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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Disclosure Statement of Financial Interest

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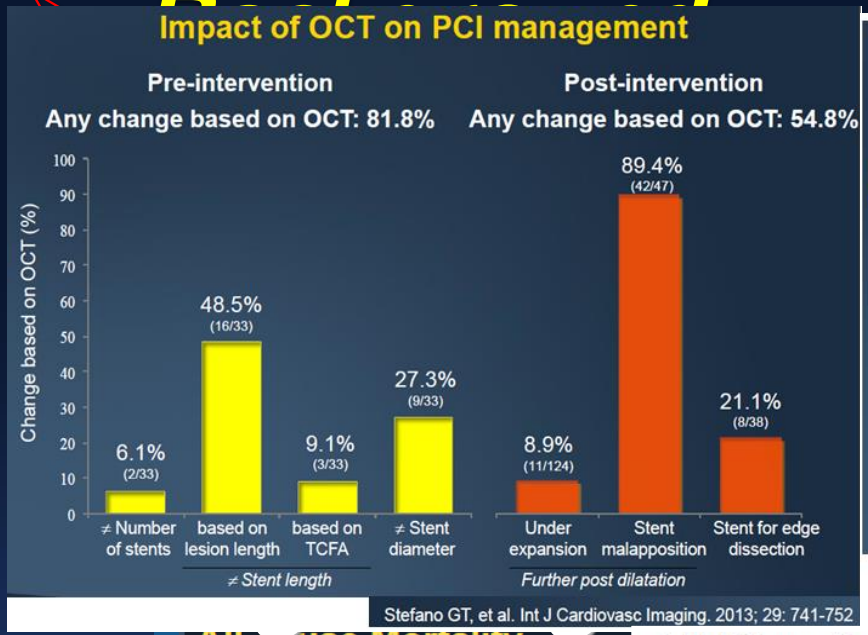
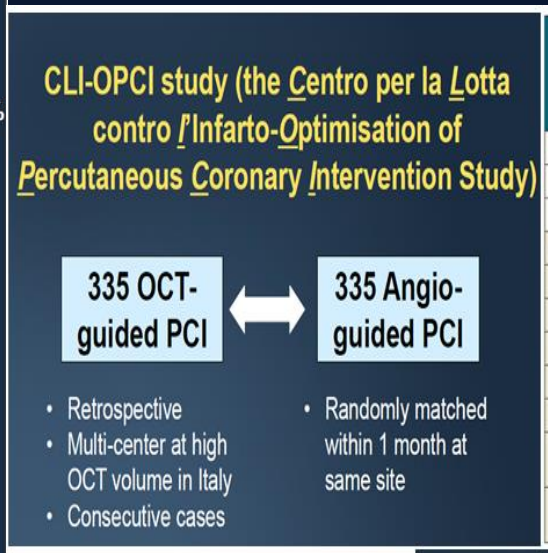
IVUS guided DES implantation decreases MACE



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



	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

0.002

Conclusion: IVUS guidan… outcomes compared with…

…ctions in PCI

DES imp… …imary PCI

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

Pavel Červinka, MD, Radim Šopček, MD, Marian Bystroň, MD, Martin Kvašňák, MD, Andrej Kupec, MD, Michaela Červinková, MD, Petr Kala, MD

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.

