2013 TCTAP

Wrap-Up Interview

Drug-Eluting Stents

Moderator

Ron Waksman

Interviewees

Bernard Chevalier, Stephen G. Ellis, Renu Virmani

Issues Briefs

Safety of the Current DES

- Incidence and risk factors of ST in 2nd generation DES
- Optimal duration of DAPT in 2nd generation DES

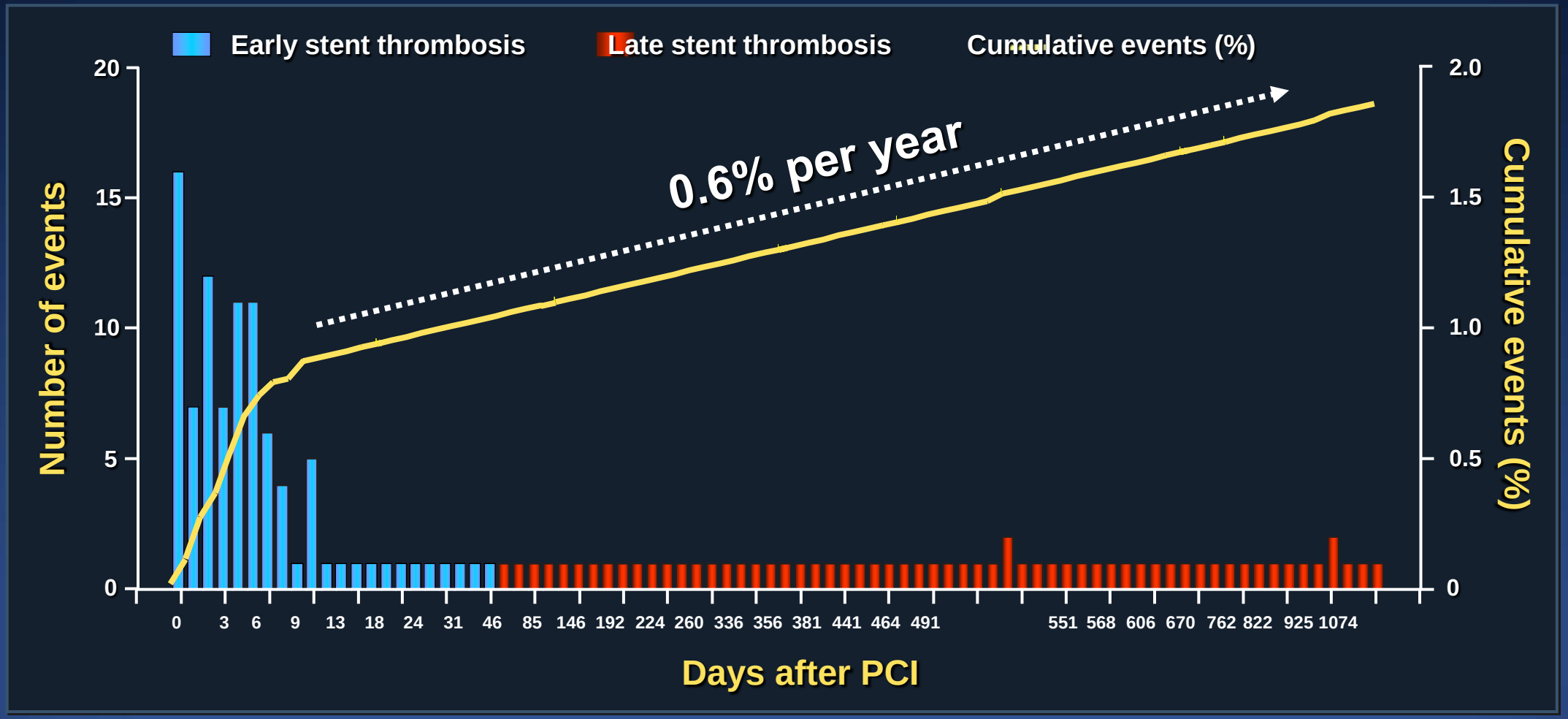
Clinical Outcomes across Different DES

- Clinical trial: RESOLUTE All Comer, PLATINUM

Future Direction

Stent thrombosis in 1st Generation DES

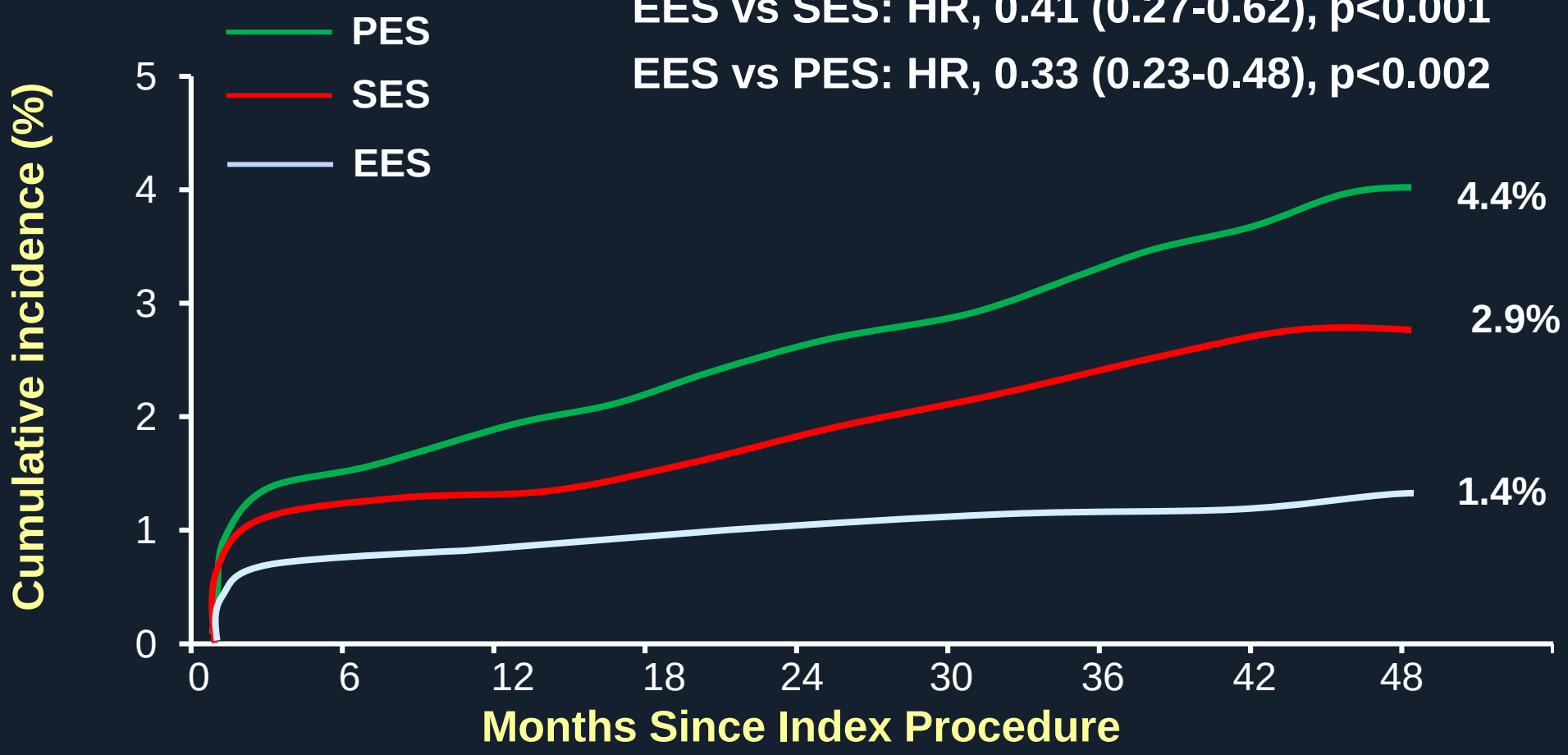
(3823 SES, 4323 PES)



