# Incidences, predictors, and clinical outcomes of acute and late stent malapposition detected by OCT after DES implantation

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Background - I

- Coronary stent malapposition is the separation of at least one stent strut from the intimal surface of the coronary arterial wall without involvement of side branches.

- In the era of DES, late-acquired stent malapposition is regarded as a potent substrate for late stent thrombosis.
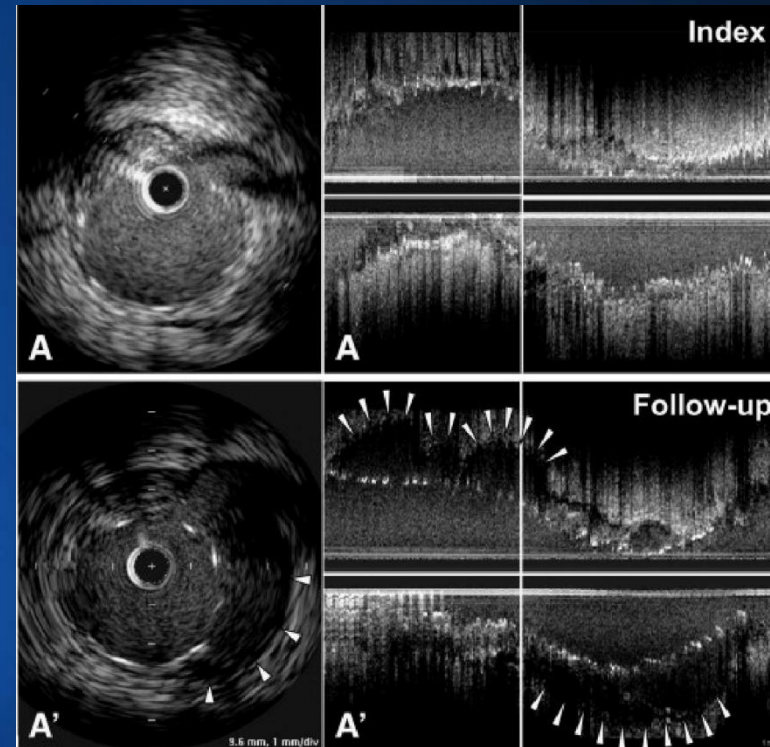

Tsujita K, *JACC Interv* 2009

Karalis I, et al. *Heart* 2012;98:1529-1536
Hassan AK, et al. *Eur Heart J* 2010;31:1172-1180
Ozaki Y, et al. *Eur Heart J* 2010;31:1470-1476

Background - II

- In previous studies, stent malapposition (SM) was detected by an IVUS, which may not completely detect stent malapposition due to limited axial resolution (100-200μm) or stent-related artifacts.

- However, optical coherence tomography (OCT) with a higher resolution (12-18μm) may detect stent malapposition with greater accuracy.
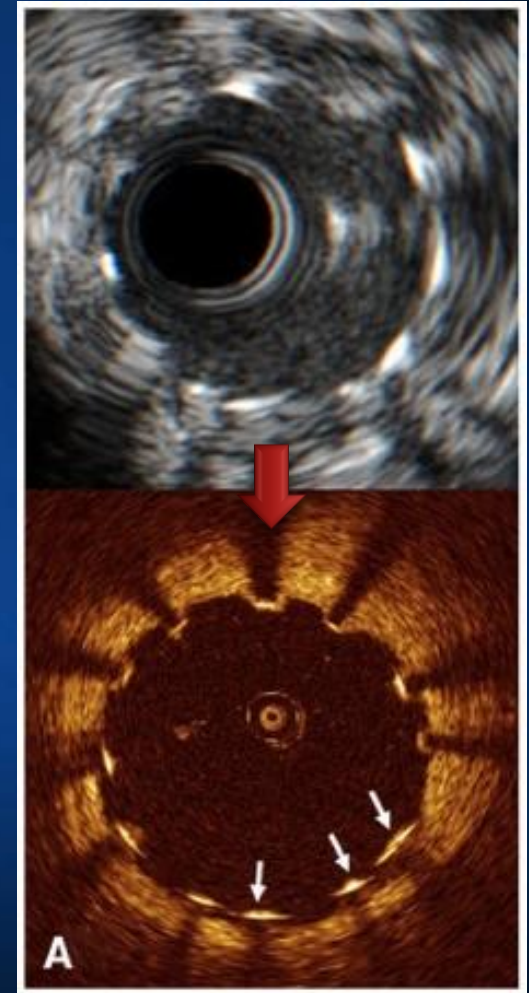
Kim WH, et al. Clin Res Cardiol 2010;99:639–644

Objectives

✓ **We investigated the incidences, predictors, and clinical outcomes of acute and late stent malapposition detected by OCT in daily clinical practice in a large number of patients who received DES.**

Methods

- ## Study population

  - Patients who received DES for de novo coronary lesions between 2009 and 2011 with post-stent and follow-up OCT were identified from the YONSEI OCT registry database.

    Exclusion criteria

    (1) DES implanted for left main coronary disease.

    (2) Overlapping DES implanted in the lesion.

    (3) Clinical follow-up period after implantation of DES < 12 months.

