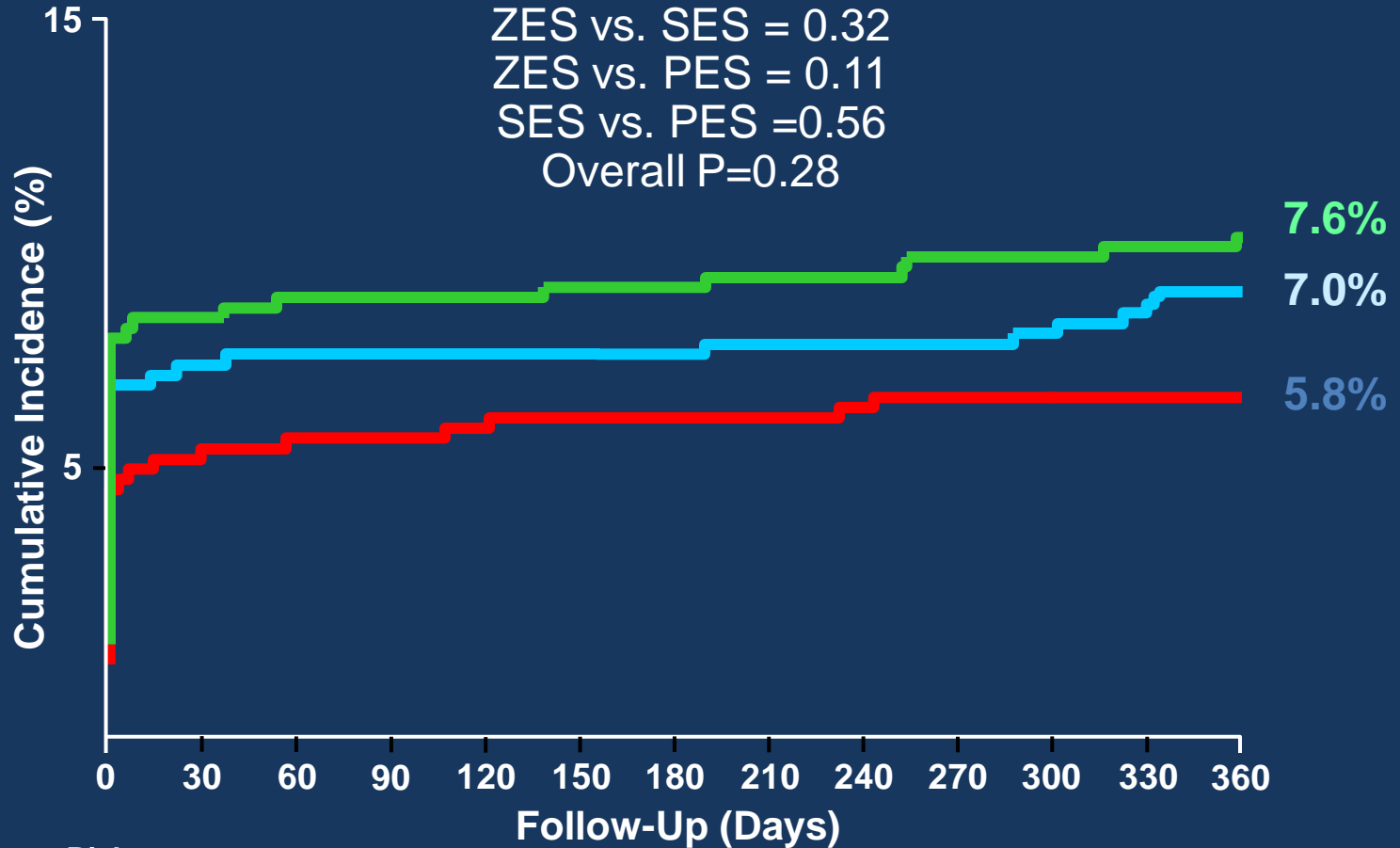


No. at Risk

ZES	883	827	816	790	782
SES	878	816	813	802	792
PES	884	821	808	763	745

Death or MI

— SES — ZES — PES

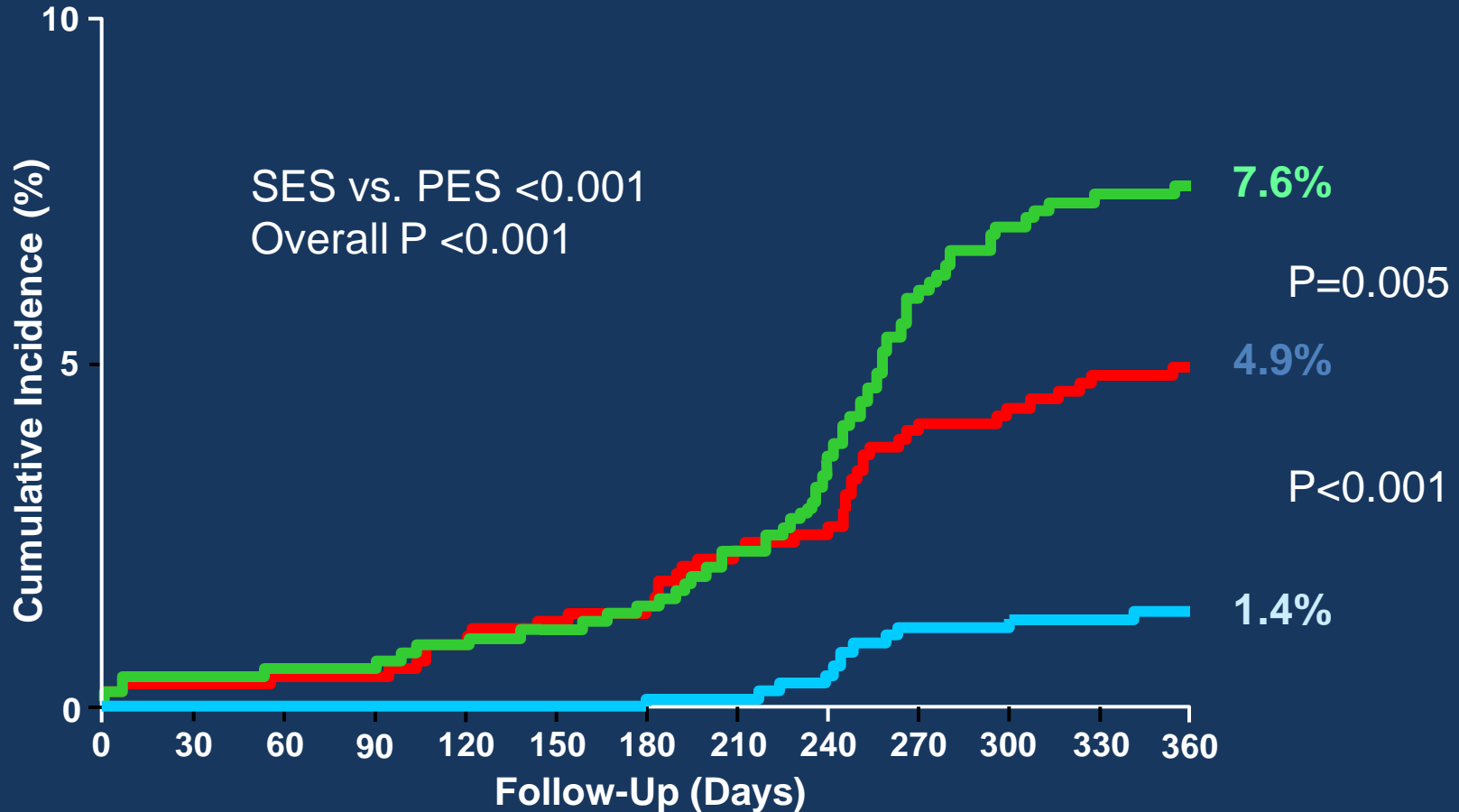


No. at Risk

ZES	883	828	824	820	820
SES	878	817	814	811	804
PES	884	821	815	808	803

Ischemic driven TLR

— SES — ZES — PES

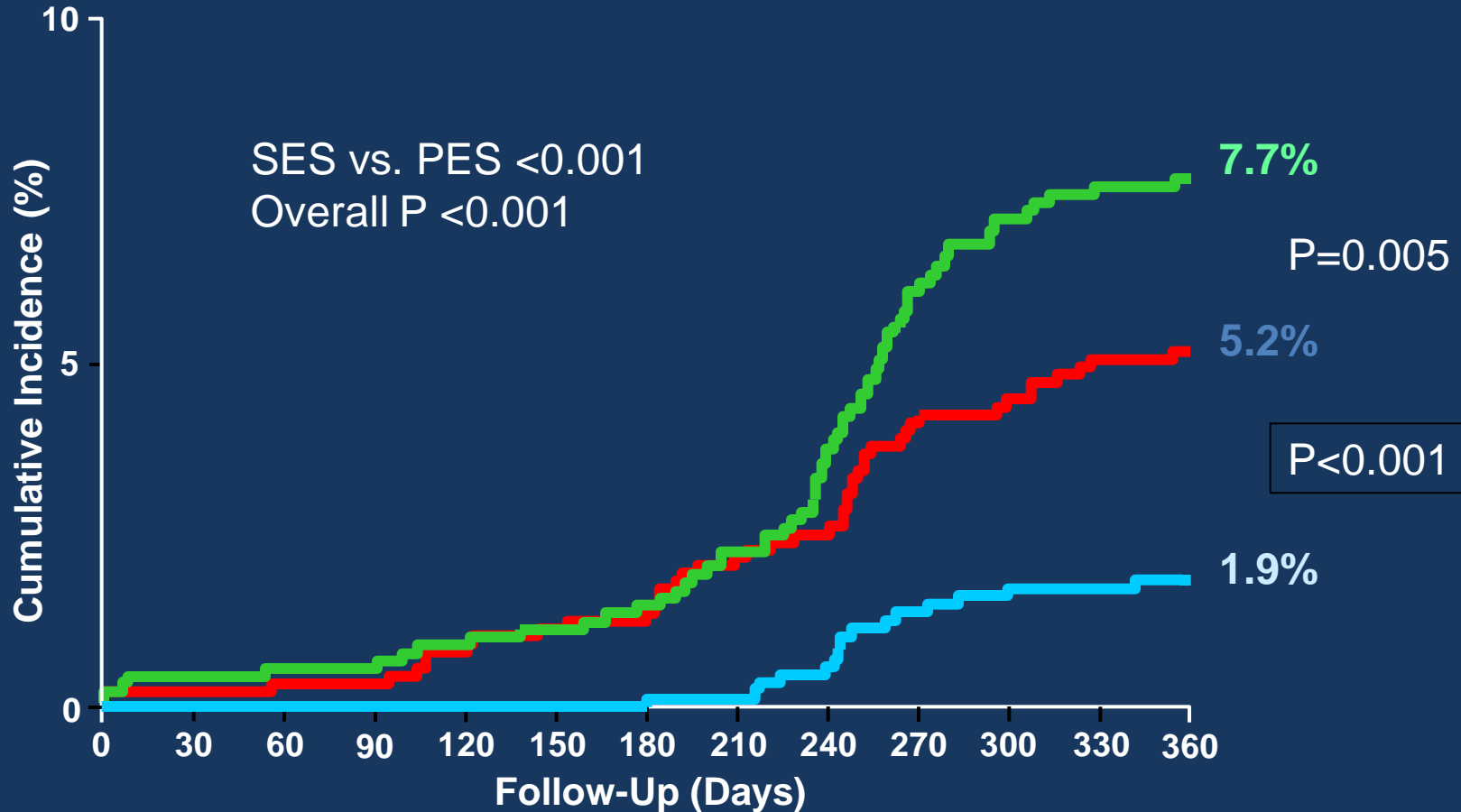


No. at Risk

ZES	883	868	857	829	822
SES	878	869	866	853	845
PES	884	875	861	813	794

Ischemic driven TVR

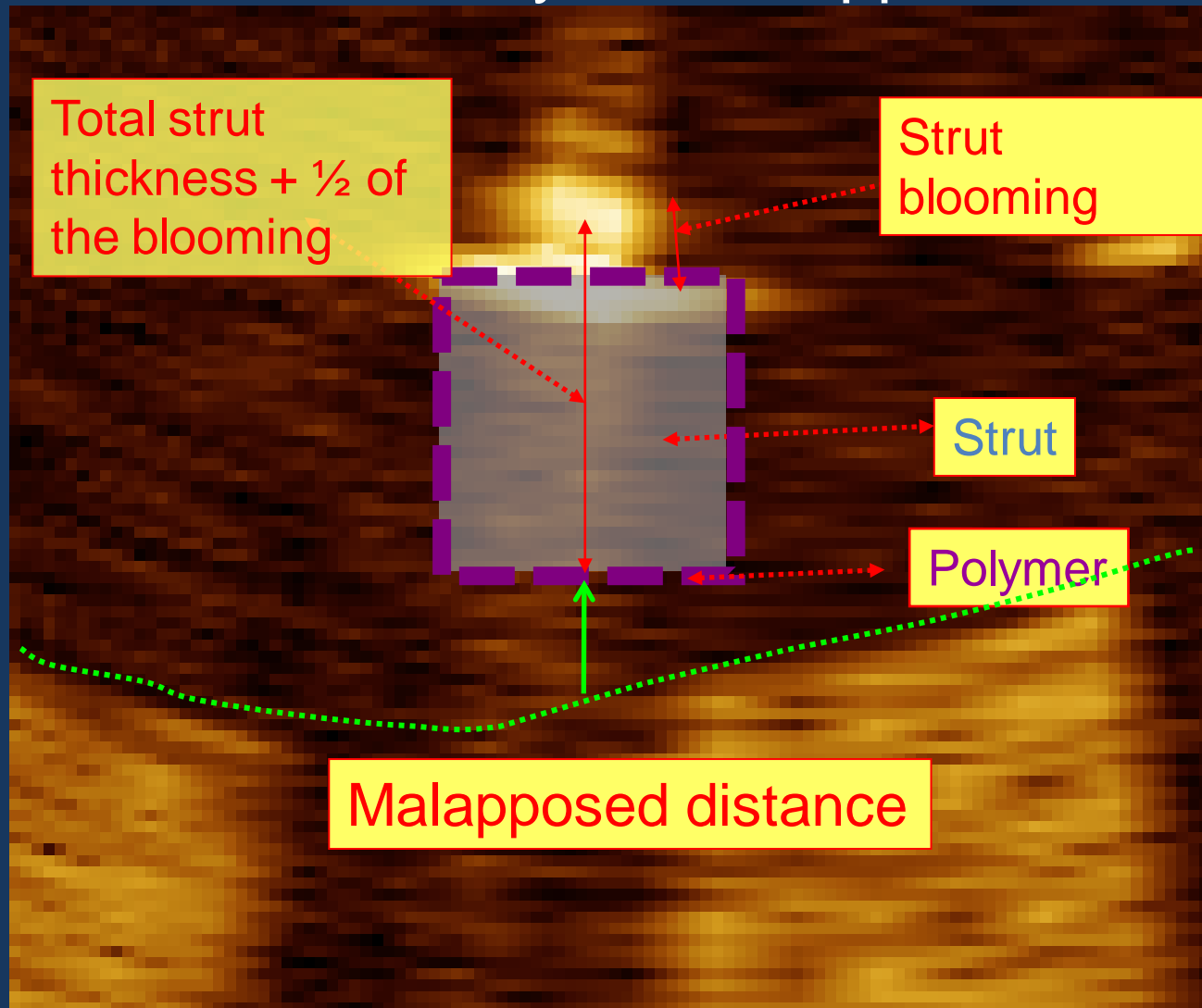
— SES — ZES — PES



No. at Risk

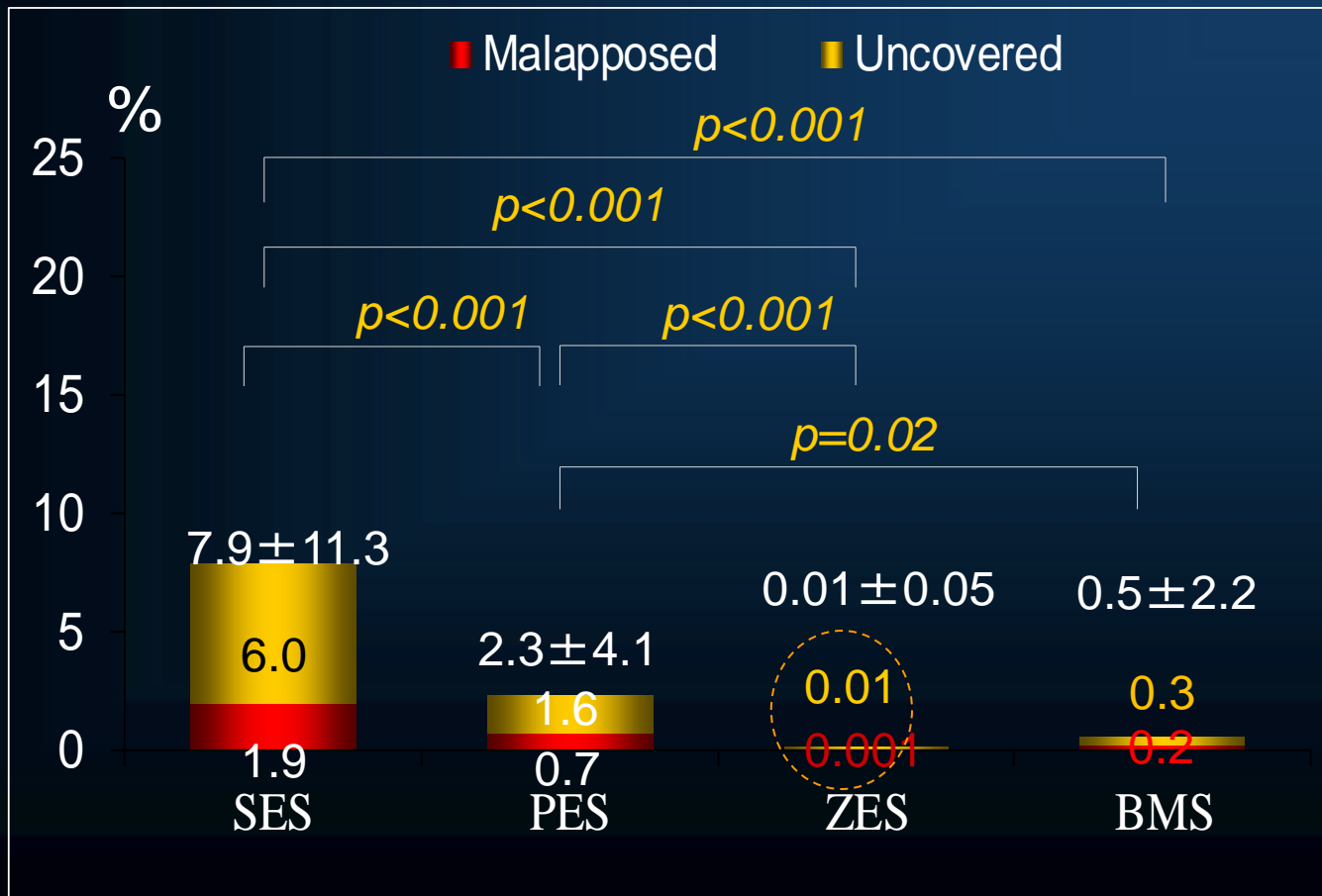
ZES	883	868	857	827	819
SES	878	869	866	851	841
PES	884	875	861	812	793

