SOCIEDAD PARAGUAYA DE CARDIOLOGIA

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XIV Jornadas SOLACI

5º Región Cono Sur

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INTERVENCIONISMO EN PUENTES DE SAFENA

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Conflictos de interés:

He aceptado numerosas lapiceras y bombones de un numeroso grupo de laboratorios de farma.
He aceptado camisetas de varios empresas de dispositivos.
Ayer tomé café en stand de Roemmers y asistí a un cocktail de Libra Paraguay.

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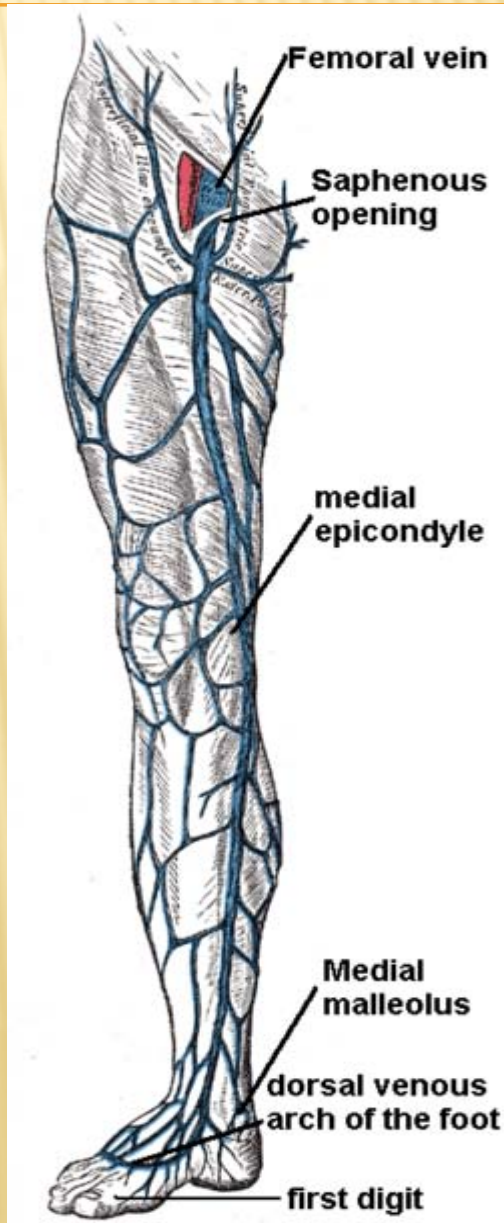
INTERVENCIONISMO EN P. SAFENA

Rene Favoloro, Argentina (1923-2000)
In 1967 created the coronary artery bypass with the saphenous vein.
This was a great discovety but also the beginning of a new disease¡¡¡¡¡



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Natural history of SVG

- In the first year: 15-30% occlusion.
- 1-2% annual occlussion from year 1 to 6.
- 4-5% annual occlussion beyond year 6.
- 10 years after CABG > 50% of graft occlusion.

De Feyter PJ, Topol EJ, Serruys PW. JACC 1993, 21:1539-49.

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Clinical Status

- After the first year: 20% of the patients have stable angina.
- After 5 years: 19% of the patients need new revascularization and 31% after 12.
- 2nd CABG have more mortality/non fatal AMI than the first.

Motwani JG, Topol EJ. Aorto coronary saphenous vein graft disease: pathogenesis, predisposition and prevention. Circulation mar 1998;97:916-31.

Natural history of SVG

- SVG lesions have more plaque burden and thrombus than CAD so they are more friable and have different response to vessel intervention with higher risk of debris embolisation, restenosis and MACE rate.

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Intervention in SVG

- PCI in SVG are 10-15% of all PTCA.

Problems:

- Poor results with balloon angioplasty.
- Inferior results with bare metal stents compared to stent implantation in CAD.
- Distal embolisation: slow flow-no reflow (10-15%) sometimes life threatening.
- High restenosis rate.

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Intervention in SVG

- Direct stenting: marginal benefit.
- Covered stents: no benefit (or low number of patients in trials).
- Auto expandable stents: no benefit.
- Thrombectomy, laser, ultrasound angioplasty: no benefit.
- Distal protection devices.
- DES vs BMS.

INTERVENCIONISMO EN P. SAFENA

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Intervention in SVG

Distal protection devices

2 types:

a) Balloon occlusion

b) Filter systems

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Intervention in SVG

Balloon occlusion technique

SAFER TRIAL

***S**VG **A**ngioplasty **F**ree of **E**mboli **R**andomized*

The SAFER Trial

*"**S**VG **A**ngioplasty **F**ree of **E**mboli **R**andomized"*

Evaluation of the Clinical Safety and Efficacy of the PercuSurge GuardWire in Saphenous Vein Graft Intervention

As presented at TCT 2000 by:

Donald S. Baim, MD FACC
Harvard Medical School
Brigham and Women's Hospital

The SAFER Trial

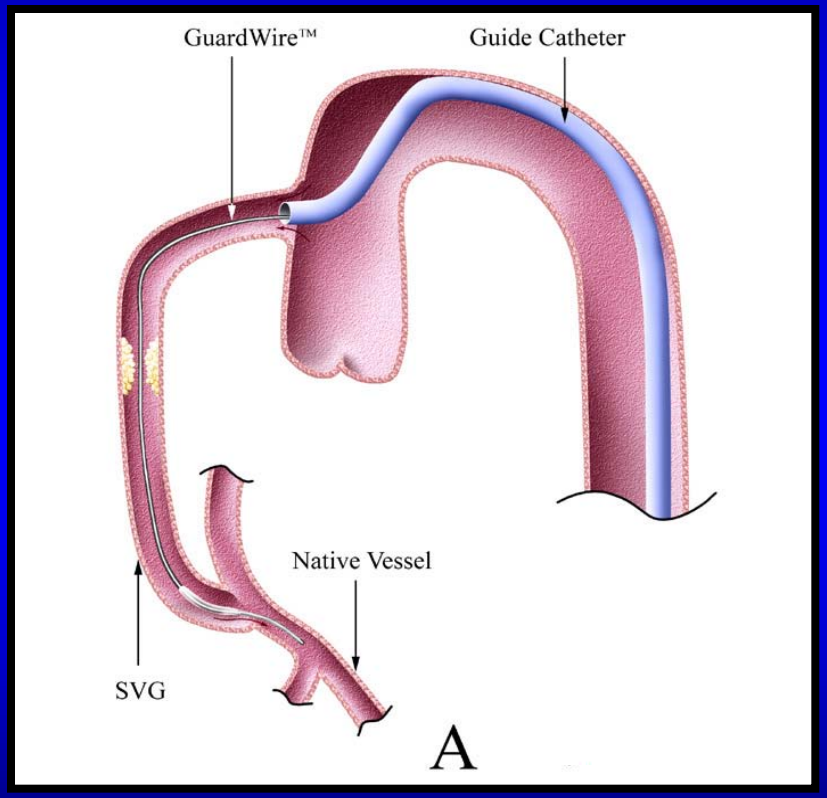
PercuSurge GuardWire® System

4 components:

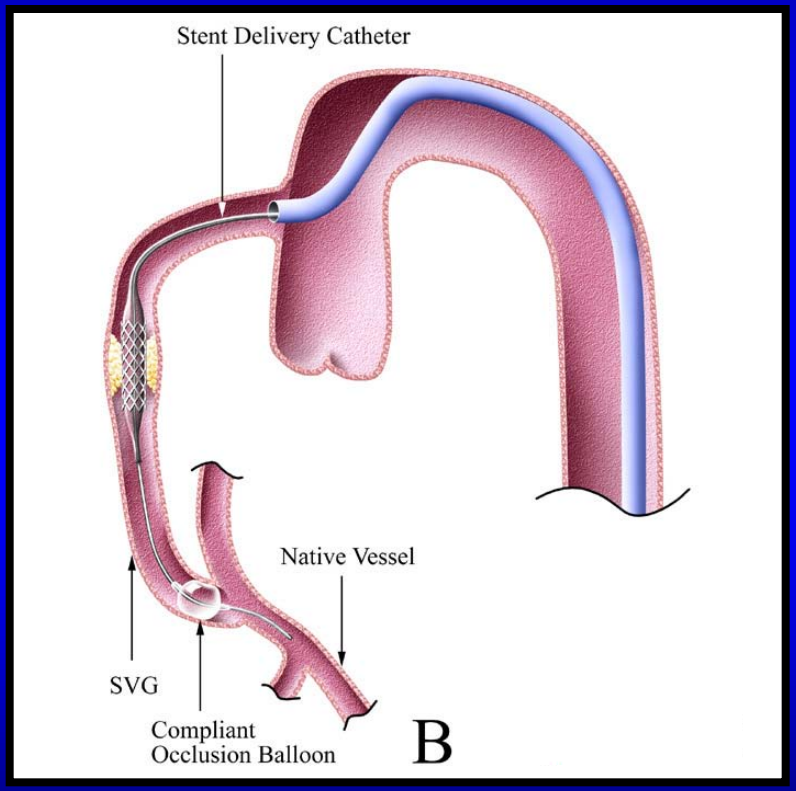
- GuardWire®
- MicroSeal® Adapter
- EZ-Flator™
- Export® catheter

