

Quels DESs pour quels patients?

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Different clinical settings

- * Diabetes
- * Small vessels
- * In stent restenosis
- * ACS
- * Multivessel disease and LM disease

The 4 principal DESs

- * Sirolimus Eluting Stent (Cypher)
- * Paclitaxel Eluting stent (Taxus)
- * Zotarolimus Eluting Stent (Endeavor)
- * Everolimus Eluting Stent (Promus or Xience)

The Main Head to Head RCTs

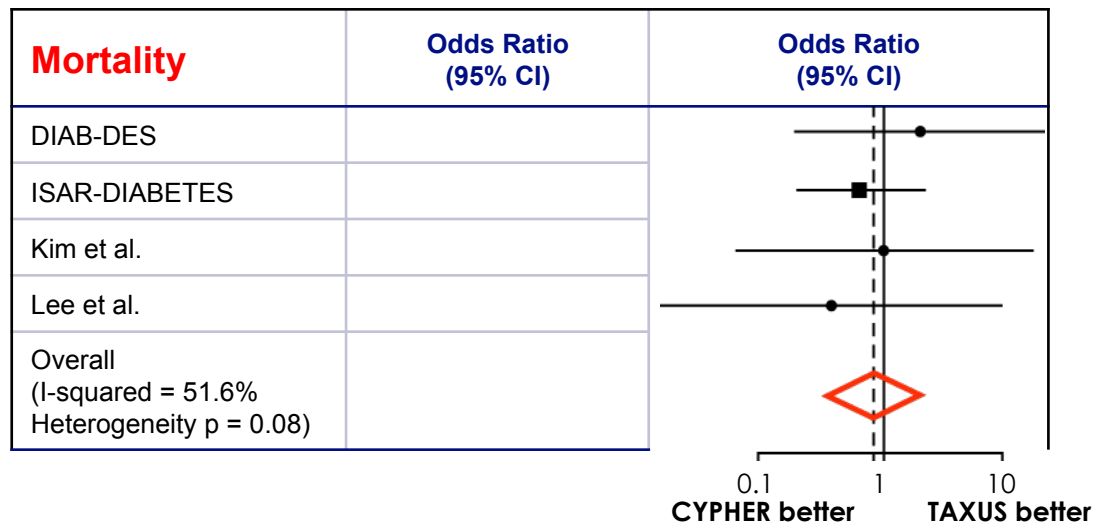
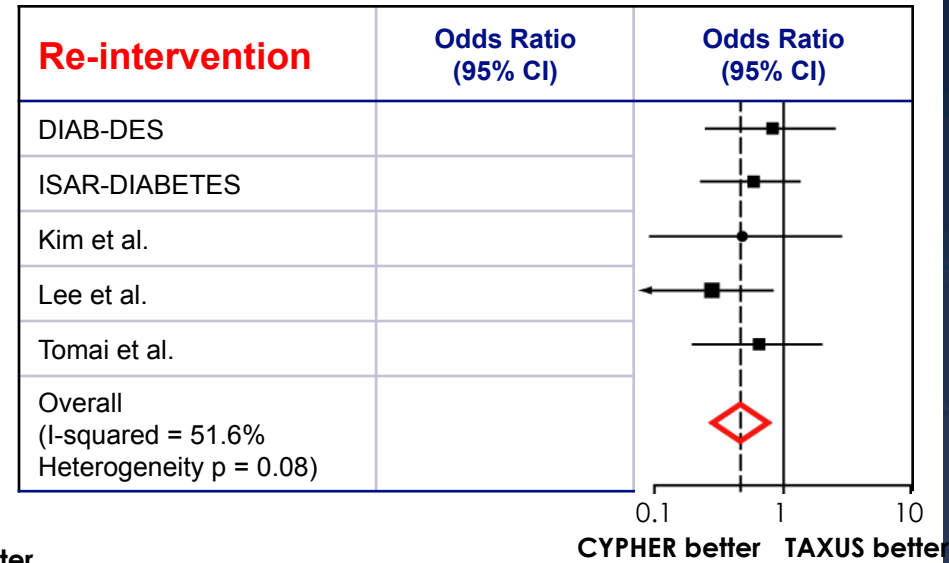
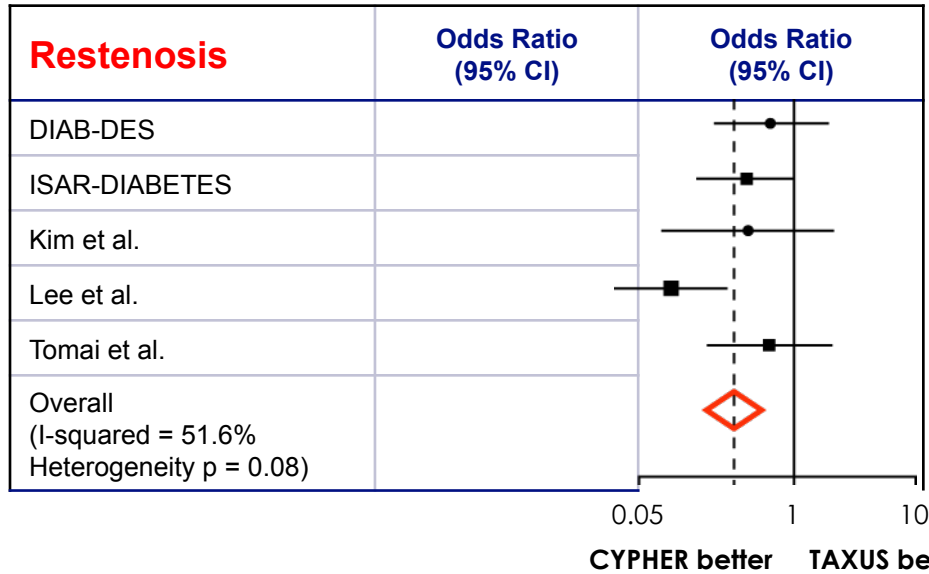
	CYPHER	TAXUS	XIENCE	ENDEAVOR
ISAR TEST II	335	-	-	339
SORT OUT III	1170	-	-	1162
ENDEAVOR III	113	-	-	323
ZEST	880	880	-	880
SORT OUT II	1065	1033	-	-
ISAR DIABETES	125	125	-	-
ISAR LEFT MAIN	305	302	-	-
ISAR SMART III	180	180	-	-
ISAR DESIRE II	225	225	-	-
SIRTAX	503	509	-	-
REALITY	684	669	-	-
PROSIT	115	116	-	-
DES DIABETES	200	200	-	-
LONG DES II	250	250	-	-
SPIRIT II	-	77	223	-
SPIRIT III	-	333	669	-
SPIRIT IV	-	1195	2416	-
COMPARE	-	903	897	-
ENDEAVOR IV	-	775	-	773
ENDEAVOR RESOLUTE	-	-	1150	1150

DESs in Diabetics

- * Sirolimus Eluting Stent (Cypher)
- * Paclitaxel Eluting stent (Taxus)
- * Zotarolimus Eluting Stent (Endeavor)
- * Everolimus Eluting Stent (Promus or Xience)

Meta-Analysis: Results

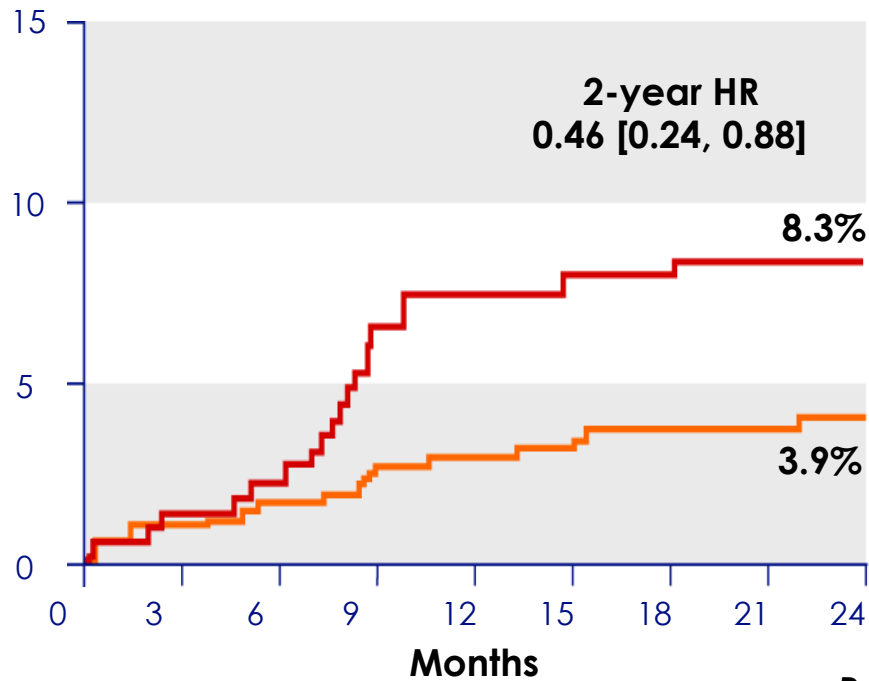
n=1009 patients with diabetes



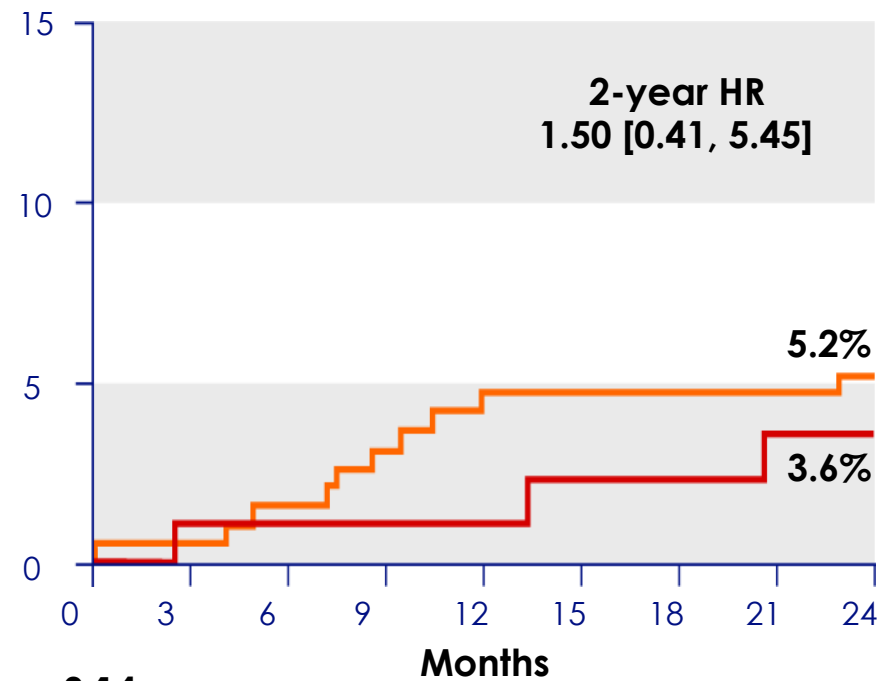
SPRIT III – Diabetic subgroup

TLR at 2 years

No Diabetes (n = 709)



Diabetes (n = 290)



