Three-Year Clinical Outcomes of SMART-STRATEGY-Randomized Trial

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Disclosure

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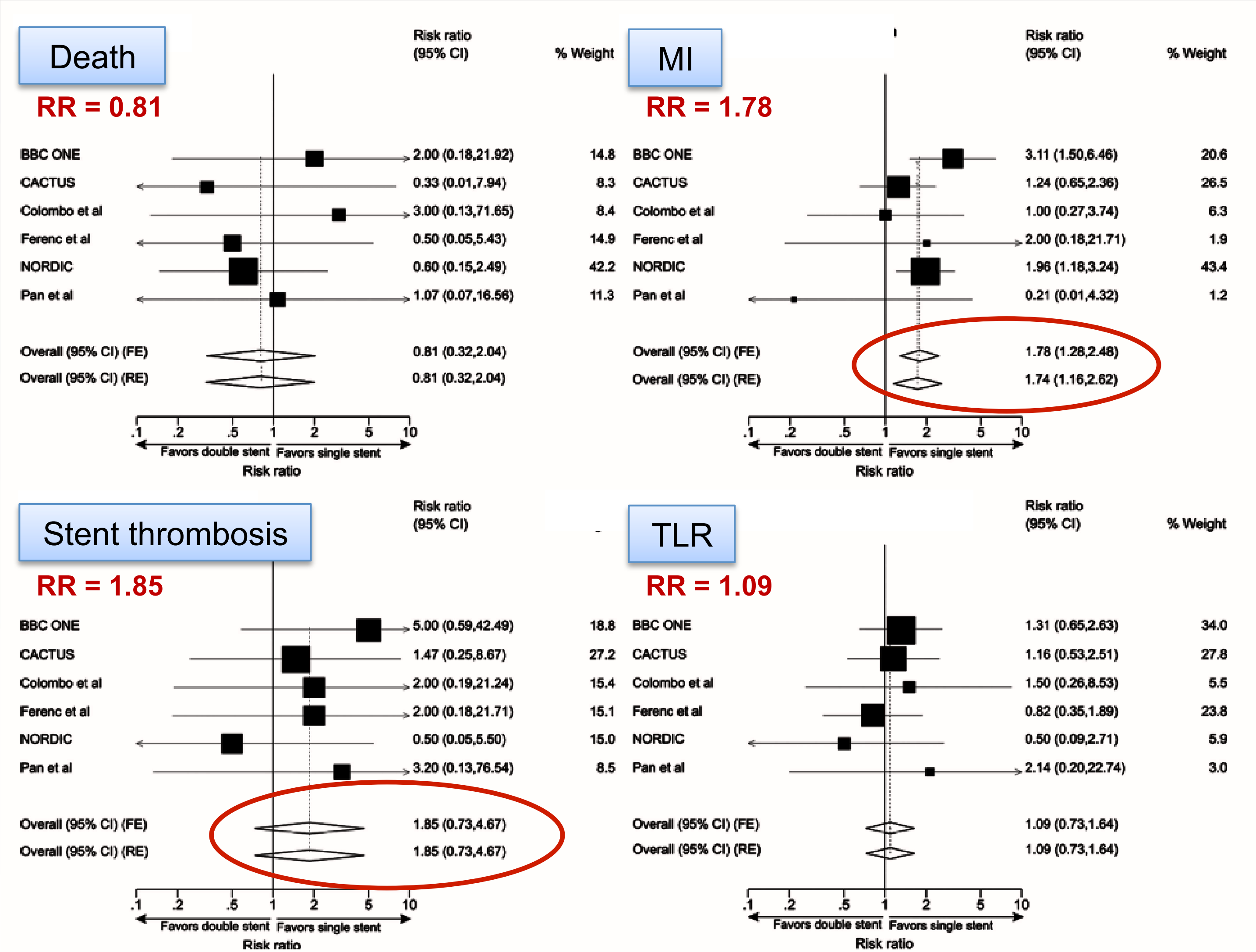
Two-stent may increase the risk of MI and stent thrombosis

- Meta-analysis
- N=1,642

BBC ONE
CACTUS
Colombo et al
Ferenc et al
NORDIC
Pan et al



Katritsis DG, Circ Cardiovasc Interv 2009

The next important issue is …

the optimal indication of side branch (SB) treatment in the provisional approach

	Ix of SB Stenting In 1-stent group	SB stenting % in 1-stent group
SIRIUS Bifurcation	Residual stenosis > 50%	52%
CACTUS	TIMI < 3 Residual stenosis > 50% SB dissection > type B	31%
NORDIC	TIMI 0 after ballooning	4.3%
BBC-ONE	TIMI < 3 Residual stenosis > 70% Threatened SB closure SB dissection > type A	1.4%