The SAFER Trial

PercuSurge GuardWire® System



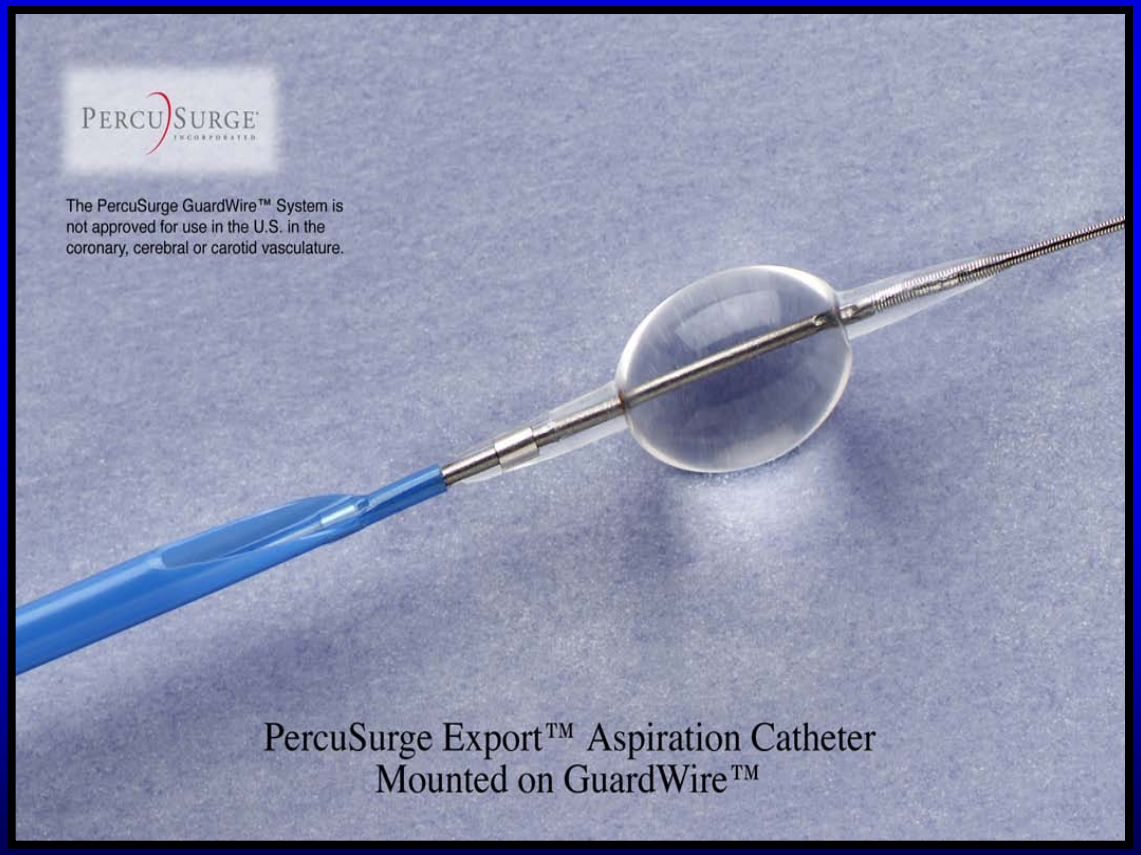
A. Lesion crossed with GuardWire®

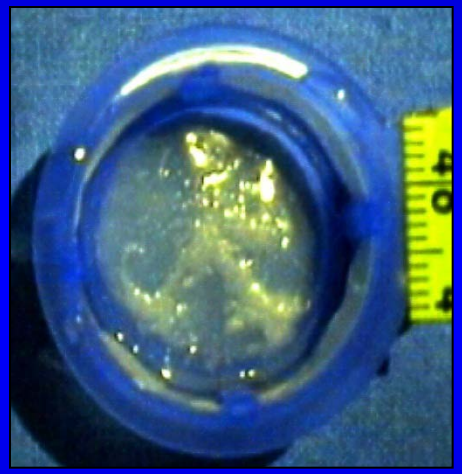


B. GuardWire® balloon inflated and intervention performed under protection. Stent placed with single wire technique

The SAFER Trial

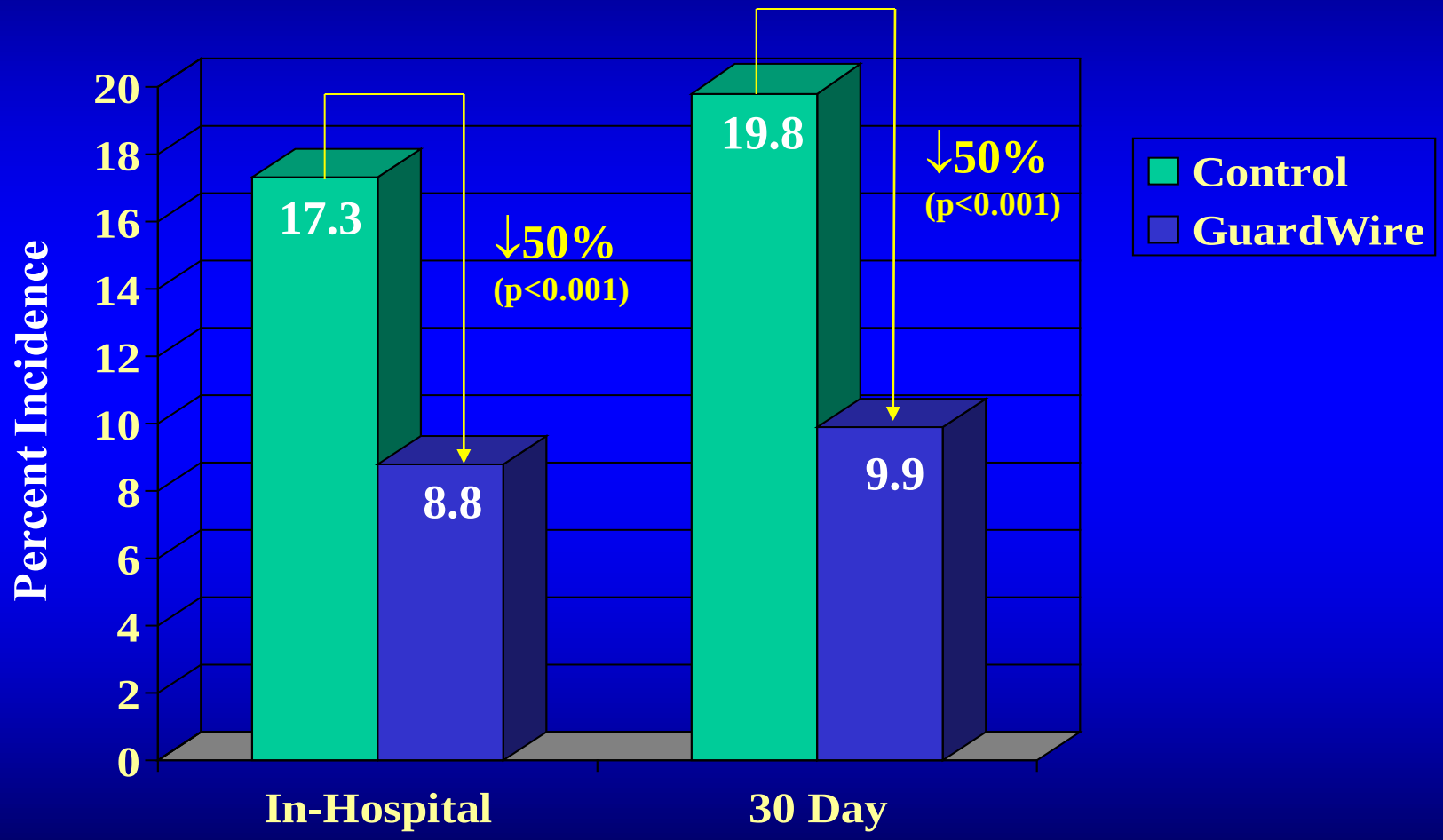
PercuSurge GuardWire® System





The SAFER Trial

Results: MACE



The SAFER Trial

Conclusions

The PercuSurge GuardWire® system proved safe and effective in

- recovering potentially embolic material
- preserving normal flow
- and reducing MACE by 50%

during the percutaneous interventional treatment of saphenous vein bypass grafts

This underscores the importance of distal embolization protection in SVG intervention

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Filter Systems

Fire Trial: 651 P were randomized to SVG PCI between Filter Wire and PercuSurge

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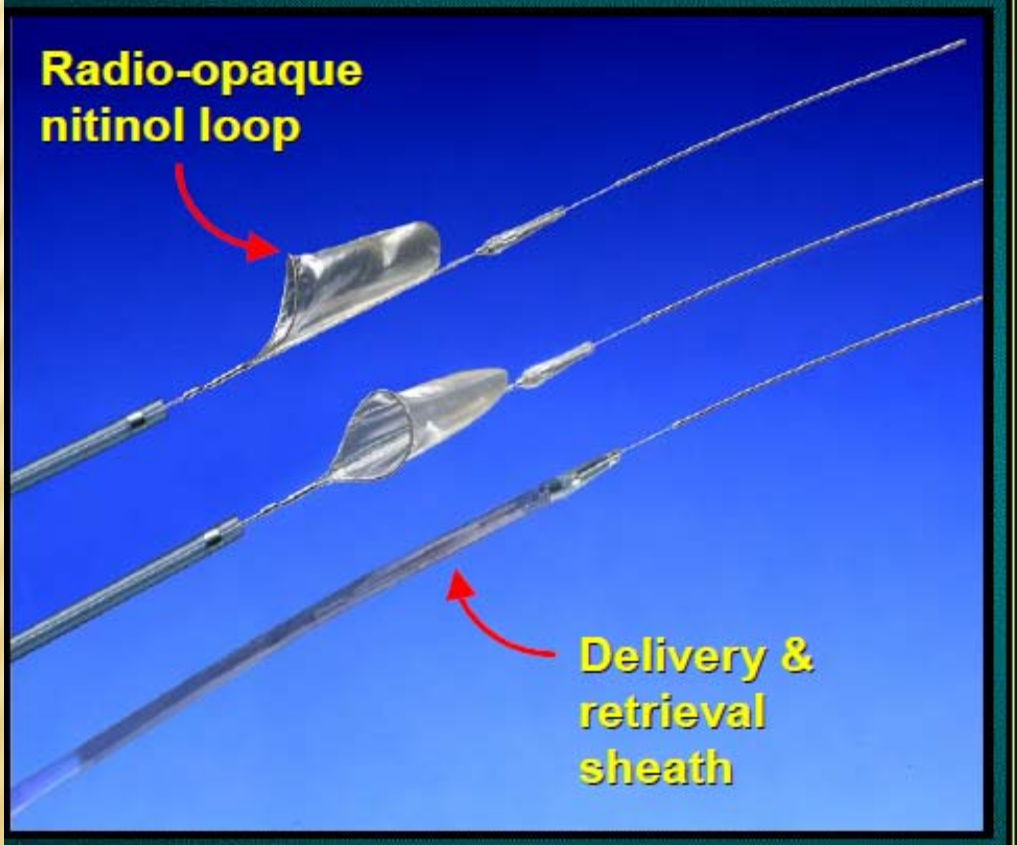
The Boston Scientific FilterWire EX™



- 0.014" wire platform
- Nitinol wire loop with elliptical design with polyurethane filter (110 *um* pores)
  - excellent perfusion, capture efficiency, and particle retention
  - one device for 3.5-5.5 mm
- 3.9F delivery/retrieval sheath

FIRE: 30-day MACE

End point	FilterWire (%)	GuardWire (%)
Death	0.9	0.9
MI	9.0	10.0
Q-wave MI	0.9	0.6
Non-Q-wave MI	8.1	9.7
TVR	1.2	1.9
Any MACE	9.9	11.6

p=NS

Stone GW. American College of Cardiology Annual Scientific Sessions. Mar 31-Apr 4, 2003; Chicago, IL.

INTERVENCIONISMO EN P. SAFENA

Lower Mace can be achieved in SVG PCI:

Stenting in Saphenous Vein Grafts with Distal Protection Using a Second Generation Filter-based Catheter

The Combined Blaze I and II Registries

D.Cox, H. Lui, R.Caputo,H.Bonnier,R. Kovach,A.Masud,
B.Brodie, T.Stuckey,H.Hermman,J.Hermiller,A.Lansky,
D.Cutlip,G.Tully,G.Stone for the BLAZE Investigators

TCT 2005

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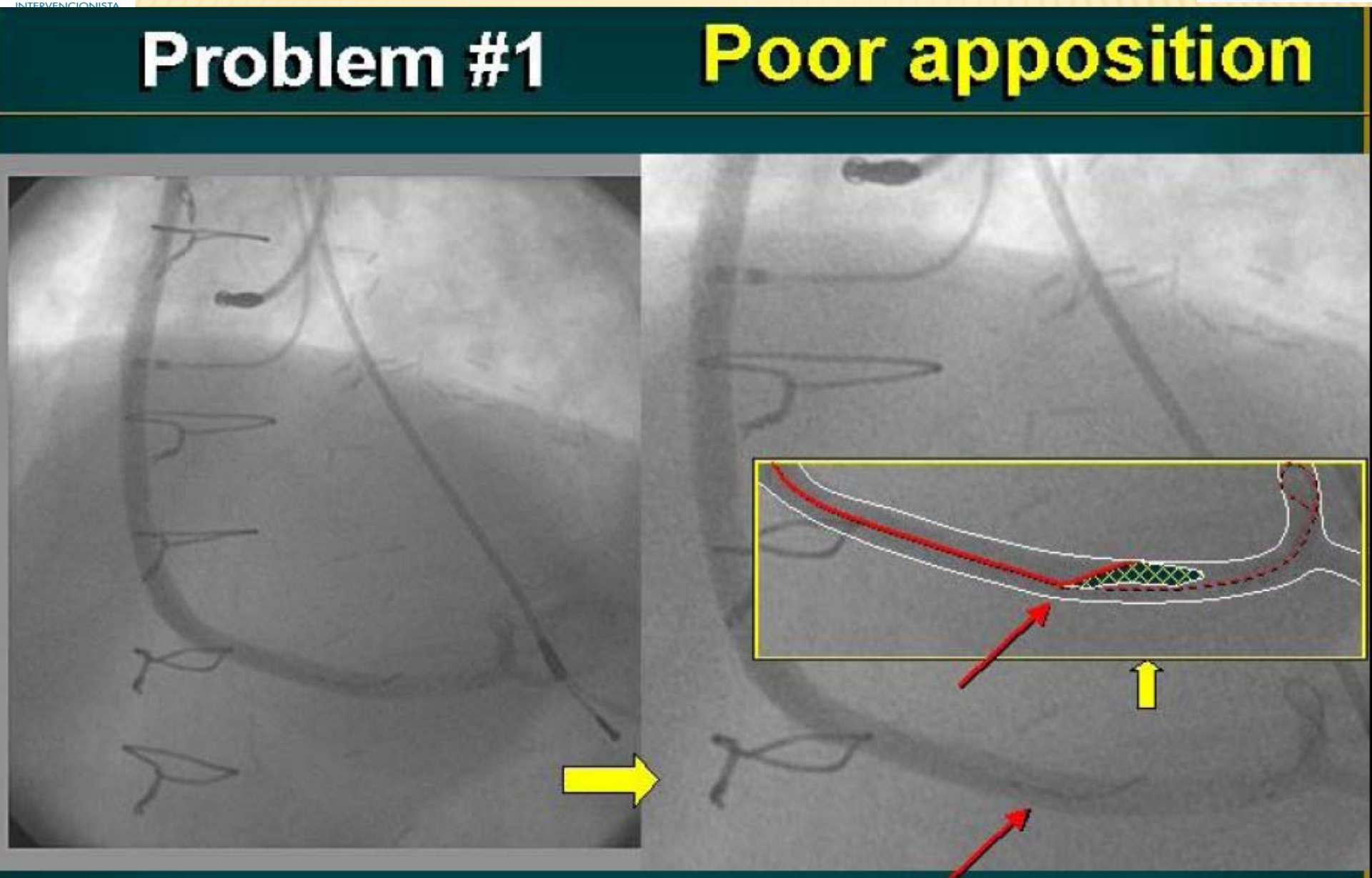

