Results of RESOLUTE Series of Studies

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CARDIOVASCULAR RESEARCH FOUNDATION
A Passion for Innovation

COLUMBIA UNIVERSITY MEDICAL CENTER
NewYork-Presbyterian

Disclosure Statement of Financial Interest

Martin B. Leon, MD

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Abbott, Boston Scientific, Edwards Lifesciences, Medtronic
• Consulting Fees/Honoraria	• Meril Lifescience, Angioscore, Micell
• Major Stock Shareholder/Equity	• Sadra, Claret, Coherex, Medinol, Valve Medical

RESOLUTE Studies

Technical Considerations

Resolute DES

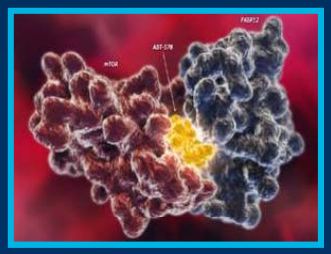
System Components

Established Components

- Driver cobalt alloy stent

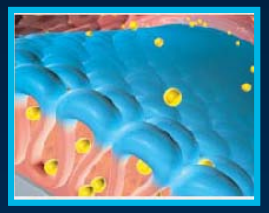
- Sprint delivery system

- Zotarolimus antiproliferative drug

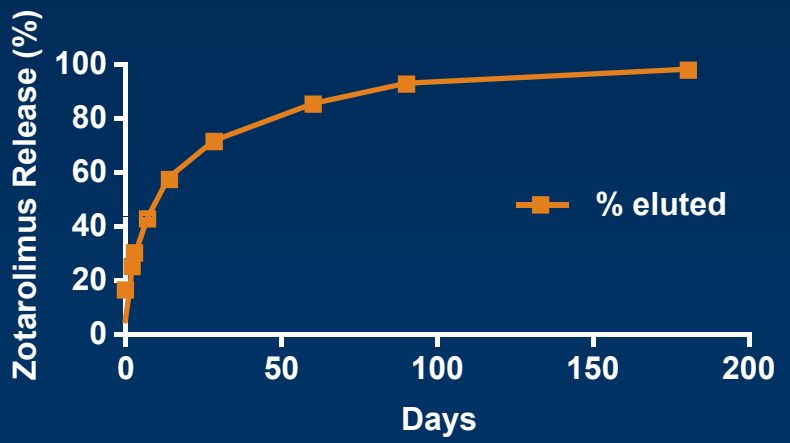


Unique Polymer Technology

- BioLinx polymer is a unique blend of three polymers to control drug release, support biocompatibility and enhance elution rate



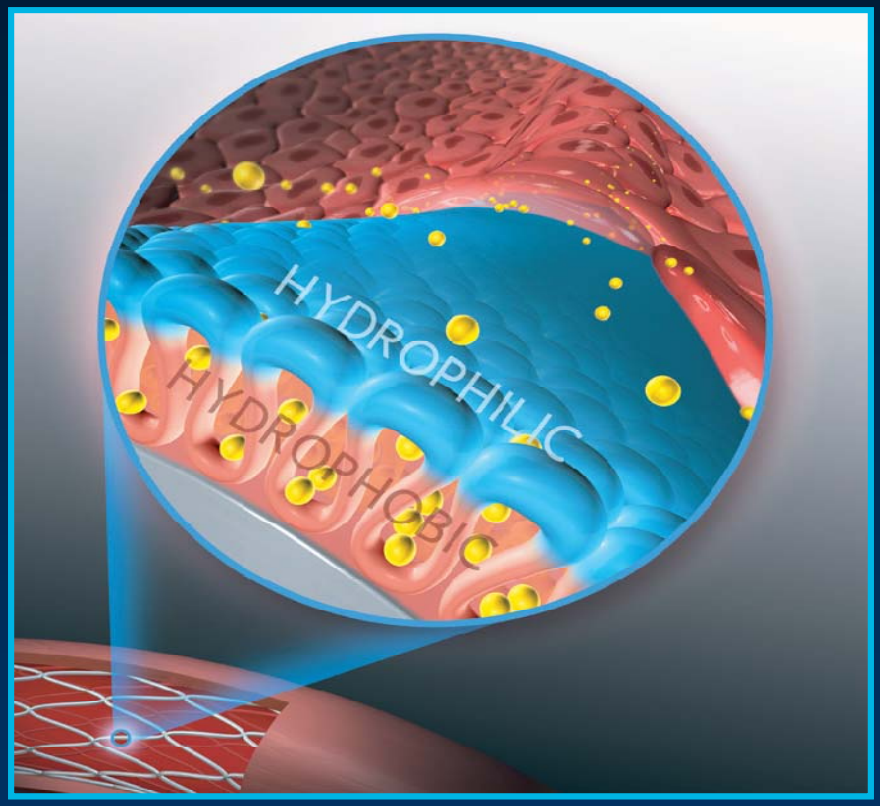
- Drug-release kinetics: complete elution by 180 days



Udipi K, et al. *EuroIntervention.* 2007; 3:137-9
Meredith IT, et al. *J Am Coll Cardiol Intv*. 2009; 2:977-85
Meredith IT, et al. *EuroIntervention*. 2007; 3:50-53

Resolute Polymer

BioLinx: a Polymer Specifically Designed for DES



Components of a safe polymer:

- Mimics the body's chemistry
- Complete drug elution
- Compatible with stent delivery

BioLinx polymer system design:

- Extended drug elution
- Low inflammation
- Minimal thrombotic risk
- Rapid and functional endothelial healing

A biostable polymer that applies the basics of membrane structure will provide extended drug elution over time while maintaining biocompatibility

Continuous Sinusoid Technology (CST)

Wire form enables multitude of new options

Integrity

Core Wire

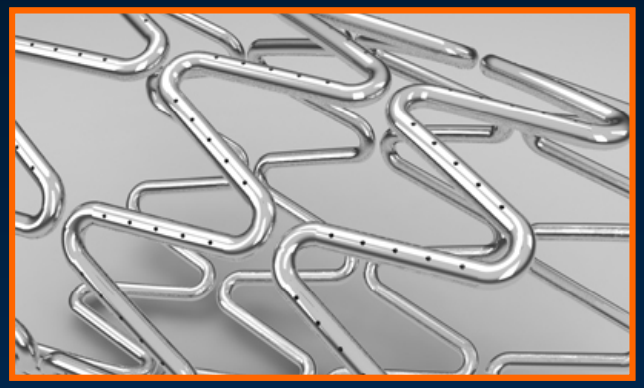
New Alloys

Bare Metal Stents

Drug Eluting Stents

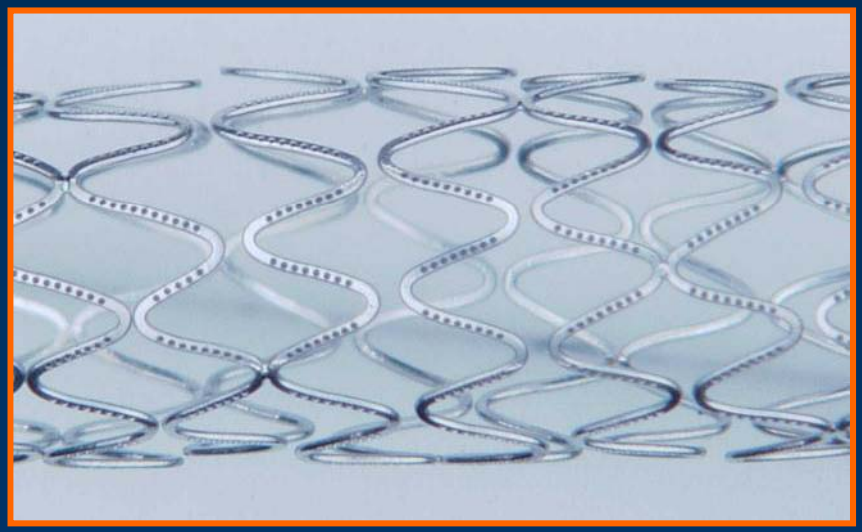
Drug Filled Stent

Drug Filled Stent (DFS) Technology



Innovative DES design

- *Controlled hole dimension and number enables tailored elution profiles*
- *Designed to address drug carrier concerns such as:*
  - *Polymer biocompatibility*
  - *Inflammation upon polymer degradation*
  - *Surface coating durability*



RESOLUTE Studies

MDT Clinical Trial Program

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RESOLUTE Global Clinical Program

5,130 patients enrolled with ≥1 year FU

Enrollment Complete - In Follow Up

RESOLUTE[1]	Non-RCT First-in-Human (R=139)	5 yr
RESOLUTE AC[2,3]	1:1 RCT vs. Xience V® (R=1,140; X=1,152)	2 yr
RESOLUTE Int	Non-RCT Observational (R=2349)	2 yr
RESOLUTE US[4]	2.25 – 3.5mm Non-RCT vs. Hx Control (R=1,242)	1 yr
	2.25 – 3.5mm Angio/IVUS Non-RCT vs. Hx Control (R=100)	1 yr
	4.0mm Angio Non-RCT vs. Hx Control (R=60)	1 yr
RESOLUTE Japan	2.5 – 3.5mm Non-RCT (R=100) vs. Hx Control	1 yr
R Japan SVS	2.25 Non-RCT vs. PG (R=63)	<1 yr
RESOLUTE US	38 mm sub-study Non-RCT vs. PG (R=110-175)	<1 yr

Enrolling / Planning

RESOLUTE Asia	Non-RCT (R≈300)	enroll
R-China Registry	Registry (R=1500 max)	enroll
R-China RCT	3:1 vs. Cypher (R=742; C=248)	plan

[1] Meredith IT, et al. *EuroIntervention.* 2010;5:692-7. [2] Serruys PW, et al. *N Engl J Med.* 2010;363:136-46.
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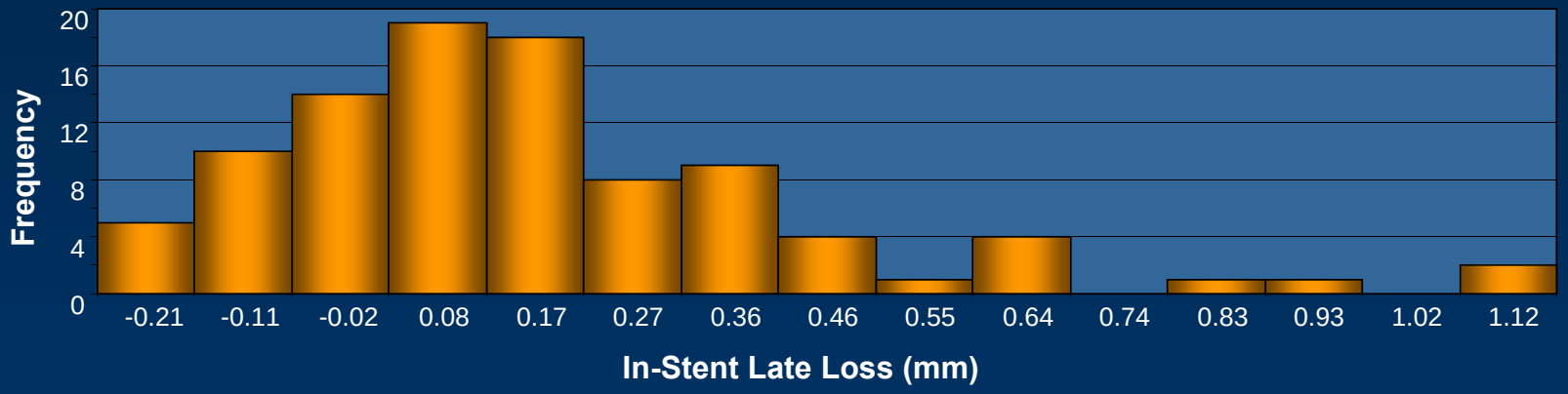
RESOLUTE Trial

Angiographic Results in 9 Month Cohort



n = 96	In-stent	In-segment
% Diameter stenosis	10.13 ± 12.63	21.08 ± 10.62
ABR n (%)	1 (1%)	2 (2.1%)

Meredith IT, et al. *J Am Coll Cardiol Intv*. 2009; 2:977-85

RESOLUTE Trial

Clinical Events to 5 Years

% (n)	*1 Year n = 130 pts 131 lesions*	*2 Year n = 130 pts 131 lesions*	*3 Year n = 129 pts 130 lesions*	*4 Year n = 129 pts 130 lesions*	*5 Year n = 129 pts 130 lesions*
Death (all)	2.3 (3)	3.1 (4)	4.7 (6)	6.2 (8)	7.1 (9)
Cardiac	0.8 (1)	0.8 (1)	0.8 (1)	0.8 (1)	1.6 (2)
MI (all)	5.4 (7)	5.4 (7)	5.4 (7)	5.4 (7)	6.3 (8)
Q Wave	0	0	0	0	0
Non Q wave	5.4 (7)	5.4 (7)	5.4 (7)	5.4 (7)	6.3 (8)
Cardiac Death + MI	6.2 (8)	6.2 (8)	6.2 (8)	6.2 (8)	7.1(9)
ST Def/Prob	0	0	0	0	0
Early (0 – 30d)	0	0	0	0	0
LST (>30d – 1yr)	0	0	0	0	0
VLST (>1 yr)	–	0	0	0	0
TLR	0.8 (1)	1.5 (2)	1.6 (2)	2.3 (3)	3.1 (4)
TVR (non-TL)	0	0	0.8 (1)	1.6 (2)	2.4 (3)
TVR	0.8 (1)	1.5 (2)	2.3 (3)	3.9 (5)	5.5 (7)
MACE	8.5 (11)	10 (13)	11.6 (15)	14.0 (18)	16.5 (21)
TVF	6.9 (9)	7.7 (10)	8.5 (11)	10.1 (13)	13.4 (17)

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RESOLUTE All Comers

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Comparison of Zotarolimus-Eluting and Everolimus-Eluting Coronary Stents

Patrick W. Serruys, M.D., Ph.D., Sigmund Silber, M.D., Ph.D., Scot Garg, M.B., Ch.B., M.R.C.P., Robert Jan van Geuns, M.D., Ph.D., Gert Richardt, M.D., Pawel E. Buszman, M.D., Ph.D., Henning Kelbæk, M.D., Adrianus Johannes van Boven, M.D., Ph.D., Sjoerd H. Hofma, M.D., Ph.D., Axel Linke, M.D., Ph.D., Volker Klauss, M.D., Ph.D., William Wijns, M.D., Ph.D., Carlos Macaya, M.D., Ph.D., Philippe Garot, M.D., Carlo DiMario, M.D., Ph.D.,

Unrestricted randomised use of two new generation drug-eluting coronary stents: 2-year patient-related versus stent-related outcomes from the RESOLUTE All Comers trial

Sigmund Silber, Stephan Windecker, Pascal Vranckx, Patrick W Serruys, on behalf of the RESOLUTE All Comers investigators

NEJM 2010;363:136-46
Lancet 2011;377:1241-47

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RESOLUTE All Comers

Clinical Trial Design

Co-PIs: Profs. Serruys, Silber, Windecker

Open label, non-inferiority trial
Any patient with symptomatic coronary artery disease eligible for DES implantation (no lesion/vessel limitations)

Resolute Stent n = 1,150

17 European sites
2300 patients randomized 1:1
Subsets: QCA 460 pts (20%); OCT 50 pts (2%)
100% monitoring

Xience V Stent n = 1,150

Clinical endpoints

Angio/OCT endpoints

Primary Endpoint:
- ***12-month target lesion failure (TLF), composite of cardiac death, target vessel MI & clinically driven TLR***

Secondary Endpoints:
- ***Clinical: Patient composite of any death, any MI, & any repeat revascularisation***
- ***QCA (powered): 13-month in-stent % diameter stenosis***
- ***QCA: % diameter stenosis, late loss, and binary restenosis***