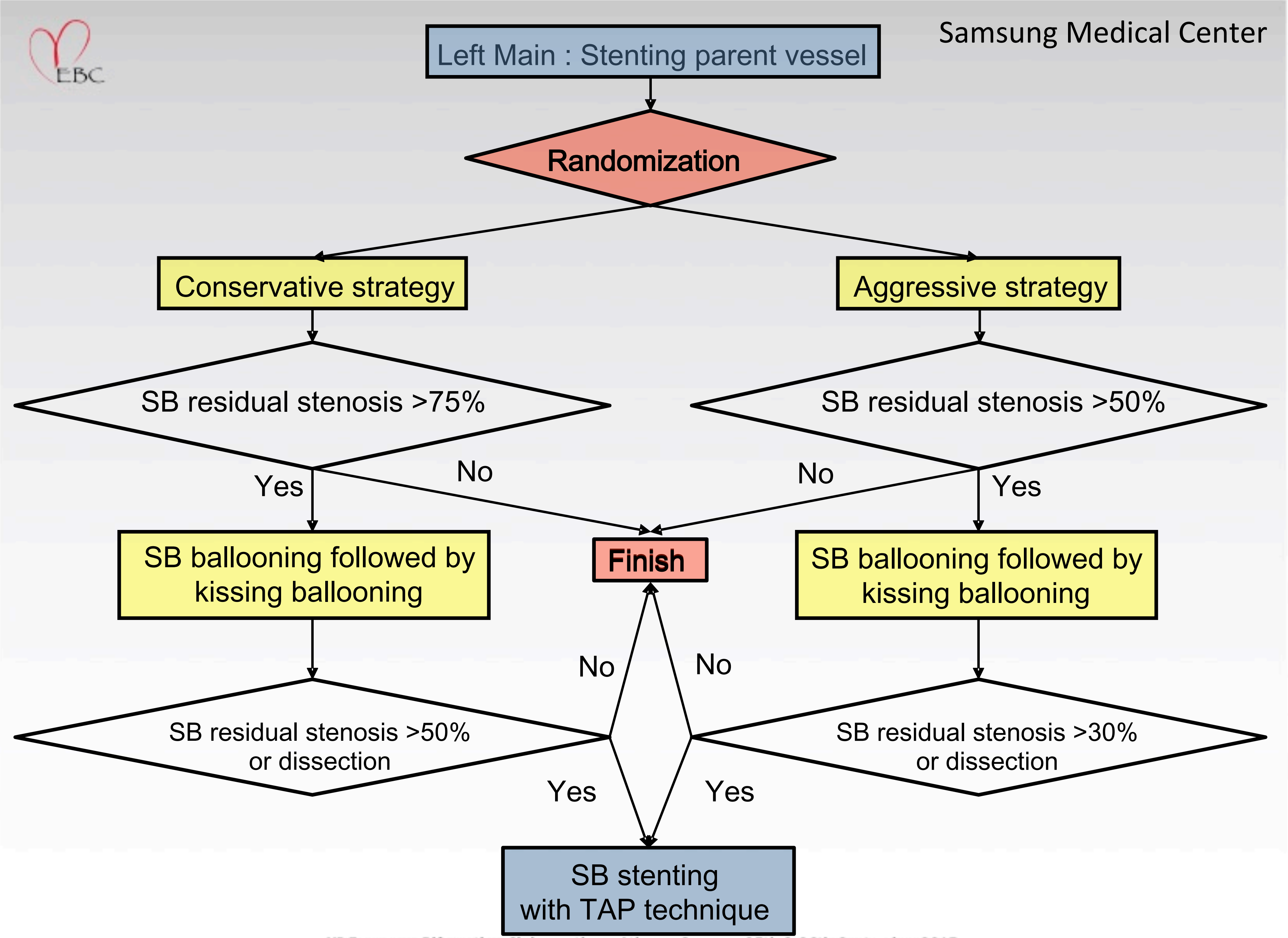
SMART-STRATEGY trial

SMart Angioplasty Research Team - Optimal STRATEGY for Provisio nal Side Branch Intervention in Coronary Bifurcation Lesions

- **Objective**
  - To determine the optimal indications for SB ballooning an d/or stenting in the provisional approach
- **Design**
  - Prospective, randomized, open-label, single-center study comparing conservative vs. aggressive strategy for SB tr eatment

Study Subjects

- **Inclusion criteria**
  - Elective coronary intervention for a de novo coronary bifurcation lesion, including unprotected LM
  - MV diameter ≥ 2.5 mm and SB diameter ≥ 2.3 mm by visual estimation.
