



# OCT STEMI: OCT guidance during stent implantation in primary PCI.

A Randomized Multicenter study  
with 9-month optical coherence tomography follow-up

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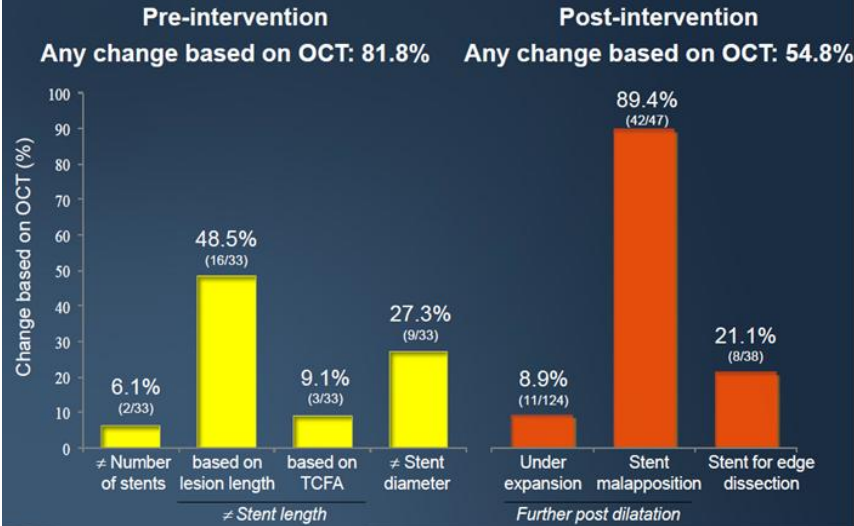
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# IVUS guided DES implantation decreases MACE

## Impact of OCT on PCI management



Stefano GT, et al. Int J Cardiovasc Imaging. 2013; 29: 741-752

## CLI-OPCI study (the Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention Study)

335 OCT-guided PCI ↔ 335 Angio-guided PCI

- Retrospective
- Multi-center at high OCT volume in Italy
- Consecutive cases
- Randomly matched within 1 month at same site

	Angiographic guidance group (n=335)	Angiographic plus OCT guidance group (n=335)	p-value
In-hospital events			
Cardiac death	3 (0.9%)	2 (0.6%)	1.0
Non-fatal myocardial infarction	22 (6.5%)	13 (3.9%)	0.118
Events at 1-year follow-up			
Death	23 (6.9%)	11 (3.3%)	0.035
Cardiac death	15 (4.5%)	4 (1.2%)	0.010
Myocardial infarction	29 (8.7%)	18 (5.4%)	0.096
Target lesion repeat revascularisation	11 (3.3%)	11 (3.3%)	1.0
Definite stent thrombosis	2 (0.6%)	1 (0.3%)	1.0
Cardiac death or myocardial infarction	43 (13.0%)	22 (6.6%)	0.006
Cardiac death, myocardial infarction, or repeat revascularisation	50 (15.1%)	32 (9.6%)	0.034

Prati F et al. EuroInt 2012;8:823-829

All-cause Mortality  
MI

Stent Thrombosis

Conclusion: IVUS guidance improves outcomes compared with

## Optical Coherence Tomography-Guided Primary Percutaneous Coronary Intervention in ST-Segment Elevation Myocardial Infarction Patients: A Pilot Study

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### Abstract

#### Background

The objective of our study was to assess whether optical coherence tomography (OCT) guidance could guide intervention to avoid balloon angioplasty and stenting during primary percutaneous coronary intervention.

#### Methods

One hundred patients with ST-segment elevation myocardial infarction and thrombus-containing lesion were enrolled in this study. Thrombus aspiration was performed in all cases followed by an OCT study. After thrombectomy, no stent was implanted in residual significant stenosis (>50%) if examination using OCT suggested that the occlusion was mostly thrombotic, provided that the patient was symptom-free and the Thrombolysis in Myocardial Infarction (TIMI) flow was ≥2. All patients managed only using thrombectomy underwent 1-week and 9-month angiography and OCT. Patients with significant lesion or those in whom thrombectomy failed to re-establish flow underwent standard treatment during the in-hospital period or at the 12-month follow-up.

