



Updated Outcome of Real-World Bifurcation Registry: COBIS Series

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Potential conflicts of interest

I have no conflicts of interest to report related to this presentation

COBIS I & II Registries



Coronary Bifurcation Stenting Registries (COBIS)

	COBIS I	COBIS II
N	1,668	2,897
Procedure period	2004.1~2006.6	2003.1~2009.12
Side branch diameter	≥ 2.0 mm	≥ 2.3 mm (by QCA)
Left main bifurcation	None	29%
2nd generation DES	None	23%
2-stent technique	18%	27%

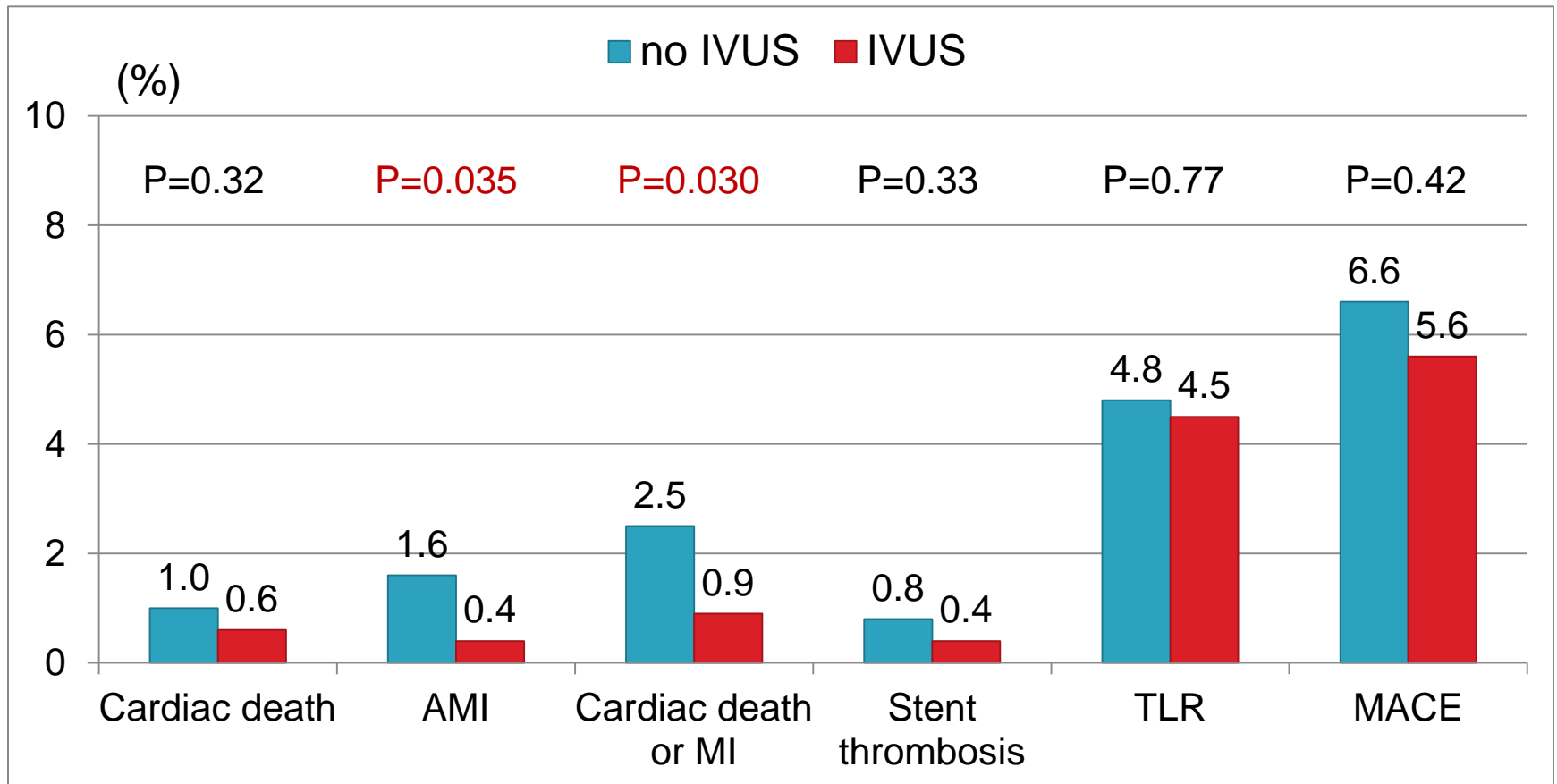
Publications in COBIS I & II Registries

COBIS I	Year	Journal	COBIS II	Year	Journal
Predictors	2010	Circ J	Predictors of SB occlusion	2013	J Am Coll Cardiol
SES vs. PES	2010	J Am Coll Cardiol	Transradial vs. transfemoral	2014	CCI
IVUS guidance	2011	Am Heart J	Left main bifurcation	2014	JACC CVI
SES vs. PES in left main	2011	Clin Cardiol	Medina 001	2014	CCI
Bifurcation angle	2012	Cardiology	2 nd generation DES	2015	JACC CVI
Final kissing ballooning	2012	Heart	Final kissing ballooning	2015	JACC CVI
Acute coronary syndrome	2012	Clin cardiol	True bifurcation	2015	Circ J
1-stent vs. 2-stent	2013	Int J Cardiol	Antiplatelet therapy	2015	Heart Vessel
2-stent techniques	2013	Int J Cardiol	EES vs . SES	2015	Circ J
Peri-procedural MI	2013	Int J Cardiol	NC balloon	2016	Eurointervention
Predilation	2014	Rev Cardiol Esp	SB stenosis	2016	Int J Cardiol
			SB failure	2016	Am J Cardiol
			2-stent strategy	2016	JACC CVI
			2-stent technique	2017	Eurointervention
			Calcification	2017	Eurointervention
			Predilation	2018	Circ J
			Acute coronary syndrome	2018	CCI
			ST elevation MI	2018	Rev Cardiol Esp