Drug Therapy: ***ASA and clopidogrel/ticlopidine > 6mo (per guidelines)***

Serruys PW, et al., N Engl J Med. 2010;363(2):136-46

RESOLUTE All Comers

Baseline Characteristics

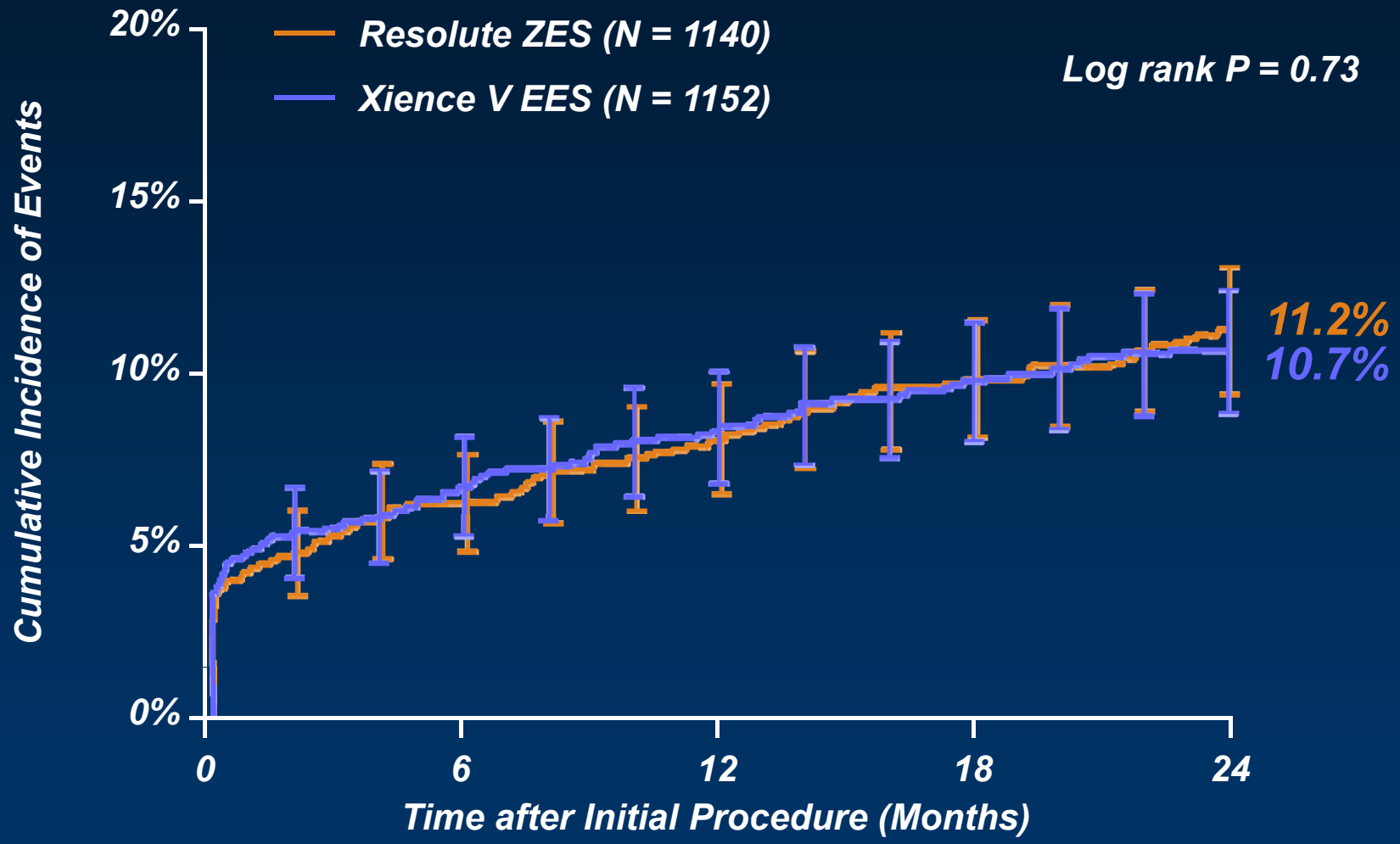
	Resolute ZES (N = 1140)	*Xience V EES (N = 1152)*	*P value*
Age (yr)	64.4 ± 10.9	64.2 ± 10.8	*0.70*
Men (%)	76.7	77.2	*0.80*
Diabetes mellitus (%)	23.5	23.4	*1.00*
IDDM	8.4	7.1	*0.28*
ACS (%)	48.3	47.7	*0.80*
AMI (within 12 hr) (%)	15.4	17.8	*0.13*
AMI (within 72 hr) (%)	28.9	28.8	*0.96*
Multivessel disease (%)	58.4	59.2	*0.73*
Small vessel (RVD ≤2.75 mm)	67.8	67.4	*0.88*
Long lesion (length >18 mm)	18.2	21.2	*0.11*
Bifurcation/trifurcation (%)	16.9	17.7	*0.62*
Total occlusion (%)	16.3	17.2	*0.61*
In-stent restenosis (%)	8.1	8.0	*0.94*
Complex Patients[1] (%)	67.0	65.6	*0.51*

[1]Complex patient definition: bifurcation, bypass grafts, ISR, AMI <72 hr, LVEF <30%, unprotected LM, >2 vessels stented, renal insufficiency or failure (creatinine >140 µmol/L), lesion length >27 mm, >1 lesion per vessel, lesion with thrombus or TO (preprocedure TIMI = 0). With the exception of long lesions (treatable with a single 38-mm length stent), Resolute DES currently is not specifically approved or the patient subsets noted in this complex patient definition.

Serruys PW, et al., N Engl J Med. 2010;363(2):136-46

RESOLUTE All Comers

Target Lesion Failure to 2 Years (Cardiac Death, TV-MI, CD-TLR)

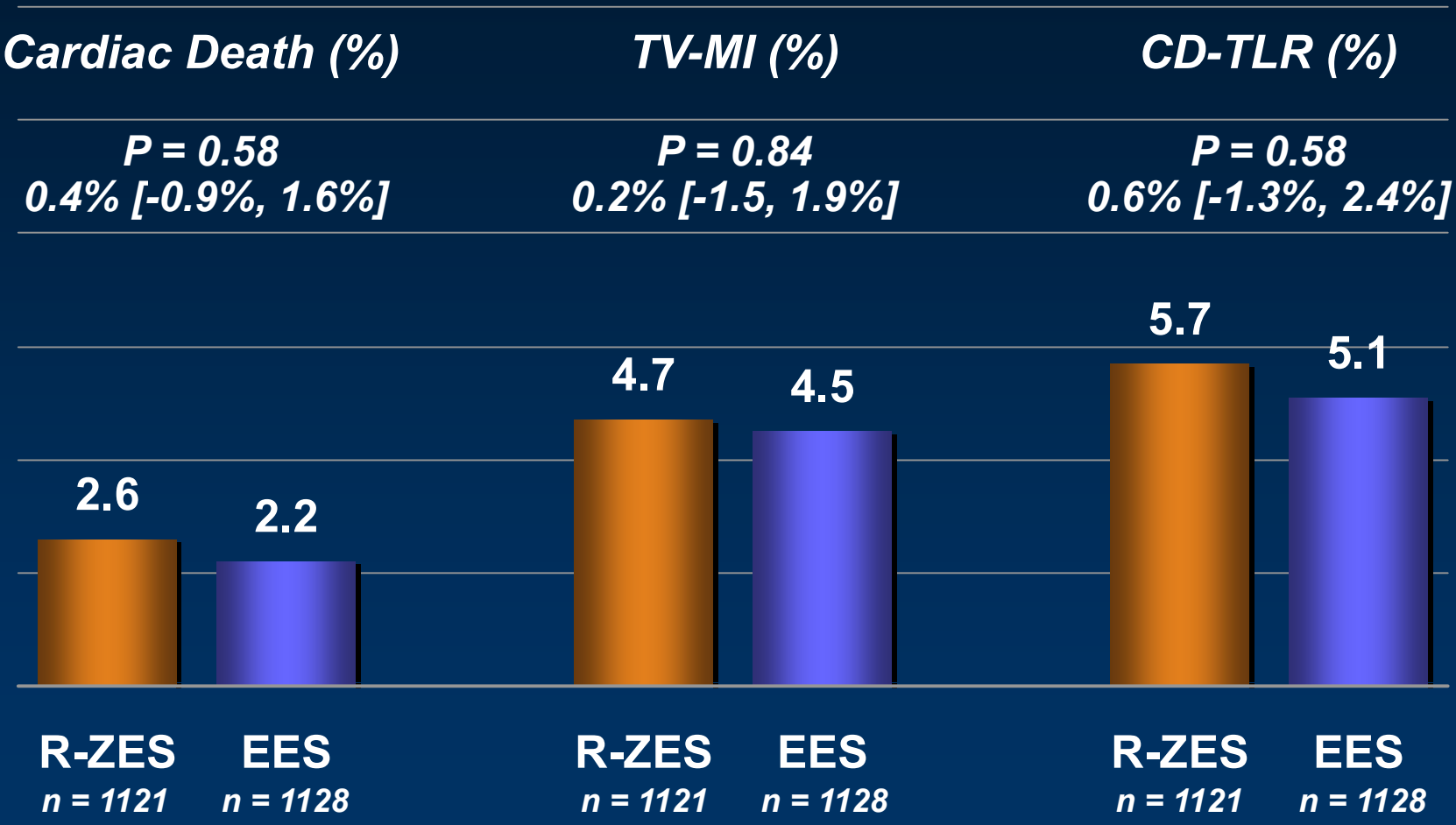


Silber S, et al. Lancet. 2011;377:1241-47

Error bars indicate a point-wise two-sided 95% confidence interval ($\pm$1.96*SE). Standard Error based on the Greenwood Formula.

RESOLUTE All Comers

Components of TLF at 2 Years



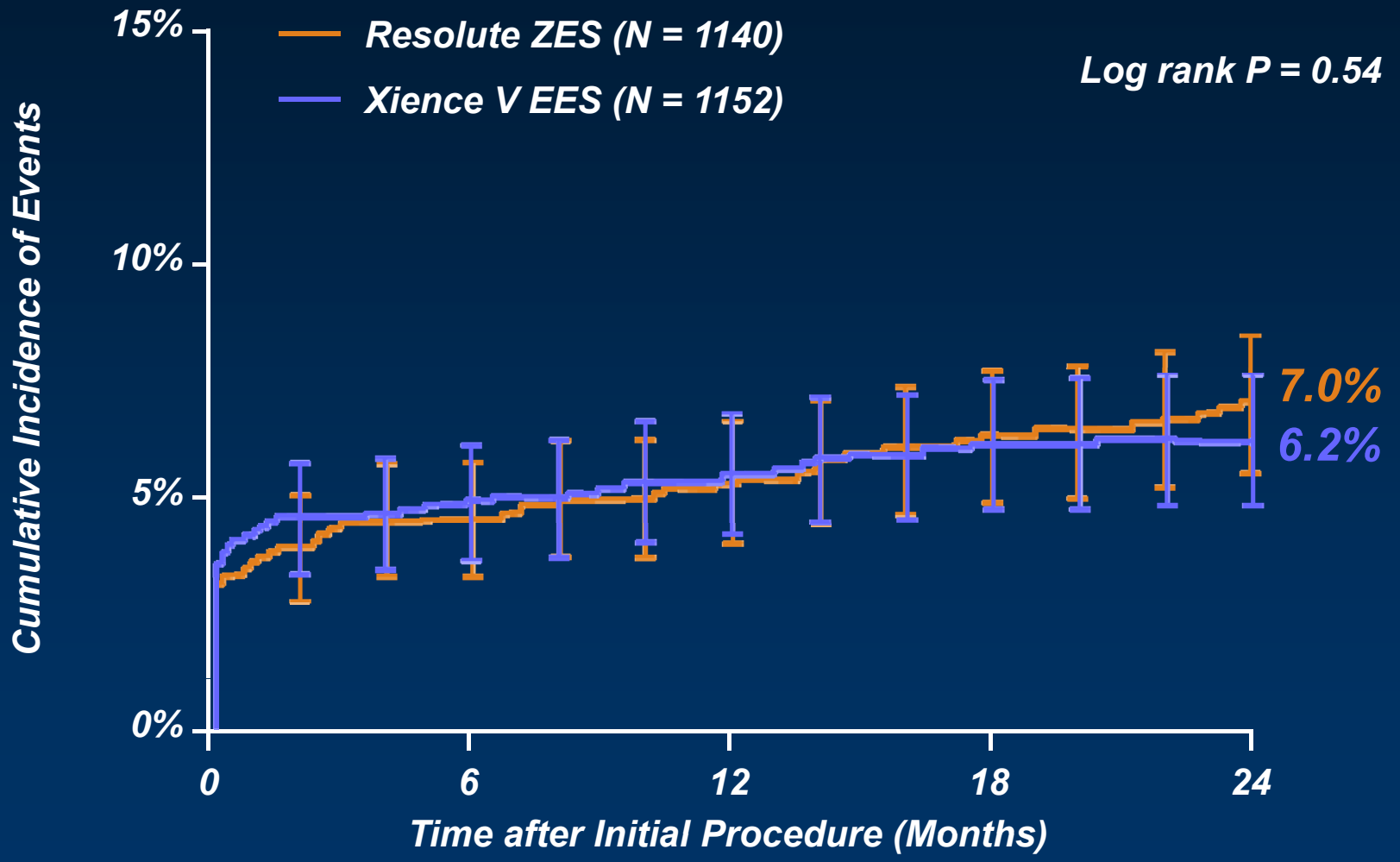
Silber S, et al. Lancet. 2011;377:1241-47

P-values are based on Fisher's Exact Test and unadjusted for multiple comparisons.

RESOLUTE All Comers was not specifically designed or powered to individually compare endpoints shown above.

RESOLUTE All Comers

Cardiac Death and Target Vessel MI at 2 Years

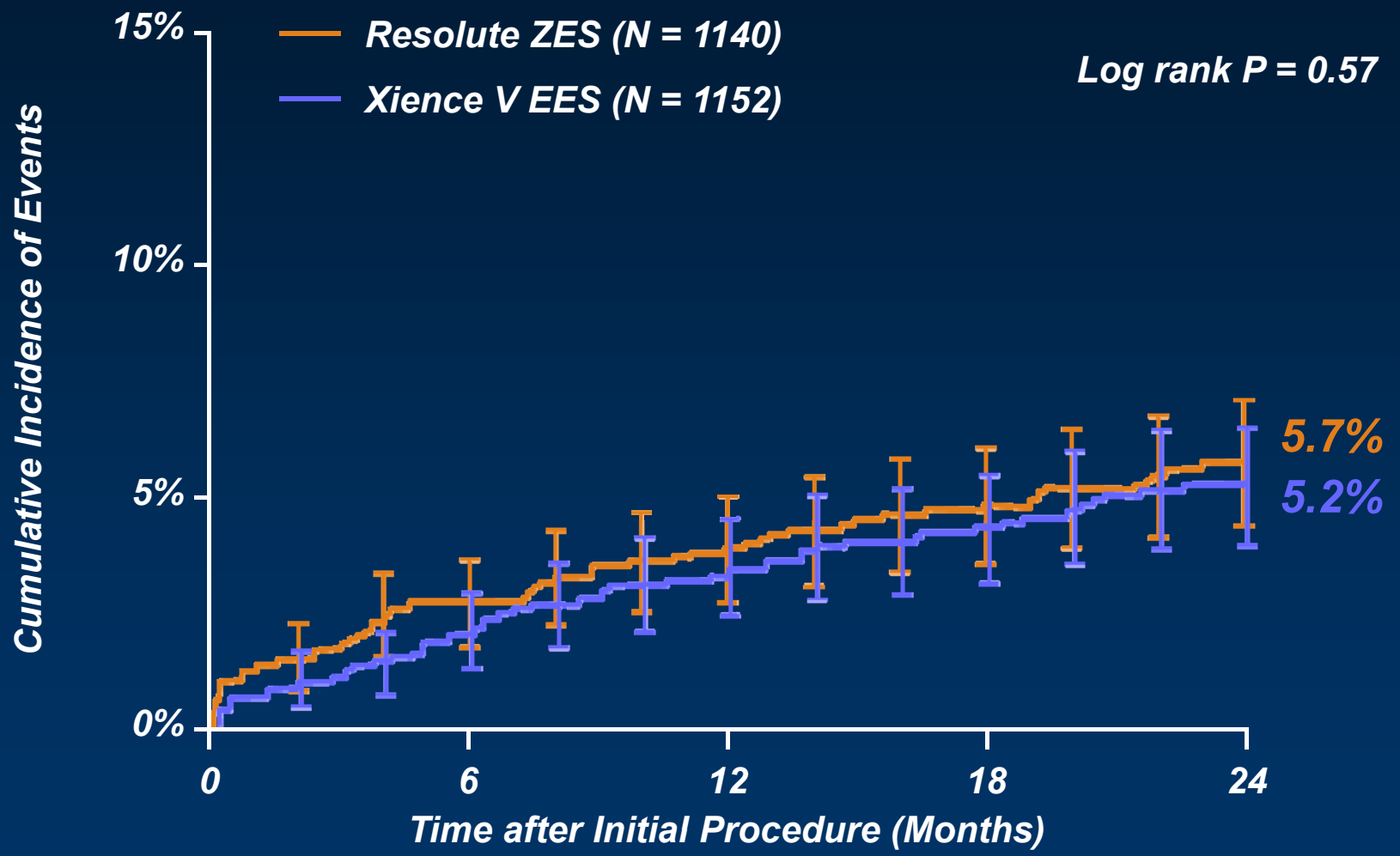


*Error bars indicate a point-wise two-sided 95% confidence interval (±1.96*SE). Standard Error based on the Greenwood Formula. P-value unadjusted for multiple comparisons. RESOLUTE All Comers was not specifically designed or powered to individually compare cardiac death / TV MI.*

Serruys PW. ACC 2011

RESOLUTE All Comers

Clinically Driven TLR at 2 Years



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P-value unadjusted for multiple comparisons. RESOLUTE All Comers was not specifically designed or powered to individually compare TLR.

Serruys PW. ACC 2011

RESOLUTE All Comers

Definite or Probable Stent Thrombosis at 2 Years

% (n)	Resolute ZES n = 1121	Xience V EES n = 1128	95% CI	P
Early (≤ 30 days)	1.1 (12)*	0.5 (6)	0.5% [-0.2%, 1.3%]	0.16
Late (31 – 360 days)	0.6 (7)*	0.2 (2)	0.4% [-0.1%, 1.0%]	0.11
Def/Prob ST at 1 year	1.6 (18)	0.7 (8)	0.9% [0.0%, 1.8%]	0.05
Very Late (> 360 days)	0.3 (3)	0.3 (3)	0.0% [-0.4%, 0.4%]	1.00
Def/Prob ST at 2 years	1.9 (21)	1.0 (11)	0.9% [-0.1%, 1.9%]	0.08

Silber S, et al. Lancet. 2011;377:1241-47

**One patient had a definite ST at day 4 and 31.*
P-values are based on Fisher's Exact Test and are unadjusted for multiple comparisons. RESOLUTE All Comers was not specifically designed or powered to individually compare stent thrombosis.