#### Results

Based on the OCT information, 20 patients (20%) were treated only with aspiration even in the presence of angiographically detected "high-grade stenosis." Angiogram and OCT performed at 1 week and 9 months showed a "normal vessel" without significant stenosis in all 20 cases. There were no cases of major adverse cardiovascular event (including death, myocardial infarction, and target lesion revascularization) during the in-hospital period or at the 12-month follow-up.

#### Conclusions

The results of our pilot study suggest that ST segment elevation myocardial infarction patients with TIMI 2/3 flow in the angiogram and without significant coronary narrowing using OCT examination (even in the presence of angiographically detected "high-grade stenosis"), in whom thrombus aspiration is performed in addition to optimal medical therapy might benefit only from thrombus aspiration without plain old balloon angioplasty/stenting during primary percutaneous coronary intervention. Validation of these preliminary data in larger randomized studies is warranted.

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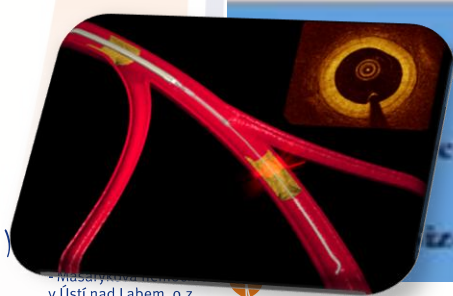
< 0.001  
Primary PCI

0.002

reductions in PCI

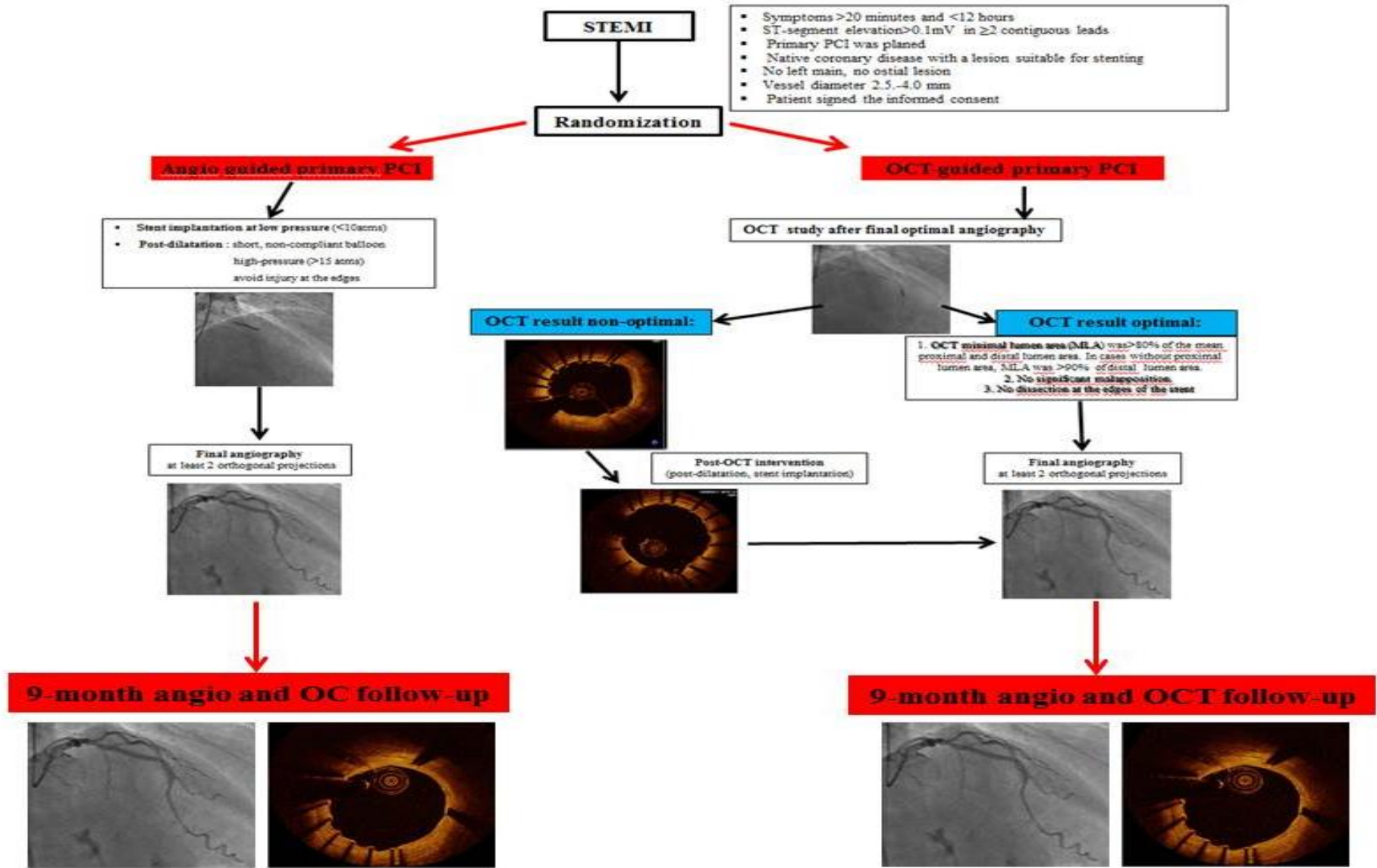
# Optical coherence tomography(OCT)