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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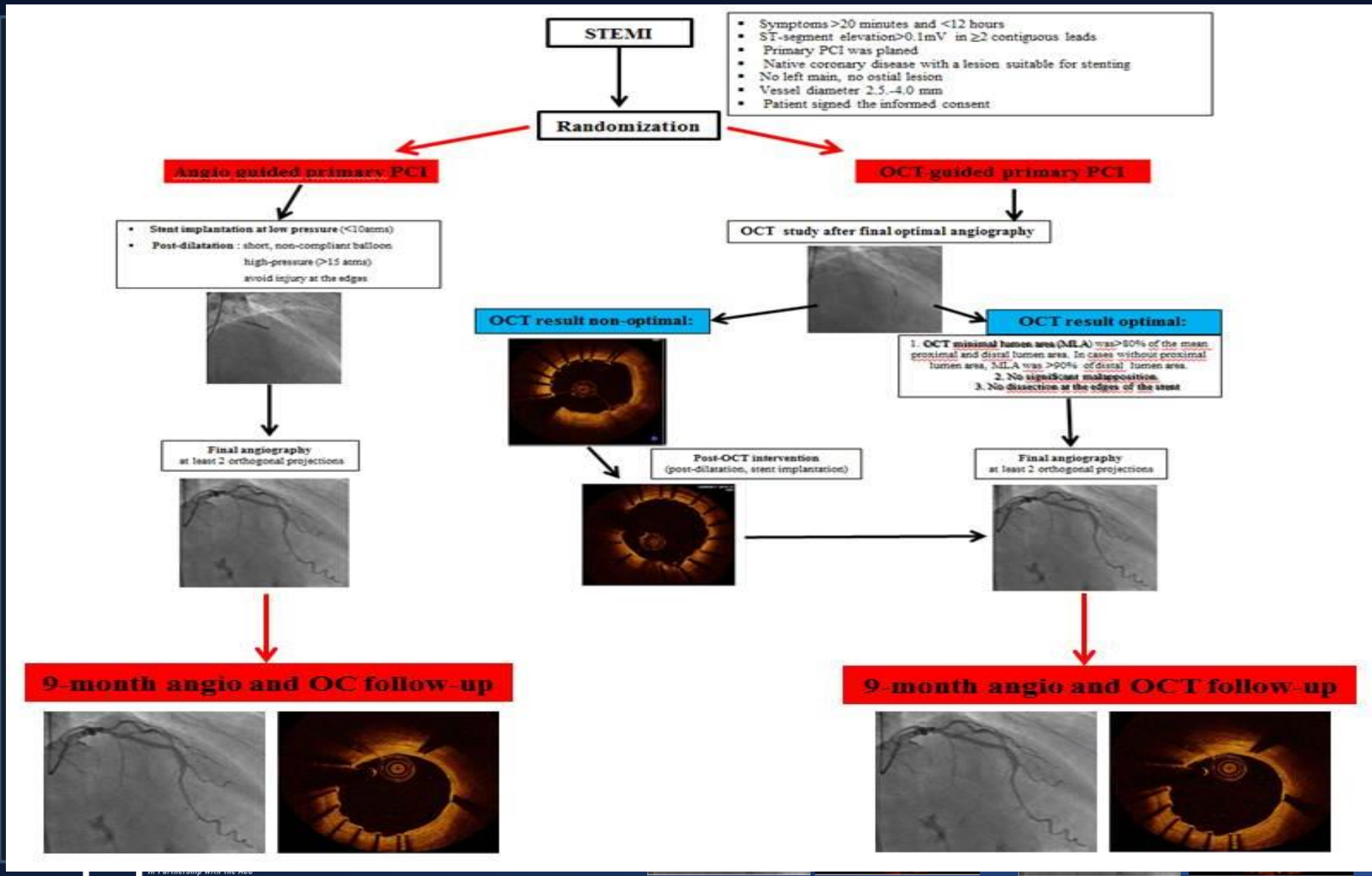
Study description



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≥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 teritory 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^2)
- **MACE´s (death, MI, ischemia driven TLR) at 9 M FU**

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

OCT analysis: Semi-automated system

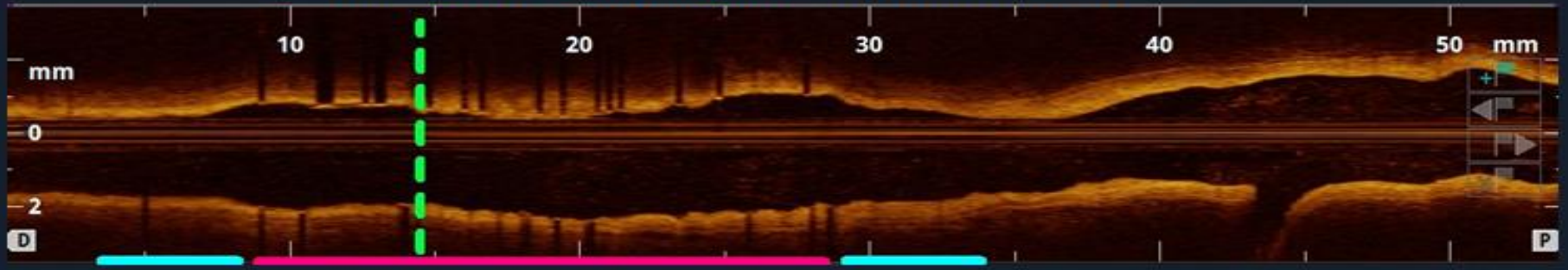
Image Analysis and Visualization Toolkit for Stent : (OCTivat-Stent)

Scheme of area stenosis calculations

Reference segement. This segment should contain no stent struts, side branches, dissections etc.