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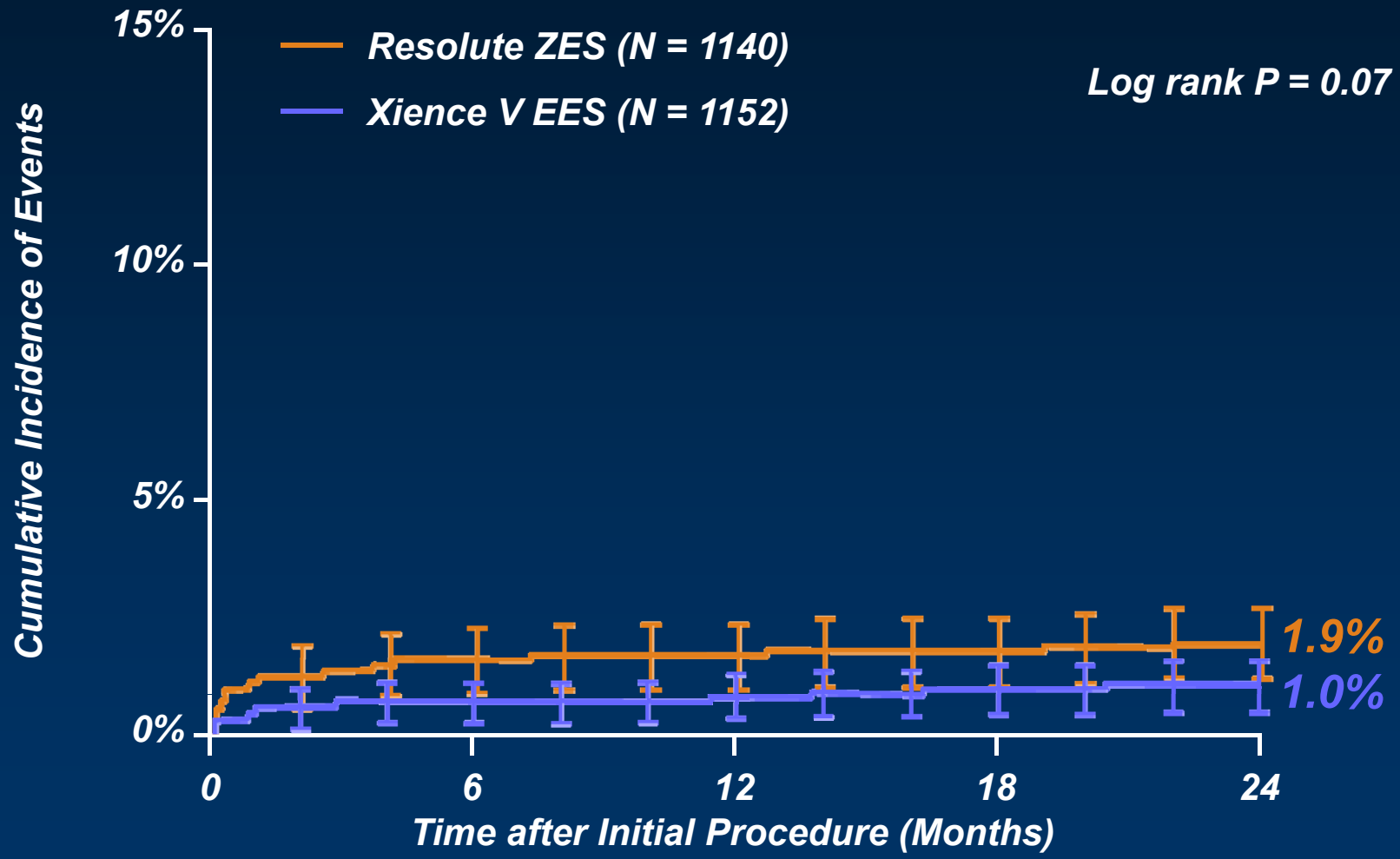

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RESOLUTE International

Prospective, Multicenter, Real World Study

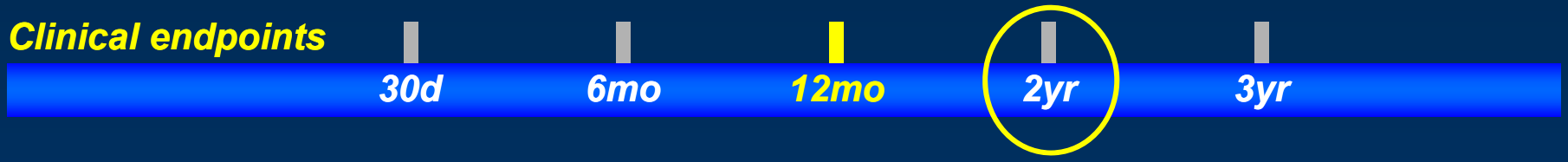
PI: J. Belardi, F–J. Neumann, P. Widimský

All patients with symptomatic coronary artery disease eligible for DES implantation (no lesion/vessel limitations)

Resolute Stent N = 2200

~100 sites International
No angiographic follow-up
25% randomly assigned to 100% monitoring

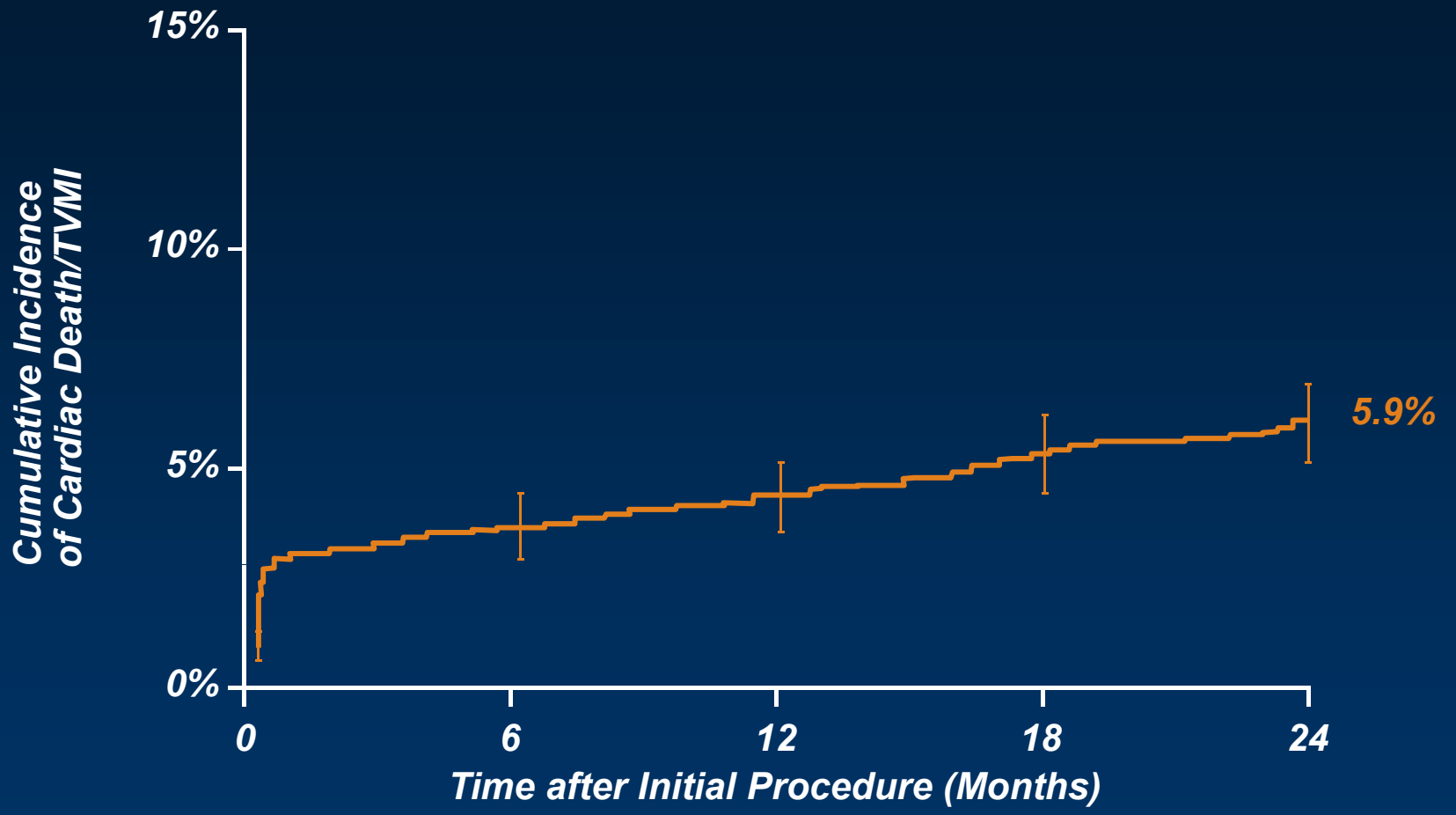
Clinical endpoints



Primary Endpoint: Composite of Cardiac Death & Target Vessel MI at 12mo
Key Secondary Endpoint: ARC Definite and Probable Stent Thrombosis at 12mo
Drug Therapy: ASA and clopidogrel/ticlopidine ≥ 6mo (per guidelines)

RESOLUTE International

Primary Endpoint: Cardiac Death & Target Vessel MI

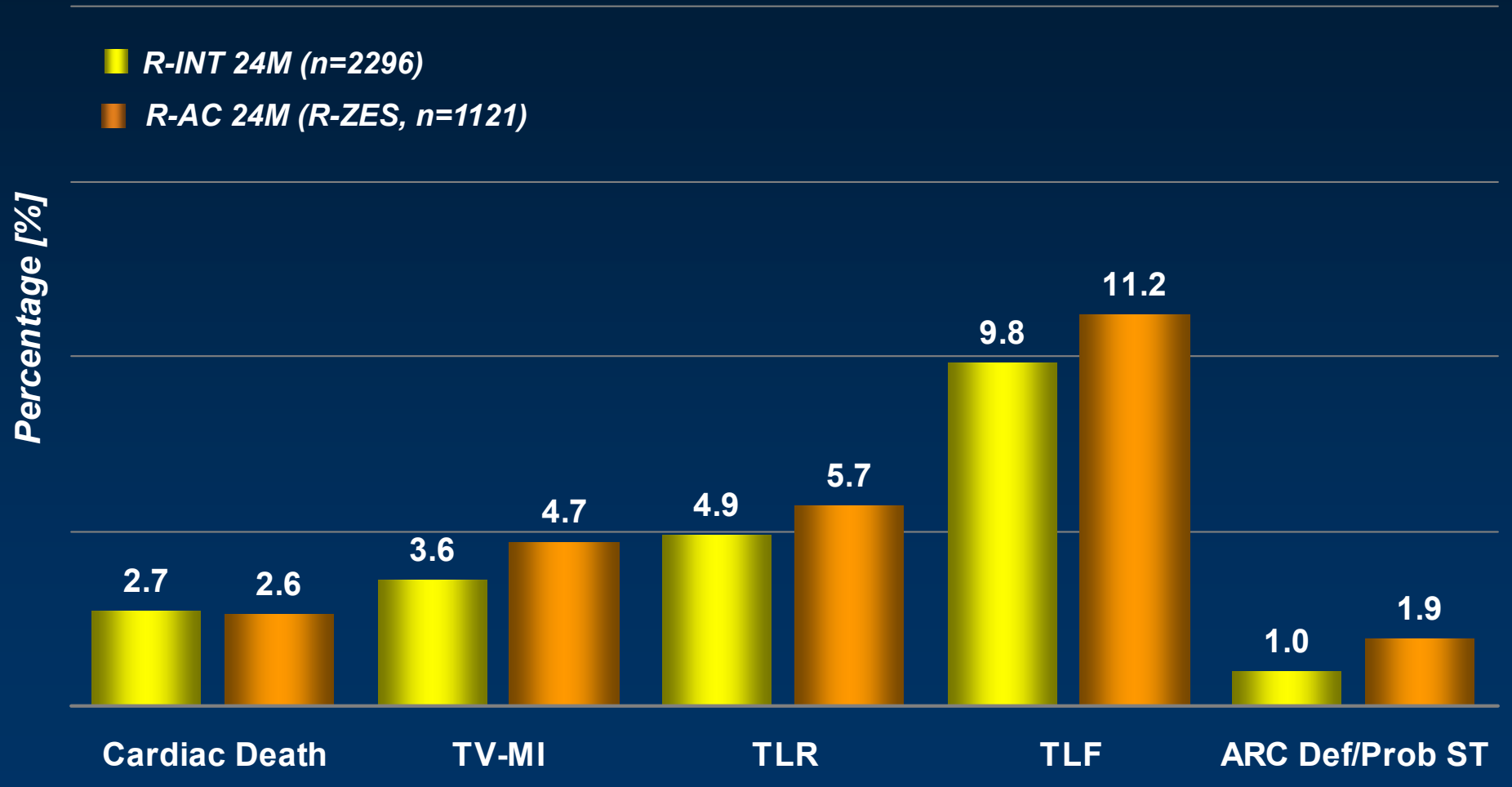


No. at risk	2349	2262	2226	2157	2130
%CI	0.7	3.5	4.2	5.2	5.9

*Error bars indicate a point-wise two-sided 95% confidence interval (±1.96*SE). Standard Error based on the Greenwood Formula.*

R-International vs. R-All Comers

Comparison of Clinical Outcomes at 24 Months



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RESOLUTE US

Clinical Study Design

PI: M. Leon, L. Mauri, A. Yeung

De Novo Native Coronary Lesion
Vessel Diameter: 2.25 – 4.2 mm
Lesion Length: ≤ 27 mm
(≤ 35 mm lesions tx w/ 38 mm stent)

Resolute stent
2.25–3.5 Clinical (n=1242)
2.25–3.5 Angio/IVUS (n=100)
4.0 Angio (n=60)
38mm Clinical (n=110–175)

N = max 1577 patients
Up to 135 US sites

Hx Controls
Performance Goals

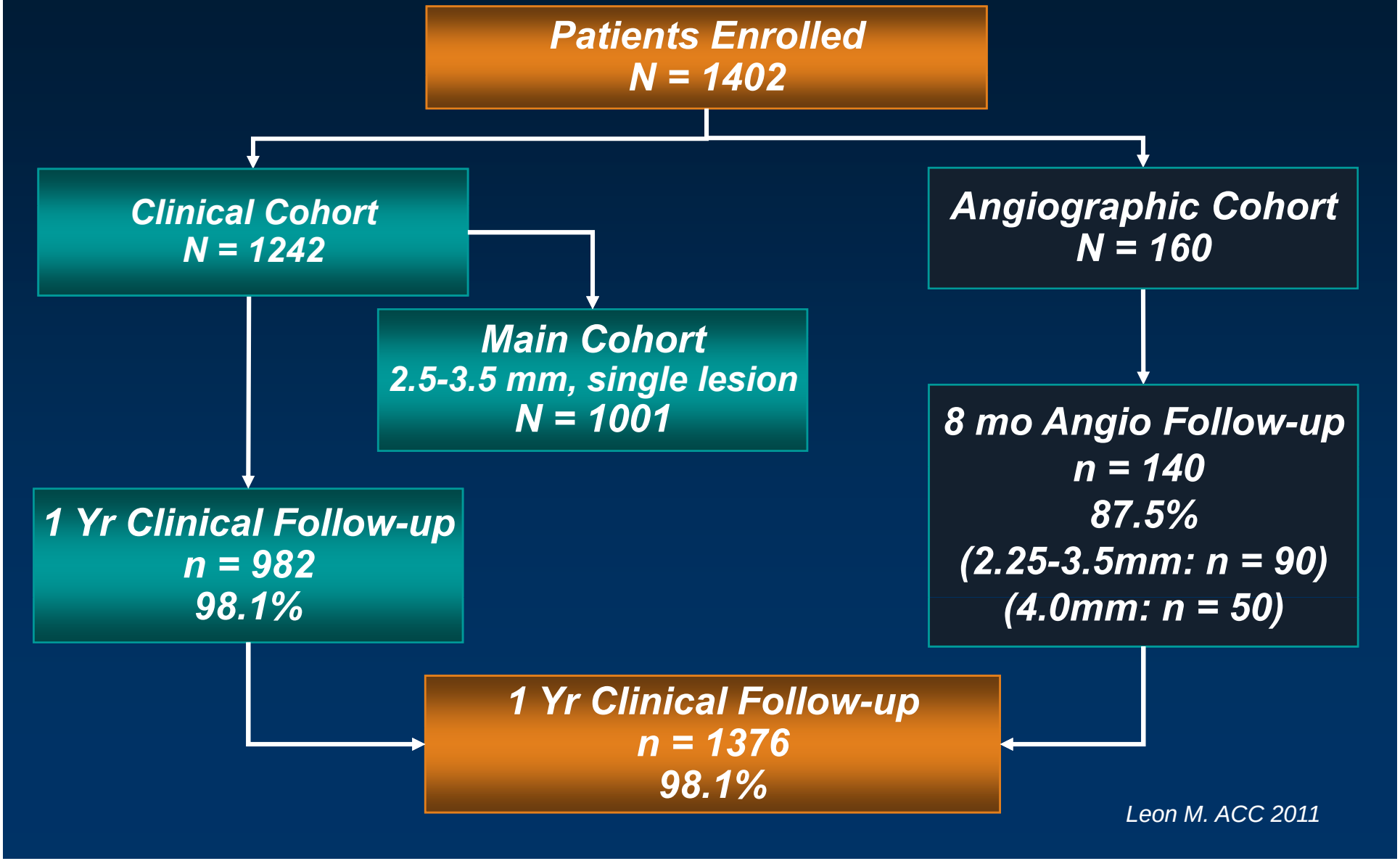
Primary Endpoints:

- ***2.25–3.5 Clinical → Target Lesion Failure at 12mo***
- ***2.25–3.5 Angio/IVUS → In-Stent LLL at 8mo***
- ***4.0 Angio → In-Segment LLL at 8mo***
- ***38 mm Clinical → Target Lesion Failure at 12mo***

Drug Therapy: ASA and clopidogrel/ticlopidine ≥ 6mo (per guidelines)