Specifications	FD-OCT	IVUS
Axial scans per second	~ 50.000 - 100.000	
Lines per frame	~ 500-1000	
Max. frame rate	100-200 fps	30
Max. Pullback speed	20-40 mm/s	1 mm/s
Wave Length	1.3 $\mu$ m	35-80 $\mu$ m
Axial resolution	10-15 $\mu$ m	150 $\mu$ m
Lateral Resolution	40-90 $\mu$ m	250 $\mu$ m
Tissue penetration	2-3.5 mm	7 mm
Field of View (FOV)	~10 mm	15 mm
Stent occlusion	X	X
Probe size (mm)	0.8 – 1 mm	1 mm





# Study description



# Statistical analysis

(Department of biostatistics, Czech Academy of Science, Prague;  
“R” version 3.0.2; R Foundation for Statistical Computing, Vienna)

- Categorical variables were described as group counts and relative frequencies
- Continuous variables were described as group means, standard deviations and totals.
- Tests of statistical hypotheses in contingency tables were performed using Fisher Exact Test based on hypergeometric distribution.
- Non-parametric Wilcoxon Rank-Sum Test was used to compare continuous outcomes across different groups.
- McNemar's test was applied for comparisons of binary categorical variables between individual stages of follow-up.
- Level of statistical significance was set to  $\alpha=0.05$  for all tests.
- In multiple testing scenarios the Bonferroni corrections of the nominal level of statistical
- Significance were applied in individual tests in order to keep the family-wise Type I error rate  $\alpha$  at 0.05.



# Definitions

- Deaths:
  - cardiac or noncardiac
  - undetermined causes reported as cardiac
- Myocardial infarction:

Q wave MI: new, pathological Q waves in  $\geq 2$  contiguous leads with post-PCI increase CK double the upper limit of normal and CK-MB  $> 10\%$  of CK level

Non-Q-wave MI: elevation of CK level to double the upper limit of normal, CK-MB  $> 10\%$  of CK level and no Q-waves
- idTLR

All reinterventions inside the stent or within 5mm proximal or distal
- Stent thrombosis (according to the Academic Research Consortium)
  - early (0-30 d.)                      - late (31-360d.)                      - very late ( $> 361$  d.)
  - definite: ACS+angiographic or autopsy ev. of thrombus or occlusion
  - probable: unexplained deaths within 30 days of the procedure or acute MI involving the target-vessel territory without angiography
  - possible: all unexplained deaths  $> 30$  days after the procedure