Stent segment

Localization of minimal in-stent lumen area



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

Results: Baseline demographic characteristics

	OCT guided pPCI	Angio guided pPCI	P value
N	105	96	
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
GPIIb/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%)		

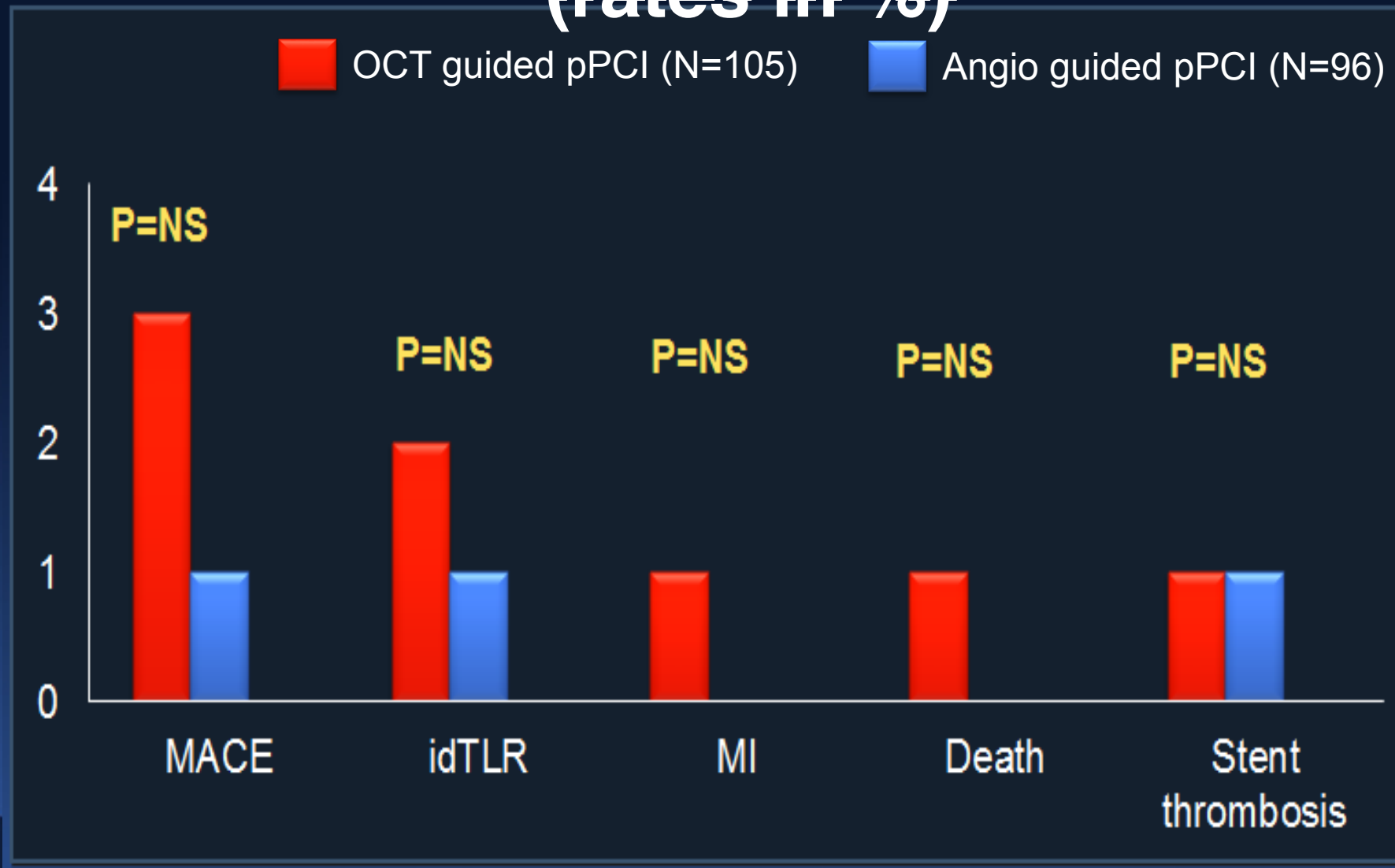
(OCT=optical coherence tomography; pPCI=primary percutaneous coronary intervention; CAD=coronary artery disease; MI=myocardial infarction;CABG=coronary artery bypass graft; LAD=left anterior descending; RCA=right coronary artery; LCx= left circumflex; values in square brackets represent quartiles 1-3)