RESOLUTE US

Patient Flow Chart



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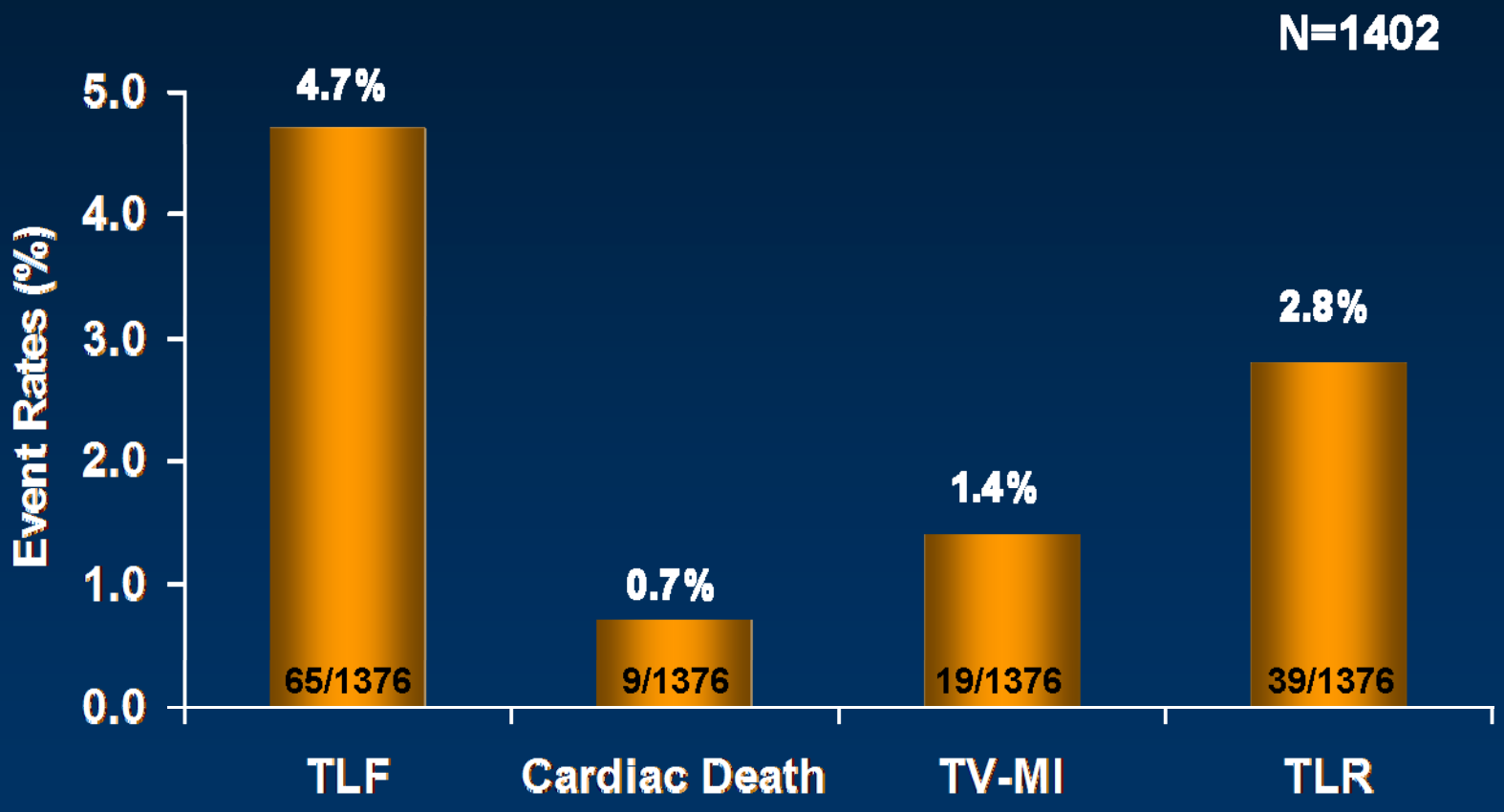
RESOLUTE US – All Patients

TLF and Components at 12 Months



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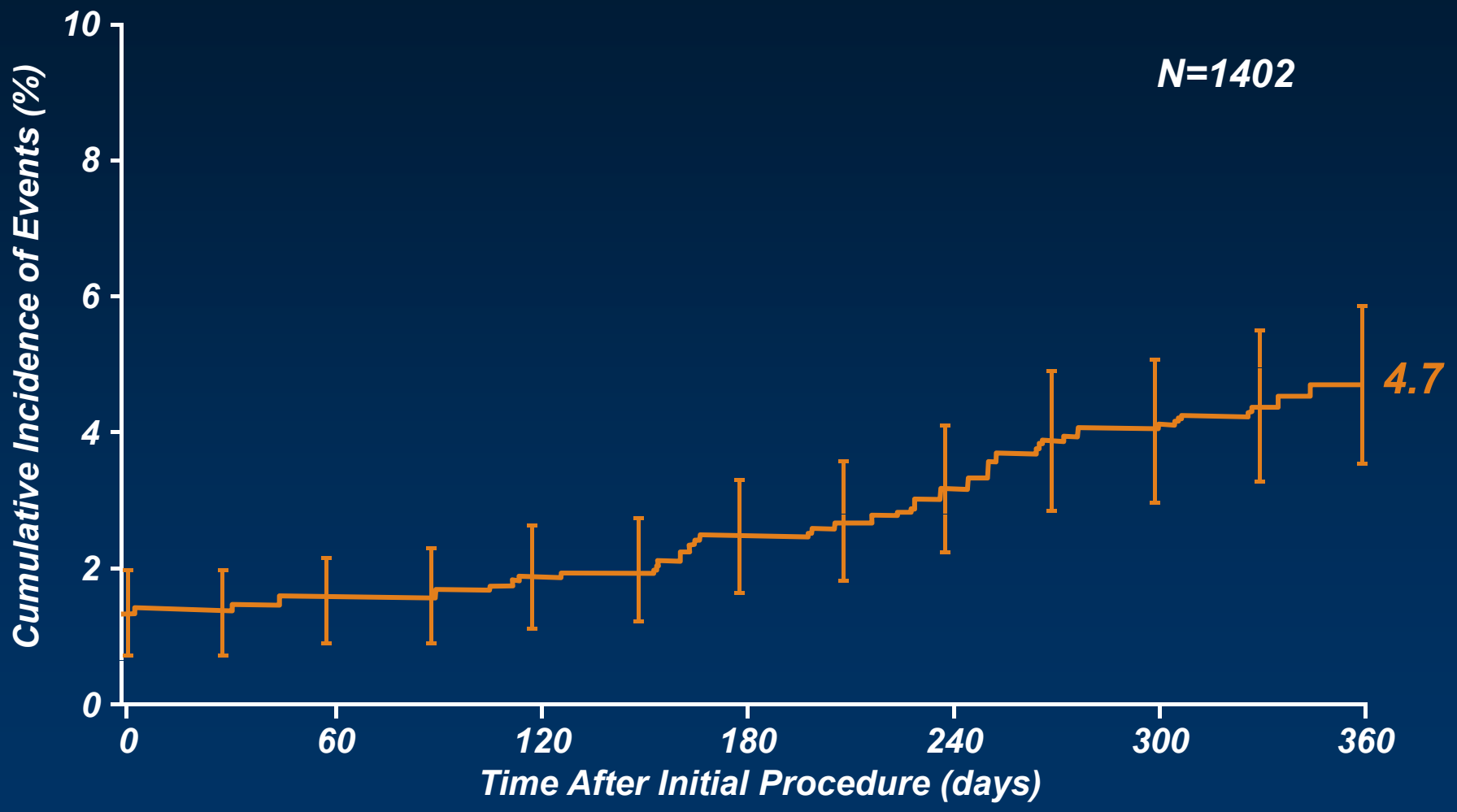
RESOLUTE US – All Patients

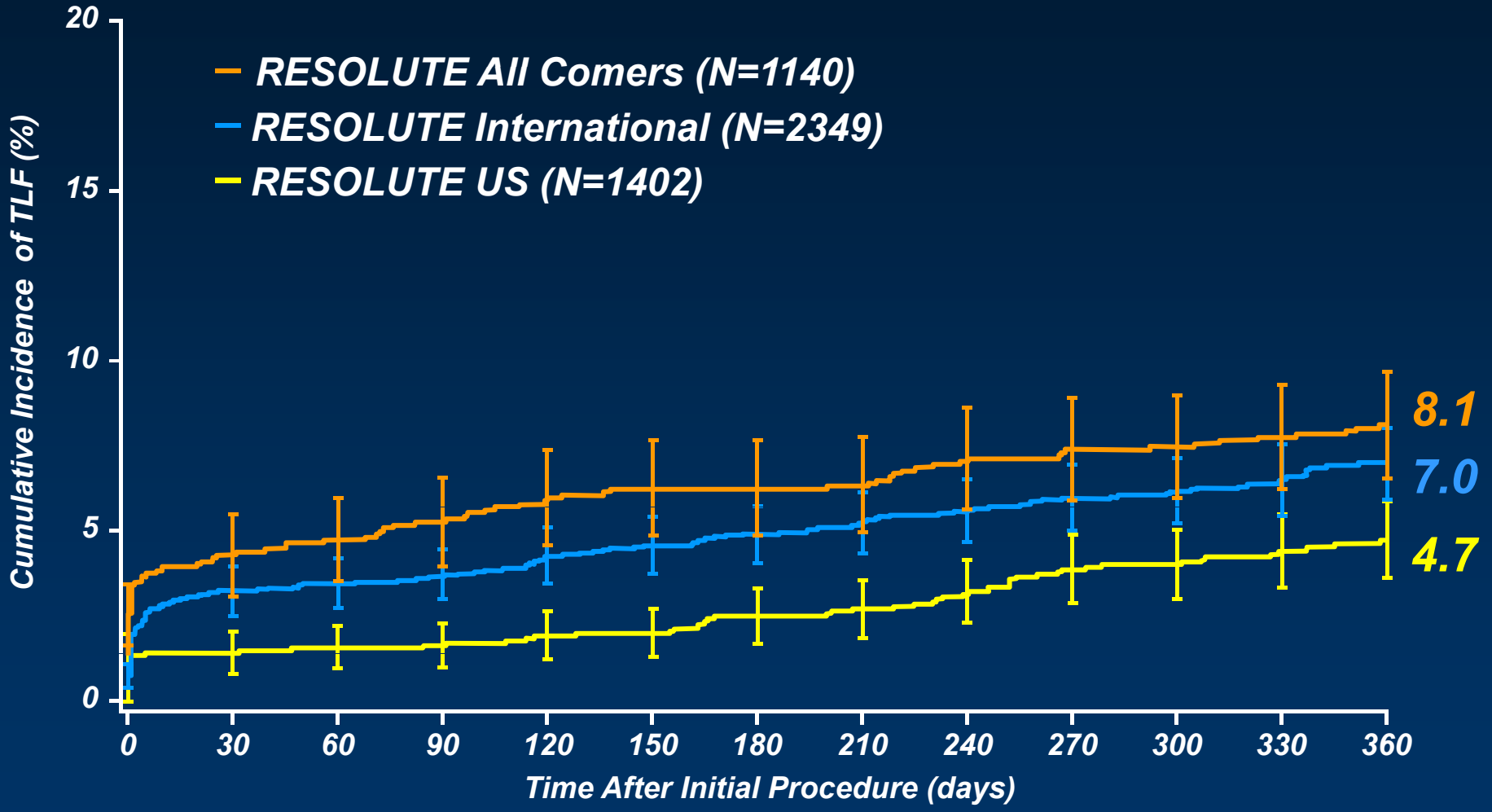
Target Lesion Failure to 12 Months (Cardiac Death, TV-MI, CD-TLR)



Yeung A, et al. J Am Coll Cardiol. 2011;57:1778-83.
*Error bars indicate a point-wise two-sided 95% confidence interval (±1.96*SE). Standard Error based on the Greenwood Formula.*

Target Lesion Failure to 12 Months

RESOLUTE US, RESOLUTE AC, RESOLUTE INT



*Error bars indicate a point-wise two-sided 95% confidence interval (±1.96*SE).*
Standard Error based on the Greenwood Formula.

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Publication of R-US study design

ARTICLE IN PRESS

Rationale and design of the clinical evaluation of the Resolute Zotarolimus-Eluting Coronary Stent System in the treatment of de novo lesions in native coronary arteries (the RESOLUTE US clinical trial)

Laura Mauri, MD, MSc,[a,b] Martin B. Leon, MD,[c] Alan C. Yeung, MD,[d] Manuela Negoita, MD,[e] Michelle J. Keyes, PhD,[f] and Joseph M. Massaro, PhD[f] *Boston, MA; New York, NY; Stanford and Santa Rosa, CA*

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Publication of R-US Outcomes

ARTICLE IN PRESS

Journal of the American College of Cardiology
© 2011 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. xx, No. x, 2011
ISSN 0735 1097/$36.00
doi:10.1016/j.jacc.2011.03.005

Clinical Evaluation of the Resolute Zotarolimus-Eluting Coronary Stent System in the Treatment of De Novo Lesions in Native Coronary Arteries

The RESOLUTE US Clinical Trial

Alan C. Yeung, MD,* Martin B. Leon, MD,‡ Ash Jain, MD,† Thaddeus R. Tolleson, MD,§ Douglas J. Spriggs, MD,‖ Brent T. Mc Laurin, MD,¶ Jeffrey J. Popma, MD,# Peter J. Fitzgerald, MD,* Donald E. Cutlip, MD,# Joseph M. Massaro, PHD,** Laura Mauri, MD, MSC,** on behalf of the RESOLUTE US Investigators

Stanford and Fremont, California; New York, New York; Tyler, Texas; Clearwater, Florida; Anderson, South Carolina; and Boston, Massachusetts

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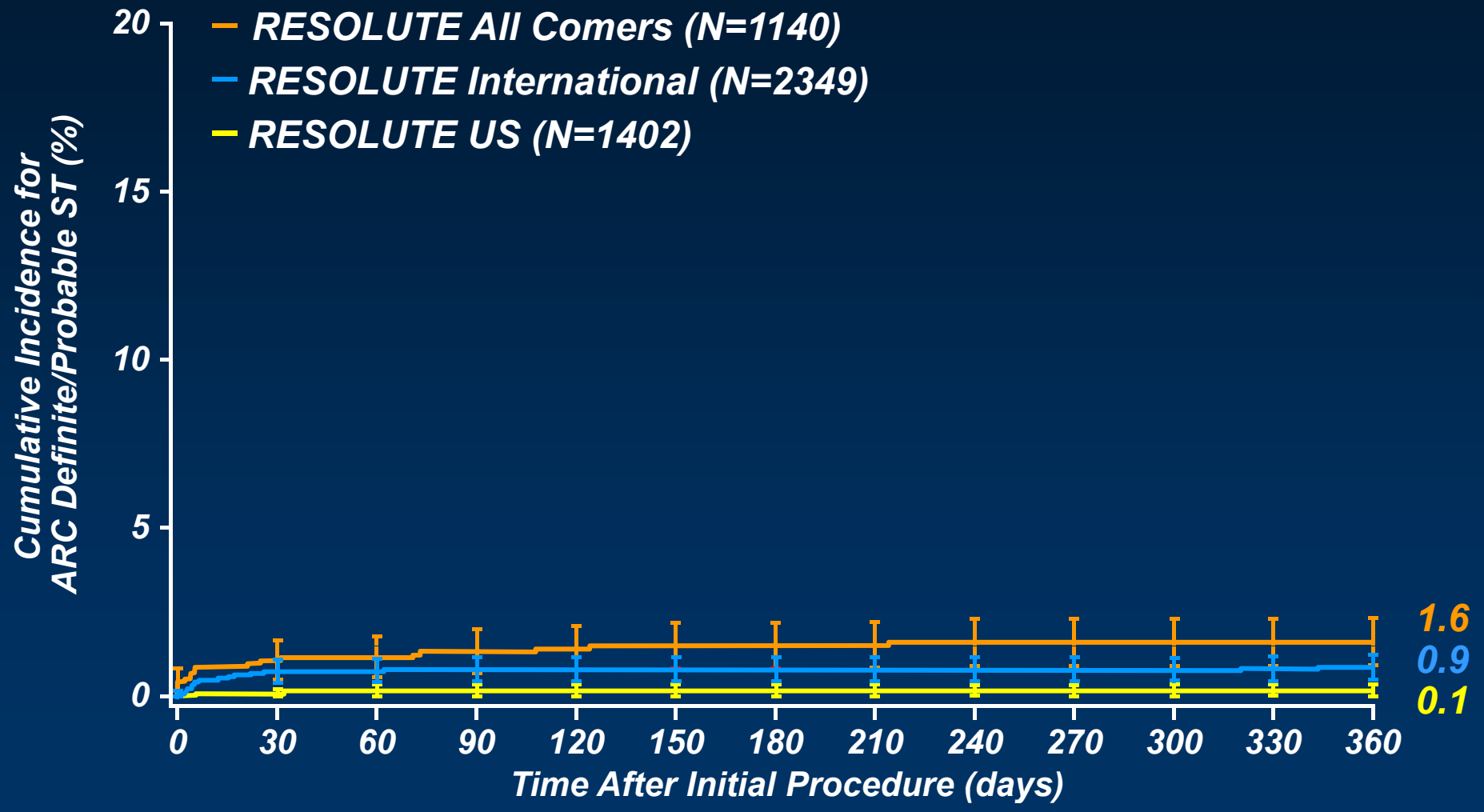
ARC Def/Prob ST to 12 Months

RESOLUTE US, RESOLUTE AC, RESOLUTE INT



*Error bars indicate a point-wise two-sided 95% confidence interval (±1.96*SE).*
Standard Error based on the Greenwood Formula.