Strut Level Analysis: Malapposition



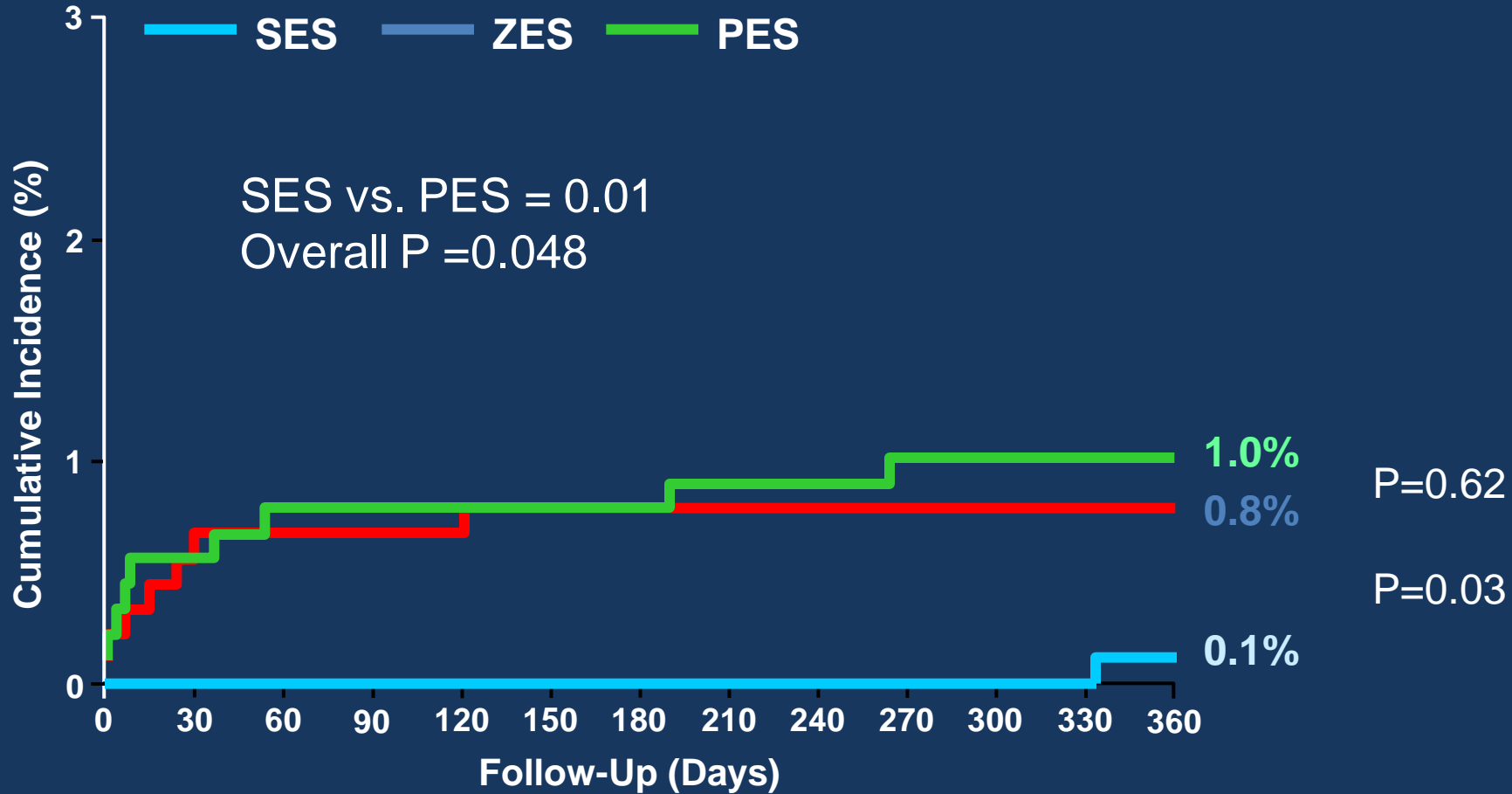
Non-overlap

Proportion of uncovered and/or malapposed struts by stent type



Stent Thrombosis

ARC Any Criteria

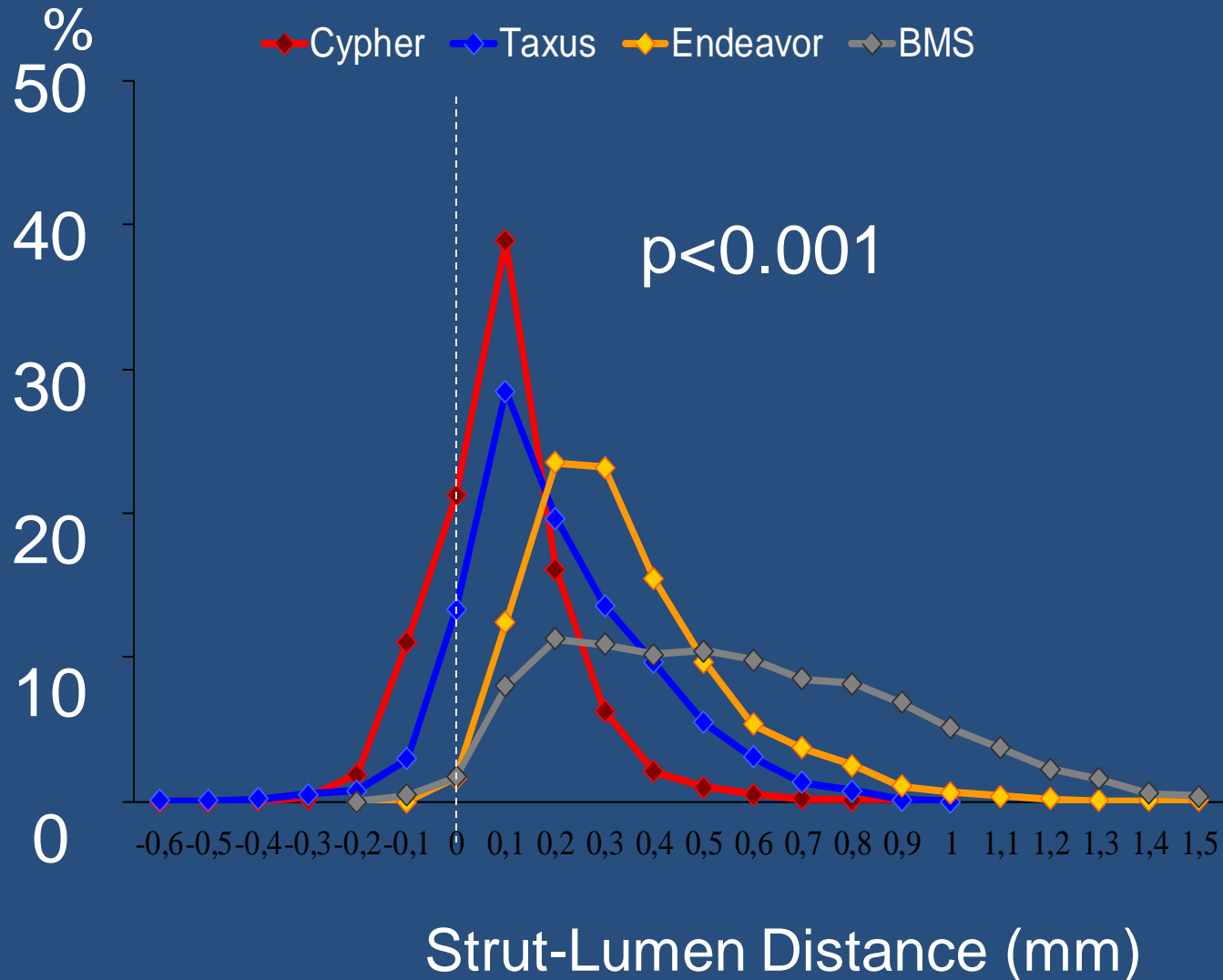


No. at Risk

ZES	883	869	866	861	861
SES	878	869	867	863	857
PES	884	875	868	859	853

Strut Level Analysis

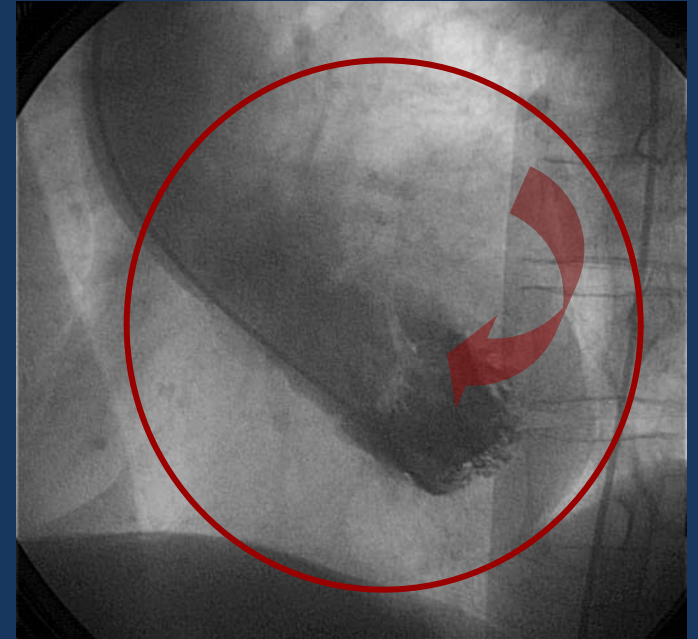
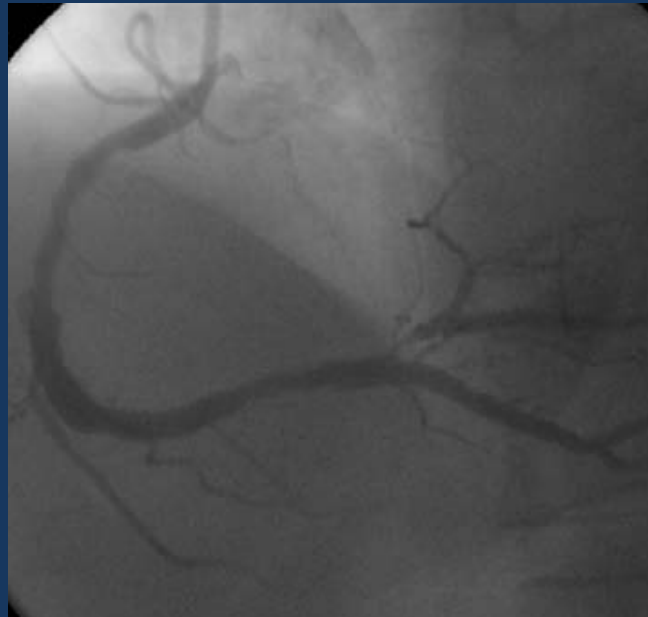
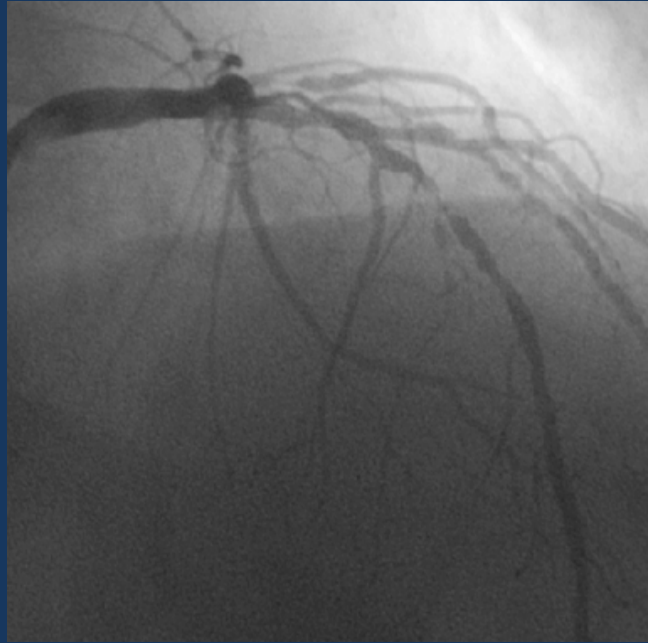
Frequency Distribution of Strut-Lumen Distance

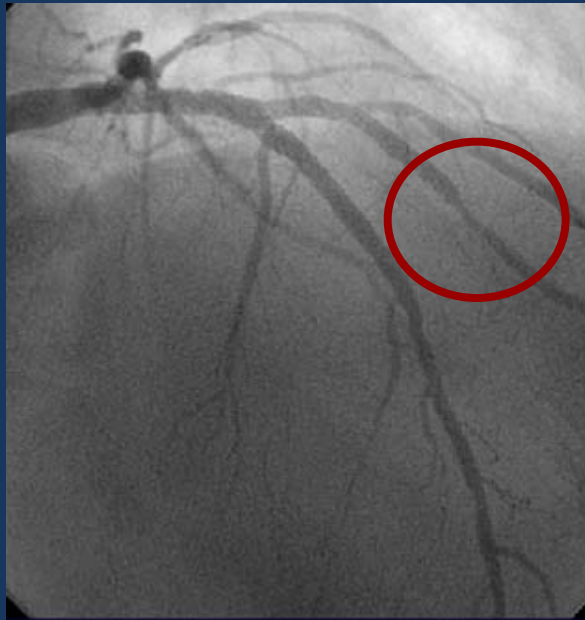
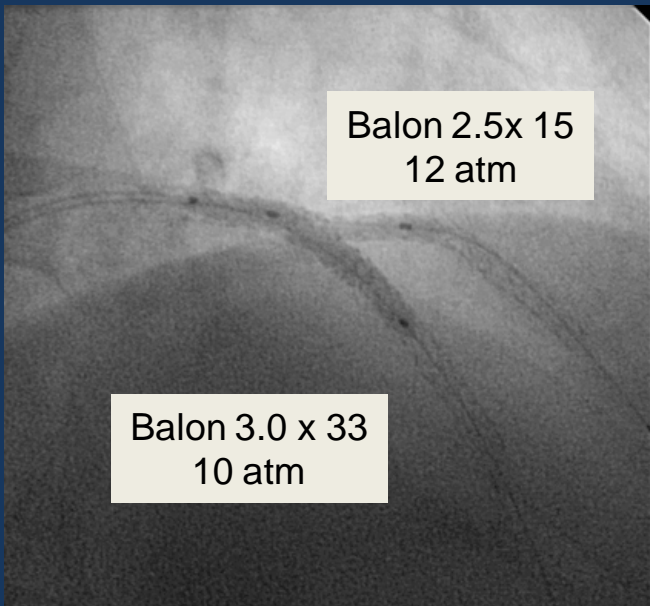
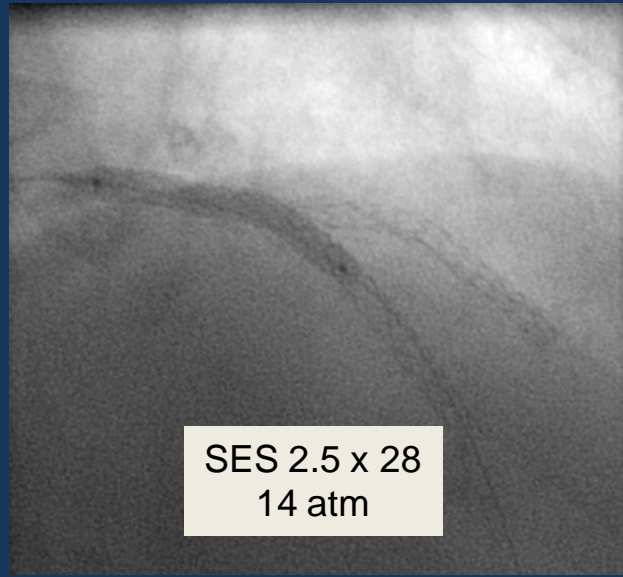
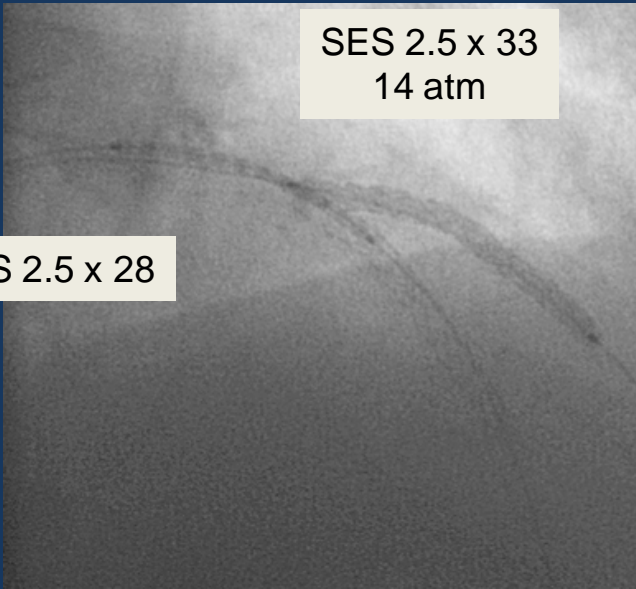


Based on ANOVA test, Kruskal-Wallis test and generalized linear model with complex sample analysis (clustered)

♂ 71 años

Angina progresiva
Dislipidemia
IHSS





Conclusiones

En escenarios clínicos y anatómicos **FAVORABLES → BMS**

En escenarios clínicos y anatómicos **ADVERSOS → DES**

EQUILIBRAR CON RIESGO HEMORRAGICO

NO TODOS LOS DES SO IGUALES



SOLACI '11

SANTIAGO DE CHILE



XVII Congreso SOLACI

XIV^a Jornada de Hemodinamia de la Sociedad
Chilena de Cardiología y Cirugía Cardiovascular

Jornada Anual de Cirugía Vascular

Curso anual de Cardiología de SOCHICAR.

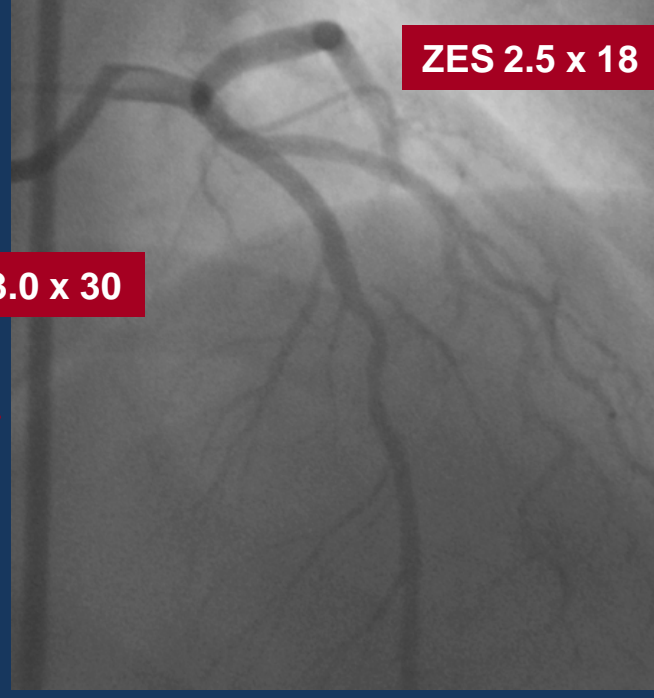
3 al 5 de Agosto
de 2011
Casapiedra
Santiago de Chile

CHILE

♀ 42 años
ACS
Dbt I
Dislipidemia
Antecedentes familiares

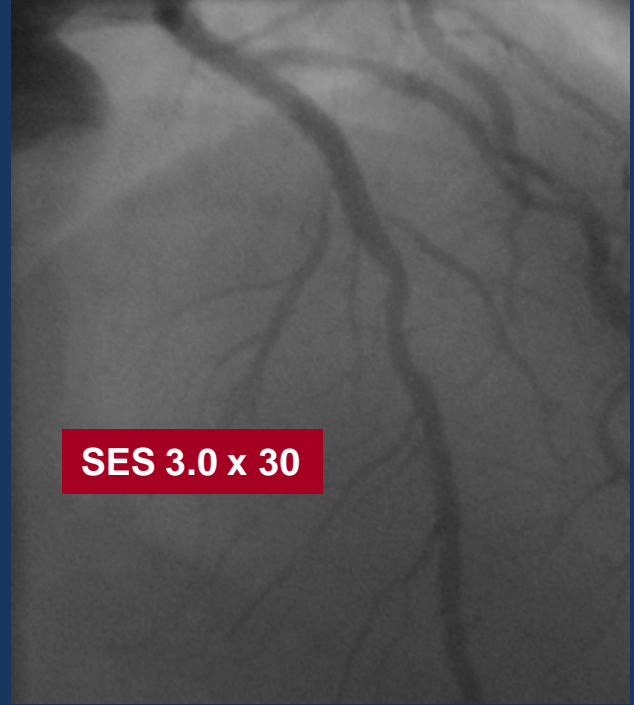
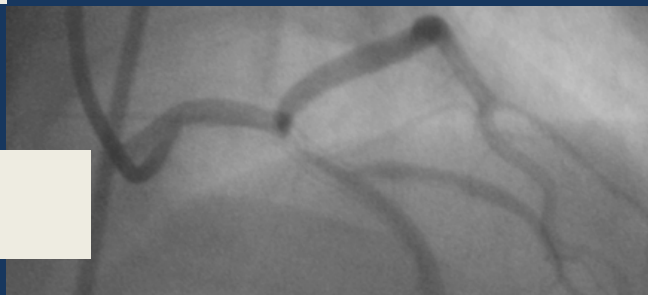