29 papers were published so far

COBIS Registry

IVUS guidance may improve safety

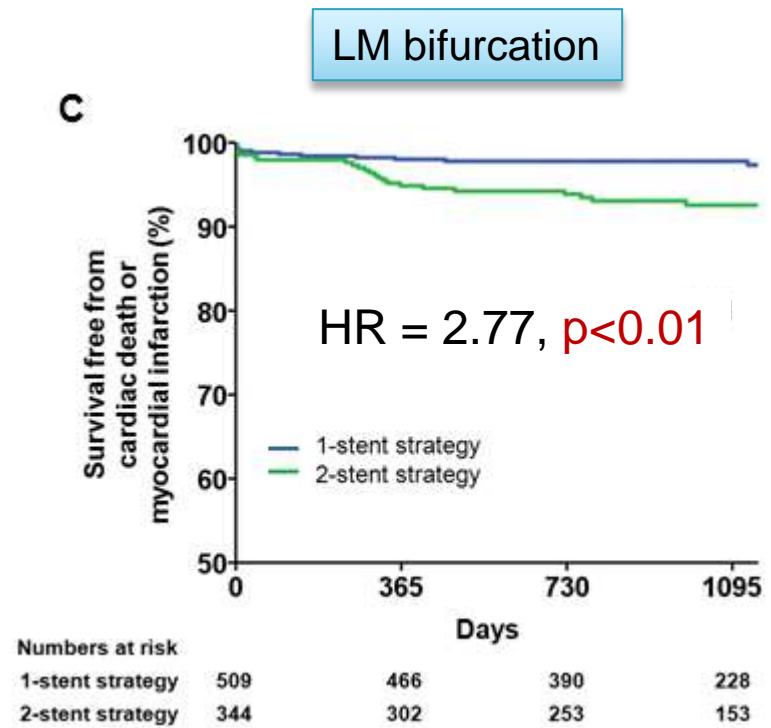
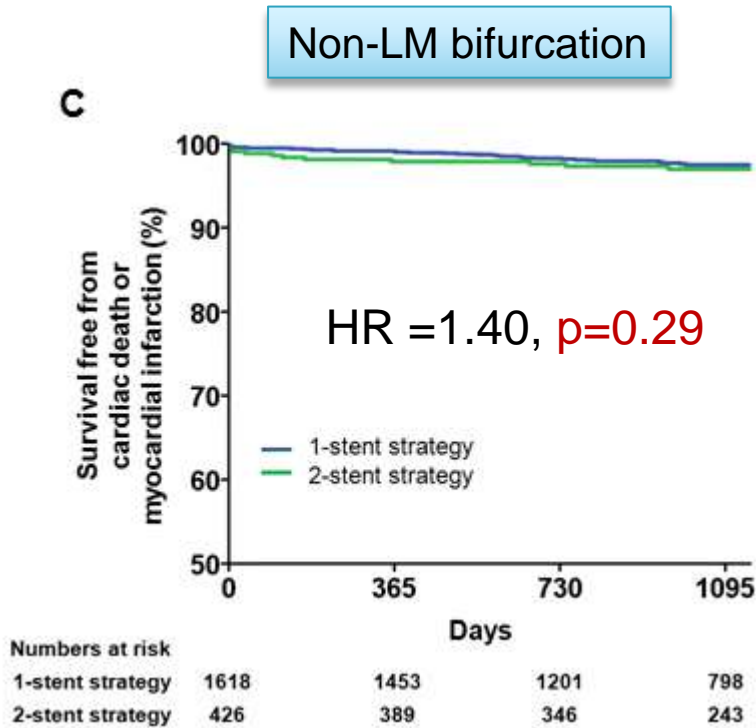


IVUS guidance improves the safety of bifurcation stenting, most likely by better stent apposition and expansion