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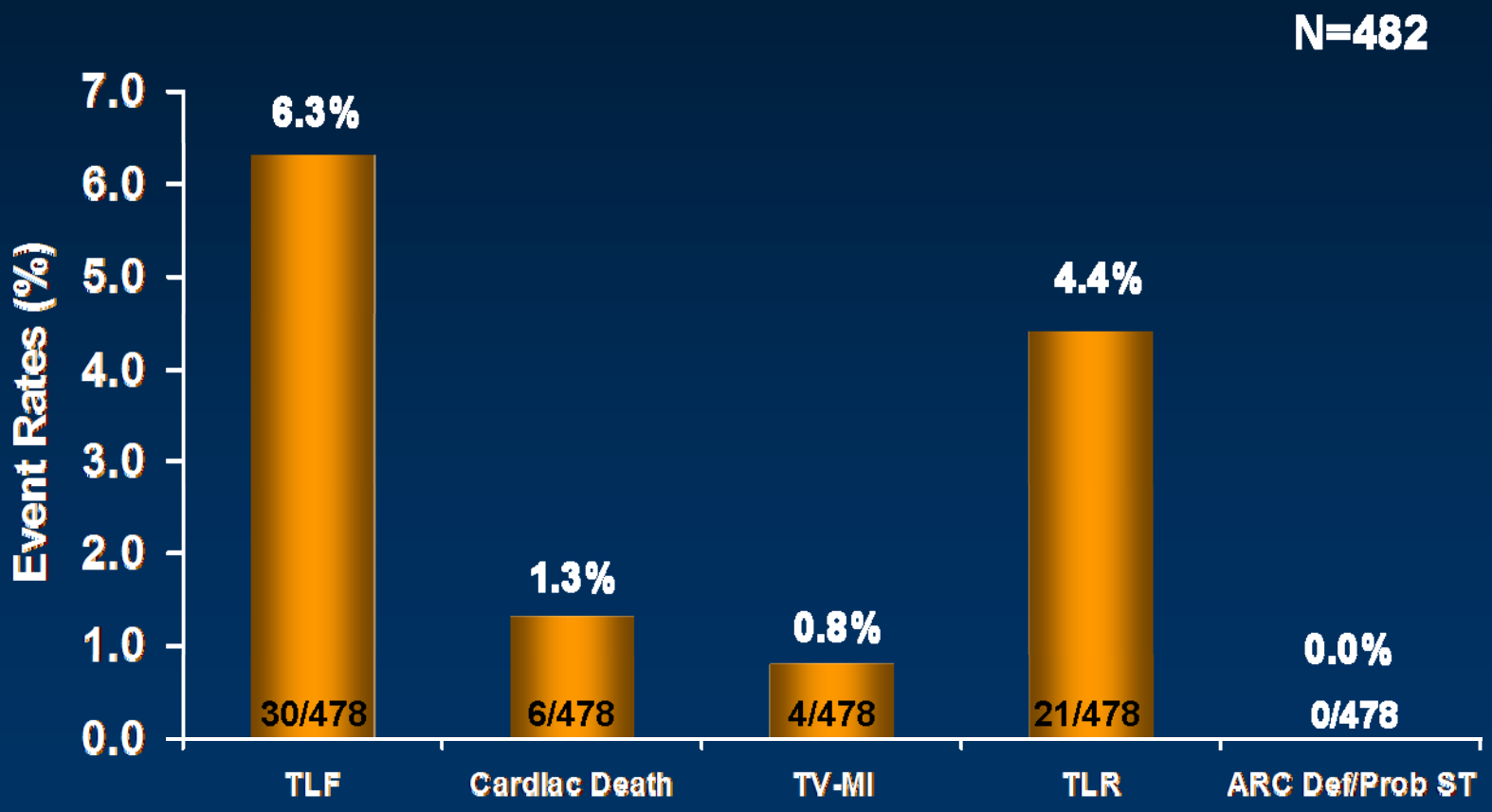
RESOLUTE US – All Diabetics

Clinical Endpoints at 12 Months



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RESOLUTE Global Clinical Program

5,130 patients enrolled with ≥1 year FU

Enrollment Complete - In Follow Up

RESOLUTE[1]	Non-RCT First-in-Human (R=139)	5 yr
RESOLUTE AC[2,3]	1:1 RCT vs. Xience V® (R=1,140; X=1,152)	2 yr
RESOLUTE Int	Non-RCT Observational (R=2349)	2 yr
RESOLUTE US[4]	2.25 – 3.5mm Non-RCT vs. Hx Control (R=1,242)	1 yr
	2.25 – 3.5mm Angio/IVUS Non-RCT vs. Hx Control (R=100)	1 yr
	4.0mm Angio Non-RCT vs. Hx Control (R=60)	1 yr
RESOLUTE Japan	2.5 – 3.5mm Non-RCT (R=100) vs. Hx Control	1 yr
R Japan SVS	2.25 Non-RCT vs. PG (R=63)	<1 yr
RESOLUTE US	38 mm sub-study Non-RCT vs. PG (R=110-175)	<1 yr

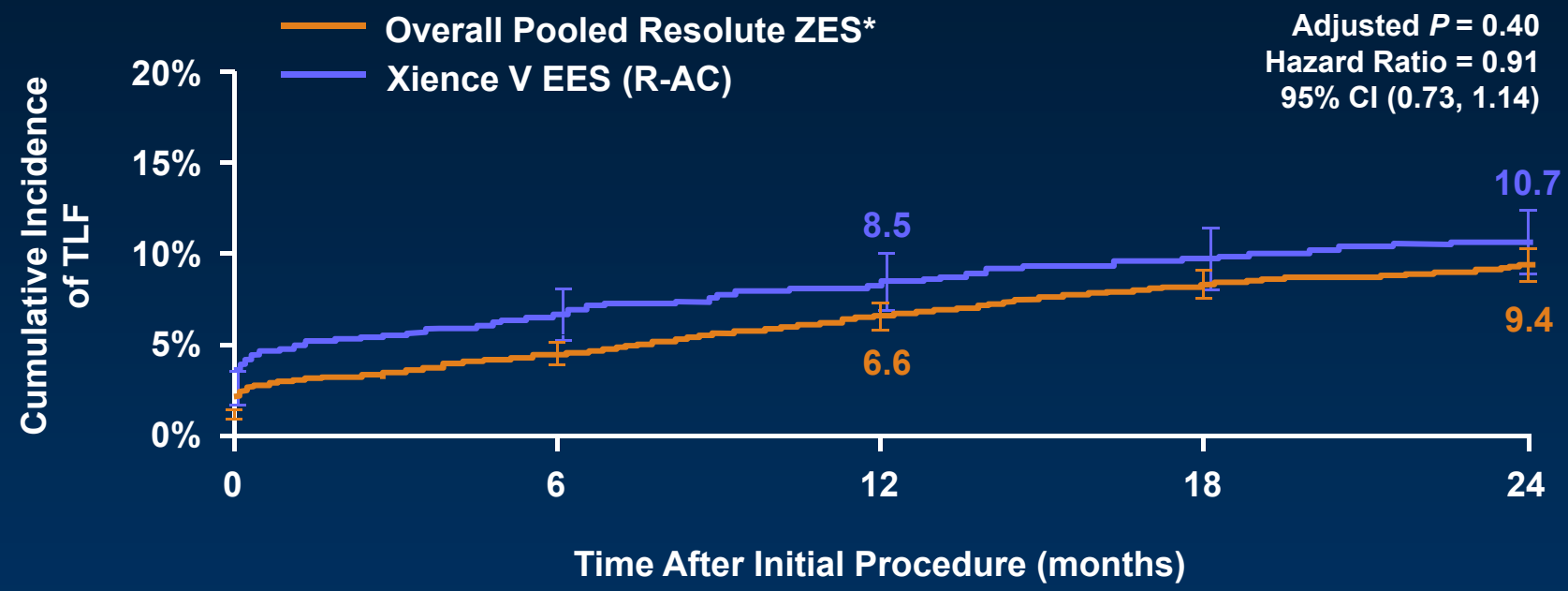
Enrolling / Planning

RESOLUTE Asia	Non-RCT (R≈300)	enroll
R-China Registry	Registry (R=1500 max)	enroll
R-China RCT	3:1 vs. Cypher (R=742; C=248)	plan

[1] Meredith IT, et al. *EuroIntervention.* 2010;5:692-7. [2] Serruys PW, et al. *N Engl J Med.* 2010;363:136-46.
[3] Silber S, et al. *Lancet.* 2011;377:1241-47. [4] Yeung AC, et al. *JACC.* 2011;57:1778-83.

RESOLUTE Pooled

Target Lesion Failure (TLF)‡ to 2 Years

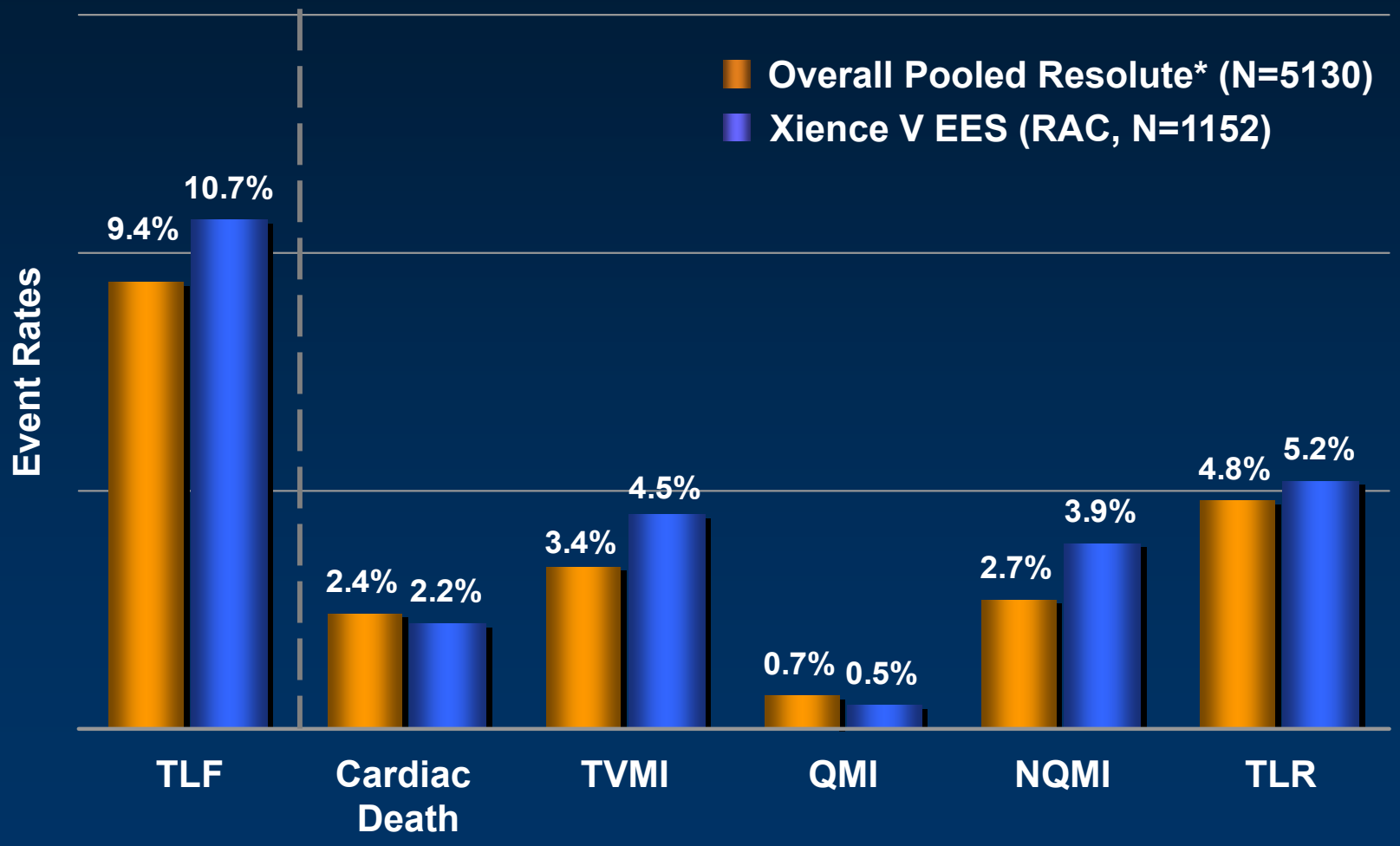


No. at risk					
R-ZES	5130	5057	4839	4301	3185
% CI	1.4	4.5	6.6	8.3	9.4
EES	1152	1121	1061	1026	998
% CI	2.6	6.7	8.5	9.8	10.7

‡Cardiac Death, TVMI, or TLR
*Pooled patient level data from RESOLUTE, R-AC, R-Int, R-US, R-Japan

RESOLUTE Pooled

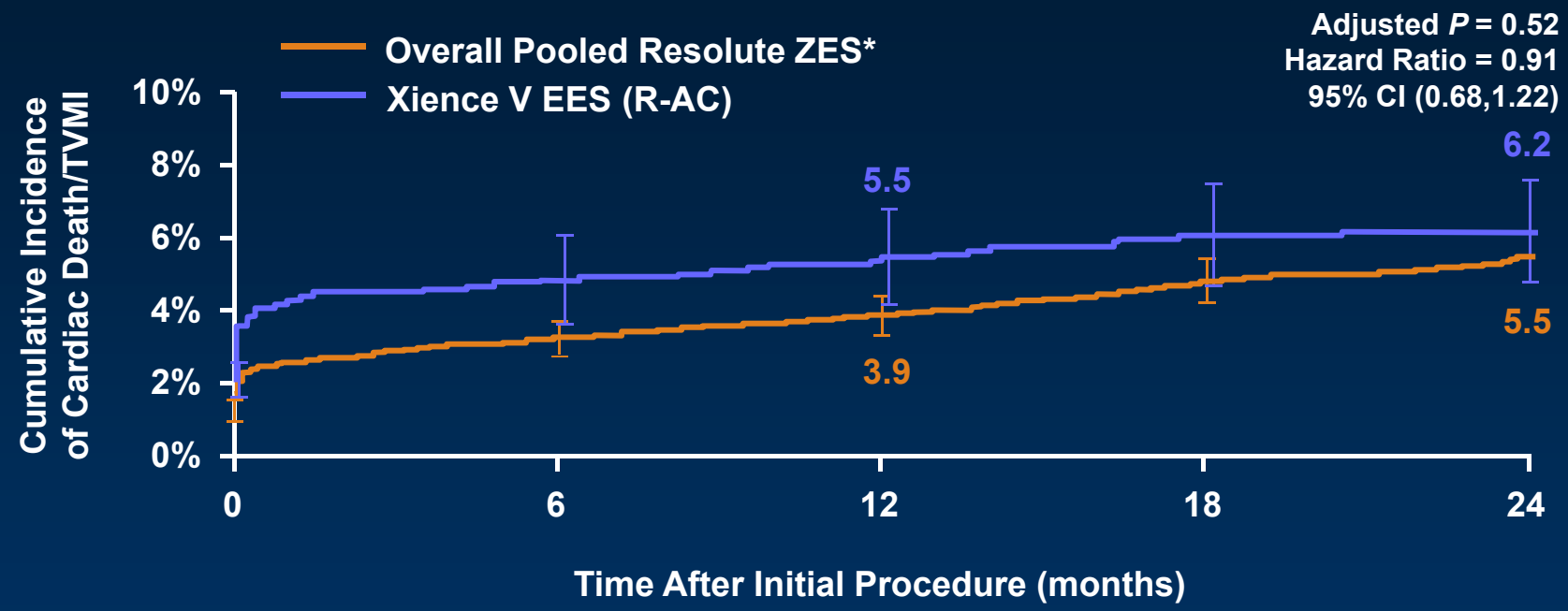
TLF and Components at 2 Years



TLF (Target Lesion Failure) is defined as Cardiac Death, TVMI, or TLR
*Pooled patient level data from RESOLUTE, R-AC, R-Int, R-US, R-Japan

RESOLUTE Pooled

Cardiac Death & Target Vessel MI to 2 Years

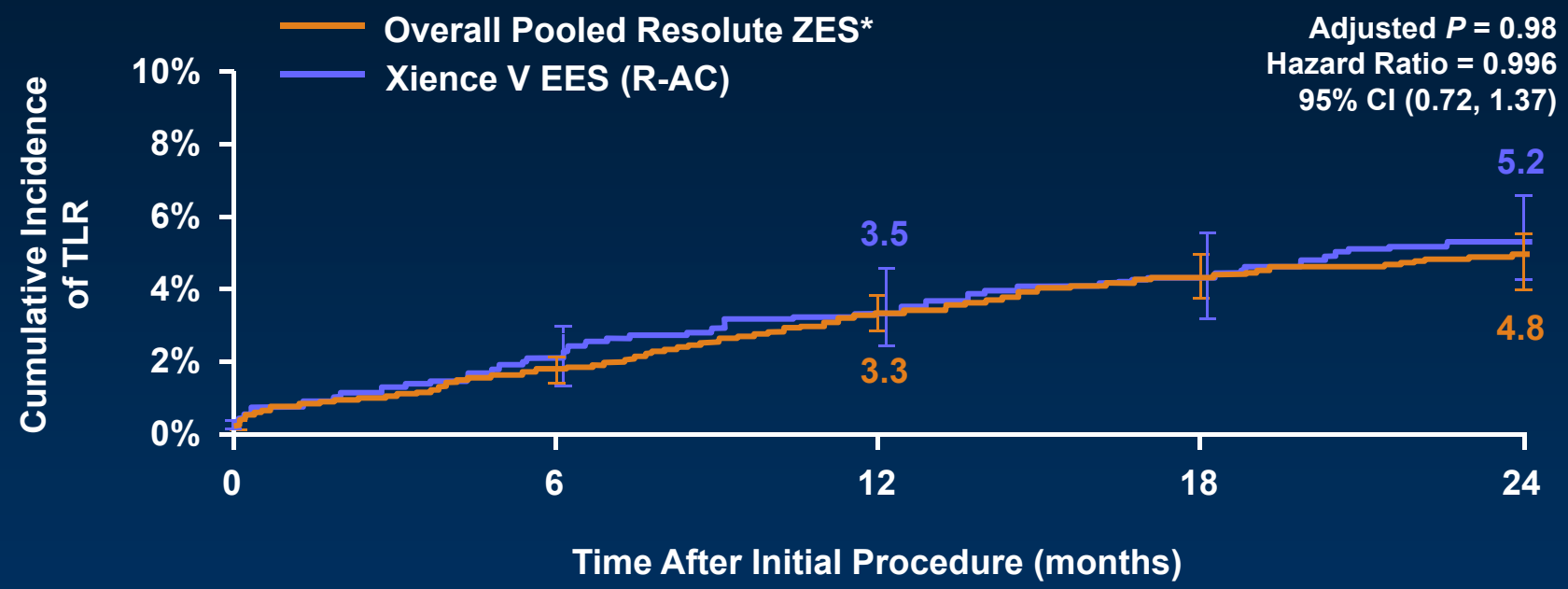


No. at risk					
R-ZES	5130	5062	4899	4425	3307
% CI	1.3	3.3	3.9	4.9	5.5
EES	1152	1121	1082	1060	1037
% CI	2.6	4.9	5.5	6.1	6.2

