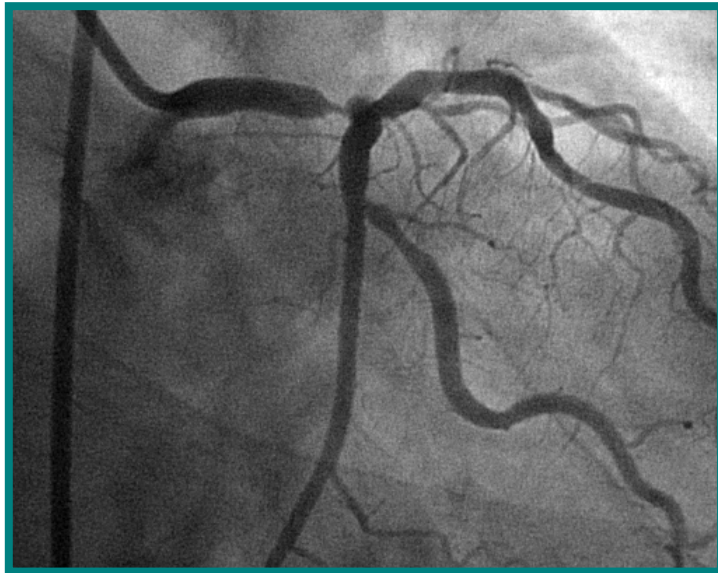


Immediate and Long-term Outcomes of Drug-eluting Stent Implantation for Unprotected Left Main Coronary Artery Disease: Comparison with Bare Metal Stent Implantation



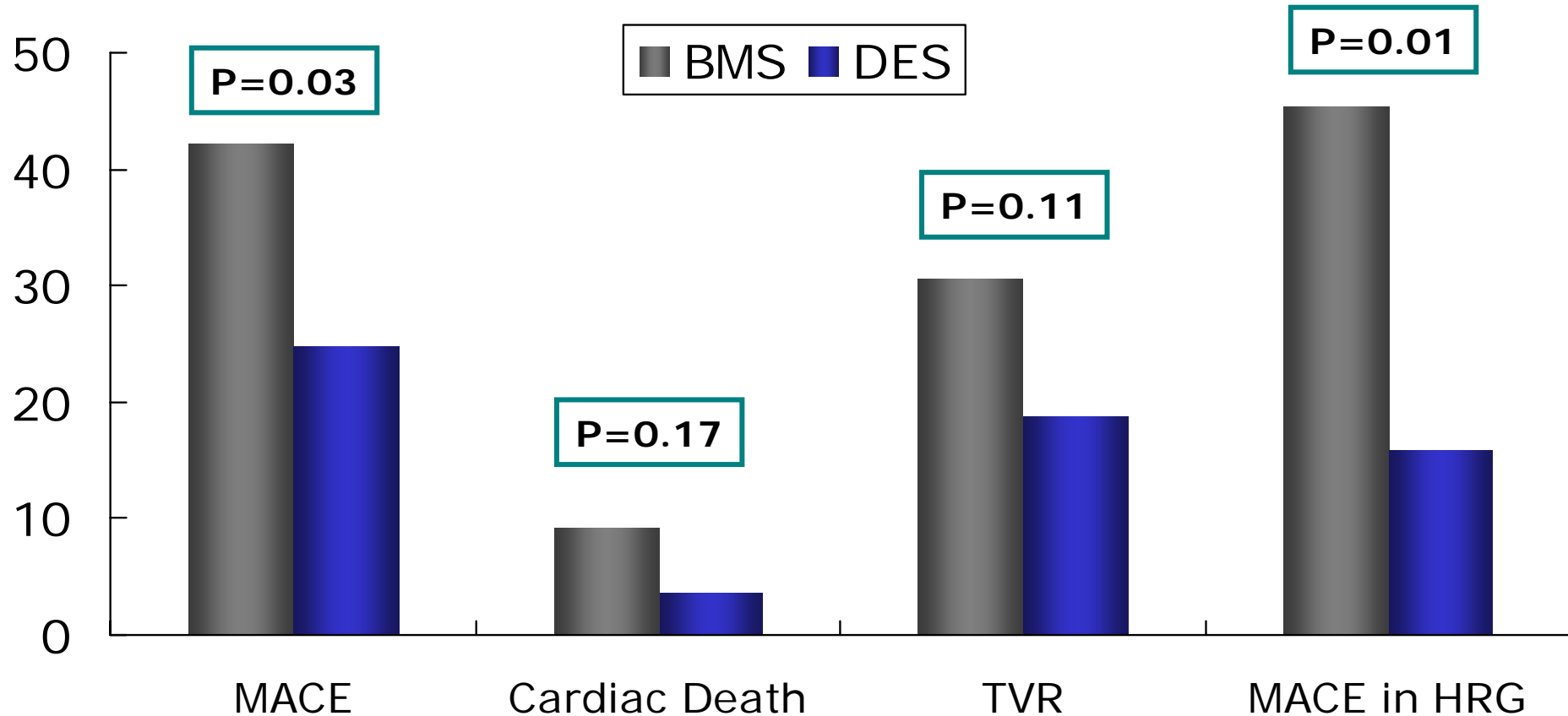
Run-Lin Gao, MD, FACC;
Bo Xu, MBBS;
Ji-Lin Chen, MD;
Yue-Jin Yang, MD;
Shu-Bin Qiao, MD; et al.
Cardiovascular Institute
and Fu Wai Hospital

Background

- **Although in the era of BMS, unprotected LMCA stenting became relatively safer and feasible, ISR remained a major limitation to long-term effectiveness and may be associated with increased long-term mortality**
- **Three major non-randomized studies comparing DES with historically matched BMS controls in LMCA published in 2005 revealed that DES were markedly superior to BMS in reducing MACE and restenosis**

Early and Mid-Term Results of DES Implantation in ULM (A. Colombo, DES, n=85)

Clinical follow-up 6 months

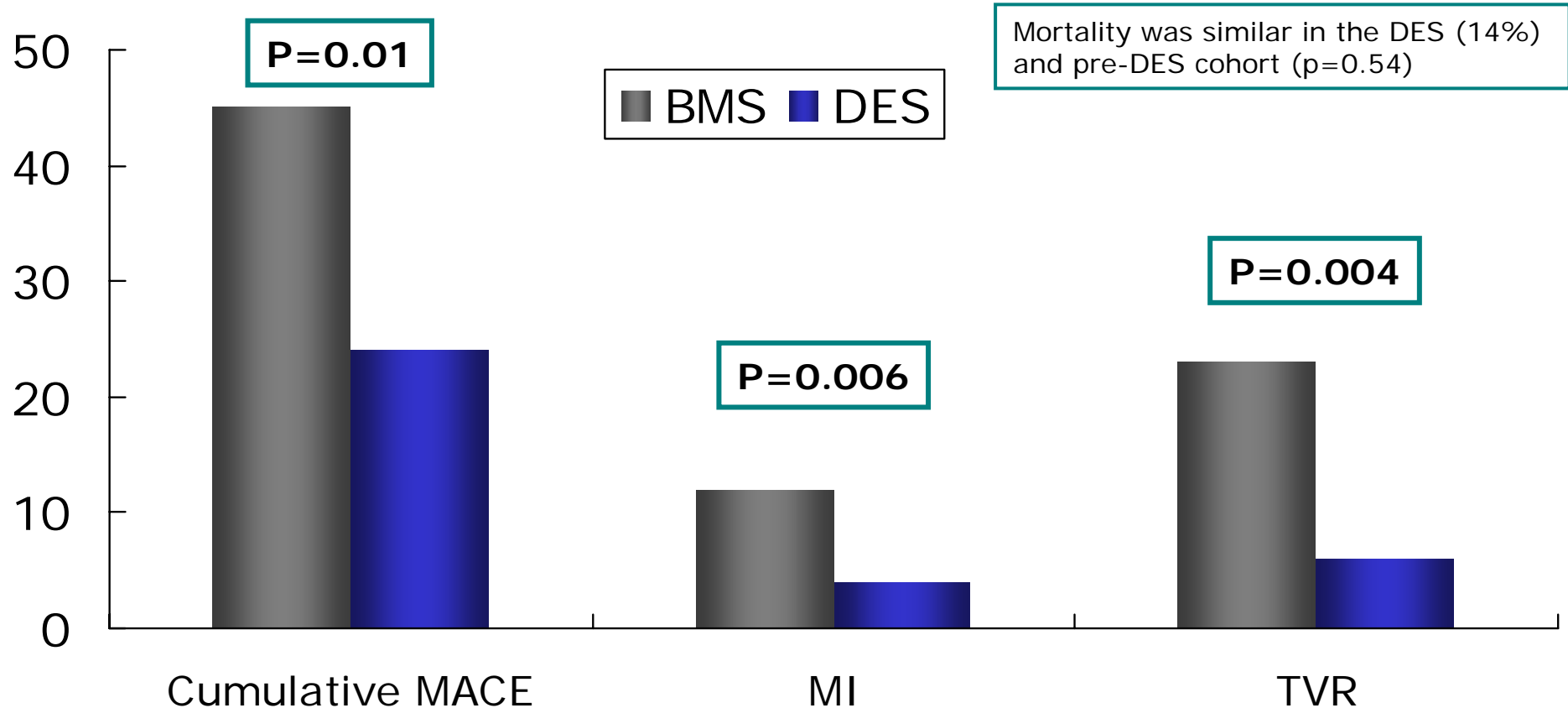


Conclusion: Implantation of a DES on ULM lesions appears to be a feasible and safe approach. Compared with prior experience with BMS, there is a reduction in MACE, including death rate, during the 6-month follow-up. The occurrence of angiographic restenosis is usually focal and treatable with repeat PCI. In addition, the finding of a relative low mortality despite a high risk profile in patients treated with DES may allow a randomized study comparing DES with surgery for ULM disease to be performed.