COBIS II Registry

1-stent vs 2-stent in LM vs. non-LM bifurcation

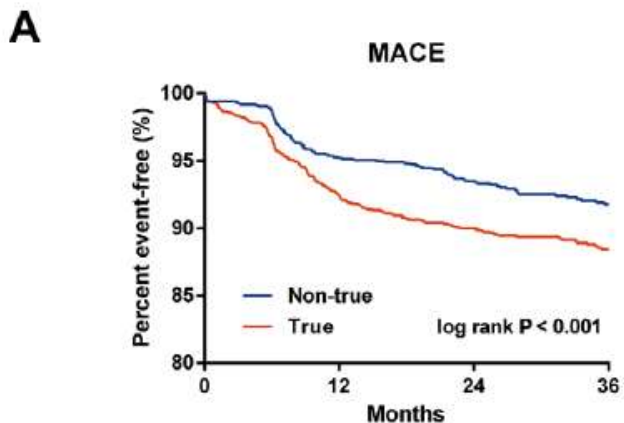
▶ Cardiac death or MI



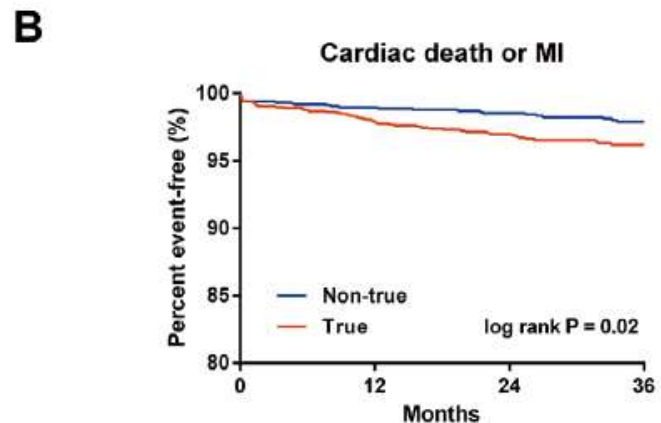
Hazard ratio was calculated by a weighted Cox proportional hazards model using inverse-probability-of-treatment weighting (IPTW) including all clinical, angiographic, and procedural variables.

COBIS II Registry

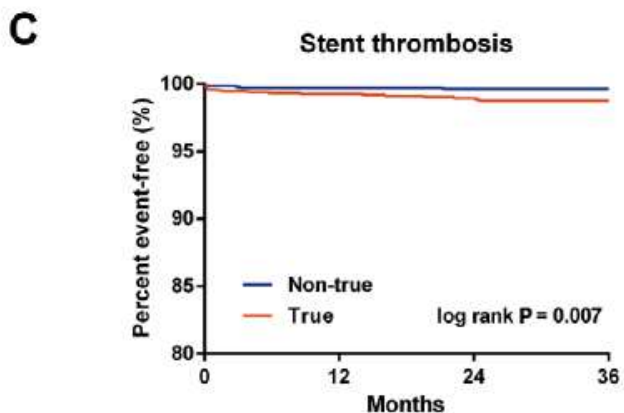
True bifurcation (Medina 111, 101, 011)



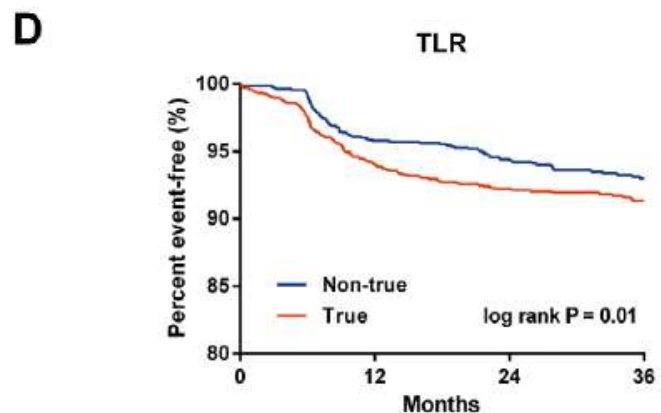
Number at risk				
Non-true	1395	1229	1026	675
True	1502	1264	1045	681



Number at risk				
Non-true	1395	1275	1080	710
True	1502	1340	1128	741



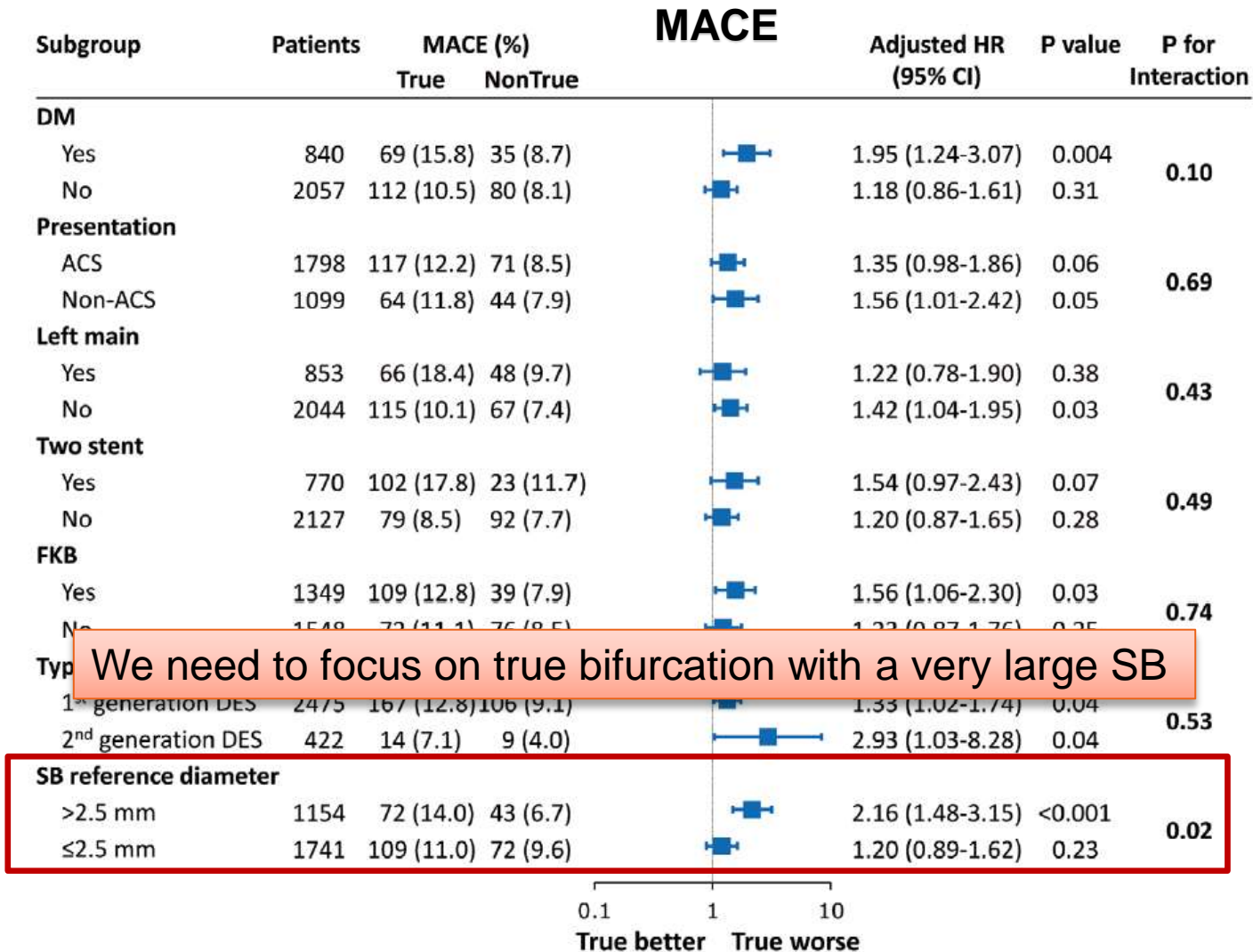
Number at risk				
Non-true	1395	1280	1086	719
True	1502	1350	1137	751