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

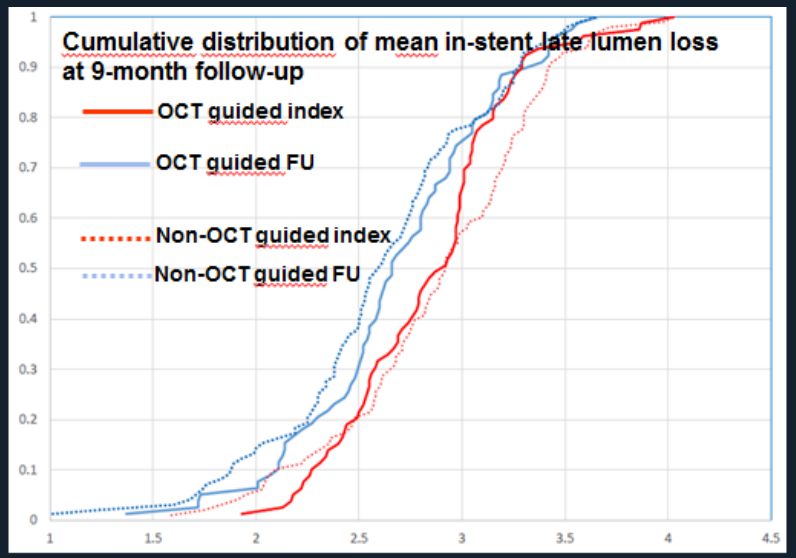
(OCT=optical coherence tomography; pPCI=primary percutaneous coronary intervention; Min. in stent D. = minimal in-stent diameter; Min. in seg. D. = minimal in-segment diameter; DS stent=diameter stenosis in-stent; DS in-segment=diameter stenosis in-segemnt; CK max=creatine kinase peak; values in square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

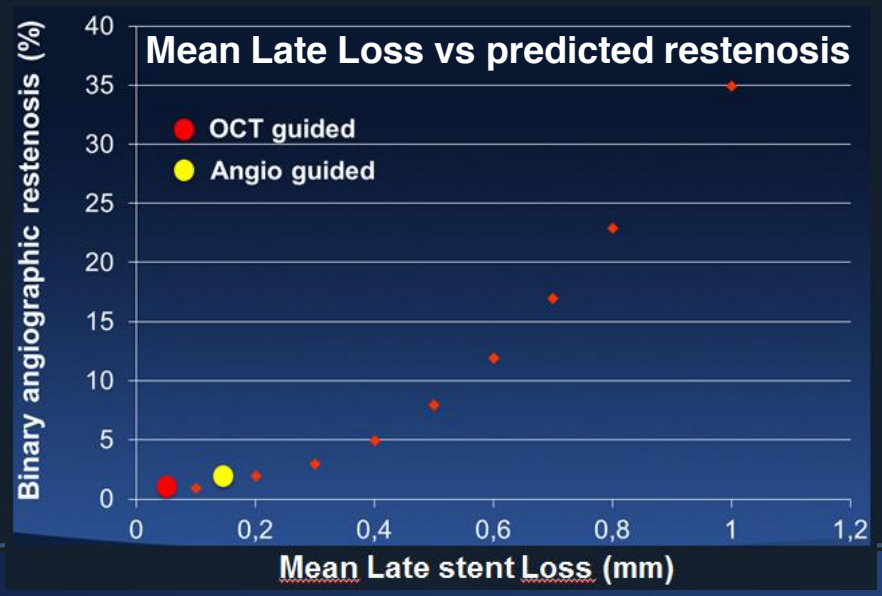
Results: 30 day clinical FU (rates in %)