Short- and Long-Term Clinical Outcome after DES Implantation for the Percutaneous Treatment of LMCA Disease (P. Serruys, RESEARCH and T-SEARCH, n=95)

Mean clinical follow-up 503 days



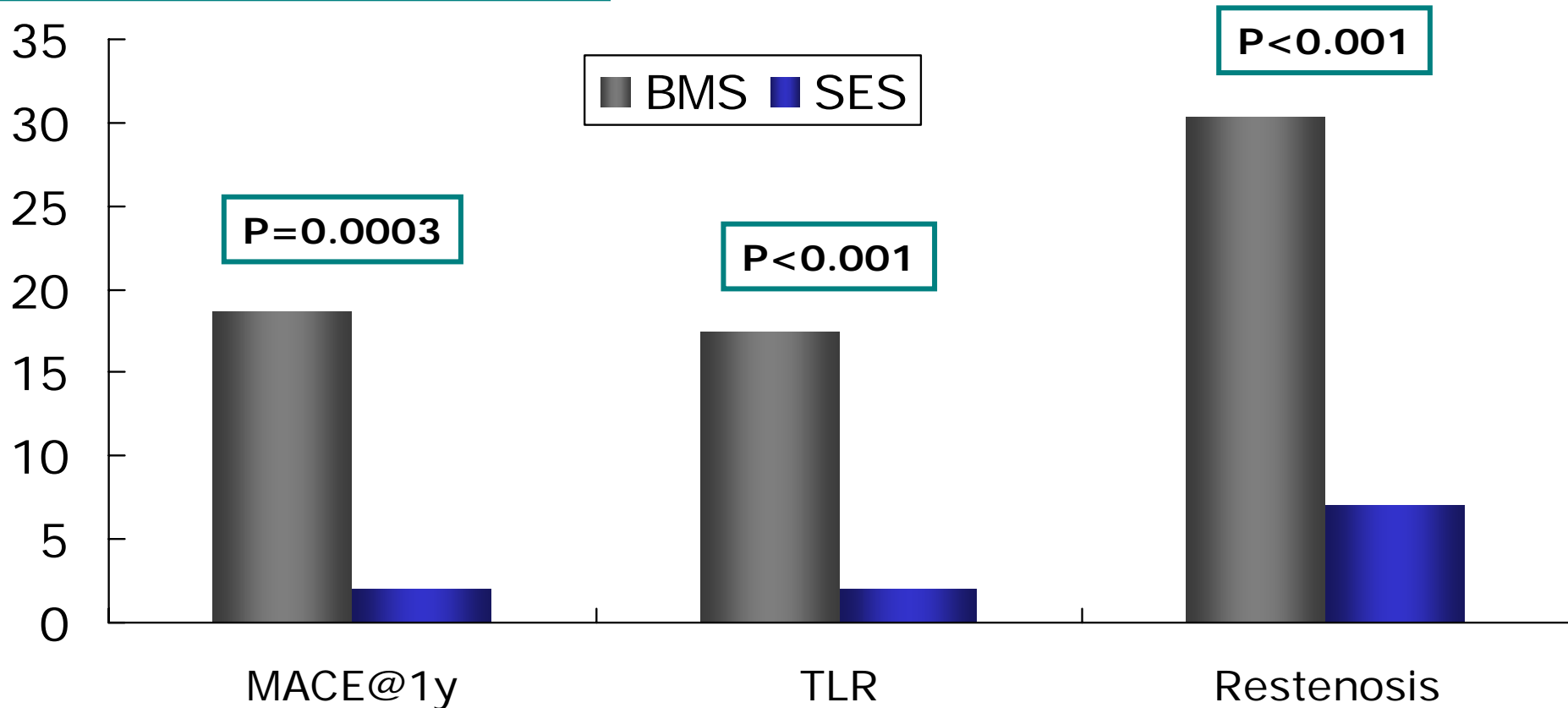
Conclusion: The use of DES as a default strategy to treat LM disease was associated with a significant reduction in adverse events. The effectiveness of DES persisted even after adjustment for clinical and procedural variables, including the Parsonnet surgical risk score.



Beijing, China
2007

Sirolimus-Eluting Stent Implantation in ULMCA Stenosis (S-J Park, SES, n=102)

Clinical follow-up 11.7 ± 3.4 months



Late lumen loss (0.05 ± 0.57 mm vs. 1.27 ± 0.90 mm, $p < 0.001$) were significantly lower in the SES group than the BMS group. In the SES group, all restenoses occurred in patients with bifurcation LMCA lesions.

Conclusion: Sirolimus-eluting stent implantation for unprotected LMCA stenosis appears safe with regard to acute and midterm complications and is more effective in preventing restenosis compared to BMS implantation.

China Interventional Therapeutics (CIT) 2007
in Conjunction with TCT at CIT & EuroPCR at CIT

Seung-Jung Park, J Am Coll Cardiol 2005;45:351-356

Fu Wai Hospital Data

- **Prospective single center registry, all consecutive patients (04/2003-02/2006) with ULM treated by DES implantation, routinely clinical follow-up at 30d, 6m, 12m and annually**
- **Historically matched BMS control – CHANCE study, 23 centers (1997-2003) retrospective registry**

Baseline Demographics

	BMS (n=224)	DES (n=220)	P-Value
Female, n (%)	58 (25.9)	43 (19.5)	0.111
Age, years	60.1±12.0	59.8±11.1	0.768
Previous MI, n (%)	53 (23.7)	71 (32.3)	0.043
Diabetes mellitus, n (%)	45 (20.1)	56 (25.5)	0.178
Hypertension, n (%)	124 (55.4)	121 (55.0)	0.940
Hyperlipidemia, n (%)	87 (38.8)	71 (32.3)	0.148
Current smoker, n (%)	65 (29.0)	71 (32.3)	0.268
Unstable angina, n (%)	175 (78.1)	153 (69.5)	0.153
LVEF, %	63.9±12.3	61.8±7.2	0.026

Baseline Lesion Characteristics

	BMS (n=224)	DES (n=220)	P-Value
LM±MVD, n (%)			<0.001
Isolated LM	116 (51.8)	45 (20.5)	
Single vessel	62 (27.7)	45 (20.5)	
Double vessel	35 (15.6)	64 (29.1)	
Triple vessel	11 (4.9)	66 (30.0)	
LM lesion location, n (%)			<0.001
Ostium	77 (34.4)	43 (19.5)	
Stem	75 (33.5)	11 (5.0)	
Bifurcation	72 (32.1)	166 (75.5)	
Pre-procedure DS at LM by visual estimate, %	81.2±12.8	82.7±10.2	0.158

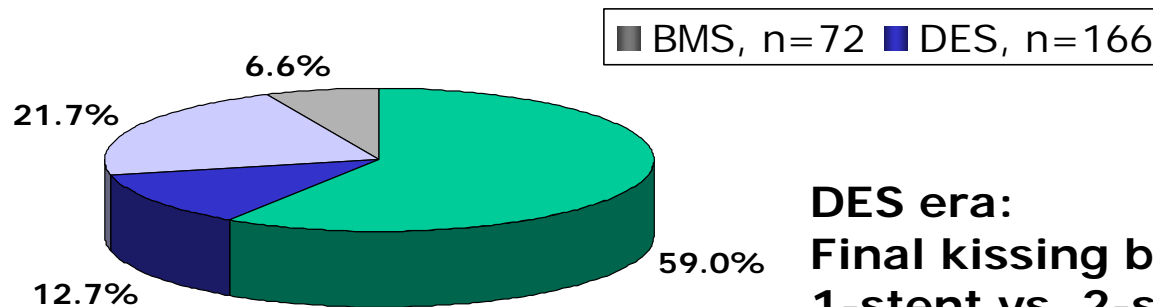
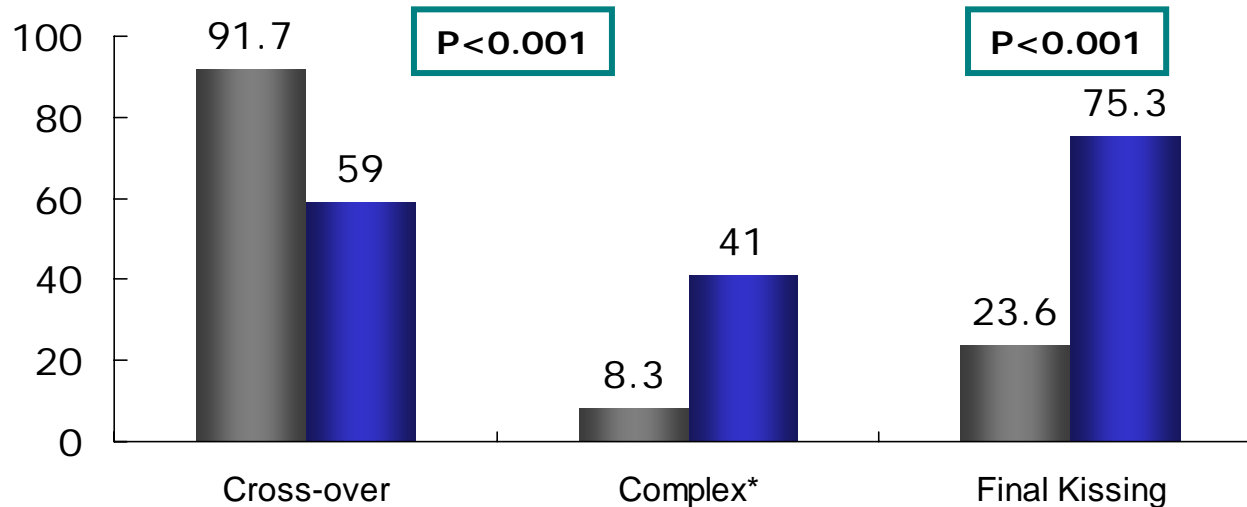
Procedure Results

	BMS (n=224)	DES (n=220)	P-Value
Pre-dilatation, n (%)	155 (69.2)	153 (69.5)	0.936
Stent diameter at LM, mm	3.69±0.41	3.45±0.40	<0.001
Stent Length at LM, mm	12.3±5.0	22.1±12.6	<0.001
Max. pres. at LM stent, atm	14.8±2.5	16.1±2.9	<0.001
Post-dilatation, n (%)	15 (6.7)	158 (71.8)	<0.001
IVUS guided, n (%)	18 (8.0)	100 (45.5)	<0.001
Post-procedure DS at LM by visual estimate, %	1.1±4.1	1.3±3.9	0.558
LM lesion success, n (%)	223 (99.6)	219 (99.5)	0.990
Procedure success*, n (%)	213 (95.1)	214 (97.3)	0.231