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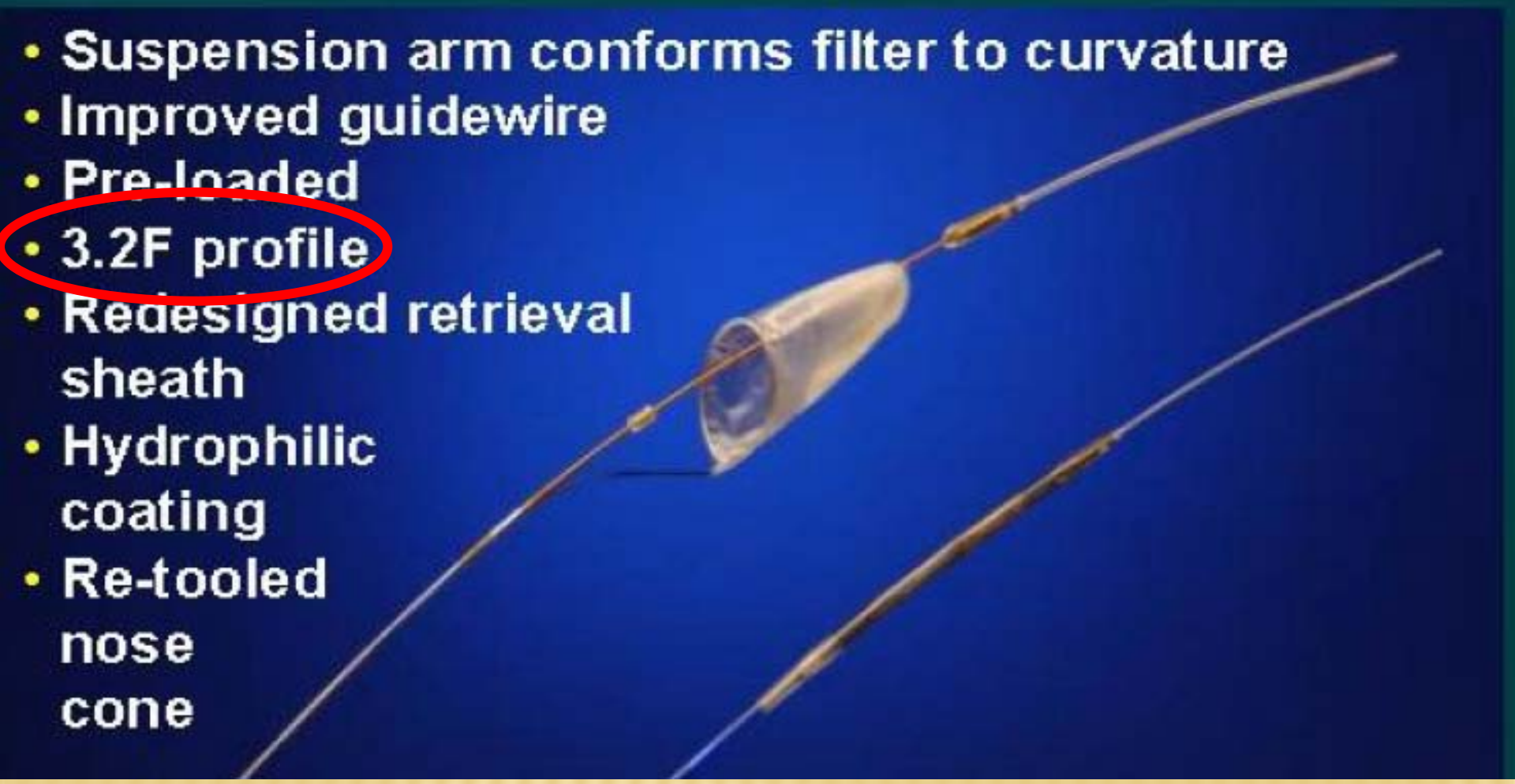
The BSC FilterWire EZ™

- Suspension arm conforms filter to curvature
- Improved guidewire
- Pre-loaded
- 3.2F profile
- Redesigned retrieval sheath
- Hydrophilic coating
- Re-tooled nose cone



INTERVENCIONISMO EN P. SAFENA

BLAZE I (3.5-5.5mm FilterWire EZ)

30-Day MACE

Hierarchical Events	n=90
Death	0 %
Q wave MI	0 %
Non-Q wave MI	6.7%
TLR	0 %
TVR	0 %
Overall MACE	**6.7 %**

TCT 2003: Decreased MACE even with more thrombotic lesions than in FIRE

INTERVENCIONISMO EN P. SAFENA

BLAZE I/II: Baseline Demographics

N	221 patients,229 lesions
Age	69.0 yrs
Male	79.2%
Diabetes	43.3%
Hx MI	59.3%
HTN	83.6%
Recent angina or MI prompting Rx	88.9%
Prior PCI of target lesion w/in 9 months	2.3%

INTERVENCIONISMO EN P. SAFENA

BLAZE I/II: Efficacy and Safety Measures

Device success	98.1%
Clinical success	93.7%
SAT	0%
Perforation	0%

30-Day MACE: FIRE vs BLAZE I/II

Hierarchical Events

	FIRE	BLAZE	P
Death	0.9%	0 %	NS
Q wave MI	0.9%	0.5%	NS
Non-Q wave MI	8.1%	4.5 %	.10
TLR	1.2%	0 %	NS
TVR (non-TLR)	1.2%	0 %	NS
Overall MACE	**9.9%**	**5.0 %**	**0.03**

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CONCLUSIONES

- La embolización distal es muy común y se asocia con un aumento de la mortalidad de 8 a 10 veces mayor.
- A pesar de que puede tratar de predecirse factores predictores muchas veces nos toma por sorpresa.
- Todos los subgrupos de pacientes parecen beneficiarse de los sist. de protección distal.

INTERVENCIONISMO EN P. SAFENA

- Direct stenting: marginal benefit.
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- Auto expandable stents: no benefit.
- Thrombectomy, laser, ultrasound angioplasty: no benefit.
- Distal protection devices.
- DES vs BMS.

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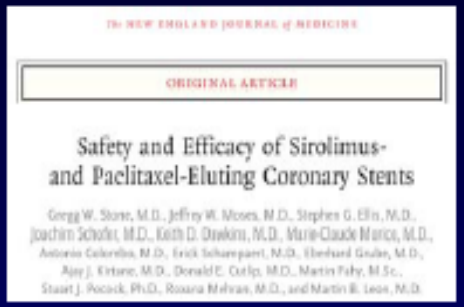
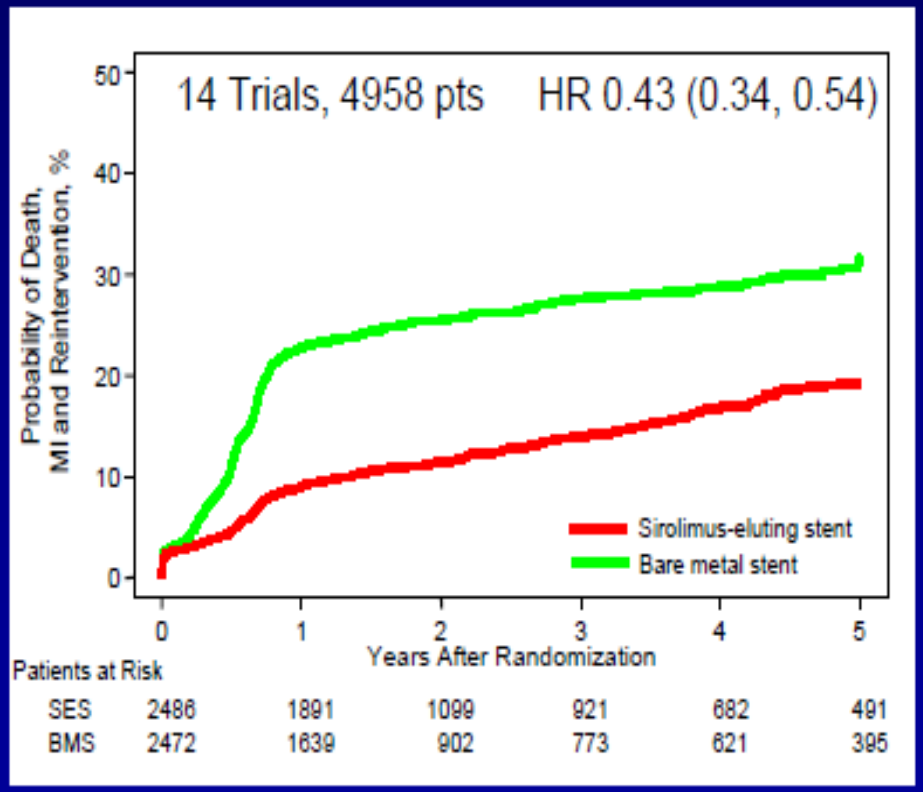
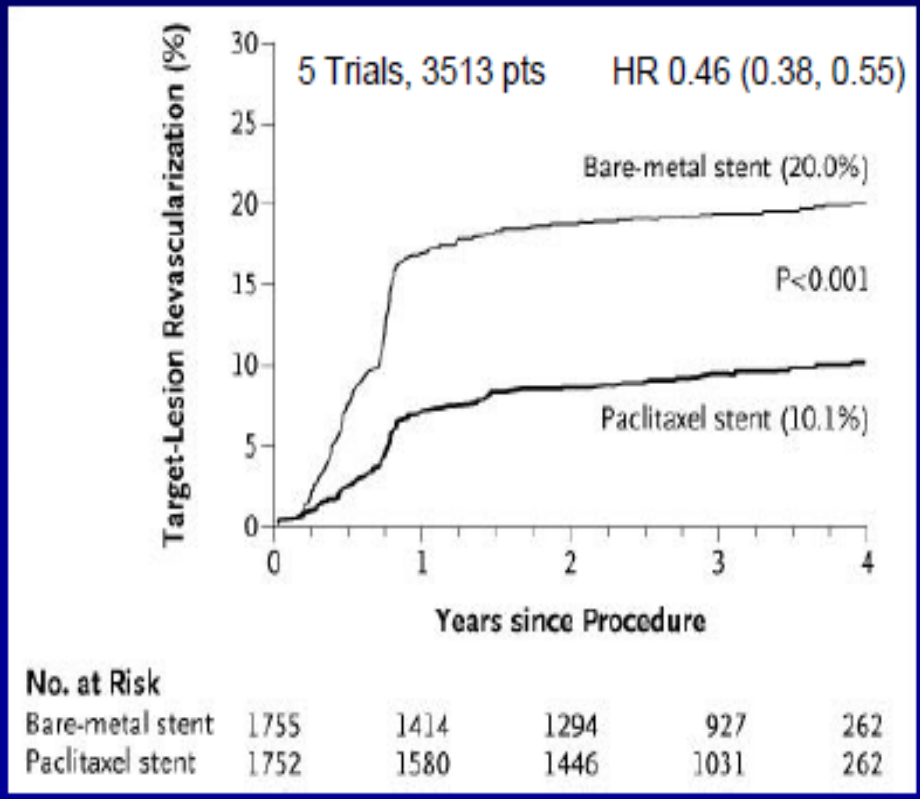
Predictors of Restenosis in SVG

- Ostial or proximal localization.
- Diffuse disease.
- SVG older than 3 y.
- Lesion lenght.
- Reference diameter.
- Diabetes.

