

IVUS-guided stent optimization

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MUSIC criteria in BMS

- **Complete apposition of stent:**
- **Adequate stent expansion:**
MSA $\geq 90\%$ of the average reference lumen area or $\geq 100\%$ of reference segment with the lowest area when the MSA is $< 9\text{mm}^2$ or
MSA $\geq 80\%$ of the average reference lumen area or $\geq 90\%$ of reference segment with the lowest area when the MSA is $> 9\text{mm}^2$
- **Symmetrical stent expansion:** defined by minimum lumen diameter divided by maximum lumen diameter ≥ 0.7

de Jaegere P, et al. *Eur Heart J* 1998;19:1214-23

Stent optimization in BMS

- **AVID trial (n=800)**

- Criteria: Stent CSA > 90% distal reference lumen
- 12 month TLR: 10.1% vs. 4.3%, p=0.01

Russo RJ, et al. *Circ Cardiovasc Interv* 2009;2:113-123

- **The TULIP trial (n=150)**

- Criteria: Stent CSA > distal reference lumen area. Stent MLD > 80% average reference lumen diameter
- 6 month TLR: 10% vs. 3%, p=0.037

Oemrawsingh PV, et al. *Circulation* 2003;107:62-67

- **OPTICUS trial (n=550)**

- Criteria: Adopted MUSIC criteria
- No difference in outcome at 12 months

Mudra H, et al. *Circulation* 2001;104:1343-1349

AVIO criteria in DES

- MSA >70% of the post-stent balloon CSA
- Post-dilation balloon size: Average of maximum and minimum diameter of EEM

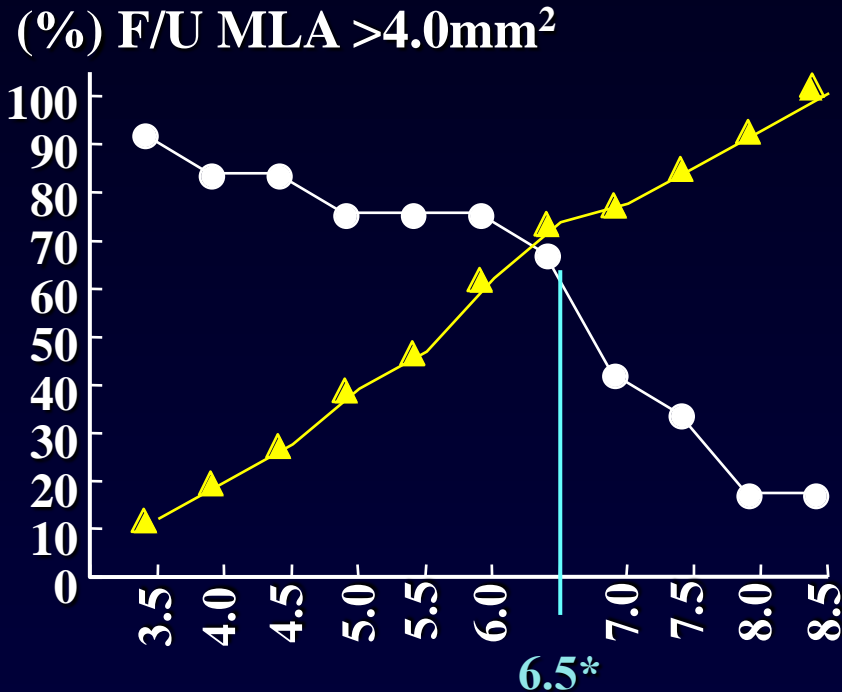
>>> this IVUS definition can not discriminate beneficial clinical outcomes

3.5	9.62	8
4.0	12.56	10
4.5	15.90	12

Chieffo A et al, Am Heart J 2013;165:65-72

“Optimal” MSA (from SIRIUS)

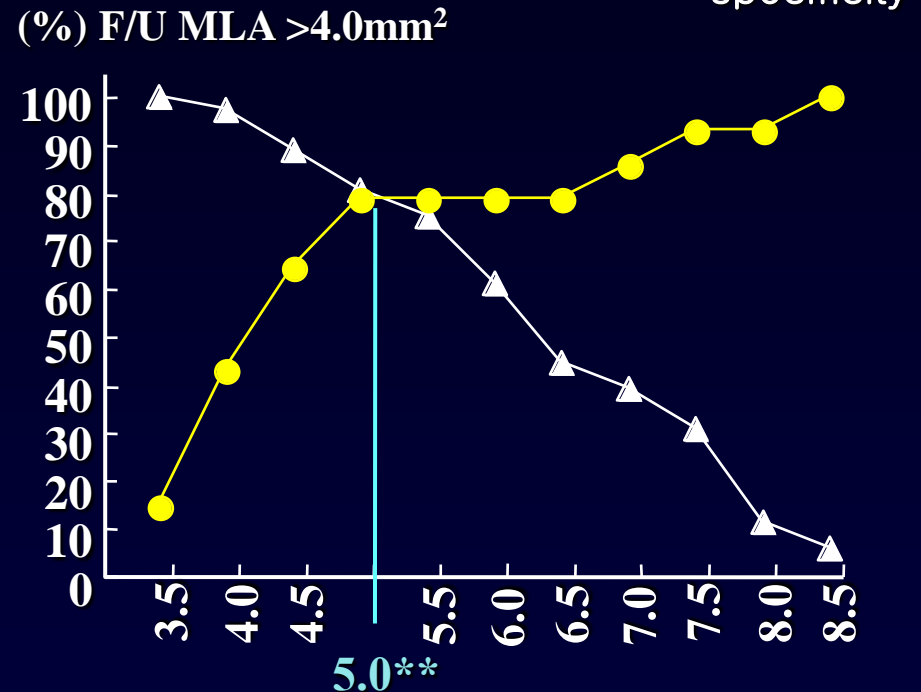
Bare Metal Stents



Minimum stent area (mm²)