DES used: CYPHER 97 (44.1%), TAXUS 93 (42.3%), FIREBIRD 30 (13.6%)

* Defined as complete revascularization in patients with all target lesions

Bifurcation Approaches

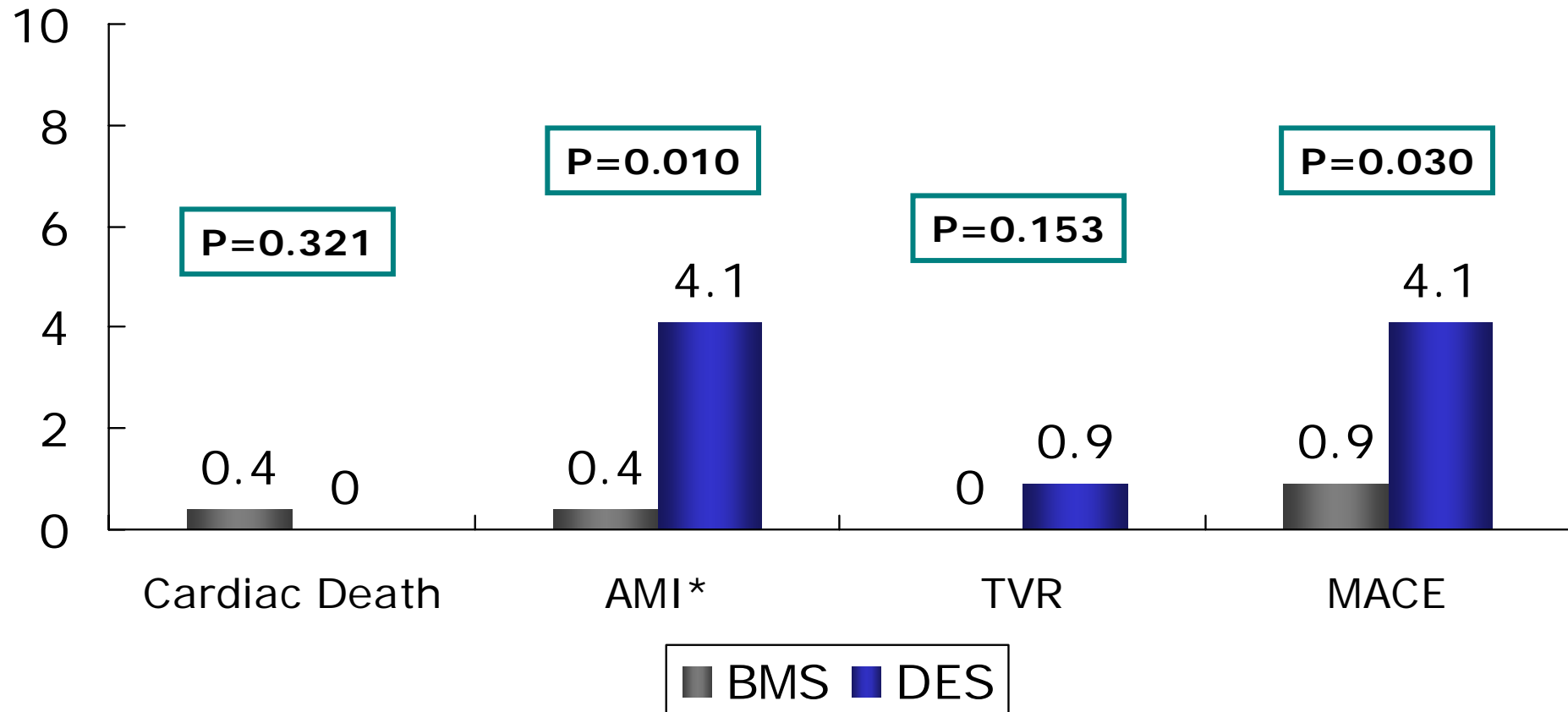


DES era:
Final kissing balloon in 125 (75.3%)
1-stent vs. 2-stent (62% vs. 94%, p < 0.001)

■ Cross-over ■ T-stenting ■ Crush stenting ■ V-stenting

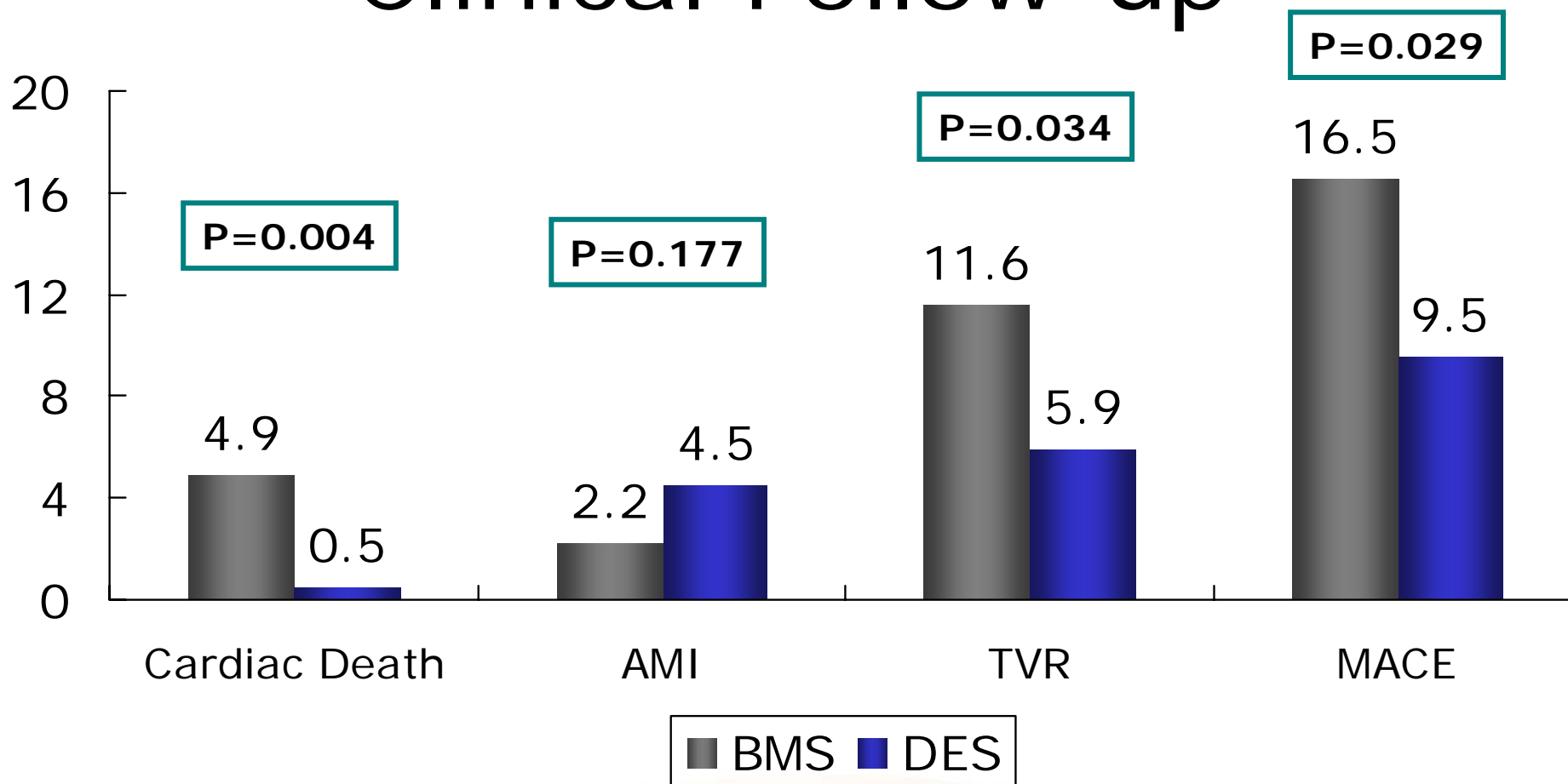
* Defined as 2-stent strategies including "T", Crush and "V" for LM bifurcation

In-Hospital Outcomes



* DES: AMI, n=9 (4.1%) including QMI, n=2, Non-QMI, n=7
all occurred in LM bifurcation cohort