Daemen J, et al, *Lancet* 2007;369:667–78

Definite Stent Thrombosis

3819 SES, 4308 PES, 4212 EES at 2 centers in Netherland and Switzerland



Raber L et al, Circulation 2012;125:1110-1121

EXAMINATION Trial
EES vs. BMS for STEMI

Endpoint at 1 year	Everolimus DES (N=751)	Bare- metal stent (N=747)	P value
Primary Endpoints (%)*	12	14.4	0.16
TVR (%)	3.9	7.0	**0.007**
TLR (%)	2.2	5.1	**0.003**
Definite ST (%)	0.5	1.9	**0.01**
Definite/ probable ST (%)	0.9	2.6	**0.01**

*all-cause death, myocardial infarction, and any revascularization

Sabate M, et al, *Lancet* 2012;380:1482–90

ACCF/AHA/SCAI 2011 for DAPT

- ✓ DAPT should be given for at least 12 months. (Class I, LOE:B)
- ✓ In the case of high bleeding risk, earlier discontinuation (<12 months) of P2Y12 inhibitor therapy is reasonable. (Class IIa, LOE:C)
- ✓ Continuation of DAPT beyond 12 months may be considered in patients undergoing DES implantation. (Class IIb, LOE:C)

Risk Factors of ST in New-generation DES

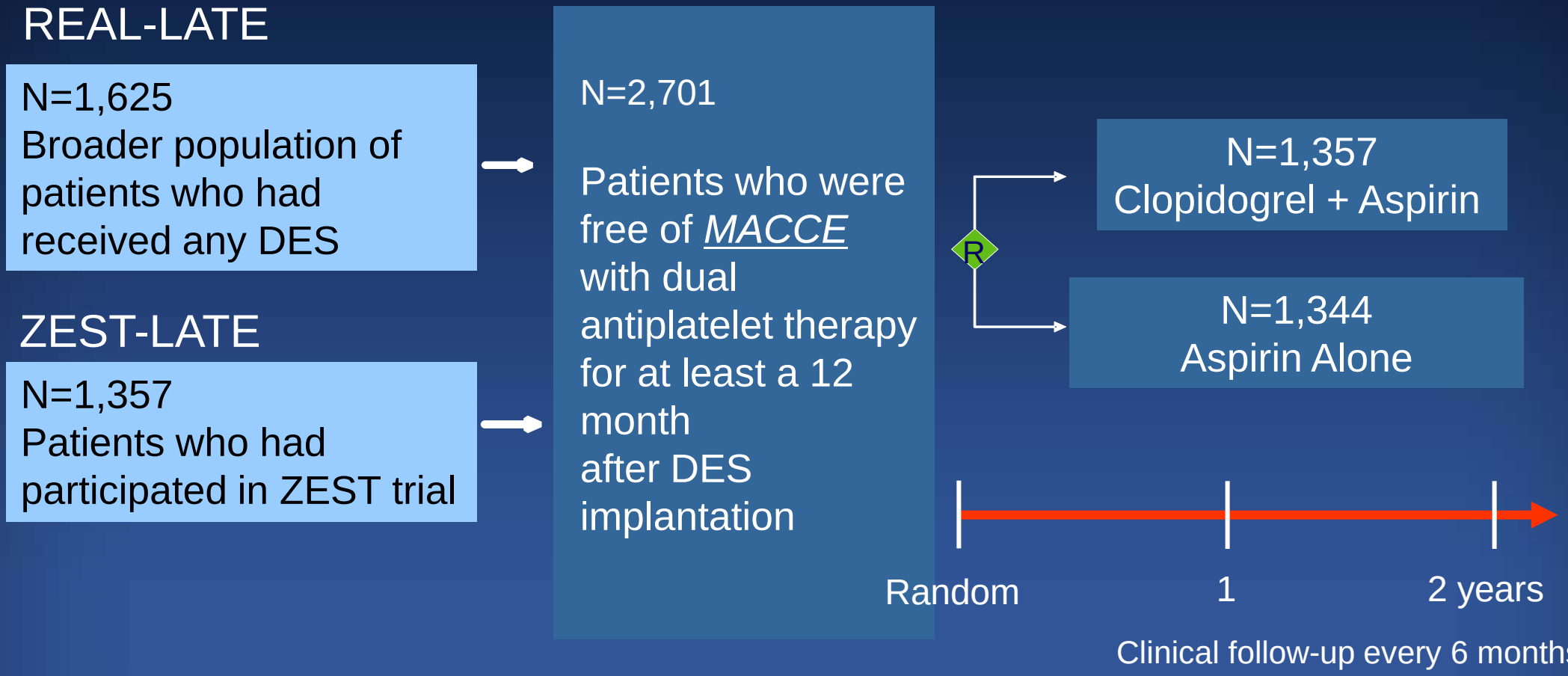
Hernandez et al. JACC Cardiovasc Interv. 2010;3:911