DES are more effective and as safe as their BMS predecessors in native coronary artery lesions







Kastrati …Schömig, NEJM 2007

Stone …Leon, NEJM 2007

INTERVENCIONISMO EN P. SAFENA

RRISC Trial

Reduction of Restenosis In Saphenous vein grafts with Cypher sirolimus-eluting stent

- Prospective, **randomized**, **double-blind**, non industry sponsored, trial comparing sirolimus-eluting stents vs. bare metal stents.
- **75** patients with **96** lesions localized in **80** diseased saphenous vein grafts were included
- Primary endpoint : in-stent **late loss**
- Secondary endpoints:
  - Clinical events (death, MI, TLR, TVR)
  - Binary angiographic restenosis in-stent/in-segment
  - IVUS measured neo-intimal hyperplasia volume

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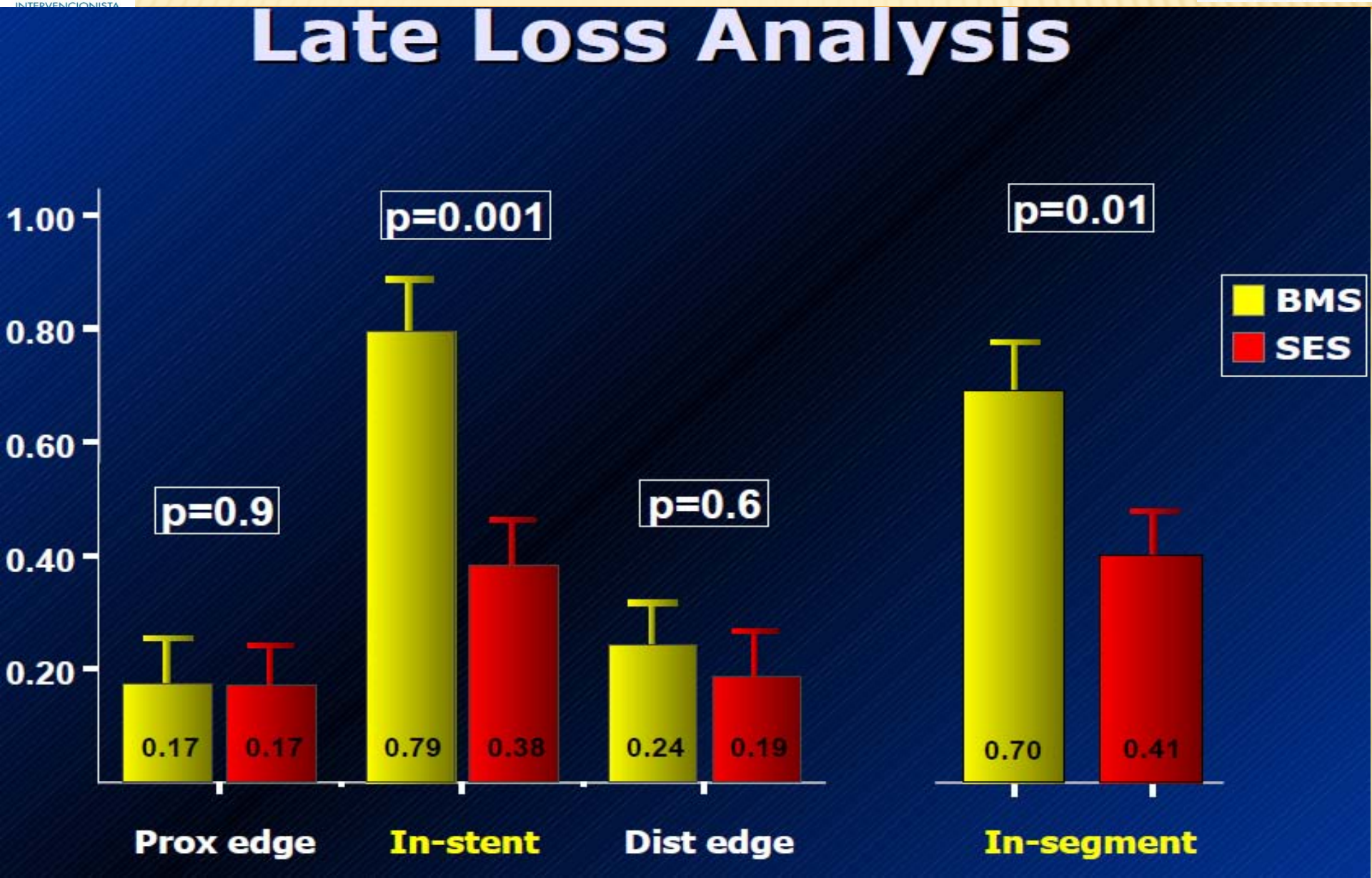
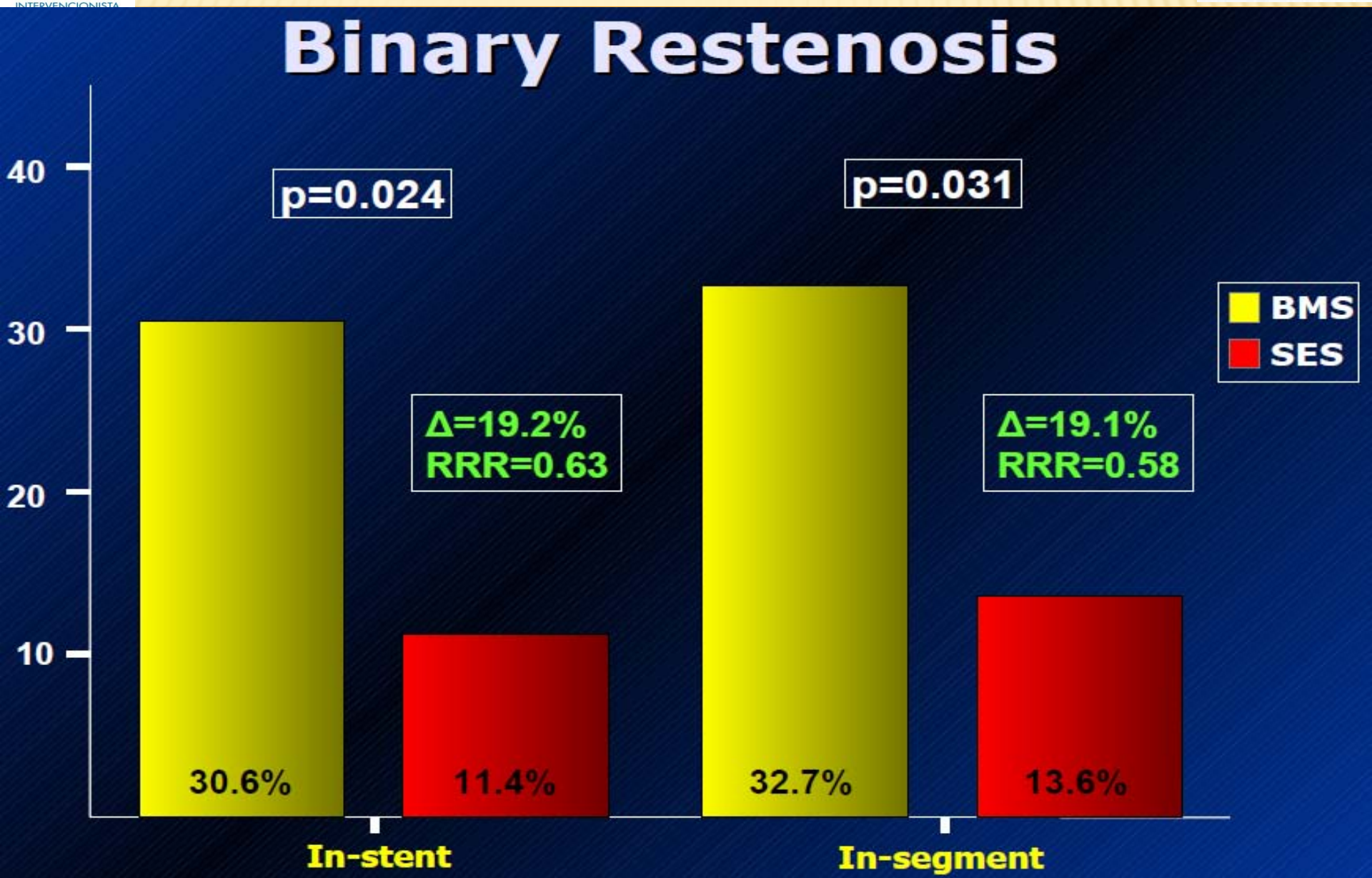


INTERVENCIONISMO EN P. SAFENA



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6-months Clinical Events

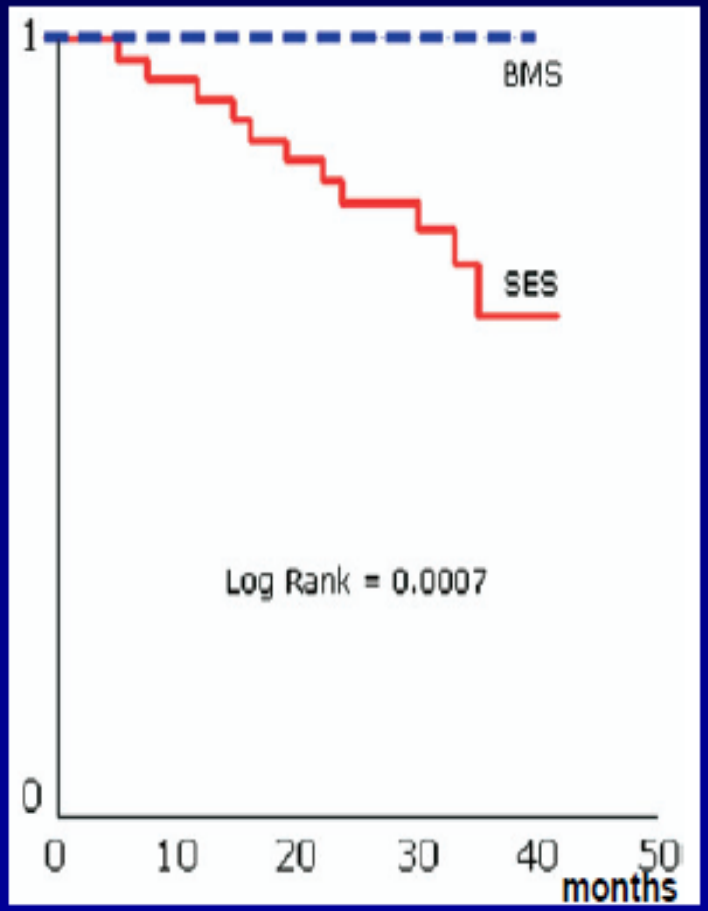
	BMS n=37	SES n=38	P value
In-hospital			
Death	0	0	
Repeat revascularization	0	0	
Periprocedural MI	1 (2.7%)	2 (5.3%)	0.99
Between discharge and 6 months			
Death	0	1 (2.6%)	0.99
Myocardial infarction	0	1 (2.6%)	0.99
TLR (per-patient)	8 (21.6%)	2 (5.3%)	**0.047**
TVR (per-patient)	10 (27%)	2 (5.3%)	**0.012**
Cumulative **6-month MACE**	11 (29.7%)	6 (15.8%)	0.15
TVF (per-patient)	11 (29.7%)	5 (13.2%)	0.08

Conclusions

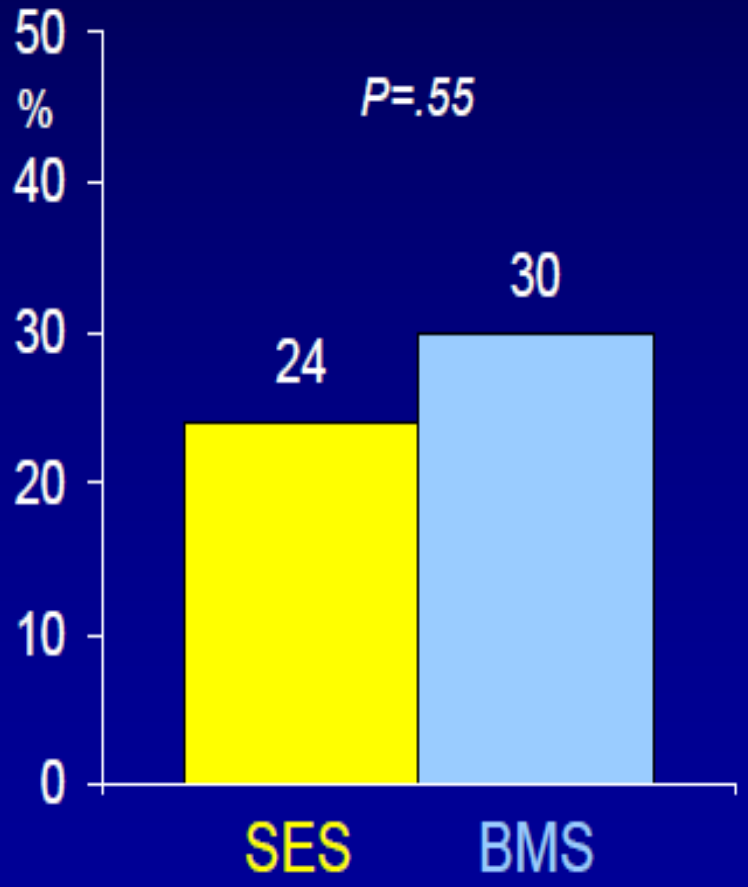
- SES determine also in SVG a significant reduction of neointimal hyperplasia as compared to BMS
- The neointimal response to SES seems higher in the overlapping segments of the stent than in the single layer segments
  (post-hoc analysis… "hypothesis-generating"!)
- No late incomplete apposition was noted