Cumulative Events at Clinical Follow-up

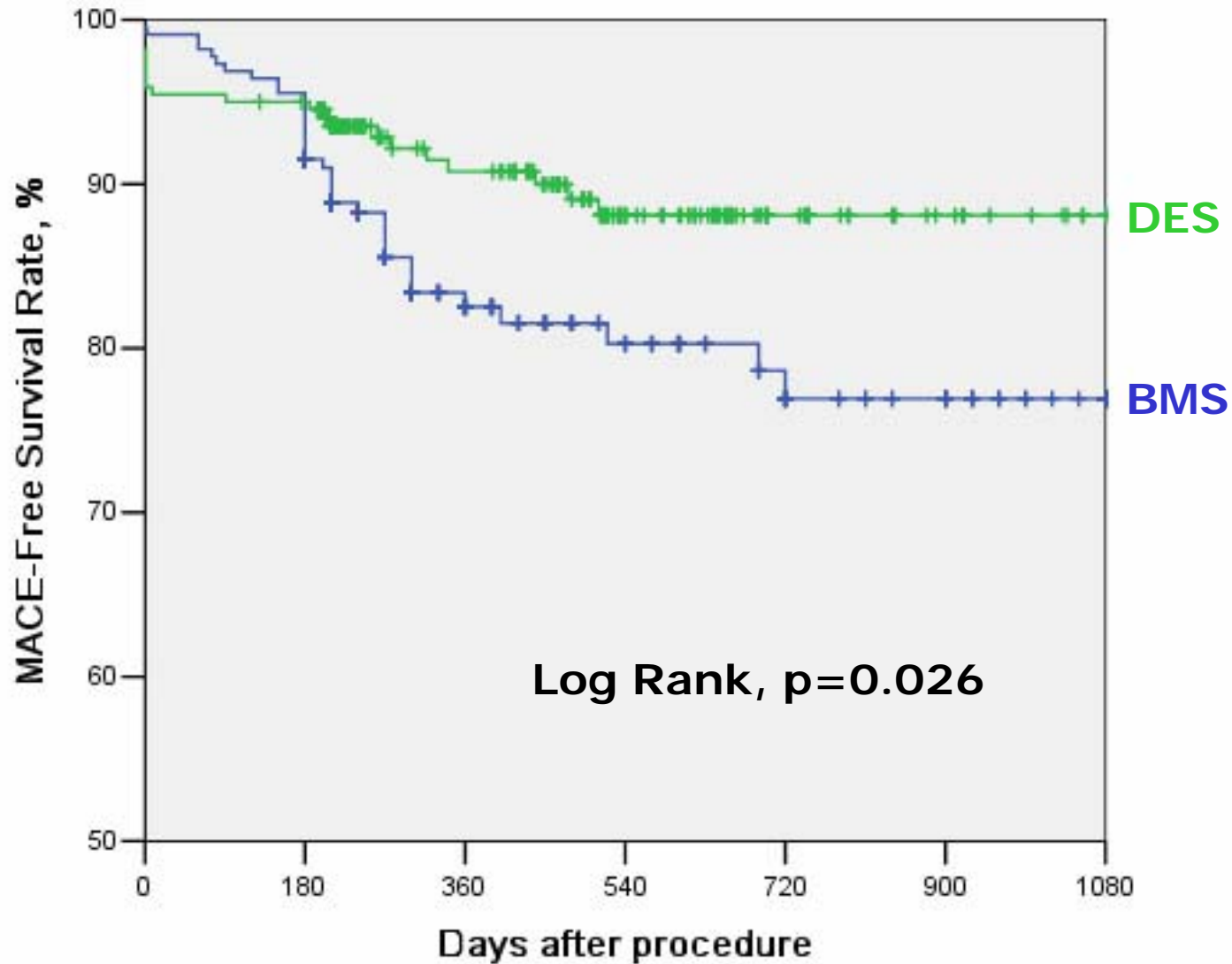


Clinical follow-up rate 100%, mean follow-up duration:
BMS (469 ± 370 days) vs. DES (463 ± 237 days), $p=0.828$