1. Bifurcations (HR 2.1, 95%CI 1.14-3.7)
2. Ejection fraction (HR 0.97, 95%CI 0.95-0.99)
3. Stent diameter (HR 0.37, 95%CI 0.17-0.81)

Naidu et al. JACC Cardiovasc Interv. 2012;5:626

1. DAPT interruption ≤30 days (HR 8.63, 95%CI 2.69-27.7)
2. Renal insufficiency (HR 3.72, 95%CI 1.71-8.09)
3. Total length of stents (10mm) (HR 1.30. 95%CI 1.16-1.47)

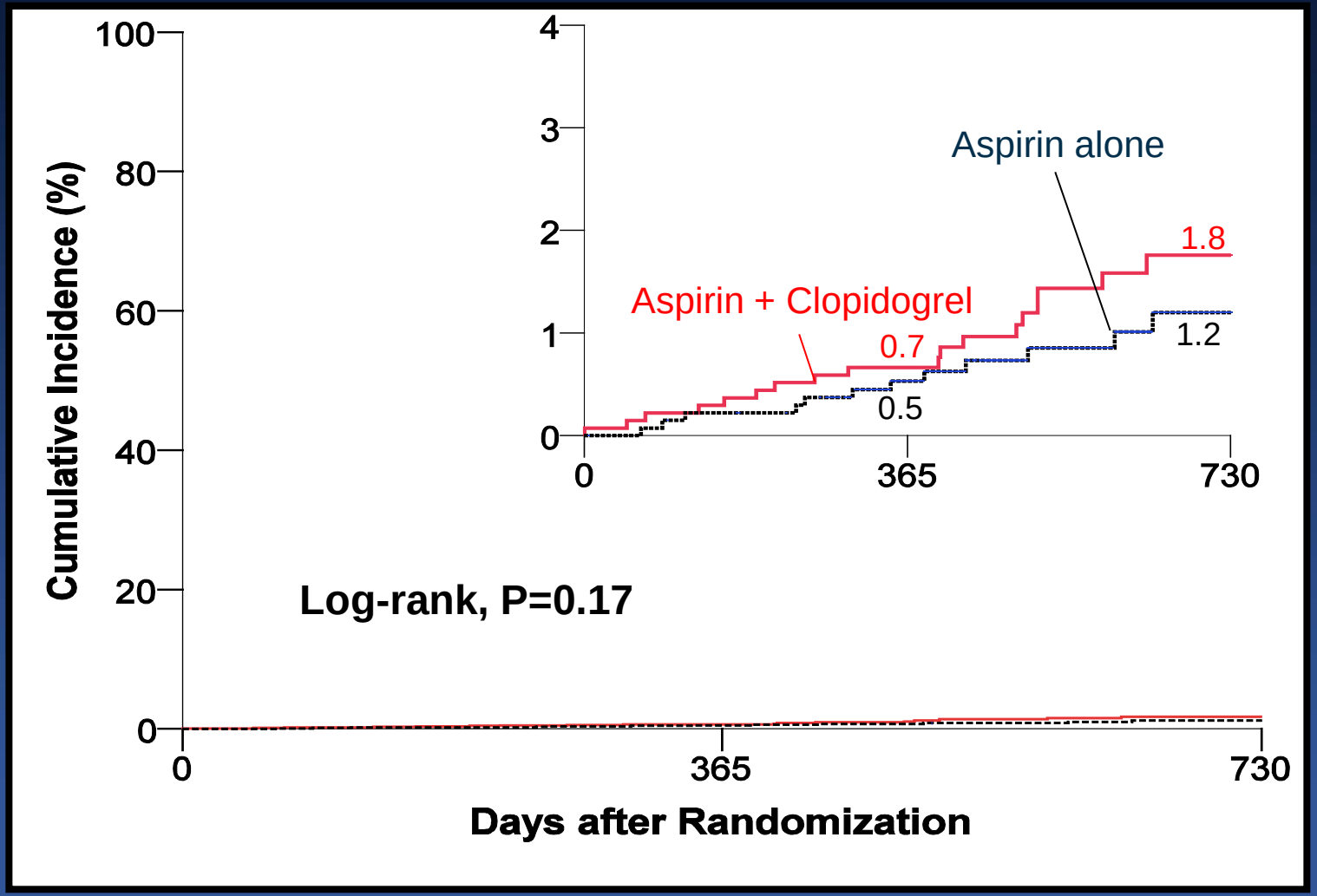