    (4) Follow-up OCT > 21 months after DES implantation

    (5) Poor quality of OCT image .

  - Ultimately, **351 patients with 356 lesions were enrolled in this study**

OCT imaging & analyses

- Two OCT systems (Model M2 and C7-XR^{TM} Imaging System)

- Analyzed at 1-mm intervals.

- **Percentage of malapposed struts (%)**

$$= \frac{\text{number of malapposed struts}}{\text{total number of struts in all cross-sections of the lesion}} \times 100$$

- **Malapposed strut:**

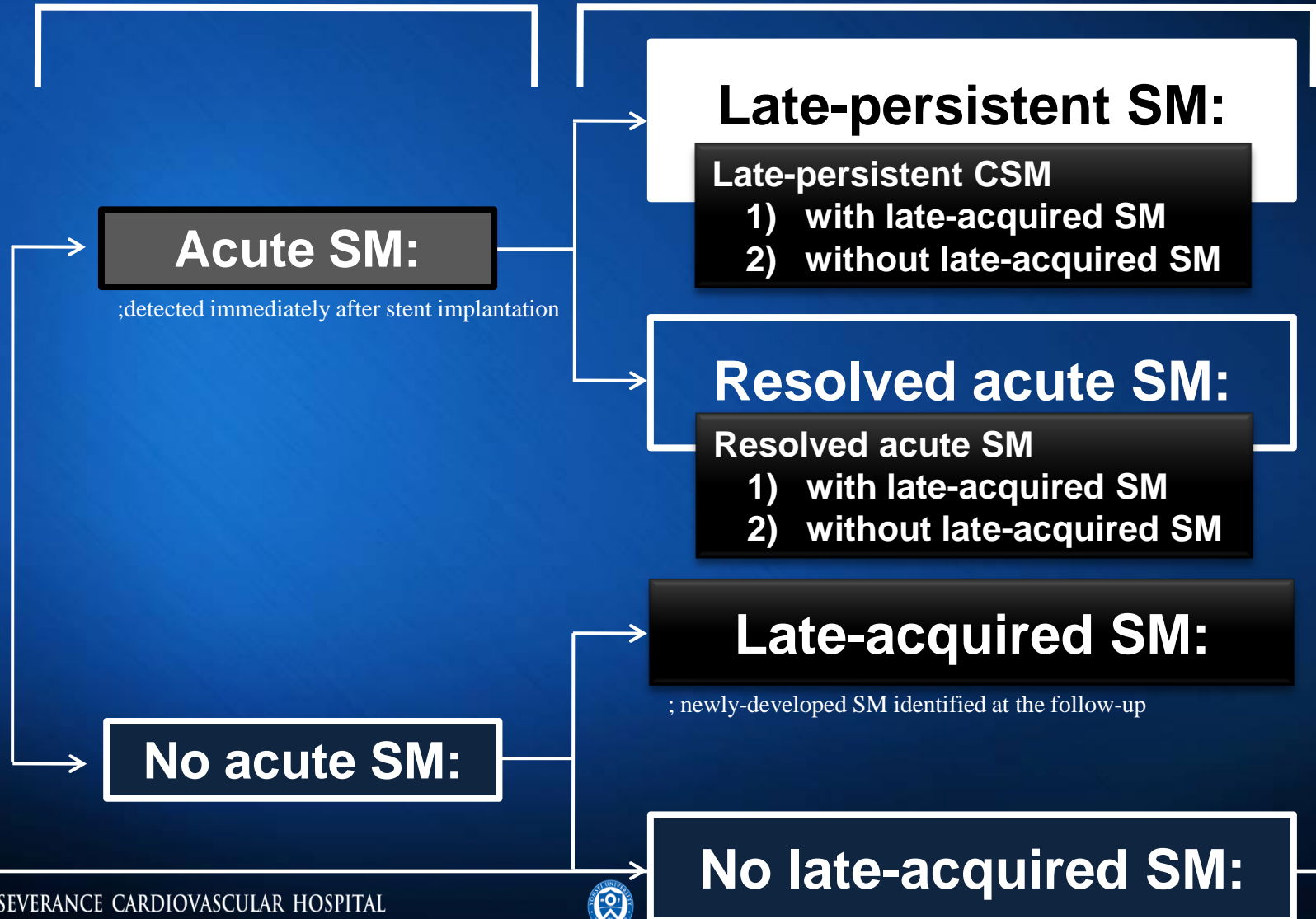 Defined as a strut that was detached from the vessel wall as follows

  1) Cypher^{TM}, ≥160 µm;

  2) Resolute® or Integrity^{TM}, ≥110 µm;

  3) Xience V®, ≥100 µm;

  4) Nobori® or Biomatrix^{TM}, ≥130 µm

Classification of stent malapposition

by timing with full lesion evaluation by frame-matching

Post-stent OCT

Follow-up OCT

Acute SM:

;detected immediately after stent implantation

Late-persistent SM:

Late-persistent CSM
1) with late-acquired SM
2) without late-acquired SM

Resolved acute SM:

Resolved acute SM
1) with late-acquired SM
2) without late-acquired SM

Late-acquired SM:

; newly-developed SM identified at the follow-up

No acute SM:

No late-acquired SM:

Classification of acute SM lesions according to post- and follow-up OCT
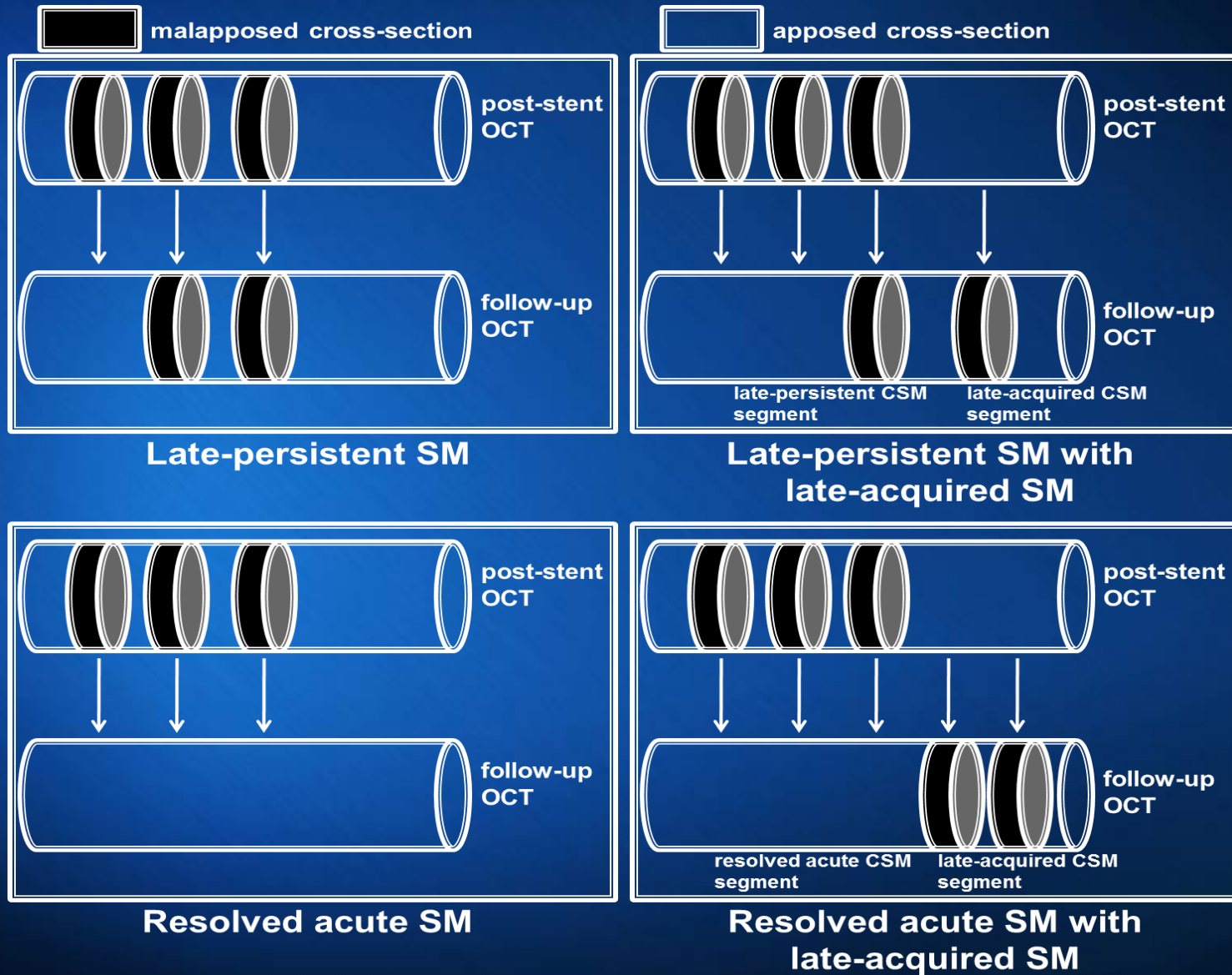
True late-acquired stent malapposition by serial OCT evaluation

Post-stent OCT

Follow-up OCT

Acute SM:

;detected immediately after stent implantation

Late-persistent SM:

Late-persistent SM with late-acquired SM

Resolved acute SM:

Resolved acute SM with late-acquired SM

Late-acquired SM:

; newly-developed SM identified at the follow-up

No acute SM:
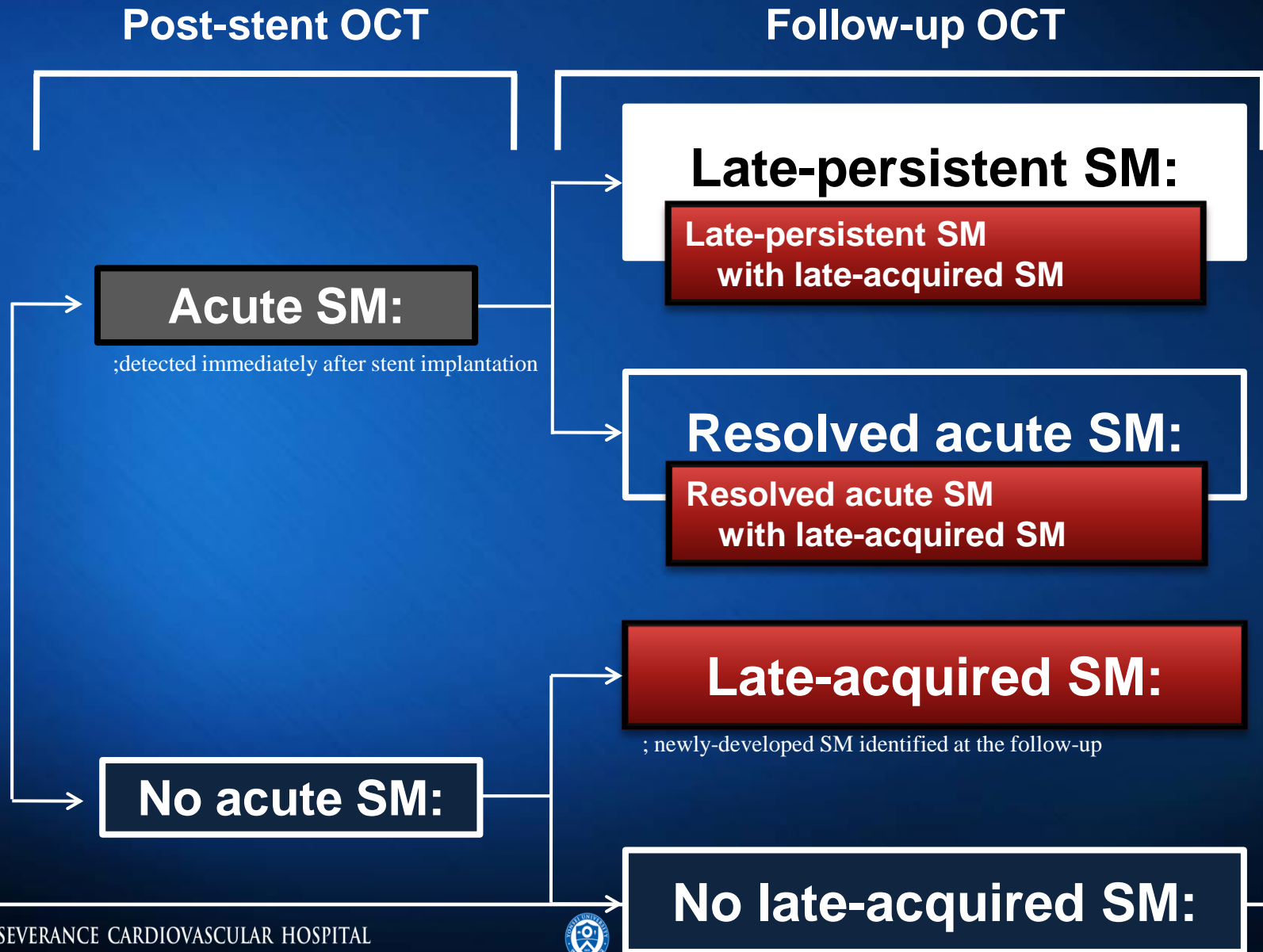
No late-acquired SM:

Statistical analyses

- Multivariate logistic regression analyses for the identification of the independent predictors of acute, late-persistent, and late-acquired SM
    - ✓ Variables with p-values <0.2 from univariate analyses were included in multivariate analyses.
    - ✓ In case of multi-collinearity problem (variance inflation factor > 10), a representative variable were selected among highly correlated covariates considering effect estimates and p-values.

- ROC analyses for the best cut-off value of separated late-persistent SM lesions from resolved acute SM lesions.