DELAYED RRISC Trial (3 y)
N=75

Survival



TLR



29% in Cypher vs 0% in BMS

Vermeersch et al., JACC 2007

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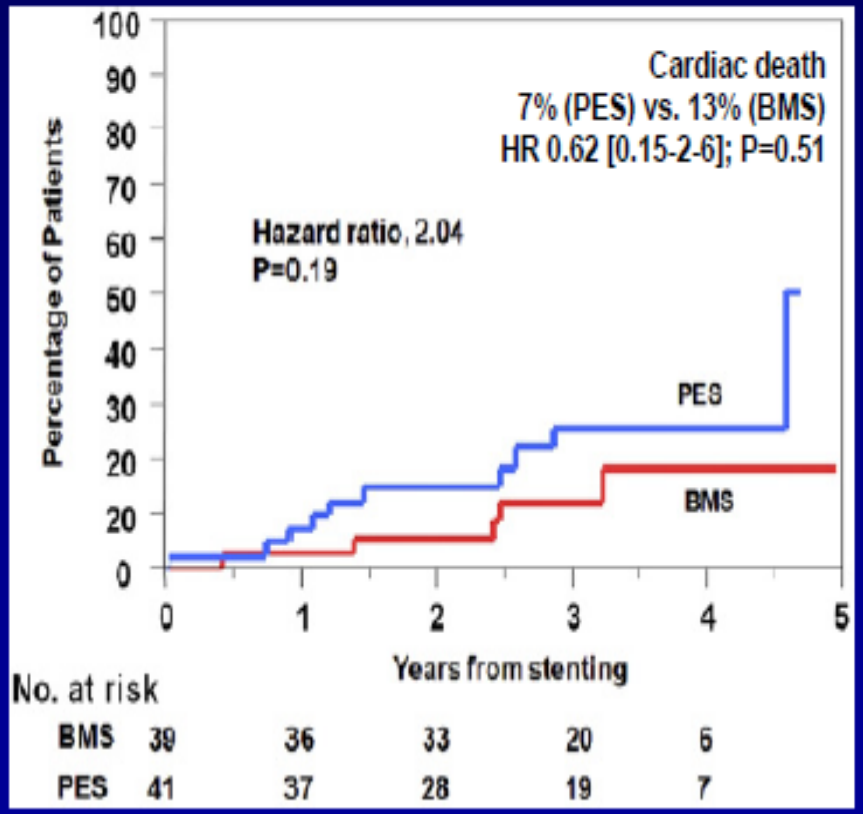
SOS TRIAL: CLINICAL OUTCOMES AT MEDIAN 1.5 YEARS

80 P

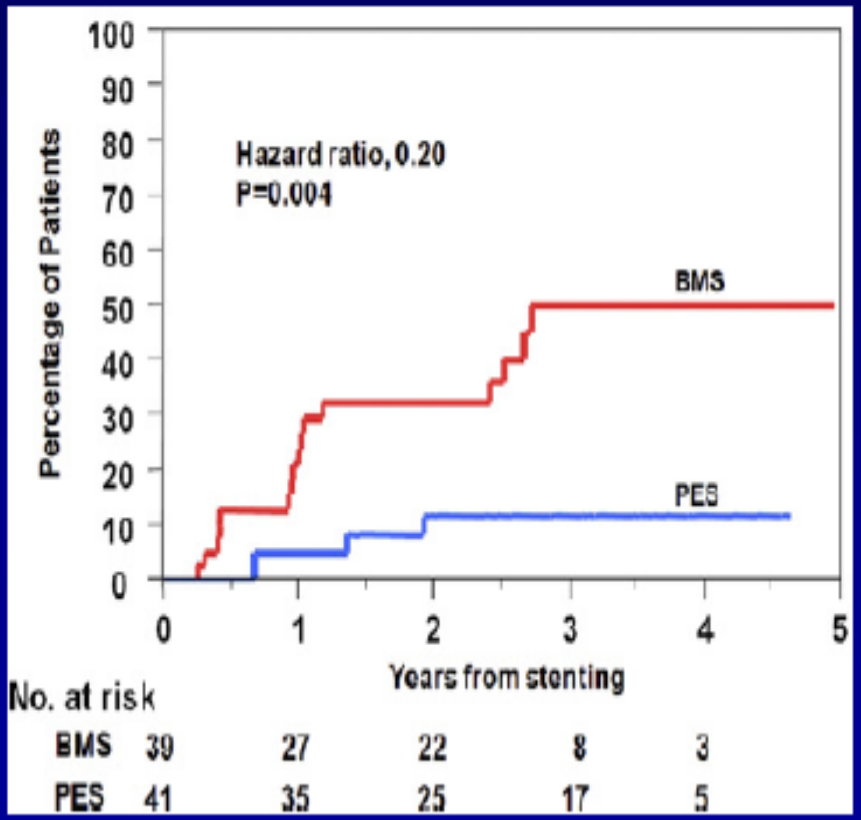
	BMS n = 39	Taxus n = 41	HR (95% CI)	*P* Value
Death	5%	12%	1.56 (0.72-4.11)	0.27
MI	31%	15%	0.67 (0.40-1.08)	0.10
TLR	28%	5%	0.38 (0.15-0.74)	0.003
TVR	31%	15%	0.66 (0.39-1.05)	0.08
TVF	46%	22%	0.65 (0.42-0.96)	0.03
MACE[a]	49%	37%	0.80 (0.57-1.12)	0.20
Definite or Probable Stent Thrombosis[b]	13%	2%	0.42 (0.10-1.05)	0.07

SOS Trial
N=80

All-cause Death



Target Lesion Revascularization



Brilakis et al., JACC Intv 2011

INTERVENCIONISMO EN P. SAFENA

ISAR-CABG:
Randomized, Superiority Trial of Drug-Eluting-Stent and Bare Metal Stent in Safenous Vein Graft Lesions

J. Mehilli, MD,
G. Richardt, F-J. Neumann, S. Massberg, K-L. Laugwitz, J. Pache, J. Hausleiter, I. Ott, M. Fusaro, T. Ibrahim, S. Schulz, R. A. Byrne, A. Schömig, A. Kastrati

Deutsches Herzzentrum & 1st Med. Klinik rechts der Isar, Technische Universität Munich, Germany

Patient Selection

Inclusion criteria

Patients with ischemic symptoms or evidence of myocardial ischemia in the presence of ≥50 % *de novo* stenosis located in saphenous vein grafts

Informed, written consent

Exclusion criteria

Cardiogenic shock

Target lesion located in arterial grafts

Malignancies with life expectancy <1 year

Allergies to study medication

Primary Endpoint

Composite of

death,

myocardial infarction

ischemia-related target lesion revascularization

at 1-year post index PCI

Secondary Endpoints

All cause mortality

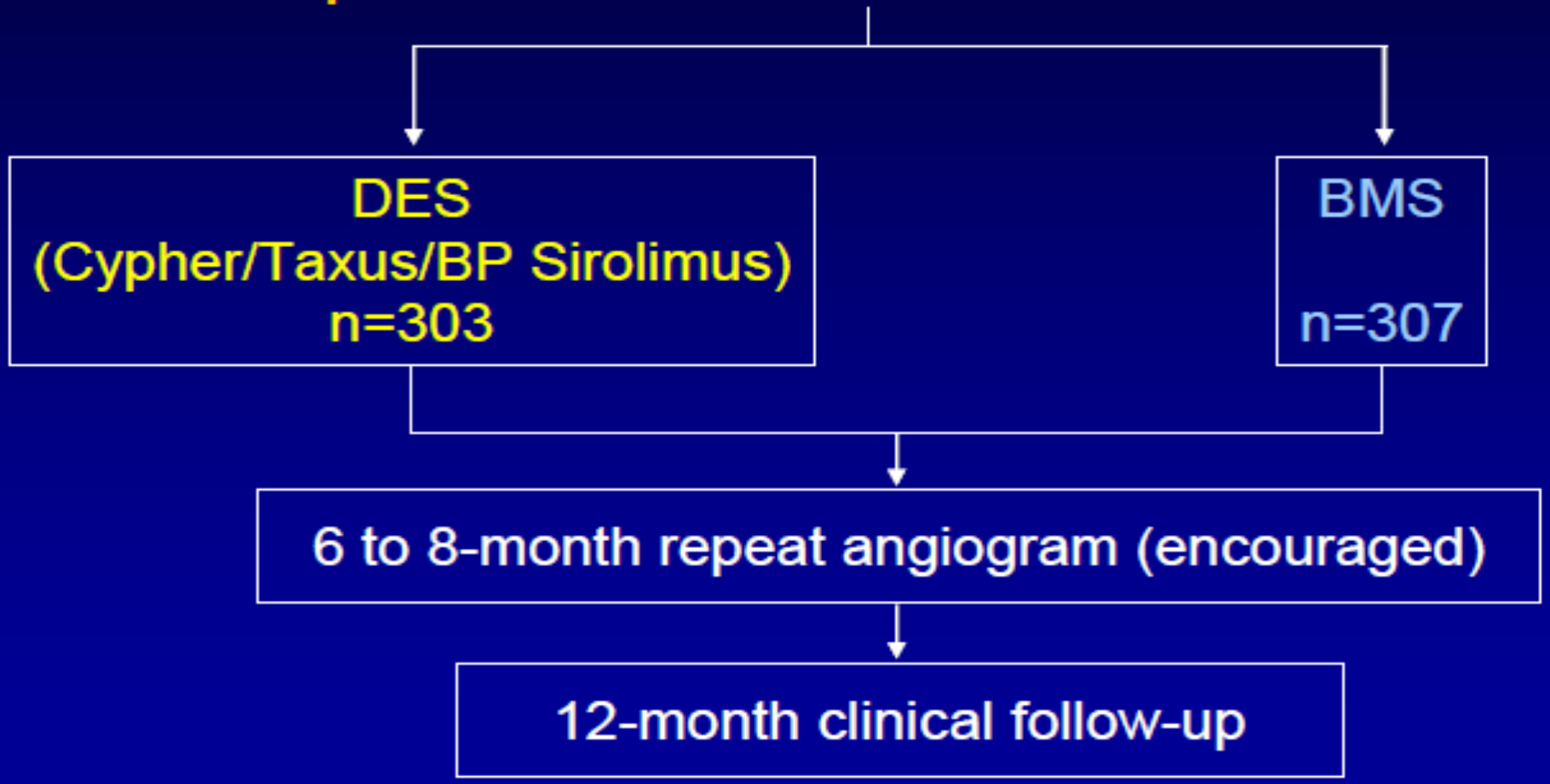
Myocardial infarction

Ischemia-related target lesion revascularization

Incidence of definite/probable stent thrombosis at 1-year post index PCI

ISAR-CABG

*I*s Drug-Eluting *S*tenting *A*ssociated With Improved *R*esults in *C*oronary *A*rtery *B*ypass *G*rafts?



Follow-Up Protocol

600 mg Clopidogrel
PCI
ASS 500 mg

Clopidogrel	2x75 mg/day until discharge 75 mg at least 6 months after index PCI
Aspirin	200 mg/d indefinitely

Baseline clinical characteristics

	DES n=303	BMS n=307
Age, years	71.4±9.0	71.5±9.3
Female, %	13	16
Art. hypertension, %	71	73
Diabetes, %	37	35
Current smoker, %	8	6
Hyperlipidemia, %	88	86
SVG age, years	13.8±5.5	13.5±5.1
History of MI, %	56	55