*predictive value=56%

Cypher



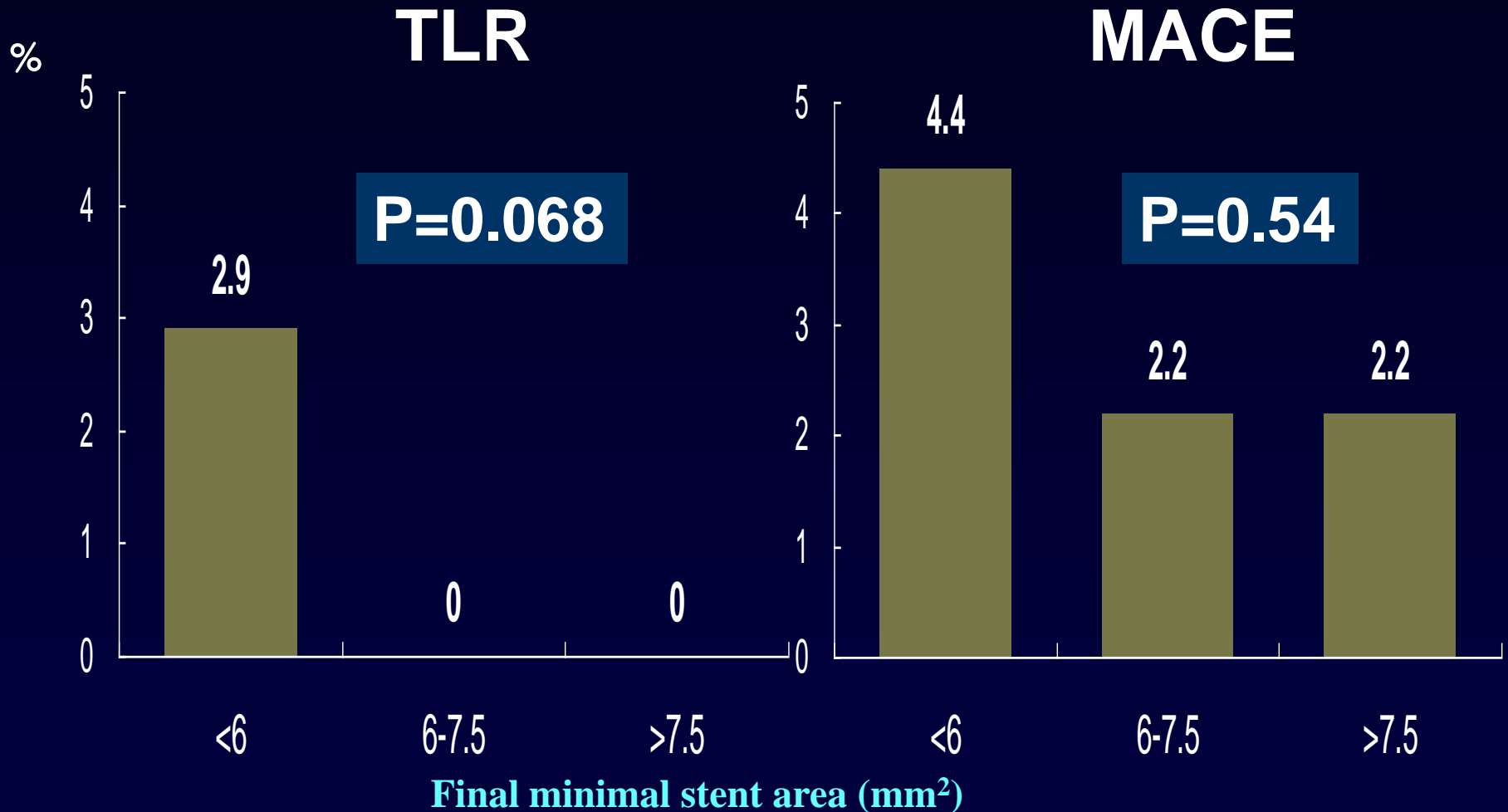
Minimum stent area (mm²)

**predictive value=90%

Sonoda et al. *JACC* 2004;43:1959-63

Optimal Stent Expansion

Total 219 patients

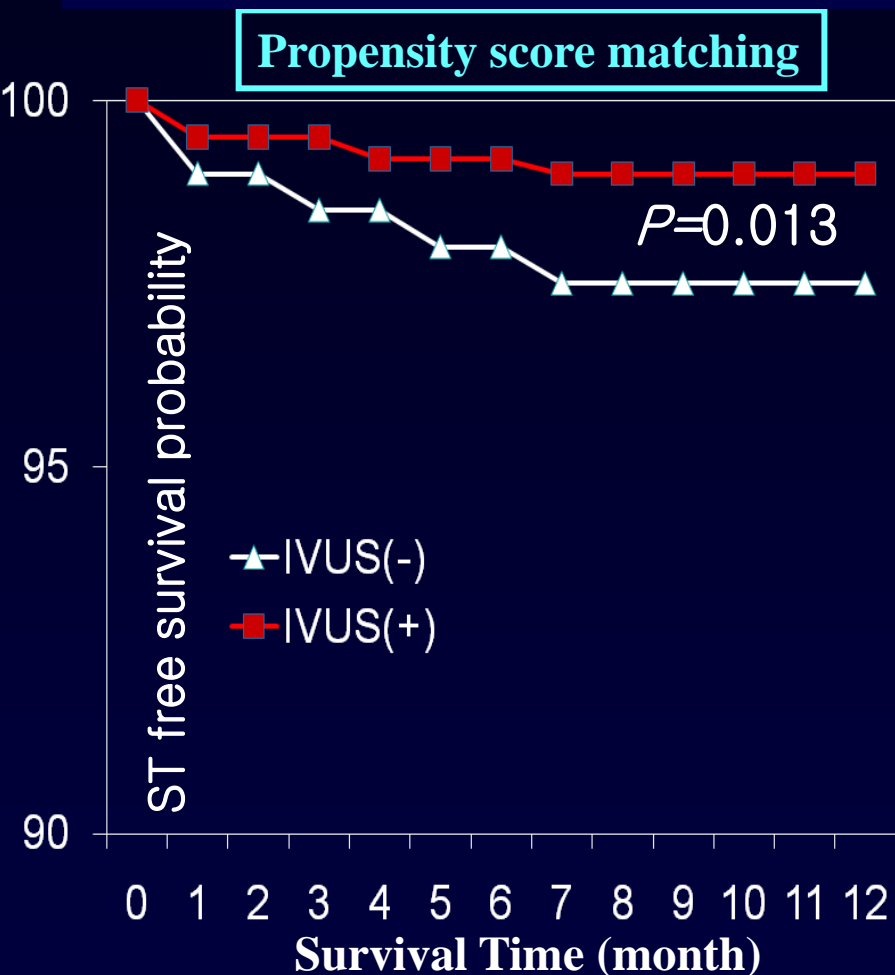


Cheneau E et al. Am J Cardiol 2005

Optimal stenting (suggested)

- Ensuring good apposition of stent struts to the vessel wall
- Adequate stent expansion to obtain MSA
 - BMS > 6.5 mm²
 - DES > 5.0 mm²
 - MSA > 90% of the distal reference lumen CSA
- Lack of major dissection, intramural hematomas and geographic misses.