# Endpoints

- OCT analysis
  - % uncovered struts
  - % area stenosis
  - Minimal lumen diameter in-stent (mm)
  - Minimal lumen area in-stent (mm<sup>2</sup>)
- MACE's (death, MI, ischemia d. TLR) at 9 M FU




*(Core lab: Cardiovascular Imaging Core Laboratories,  
Hospitals, Case Medical Center, Cleveland, USA*

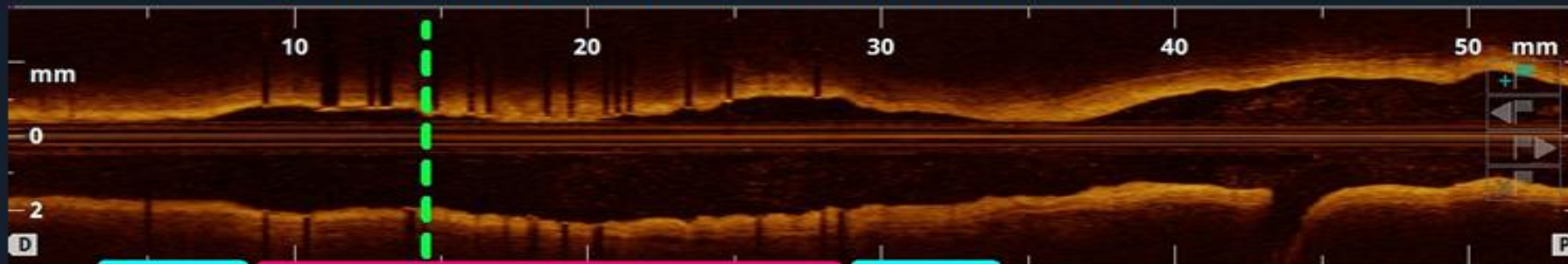


# OCT analysis: Semi-automated system

Image Analysis and Visualization Toolkit for Stent :  
(OCTivat-Stent)

## Scheme of area stenosis calculations

-  **Reference segment. This segment should contain no stent struts, side branches, dissections etc.**
-  **Stent segment**
-  **Localization of minimal in-stent lumen area**



$\text{Distal MLA} + \text{Proximal MLA} / 2 = \text{Mean MLA (mm}^2\text{)}$

$$\frac{\text{Mean MLA (mm}^2\text{)} - \text{Minimal MLA in-stent (mm}^2\text{)}}{\text{Mean MLA (mm}^2\text{)}} = \text{AS (\%)}$$





# Results: Baseline demographic characteristics

	OCT guided pPCI	Angio guided pPCI	P value
<b>N</b>	<b>105</b>	<b>96</b>	
Age (years)	57 [46-70]	59 [47-72]	NS
Male	83%	87%	NS
Smoking (%)	64	59	NS
Diabetes Mel. (%)	17	26	NS
Hypertension (%)	50	52	NS
History of CAD			
Previous MI (%)	1	6	NS
Previous PCI (%)	4	4	NS
Previous CABG (%)	0	0	NS
Killip class			
I (%)	98	98	NS
II (%)	2	0	NS
III (%)	0	2	NS
Treated vessels			
LAD (%)	39	33	NS
RCA (%)	46	54	NS
LCx (%)	15	13	NS



# Results: Procedural characteristics

	OCT guided pPCI	Angio guided pPCI	P value
N	105	96	
TIMI flow (%)			
0-II	94	93	NS
MLD (mm)	0.29±0.46	0.51±0.56	0.03
GP1Ib/IIIa i (%)	34	30	NS
DS (%)	92±13.5	87±16.6	0.01
Aspiration (%)	45	39	NS
DAPT before (%)	100	98	NS
Number of stents/patient	1.4	1.2	0.03
Direct stenting (%)	59	60	NS
Total length of stents (mm)	26.5±13.8	24.3±11.2	NS
Max. implant. pressure (atms)	18.0±2.6	17.2±2.5	0.02
Fluoroscopy time (minutes)	11.2±5.33	8.3±4.6	<0.0001
Stage PCI (%)	6	7	NS
Stage CABG (%)	1	0	NS
> 1 OCT	29/105 (28%)		
- Mallaposition	17/29 (59%)		
- Any dissection	12/29 (41%)		