ZES 3.0 x 30

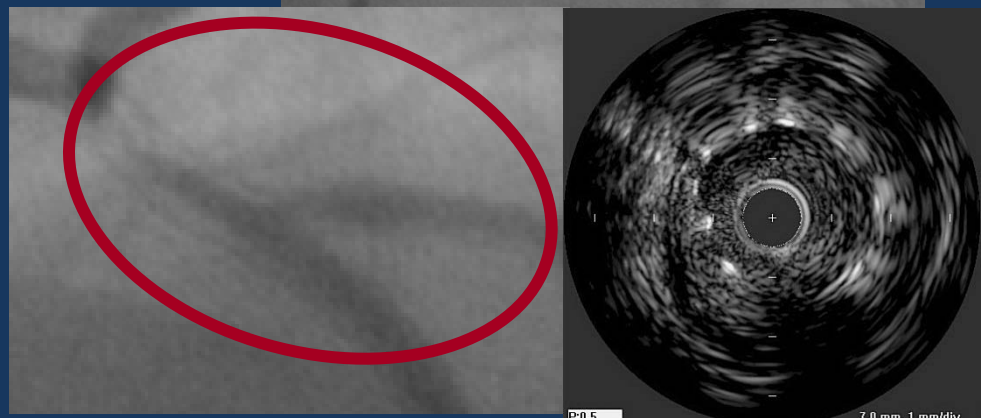


ZES 2.5 x 18

3 meses

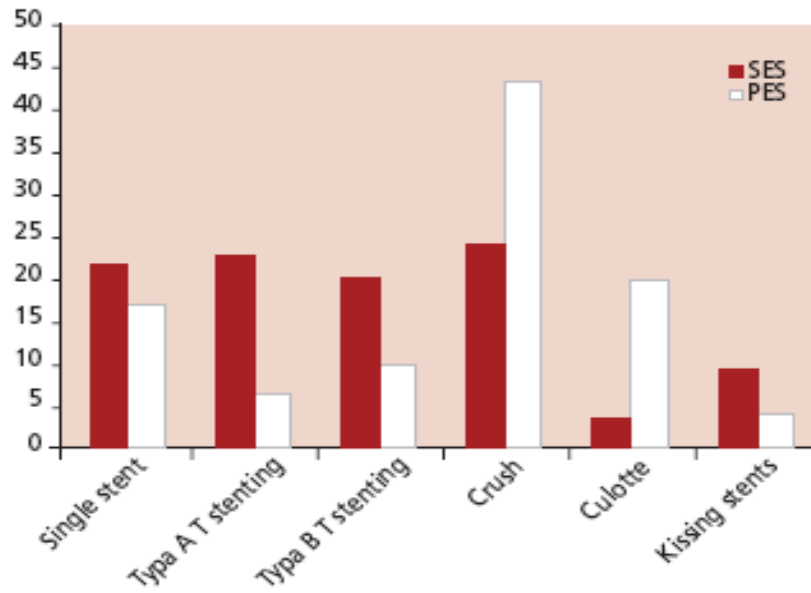


SES 3.0 x 30



Coronary lesions: and Paclitaxel-eluting stents

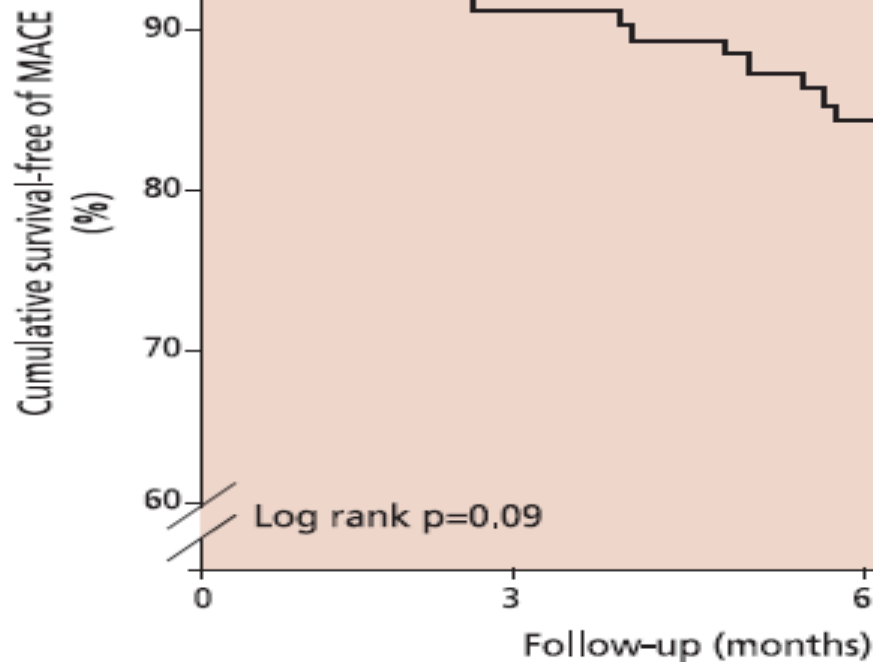
Hoye et al.



Independent predictors of major adverse cardiac events

at 6 months

Odds ratio	95% confidence intervals
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SES: 86.7%

PES: 78.6%

1.02	1.01 to 1.05
2.75	1.1 to 7.2
2.15	1.2 to 4.0
1.36	1.0 to 1.9
2.35	1.1 to 5.0
0.71	0.4 to 1.0
0.45	0.19 to 0.95