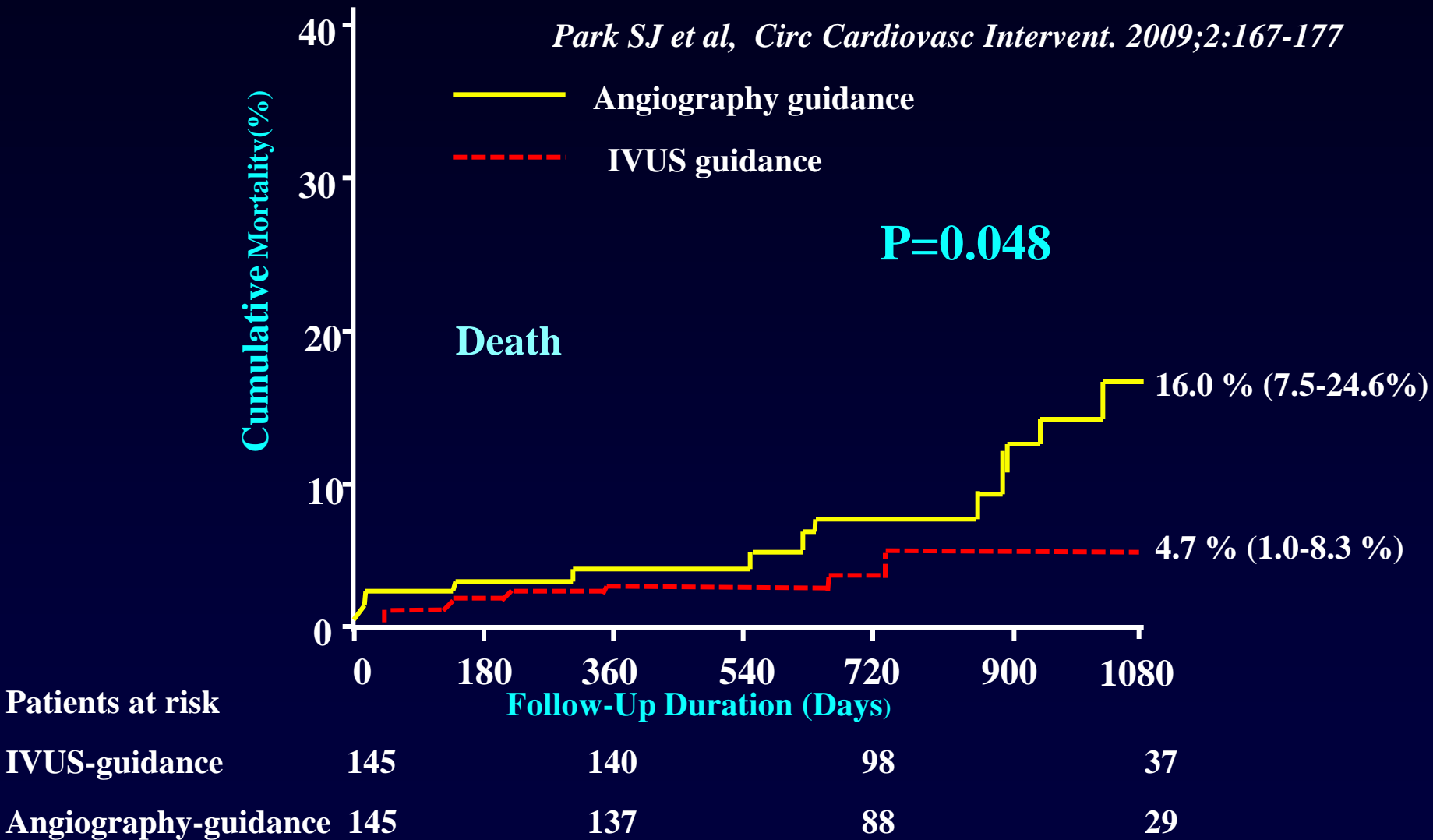
The Potential Clinical Utility of IVUS Guided PCI with DES: reduced ST & TLR



	IVUS (n=884)	No IVUS (n=884)	p-Value
In-hospital outcomes, n(%)			
Death	11(1.2%)	20(2.3%)	0.11
Q-wave MI	1(0.1%)	8(0.9%)	0.02
30 Day outcomes, n(%)			
MACE	25(2.8%)	46(5.2%)	0.01
Death	15(1.7%)	29(3.3%)	0.03
TLR	6(0.7%)	15(1.7%)	0.05
Cumulative ST	4(0.5%)	12(1.4%)	0.046
12 Month outcomes, n(%)			
MACE	128(14.5%)	143(16.2%)	0.33
Death	50(5.7%)	62(7.1%)	0.24
TLR	43(5.1%)	61(7.2%)	0.07
Definite ST	6(0.7%)	18(2.0%)	0.013