(OCT=optical coherence tomography; pPCI=primary percutaneous coronary intervention; CAD=coronary artery disease; MI=myocardial infarction; CABG=coronary artery bypass graft; LAD=left anterior descending; RCA=right coronary artery; LCx= left circumflex; values in square brackets represent quartiles 1-3)





# Results: Post-procedural characteristics

	OCT guided pPCI	pPCI alone	P value
N	105	96	
TIMI flow (%)			
0-II	4	6	NS
III	96	94	NS
Min. in stent D. (mm)	2.8±0.41	2.9±0.51	NS
Min. in seg. D. (mm)	2.5±0.49	2.5±0.56	NS
DS stent (%)	12±4.69	12±5.97	NS
DS segment (%)	20±9.35	20±10.96	NS
CK max (µkat/l)	24 [11.4-47.5]	20 [11-35]	NS
Troponin T max (µg/l)	13.1 [3.58-49.8]	17.6 [3.51-91.6]	NS

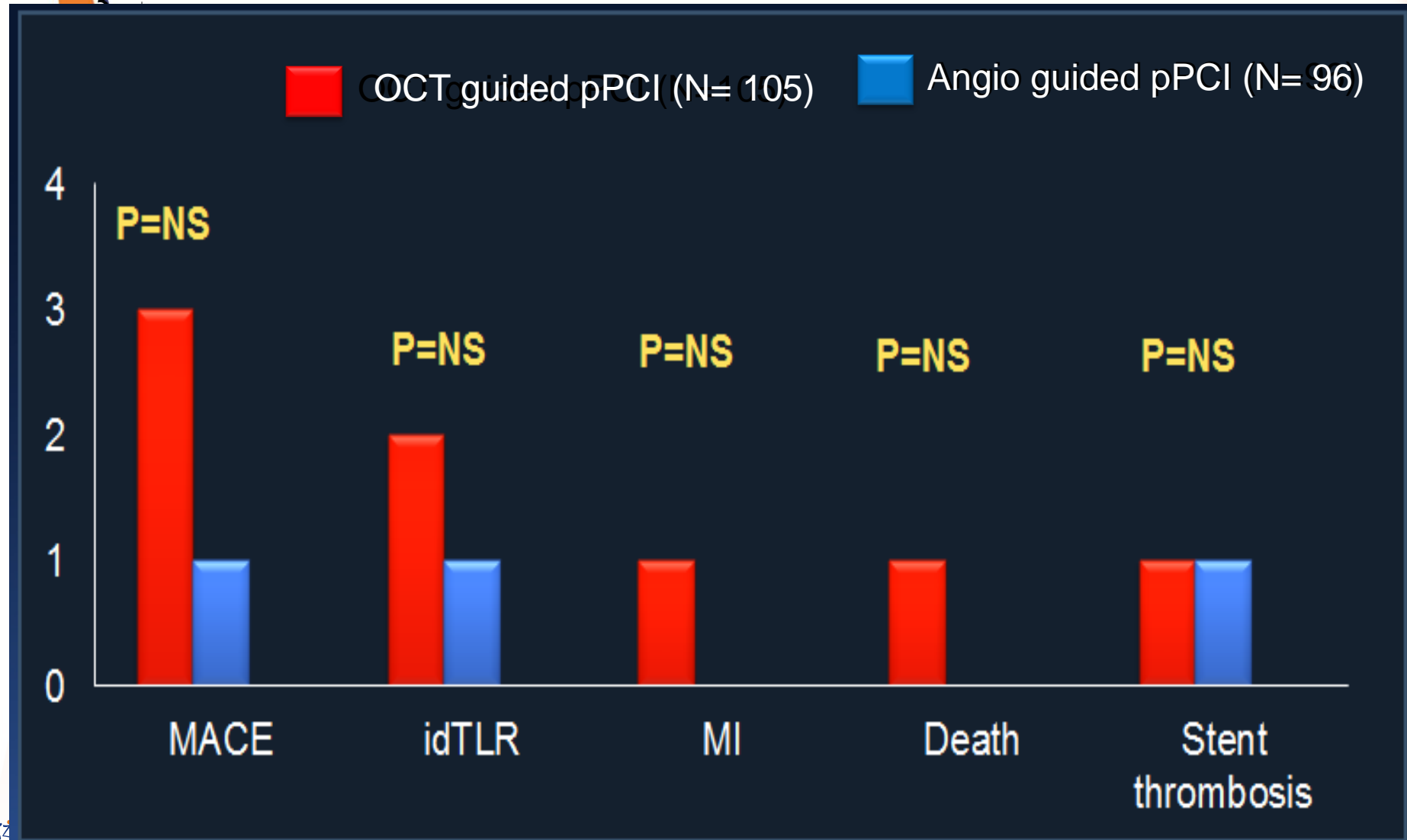
*(OCT=optical coherence tomography; pPCI=primary percutaneous coronary intervention; Min. in stent D. = minimal in-stent diameter; Min. in seg. D. = minimal in-segment diameter; DS stent=diameter stenosis in-stent; DS in-segment=diameter stenosis in-segment; CK max=creatine kinase peak; values in square brackets represent quartiles 1-3)*