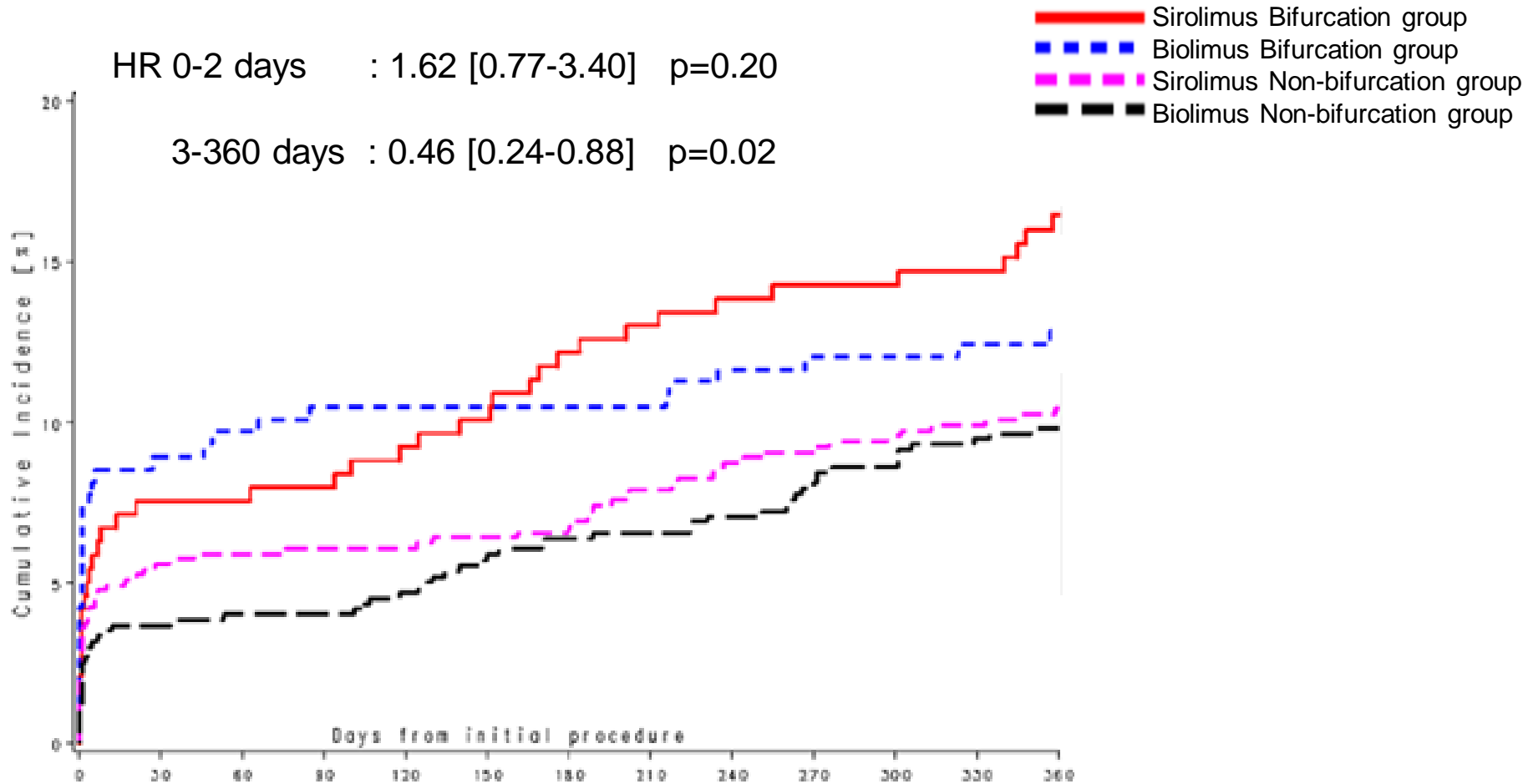
MACE*

*MI, cardiac death and clinically driven TVR

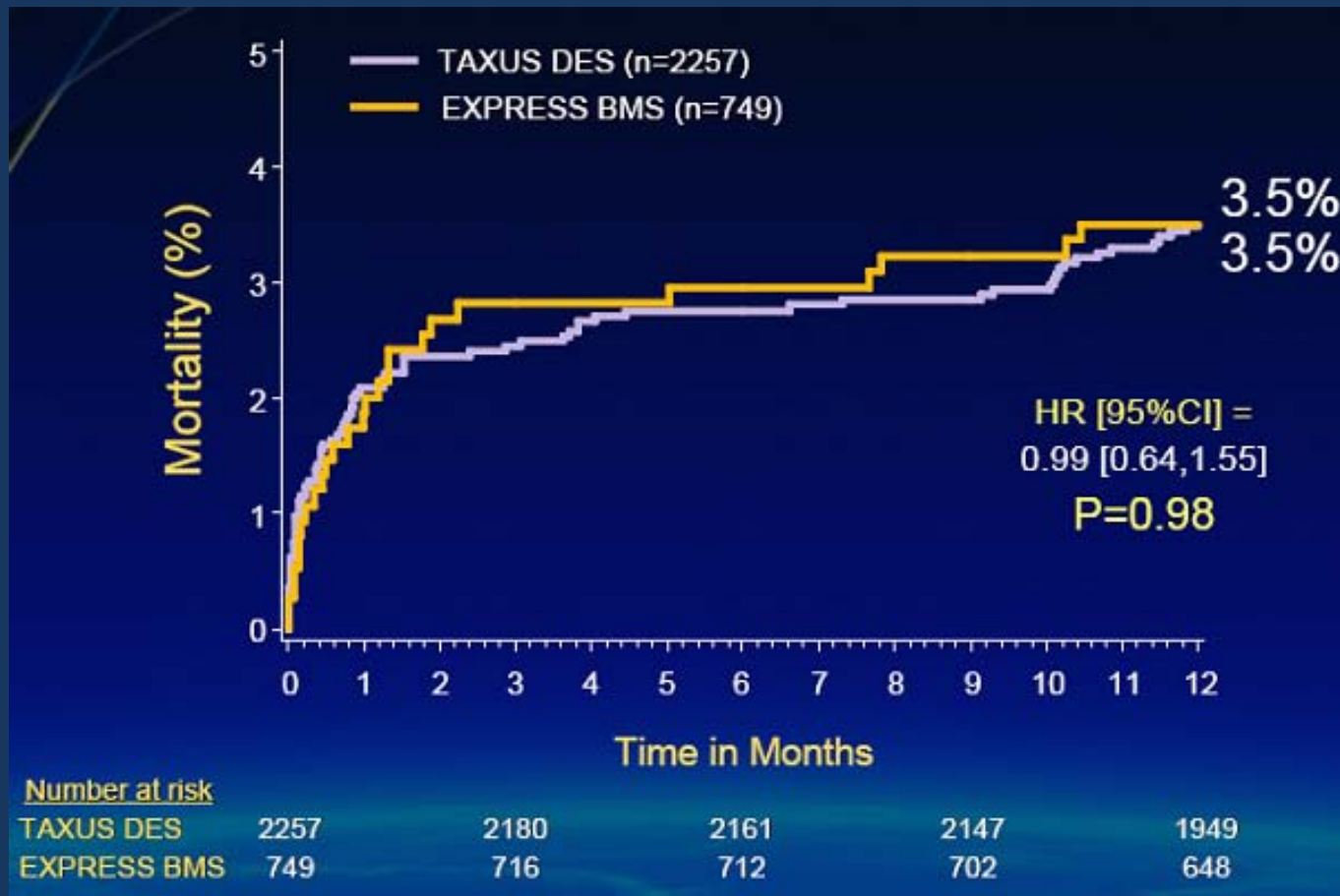
Bifurcation Group BES vs. SES

HR 0-2 days : 1.62 [0.77-3.40] p=0.20

3-360 days : 0.46 [0.24-0.88] p=0.02

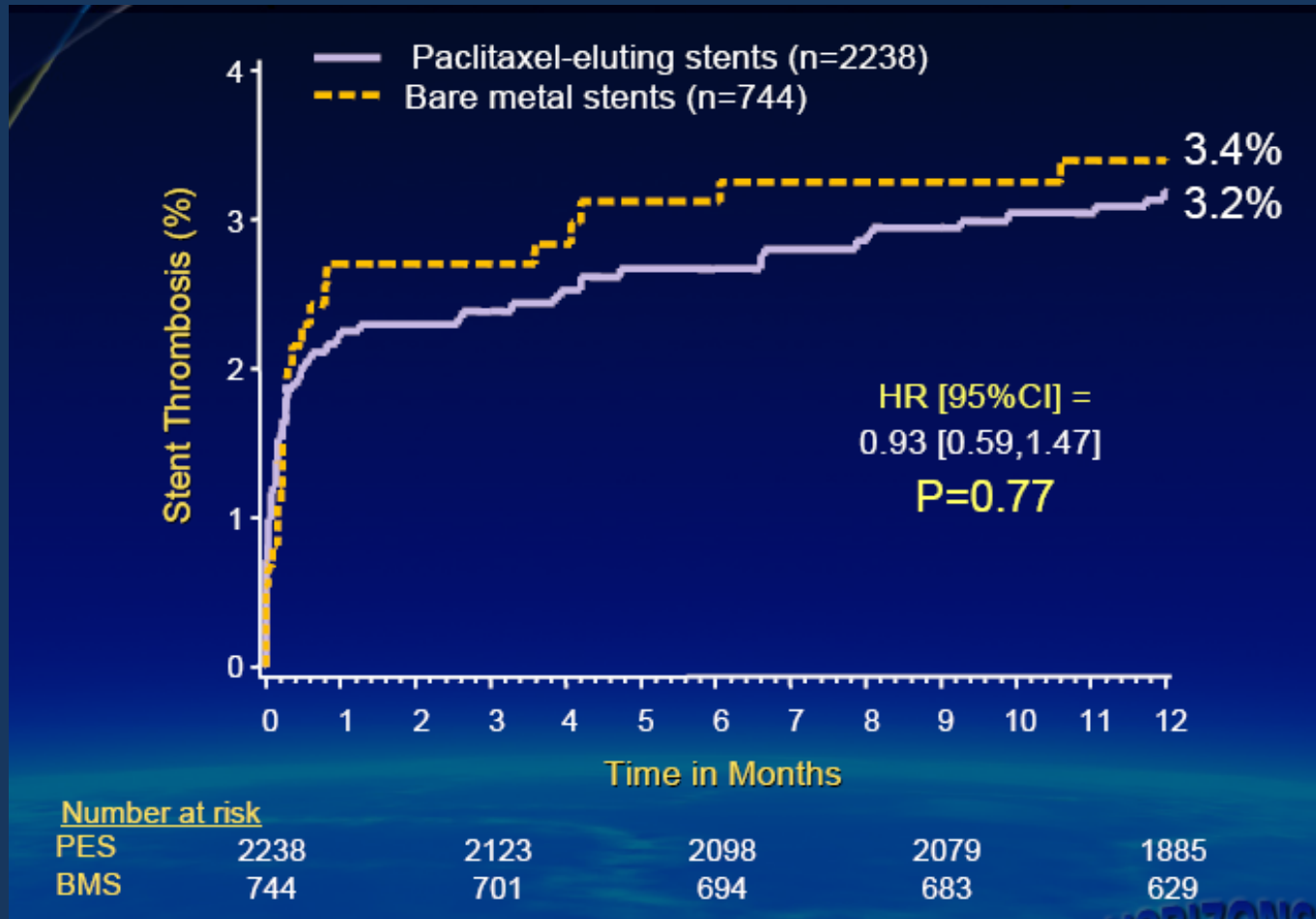


HORIZONS AMI All-Cause Mortality

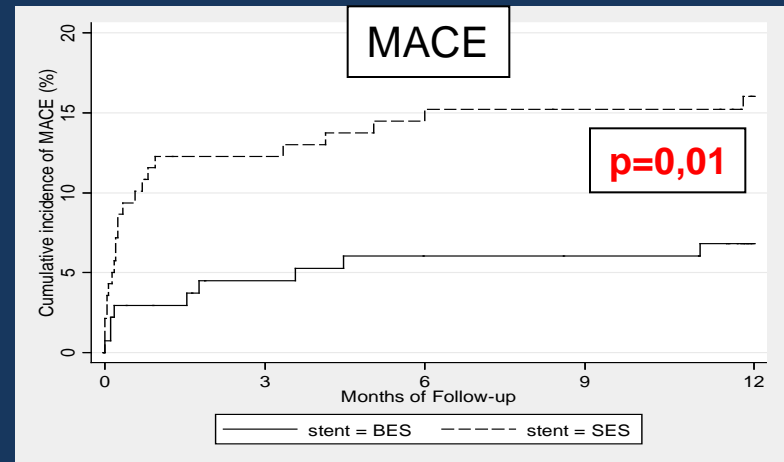
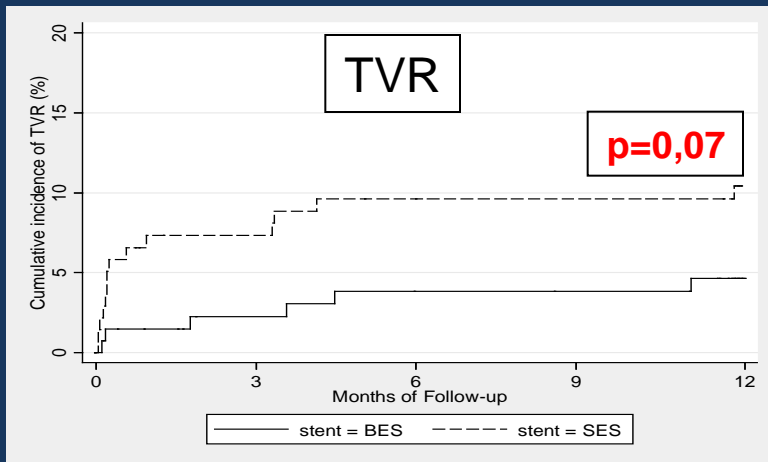
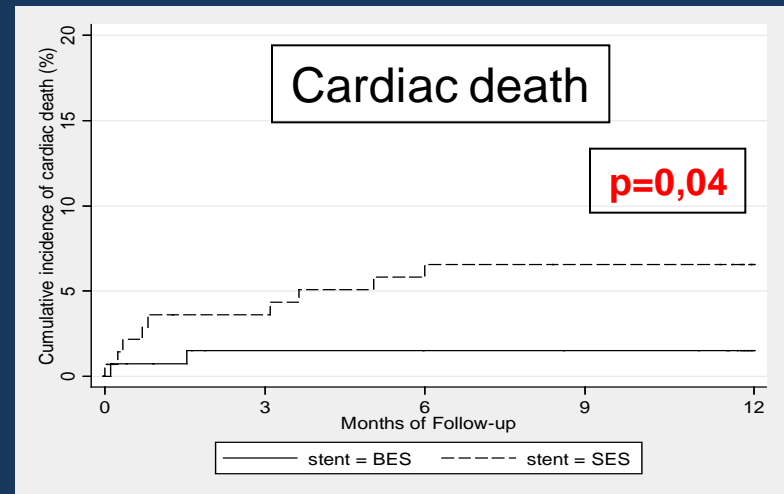
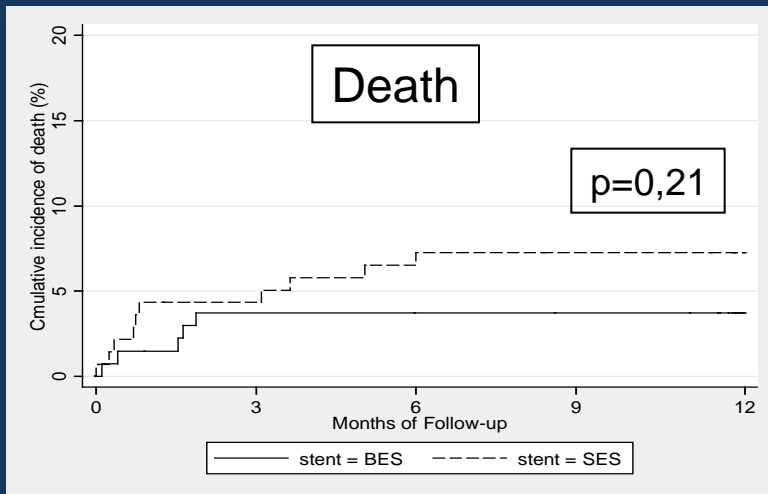


HORIZONS AMI

Stent thrombosis

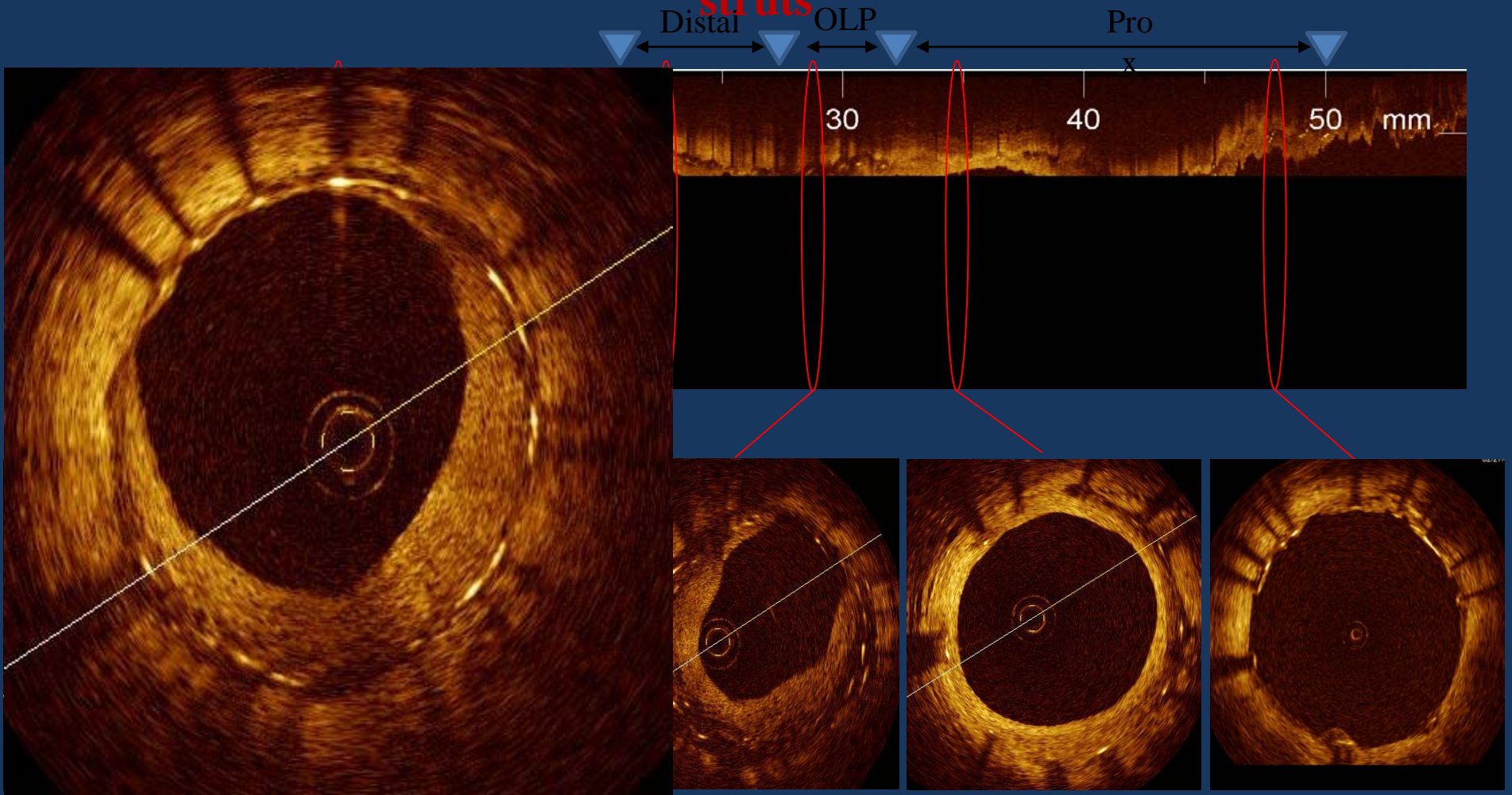


One-Year Cumulative Incidence of Death, Cardiac Death, TVR and MACE