DES-LATE Trial



From July 2007 through September 2008

SJ Park et al. N Engl J Med 2010;362:1374-82

Primary Endpoint: Cardiac Death or MI



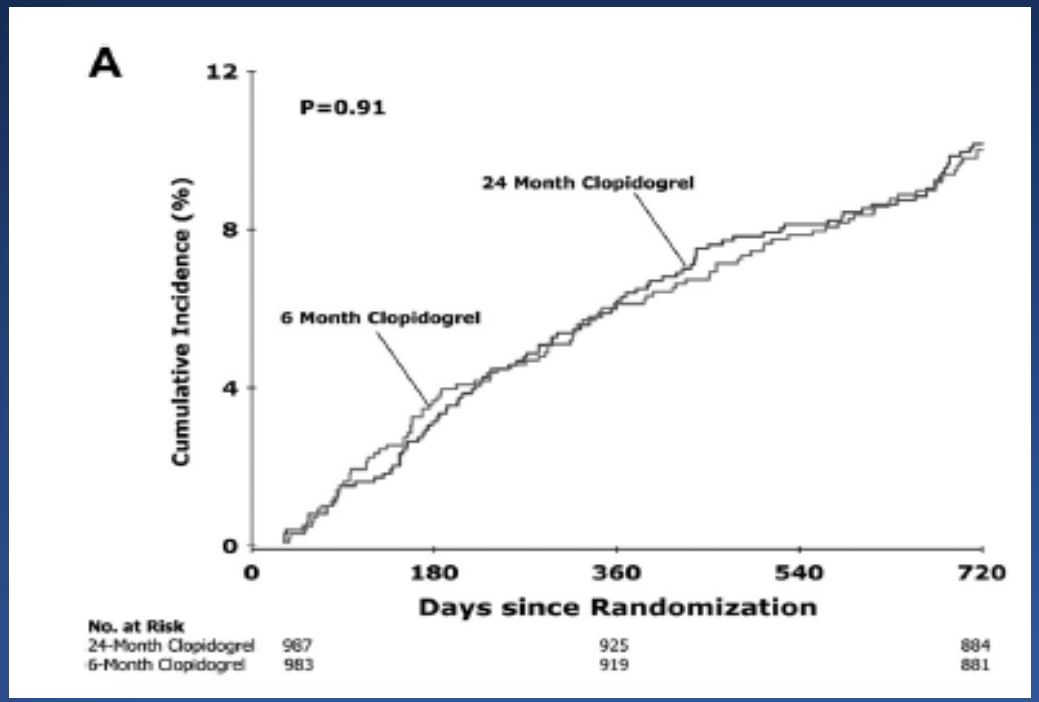
No. at Risk

Continuation group	1357	1122	299
Discontinuation group	1344	1100	301

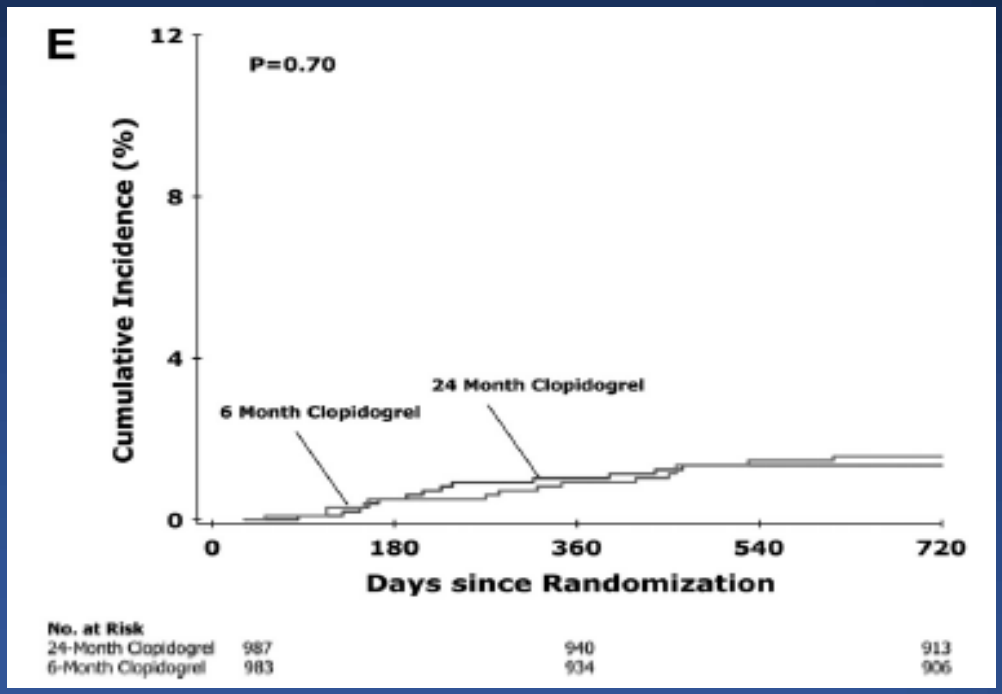
SJ Park et al. N Engl J Med 2010;362:1374-82