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# Results: 30 day clinical FU (rates in %)

# Results: 9-month clinical FU (%)



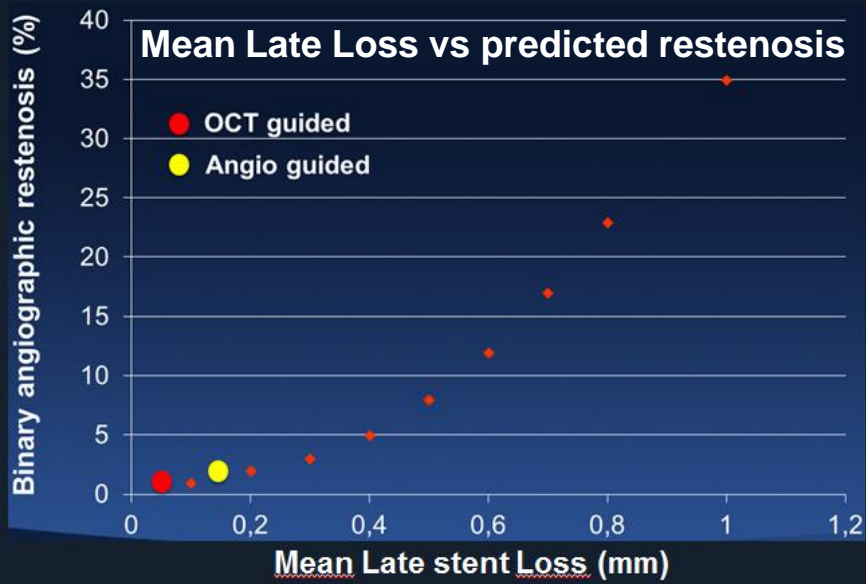
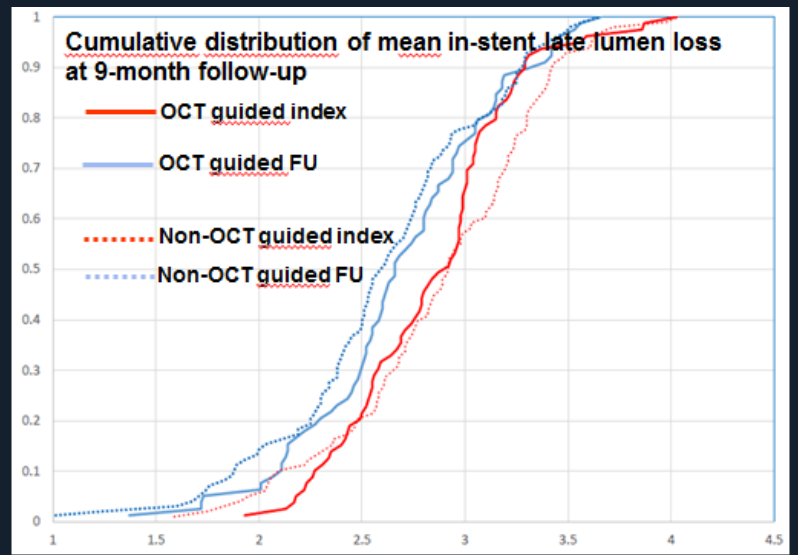
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# Results: Angiographic data at 9-month FU