Six Month OCT Analysis: 75/76 eligible patients

Analyzed: 250 stented segments every 0.3 mm (6968 cross-sections), 53.047 struts



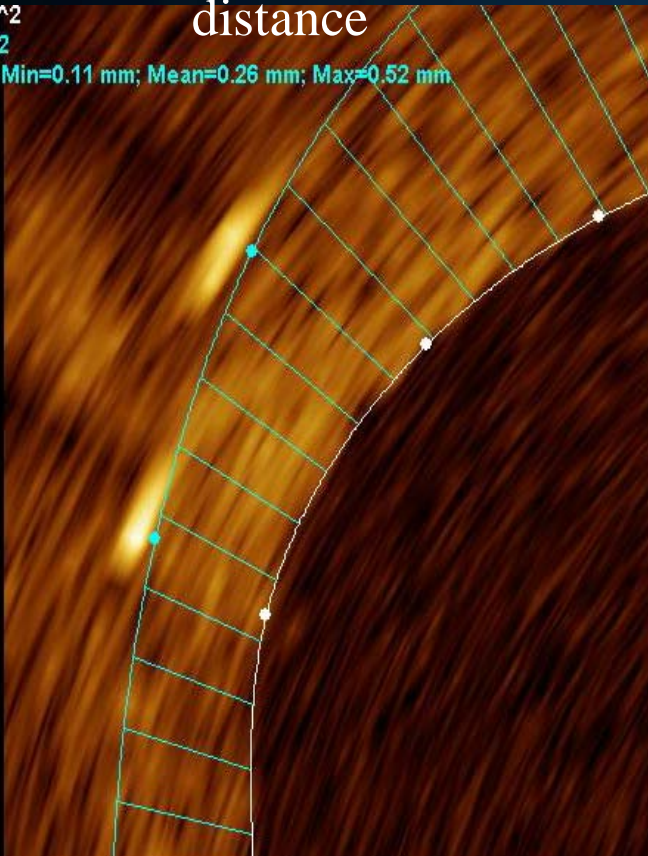
Quantitative Strut Level Analysis

Semi-Automated delineated contours at radial 1degree increments

Lumen Area, Stent Area, Strut -Lumen

A Lumen: 5.43mm²
 B Stent: 7.76mm²
 C Thickness A B: Min=0.11 mm; Mean=0.26 mm; Max=0.52 mm

distance



Zoom: 5.5x

Strut-wall Distance



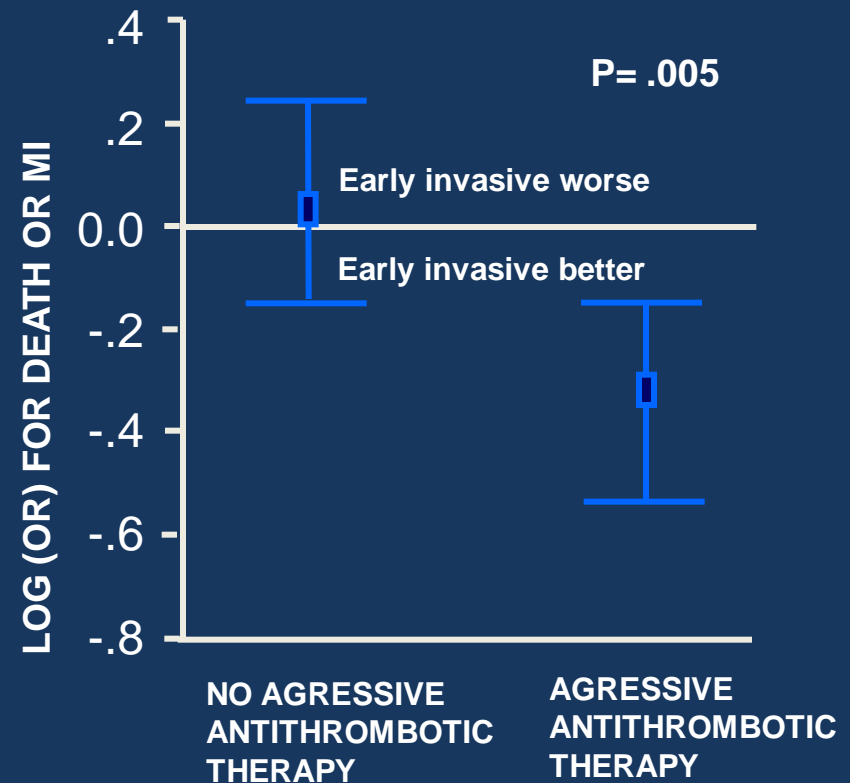
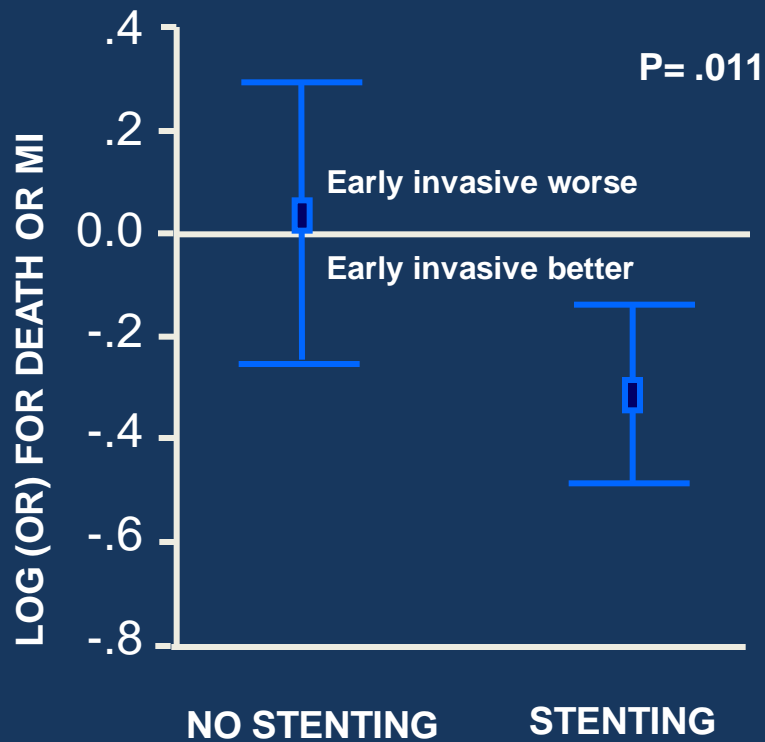
Inter-observer variability: 39 frames, 333 struts