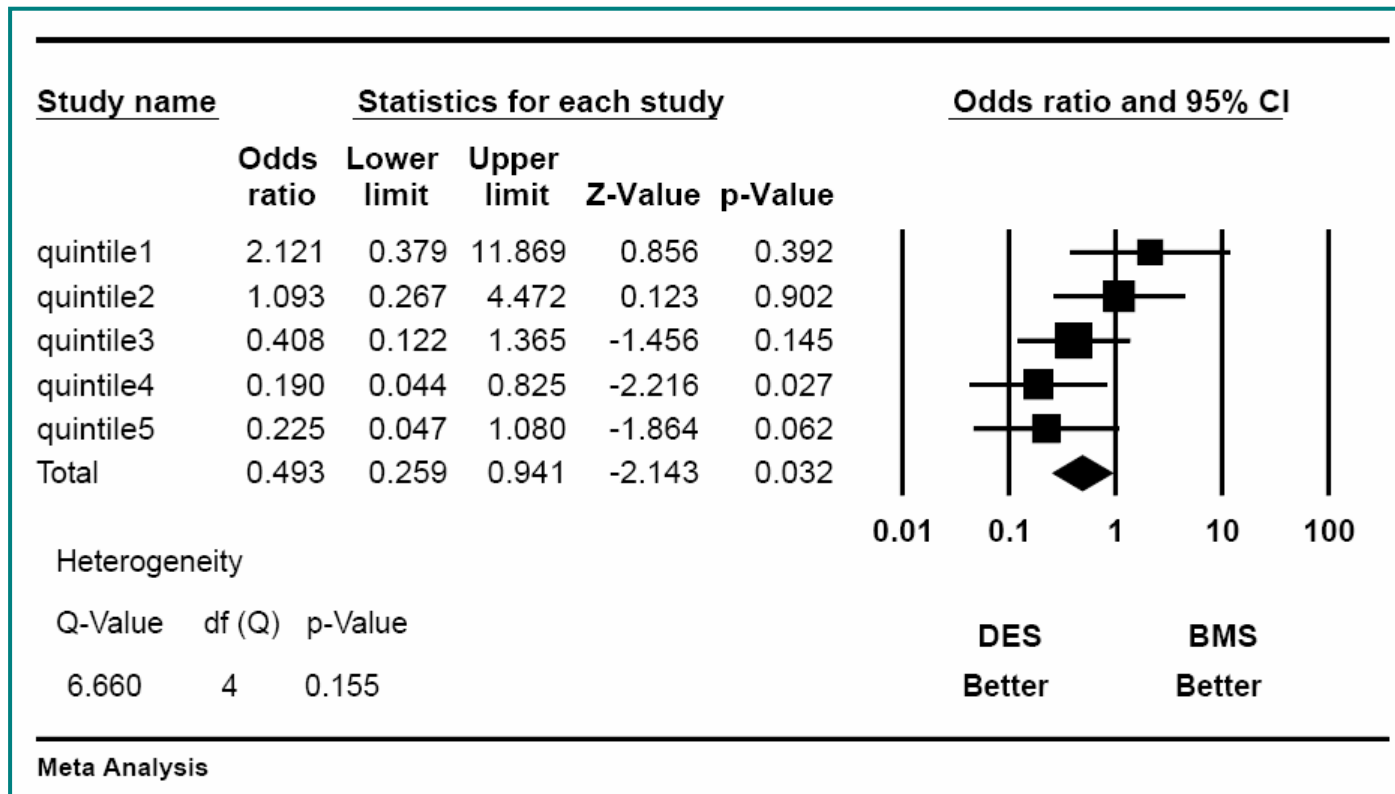


Beijing, China

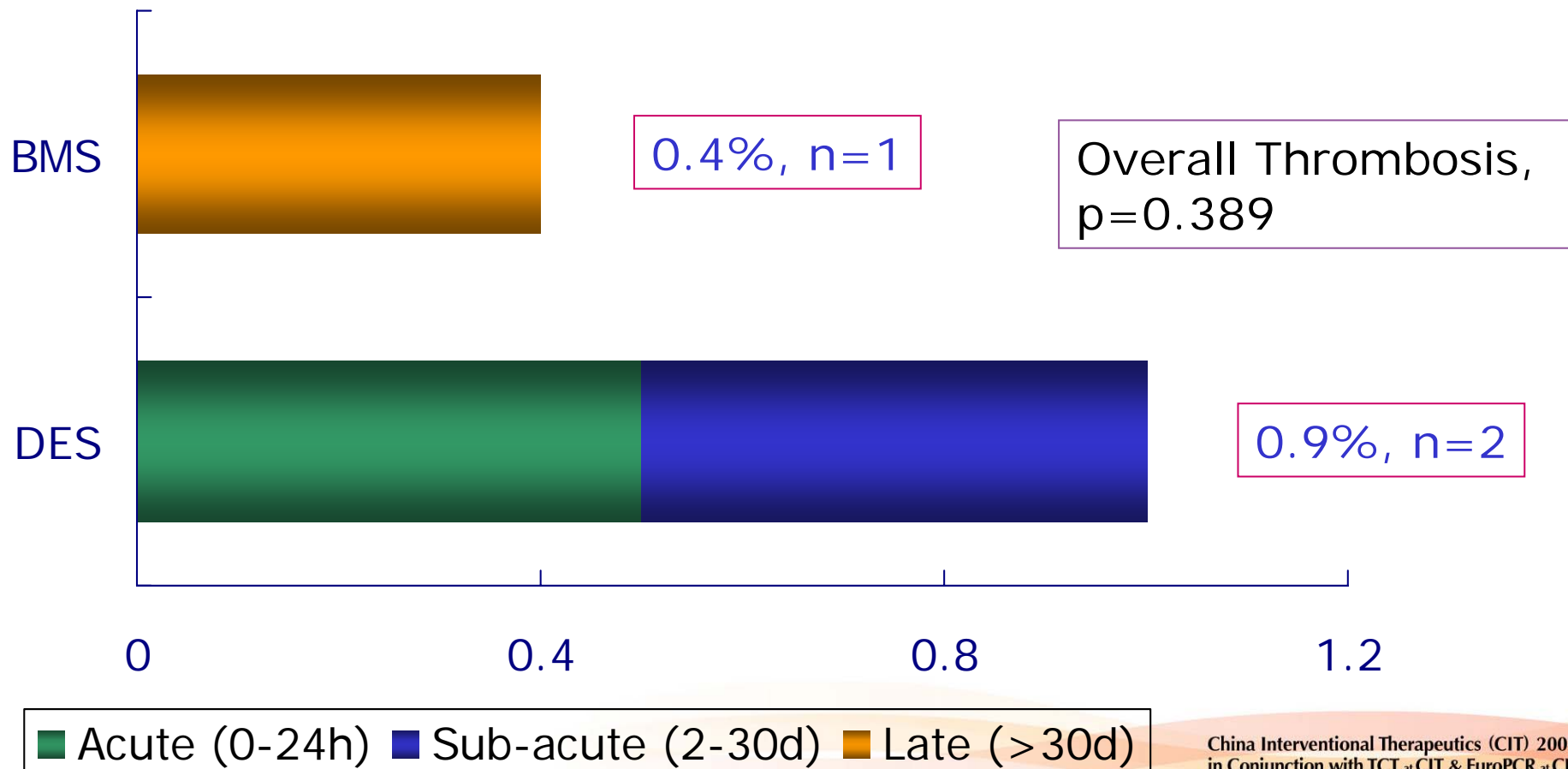
Kaplan-Meier MACE-free Survival



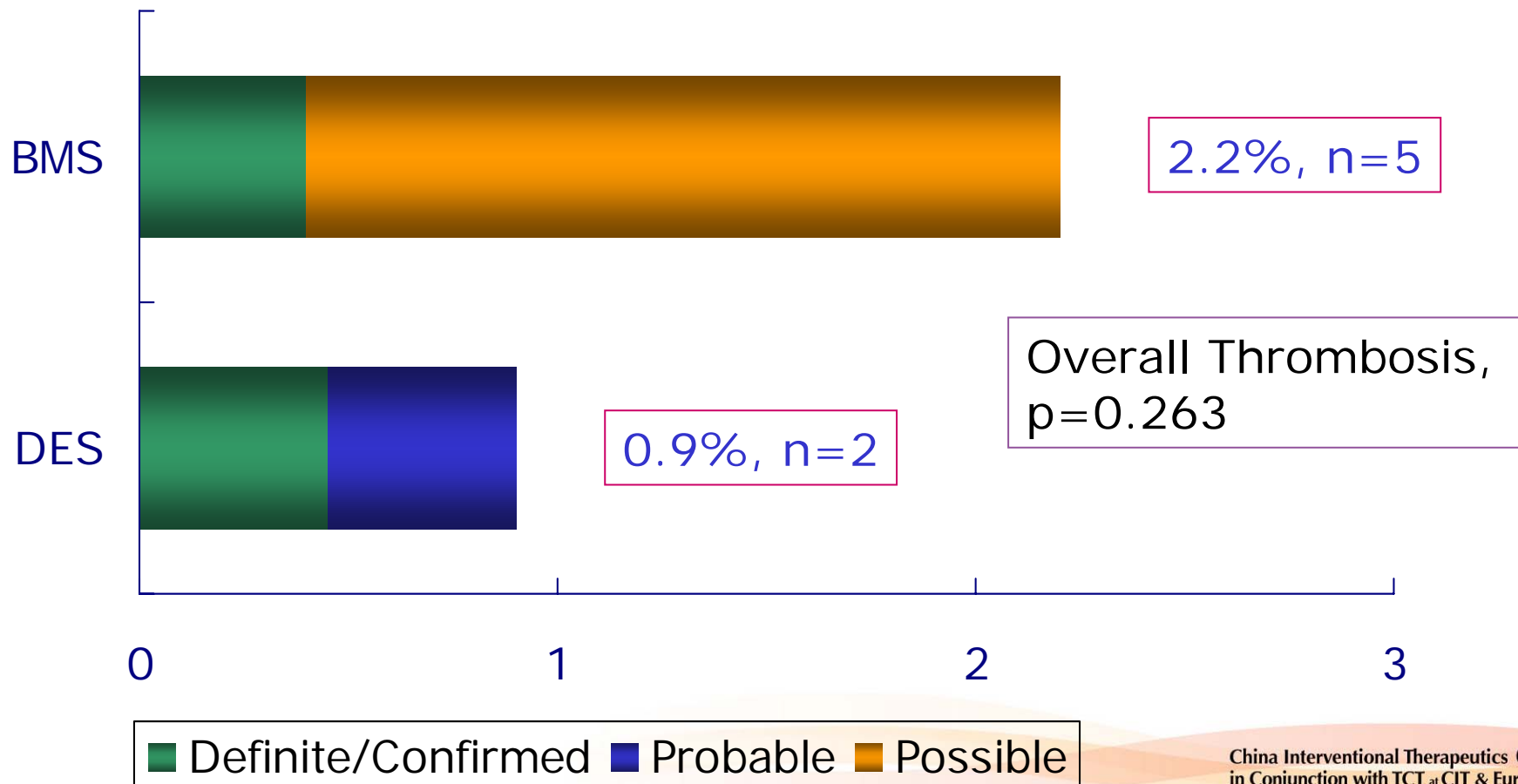
Results of Meta-Analysis for MACE Using Propensity Scoring



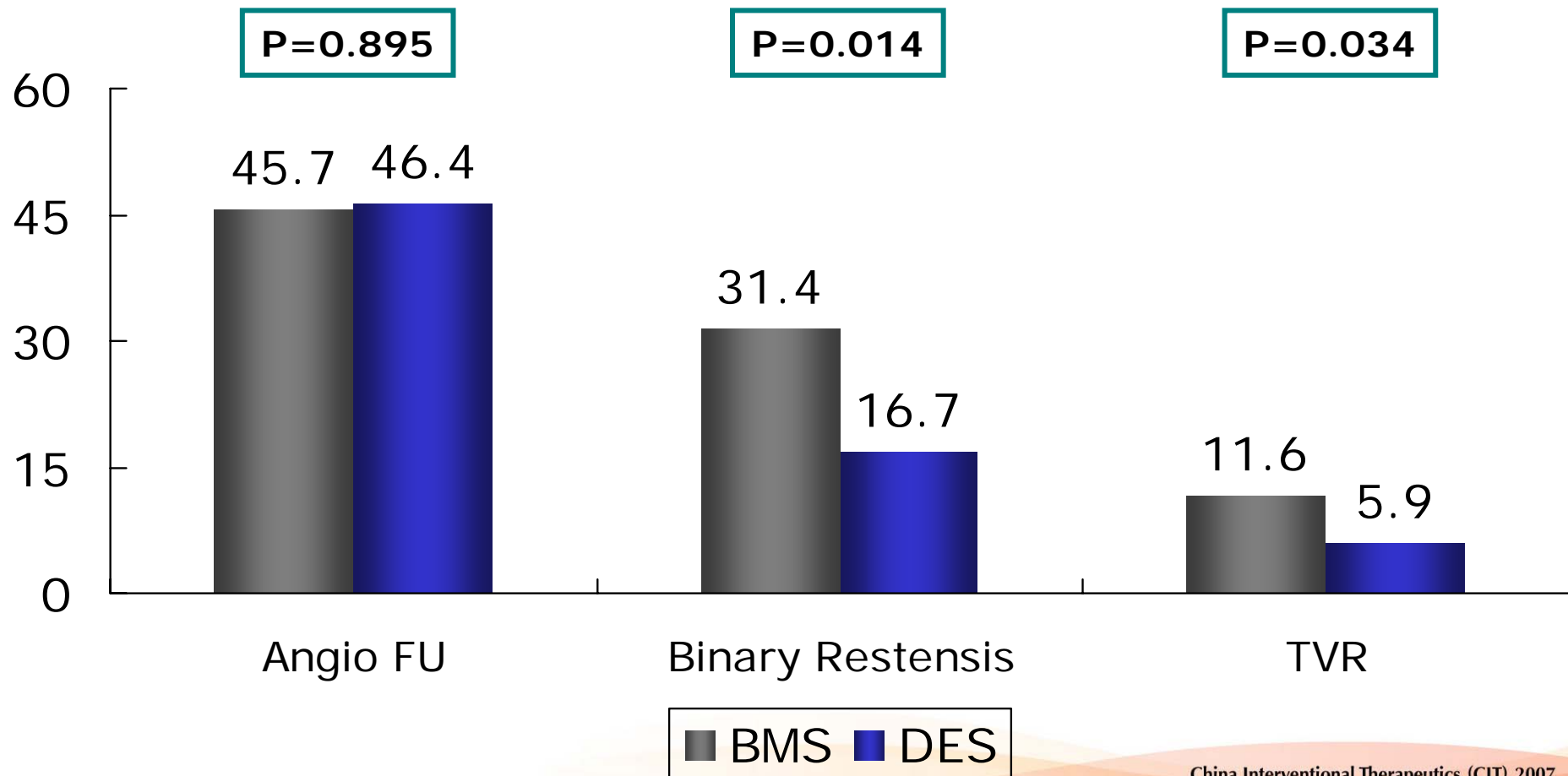
LM Stent Thrombosis Adjudicated Using CYPHER Trials' Definition