	OCT guided pPCI	pPCI alone	P value
N	95	91	
Binary in-stent restenosis (%)	2 (2%)	3 (3%)	NS
DS in stent (%)	17.0 ±13.68	16.0 ±9.99	NS
DS in segment (%)	27.8 ±16.5	27.5 ±13.3	NS
Late lumen loss in-stent (mm)	0.05 ±0.5	0.15 ±0.34	NS
Late lumen loss in-segment (mm)	0.06 ±0.49	0.18 ±0.32	NS
Minimal in-stent diameter (mm)	2.7 ±0.47	2.6 (±0.52)	NS
Minimal in-segment diameter (mm)	2.3 ±0.51	2.3 ±0.59	NS
Reference stent diameter (mm)	3.2 ±0.55	3.1 ±0.52	NS
Reference segment diameter (mm)	3.1 ±0.7	3.2 ±0.6	NS



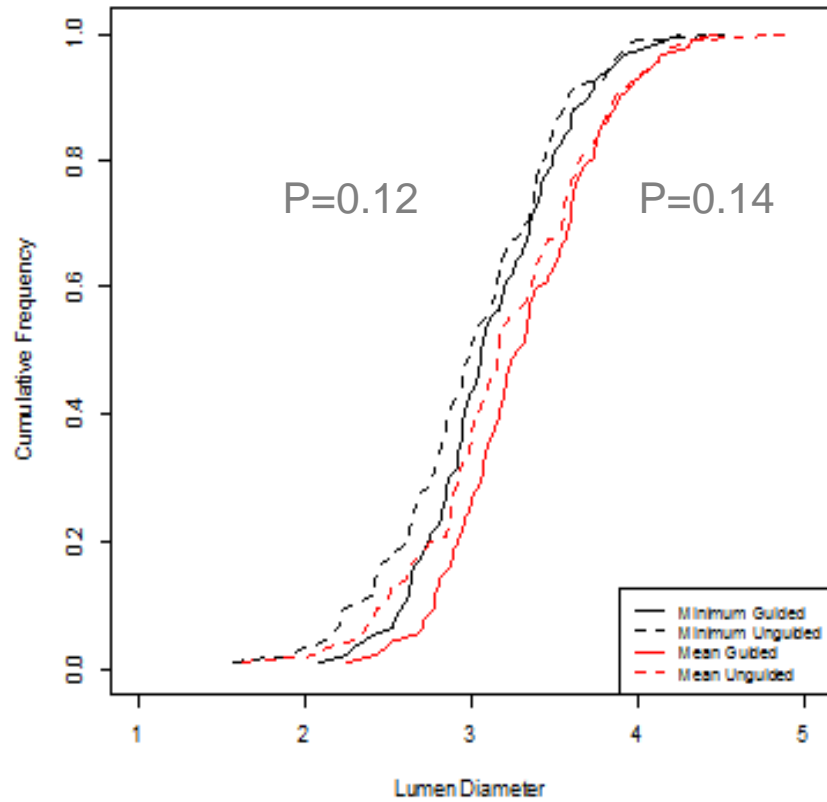
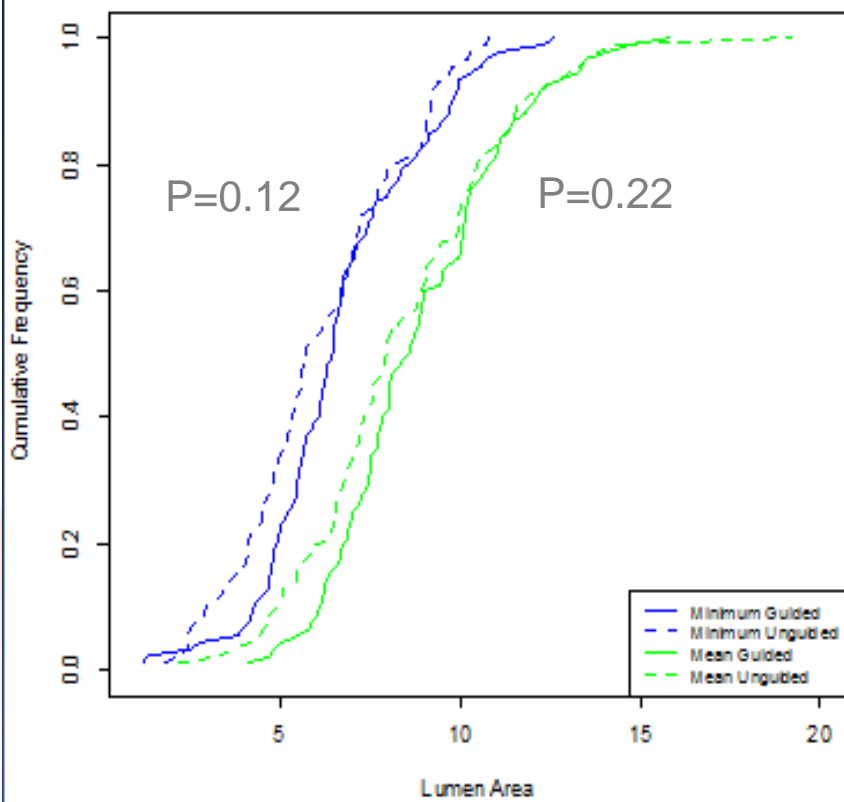
# Results: OCT data at 9-month FU