$R = 0.997$

	Observer 1	Observer 2	Delta	SD
<i>Strut-Lumen distance</i>	0.38±0.03	0.38±0.03	0.00	0.00

Invasive vs. Conservative in **NSTEMI**

Very early PCI in ACS



Meta-regression. Am Heart J 2005

DES vs. BMS

in **NSTEMI**

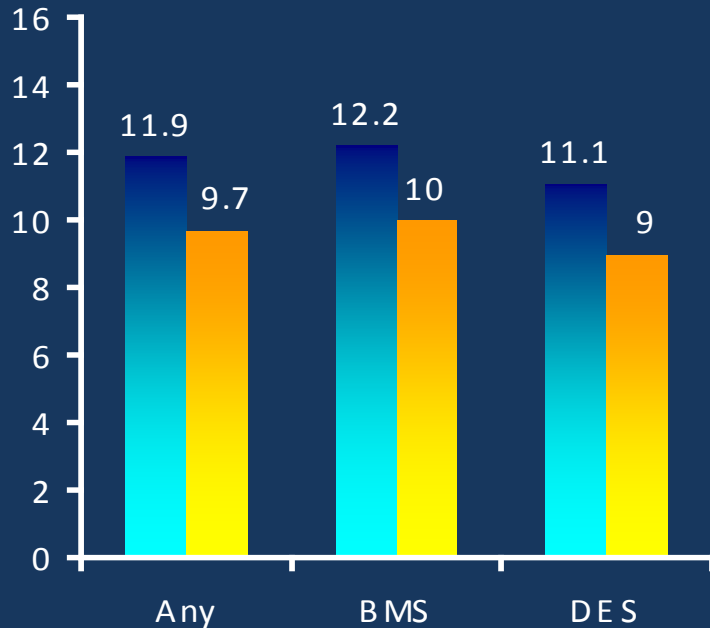
TRITON/TIMI 38
Key Efficacy, Safety EP:
Stratified by Stent Type

CVD/MI/CVA

HR 0.81
(0.72-0.90)
p=0.0001

HR 0.80
(0.69-0.93)
p=0.003

HR 0.82
(0.69-0.97)
p=0.02



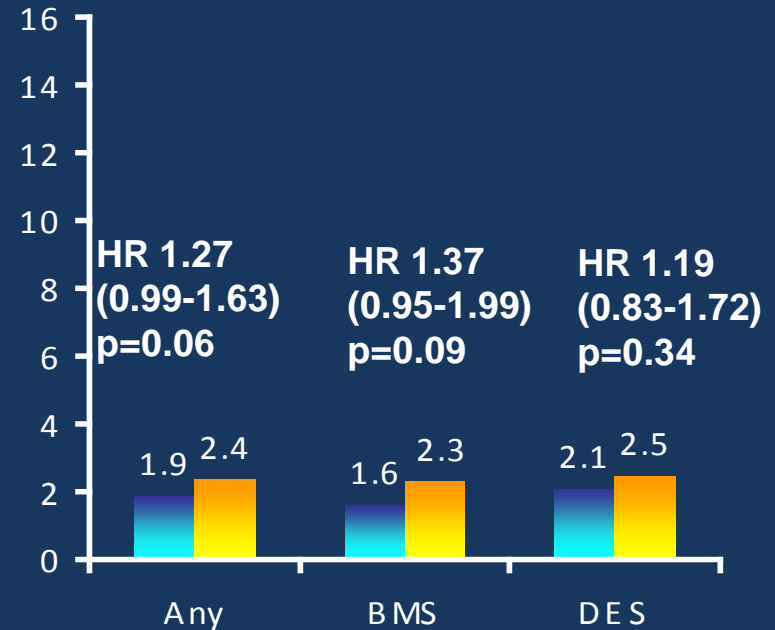
N=12844

N=6461

N=5743

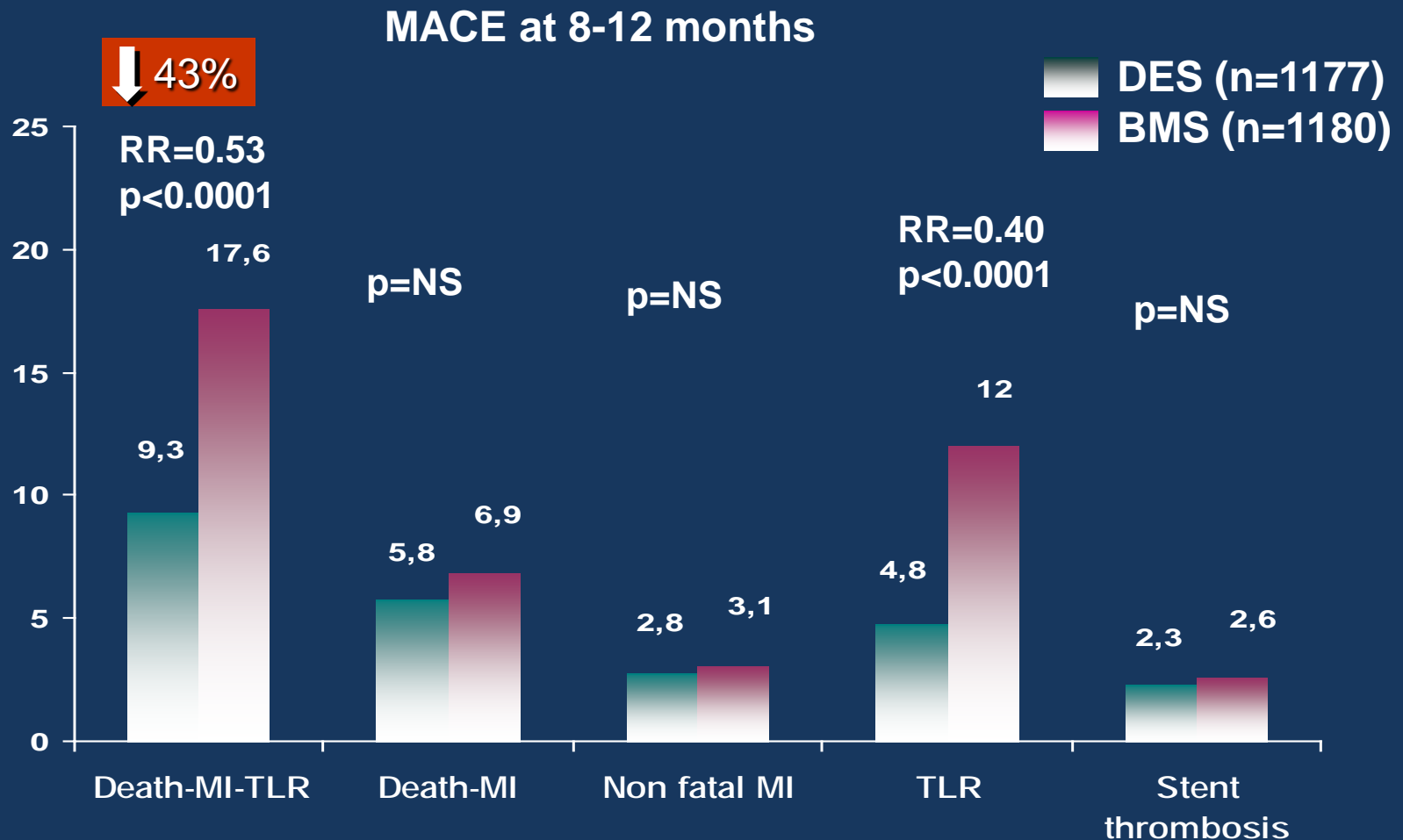
Major Bleeding

CLOPIDOGREL
PRASUGREL



DES for AMI

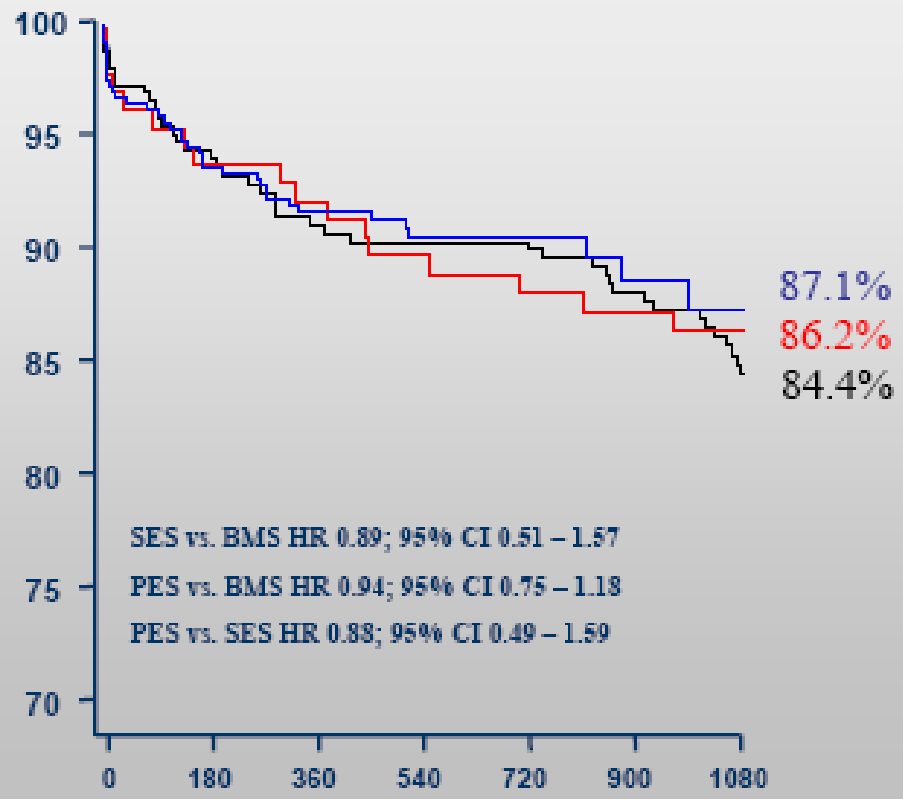
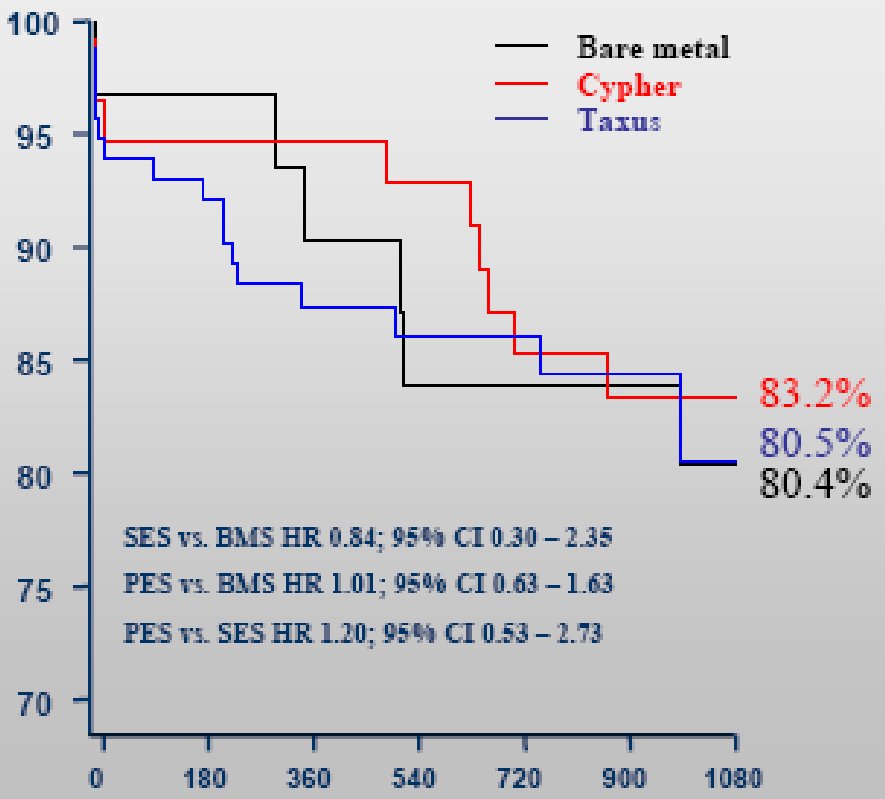
Metanalysis (n= 2357 p)