Number at risk				
Non-true	1395	1231	1030	679
True	1502	1274	1054	692

COBIS II Registry

True bifurcation (Medina 111, 101, 011)



We need to focus on true bifurcation with a very large SB

SB reference diameter

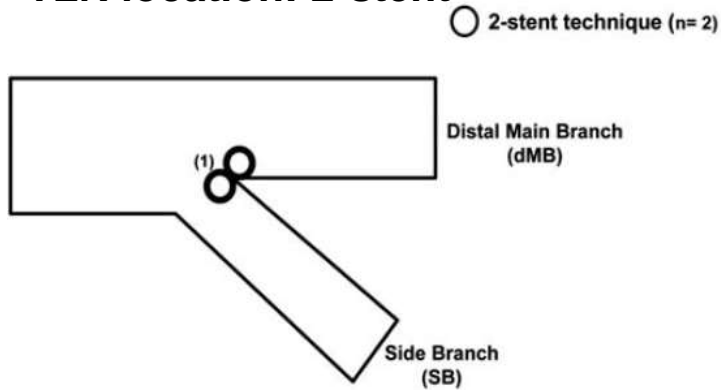
COBIS II Registry

Medina 0,0,1 bifurcation lesion

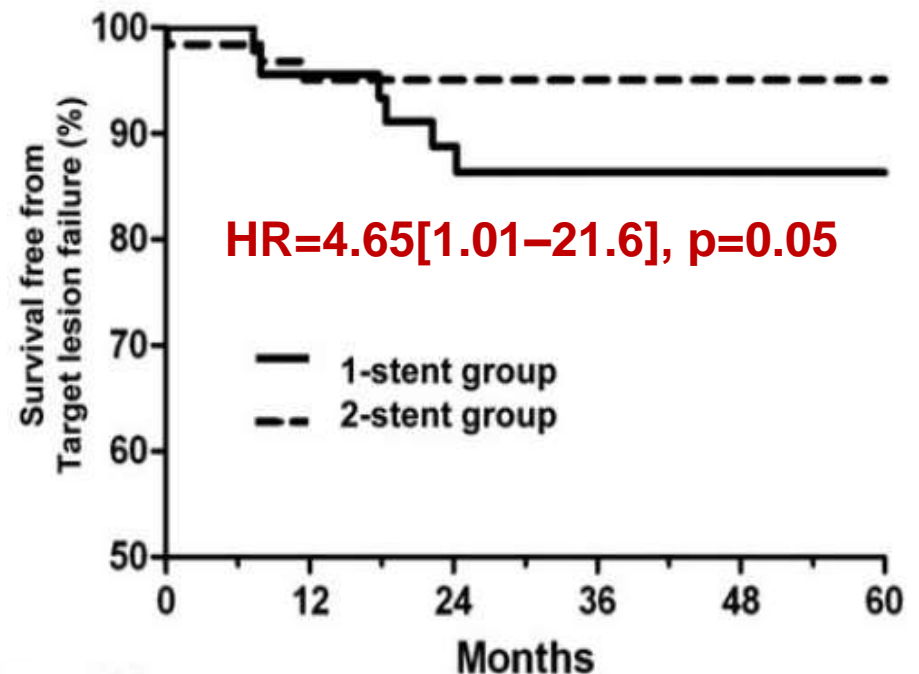
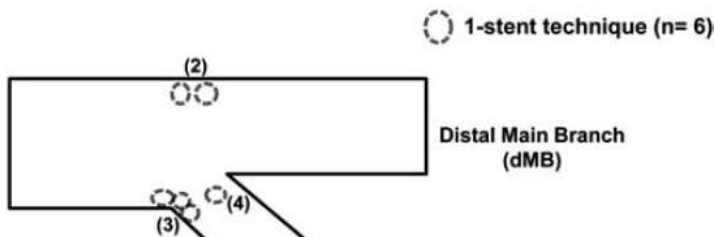


▶ N=113, with Medina 0,0,1 bifurcation lesion

TLR location: 2-stent



TLR location: 1-stent



Two-stent technique may be better than 1-stent technique, particularly when main vessel is diseased.