*Pooled patient level data from RESOLUTE, R-AC, R-Int, R-US, R-Japan

RESOLUTE Pooled

Target Lesion Revascularization to 2 Years

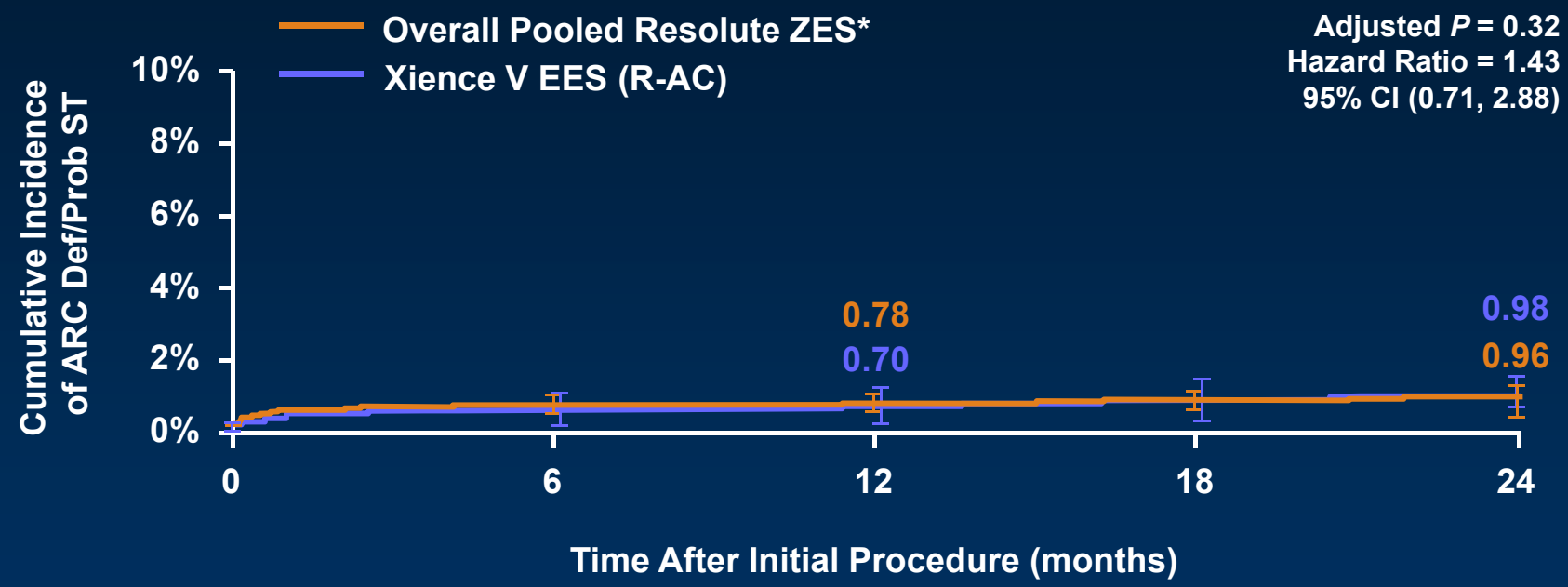


No. at risk					
R-ZES	5130	5121	4947	4409	3279
% CI	0.1	1.7	3.3	4.3	4.8
EES	1152	1148	1100	1064	1035
% CI	0.1	2.1	3.5	4.3	5.2

TLR is clinically driven
*Pooled patient level data from RESOLUTE, R-AC, R-Int, R-US, R-Japan

RESOLUTE Pooled

Stent Thrombosis ARC Definite/Probable to 2 Years



No. at risk					
R-ZES	5130	5122	5007	4533	3406
% CI	0.12	0.72	0.78	0.87	0.96
EES	1152	1149	1121	1099	1075
% CI	0.00	0.61	0.70	0.89	0.98

Outcomes remain consistent when adjusted for duration of DAPT.
*Pooled patient level data from RESOLUTE, R-AC, R-Int, R-US, R-Japan

RESOLUTE Studies

ISAR-TEST 5: Randomized, Non-inferiority Trial of Rapamycin/Probucol- and Zotarolimus-Eluting Stents

J. Mehilli, MD

A. Kastrati, R.A. Byrne, S. Massberg, K. Tiroch, S. Schulz, J. Pache, M. Fusaro, K-L. Laugwitz, A. Schömig

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

RESOLUTE Studies
ISAR-TEST 5

Polymer-Free Sirolimus- and Probucol-Eluting Versus New Generation Zotarolimus-Eluting Stents in Coronary Artery Disease

The Intracoronary Stenting and Angiographic Results: Test Efficacy of Sirolimus- and Probucol-Eluting Versus Zotarolimus-Eluting Stents (ISAR-TEST 5) Trial

Steffen Massberg, MD; Robert A. Byrne, MB BCh; Adnan Kastrati, MD; Stefanie Schulz, MD; Jürgen Pache, MD; Jörg Hausleiter, MD; Tareq Ibrahim, MD; Massimiliano Fusaro, MD; Ilka Ott, MD; Albert Schömig, MD; Karl-Ludwig Laugwitz, MD; Julinda Mehilli, MD; on behalf of the Intracoronary Stenting and Angiographic Results: Test Efficacy of Sirolimus- and Probucol-Eluting Versus Zotarolimus- Eluting Stents (ISAR-TEST 5) Investigators

Circulation 2011;124:624-632

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ISAR-TEST-5

***I**ntracoronary **S**tenting and **A**ngiographic **R**esults:*
***T**est **E**fficacy of Rapamycis/Probucol- and Zotarolimus-Eluting **ST**ents - 5*

3002 patients with *de novo* lesions

Rapamycin/Probucol-Eluting DES
(Dual-DES)
n=2002

Zotarolimus-Eluting DES
(ZES)
n=1000

6 to 8-month repeat angiogram

12-month clinical follow-up

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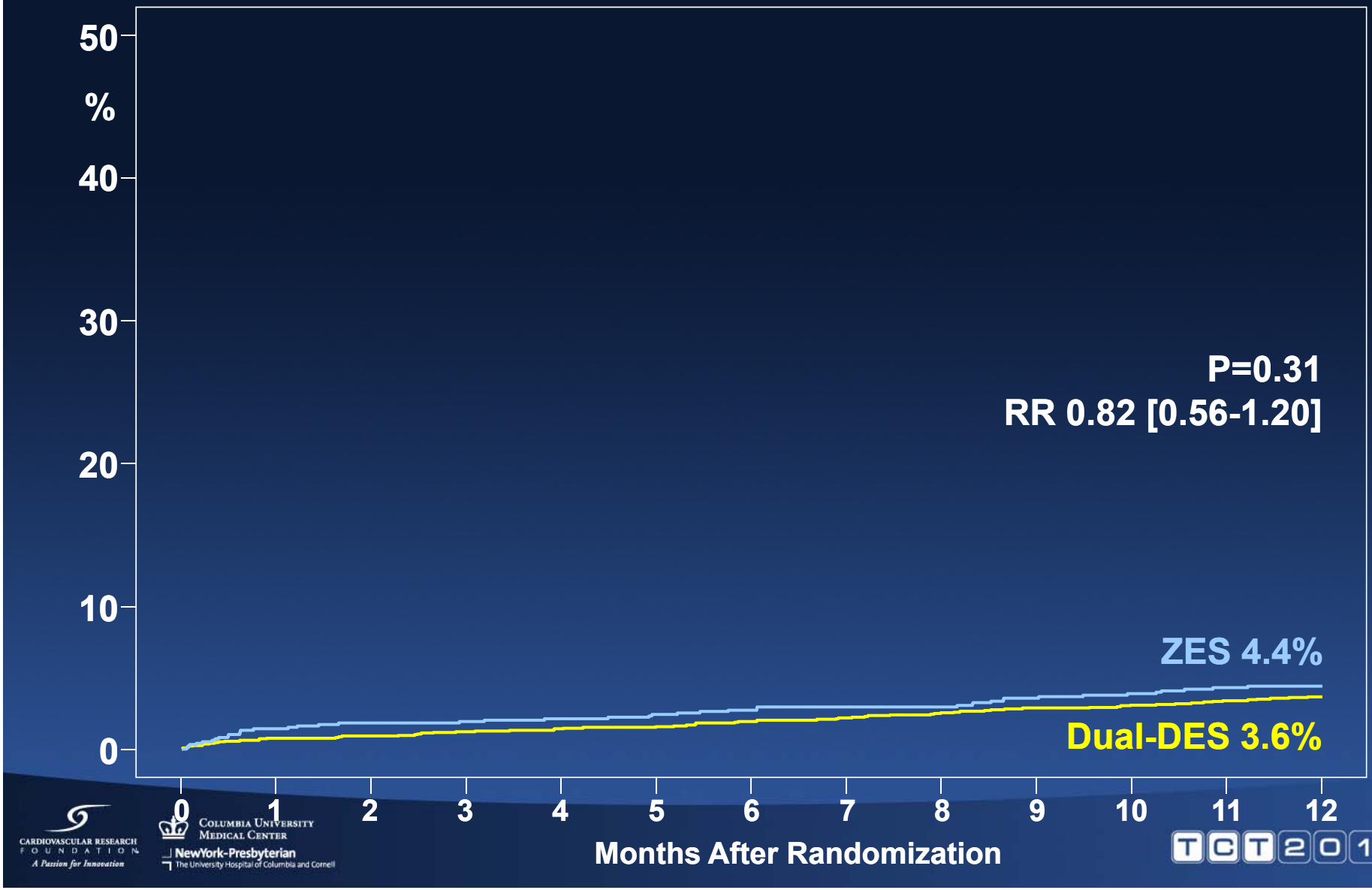
TCT2010

All-Cause Death at 1 Year



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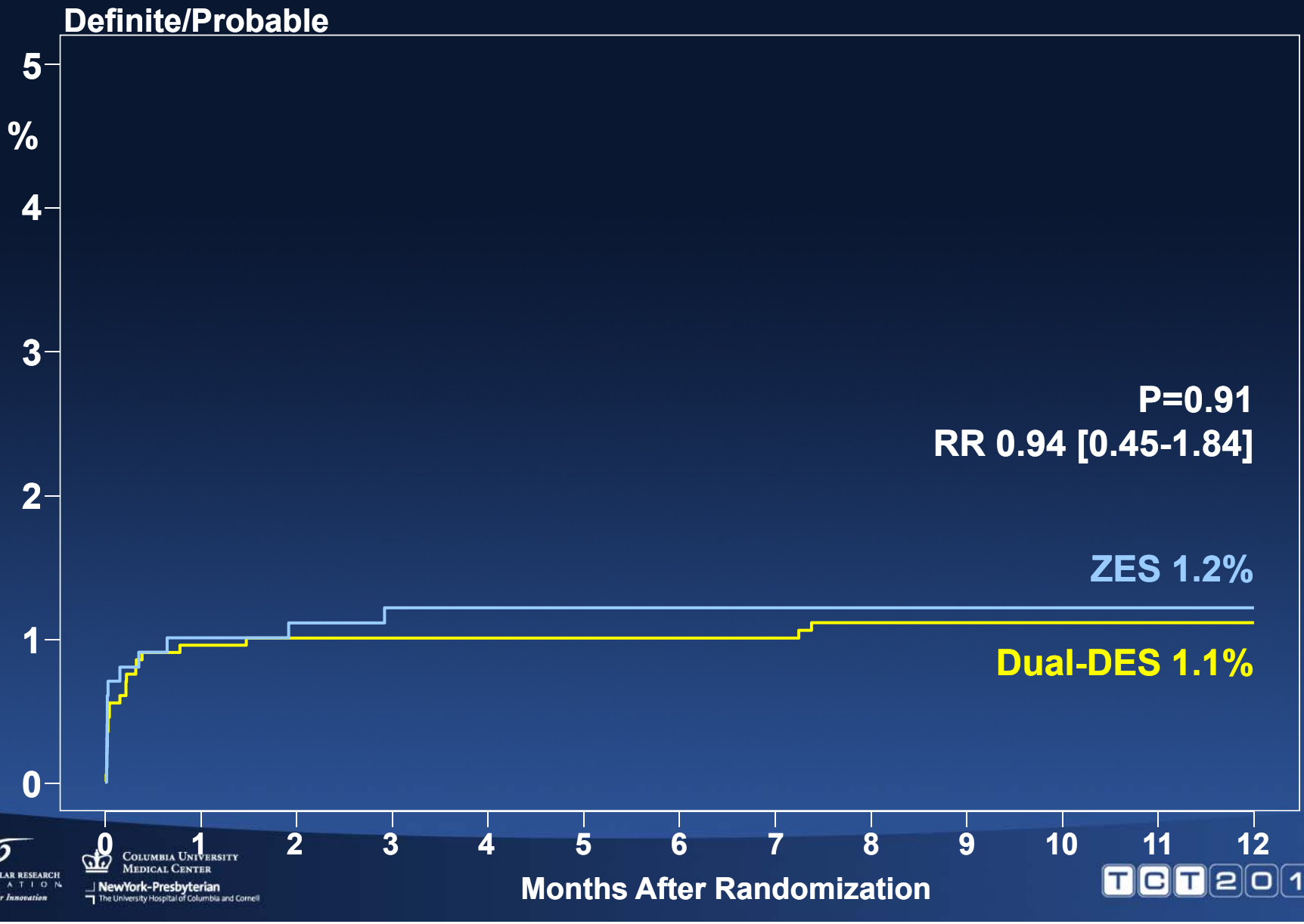
TCT2010

Stent Thrombosis at 1 Year



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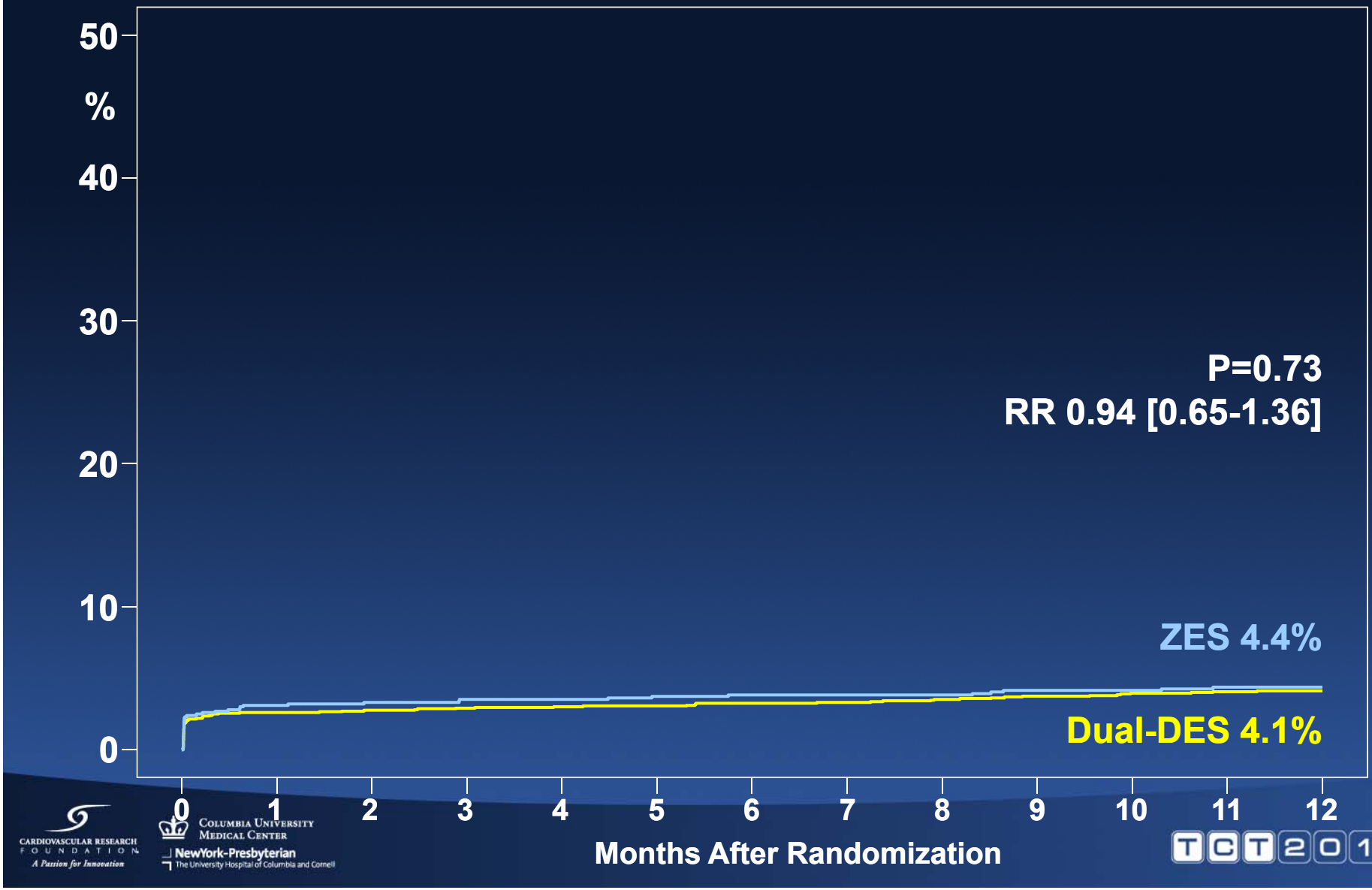
Cardiac Death or MI at 1 Year