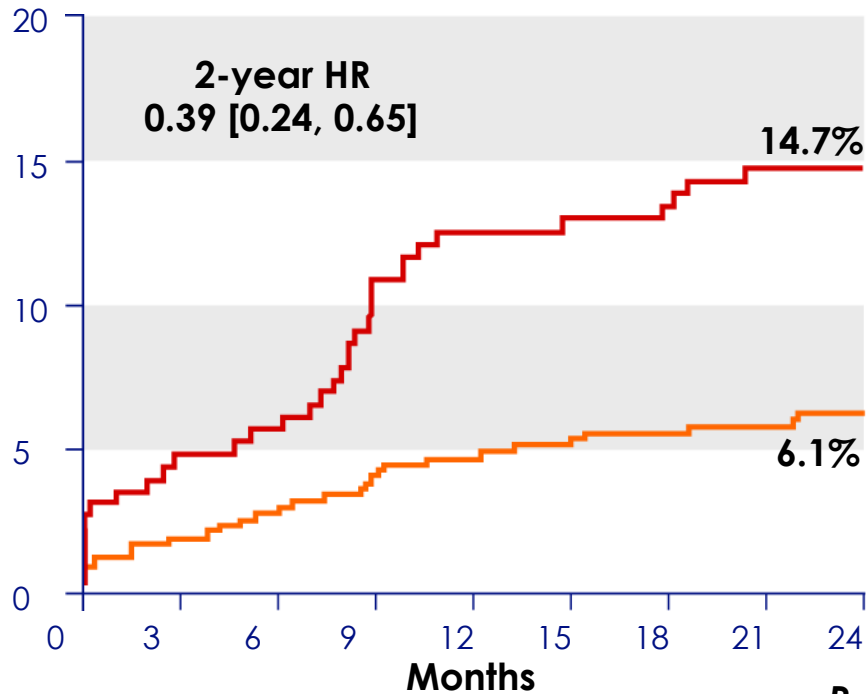
$P_{\text{interaction}} = 0.14$

TAXUS® Stent XIENCE V® Stent

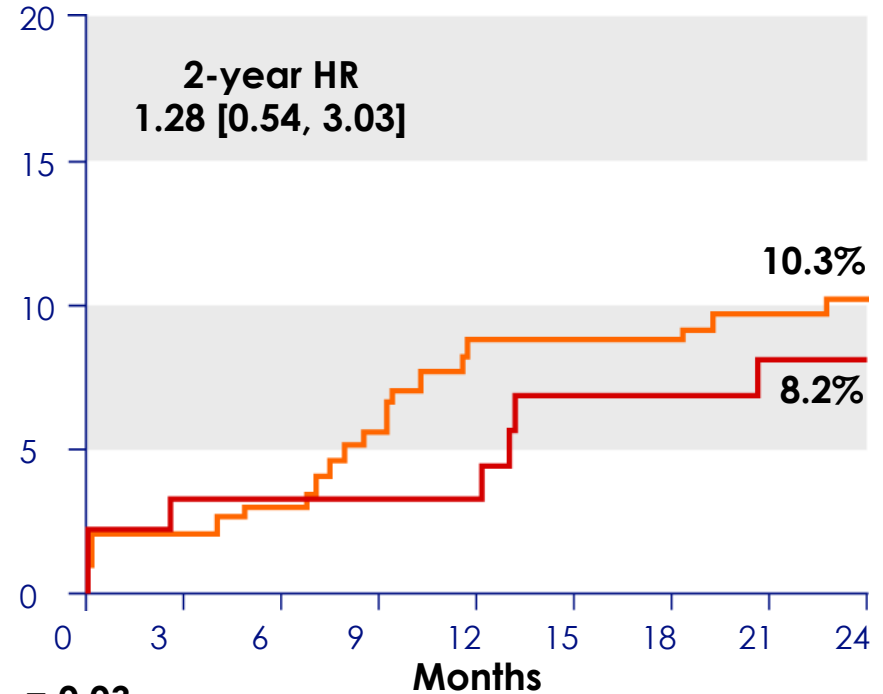
SPRIT III – Diabetic subgroup

MACE at 2 years

No Diabetes (n = 709)



Diabetes (n = 290)



$P_{\text{interaction}} = 0.03$

TAXUS® Stent XIENCE V® Stent

SPIRIT IV Subgroup Analysis: TLF at 1 Year

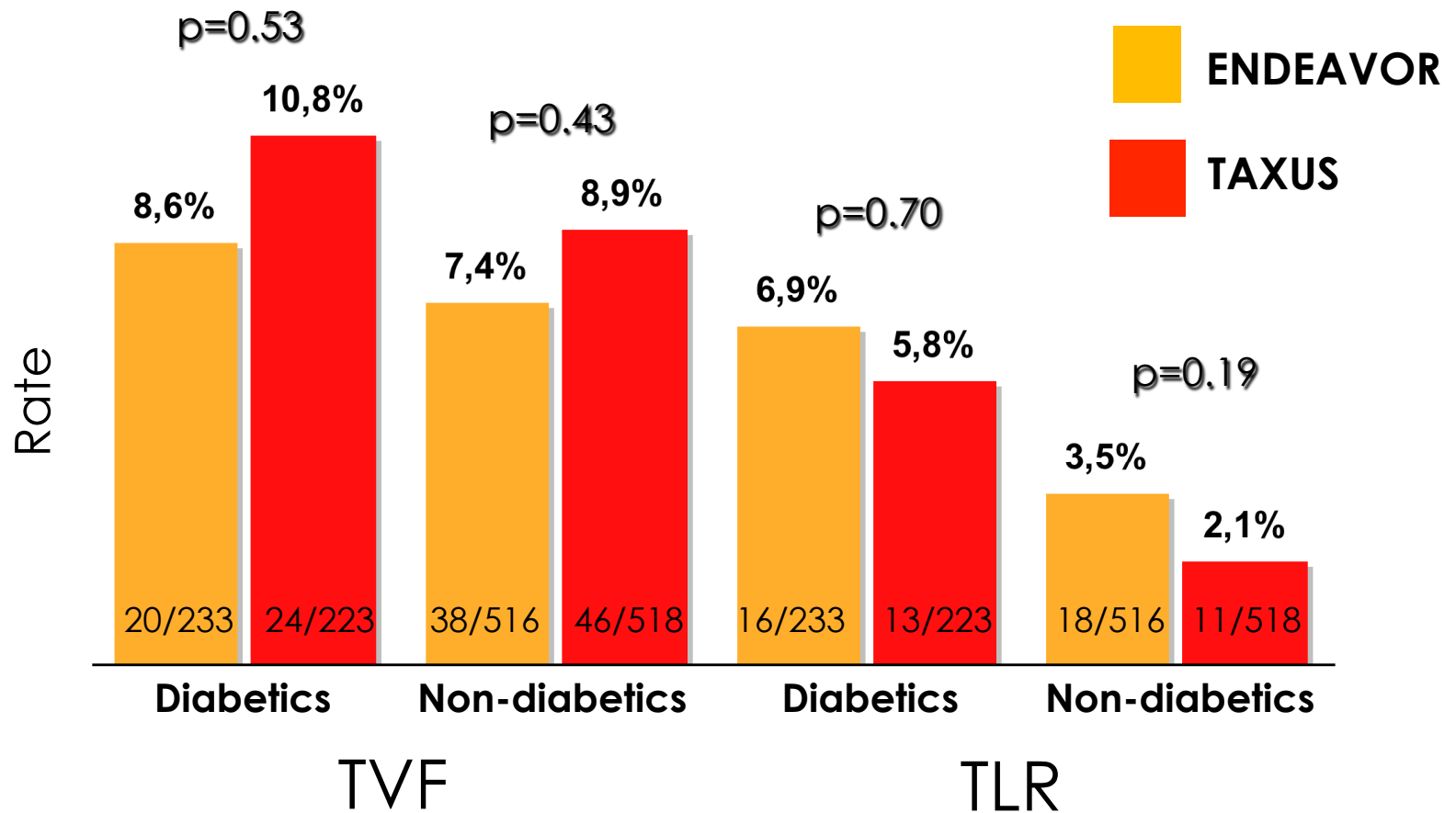
Group	EES (%)	PES (%)	Relative Risk (95% CI)	Relative Risk (95% CI)	P interaction
All randomized (n=3687)	4.2	6.8		0.62 [0.46, 0.82]	—
Single lesion treated (n=2710)	3.9	5.7		0.68 [0.48, 0.96]	0.34
Two or more lesions treated (n=901)	5.1	10.0		0.51 [0.32, 0.83]	
RVD > 2.75 mm (n=1351)	3.9	4.7		0.83 [0.49, 1.41]	0.29
RVD ≤ 2.75 mm (n=1352)	3.9	6.8		0.57 [0.35, 0.91]	
Lesion length > 13.3 mm (n=1346)	4.5	6.9		0.65 [0.41, 1.03]	0.79
Lesion length ≤ 13.3 mm (n=1349)	3.2	4.5		0.71 [0.41, 1.23]	
Bailout stent required (n=221)	5.0	14.5		0.35 [0.14, 0.86]	0.19
No bailout stent required (n=3390)	4.1	6.4		0.65 [0.48, 0.87]	
Diabetes (n=1140)	6.4	6.9		0.94 [0.59, 1.49]	0.02
No diabetes (n=2467)	3.1	6.7		0.47 [0.32, 0.68]	

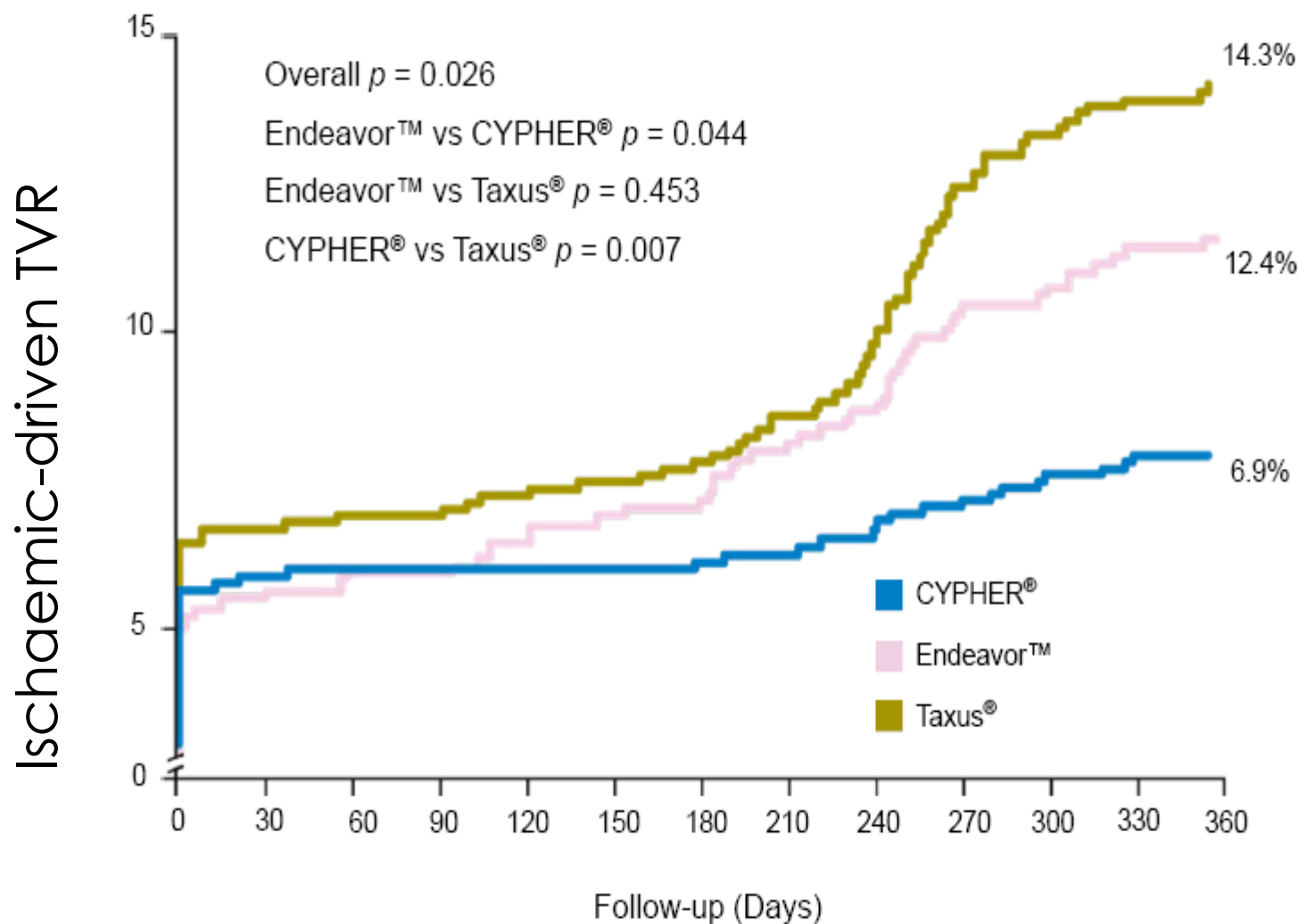
0.1 1 10
EES better PES better

TLF = cardiac death, target vessel MI, or ischemia-driven TLR; 1 Year = 365 ± 28 days
 Single lesion treated data are used for RVD & lesion length subgroup analyses