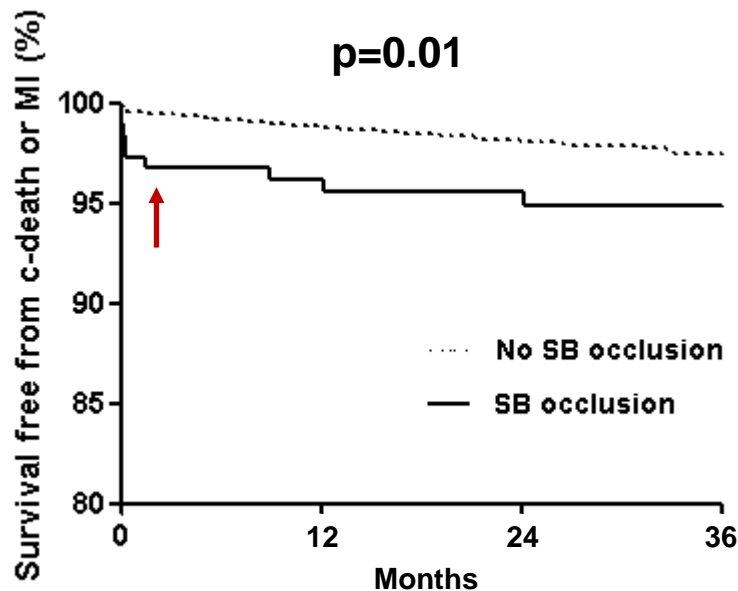
COBIS II Registry

Clinical impact of SB occlusion



- ▶ Main vessel first stenting strategy: N=2,227
- ▶ SB occlusion after MV stenting (TIMI flow <3): N=187, 8.4%

Cardiac Death / MI



SB occlusion	187	163	128	83
No SB occlusion	2040	1851	1542	991

Predictors of SB occlusion

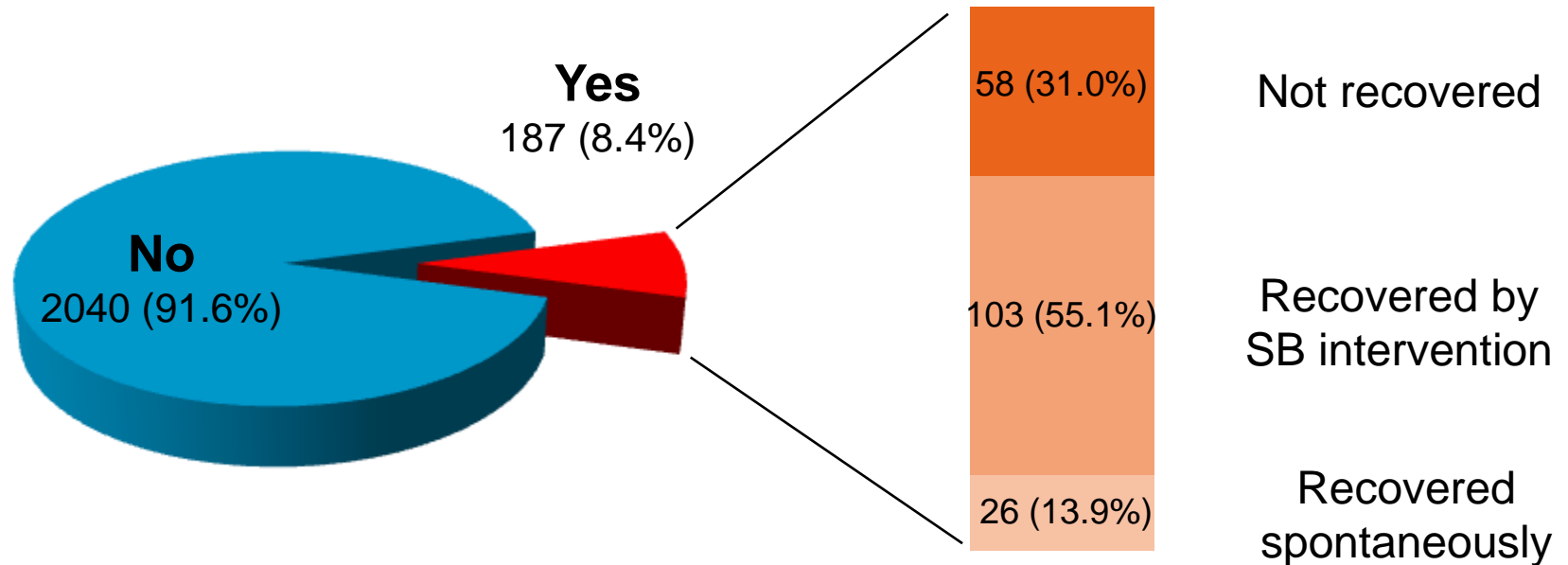
Variables	OR [95% CI]	p Value
SB DS \geq 50%	2.34 [1.59-3.43]	<0.001
SB lesion length (by 1 mm)	1.03 [1.003-1.06]	<0.001
Left main lesions	0.34 [0.16-0.72]	0.005
Proximal MV DS \geq 50%	2.34 [1.57-3.50]	0.03
Acute coronary syndrome	1.53 [1.06-2.19]	0.02

ACS = acute coronary syndrome, DS = diameter stenosis, SB = side branch, MV = main vessel

Important non-predictors:
jailed wire technique, SB pre-dilation, IVUS guidance

COBIS II Registry

Fate of Occluded SB after MV stenting



Jailed wire in the SB was associated with flow recovery (74.8% versus 57.8%, $p = 0.02$).