- Cumulative incidences of clinical events during the follow-up
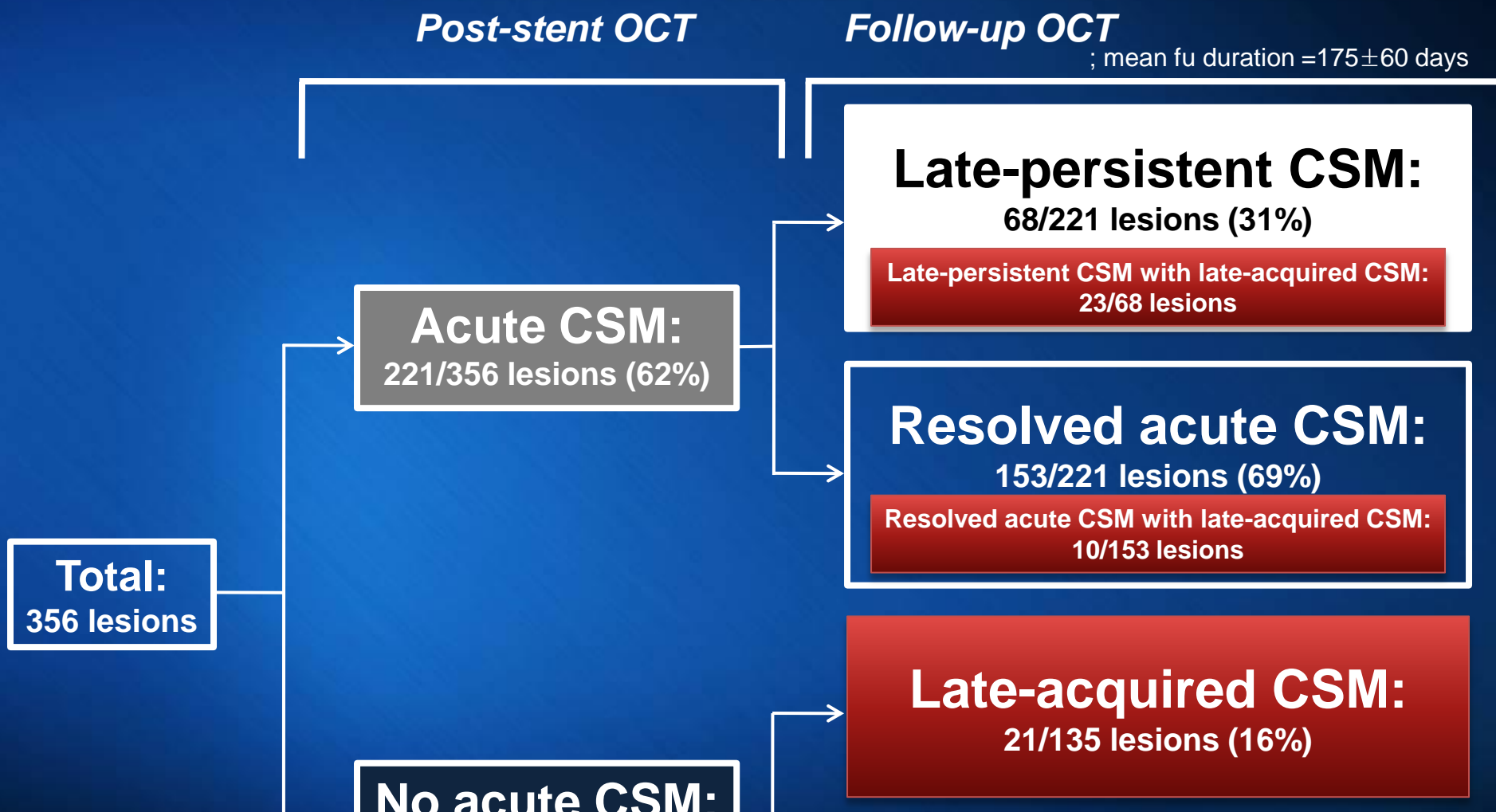   - ✓ Kaplan-Meier method using log-rank tests.

Results

Baseline characteristics

Clinical characteristics	n=351 patients
Age, years	68.9 $\pm$ 18.4
Male	240 (68%)
Clinical presentation of acute coronary syndrome	106 (30%)
Cardiovascular risk factors	
Hypertension	211 (60%)
Diabetes mellitus	104 (30%)
Dyslipidemia	189 (54%)
Current smoking	71 (20%)
Procedural characteristics	**n=356 lesions**
Lesion in left anterior descending artery	200 (56%)
B2- or C-type lesion	156 (44%)
Calcified lesion	59 (17%)
Type of stent	
Sirolimus-eluting stent (Cypher^{TM})	83 (23%)
Zotarolimus-eluting stent (Endeavor® Resolute/Resolute Integrity^{TM})	120 (34%)
Everolimus-eluting stent (Xience V®)	30 (8%)
Biolimus A9-eluting stent (Nobori®)	52 (15%)
Biolimus A9-eluting stent (Biomatrix^{TM})	71 (20%)
Post-dilation, n (%)	198 (55%)

QCA analysis

Lesions	n=356
Reference vessel diameter, mm	3.0 ± 0.4
Minimal lumen diameter, mm	
Pre-intervention	1.0 ± 0.5
Post-intervention	2.7 ± 0.4
Follow-up	2.5 ± 0.5
Diameter stenosis, %	
Pre-intervention	65 ± 15
Post-intervention	11 ± 8
Follow-up	15 ± 12
Lesion length, mm	17.7 ± 6.4
Stent diameter, mm	3.2 ± 0.4
Stent length, mm	18.9 ± 5.2

Incidences of acute and late stent malapposition

Post-stent OCT

Follow-up OCT
; mean fu duration =175±60 days

Total:
356 lesions

Acute CSM:
221/356 lesions (62%)

Late-persistent CSM:
68/221 lesions (31%)

Late-persistent CSM with late-acquired CSM:
23/68 lesions

Resolved acute CSM:
153/221 lesions (69%)

Resolved acute CSM with late-acquired CSM:
10/153 lesions

Late-acquired CSM:
21/135 lesions (16%)

No acute CSM:

Total late-acquired stent malapposition lesions were detected in 54 of 356 (15%) lesions on follow-up OCT images;

SES, 16% (13/83), ZES, 15% (18/120), EES, 13% (4/30), and BES, 15% (19/123) (p = 0.991).