- **Exclusion criteria**
  - Hemodynamic instability
  - LVEF <25%
  - Primary PCI for ST-elevation MI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Left Main : Stenting parent vessel
Randomization
Conservative strategy
Aggressive strategy
SB residual stenosis >75%
SB residual stenosis >50%
Yes
No
No
Yes
SB ballooning followed by kissing ballooning
Finish
SB ballooning followed by kissing ballooning
No
No
SB residual stenosis >50% or dissection
SB residual stenosis >30% or dissection
Yes
Yes
SB stenting with TAP technique

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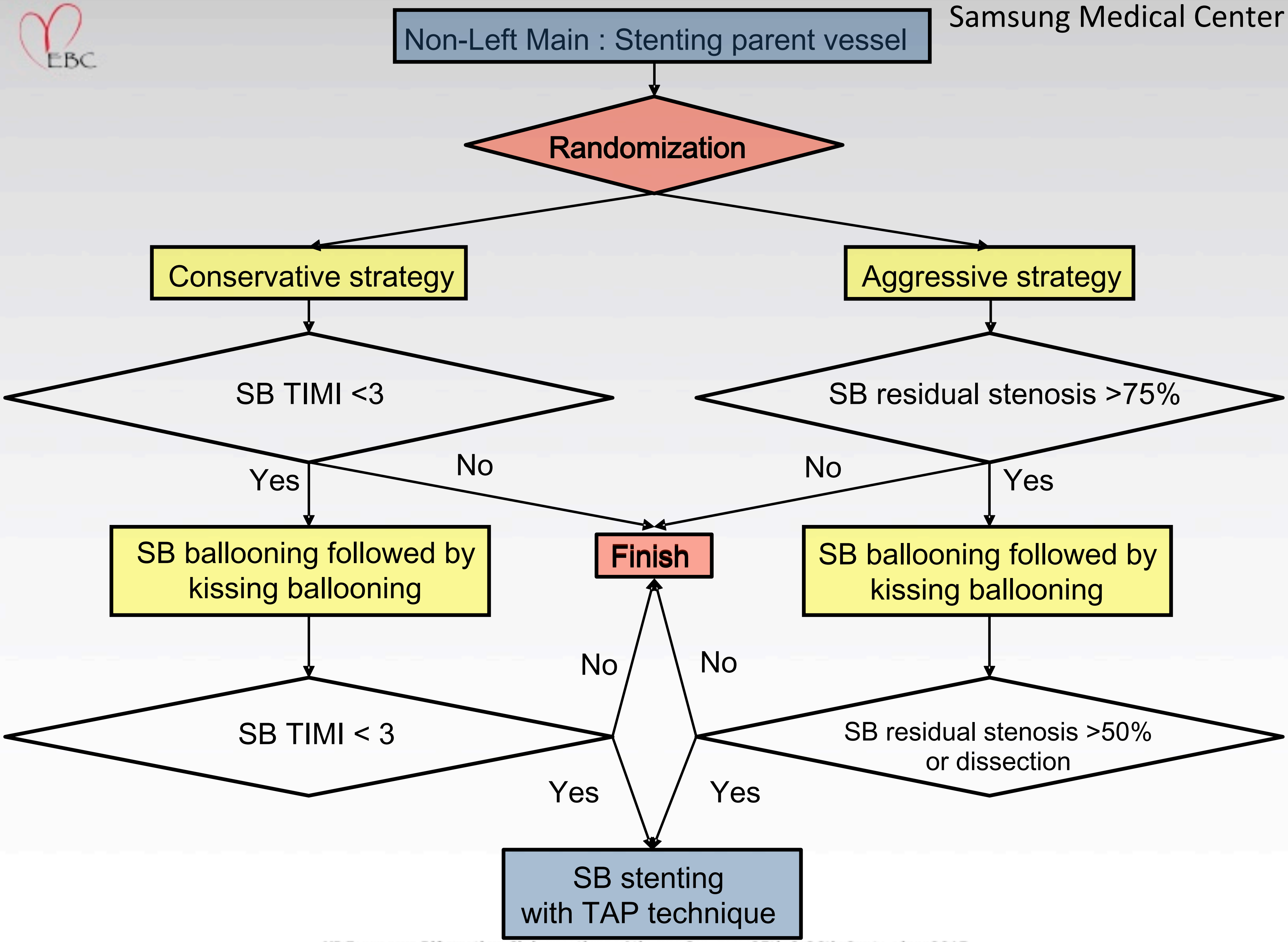