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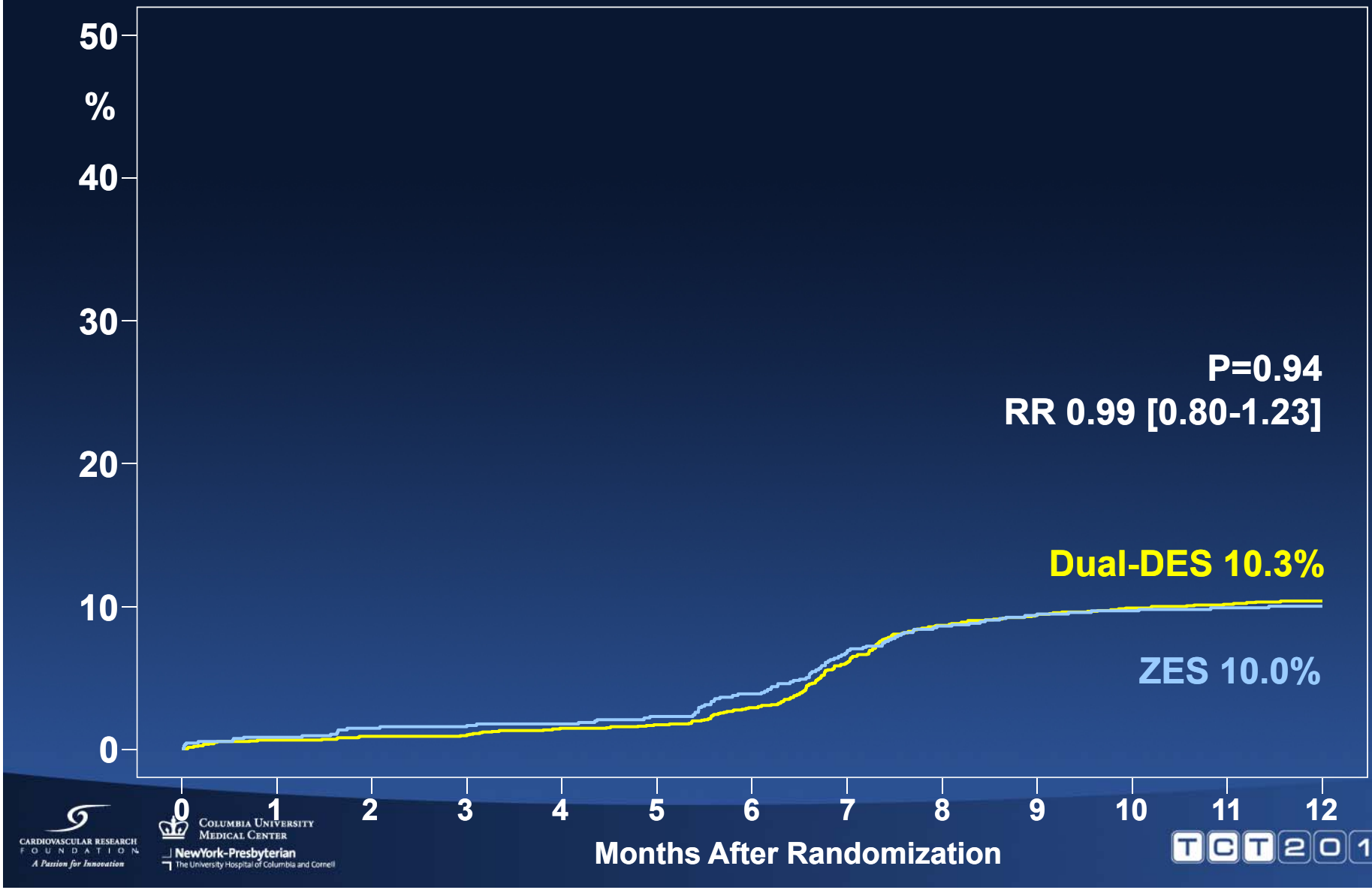
Target Lesion Revascularization



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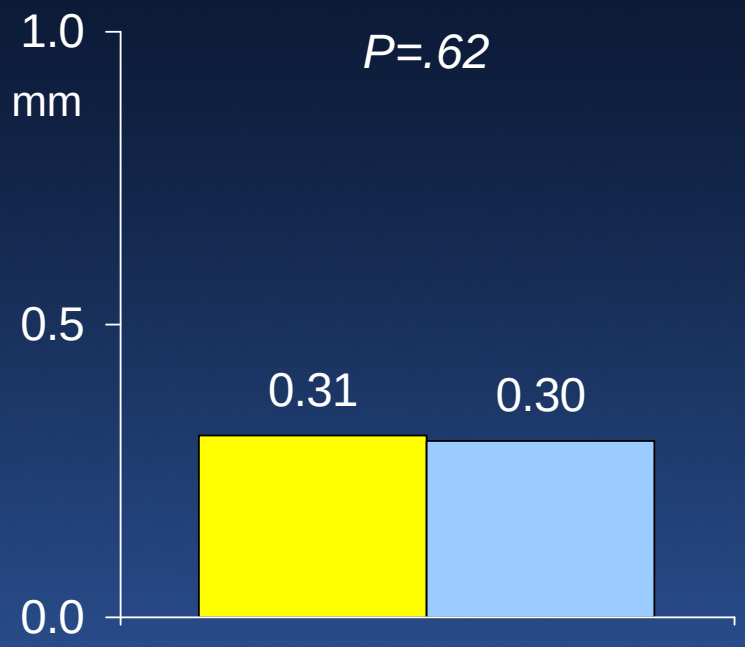
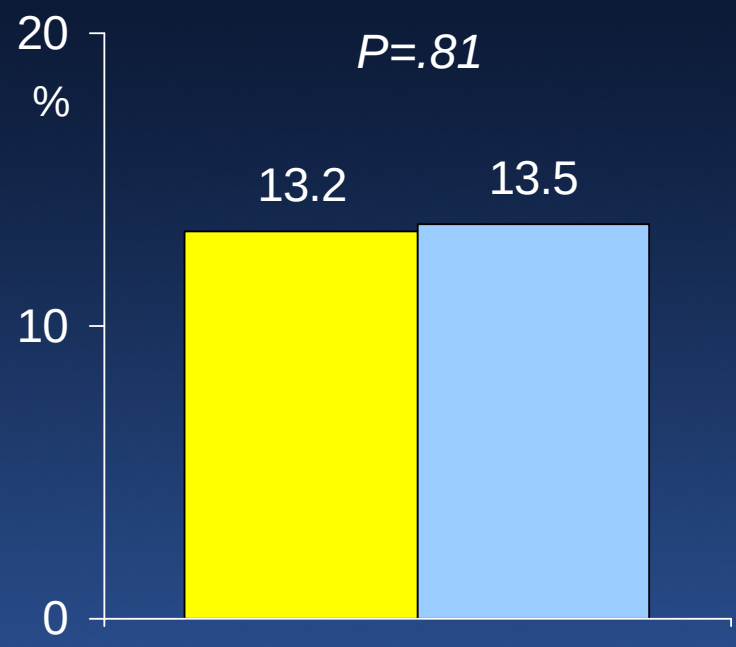
Angiographic Restenosis

In-stent late lumen loss

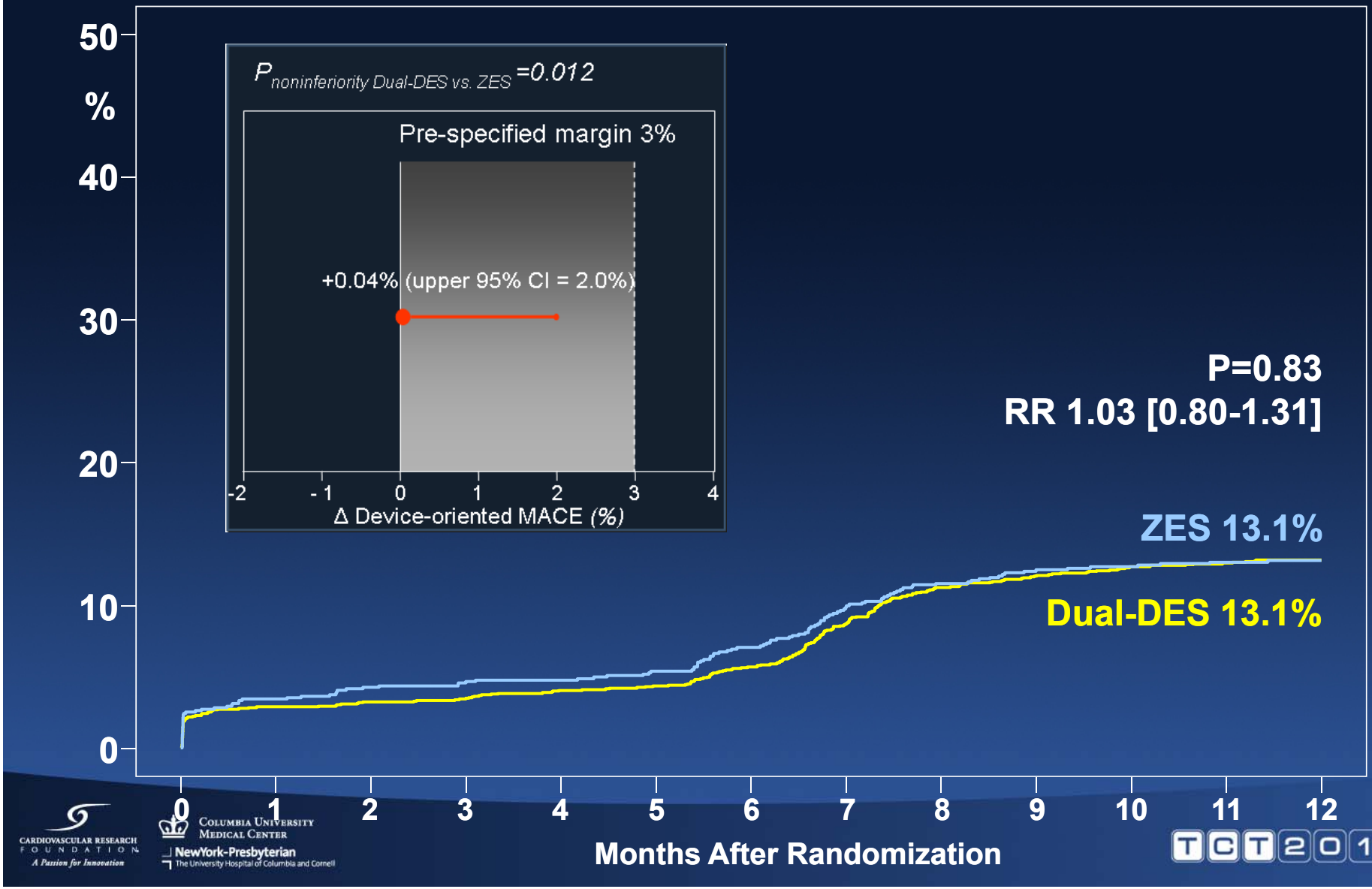


In-segment binary restenosis



Dual-DES ZES

Cardiac Death/TV-related MI/TLR



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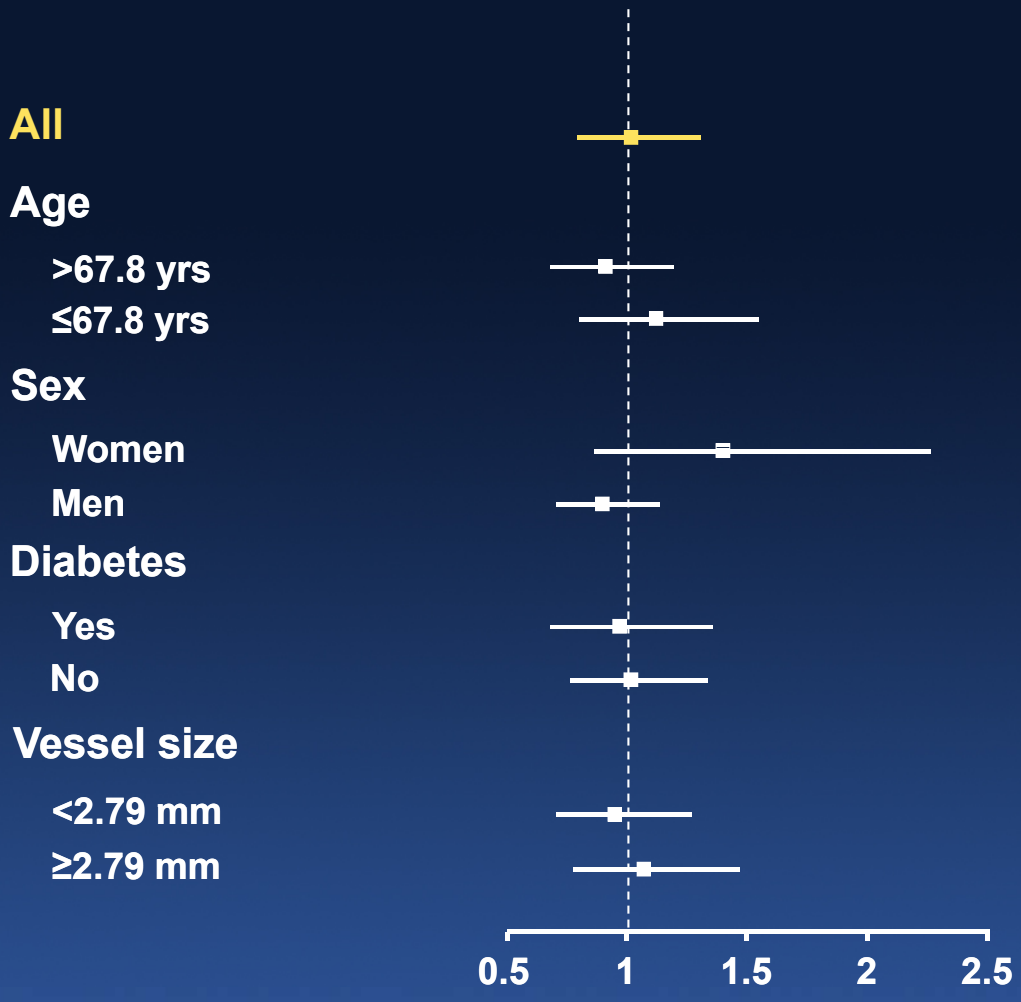
Primary Endpoint in Different Subgroups



		$P_{interaction}$
All	1.03 (0.80, 1.31)	
Age		0.51
>67.8 yrs	0.91 (0.69, 1.20)	
≤67.8 yrs	1.12 (0.81, 1.55)	
Sex		0.10
Women	1.40 (0.87, 2.26)	
Men	0.90 (0.71, 1.14)	
Diabetes		0.82
Yes	0.97 (0.69, 1.36)	
No	1.02 (0.77, 1.34)	
Vessel size		0.38
<2.79 mm	0.95 (0.71, 1.27)	
≥2.79 mm	1.07 (0.78, 1.47)	

TWENTE

A Prospective, Randomized Trial of Zotarolimus-Eluting Stents and Everolimus-Eluting Stents in Patients With Coronary Artery Disease

Clemens von Birgelen, MD PhD

Thoraxcentrum Twente, MST, and MIRA Institute,
University of Twente, Enschede, the Netherlands

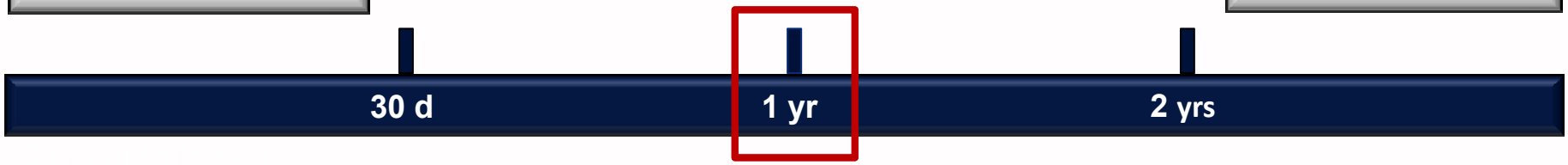
TWENTE Study Design

- Patients with stable angina or non-ST-elevation ACS requiring DES
- No limit of number of lesions or vessels treated
- No limit of lesion length
- No limit of reference vessel size

Zotarolimus-eluting Resolute n = 690

1:1 Randomization

Everolimus-eluting Xience V n = 690

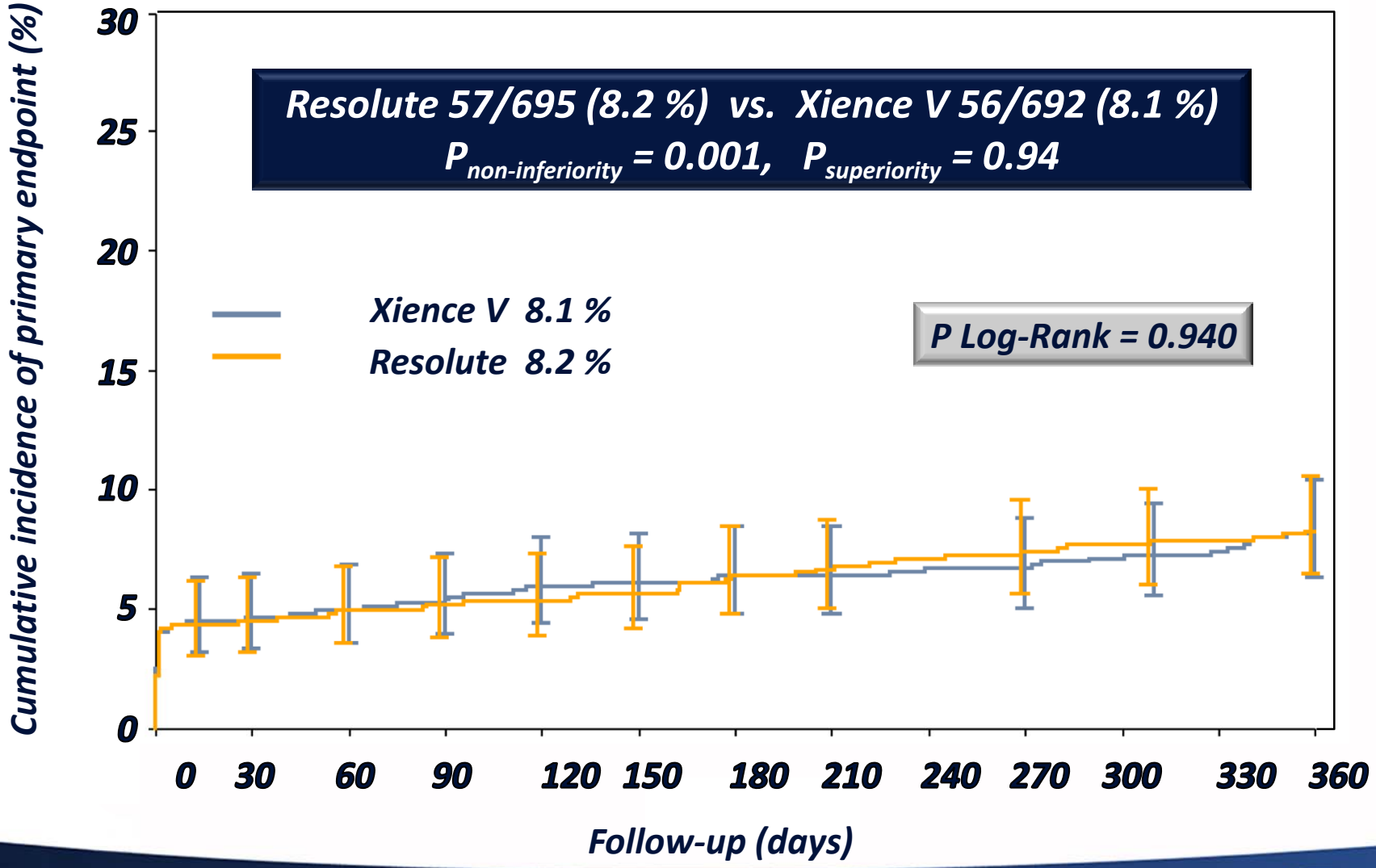


Control angiography only if clinically indicated

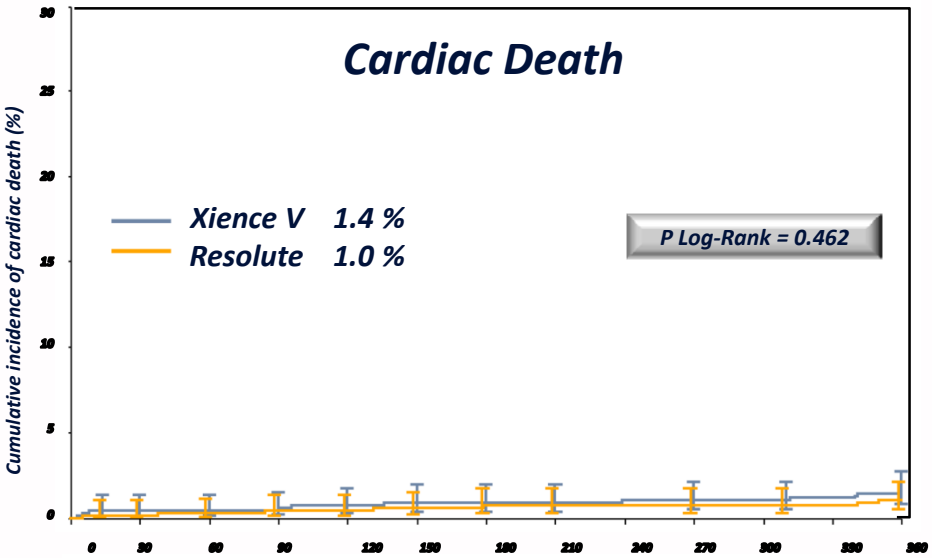
Primary endpoint	Target vessel failure at one year
Secondary endpoints	Components of primary endpoint; stent thrombosis; patient oriented composite endpoint