Predictors of acute stent malapposition

	Univariate analysis			Multivariate analysis		
	Acute SM lesions (n=221)	No acute SM lesions (n=135)	p	Odds ratio	95% CI	p
Post-stent OCT						
Acute malapposed struts, %	5.2±6.2	0	-			
Maximum acute SM CSA, mm^2	1.16±0.69	0	-			
Acute SM volume, mm^3	3.05±3.67	0	-			
Acute SM volume, % (of stent volume)	2.4±2.6	0	-			
Acute SM within stent edges	116 (53%)	0	-			
Reference vessel diameter, mm	3.02±0.41	2.88±0.45	0.025	1.22	0.51-2.92	0.650
Baseline diameter stenosis >70%	61 (28%)	17 (13%)	0.001	2.45	1.19-5.06	0.015
Calcified lesion	55 (25%)	4 (3%)	<0.001	11.19	3.52-35.63	<0.001
Stent length >25 mm	32 (15%)	10 (7%)	0.045	3.80	1.11-13.03	0.033

Predictors of late-persistent SM

	Univariate analysis			Multivariate analysis		
	Late-persistent SM lesions (n=68)	Resolved acute SM lesions (n=153)	p	Odds ratio	95% CI	p
Follow-up OCT						
Time intervals after index procedure, days	175±40	176±70	0.808			
Late-persistent malapposed struts, %	2.5±3.6	0	-			
Maximum late-persistent SM CSA, mm^2	0.88±0.71	0	-			
Late-persistent SM volume, mm^3	1.28±2.16	0	-			
Late-persistent SM volume, % (of stent volume)	1.1±1.8	0	-			
Late-persistent SM within stent edges	50 (74%)	0	-			
Post-stent OCT						
Acute malapposed struts, %	6.6±5.8	4.5±6.3	0.022*			
Maximum acute SM CSA, mm^2	1.46±0.74	0.99±0.60	0.001*			
Acute SM volume, mm^3	**4.64±4.48**	**2.19±2.81**	**0.001**	**1.17**	**1.01-1.35**	**0.044**
Acute SM volume, % (of stent volume)	3.3±3.1	1.9±2.2	0.005*			
Acute SM within stent edges	**49 (72%)**	**67 (44%)**	**<0.001**	**6.31**	**2.03-19.60**	**0.001**
Reference vessel diameter, mm	30 (44%)	43 (28%)				
Stent diameter, mm	19 (28%)	24 (16%)				

* excluded from multivariate analysis because of multi-collinearity problem.