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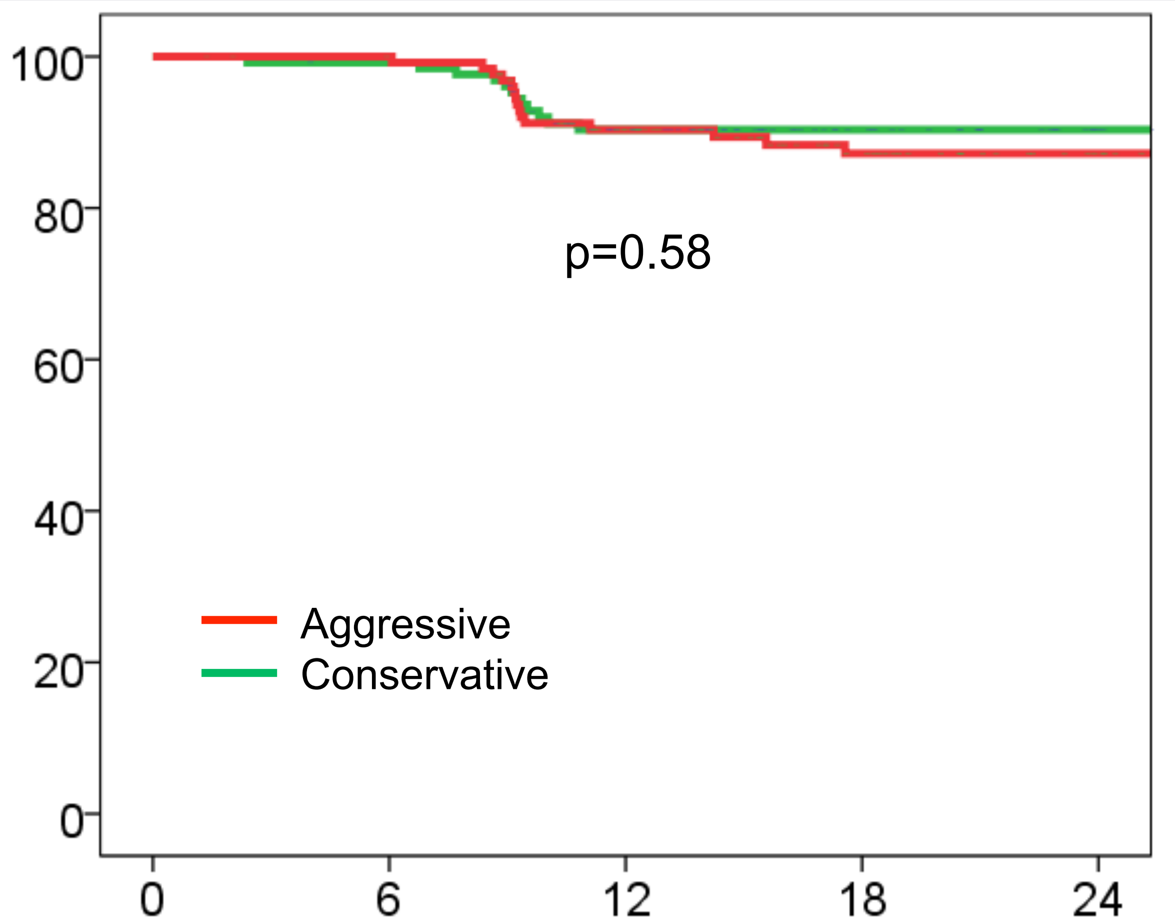
TVF-free Survival at 1 year

Median FU 23.9 [15.3-37.5] months



Song YB, Hahn JY, HC Gwon et al. J Am Coll Cardiol Intv 2012.

Three year follow-up study

- There has been paucity of long-term data on com parison between aggressive versus conservative strategy in bifurcation lesions.