LM Stent Thrombosis Adjudicated Using ARC Definition



Overall Restenosis

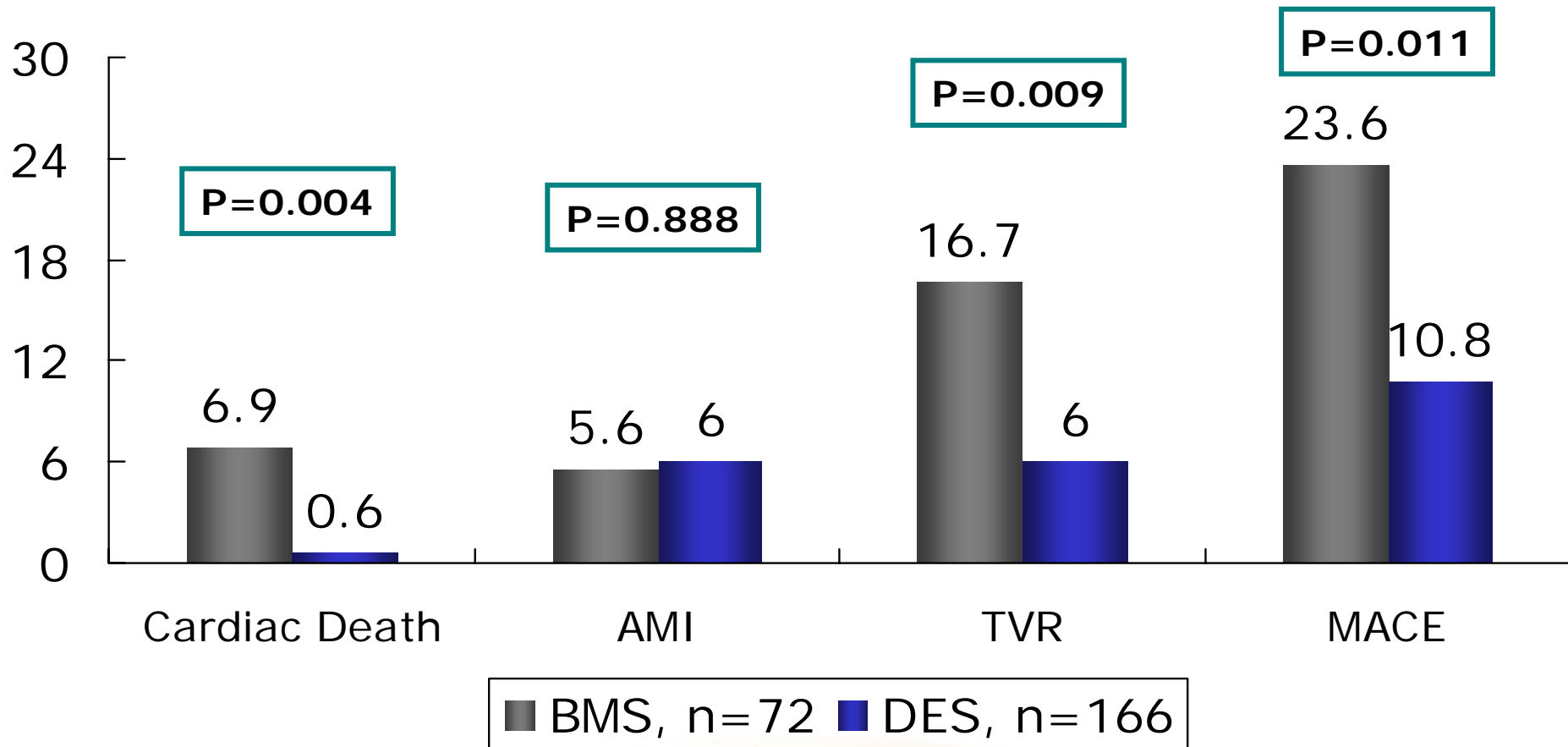


Bifurcation Subgroup Baseline

	BMS (n=72)	DES (n=166)	P-Value
Female, n (%)	11 (15.3)	29 (17.5)	0.678
Age, years	63.0±12.6	60.2±10.8	0.089
Previous MI, n (%)	22 (30.6)	57 (34.3)	0.569
Diabetes mellitus, n (%)	15 (20.8)	40 (24.1)	0.583
Unstable angina, n (%)	55 (76.4)	120 (72.3)	0.869
LVEF, %	61.9±12.1	61.3±7.4	0.701
LM+MVD, n (%)	45 (62.5)	133 (80.1)	<0.001
IVUS guided, n (%)	6 (8.3)	75 (45.2)	<0.001
2-stent strategy used, n (%)	6 (8.3)	68 (41.0)	<0.001
Final kissing balloon, n (%)	17 (23.6)	125 (75.3)	<0.001
Procedure success*, n (%)	65 (90.3)	160 (96.4)	0.057

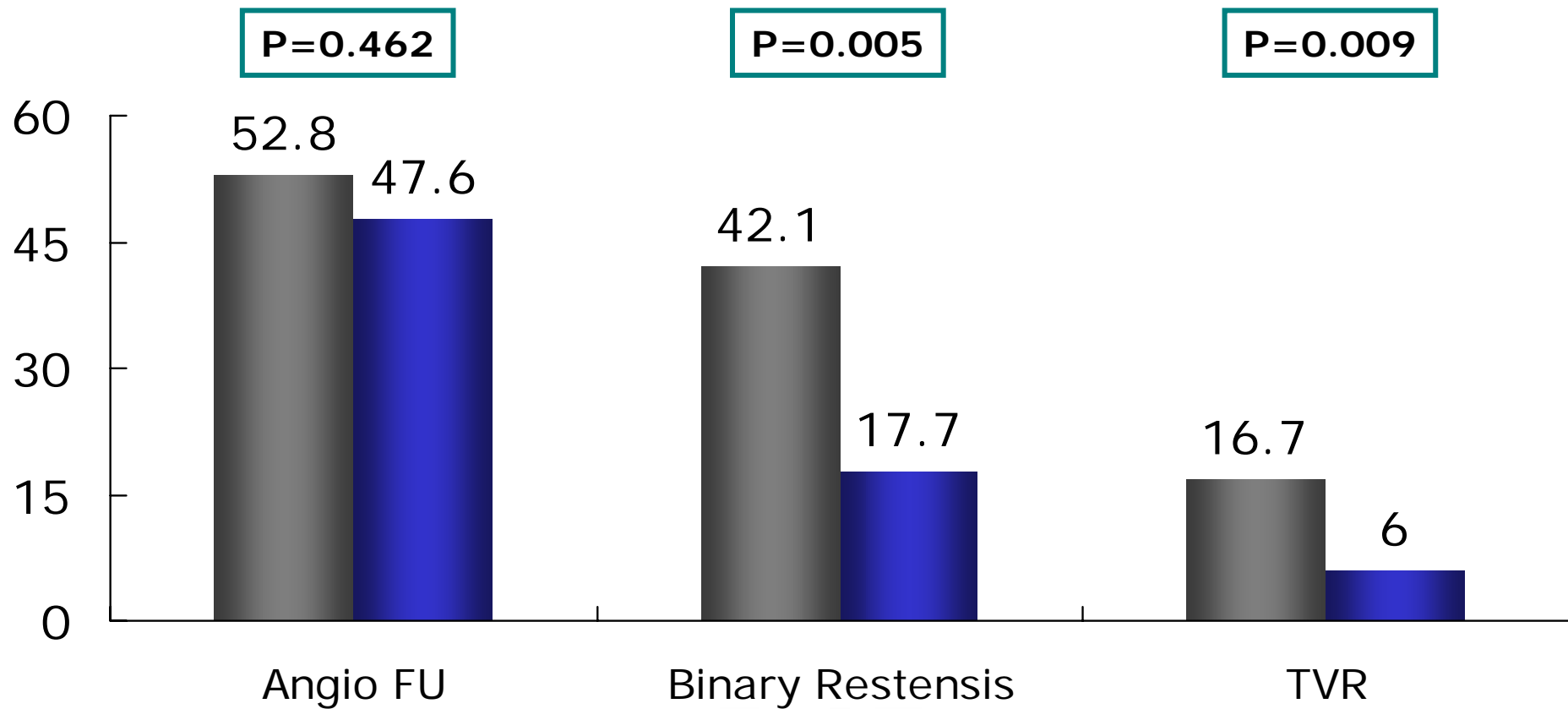
* Defined as complete revascularization in patients with all target lesions

Cumulative Events of Bifur. Subgroup at Follow-up



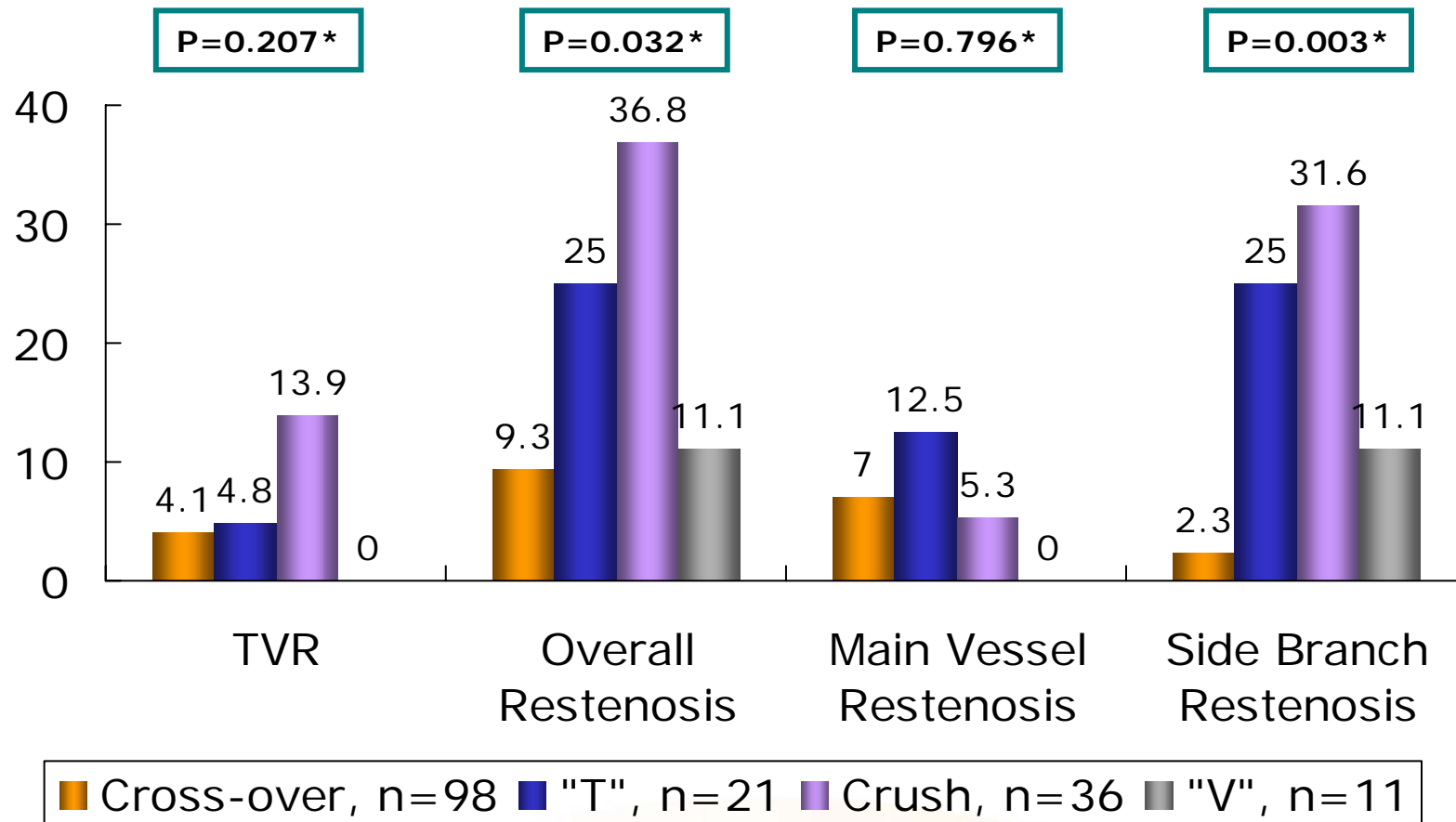
Clinical follow-up rate 100%, mean follow-up duration:
BMS (459 ± 339 days) vs. DES (464 ± 231 days), $p=0.911$