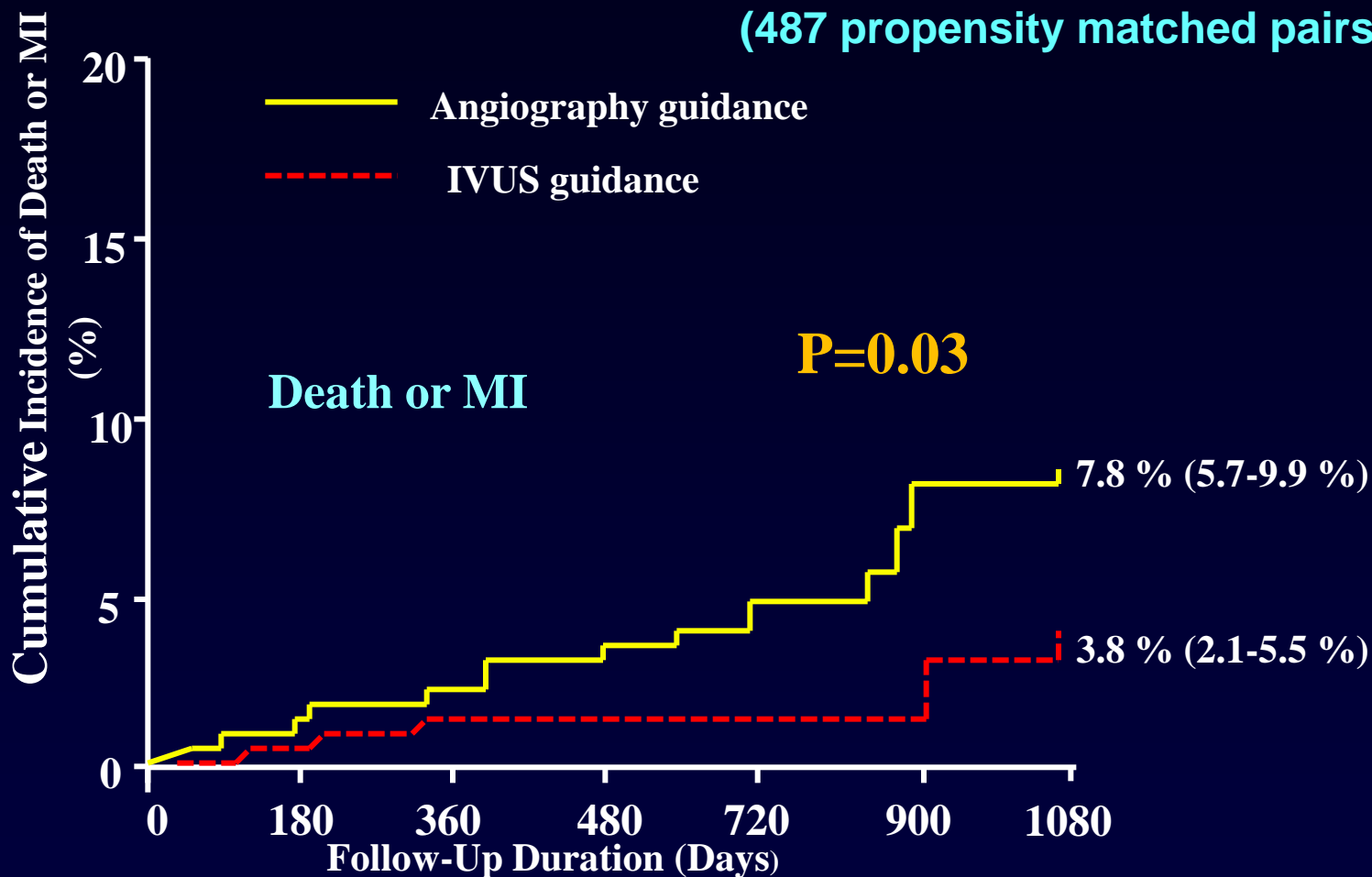
Roy P, Eur Heart J 2008;29:1851-1857

MAIN-COMPARE registry: 3-year mortality (145 propensity matched pairs)



Impact of IVUS-Guidance on 3-Year Clinical Outcomes: DES for Bifurcation Lesions from a Korean multi-center bifurcation registry

(487 propensity matched pairs)



Patients at risk

IVUS-guidance

487

467

281

118

Angiography-guidance

487

469

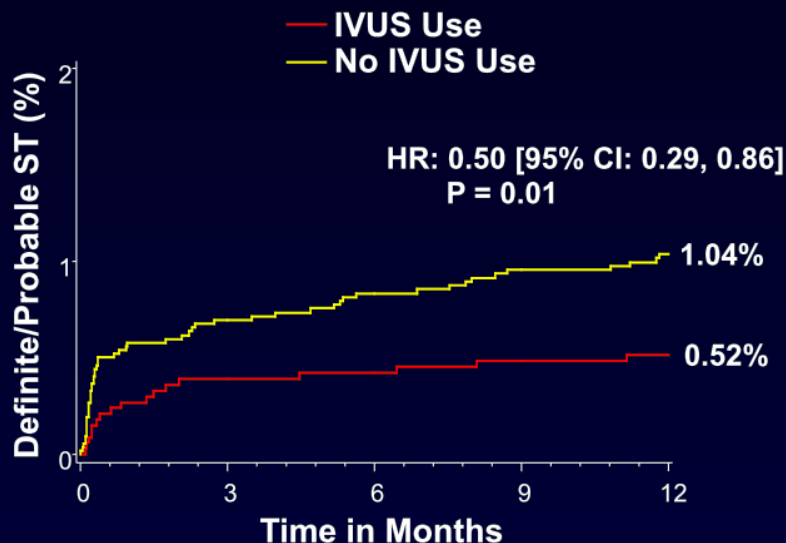
346

124

Kim JS, Hong MK, et al. Am Heart J 2011;161:180-187

ADAPT-DES substudy (n=8,583 pts, IVUS=3,349 pts and no IVUS=5,234 pts)

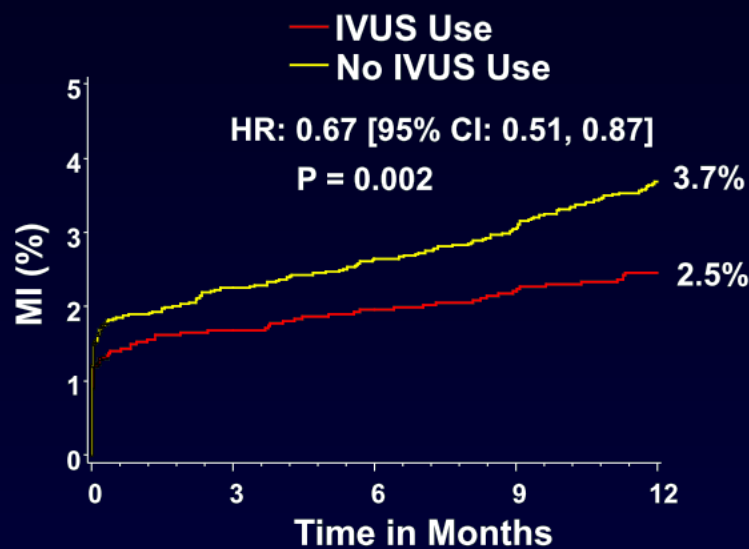
Definite/Probable Stent Thrombosis



Number at risk:	0	3	6	9	12
IVUS Use	3349	3251	3221	3197	3023
No IVUS Use	5234	5015	4978	4938	4585