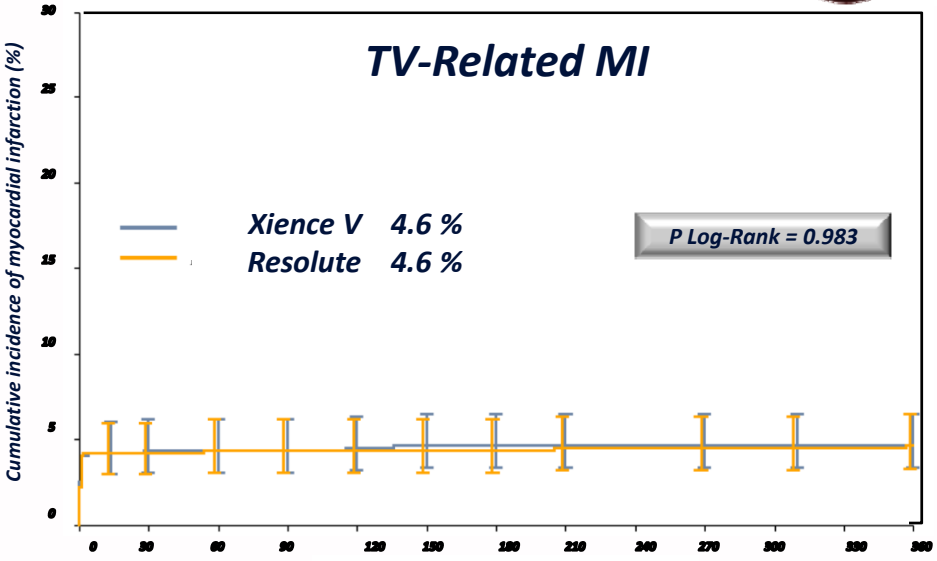
Primary Endpoint

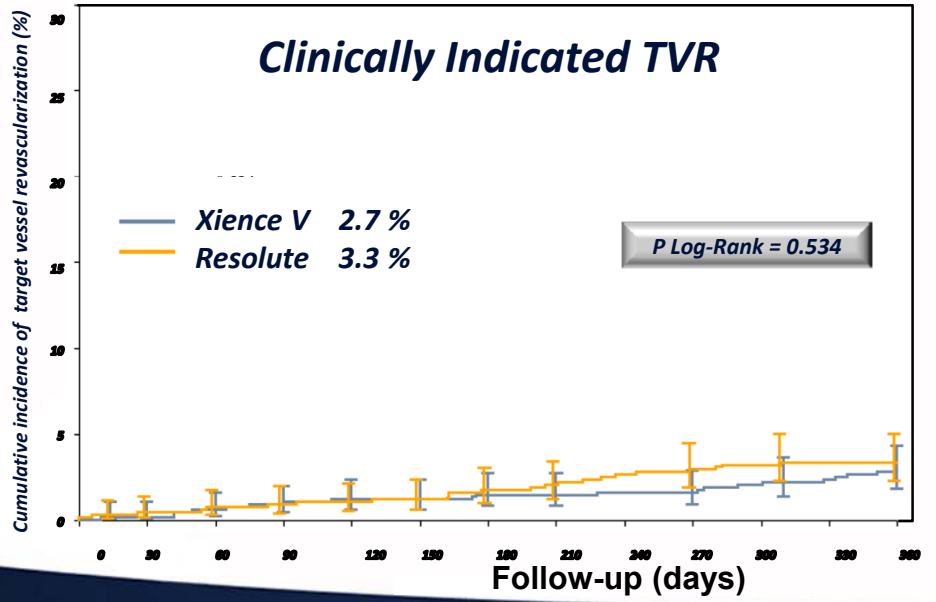
Target Vessel Failure at 1 year



Secondary: Components of TVF





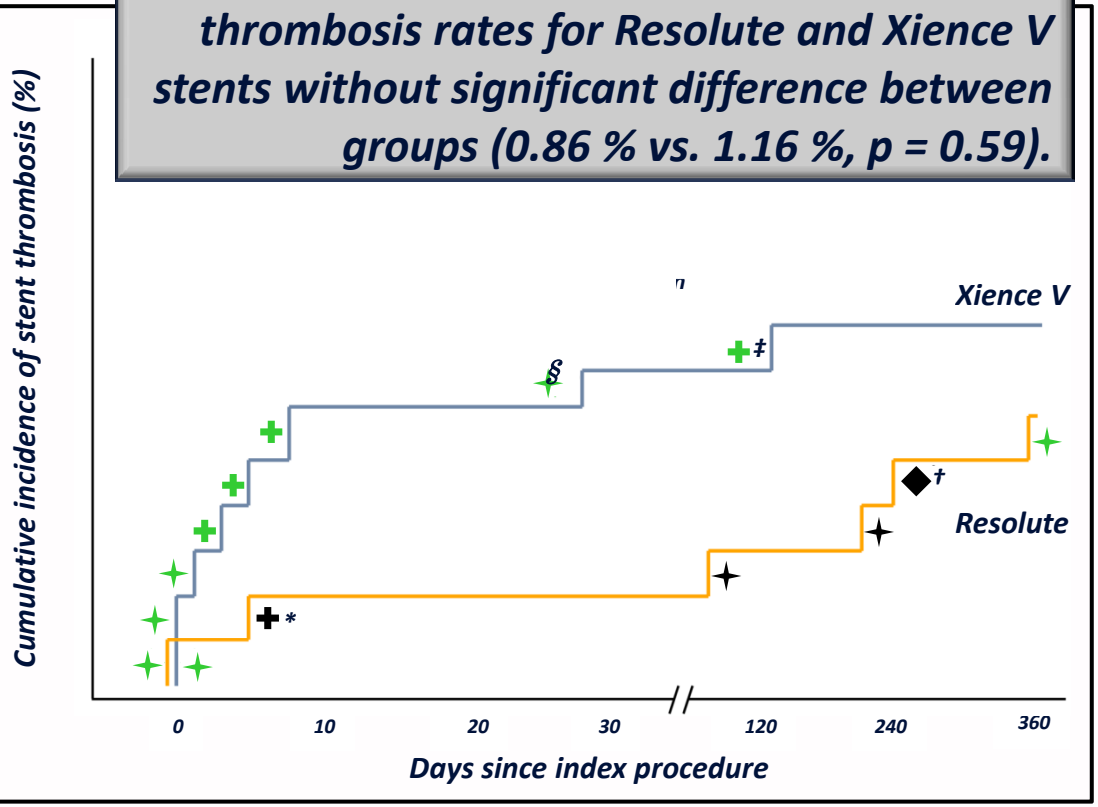


No significant difference in the components of the primary endpoint TVF at 1 year between Resolute and Xience V.

MI = myocardial infarction
TV = target vessel
TVF = target vessel failure
TVR = target vessel revascularization

Secondary: Stent Thrombosis (ARC Definition)

Relatively low definite plus probable stent thrombosis rates for Resolute and Xience V stents without significant difference between groups (0.86 % vs. 1.16 %, p = 0.59).



Low definite stent thrombosis rates for Resolute and Xience V stents without significant difference between groups (0.58 % vs. 0 %, p = 0.12).

Definite stent thrombosis

- ✚ Cardiac Death
- ✦ Myocardial Infarction
- ◆ Target-Vessel Revascularization

Probable stent thrombosis

- ✚ Cardiac Death
- ✦ Myocardial Infarction

* Cardiac death. Patient enrolled for stenting of LAD + RCA (7 days after NSTEMI, treated with BMS in CX)

† TVR. Patient not on DAPT (ASA intolerance; clopidogrel + OAC)

‡ Cardiac death. Patient not on DAPT (ASA only)

§ Non-Q-wave MI. Patient not on DAPT (clopidogrel + OAC)

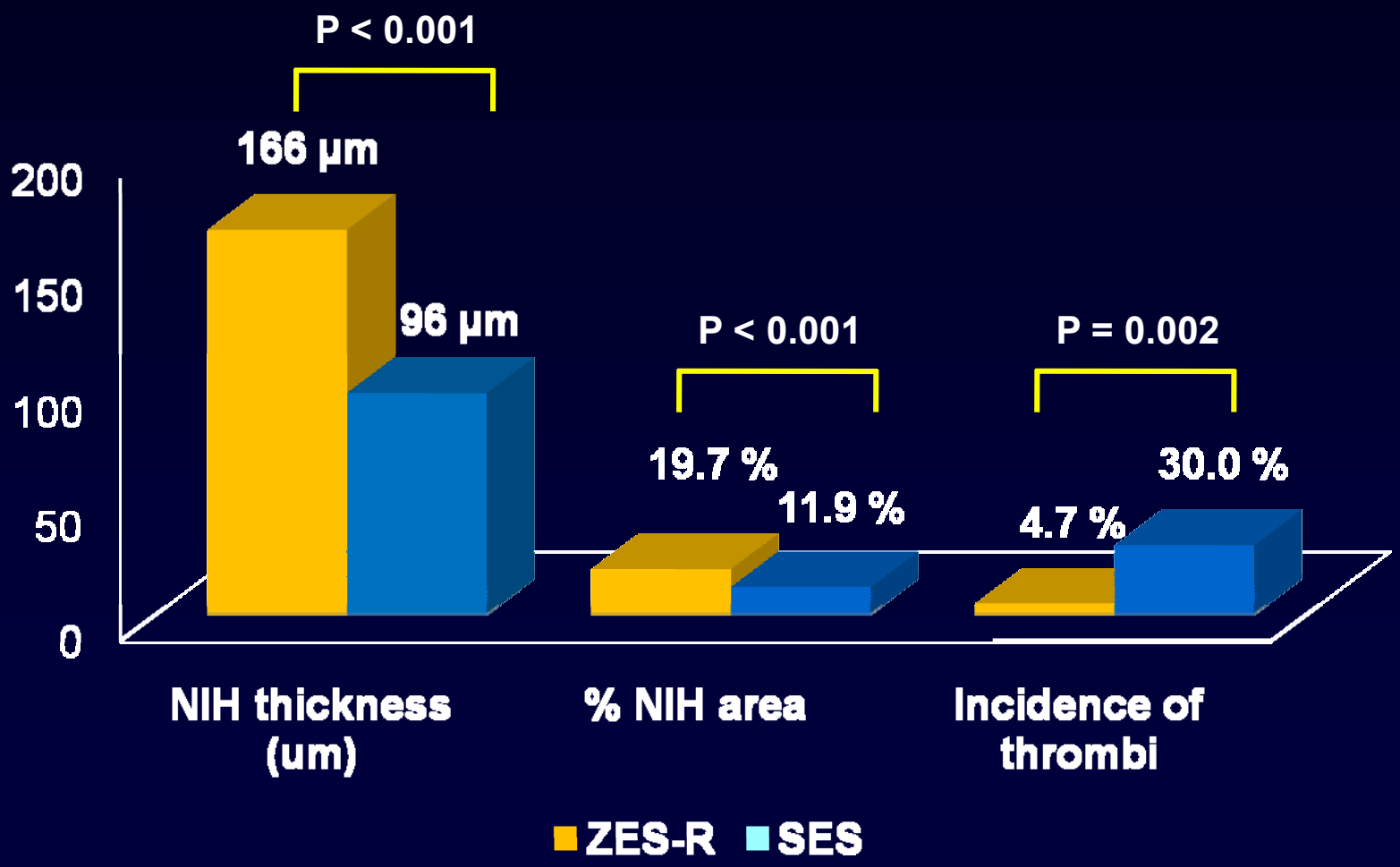
Favorable Neointimal Coverage in Resolute at 9 Months after Stent Implantation: Comparison with Cypher Stent using Optical Coherence Tomography

Jin-sun Kim, MD, **Jung-Sun Kim, MD, Ph D**, Young-Guk Ko, MD, Donghoon Choi, MD, Ph D, Myeong-Ki Hong, MD, Ph D, Yangsoo Jang, MD, Ph D, Namsik Chung, MD, Ph D, Won-Heum Shim, MD, Ph D, Seung-Yun Cho, MD, Ph D

Division of Cardiology, Severance Cardiovascular Hospital, Yonsei University College of Medicine, Seoul, Korea

OCT findings at 9-month after stent implantation

123 stents (43 ZES-R and 80 SES)



OCT findings at 9-month after stent implantation

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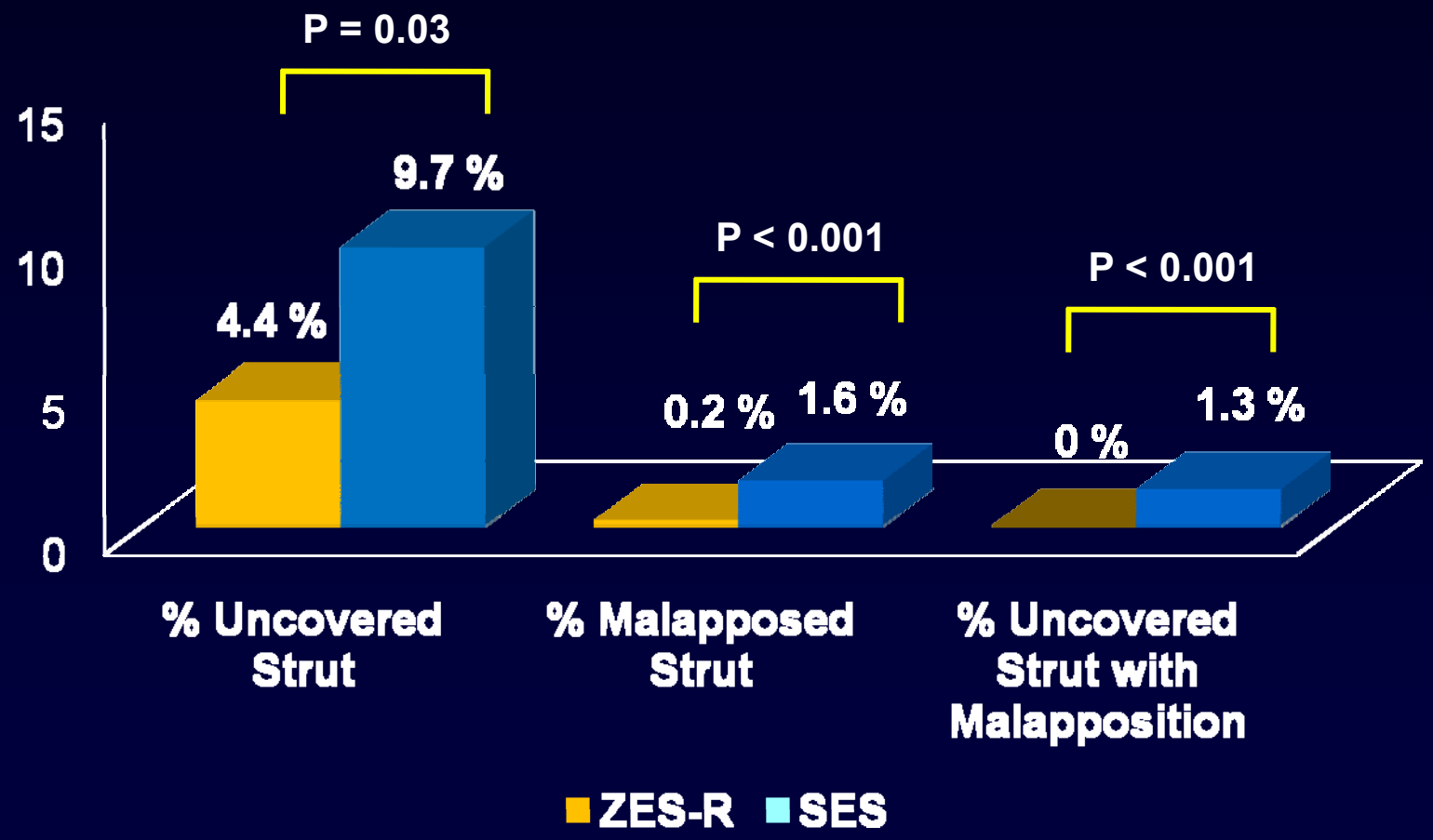

RESOLUTE Studies
Conclusions

- The RESOLUTE ZES has favorable design features including a highly deliverable stent and prolonged drug elution from a new hydrophilic, biocompatible durable polymer.
- A comprehensive global study program (> 5,000 patients) indicates…
  - a favorable safety profile
  - low TLR and angiographic restenosis
- Direct RCT comparisons with the market-leading EES showed comparable safety and effectiveness