PRODIGY Trial: 6 Mo vs. 24 Mo DAPT

Death, MI, and Stroke

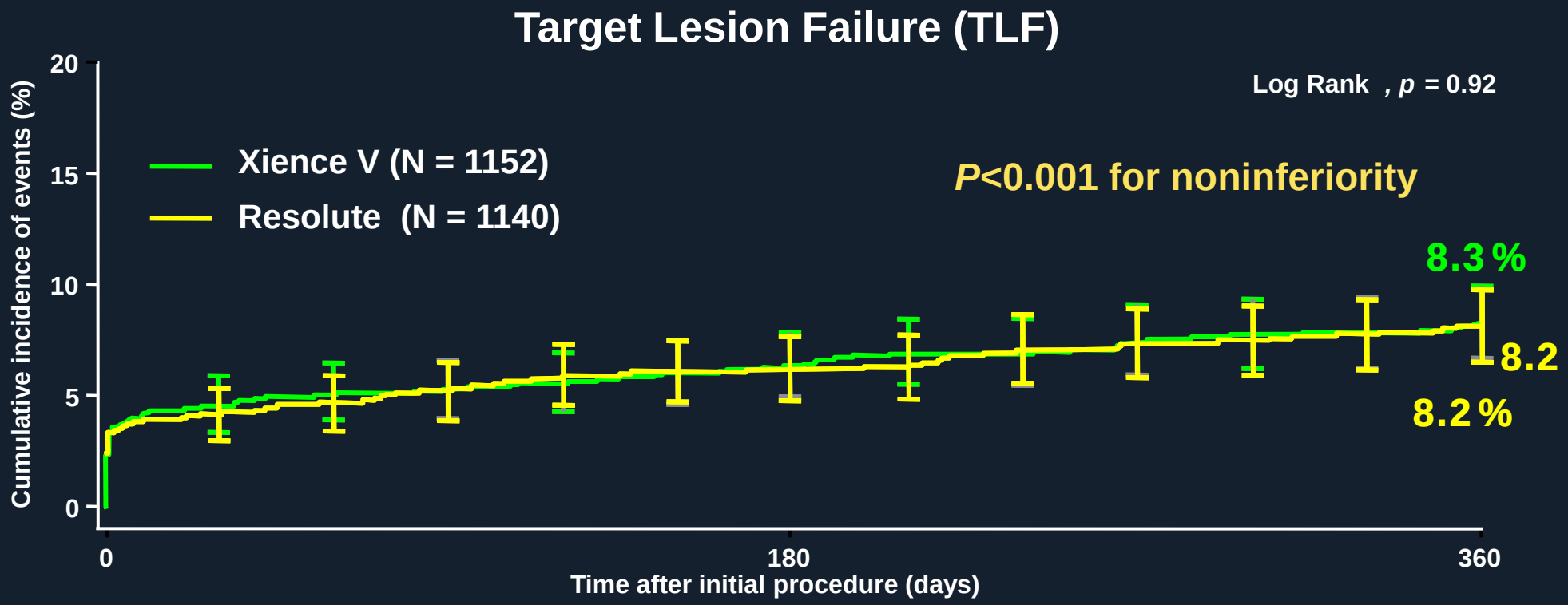


Stent thrombosis



Valgimigli M et al. Circulation. 2012;125:2015

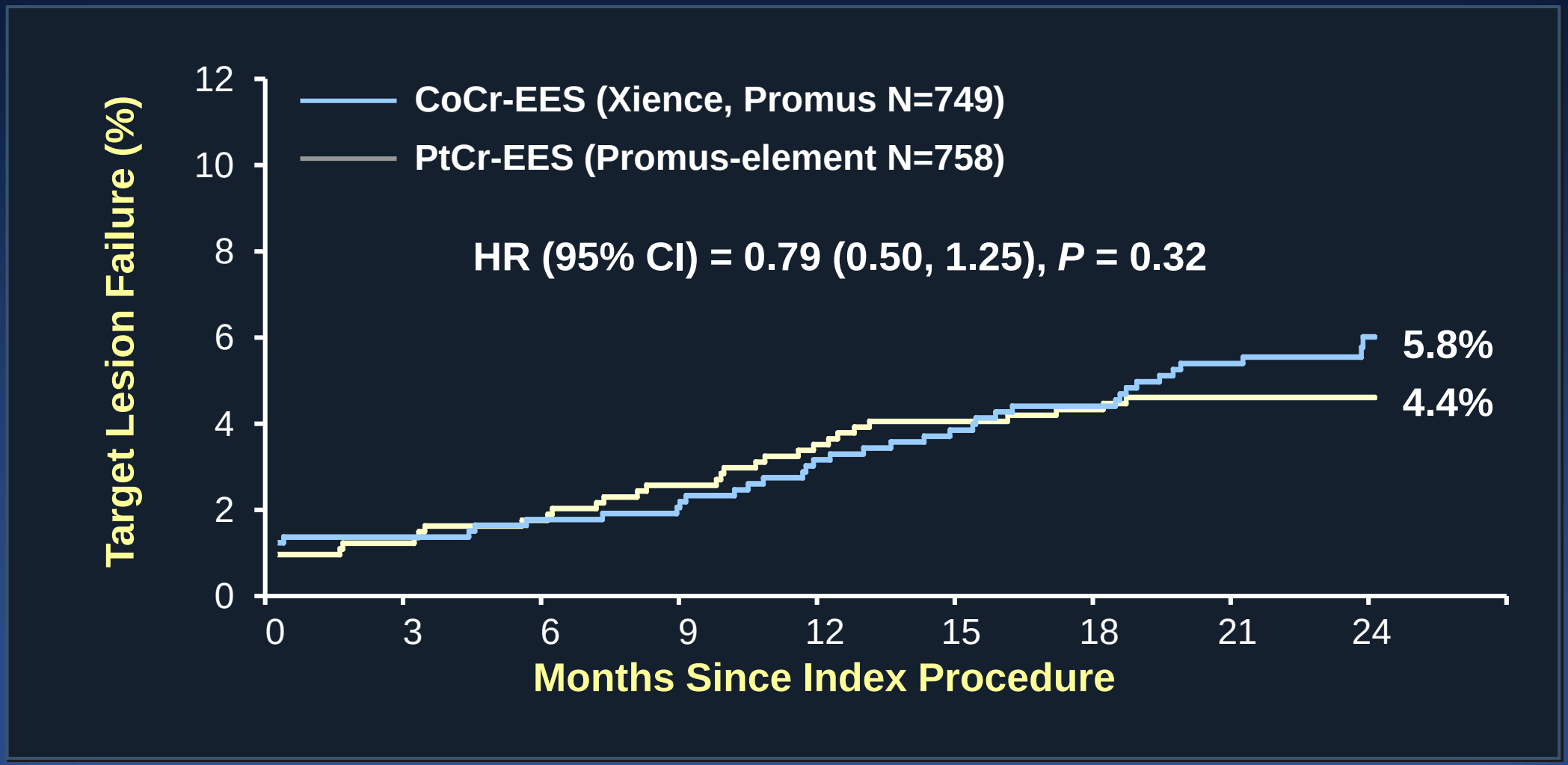
RESOLUTE All Comers



TLF = Cardiac death, target vessel MI, clinically indicated TLR.