FKB and POT

Final kissing ballooning in 1-stent technique



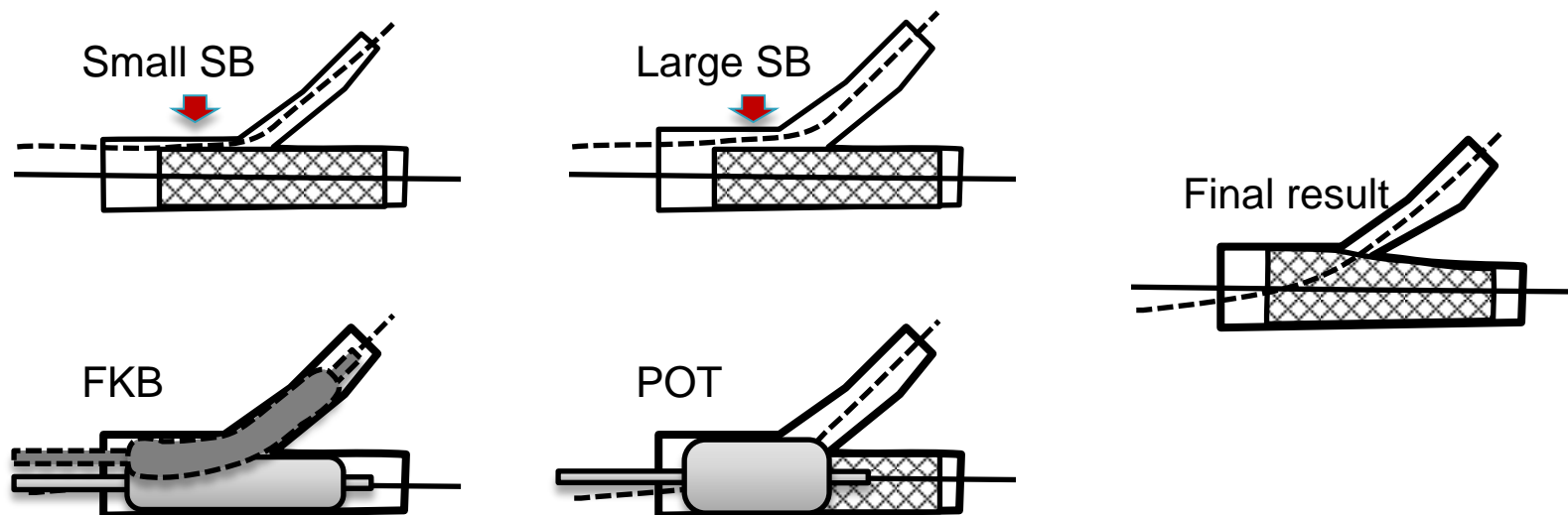
	Number Design	Primary endpoint	Outcomes	Results	Memo
Niemela M (NORDIC III) Circulation 2011	N=477 RCT	6-mo MACE	FKB 2.9%, non-FKB 2.9% P=NS	Neutral	
Gwon HC (COBIS I) Heart 2012	N=1,065 Registry	2-year MACE	FKB 9.5%, non-FKB 4.5% p=0.02	Worse	Higher MV TLR In FKB group
Yamawaki M Circ J 2014	N=253 Registry	3-year MACE	FKB 14.6% vs. non-FKB 6.9% p=0.07	Worse	Higher MV restenosis in FKB-group
Kim TH Int J Cardiol 2014	N=251 Registry	3-year MACE	FKB HR=0.40 (95% CI 0.19–0.84), p=0.015	Better	ACS patients
Biondi-Zoccai G Heart Vessels 2014	N=2,813 Registry	2-year MACE	HR=1.01 (0.80–1.23) p=0.91	Neutral	
Gao Z Chin Med J 2015	N=790 Registry	4-year MACE	FKB: 7.8%, non-FKB 10.0% p=0.33	Neutral	Left main bifurcation
Kim YH (CROSS) JACC CVI 2015	N=306 RCT	1-year MACE	FKB 14.0%, non-FKB 11.6% p=0.57	Worse	Higher MV restenosis in FKB group
Yu CW (COBIS II) JACC CVI 2015	N=1,901 Registry	3-year MACE	HR=0.50 (95% CI: 0.30-0.85), p = 0.01	Better	Lower MV TLR in FKB group