Restenosis in Bifur. Subgroup



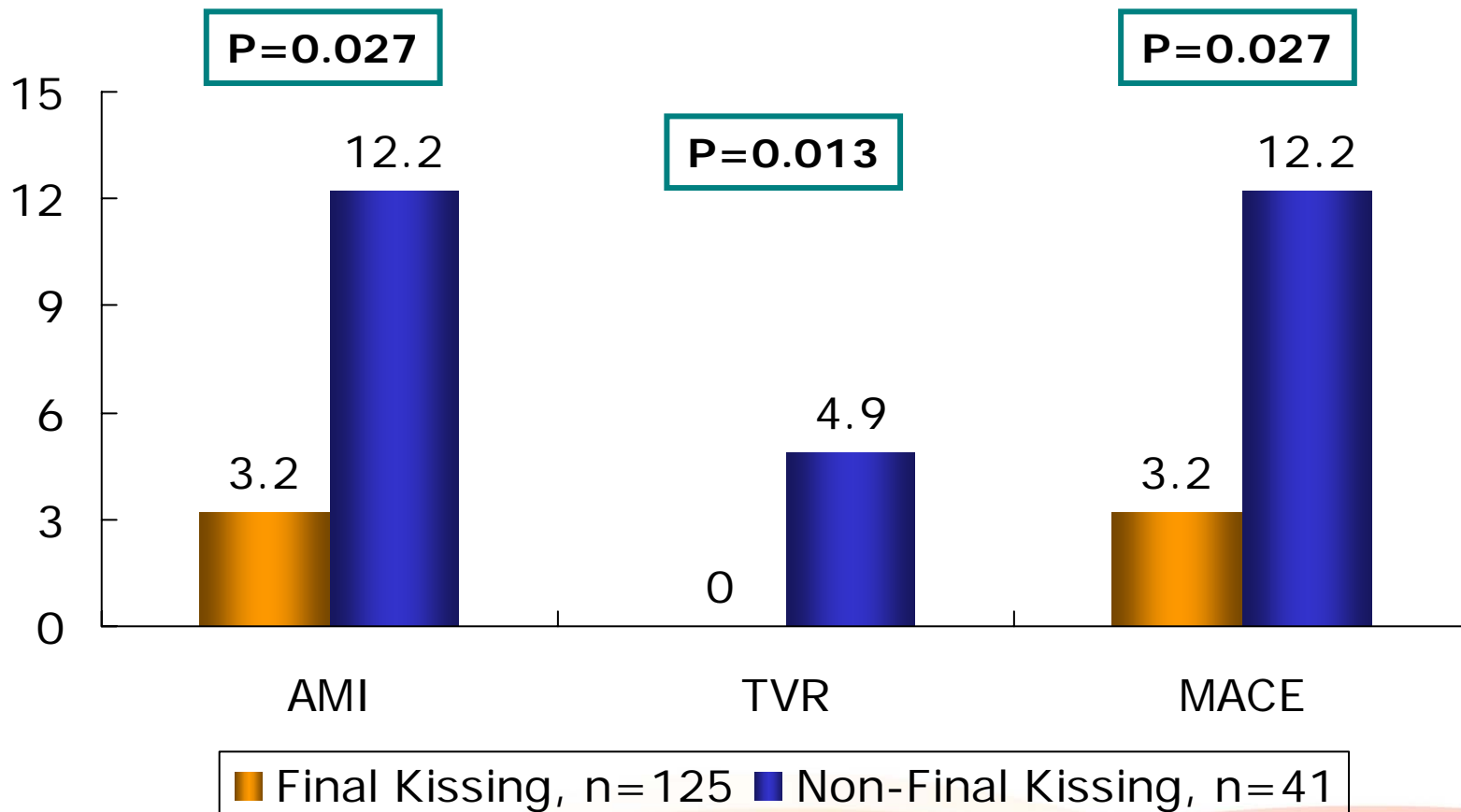
■ BMS ■ DES

Restenosis in Bifur. Subgroup in DES Era

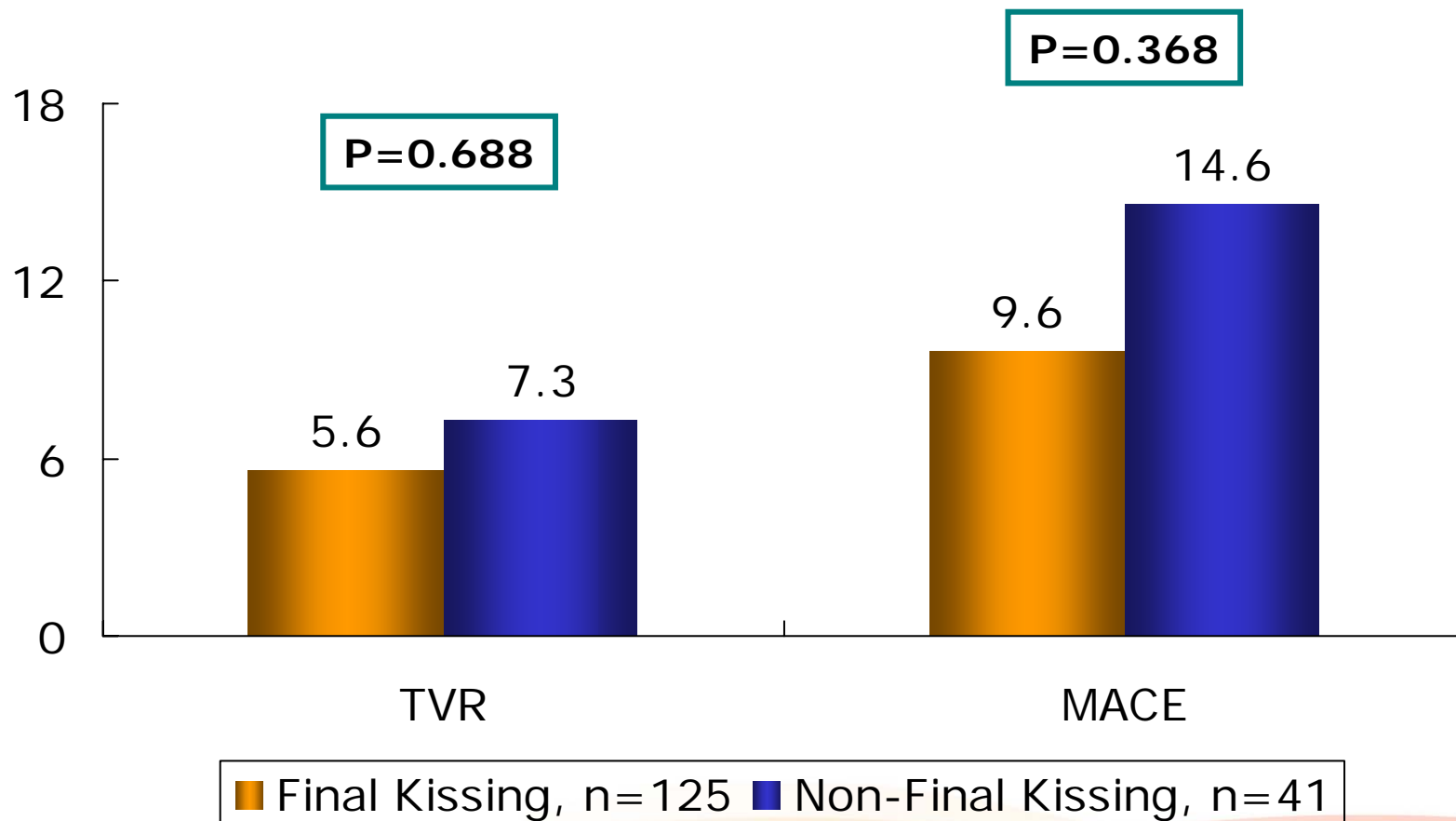


*Comparing Cross-over with complex strategy total

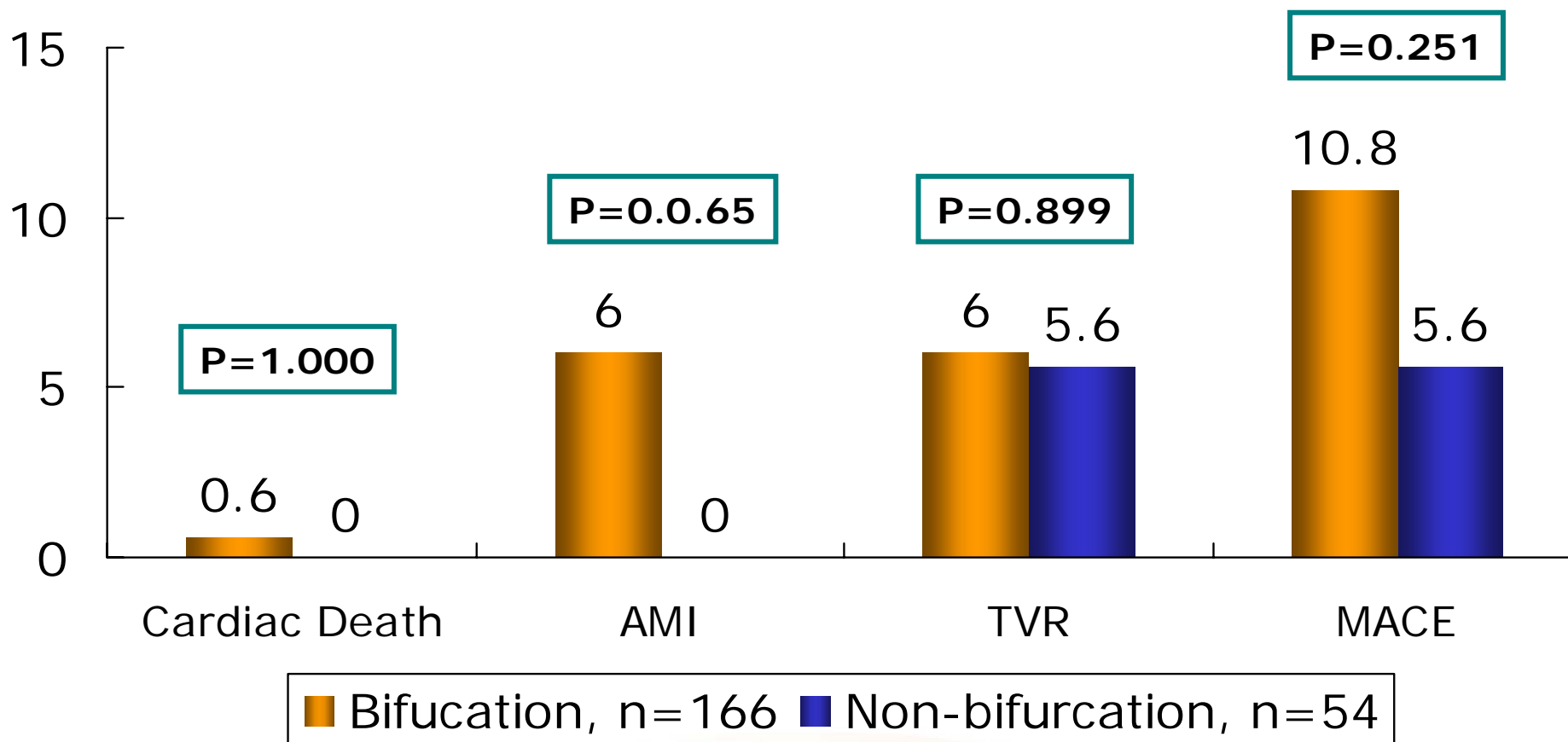
Final Kissing Impact on In-Hospital MACE in DES Era