IVUS use: HR 0.35, p=0.0012

MI



Number at risk:	0	3	6	9	12
IVUS Use	3349	3209	3171	3141	2969
No IVUS Use	5234	4932	4882	4830	4460

IVUS use: HR 0.65, p=0.0034

IVUS guidance during DES PCI may result in less stent thrombosis as well as fewer myocardial infarctions

Maehara A, TCT 2012

AVIO trial: random between IVUS vs. angiography guided DES in complex lesions

24 month outcomes	IVUS (n=142)	Angiography (n=142)	p
MACE	16.9%	23.2%	NS
Cardiac death	0%	1.4%	NS
MI	7.0%	8.5%	NS
TLR	9.2%	11.9%	NS
TVR	9.8%	15.5%	NS
Stent length, mm	23.9±6.74	23.2±6.51	0.49

Chieffo A et al, Am Heart J 2013;165:65-72

HOME DES IVUS randomized study

	DES (N=105)	DES+IVUS (N=105)	P-value
Stent length, mm	22.1	23.6	NS
Type C lesion (%)	24	27	NS
18-month F/U			
MACE (%)	12	11	NS
Death (%)	2	3	NS
MI	4	1	NS
TLR	6	6	NS
Stent thrombosis	6	4	NS

This study failed to demonstrate the superiority of the IVUS guidance during DES implantation over standard high pressure post dilation.

Jakabcin J, et al. *Catheter Cardiovasc Interv* 2010;75:578-583

IVUS predictors of angiographic restenosis after SES (n=543 lesions).

1. IVUS minimum stent CSA (OR=0.584, 95% CI 0.385–0.885, p=0.011), 5.5 mm²

2. Total stent length measured by IVUS (OR=1.028, 95% CI 1.002–1.055, p=0.038), 40 mm.

Hong MK, et al. Eur Heart J 2006; 27: 1305-1310

IVUS predictors of angiographic restenosis after SES.

(N=543 lesions)

Angiographic restenosis rate

Stent CSA

Stent length	Total	< 5.5 mm ²	≥ 5.5 mm ²	p
Total	21/543 (3.9%)	14/189 (7.4%)	7/354 (2.0%)	0.002
< 40 mm	4/411 (1.0%)	3/127 (2.4%)	1/284 (0.4%)	0.090
≥ 40 mm	17/132 (12.9%)	11/62 (17.7%)	6/70 (8.6%)	0.116
p	<0.001	<0.001	<0.001	

Hong MK, et al. Eur Heart J 2006; 27: 1305-1310

The value of stent length 31.5 mm is a threshold for the prediction of DES thrombosis.

3,145 patients (4,667 lesions)

3-year clinical outcomes

Stent length	≥ 31.5 mm	< 31.5 mm	p
Stent thrombosis	4.0%	0.7%	<0.001
Death	5.2%	3.0%	0.005
MI	2.4%	0.7%	0.001

Suh J et al, J Am Coll Cardiol Intv 2010;3:383-9

There are no randomized studies to evaluate the usefulness of IVUS in the subsets of long coronary lesions in DES era.

RESET multicenter randomized clinical trial

2,148 patients enrolled and randomized

Divided into 4 subsets and 1:1 randomization was performed.

31 patients excluded
- 16 Withdrawal of consent
- 15 Met exclusion criteria

- E-ZES + 3-month DAPT
- Standard Therapy:
Other DES with 12-month DAPT

E-ZES + 3-month DAPT (n=1059)

Standard therapy (n=1058)

Diabetes mellitus subset (N=292)

Acute coronary syndrome subset (N=601)

Short-length DES Subset (N=681)

Long-length DES Subset (N=543)

E-ZES (n=146)

R-ZES (n=146)

E-ZES (n=301)

R-ZES (n=300)

E-ZES (n=341)

SES (n=340)

E-ZES (n=271)

EES (n=272)

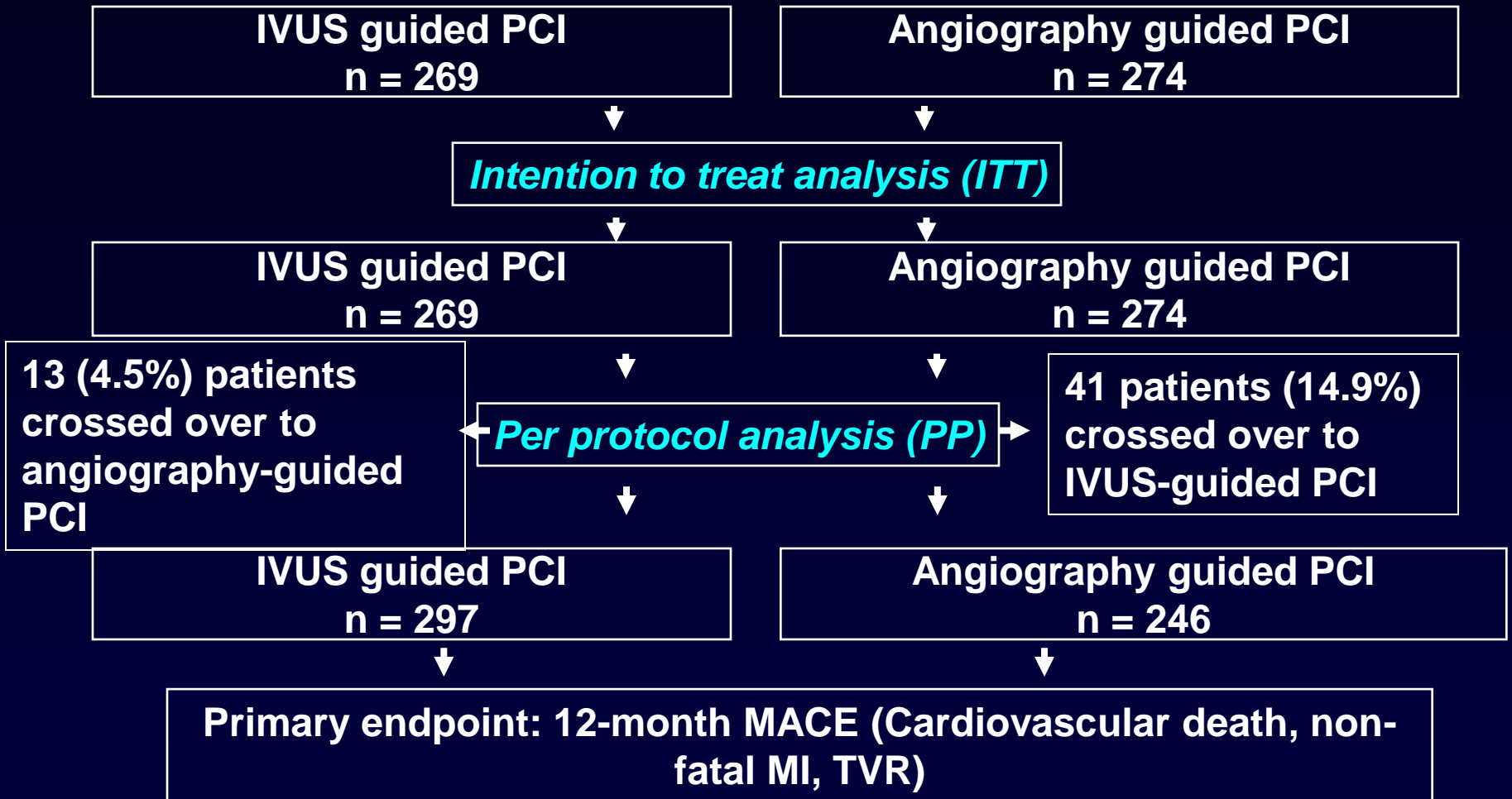
R-ZES = Resolute zotarolimus-eluting stent ; SES = sirolimus-eluting stent; EES = everolimus-eluting stents