- **Primary endpoint**
  - 36-month target vessel failure (TVF)
    - A composite of cardiac death, spontaneous myocardial infa rction, or target vessel revascularization

Baseline Clinical Characteristics

N=258	Conservative (n=128)	Aggressive (n=130)	p Value
Age (years)	61.8±10.1	61.5±10.2	0.83
Male	105 (82.0)	108 (83.1)	0.83
Clinical presentation			0.51
Stable angina & silent ischemia	93 (72.7)	89 (68.5)	
Unstable angina	26 (20.3)	31 (23.8)	
Myocardial infarction	9 (7.0)	10 (7.7)	
Hypertension	70 (54.7)	75 (57.7)	0.63
Diabetes mellitus	37 (28.9)	33 (25.4)	0.53
Dyslipidemia	16 (12.5)	17 (13.1)	0.89
Current smoker	33 (25.8)	23 (17.7)	0.12
Cerebrovascular accident	5 (3.9)	10 (7.7)	0.19
Chronic renal failure	2 (1.6)	4 (3.1)	0.68
Previous MI	7 (5.5)	5 (3.8)	0.54
Previous PCI	14 (10.9)	9 (6.9)	0.26
LVEF (%)	60.5±7.3	59.3±10.7	0.41

Lesion Characteristics

	Conservative (n=128)	Aggressive (n=130)	p Value
Target vessel			0.91
Left main bifurcation	57 (44.5)	57 (43.8)	
Non-left main bifurcation	71 (55.5)	73 (56.2)	
LAD/diagonal	52 (40.6)	66 (50.8)	
LCX/OM	10 (7.8)	3 (2.3)	
RCA bifurcation	9 (7.0)	4 (3.1)	
Medina classification			0.74
True bifurcation	82 (64.1)	89 (68.5)	0.46
1.1.1	68 (53.1)	76 (58.5)	
1.0.1	8 (6.3)	4 (3.1)	
0.1.1	6 (4.7)	9 (6.9)	
Non-true bifurcation	46 (35.9)	41 (31.5)	0.46
1.0.0	2 (1.6)	2 (1.5)	
0.1.0	26 (20.3)	19 (14.6)	
1.1.0	17 (13.3)	19 (14.6)	
0.0.1	1 (0.8)	1 (0.8)	

Procedural Characteristics

	Conservative (n=128)	Aggressive (n=130)	p Value
Remote site intervention	39 (30.5)	35 (26.9)	0.53
Treatment per protocol	128 (100)	129 (99.2)	>0.99
Type of stent used			0.72
Sirolimus-eluting stent	60 (46.9)	62 (47.7)	
Everolimus-eluting stent	53 (41.4)	49 (37.7)	
Other DES	15 (11.7)	19 (14.6)	
Main vessel			
No. of stents per lesion	1.2±0.4	1.2±0.4	0.41
Total stent length (mm)	24.9±5.6	25.1±5.3	0.76
Maximal stent diameter (mm)	3.3±0.4	3.3±0.4	0.45
Side branch (n=48)	n=9	n=39	
No. of stents per lesion	1.0±0.0	1.0±0.2	0.64
Total stent length (mm)	18.4±7.8	17.7±5.6	0.73
Maximal stent diameter (mm)	2.8±0.2	2.9±0.4	0.46

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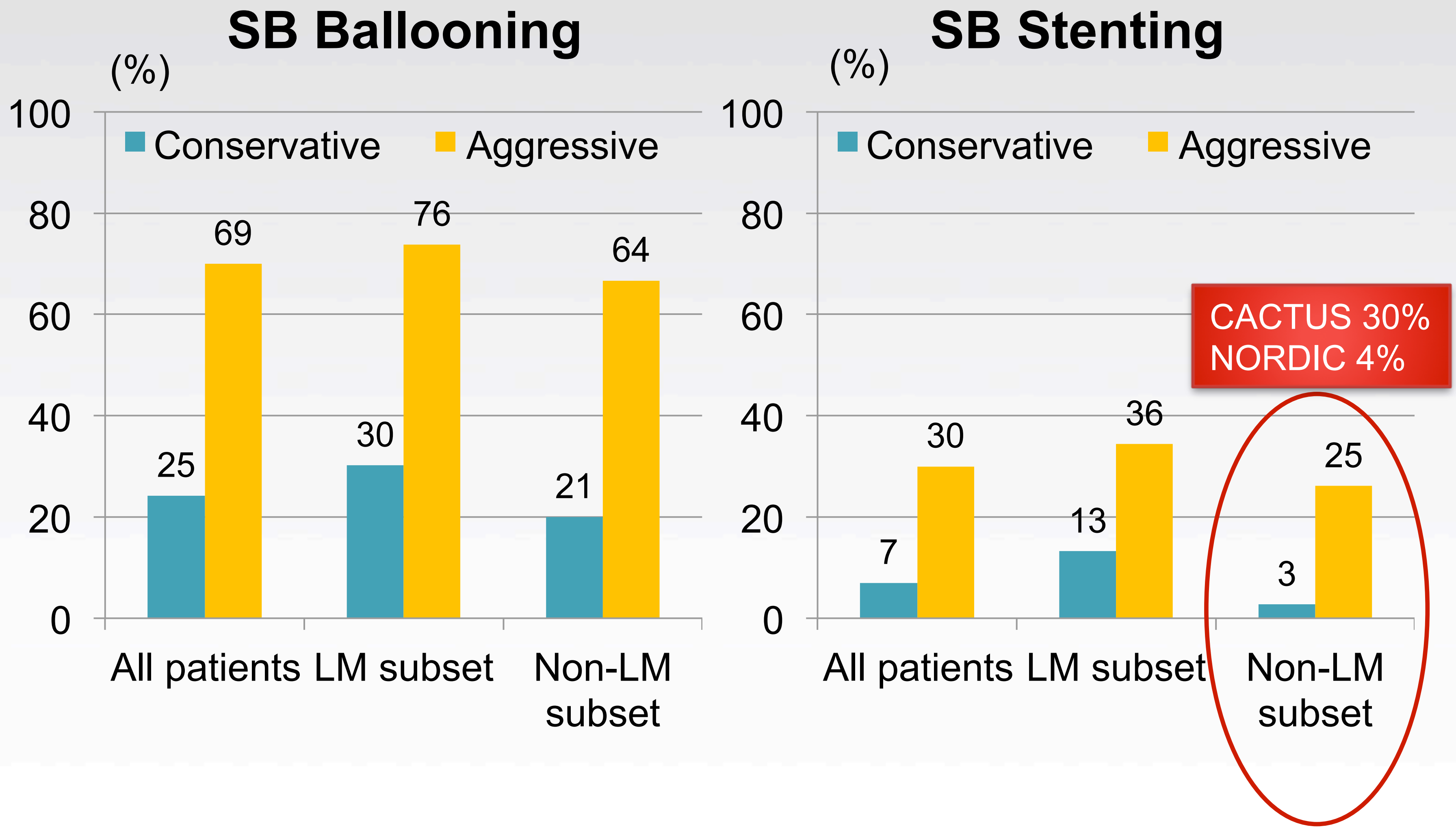
SB intervention