FKB vs. non-FKB in COBIS I and COBIS II

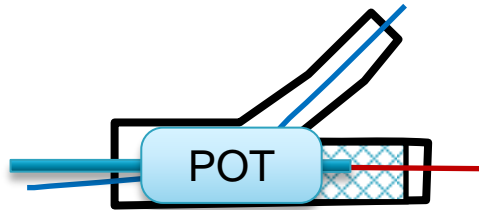
	COBIS I			COBIS II		
	FKB	No FKB	p-value	FKB	No FKB	p-value
Included case	1,065			1,901		
Inclusion	SB \geq 2.0 mm			SB \geq 2.3 mm (QCA-confirmed)		
LM bifurcation	Excluded			Included		
MACE (%)	9.5	4.5	0.02	6.8	9.7	0.02
TLR MV (%)	8.6	3.4	0.004	5.7	7.3	0.04
TLR SB (%)	1.8	0.0	-	2.2	3.3	0.21
MV proximal MLD (mm)	2.8 \pm 0.5	2.7 \pm 0.5	0.001	3.3 \pm 0.6	3.0 \pm 0.6	<0.001
MV distal MLD (mm)	2.5 \pm 0.5	2.5 \pm 0.5	0.39	2.8 \pm 0.5	2.7 \pm 0.6	0.04
SB os MLD (mm)	1.4 \pm 0.4	1.0 \pm 0.5	<0.001	1.9 \pm 0.6	1.4 \pm 0.7	<0.001
SB distal MLD (mm)	1.7 \pm 0.5	1.5 \pm 0.6	<0.001	2.2 \pm 0.6	2.0 \pm 0.7	0.04

FKB is more beneficial for the bifurcation lesion with a large SB

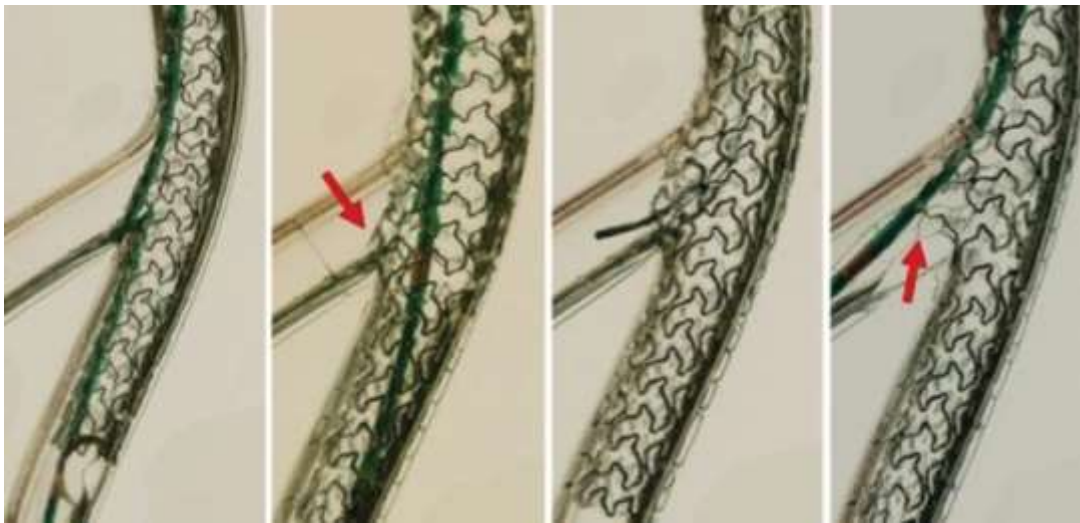
- ▶ Because the size discrepancy between proximal and distal MV is larger, where the optimal expansion of MV stent is more important.



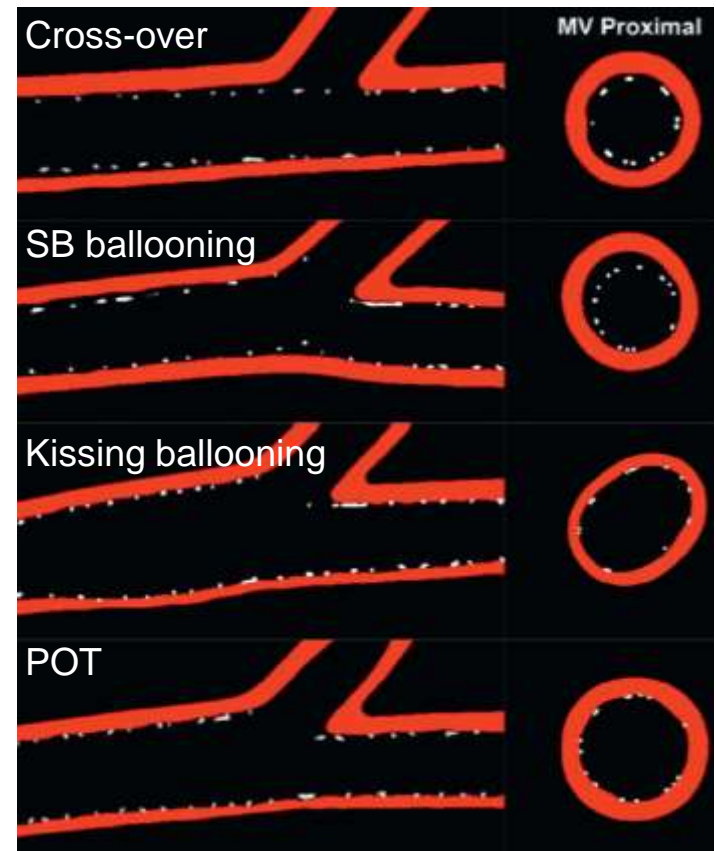
Proximal optimization technique (POT)



It also improves a proximal MV stent apposition and eccentricity



The POT is performed by postdilating the MV stent just proximal to the carina, with a short NC balloon sized for the proximal MV reference diameter.