Serruys PW et al. NEJM 2010;363:136-146

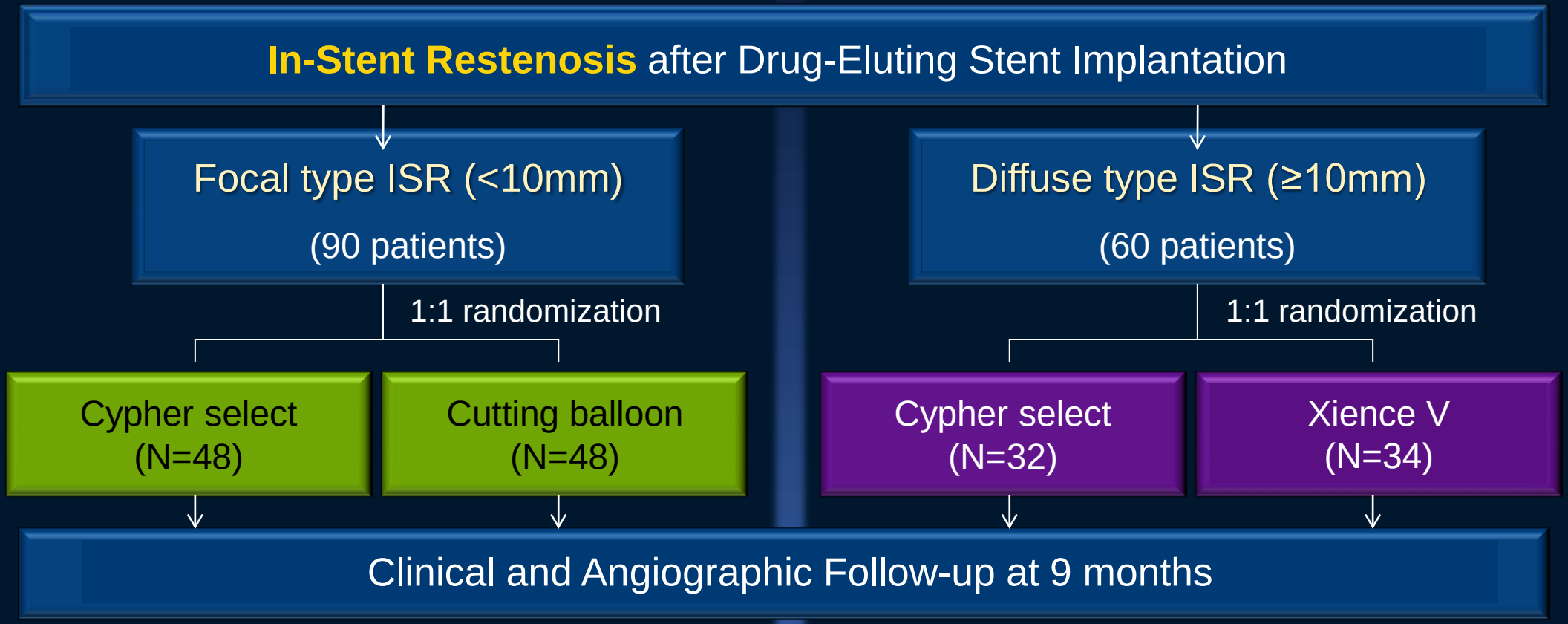
PLATINUM Trial: 2 year Results



TLF = cardiac death or MI related to the target vessel or ischemia-driven TLR.

Stone GW et al. J Am Coll Cardiol. 2011 Apr 19;57:1700

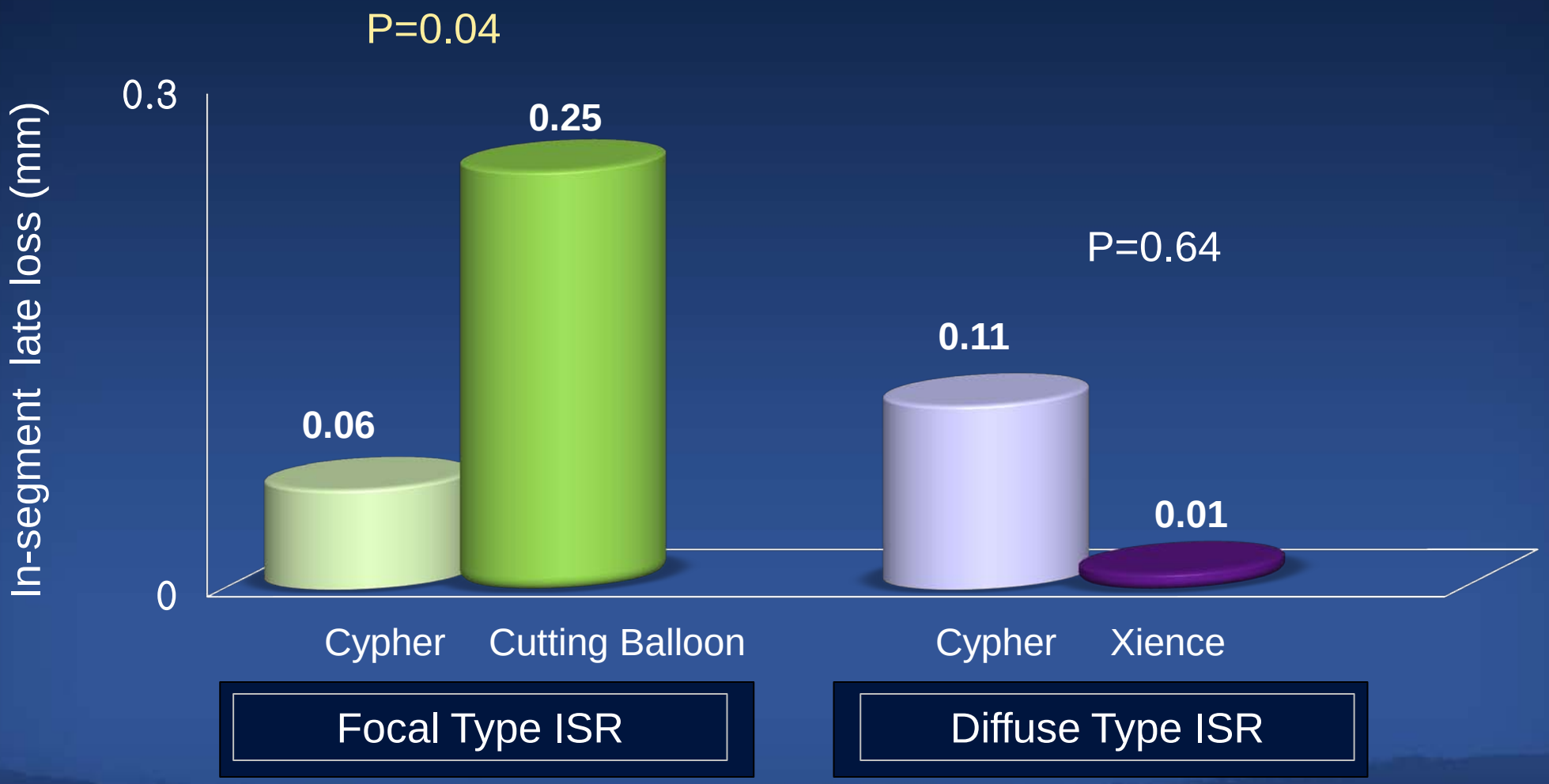
DIFFUSE- and FOCAL-ISR Trial



Primary end point: In-segment late loss at 9 months
Secondary end point: Angiographic restenosis at 9 months
Each clinical parameters at 9 months