Clinical Outcomes at 36-month

	Conservative (n=128)	Aggressive (n=130)	p Value
1° EP: TVF*	**15 (11.7)**	**27 (20.8)**	**0.049**
Cardiac death or MI	1 (0.8)	8 (6.2)	0.04
Cardiac death	1 (0.8)	4 (3.1)	0.37
Spontaneous MI	0	4 (3.1)	0.12
Stent thrombosis	0	2 (1.5)	0.50
TBR	7 (5.5)	9 (6.9)	0.85
TLR	11 (8.6)	15 (11.5)	0.43
TLR for MV	5 (3.9)	12 (9.2)	0.08
TLR for SB	6 (4.7)	7 (5.4)	0.80
TVR	14 (10.9)	21 (16.2)	0.22

TVF = target vessel failure, MI = myocardial infarction, TBR = target bifurcation revascularization, TLR = target lesion revascularization, TVR = target vessel revascularization, MV = main vessel)

* Defined as a composite of cardiac death, spontaneous MI, or TVR

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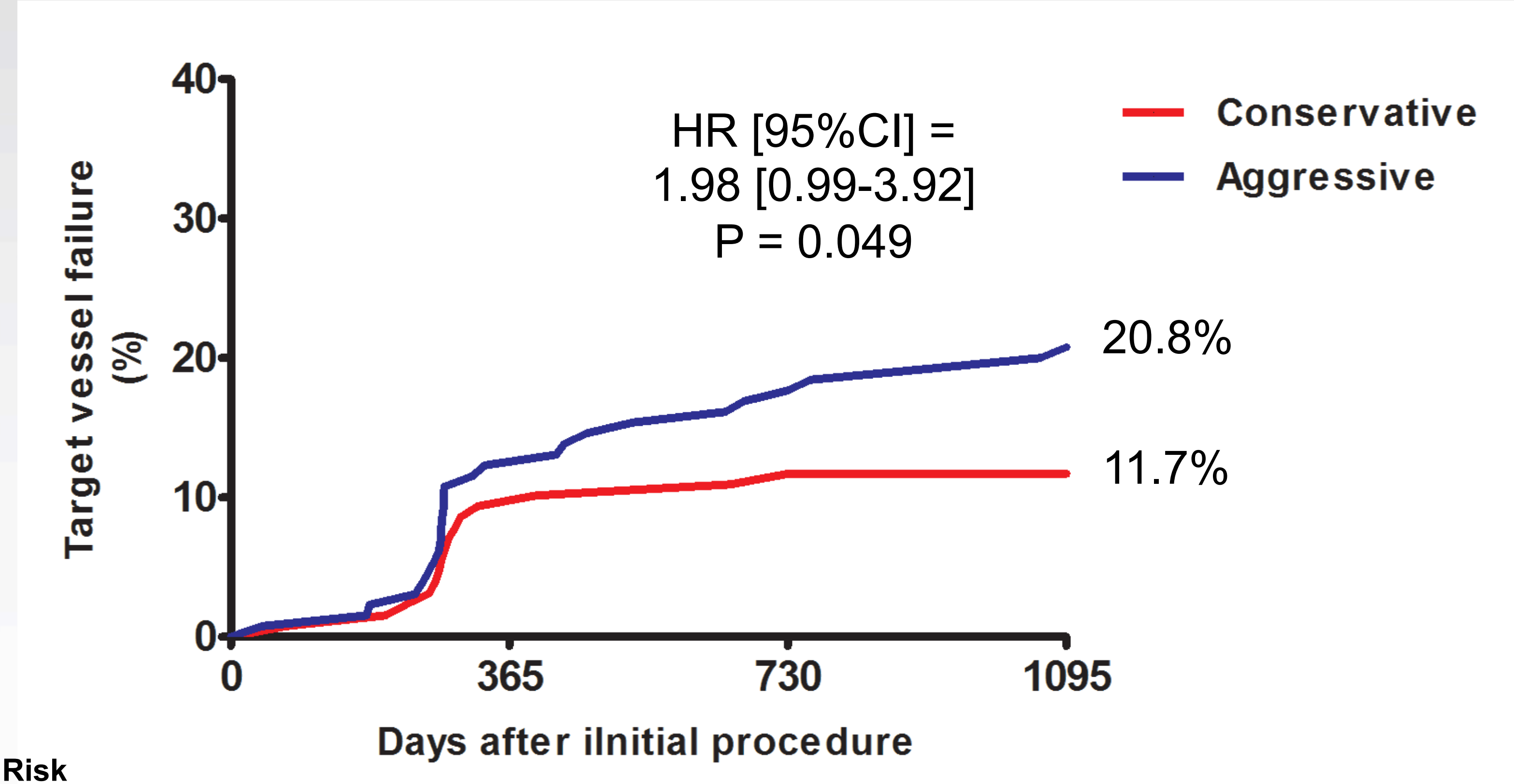
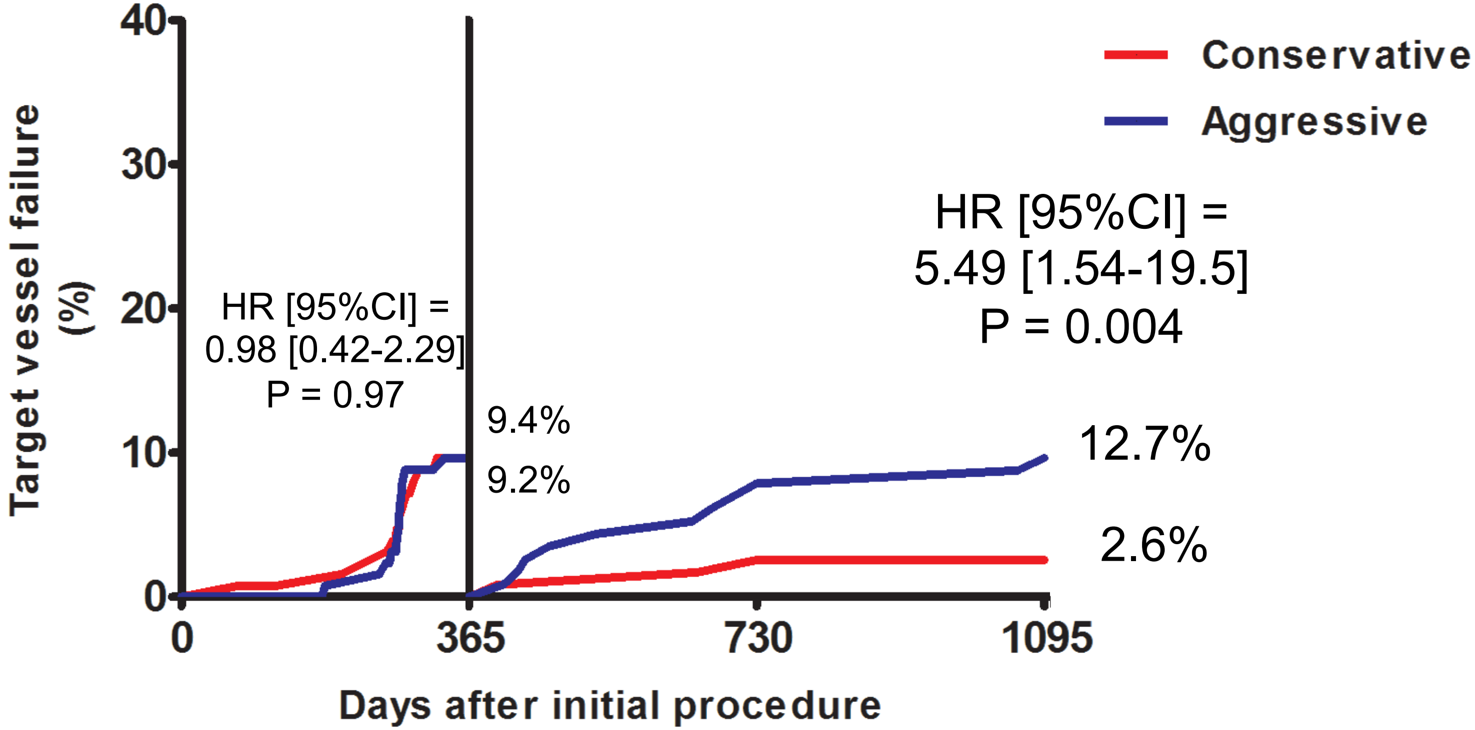
TVF through 3 years