Receiver-operating curve demonstrating the best cut-off value for acute SM volume, separating late-persistent SM lesions from resolved acute SM
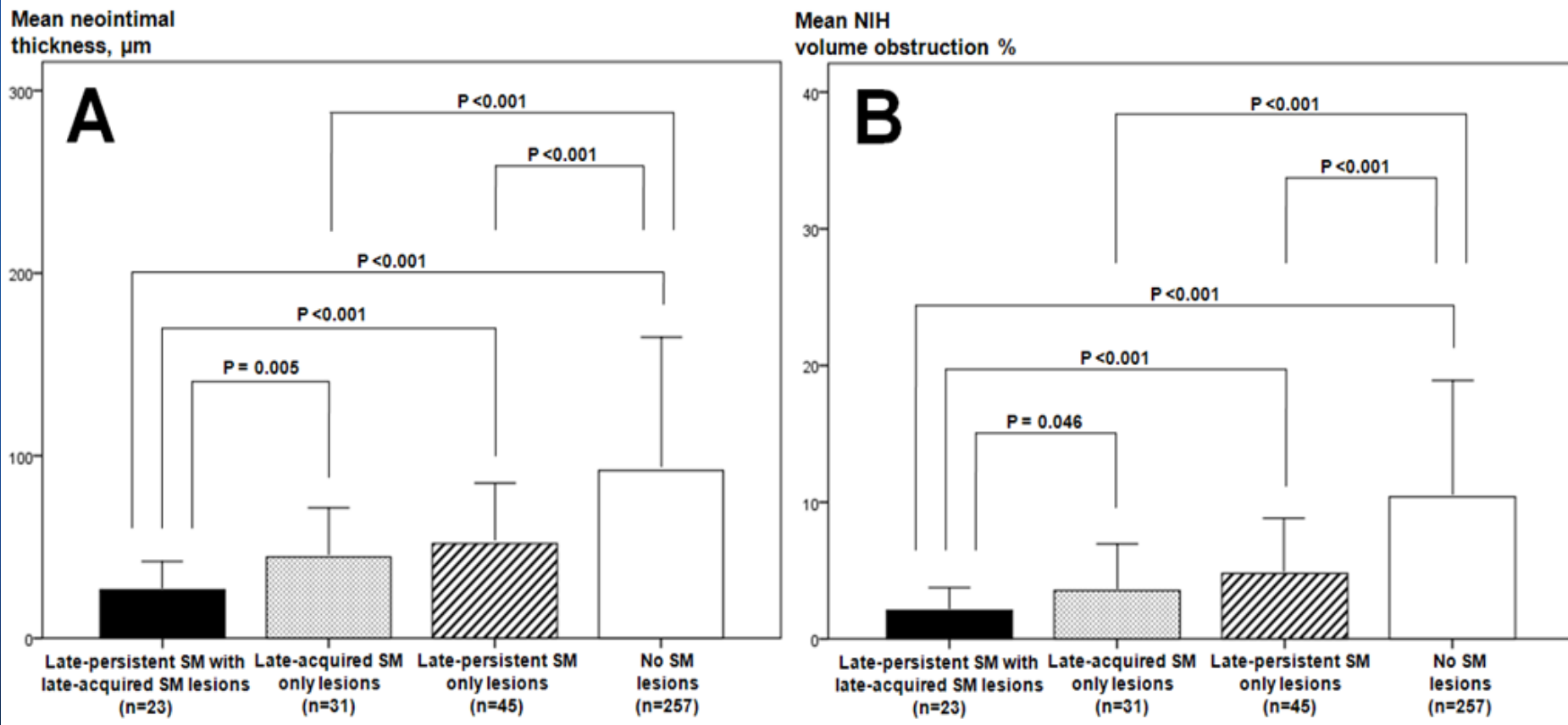
Percentage of late-persistent SM lesions according to the quintiles of total acute SM area
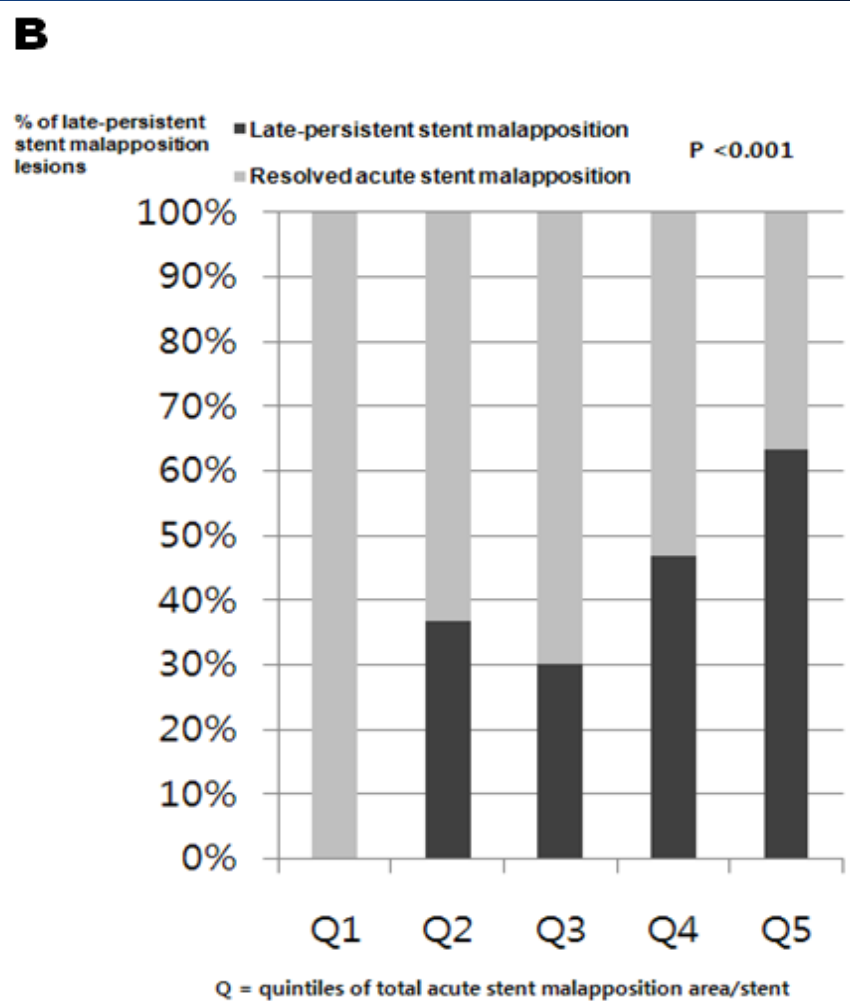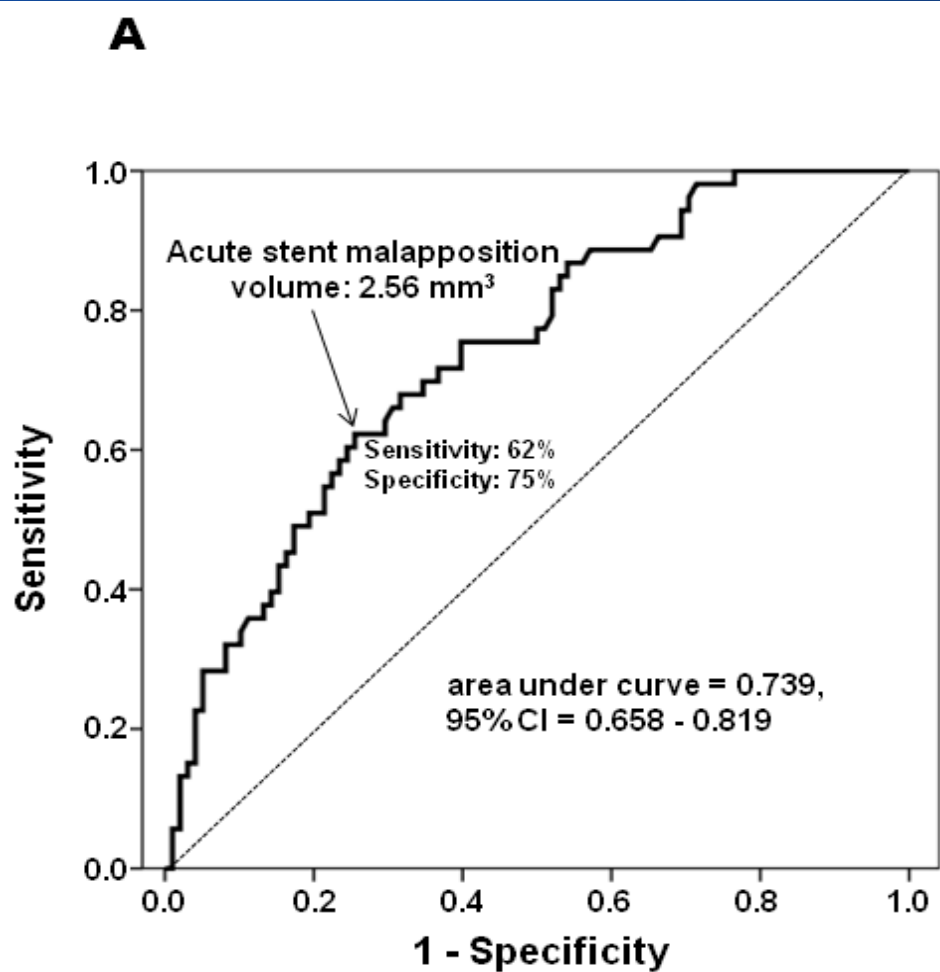
Predictors of late-acquired SM