ENDEAVOR IV: Diabetics TVF and TLR at 12 months

477 diabetics (30.8% patients)





DESs in small vessels

- * Sirolimus Eluting Stent (Cypher)
- * Paclitaxel Eluting stent (Taxus)
- * Zotarolimus Eluting Stent (Endeavor)
- * Everolimus Eluting Stent (Promus or Xience)

REALITY

Mean RVD: 2.40 mm n=1353 patients

Angiographic	CYPHER	TAXUS
Reference Vessel Diameter (mm)	2.40	2.40
Lesion Length (mm)	16.96	17.31

REALITY	CYPHER®	TAXUS®	RRR*	p value
In-Stent MLD [†] (mm) Post-procedure	2.08	2.16	–	< 0.001
In-Stent MLD (mm) 8 Months	2.00	1.85	–	< 0.001
In-Lesion Late Loss (mm)	0.04	0.16	75%	< 0.001
In-Stent Late Loss (mm)	0.09	0.31	71%	< 0.001
Proximal Late Loss (mm)	0.03	0.14	79%	< 0.001
Distal Late Loss (mm)	-0.07	-0.01	–	< 0.001
In-Stent Diameter Stenosis %	29.11	31.06	–	< 0.001
In-Stent Binary Restenosis %	7.0	8.3	–	ns
In-Lesion Binary Restenosis %	9.6	11.1	–	ns

ISAR-SMART 3

Mean RVD: 2.40 mm

Diabetics: excluded

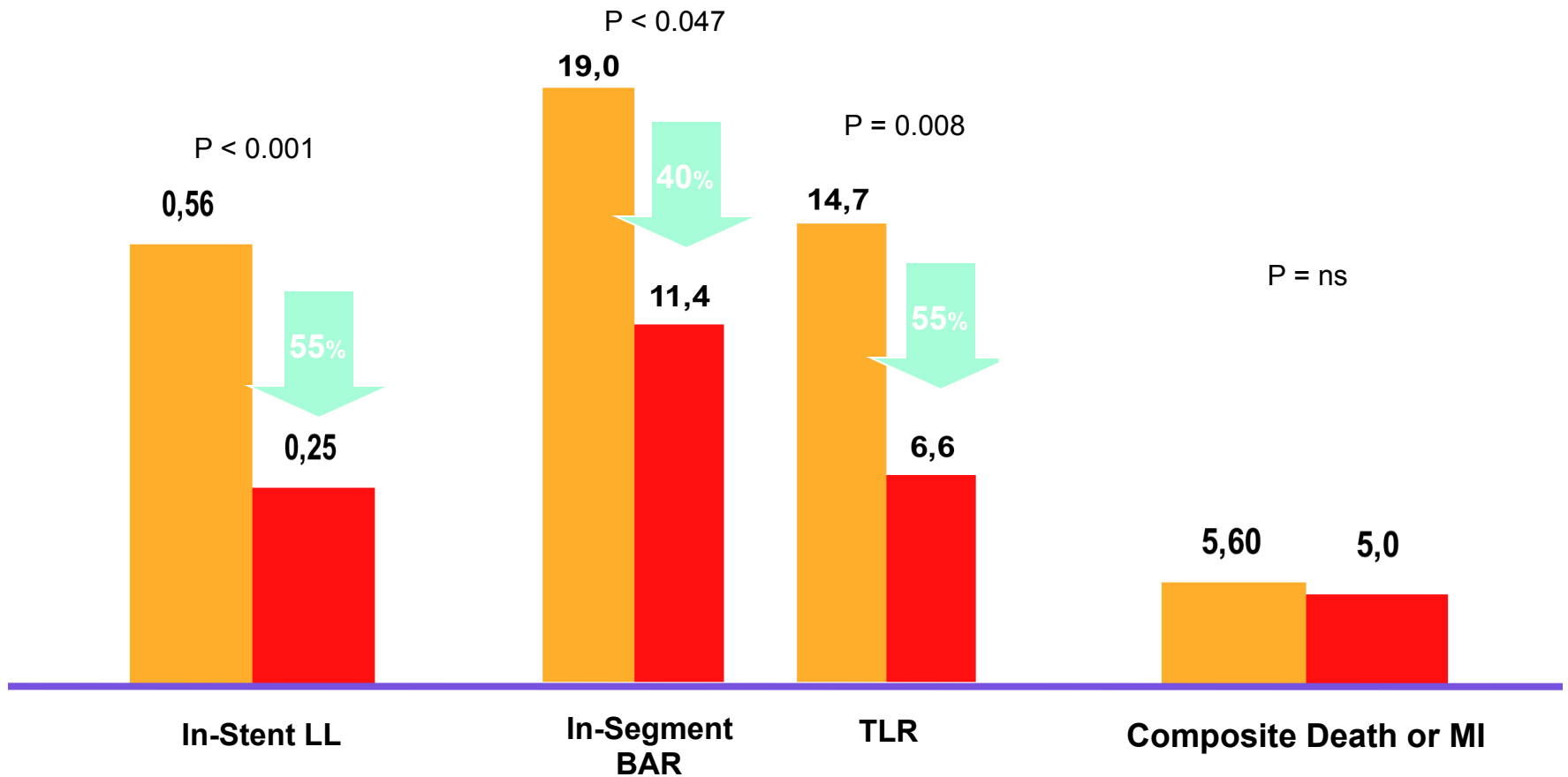
8/12-Month Outcomes

■ Taxus (n=180) ■ Cypher (n=180)

Late Loss, mm

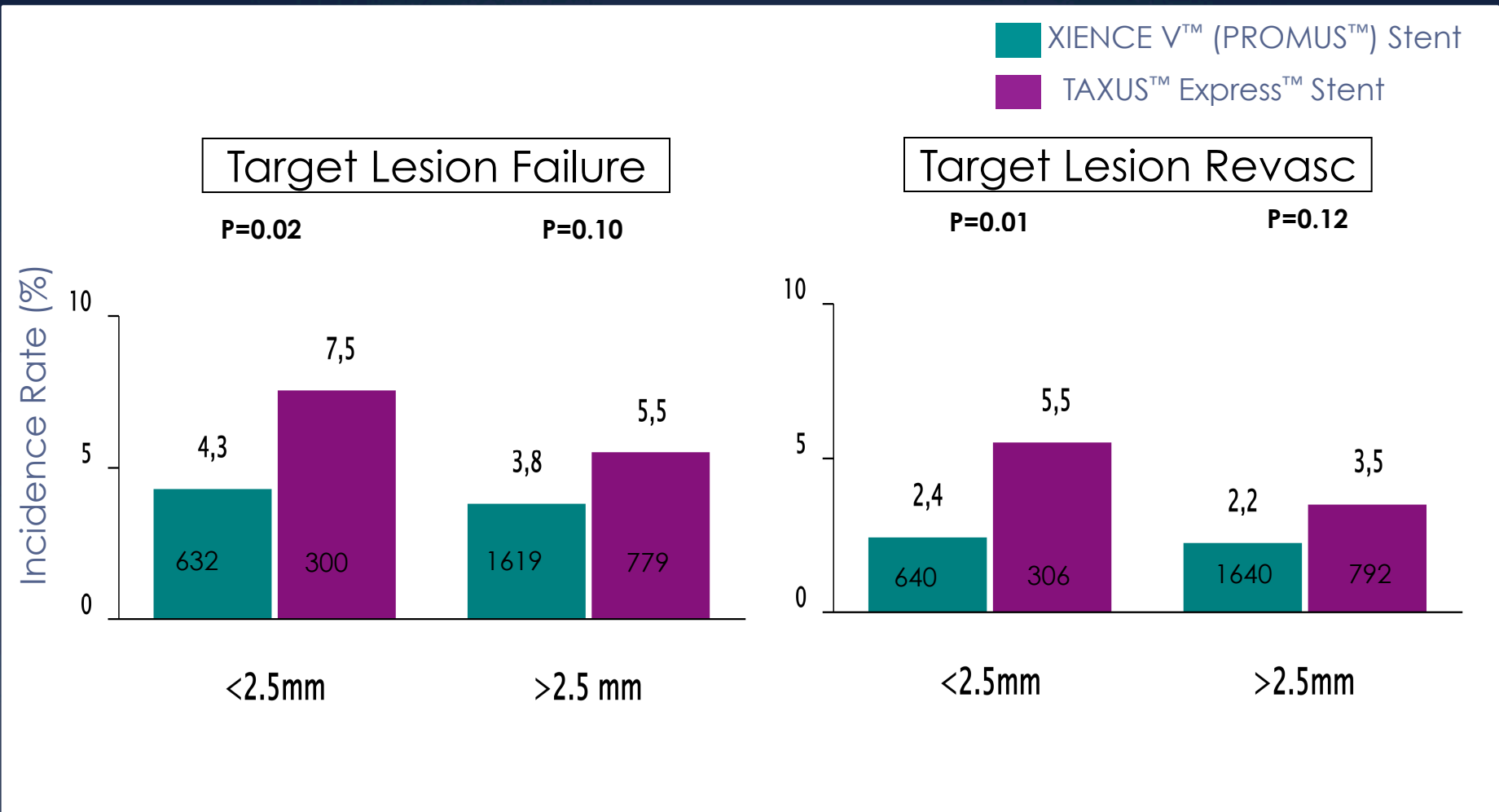
Restenosis, %

Safety, %



SPIRIT III/IV Pooled Small Vessel Results

1-Year Clinical Results: TLF/TLR



Kaplan-Meier rates. *n=patients at risk

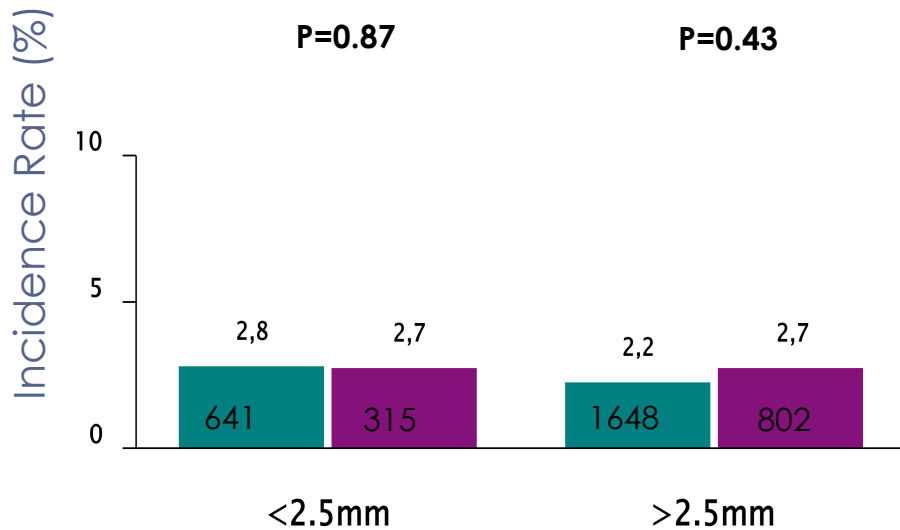
Presented by James Hermiller, MD, ACC 2010. The PROMUS™ Stent is a private-labeled XIENCE V™ Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. XIENCE V is a trademark of Abbott Laboratories group of companies. SPIRIT is sponsored by Abbott. TVF = Cardiac Death, MI or Ischemia Driven TVR. MACE = Cardiac Death, MI or Ischemia-driven TLR.