COBIS II POT Study

Clinical outcomes



- Patients with **SB diameter ≥ 2.5 mm in core-lab QCA (N=1,191)**
- Propensity score-matching population

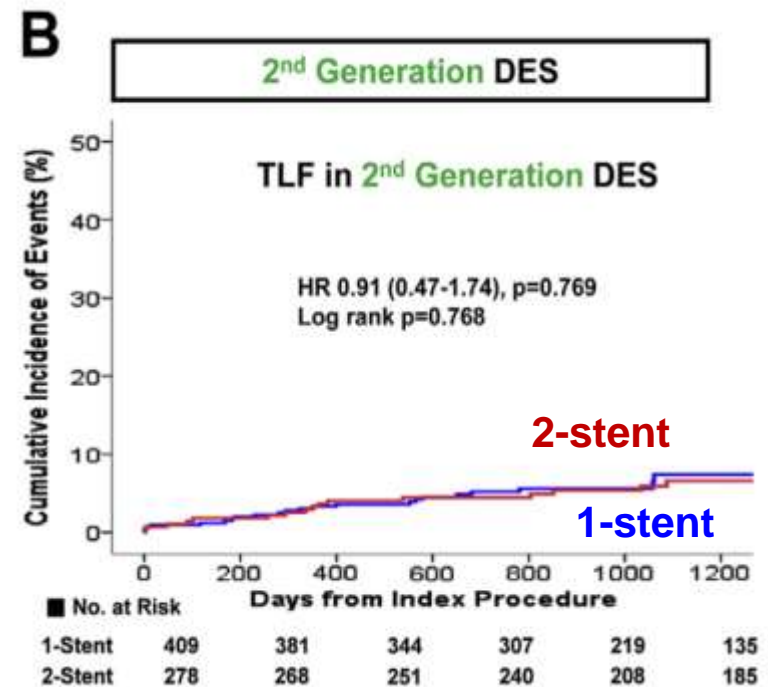
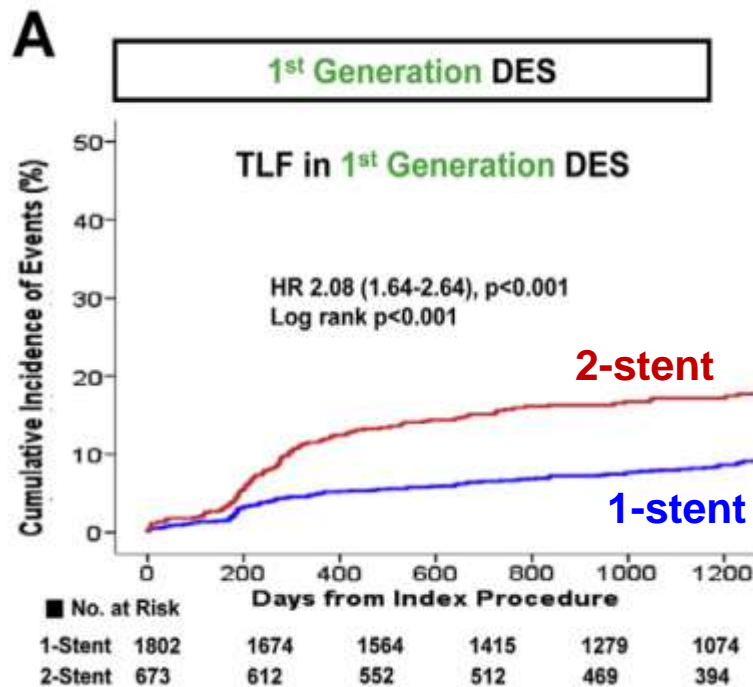
	POT (n=204)	No POT (n=665)	HR (95% CI)	p value
MACE	6 (2.9)	78 (11.7)	0.25 (0.11-0.60)	0.002
All-cause death	7 (3.4)	25 (3.8)	0.97 (0.41-2.33)	0.95
Cardiac death	1 (0.5)	9 (1.4)	0.37 (0.05-2.97)	0.35
Myocardial infarction	0	12 (1.8)	-	-
Stent thrombosis	2 (1.0)	8 (1.2)	0.98 (0.20-4.77)	0.98
TLR	5 (2.5)	61 (9.2)	0.27 (0.10-0.69)	0.006
MV, proximal	3 (1.5)	40 (6.0)	0.25 (0.07-0.82)	0.02
MV, distal	4 (2.0)	47 (7.1)	0.28 (0.10-0.80)	0.02
SB	4 (2.0)	35 (5.3)	0.37 (0.13-1.09)	0.07
Both vessels	5 (2.5)	48 (7.2)	0.34 (0.13-0.88)	0.03

The limitations of COBIS II registry

- ▶ Too many papers from one Korean registry?
- ▶ 2nd generation DES only in 24% of patients.

Impact of 2nd generation DES

- ▶ 2,897 patients from COBIS II, 265 patients from EXCELLENT registry and RESOLUTE-Korea registry



COBIS III registry

- ▶ Design and inclusion criteria
 - Same as that of COBIS II registry
- ▶ Steered and sponsored by Korean Bifurcation Club
- ▶ All 2nd generation DES in 2010.1 ~ 2014.12
 - 6,000 patients were enrolled, so far
- ▶ QCA analysis is underway.

Thank you for your attention