Kim BK, Hong MK, et al. JACC 2012;60;1340-1348

**Randomized comparison of
clinical outcomes between IVUS
and angiography guided DES
implantation for long coronary
artery stenoses:
RESET Long substudy**

Kim JS, Hong MK, et al. *J Am Coll Cardiol Intv* 2013;6:369-376

RESET Long Lesions (Randomization between IVUS vs. Angiography)

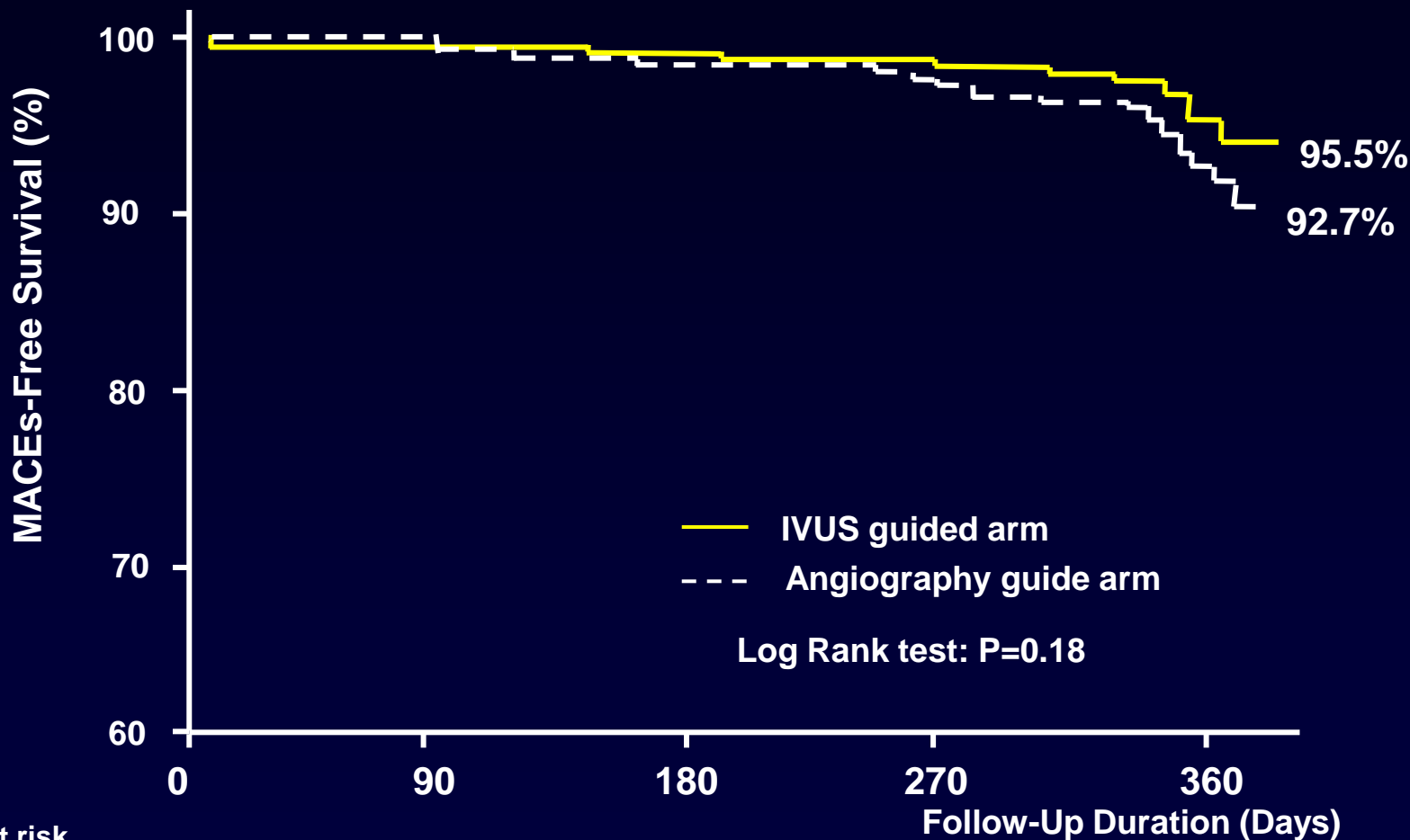


Kim JS, Hong MK, et al. *J Am Coll Cardiol Interv* 2013;6:369-376

Baseline procedural characteristics (ITT)