SPRIT III/IV Pooled Small Vessel Results

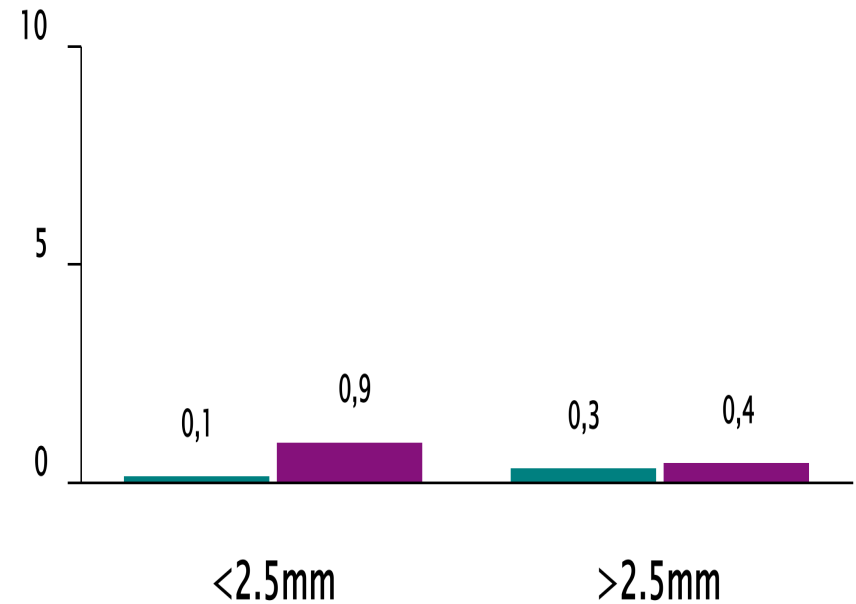
1-Year Clinical Results: Cardiac Death/MI and ST

■ XIENCE V™ (PROMUS™) Stent
■ TAXUS™ Express™ Stent

Cardiac Death or MI



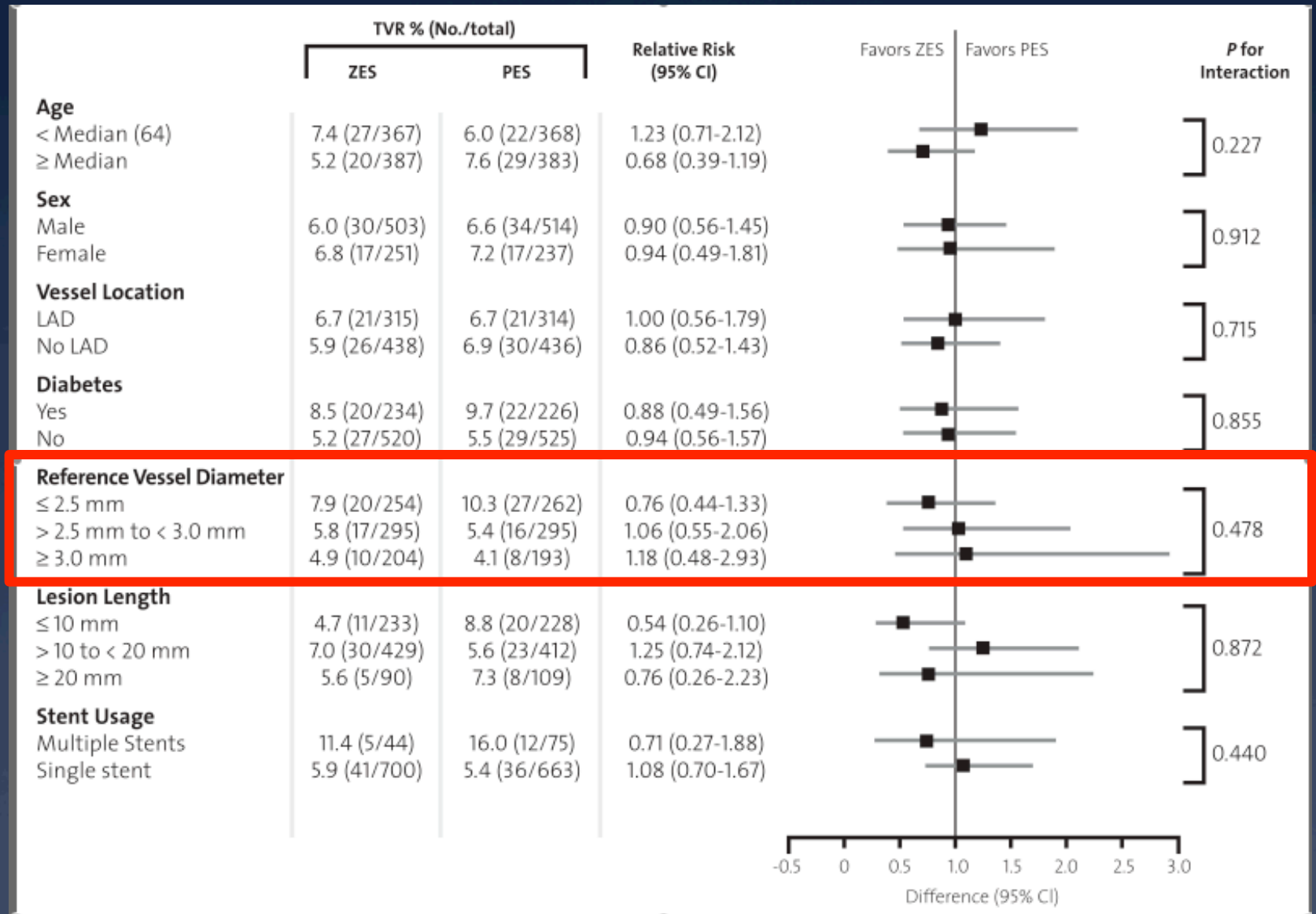
ARC Stent Thrombosis



Kaplan-Meier rates. *n=patients at risk

Presented by James Hermiller, MD, ACC 2010. The PROMUS™ Stent is a private-labeled XIENCE V™ Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. XIENCE V is a trademark of Abbott Laboratories group of companies. SPRIT is sponsored by Abbott. TVF = Cardiac Death, MI or Ischemia Driven TVR. MACE = Cardiac Death, MI or Ischemia-driven TLR.

ENDEAVOR IV



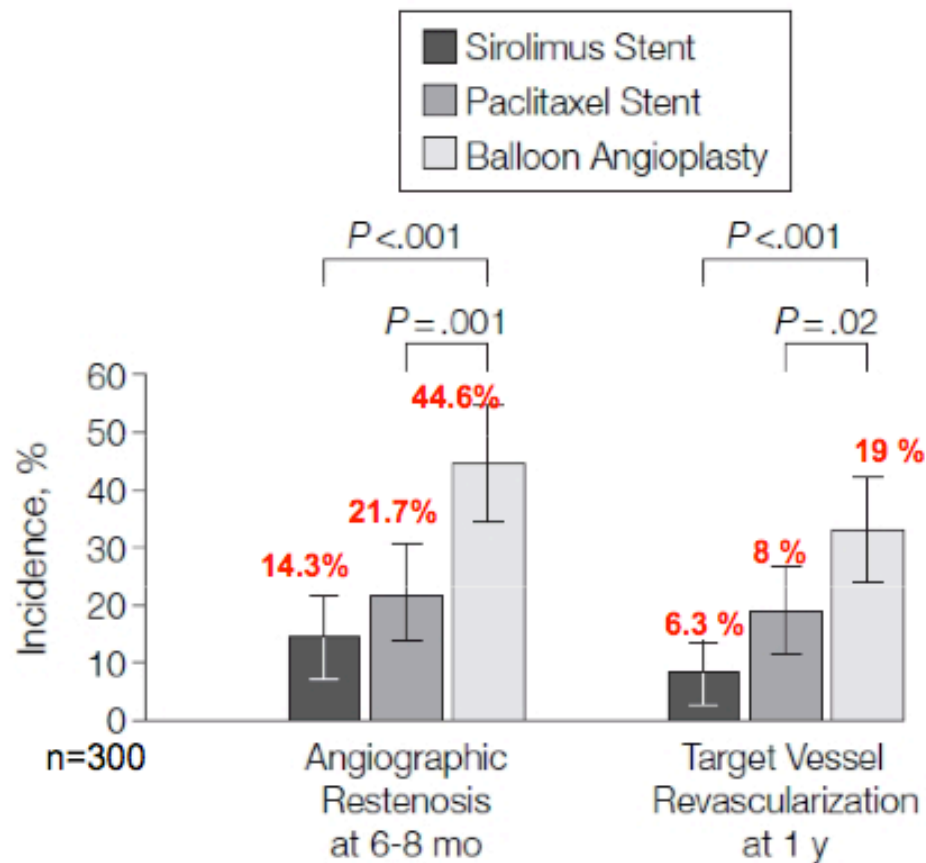
DESs for in stent restenosis

- * In BMS restenosis
 - * Sirolimus Eluting Stent (Cypher)
 - * Paclitaxel Eluting stent (Taxus)