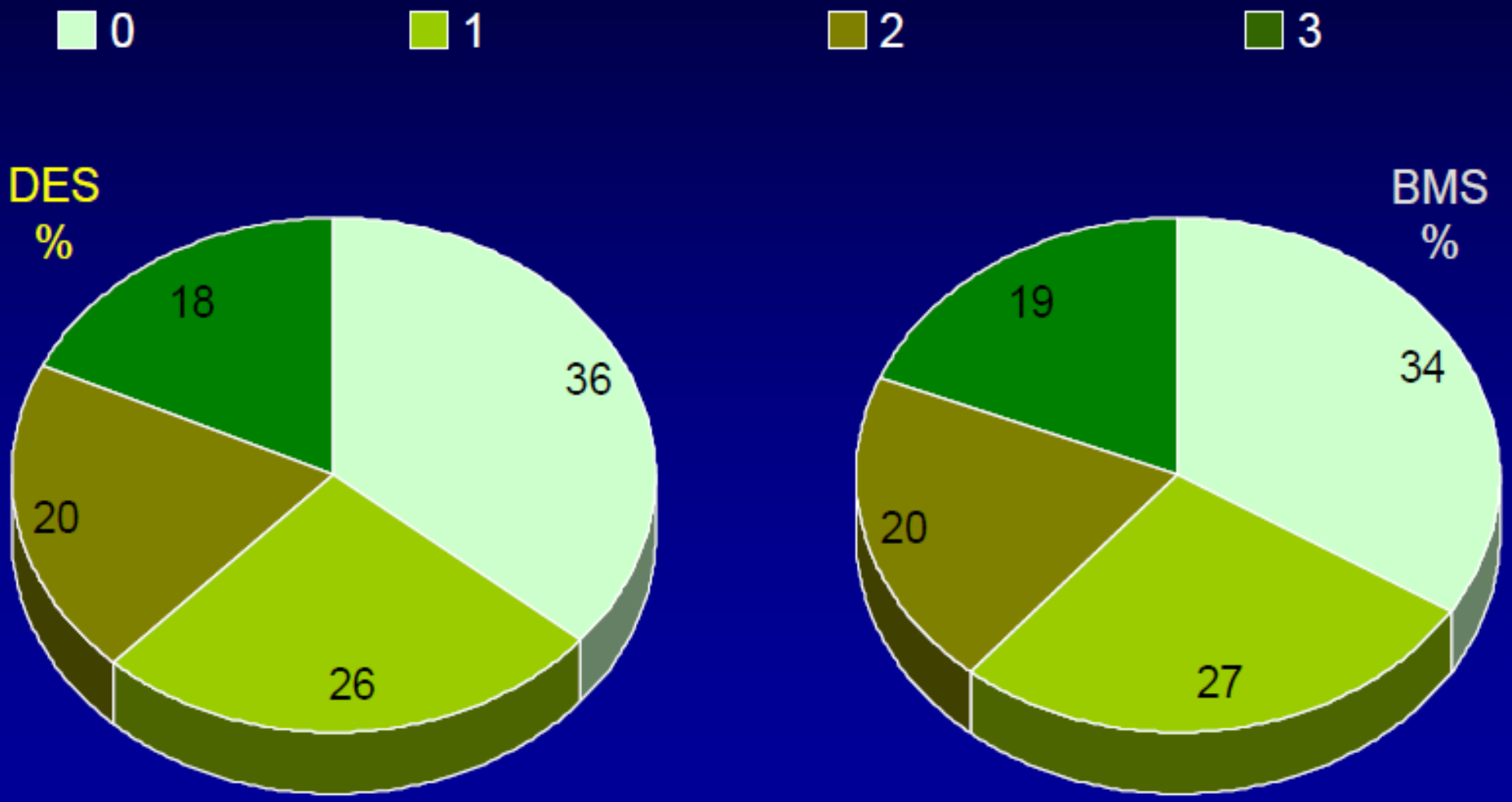
Baseline clinical characteristics, II

	DES n=303	BMS n=307
Clinical presentation, %		
acute MI	17	13
unstable angina	21	27
stable angina	62	60
Multivessel disease, %	98	99
Multilesion PCI, %	24	22
>1 SVGs treated/patient, %	4.0	3.6
LV ejection fraction, %	49.2±12.2	49.5±13.8

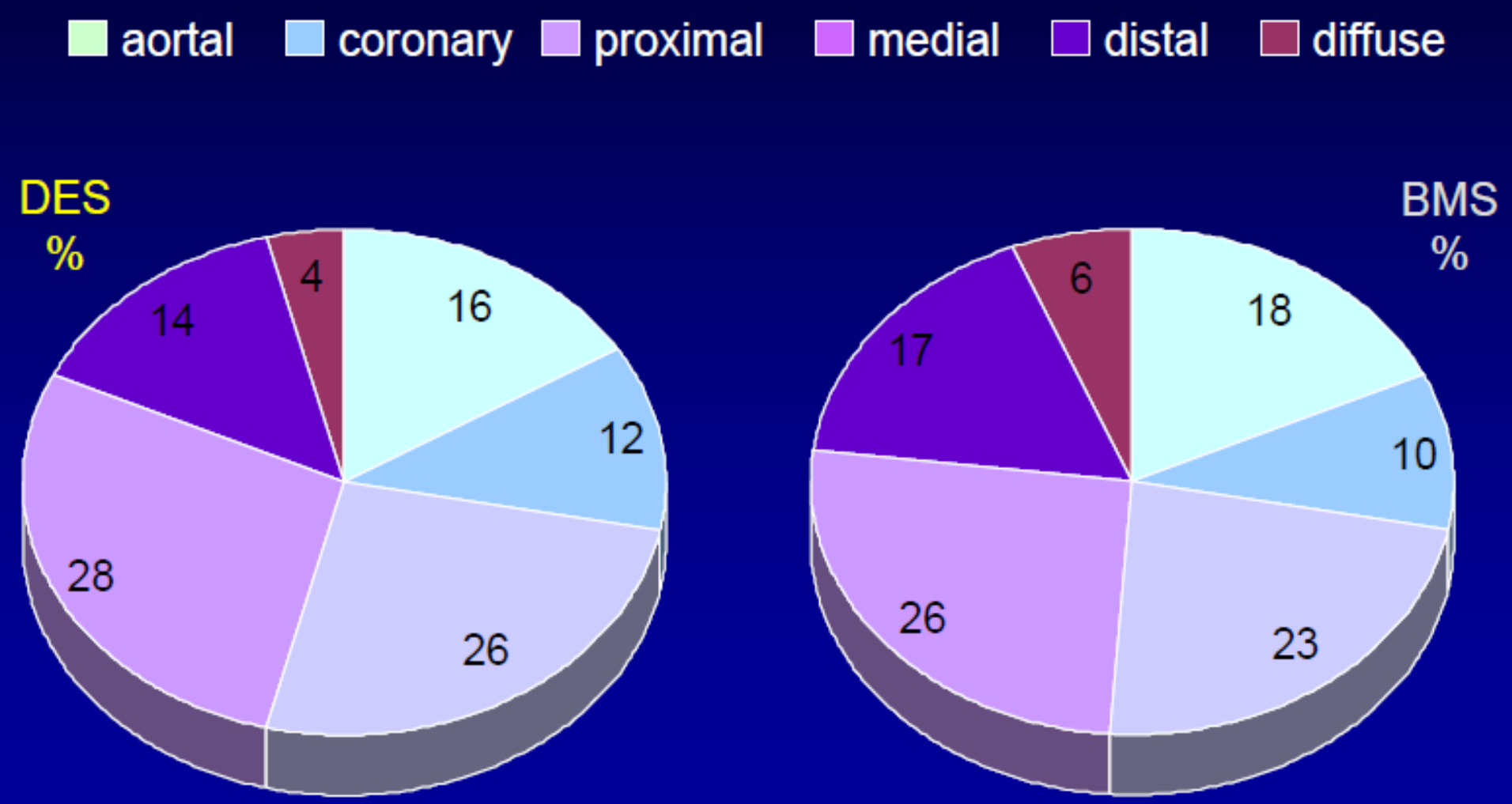
Angiographic characteristics

	DES n=386	BMS n=385
Recipient vessel, %		
LAD/diagonal	32.0	31.0
LCx/marginal	35.0	36.0
RCA/PDA	33.0	33.0
Vessel size, mm	3.36±0.67	3.38±0.73
Total stented length, mm	26.8±15.4	27.5±17.7

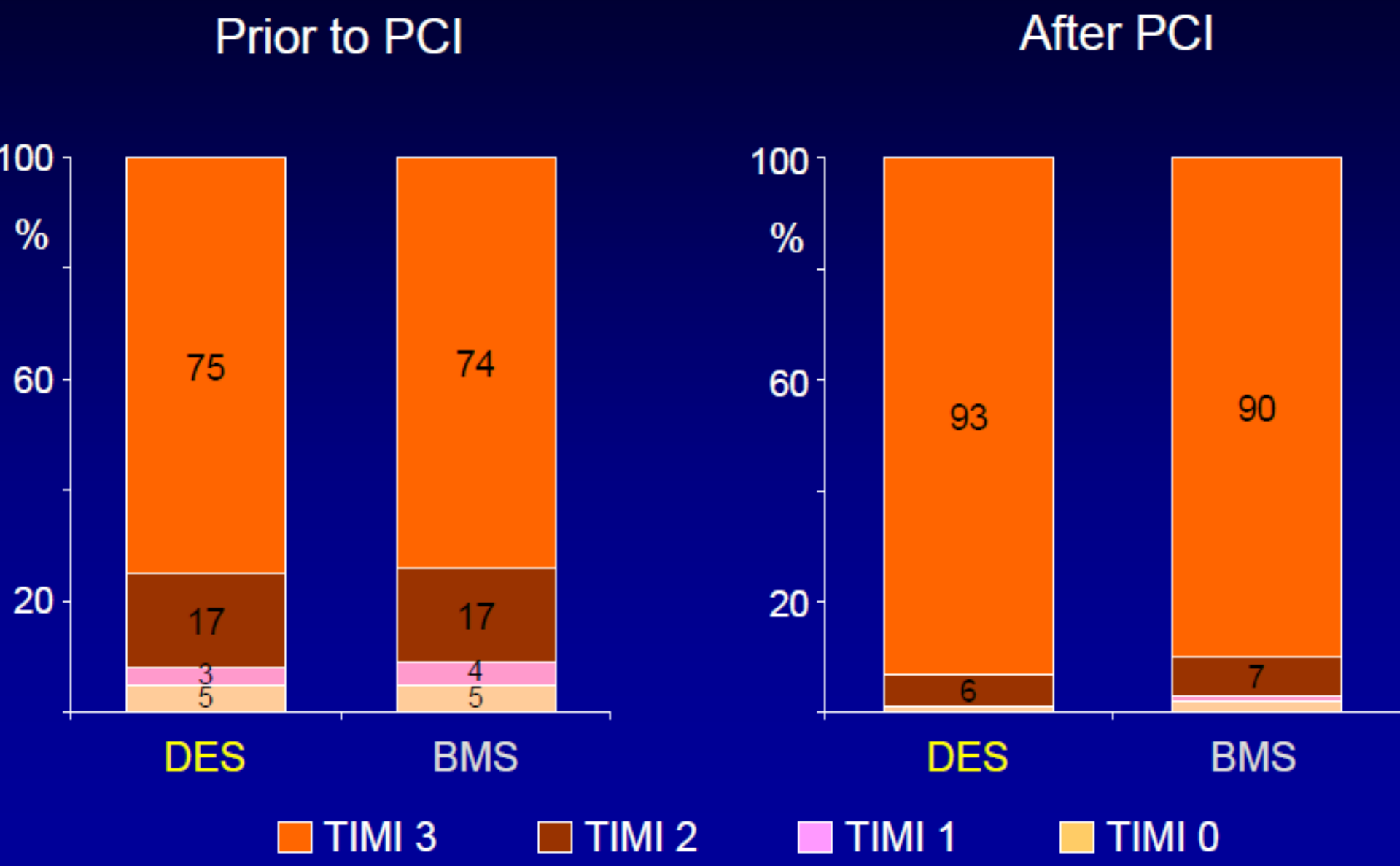
Distribution of SVG Degeneration Score



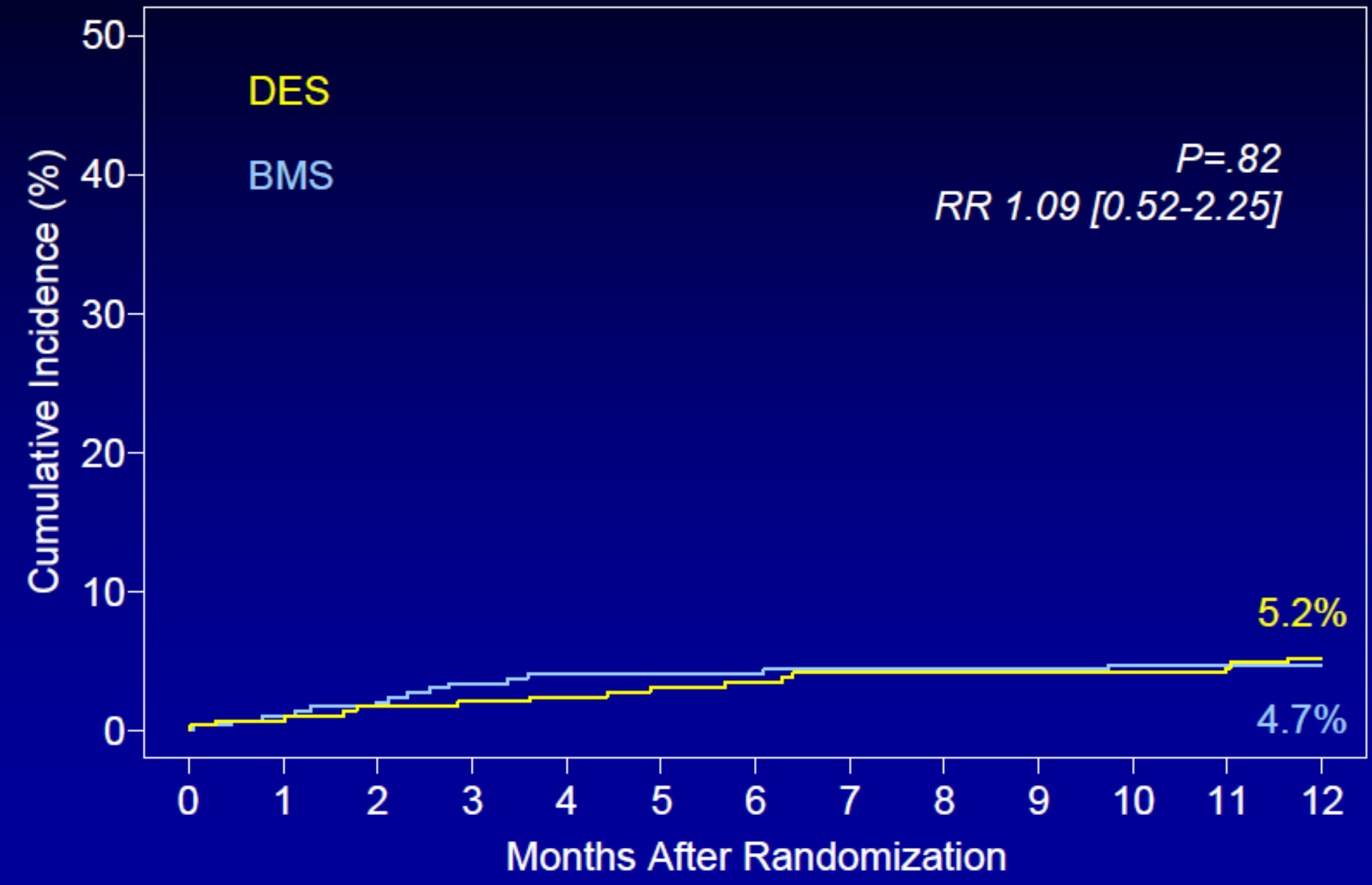
Distribution of Lesion Location within the SVGs