Song HG et all. J Am Coll Cardiol 2012;59:1093

Primary End Point
In-segment Late Loss at 9 Moths



Song HG et all. J Am Coll Cardiol 2012;59:1093

ISAR-DESIRE 3

ISAR-DESIRE 3: Intracoronary Stenting and Angiographic Results: Drug Eluting Stents for In-Stent Restenosis: 3 Treatment Approaches

Design

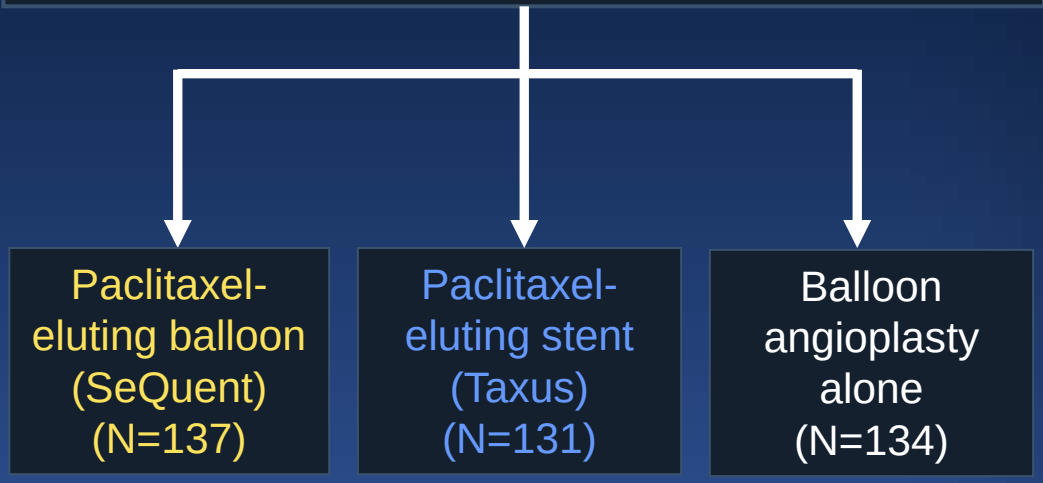
DESIGN:
Prospective, randomized, active controlled, multicenter clinical trial

INCLUSION CRITERIA:
1.Stenosis > 50% in “limus”-eluting DES
2.Symptoms/signs of ischemia

EXCLUSION CRITERIA:
1.Lesion in left main stem
2.Acute STEMI
3.Cardiogenic shock

SPONSOR: Deutsches Herzzentrum

402 patients with DES-restenosis enrolled between August 2009 and October 2011 in 3 centers in Germany



Angiographic follow-up at 6-8 months in 84.1% (N=338)

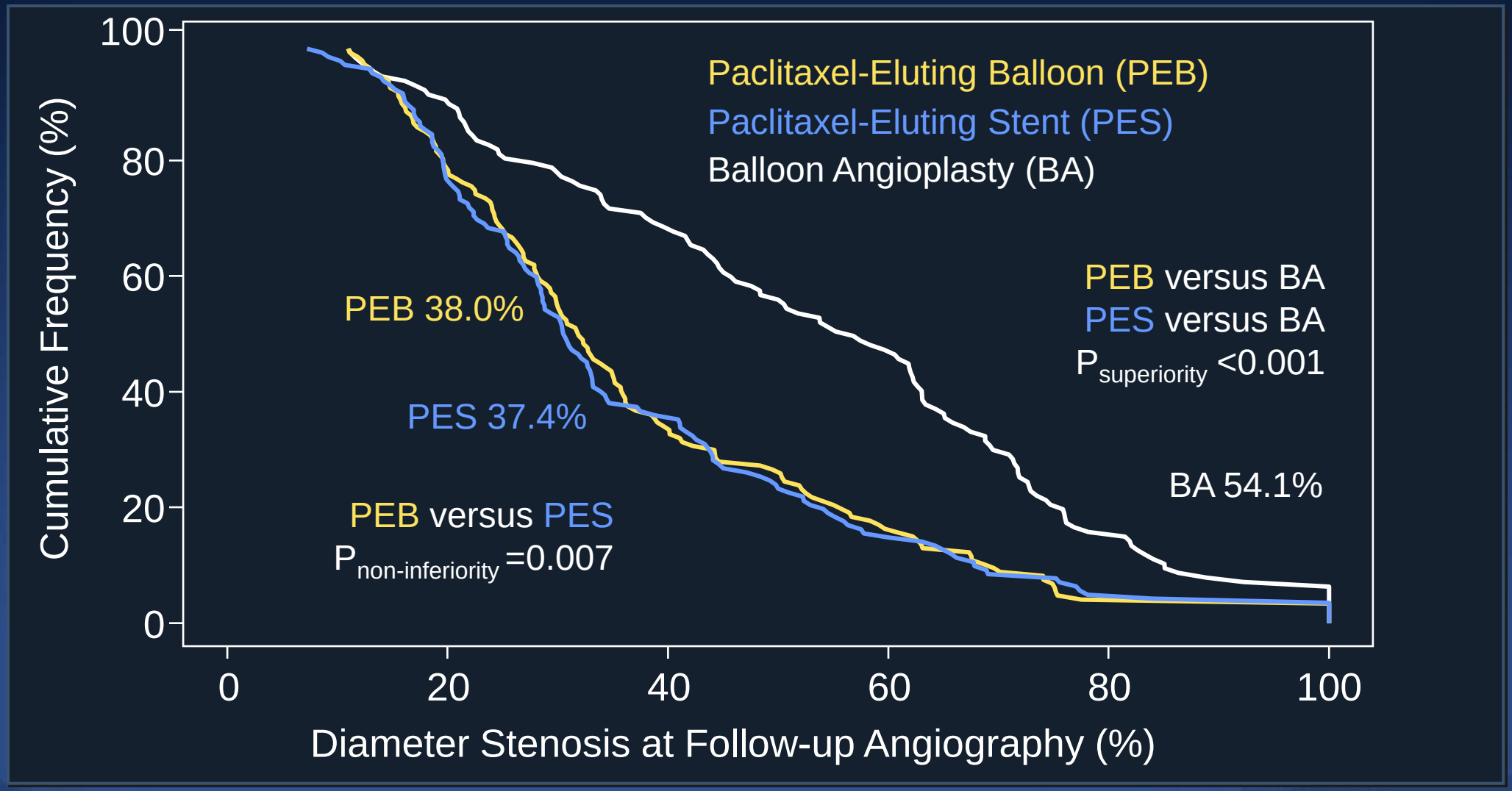
Clinical follow-up at 12 months in 97.5% (N=392)