	Univariate analysis		
	Late-acquired SM lesions (n=54)	No late-acquired SM lesions (n=302)	p
Follow-up OCT			
Time intervals after index procedure, days	173±43	175±63	0.841
Late-acquired malapposed struts, %	3.8±4.5	0	-
Maximum late-acquired SM CSA, mm^2	0.95±0.90	0	-
Late-acquired SM volume, mm^3	2.06±3.24	0	-
Late-acquired SM volume, % (of stent volume)	1.7±3.1	0	-
Late-acquired SM within stent body	33 (61%)	0	-
Acute coronary syndrome*	18 (33%)	88 (30%)	0.586
Dyslipidemia*	34 (63%)	155 (52%)	0.144
B2- or C-type lesion	24 (44%)	132 (44%)	0.745
Baseline diameter stenosis, %	69±20	65±14	0.299
Stent diameter, mm	3.22±0.37	3.14±0.36	0.178
Stent length, mm	19.0±5.4	18.9±5.1	0.955
Post-stent OCT			
Plaque/thrombus prolapse	**38 (70%)**	**128 (42%)**	**<0.001**

* *Analyzed in patient level.

Comparison among 4 groups according to the presence or absence of late-persistent SM and late-acquired SM on follow-up OCT

✓ **Lesions classified as late-persistent SM with late-acquired SM had the smallest NIH thicknesses and lowest percentages of NIH volume obstruction**

Clinical outcomes

	Overall patients (n=351)	Both late-persistent and late-acquired SM (n=23)	Late-acquired SM alone (n=31)	Late-persistent SM alone (n=45)	No SM (n=252)	p
Follow-up duration after PCI, months	28.6±10.3	24.3±4.3	27.7±10.0	28.4±9.2	29.1±10.8	0.175
Follow-up duration after follow-up OCT, months	22.8±10.4	18.4±4.4	22.0±10.4	22.6±8.9	23.3±10.9	0.180
Composite of clinical events	10 (5.5%)	0 (0%)	1 (3.2%)	1 (3.2%)	8 (6.0%)	*
Cardiovascular death	1 (1.3%)	0 (0%)	0 (0%)	0 (0%)	1 (1.6%)	*
Non-fatal myocardial infarction	1 (0.3%)	0 (0%)	0 (0%)	0 (0%)	1 (0.4%)	*
Stent thrombosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	*
Target lesion revascularization	8 (4.0%)	0 (0%)	1 (3.2%)	1 (3.2%)	6 (4.1%)	*
Duration of dual anti-platelet therapy, months	14.2±8.2	11.9±5.3	15.5±6.4	13.8±7.1	14.3±8.7	0.417
At least 12 months of dual anti-platelet therapy	262 (75%)	15 (65%)	27 (87%)	36 (80%)	184 (73%)	0.199

Summary

To the best of our knowledge, this is the first study to investigate OCT-detected acute and late SM in a large number of patients in clinical practice.

- The incidence of stent malapposition detected by OCT was relatively high; 62% on post-OCT

- **Predictors for acute SM** were 1) severe stenosis, 2) calcified lesions, and 3) longer stent length.

- **Predictors of late-persistent SM** were 1) the presence of acute SM within the stent edge and 2) a larger volume of acute SM.

- **Late-acquired SM** was associated with plaque/thrombus prolapse detected on post-stent OCT images.

- Long-term clinical outcomes of SM detected by OCT were favorable.

Limitation

- The present study may have potential selection bias due to the characteristics of cross-sectional investigation and exclusion of the overlapping DES-treated lesions.

- Pre-intervention OCT was not performed.

Conclusion

- ✓ **OCT-detected stent malapposition was frequently observed and had specific predictors.**

- ✓ **Long-term clinical outcomes were favorable in stent malapposition detected by OCT.**