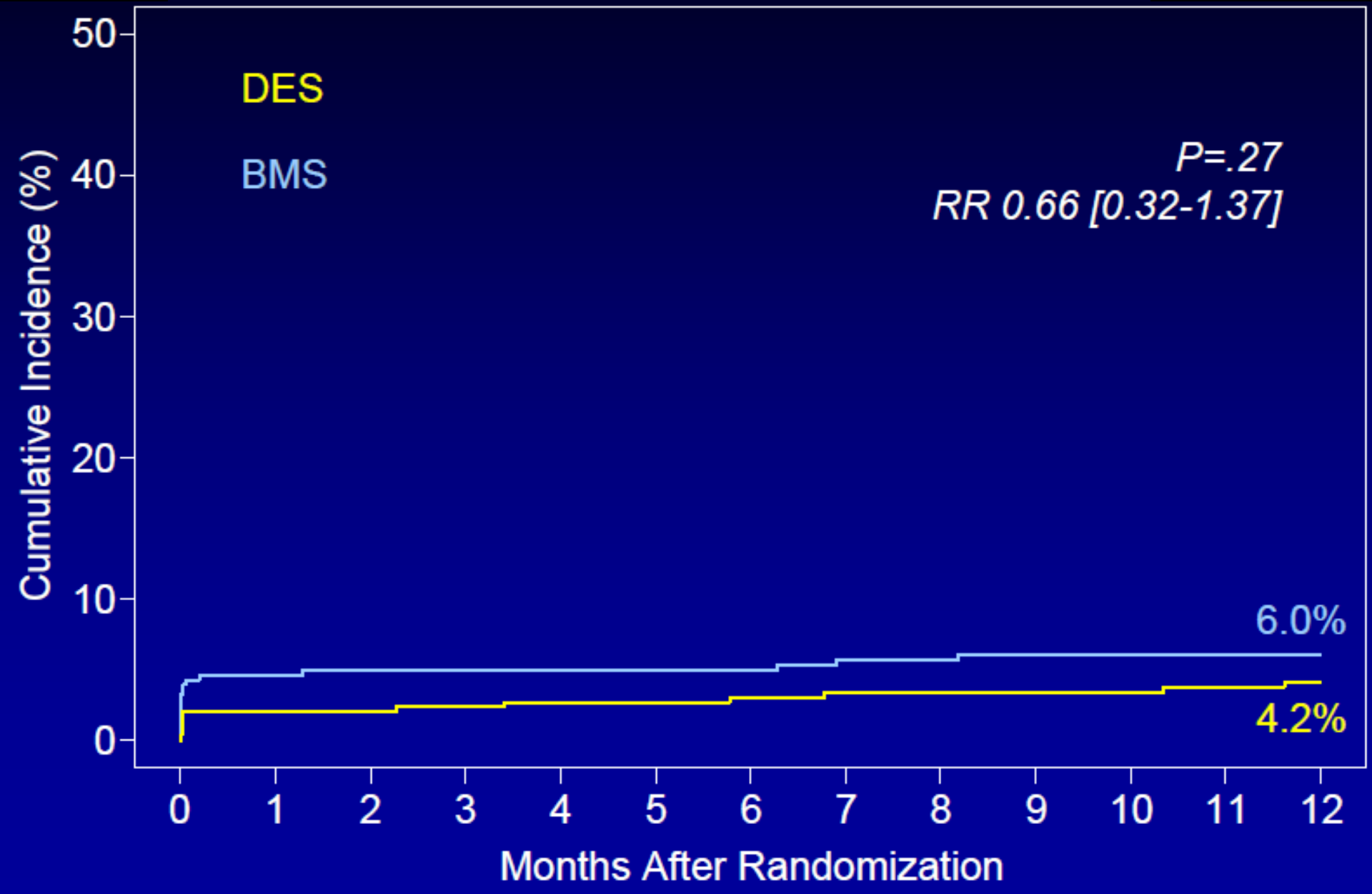
Distribution of TIMI Flow Rates



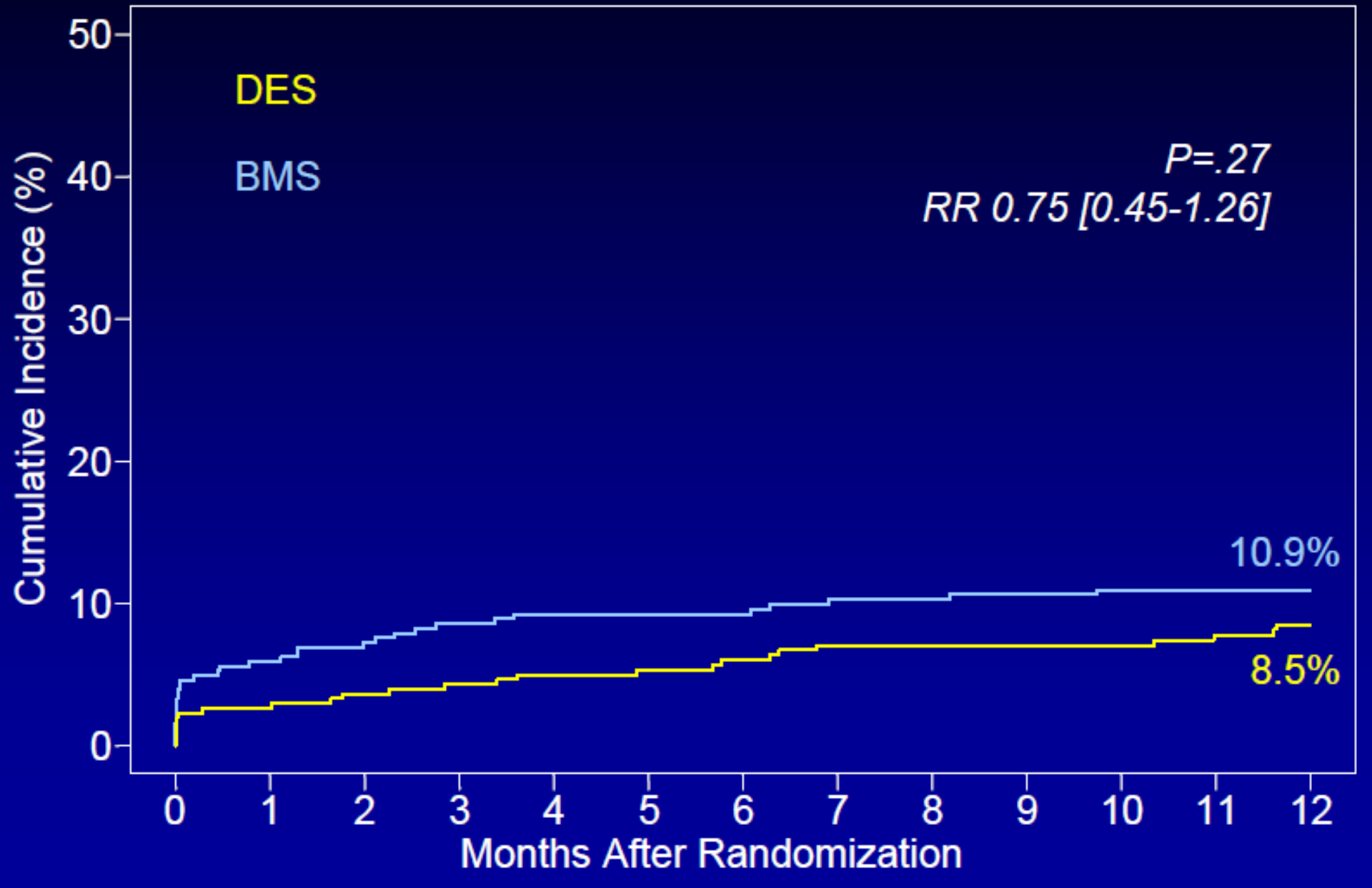
All-cause Death



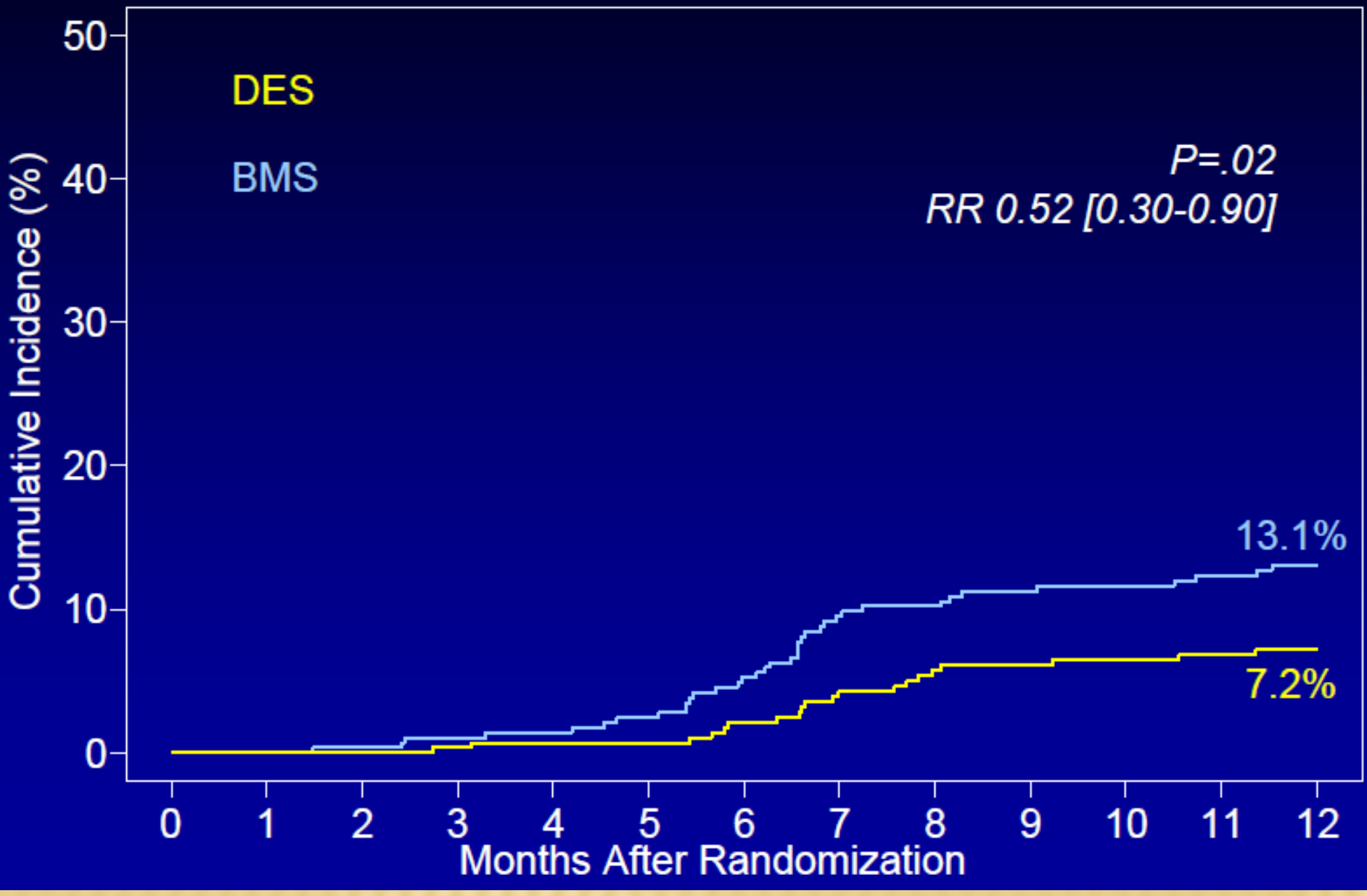
Myocardial Infarction



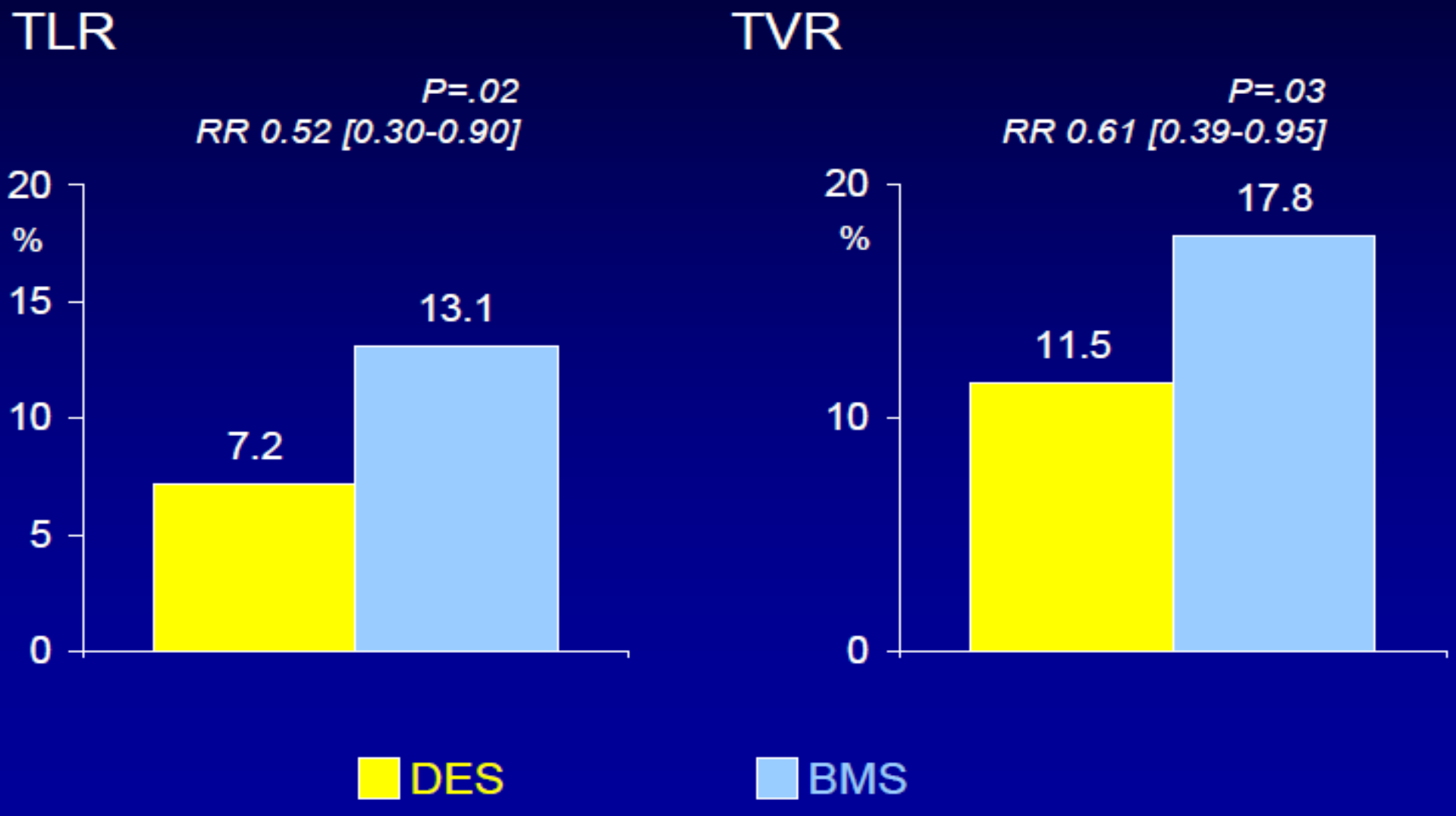
Death or Myocardial Infarction



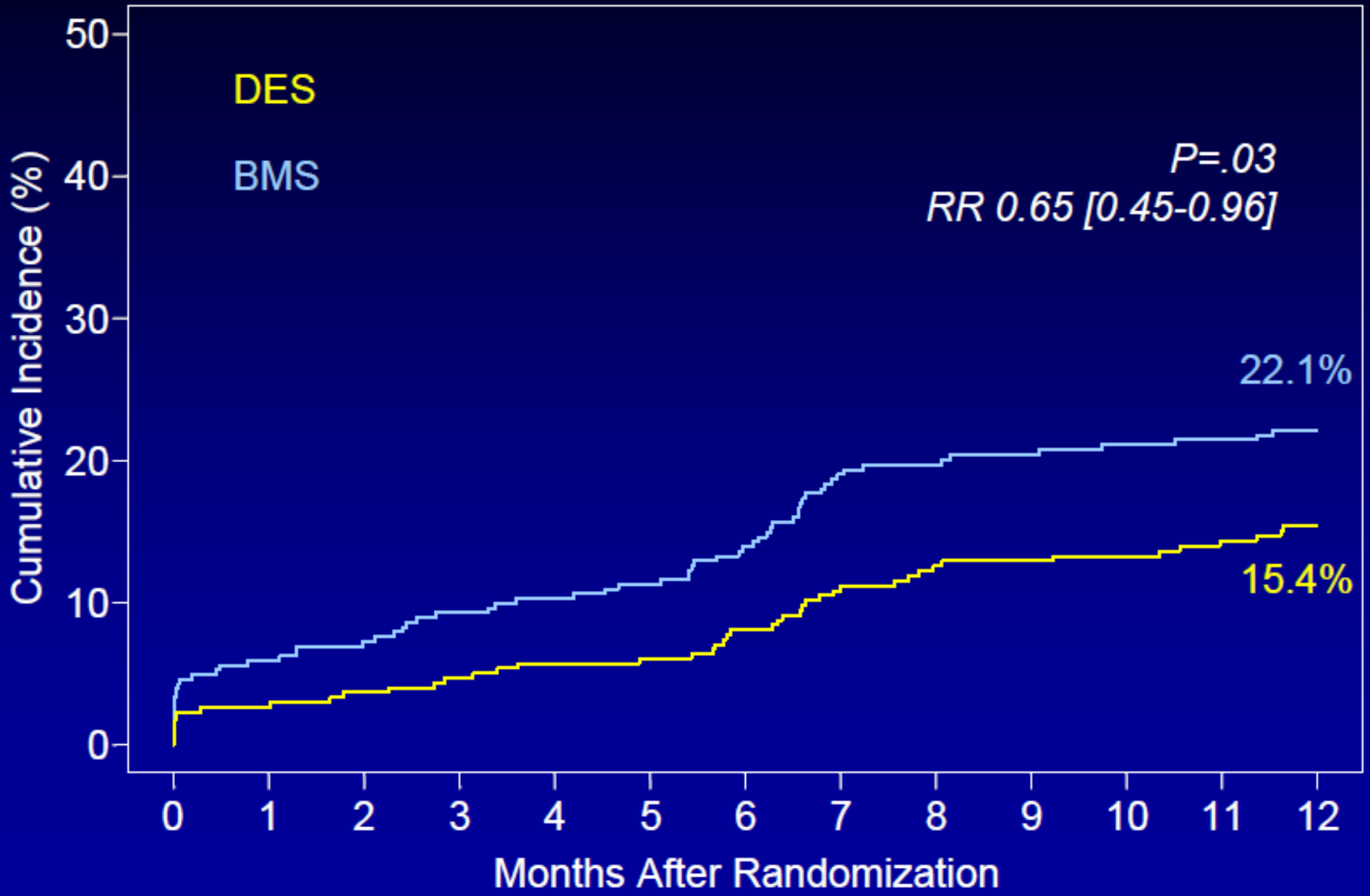
Target Lesion Revascularization



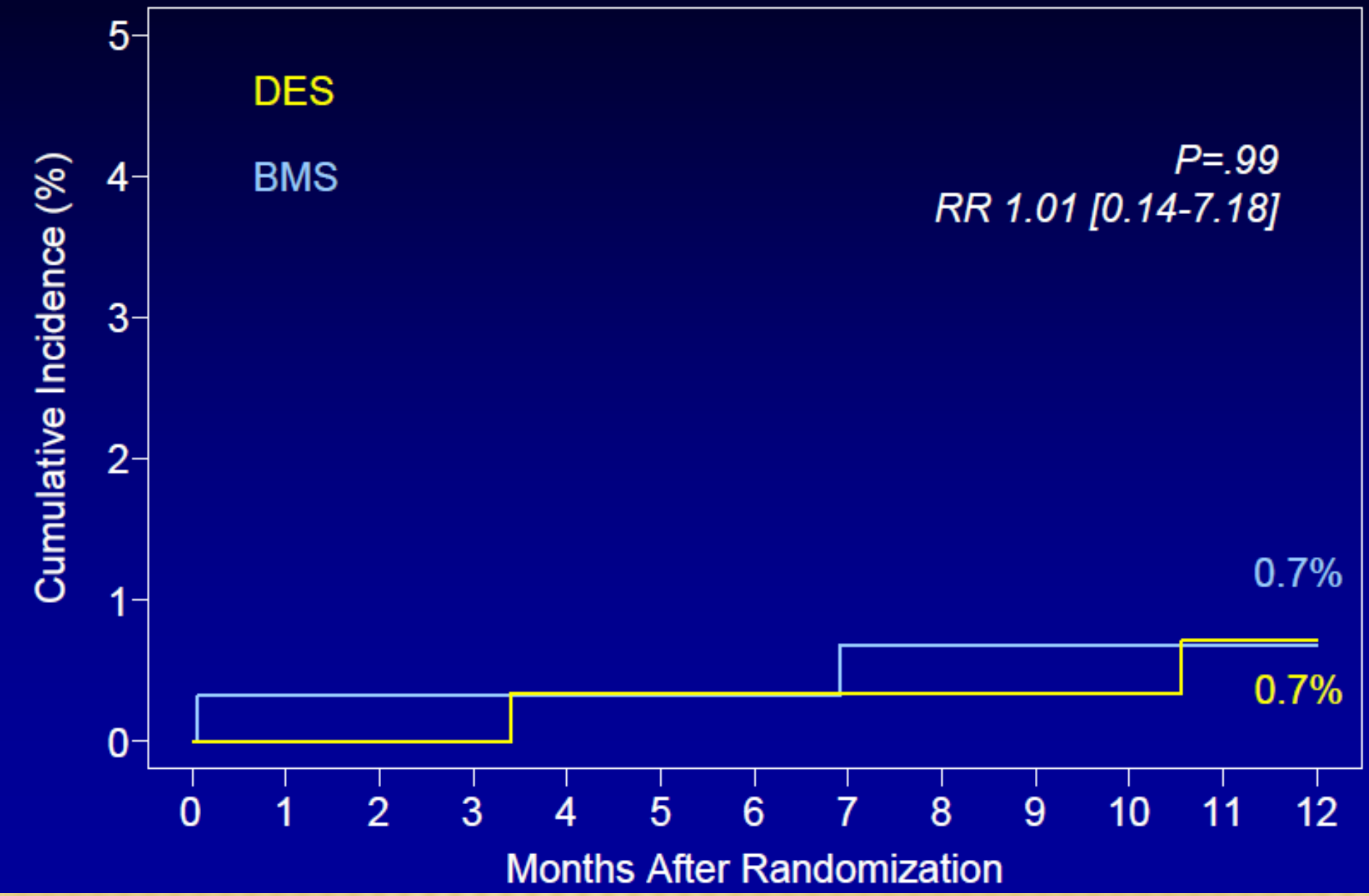
Target Vessel Revascularization



Primary Endpoint: Death/MI/TLR



Definite/Probable Stent Thrombosis



Summary

Out to 12 months drug-eluting stents are superior to bare metal stents in a large-scale study powered for clinical endpoints.

The need for repeat revascularizations was reduced by ~50% with DES as compared to BMS.

DES were comparable to BMS regarding safety parameters – stent thrombosis, death or MI.

INTERVENCIONISMO EN P. SAFENA

Mensaje para llevar a casa:

- *Todos los pacientes deben llevar dispositivo de protección.*
- *Todos los pacientes debe llevar DES.*

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

PROXIMAS JORNADAS DE SOLACI

Jornada de Región andina: *27 y 28 de octubre en Bogotá-Colombia.*

Jornada de Centroamérica y el Caribe: *24 y 25 de noviembre en San Pedro Sula-Honduras.*

Gracias por su atención¡¡¡¡¡

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