Numbers at Risk

Conservative Group	128	117	114	113
Aggressive Group	130	115	108	104

TVF from 1 year to 3 years (landmark analysis)



Numbers at Risk

Conservative Group	**128**	**117**	**115**	**113**
Aggressive Group	**130**	**118**	**107**	**104**

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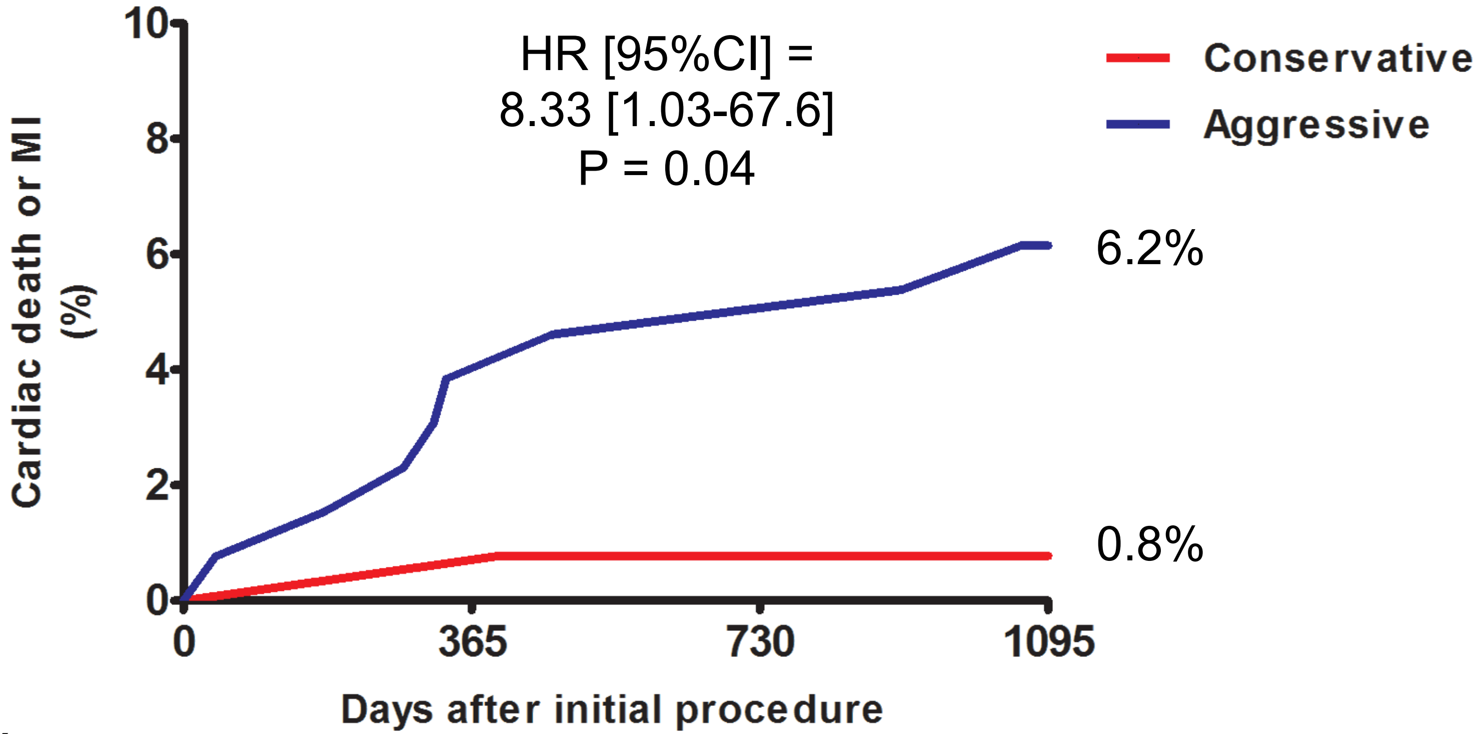
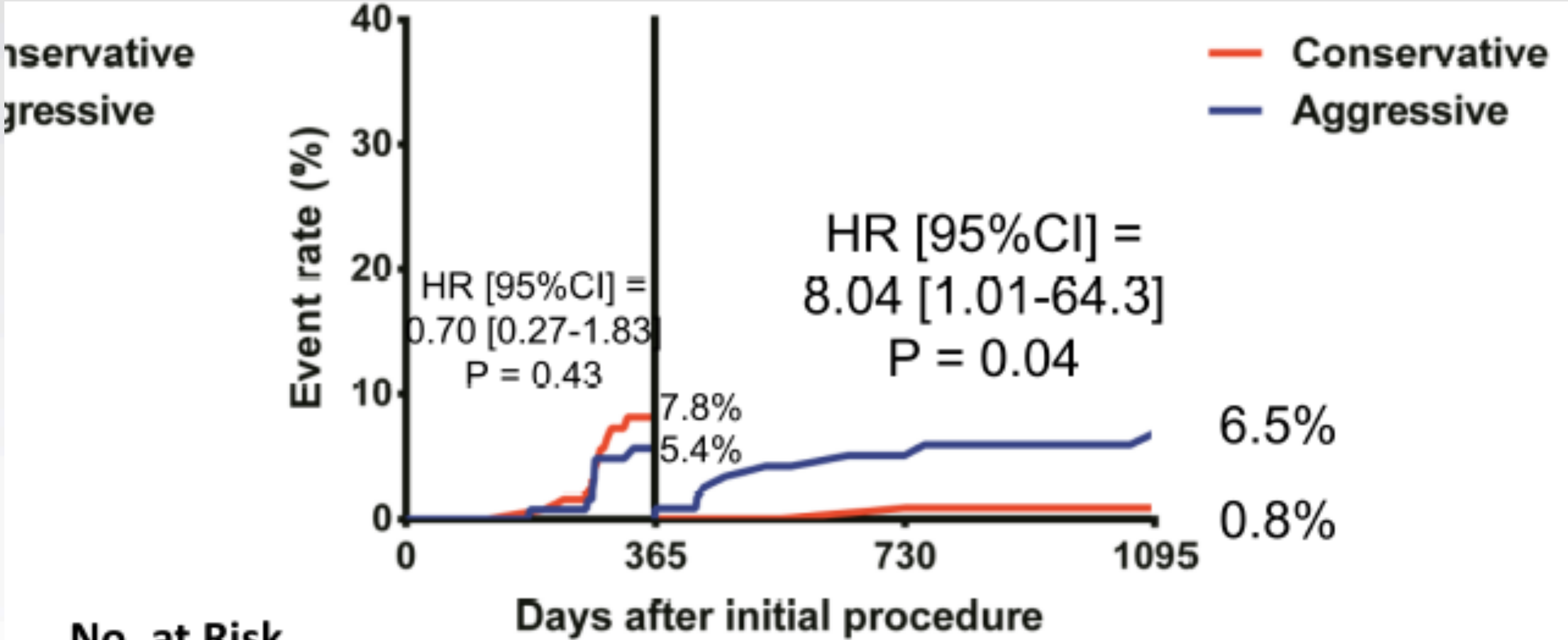
Cardiac death or MI through 3 years