	OCT-guided pPCI	Angio-guided pPCI	P value
<b>N</b>	95 (90.5%)	91 (94.8%)	
<b>Mean Lumen diameter in-stent (mm)</b>	3.4 ±0.6	3.3± 0.6	NS
<b>Minimal lumen diameter in-stent (mm)</b>	3.2±0.5	3.0±0.6	NS
<b>Mean lumen area in-stent (mm<sup>2</sup>)</b>	8.9±2.4	8.4±2.9	NS
<b>Minimal lumen area in-stent (mm<sup>2</sup>)</b>	6.67±2.21	6.13±2.25	NS
<b>Mean NIH area (mm<sup>2</sup>)</b>	1.2±0.6	1.3±0.8	NS
<b>Area stenosis (%)</b>	4.4±24.0	15.9±21.98	0.0011
<b>Number of uncovered struts (%)</b>	12.8±13.1	16.8±15.8	0.0655
<b>Absolute number of uncovered struts</b>	11470/84882	12094/71578	P<0.001
<b>% malapposed struts</b>	0.82±2.85	0.82±1.43	NS



# Results: OCT data at 9-month FU

## Cumulative distribution of mean/minimum lumen area and diameter in-stent at 9-month follow-up





# Conclusions

The first longitudinal, randomized investigation of the role of OCT-guidance in the setting of pPCI for STEMI showed:

- No complications related to the OCT procedure.
- Overall very low rate of MACE, binary restenosis, ST and late lumen loss, high percentage of struts coverage in both second generation DES platforms.
- More stents and longer fluoroscopy time in the OCT guided pPCI. (Aggressive treatment of dissections)
- ***Smaller area stenosis and a trend towards better stent strut coverage in the OCT-guided group at 9 months.***

Whether such improvements in OCT endpoints will have a positive impact on late clinical outcomes demands both a larger and longer-term follow-up study



**Děkuji za pozornost**