	IVUS (n=269)	Angiography (n=274)	P
No. of target long lesion			
Type of stents, # (%)			0.90
Zotarolimus-eluting stent	135 (50.2%)	136 (49.6%)	
Everolimus-eluting stent	134 (49.8%)	138 (50.4%)	
Lesion length, mm	33.2 ± 12.6	33.2 ± 11.5	0.96
Total stent length, mm	37.7 ± 12.1	37.5 ± 11.3	0.84
Adjunct post-dilatation, # (%)	147 (54.6%)	122 (44.5%)	0.03
Reference diameter, mm	2.98 ± 0.41	2.97 ± 0.44	0.78
Minimal lumen diameter, mm			
Pre-intervention	0.96 ± 0.39	0.93 ± 0.41	0.47
Post-intervention	2.60 ± 0.37	2.58 ± 0.40	0.68

Kaplan Meier MACE-free survival (ITT)



Patients at risk

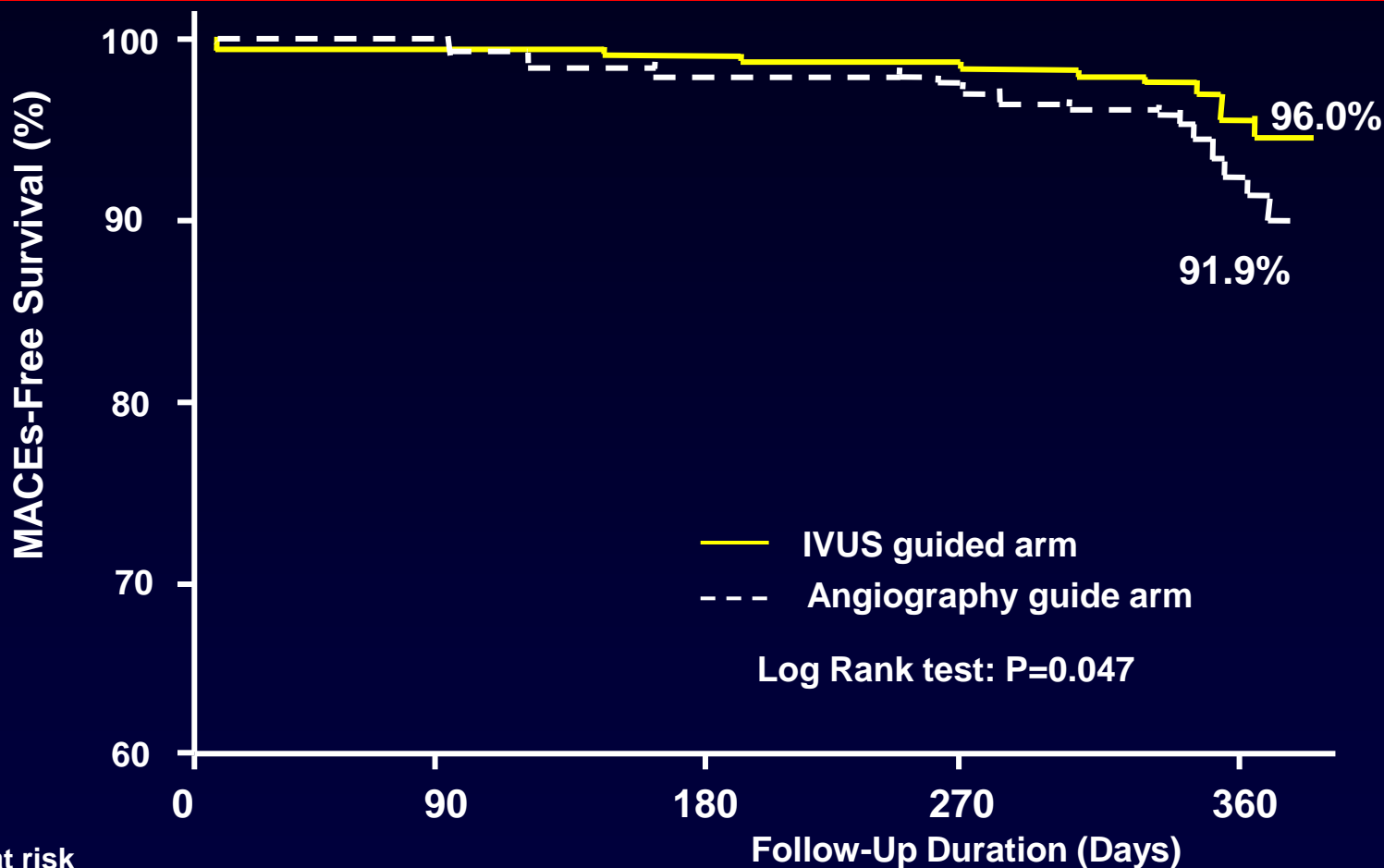
	0	90	180	270	360
IVUS arm	269	267	264	262	248
Angiography arm	274	270	266	264	253

Kim JS, Hong MK, et al. *J Am Coll Cardiol Intv* 2013;6:369-376

Baseline procedural characteristics (PP)