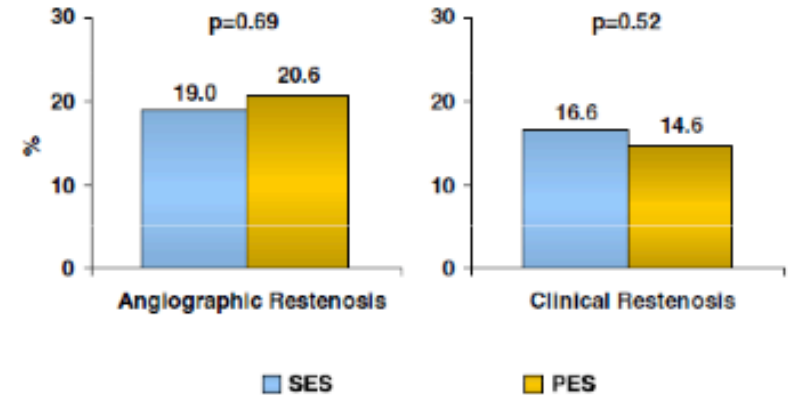
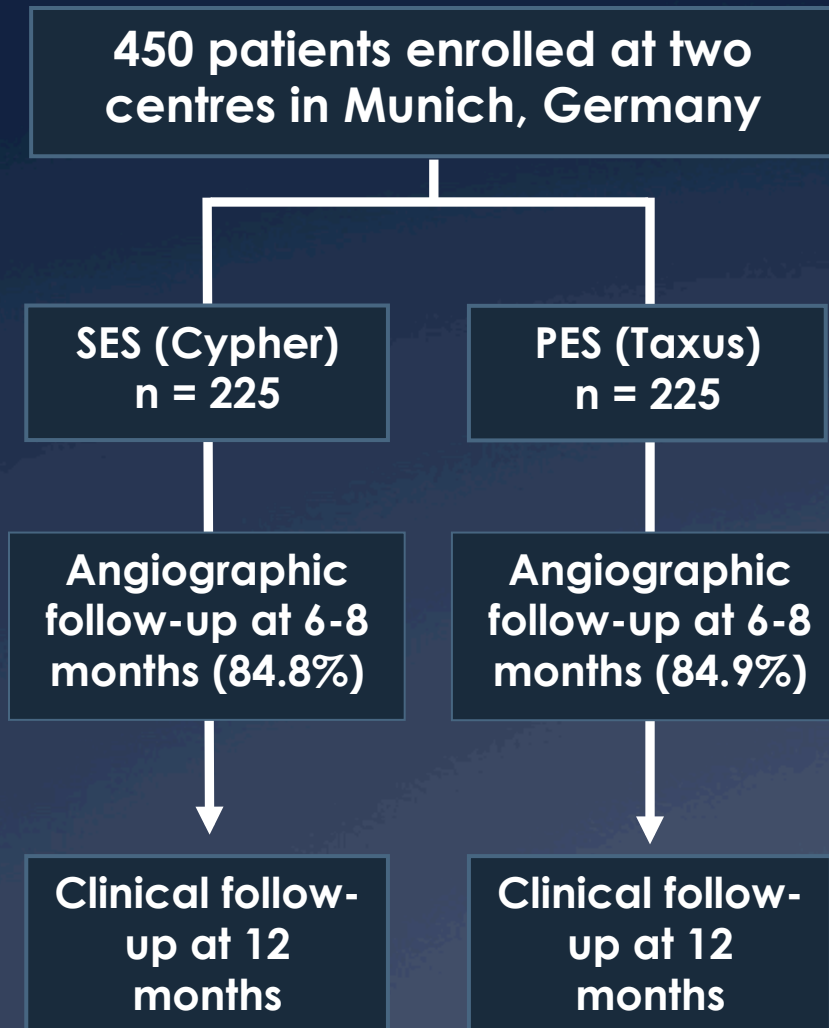
- * In DES restenosis
 - * Sirolimus Eluting Stent (Cypher)
 - * Paclitaxel Eluting stent (Taxus)

Repeat Stenting using a DES

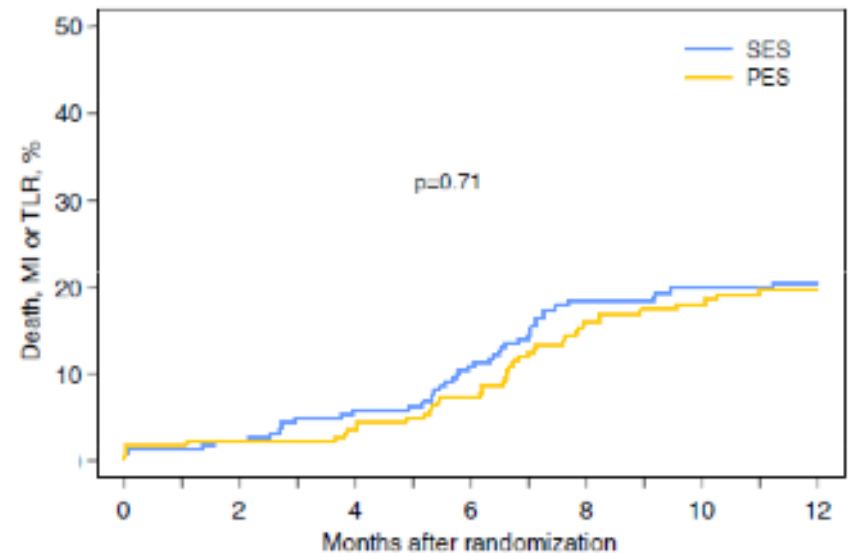
- ISAR – DESIRE trial



ISAR-DESIRE II



Angiographic Restenosis at 6 to 8 Months and Clinical Restenosis at 1 Year

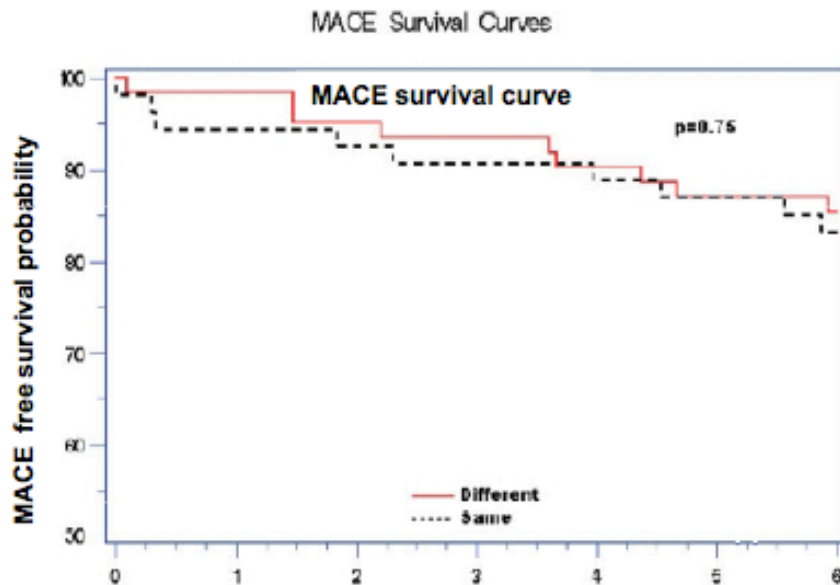


Composite of Death, MI, or TLR

Washington Hospital Center Registry

Treatment of DES restenosis With the same versus different DES

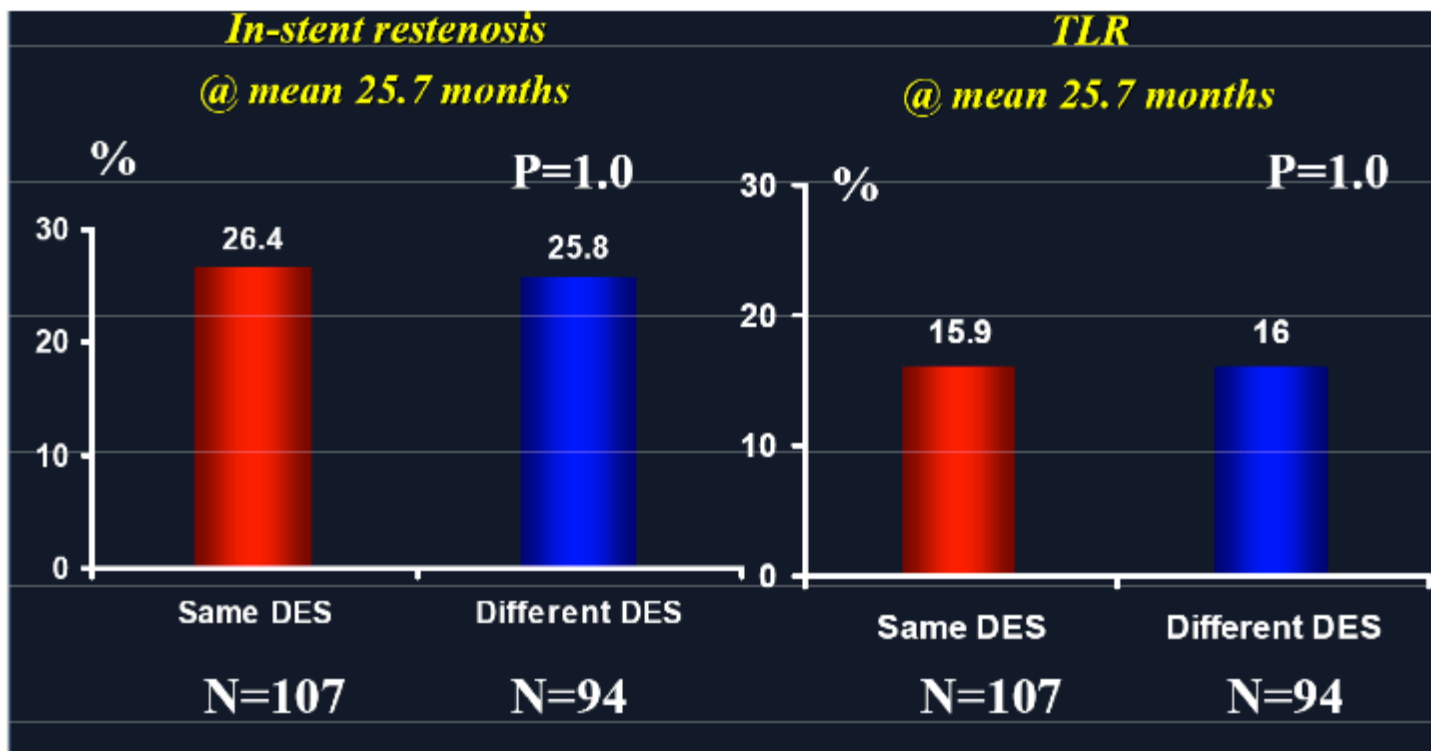
Shaila Garg, MD, Kimberly Smith, BS, Rebecca Torguson, BS,
Teruo Okabe, MD, Tina L. Pinto Slottow, MD, Daniel H. Steinberg, MD,
Probal Roy, MD, Zhenyi Xue, MS, Natalie Gevorkian, MD,
Lowell F. Satler, MD, Kenneth M. Kent, MD, William O. Suddath, MD,
Augusto D. Pichard, MD, and Ron Waksman,* MD



- **Switch strategy** → **inconclusive**
- **1st generation DES comparison**
(cypher , Taxus)

n=112

Does the switch therapy work?