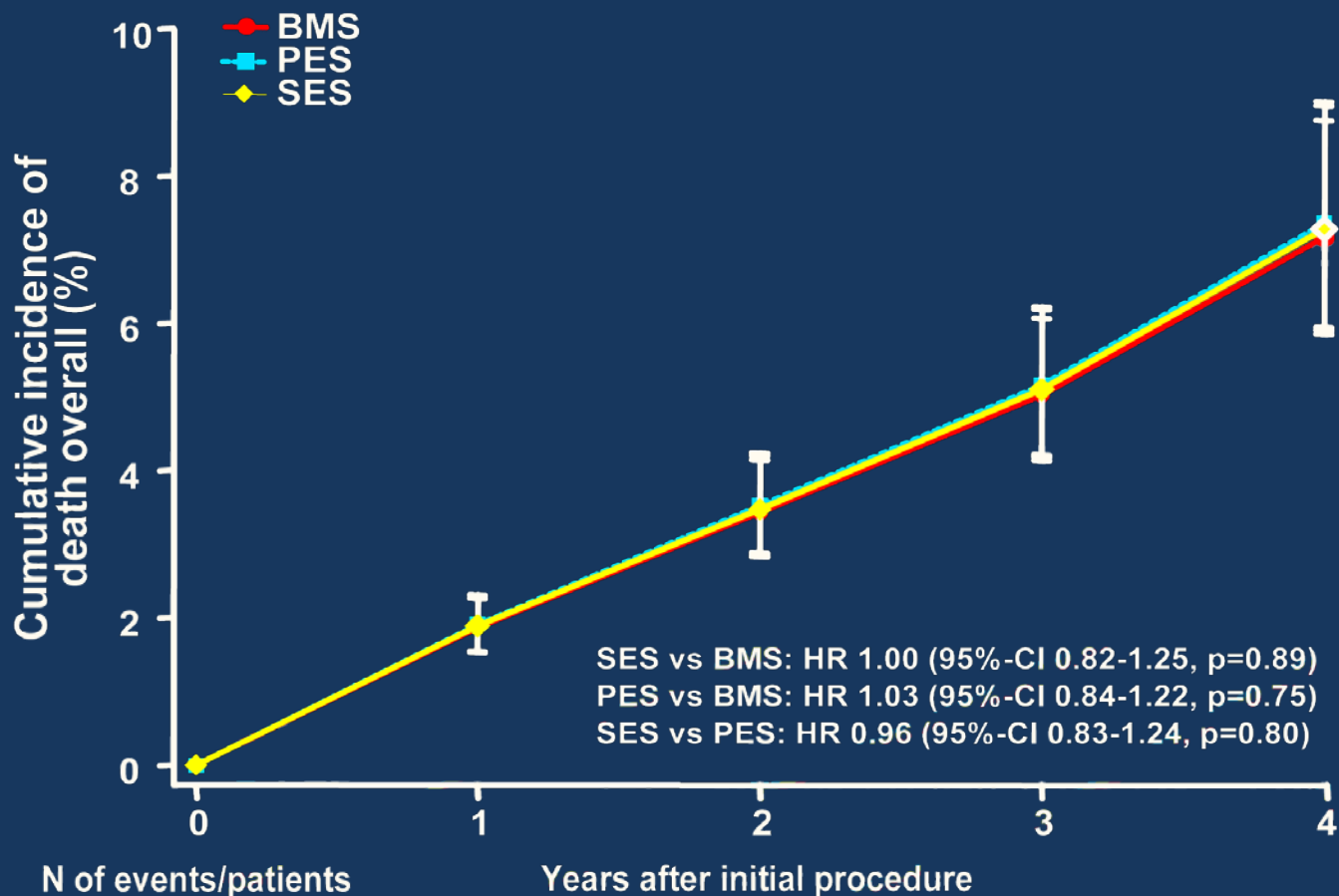
All-cause mortality at 3 years

Insulin dependent

Non-Insulin dependent

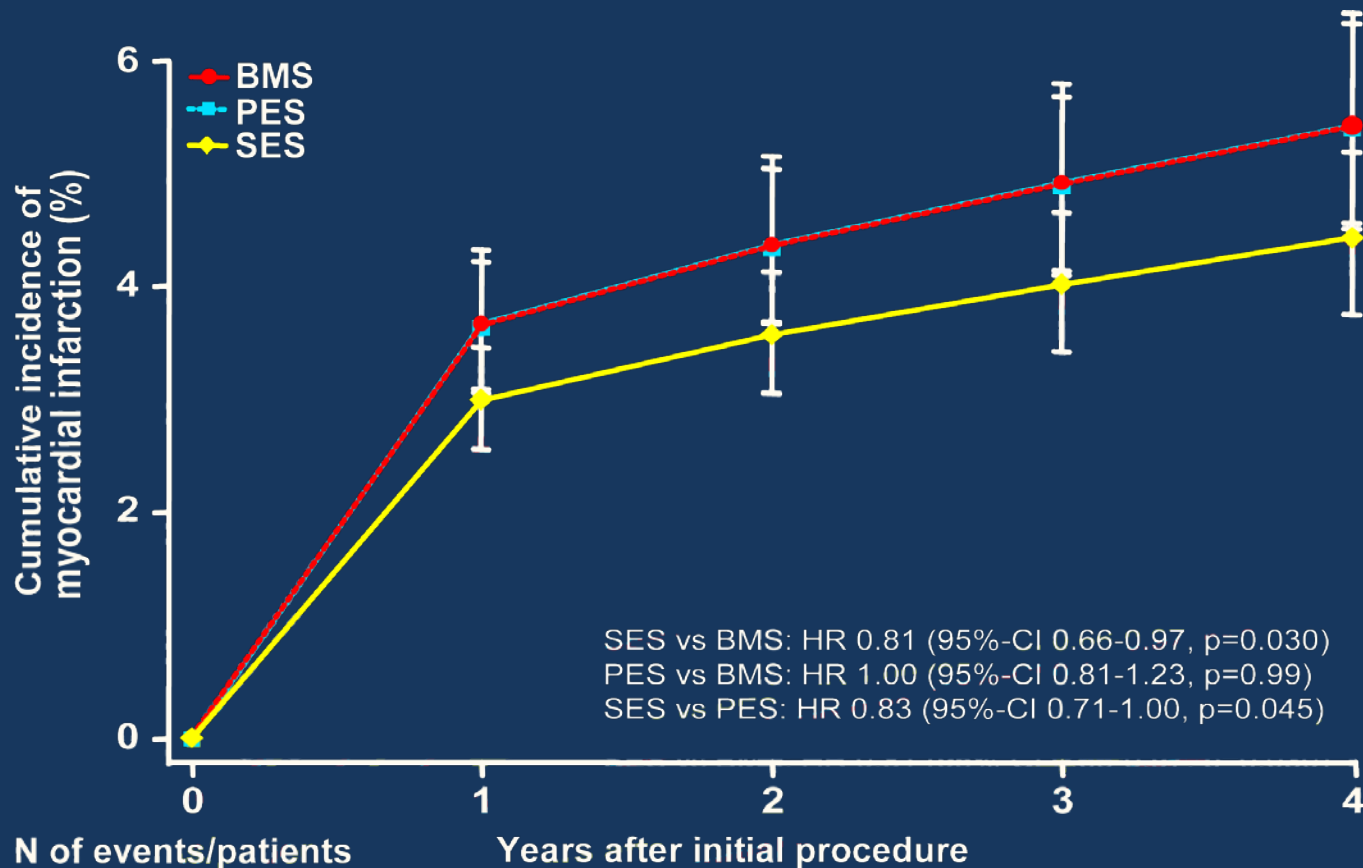


Cumulative Incidence of All Death

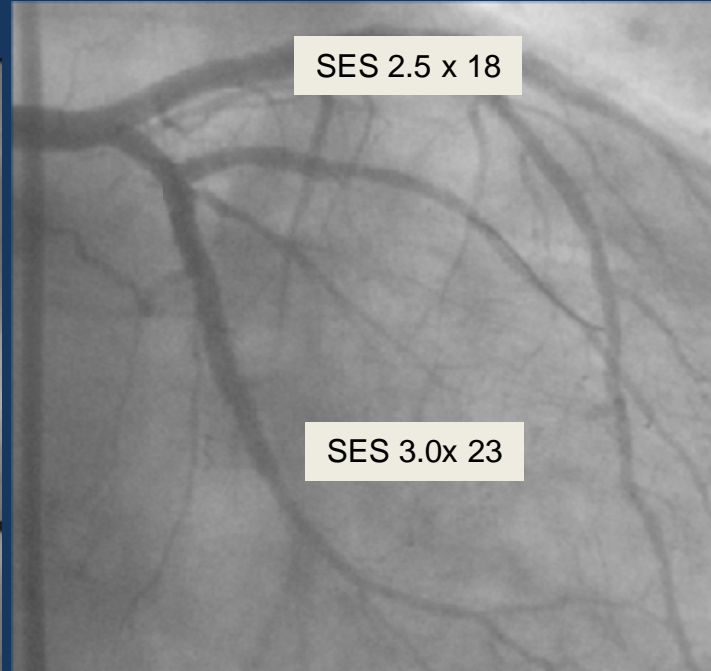
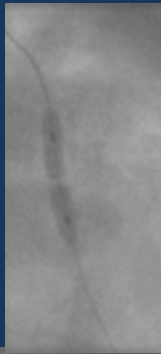
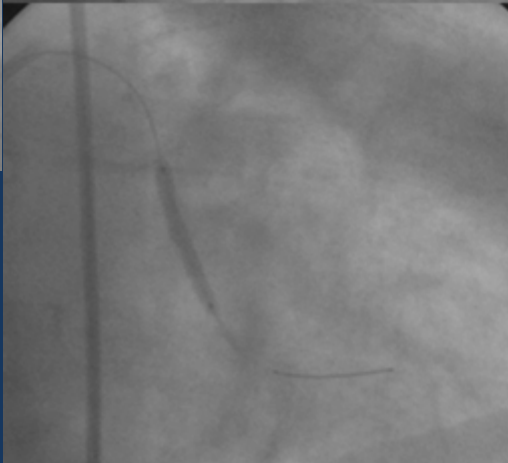
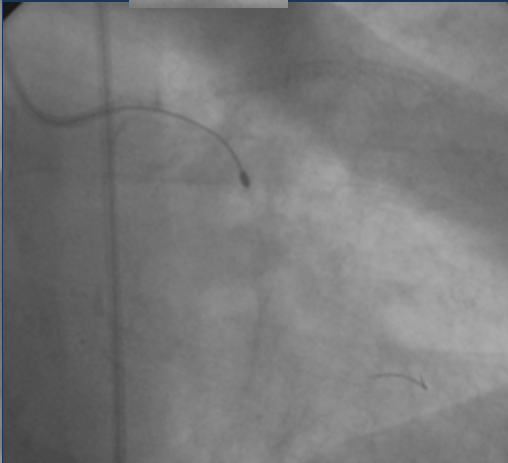


	N of events/patients		Years after initial procedure		
	0	1	2	3	4
BMS	4921	109/4904	48/3340	31/2264	44/1875
PES	6331	138/6283	78/4263	32/2187	15/869
SES	6771	139/6730	72/4041	38/2340	24/1081

Cumulative Incidence of Myocardial Infarction

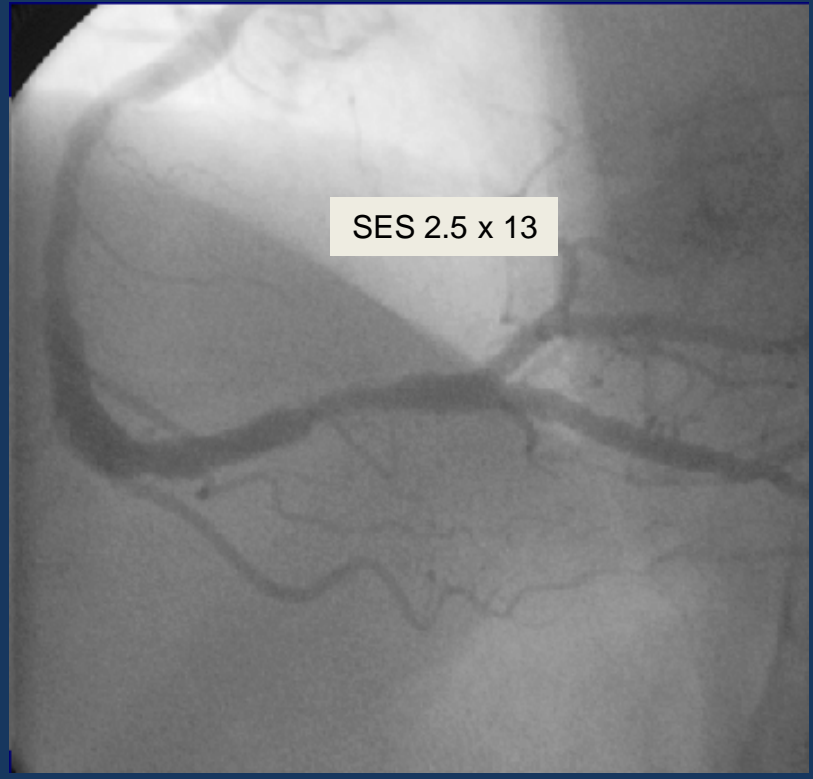


	1		2		3		4	
N of events/patients	Years after initial procedure		Years after initial procedure		Years after initial procedure		Years after initial procedure	
BMS	4891	210/4874	20/3174	17/2129	9/1745			
PES	6300	249/6252	47/4057	15/2054	8/805			
SES	6771	232/6730	25/3884	11/2236	7/1025			