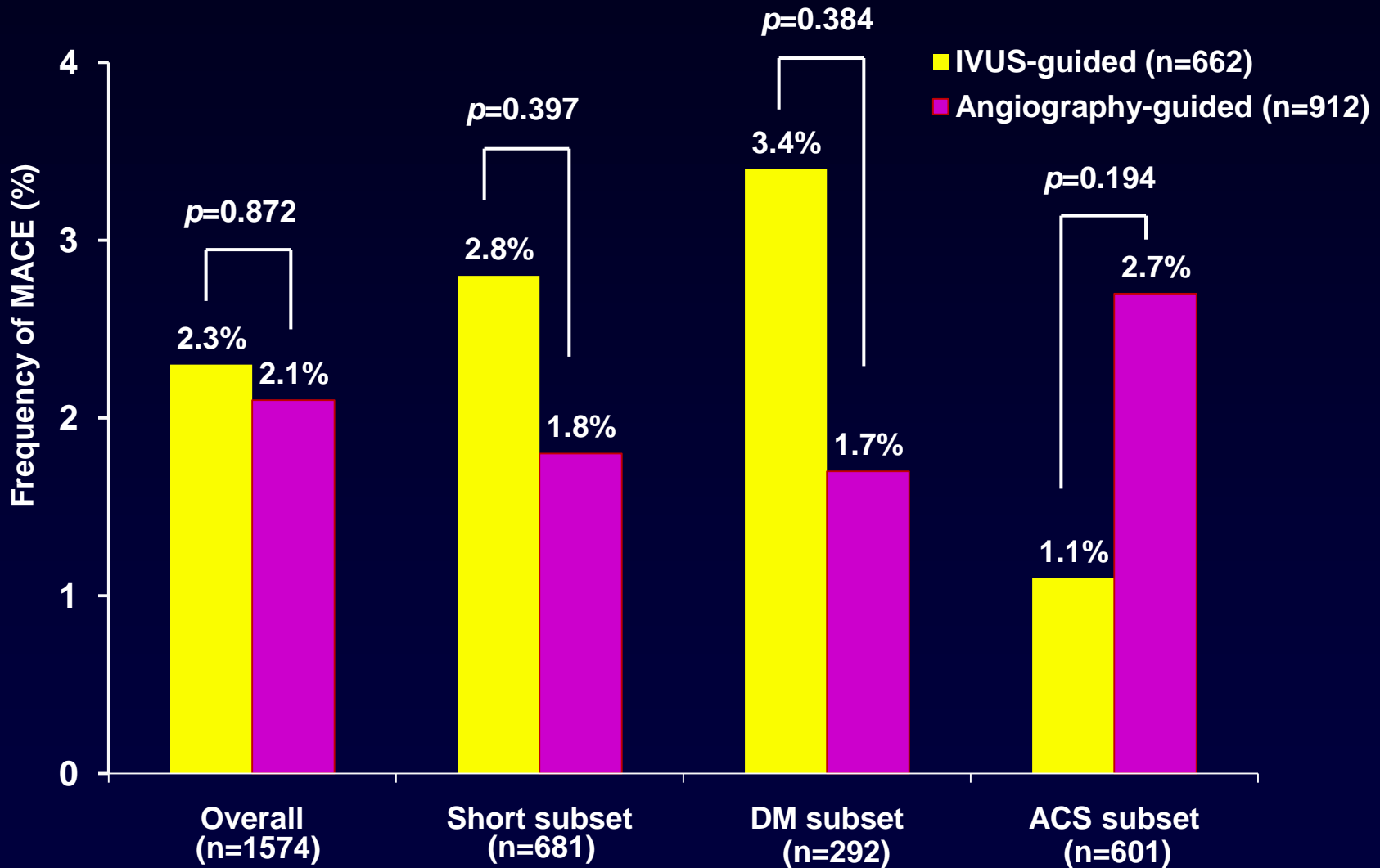
	IVUS (n=297)	Angiography (n=246)	P
No. of target long lesions			
Type of stents, # (%)			0.89
Zotarolimus-eluting stent	149 (50.2%)	122 (49.6%)	
Everolimus-eluting stent	148 (49.8%)	124 (50.4%)	
Lesion length, mm	33.3 ± 12.8	33.2 ± 11.1	0.93
Total stent length, mm	37.8 ± 12.0	37.4 ± 11.4	0.75
Adjunct post-dilatation, # (%)	162 (54.6%)	112 (45.5%)	0.05
Reference diameter, mm	2.99 ± 0.43	2.96 ± 0.41	0.28
Minimal lumen diameter, mm			
Pre-intervention	0.97 ± 0.40	0.91 ± 0.40	0.13
Post-intervention	2.62 ± 0.29	2.55 ± 0.36	0.04

Kaplan Meier MACE-free survival (PP)



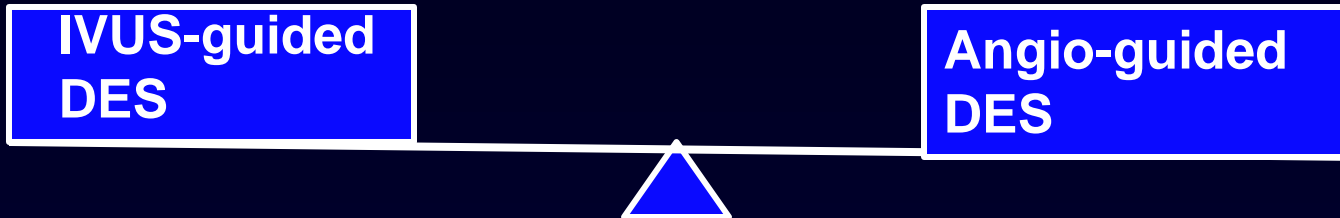
Kim JS, Hong MK, et al. *J Am Coll Cardiol Intv* 2013;6:369-376

Usefulness of IVUS in short-length narrowings (DES length ≤ 24 mm) in RESET trials

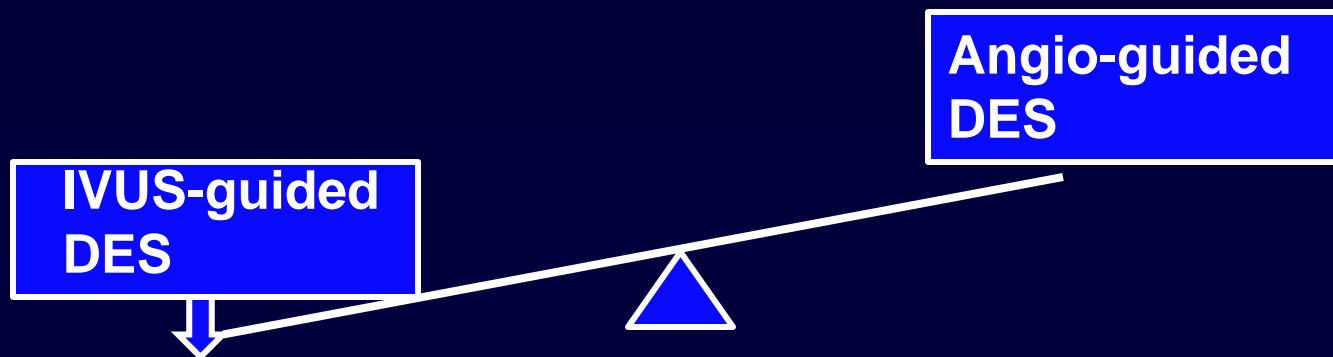


Yoon YW, Hong MK, et al. *Am J Cardiol* 2013;112:642-646

In simple lesions regardless of clinical presentations (i.e. ACS or DM)



In complex lesions (i.e. long lesions, CTO lesions, bifurcation and LM lesions)



Better clinical outcomes

Conclusions

Use of IVUS should be considered in lesions with complex morphology even in the era of DES.