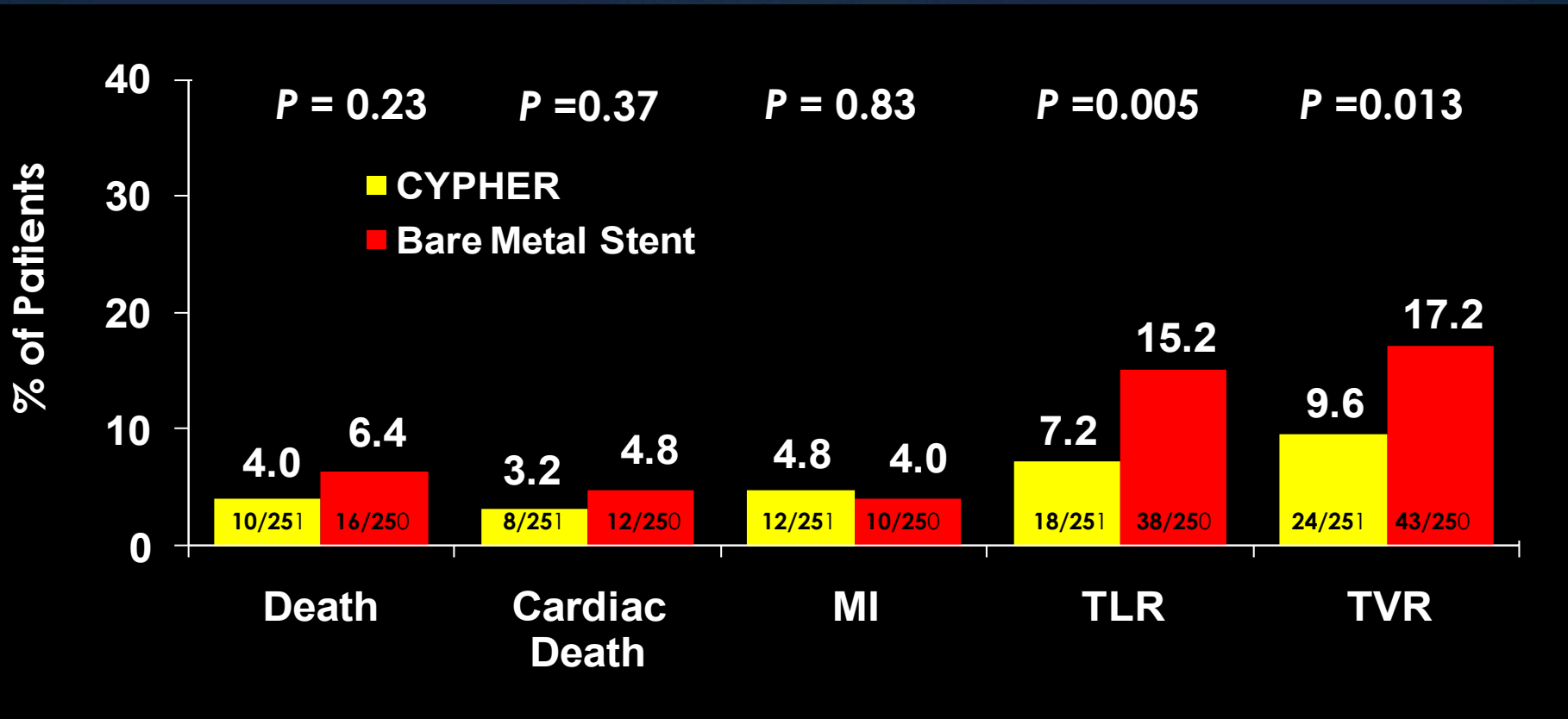
DESs in ACS

- * Sirolimus Eluting Stent (Cypher)
- * Paclitaxel Eluting stent (Taxus)

TYPHOON

Clinical Outcomes at 4 Years

Academic Research Consortium / Dublin-Defined Events

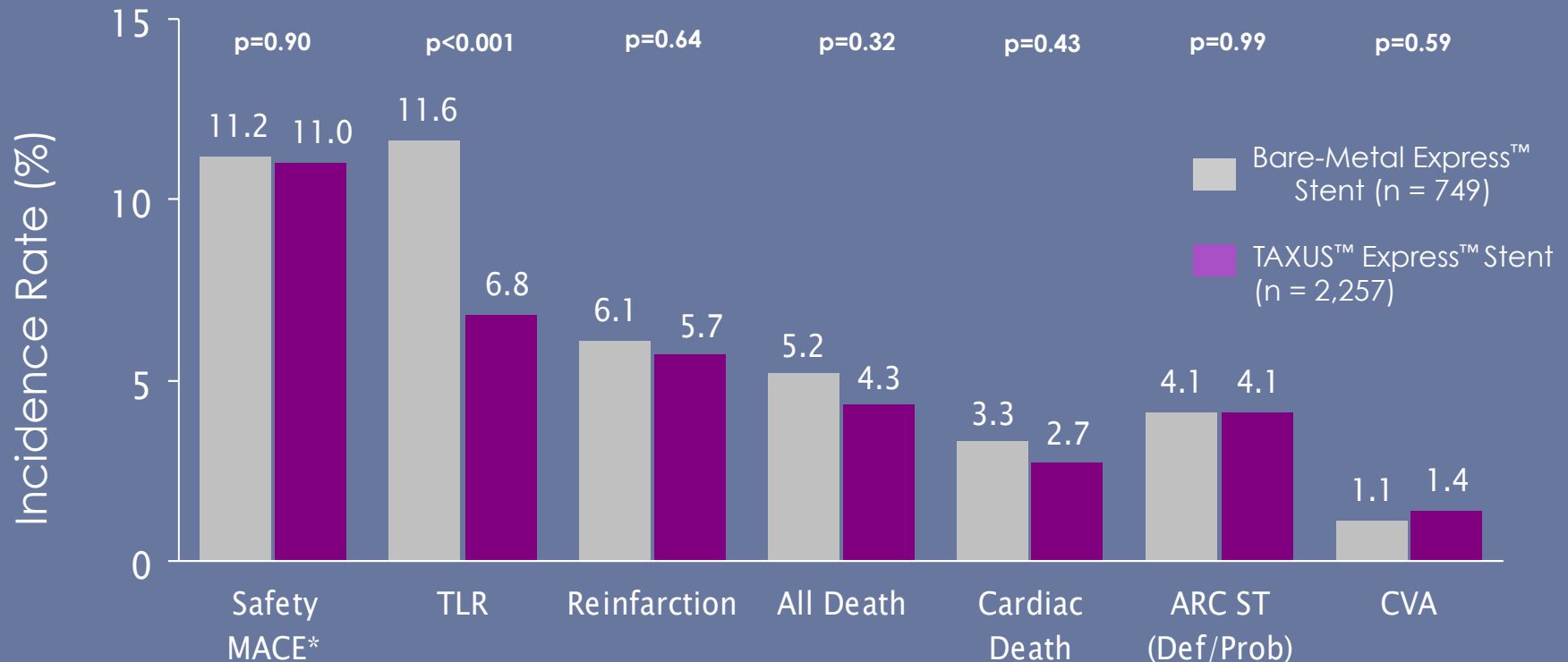


MI: myocardial infarction, TLR: target lesion revascularization, TVR: target vessel revascularisation, Non- hierarchical events

HORIZONS-AMI Trial

24-Month Clinical Results

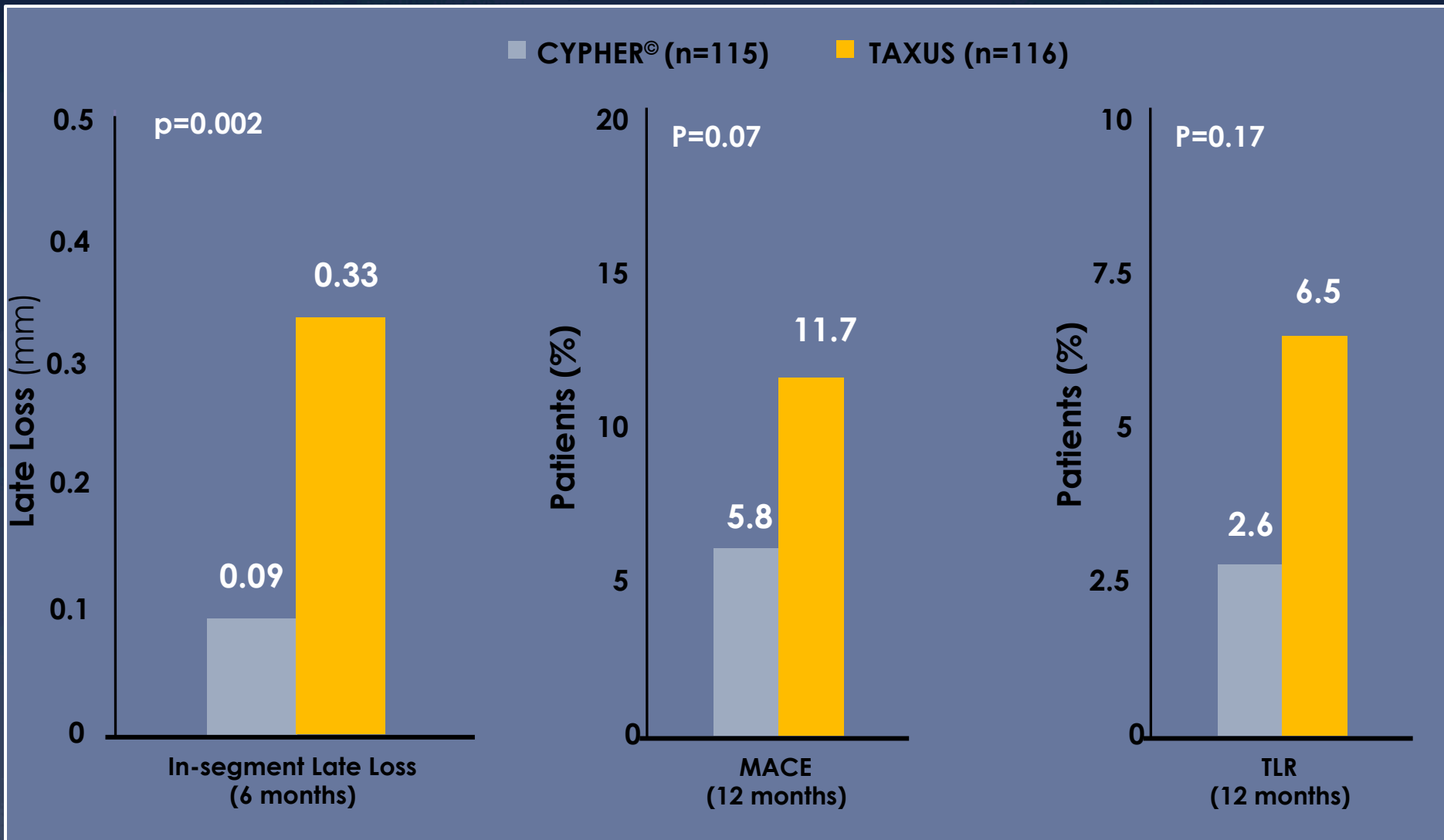
Design: *Prospective, randomized 3:1 (TAXUS Express Stents to Express Bare Metal Stent)*
 Location & Sites: *Global (11 countries) and 123 centers*
 Patients: *3,062 STEMI Patients / 3,006 patients randomized to stents*
 Princ. Investigator *Gregg W. Stone, MD*



*Safety MACE = Death, Reinfarction, Stroke, or Stent Thrombosis

PROSIT

Cypher vs Taxus at 12 months



DESs for LM and/or multivessel disease

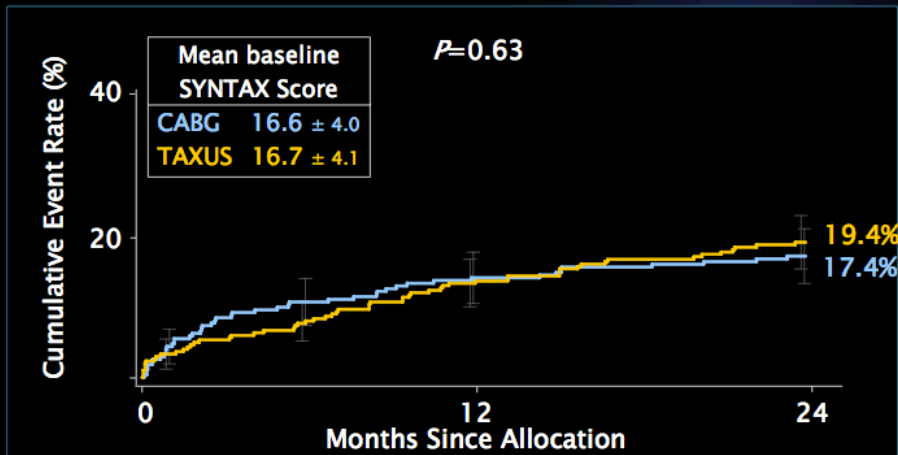
- * Sirolimus Eluting Stent (Cypher)
- * Paclitaxel Eluting stent (Taxus)