Numbers at Risk

Conservative Group	128	127	127	127
Aggressive Group	130	126	125	122

TLR: landmark analysis at 1 year



No. at Risk				
Conservative	128	117	114	112
Aggressive	130	120	111	108

Study limitations

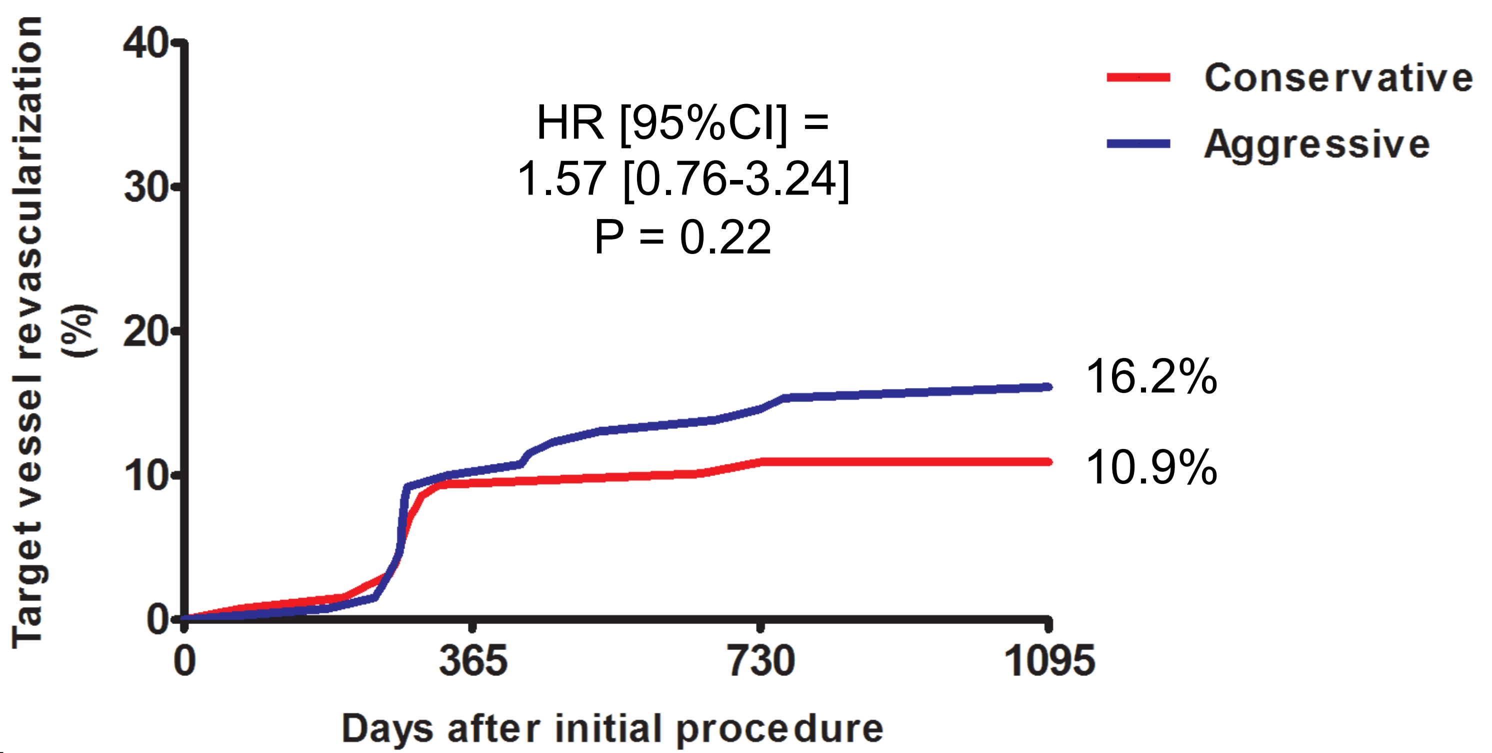
- The statistical power was low because of a lower event rate than expected.
- This study was designed to include coronary bifurcation lesions with MV diameter ≥2.5 mm and SB diameter ≥2.3 mm by visual estimation, not quantitative coronary angiographic analysis.
- Because the study was an open-label trial, both patients and operators were not blinded to the strategy used, which might have introduced bias in the assessment of symptoms at follow-up.

Summary

- At 3 years, conservative strategy was associated with a lower incidence of TVF mainly due to decreased risk of cardiac death or MI and TLR in the MV.
- The clinical benefits of a conservative strategy for provisional SB intervention was remarkable between 1 year and 3 years in landmark analysis .
- The conservative strategy might be considered as the preferred approach for provisional SB intervention.

감사합니다.
Thank you for your attention.

TVR through 3 years



Numbers at Risk

Conservative Group	128	117	116	114
Aggressive Group	130	118	112	110

No interaction between treatment strategy and LM lesions

	Left main bifurcation			Non-left main bifurcation			
	Conservative (n=57)	Aggressive (n=57)	Hazard ratio (95% CI)	Conservative (n=71)	Aggressive (n=73)	Hazard ratio (95% CI)	Interaction p Value
TVF*	8 (14.0)	13 (22.8)	1.69 (0.70-4.07)	7 (9.9)	14 (19.2)	2.02 (0.81-5.00)	0.80
Cardiac death or MI	0	4 (7.0)	-	1 (1.4)	4 (5.5)	3.98 (0.44-35.6)	1.00
Cardiac death	0	3 (5.3)	-	1 (1.4)	1 (1.4)	0.97 (0.06-15.5)	1.00
Spontaneous MI	0	1 (1.8)	-	0	3 (4.1)	-	-
Definite or probable ST	0	2 (3.5)	-	0	0	-	-
TBR	5 (8.8)	7 (12.3)	1.47 (0.47-4.64)	2 (2.8)	2 (2.7)	0.96 (0.14-6.83)	0.71
TLR	6 (10.5)	7 (12.3)	1.21 (0.41-3.59)	5 (7.0)	8 (11.0)	1.58 (0.52-4.82)	0.74
TLR for main vessel	2 (3.5)	4 (7.0)	2.07 (0.38-11.3)	3 (4.2)	8 (11.0)	2.68 (0.71-10.1)	0.81
TLR for side branch	4 (7.0)	6 (10.5)	1.58 (0.45-5.61)	2 (2.8)	1 (1.4)	0.48 (0.04-5.29)	0.39
TVR	8 (14.0)	10 (17.5)	1.30 (0.51-3.31)	6 (8.5)	11 (15.1)	1.84 (0.68-4.98)	0.63

Independent Predictors of TVF and TLR

	Hazard Ratio (95% CI)	p Value
TVF*		
Crossover to 2-stent (versus 1-stent) technique	3.27 (1.75-6.12)	<0.001
Remote site intervention	2.38 (1.27-4.44)	0.007
Stent length of main vessel (per 10 mm)	1.84 (1.03-3.29)	0.04
Second-generation DES (versus first-generation DES)	0.50 (0.26-0.96)	0.04
TLR†		
Crossover to 2-stent (versus 1-stent) technique	2.52 (1.12-5.70)	0.03
Remote site intervention	2.15 (0.98-4.73)	0.06
Second-generation DES (versus first-generation DES)	0.33 (0.14-0.80)	0.01