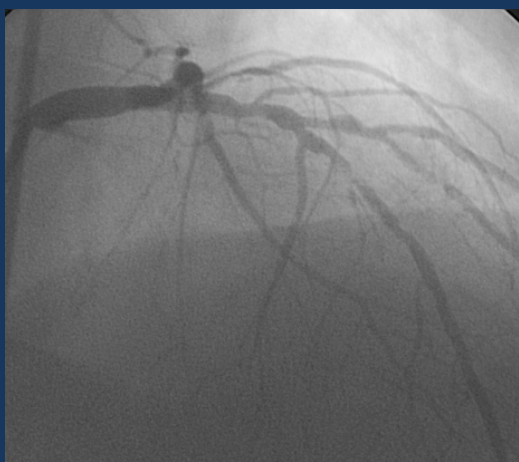


SES 2.5 x 18

SES 3.0x 23

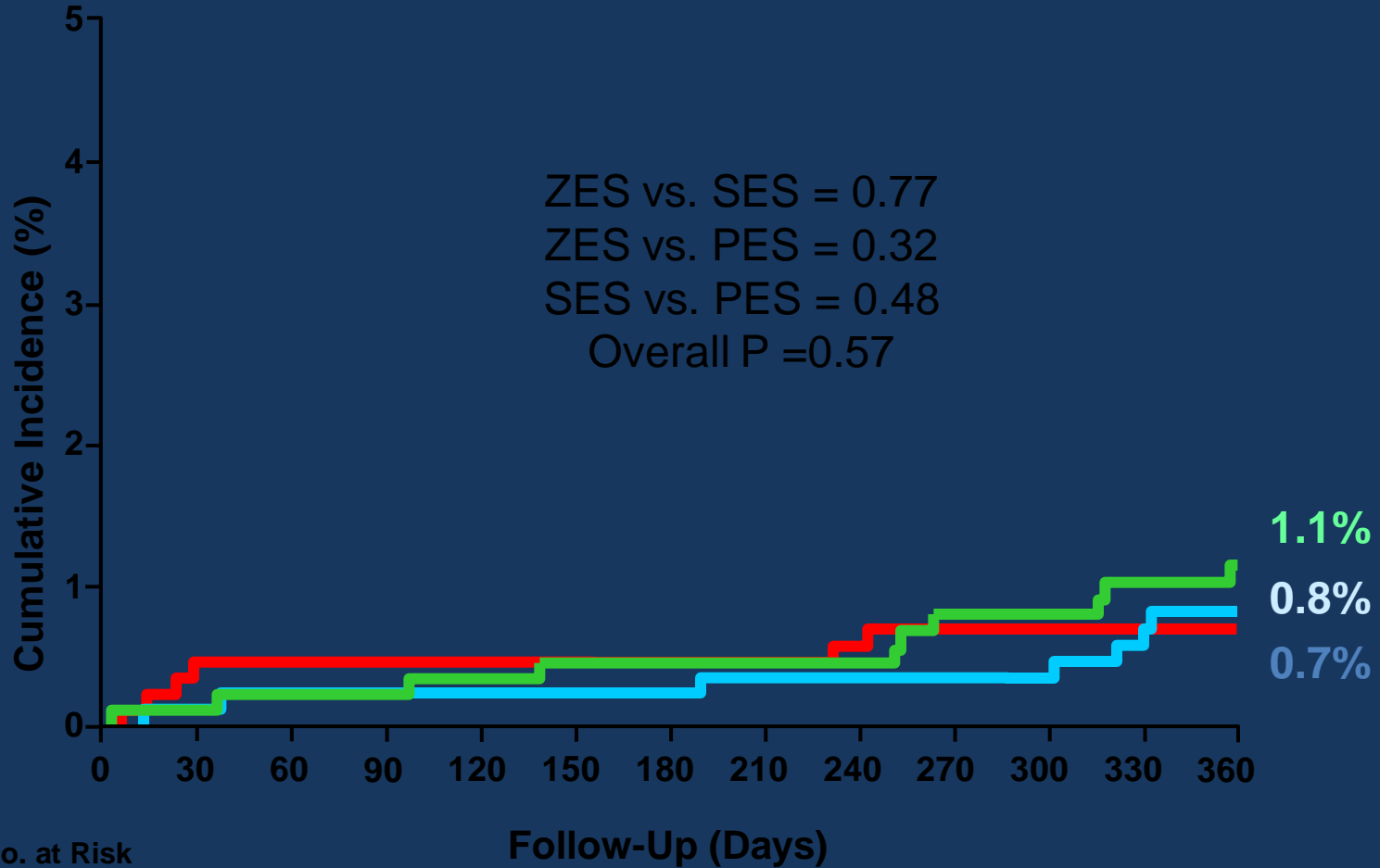


SES 2.5 x 13



Death

— SES — ZES — PES

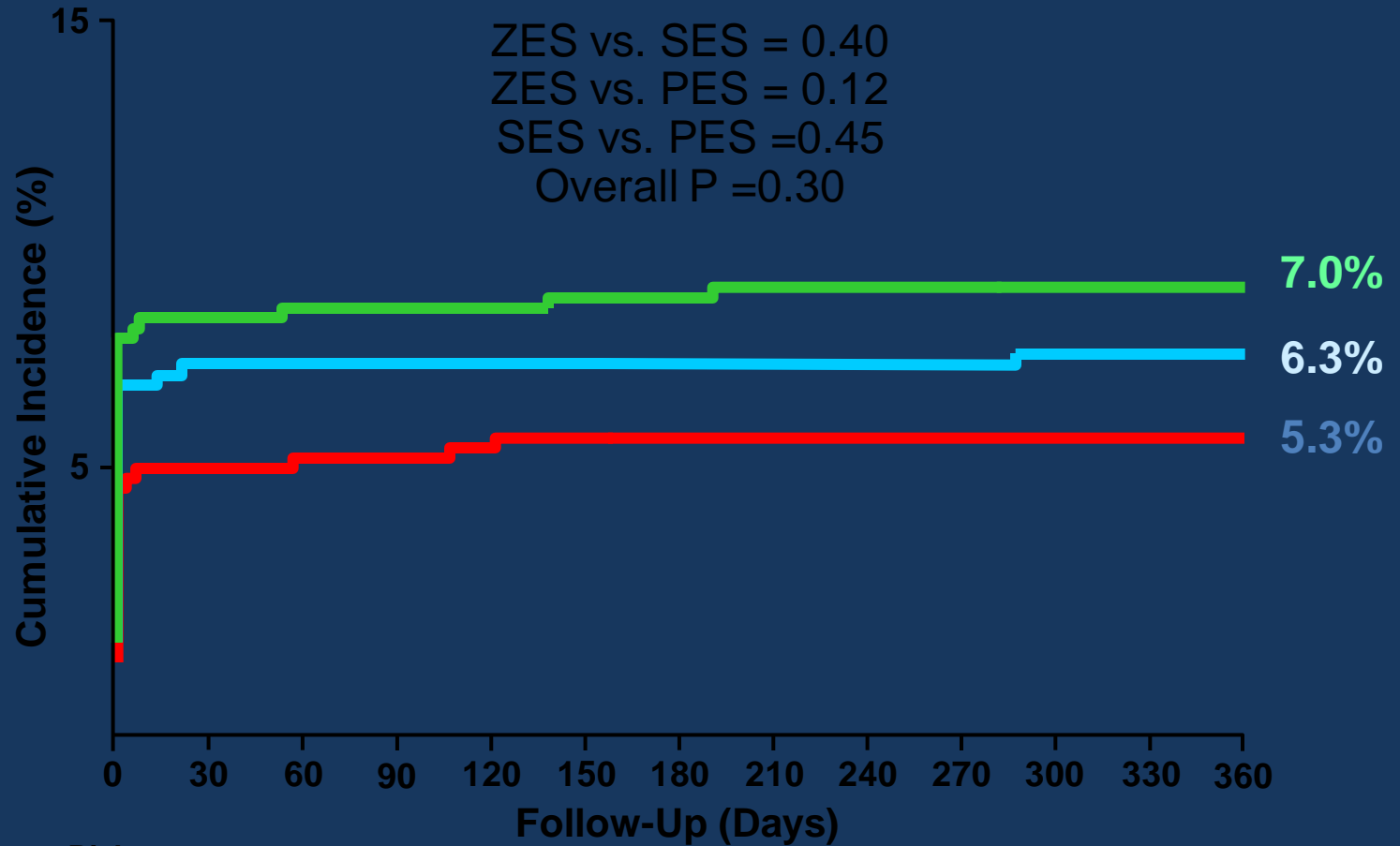


No. at Risk

ZES	883	871	869	864	864
SES	878	869	867	863	857
PES	884	880	873	865	859

MI

SES ZES PES

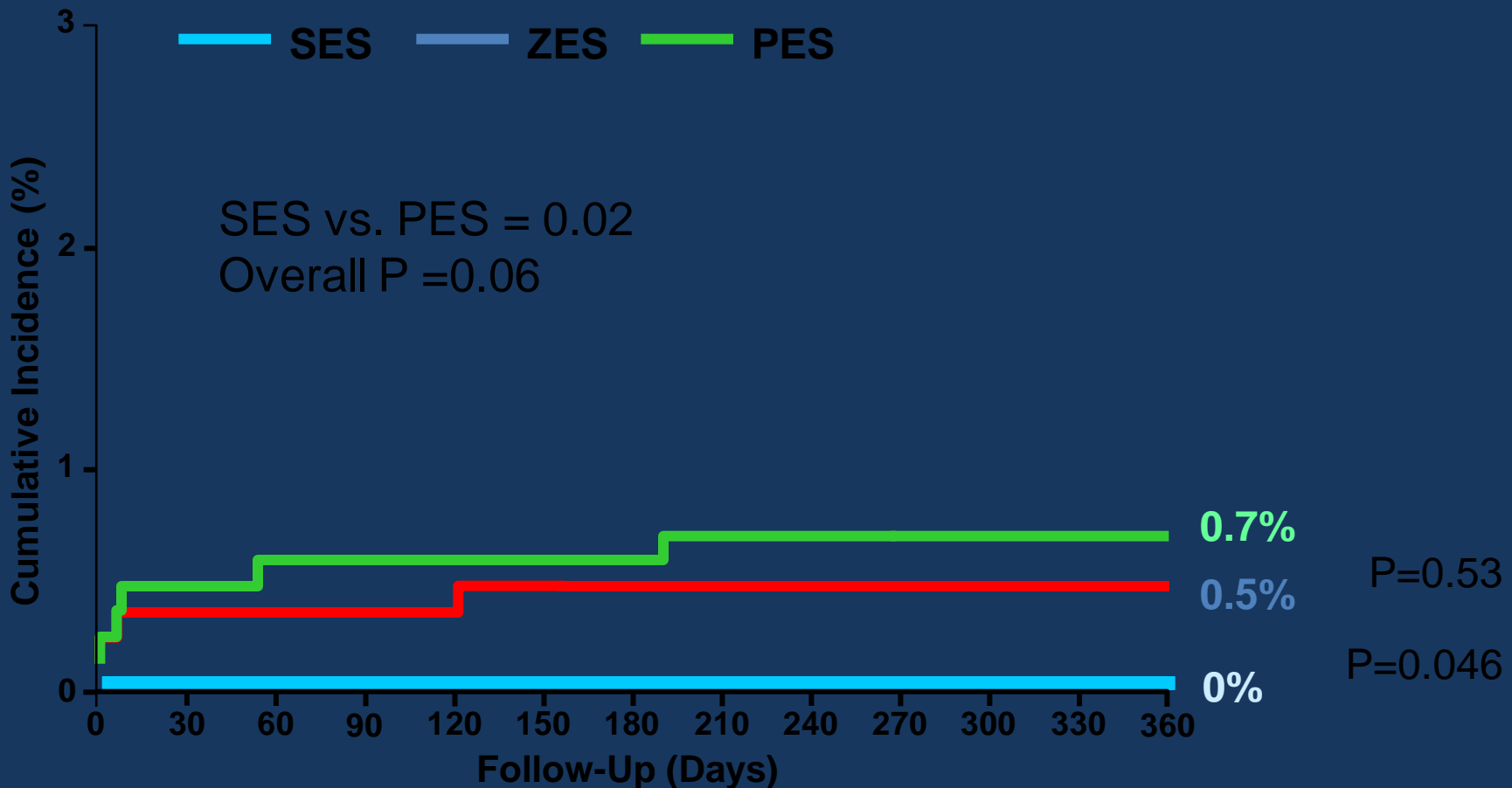


No. at Risk

ZES	883	828	824	820	820
SES	878	817	814	811	804
PES	884	821	815	808	803

Stent Thrombosis

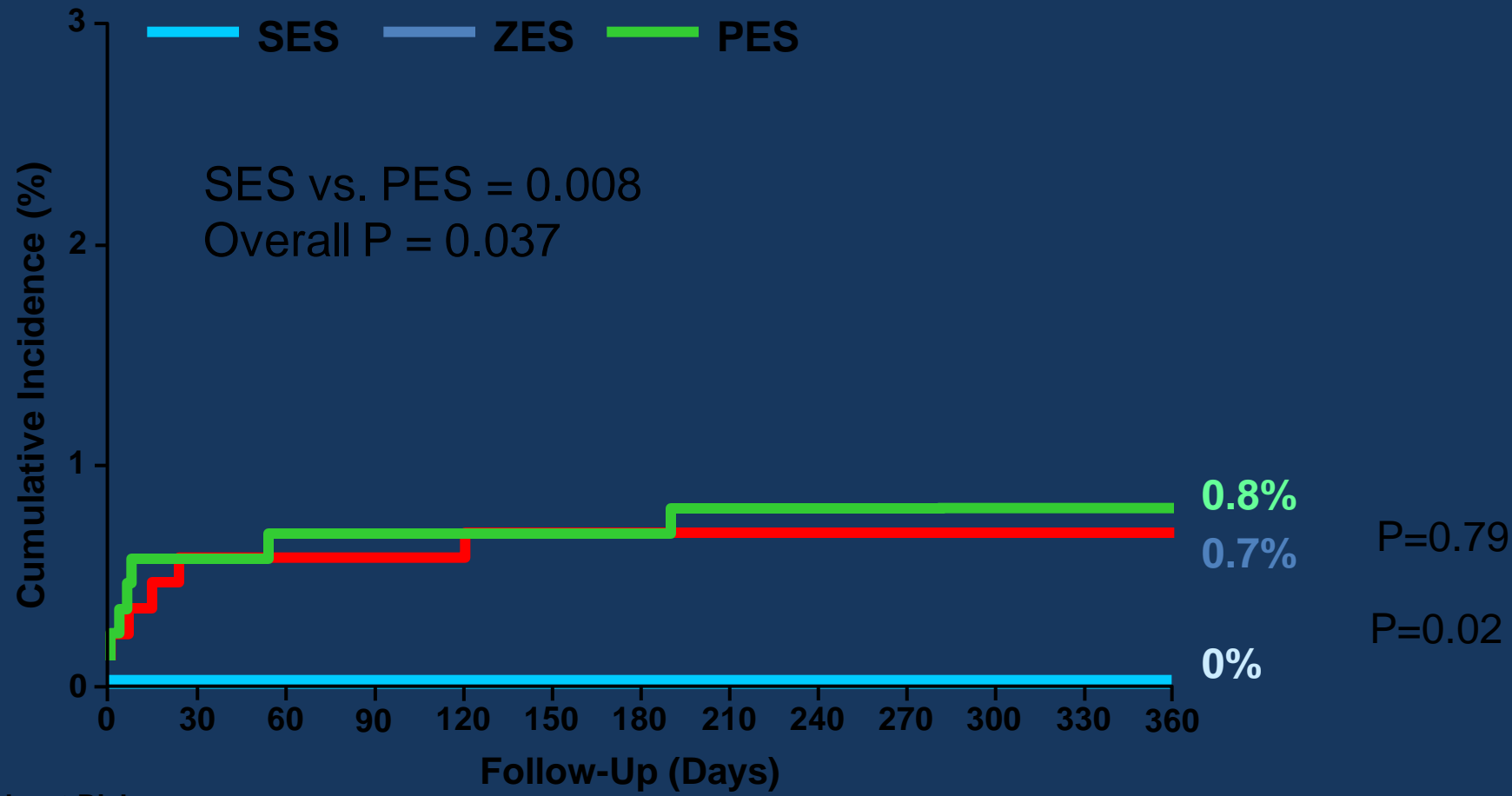
: ARC Definite Criteria



No. at Risk						
ZES	883	869	866	861	861	
SES	878	869	867	863	857	
PES	884	875	868	859	853	

Stent Thrombosis

: ARC Definite or Probable Criteria



No. at Risk						
ZES	883	869	866	861	861	
SES	878	869	867	863	857	
PES	884	875	868	859	853	

Secondary Endpoint: Overlap

Proportion of uncovered and/or malapposed struts by stent type