MACCE to 2 Years by SYNTAX Score Tercile

Low Scores (0-22)

SYNTAX

CABG (N=275) TAXUS (N=299)



Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Calculated by core laboratory; ITT population

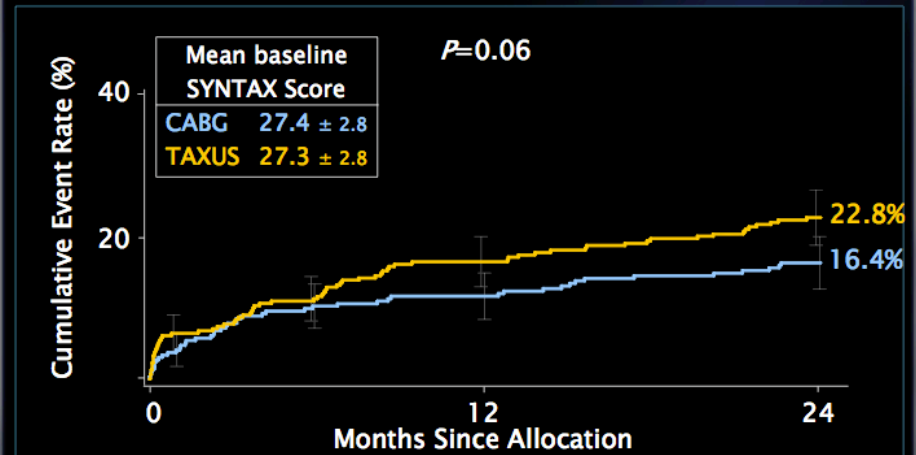
ESC 2009 - Two-year Outcomes of the SYNTAX Trial - Kapotein - Slide 14

MACCE to 2 Years by SYNTAX Score Tercile

Intermediate Scores (23-32)

SYNTAX

CABG (N=300) TAXUS (N=310)



Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Calculated by core laboratory; ITT population

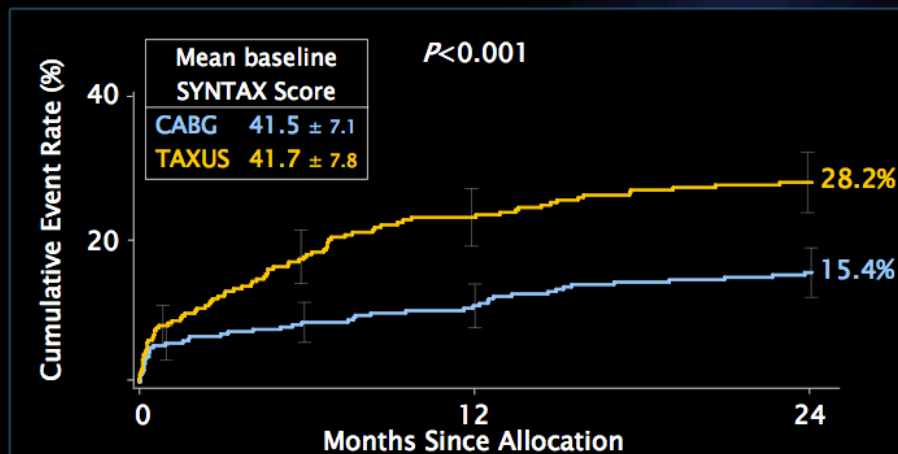
ESC 2009 - Two-year Outcomes of the SYNTAX Trial - Kapotein - Slide 15

MACCE to 2 Years by SYNTAX Score Tercile

High Scores (≥33)

SYNTAX

CABG (N=315) TAXUS (N=290)



Cumulative KM Event Rate ± 1.5 SE; log-rank P value

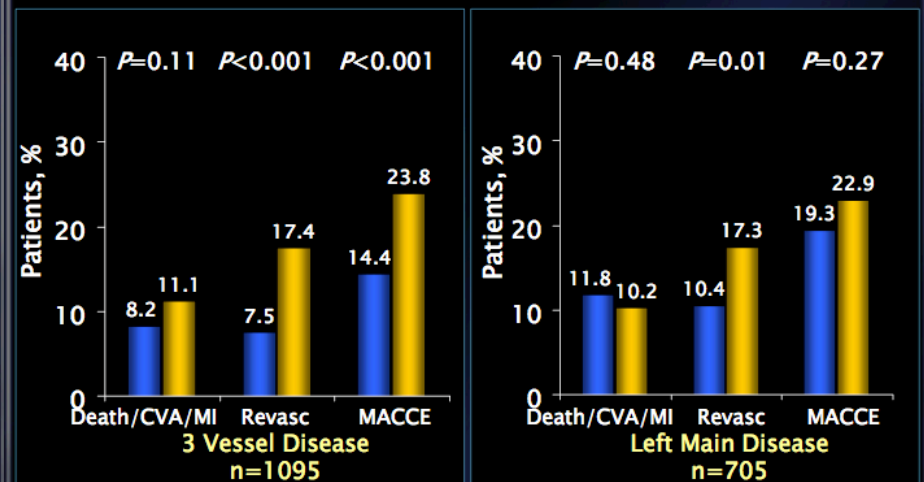
Calculated by core laboratory; ITT population

ESC 2009 - Two-year Outcomes of the SYNTAX Trial - Kapotein - Slide 16

2 Year Outcomes in 3VD and LM Subgroups

SYNTAX

CABG TAXUS



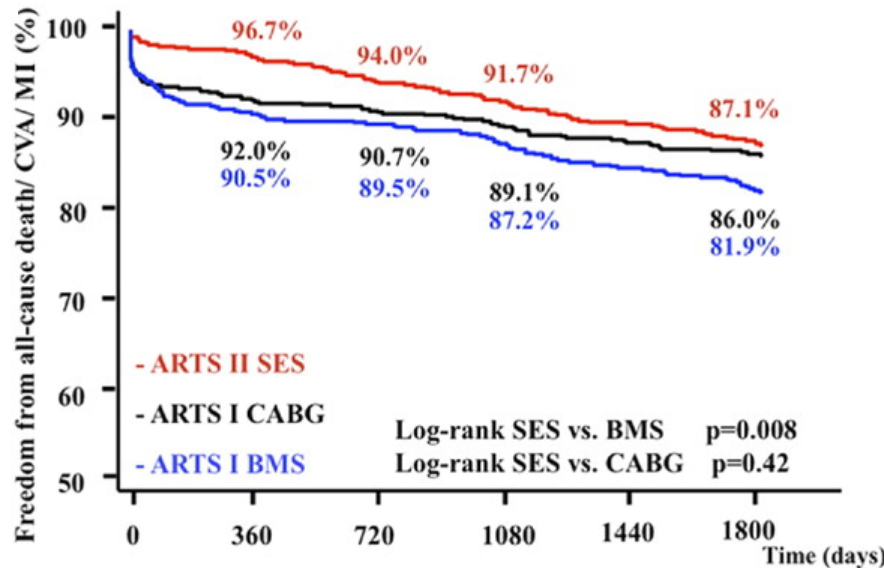
Time-to-Event; Log-rank P value

ESC 2009 - Two-year Outcomes of the SYNTAX Trial - Kapotein - Slide 17

ITT population

ARTS II vs ARTS I

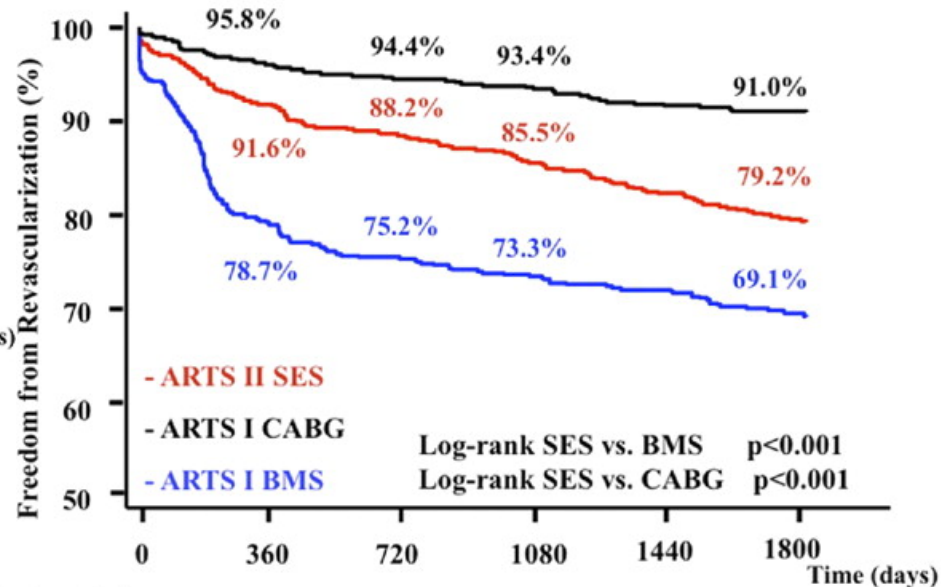
Death/CVA/MI



Patients at risk

	1 year	2 years	3 years	4 years	5 years
ARTS-I CABG	553	544	535	523	515
ARTS-I BMS	543	536	521	507	491
ARTS-II SES	598	587	581	566	487