No significant differences across groups

Byrne RA et al. Lancet 2013 (in print)

ISAR-DESIRE3: Primary Endpoint

Diameter Stenosis at Follow-up Angiography



ISAR-DESIRE 3: Intracoronary Stenting and Angiographic Results: Drug Eluting Stents for In-Stent Restenosis: 3 Treatment Approaches

Second-generation DES
Better than BMS / first-generation DES

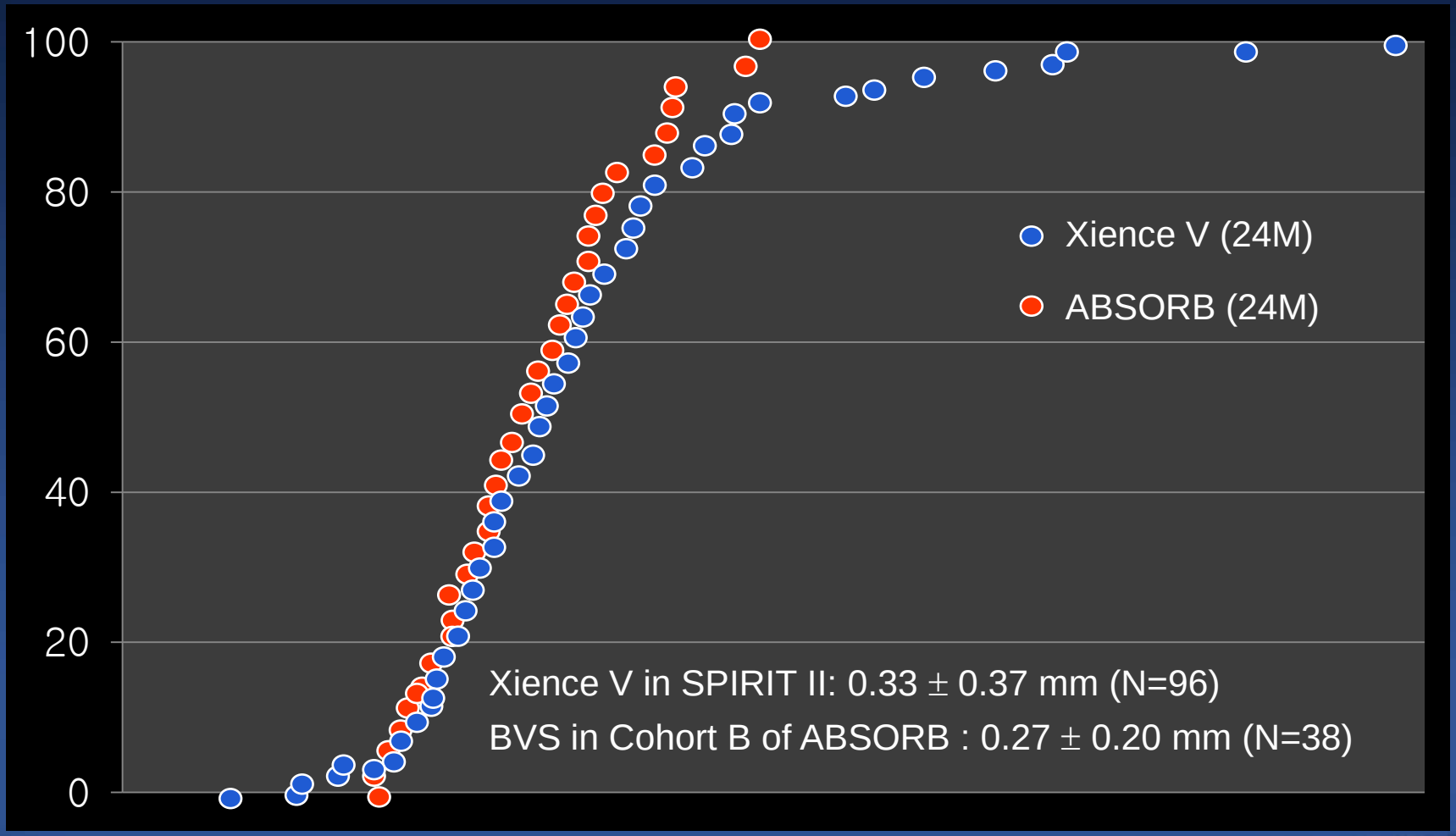
New DES	Compared with BMS	Compared with old DES	
		Taxus (Taxol DES)	Cypher (sirolimus DES)
Cardiac death and MI			
Everolimus-eluting stent	↔	↓ (30-40%)	↔
Zotarolimus-eluting stent	↔	↓ (30-40%)	↔
Repeat revascularization			
Everolimus-eluting stent	↓ (60-80%)	↓ (40-50%)	↔
Zotarolimus-eluting stent	↓ (60-80%)	↓ (30-40%)	↔
Stent thrombosis			
Everolimus-eluting stent	↔	↓ (30-40%)	↓ (30-40%)
Zotarolimus-eluting stent	↔	↓ (30-40%)	↓ (30-40%)

Stefanini GG, Holmes DR. N Engl J Med 2013;368:254

Bioabsorbable Stent is the Future?

- ✓ Radial Strength
- ✓ Aggressive Lesion Preparation
- ✓ Deliverability
- ✓ Cost
- ✓ Long Term Clinical Outcomes

Bioabsorbable Stent
Not inferior late loss compared with Xience-V



Chevalier TCT 2012

Discussion

- Different outcomes across different DES
- DES stent thrombosis in the current era
- Treatment of DES ISR
- Ideal DES platform
- Future role of bioabsorbable DES