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





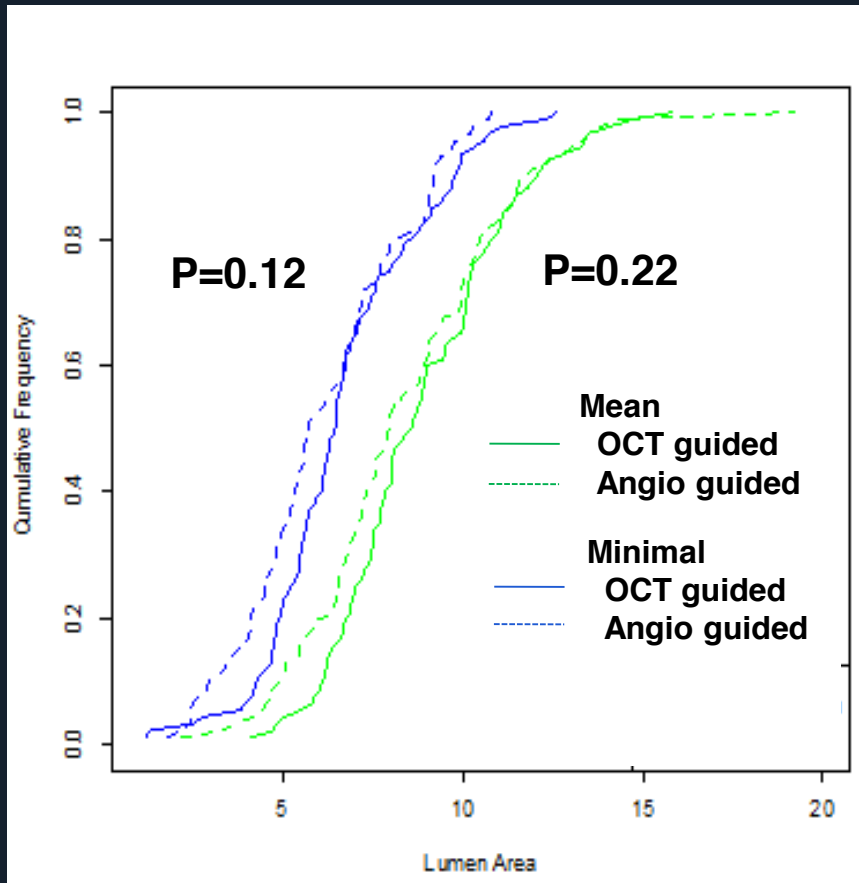
(Presented during EuroPCR 2014-Late breaking trials and innovations)

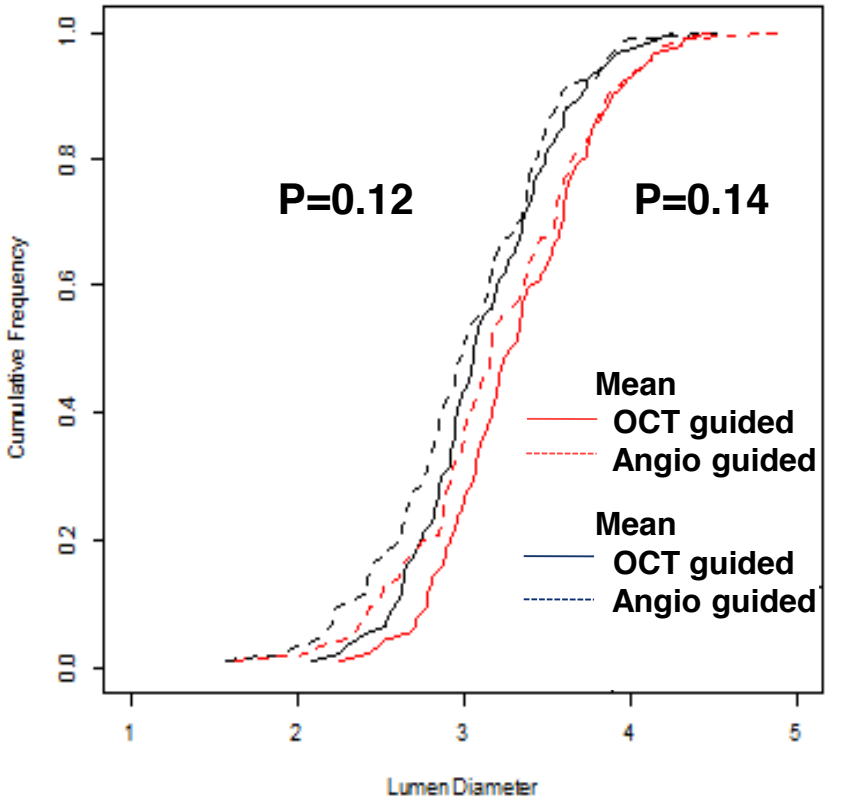
Results: OCT data at 9-month FU

	OCT-guided pPCI	Angio-guided pPCI	P value
N	95 (90.5%)	91 (94.8%)	
Mean Lumen diameter in-stent (mm)	3.4 ±0.6	3.3± 0.6	NS
Minimal lumen diameter in-stent (mm)	3.2±0.5	3.0±0.6	NS
Mean lumen area in-stent (mm^2)	8.9±2.4	8.4±2.9	NS
Minimal lumen area in-stent (mm^2)	9.1±2.9	8.6±3.3	NS
Mean NIH area (mm^2)	1.2±0.6	1.3±0.8	NS
Area stenosis (%)	4.4±24.0	15.9±21.98	0.0011
Number of uncovered struts (%)	12.8±13.1	16.8±15.8	0.0655
Absolute number of uncovered struts	11470/84882	12094/71578	P<0.001

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

Thank you for your attention