Revascularization

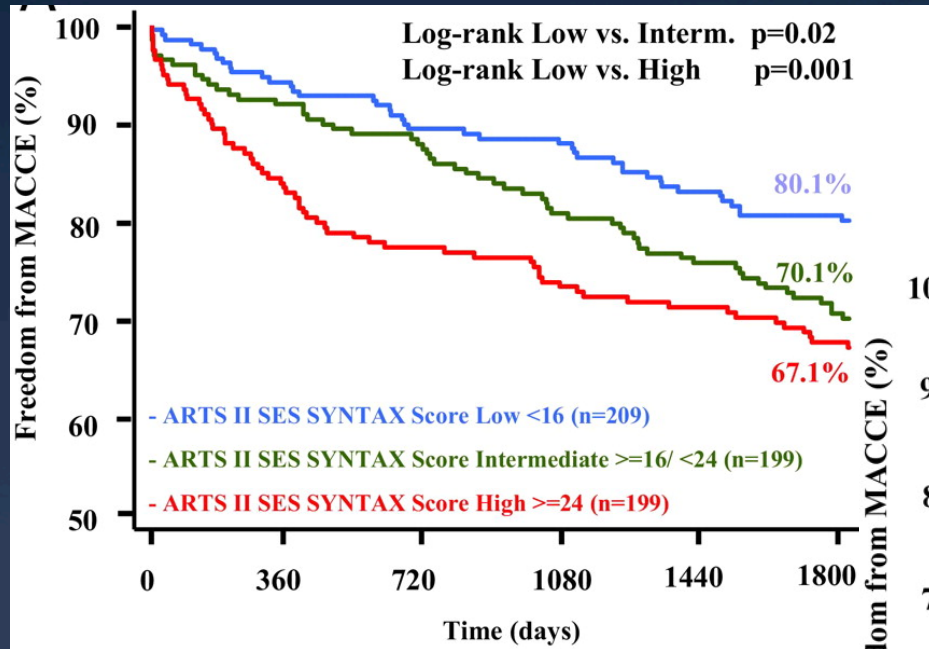


Patients at risk

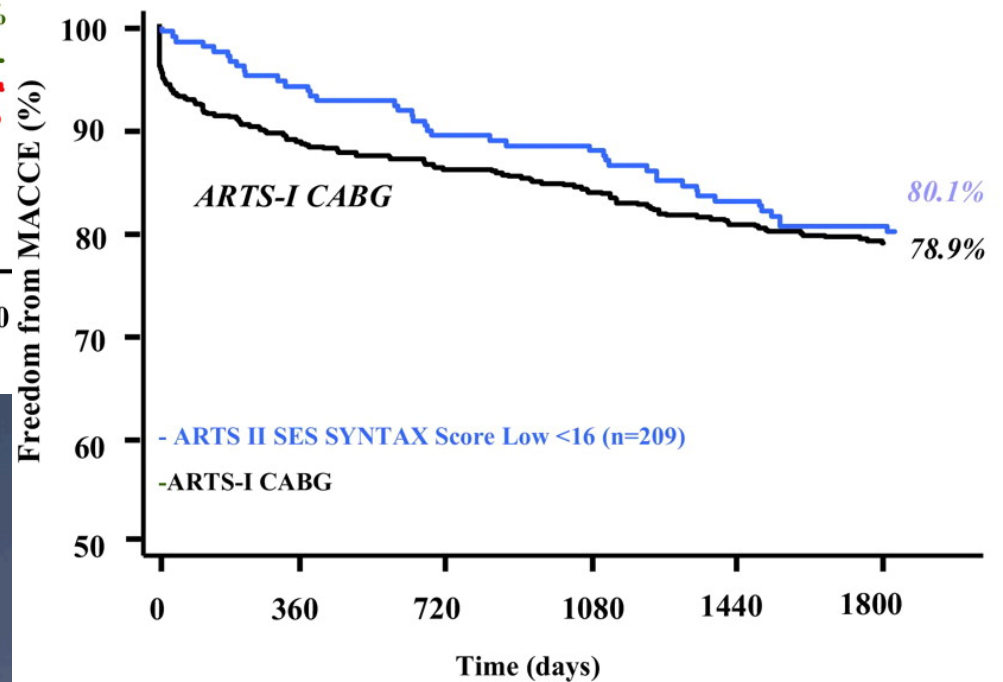
	1 year	2 years	3 years	4 years	5 years
ARTS-I CABG	566	552	541	523	511
ARTS-I BMS	464	441	422	408	382
ARTS-II SES	552	524	492	472	423

ARTS II vs ARTS I

MACCE

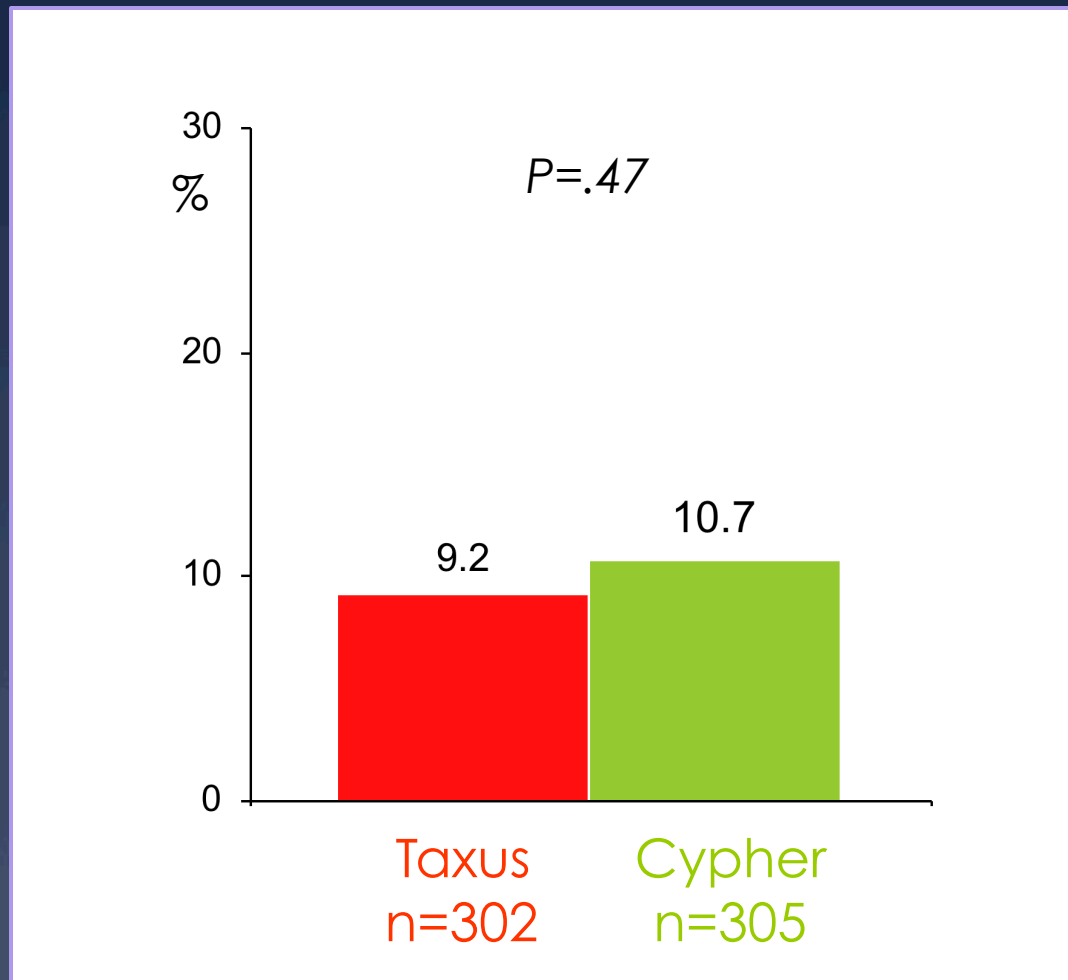


MACCE



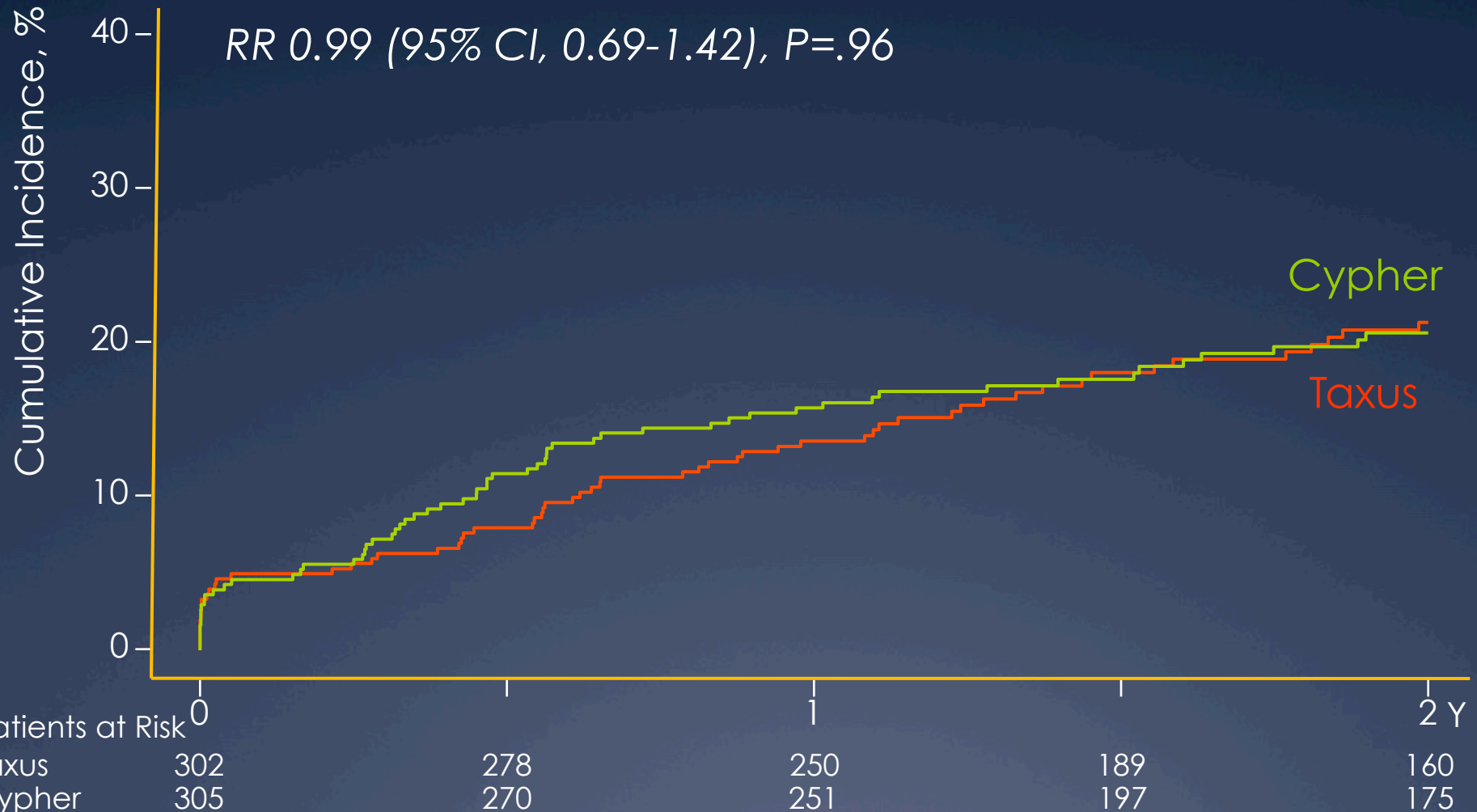
ISAR-LEFT MAIN

2-Year Target Lesion Revascularization



ISAR-LEFT MAIN

Death, Myocardial Infarction or Reintervention
- 2-Year Follow-Up -



A Mechanic Issue

	Cypher	Taxus	Xience V	Endeavor
Deliverability	* * (*)	* * (*)	* * *	* * *
Procedural Safety				
- <i>Peri-procedural MI</i>	* * *	* *	* * *	* * *
- <i>Stent Fracture</i>	* *	* *	* * *	* * *
Stent Thrombosis				
- <i>Early (< 1 year)</i>	**	**	* *	* *
- <i>Very Late</i>	**	**	* *	* * *
Efficacy				
- <i>Pivotal trial</i>	* * *	* * *	* * *	* * (*)
- <i>Off label Use</i>	* * *	* * *	* * * [*]	* *
Overall Performance	* * (*)	* * (*)	* * (*)	* * (*)

* Poor * * Acceptable * * * Excellent * * * * Outstanding

Conclusion

- * In general, no differences between the different DESs in terms of Death, MI
- * In general, The Cypher stent seems to have a better LL and TLR than others
- * The mechanic issue

The New DESs

- * Nobori
- * Taxus Element
- * Promus Element (PERSEUS)
- * Endeavor Resolute (RESOLUTE)
- * Nevo SES
- *