Final Kissing Impact on Long-term Outcome in DES Era

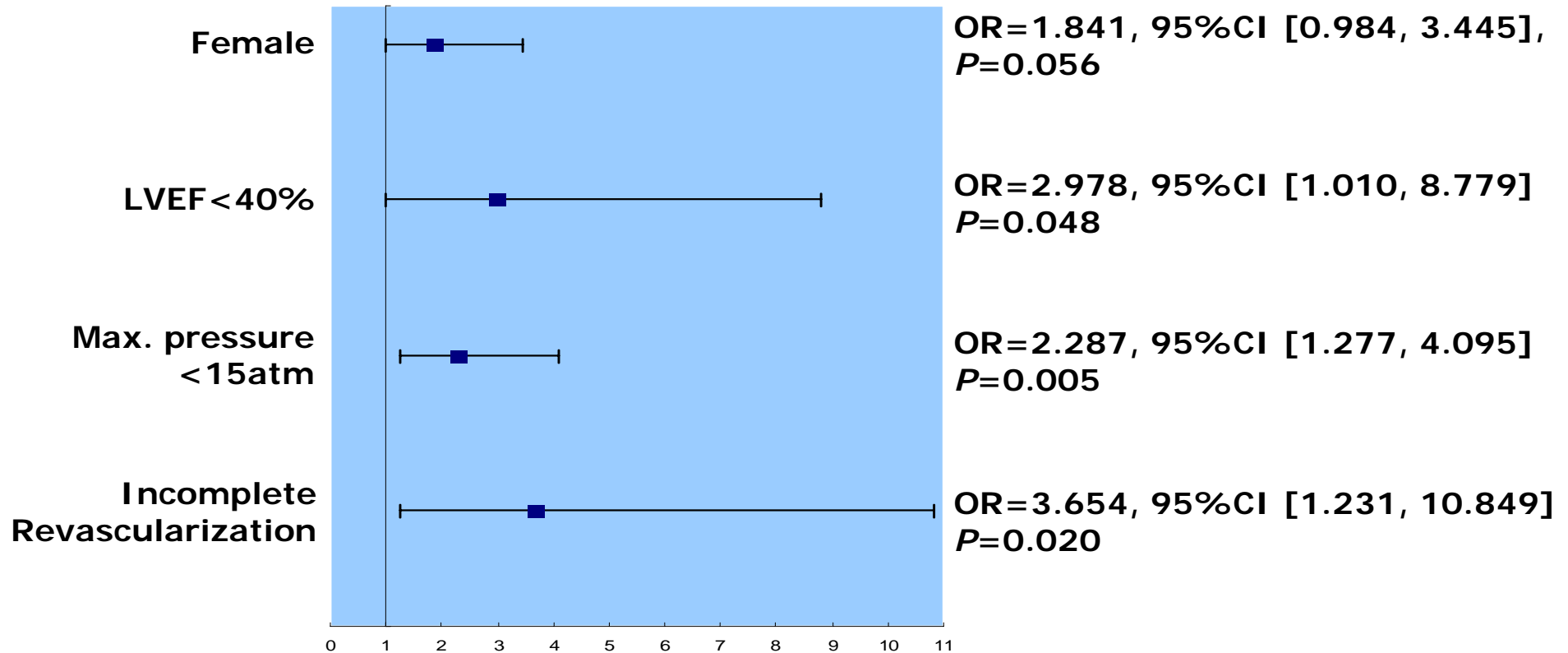


Comparison of Cumulative MACE between Bifurcation and Non-bifurcation Cases in DES Stenting



Clinical follow-up rate 100%, mean follow-up duration:
Bifur. (464 ± 231 days) vs. Non-Bifur. (459 ± 256 days), $p=0.893$

Predictors of MACE by Logistic Regression



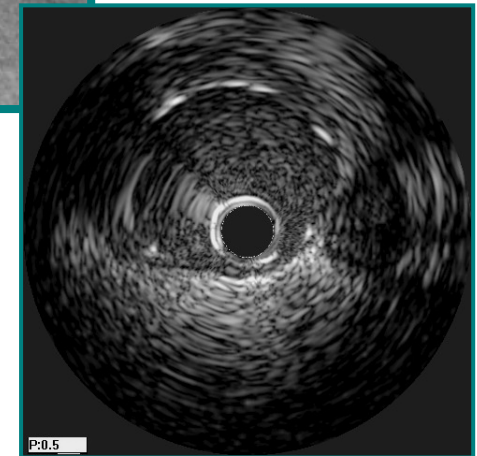
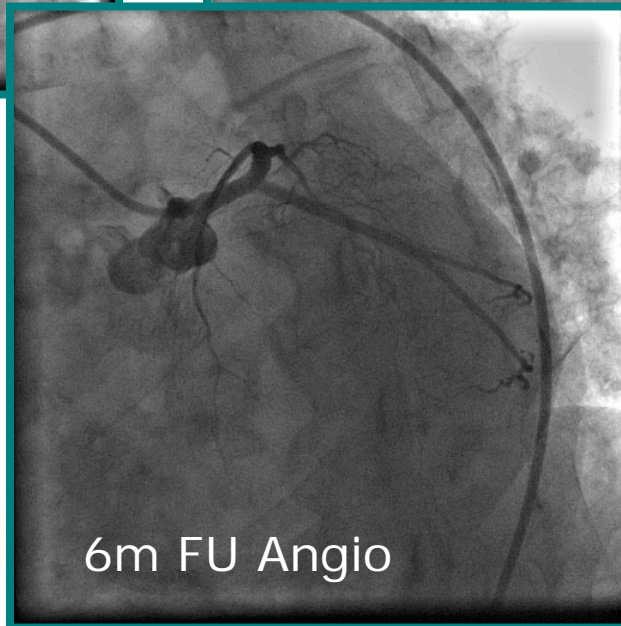
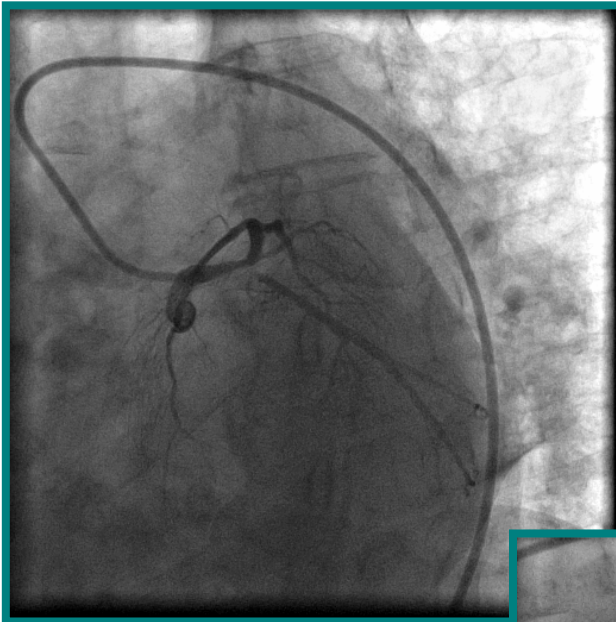
Univariable test ($p < 0.1$): LM BMS use ($p = 0.029$), female gender ($p = 0.051$), low LVEF ($p = 0.009$), LM pre-procedure %DS by visual estimate ($p = 0.043$), low LM stenting maximal pressure ($p = 0.003$), no LM post-dilatation ($p = 0.028$) and incomplete revascularization ($p = 0.006$) were enrolled.

SES vs. PES

	SES (n=127)	PES (n=93)	P-Value
Cardiac death, n (%)	1 (0.8)	0 (0)	1.000*
AMI, n (%)	8 (6.3)	2 (2.2)	0.144
TVR, n (%)	6 (4.7)	7 (7.5)	0.384
MACE, n (%)	12 (9.4)	9 (9.7)	0.955
Angiographic FU, n (%)	60 (47.2)	42 (45.2)	0.760
Binary restenosis, n (%)	7 (11.7)	10 (23.8)	0.105
LM bifurcation, n (%)	108 (85.0)	58 (62.4)	<0.001
TVR, n (%)	6 (5.6)	4 (6.9)	0.729
MACE, n (%)	12 (11.1)	6 (10.3)	0.880
Angio FU, n (%)	56 (51.9)	23 (39.7)	0.134
Binary restenosis, n (%)			
Overall	7 (12.5)	7 (30.4)	0.058
Main vessel	1 (1.8)	4 (17.4)	0.023*
Side branch	6 (10.7)	4 (17.4)	0.417

* Fisher's Exact Test (2 sided)

Case Example



Summary

- In DES era patients with more complex ULM lesion and at higher clinical risk were enrolled, treatment strategy appears to be more “aggressive”
- Long-term follow-up revealed DES is statistically superior to BMS in cardiac death ($p=0.004$), MACE ($p=0.029$), TVR ($p=0.034$) and binary restenosis ($p=0.011$) with acceptable thrombosis rate (0.9%)
- Although treatment strategy for LM bifurcation still need to be optimized, current technique may be feasible
- The predictors of MACE are low LVEF ($OR=2.978$), low pressure at LM stent implantation ($OR=2.287$) and incomplete revascularization for LM combined with MVD ($OR=3.654$)

Conclusion

- **DES stenting could be an alternative therapy for unprotected LMCA disease in carefully selected patients**
- **However, randomized clinical trials with longer follow-up to further evaluate the efficacy and safety of DES stenting versus CABG to treat unprotected LMCA stenosis are needed**



Thank you