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Safety and Feasibility of Optical Coherence Tomography: A Single Center Experience

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Background: Optical coherence tomography (OCT) is increasingly used in the catheterization laboratory. Previous smaller studies have reported the safety of OCT in different clinical settings, however large datasets are still lacking. We report safety of intracoronary Fourier Domain OCT (FD-OCT) imaging in a real world series of consecutive patients that underwent OCT during coronary catheterization in our center. **Methods:** Prospective, single center registry in patients scheduled for coronary angiography or intervention (n=1,157) undergoing intracoronary OCT between April 2008 and December 2013. In total, 3,076 pullbacks were performed with 7 different OCT-systems. Any complication that occurred during or within the immediate 24hour period following OCT examination was registered and classified as either procedure or OCT-related event (self-limiting, requiring action or major adverse event). FD-OCT was performed during continuous intracoronary flushing with x-ray contrast through the guide catheter using an injector pump (flow rate 3-4ml/sec). A bolus of intracoronary nitroglycerine was routinely administered before introduction of the OCT catheter into the coronary artery.

Results: OCT was performed in an unselected group of patients with the only exclusion criteria of acute life-threatening hemodynamic instability and extensive calcifications (Table 1). OCT imaging was successfully performed in all patients. There were 47 angiographic adverse findings related to the catheterization and/or PCI procedure and no major adverse cardiac events were related to OCT imaging. Nine events were directly related to OCT imaging, but all were considered self-limiting or easily treatable. The event rate was 0.8% per patient and 0.3% per pullback.

Table 1. Patient characteristics and complication overview. *All transient. LAD: left anterior descending artery; LCX: left circumflex artery; RCA: right coronary artery.

Indications for catheterization	n = 1,157 (%)	Imaged vessel	Pullbacks, n = 3,076 (%)
Stable angina	435 (37.6)	LAD	1482 (48.1)
Unstable angina	180 (15.6)	Cx	576 (18.7)
Myocardial infarction	379 (32.8)	RCA	846 (27.5)
Follow-up	125 (10.8)	Other	172 (5.6)
Other	38 (3.3)		
Procedure related complications		OCT related complications*	
Dissection	36 (3.1)	ST elevation	3 (0.3)
Perforation	0	Bradycardia	1 (0.1)
Vessel occlusion	0	Dissection	0
Sidebranch occlusion	5 (0.4)	Perforation	0
No reflow (including TIMI-II flow)	6 (0.5)	Coronary spasm	4 (0.3)
		Thrombus formation	0
		Air embolism	1 (0.1)
		Arrhythmias	0

Conclusions: OCT is safe and feasible in unselected patients. Imaging related events were scarce, self-limiting or easily treatable, and transient.

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Long-term Vascular Response to Biodegradable Polymer Biolimus-Eluting Stents in Comparison With Durable Polymer Sirolimus-Eluting Stents and Bare-Metal Stents: Five-year Follow-up Optical Coherence Tomography Study

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Background: Long-term vessel response after biodegradable polymer biolimuseluting stents (BES) implantation remains unclear. We sought to evaluate the vascular response of biodegradable polymer BES at 5 years after stent implantation using optical coherence tomography (OCT) as compared with that of durable polymer sirolimus-eluting stents (SES) and bare-metal stents (BMS).

Methods: Five-year follow-up OCT was performed in 30 patients with 33 stents (10 with 12 BES; 10 with 11 SES; 10 with 10 BMS). Quantitative parameters and qualitative characteristics of the neointima were evaluated.

Results: A total of 5,178 struts (BES, n=2,056; SES, n=1,410; BMS, n=1,712) were analyzed. The percentage of uncovered struts was 0.7% of the BES group, which was significantly lower and higher than that of the SES and BMS groups (3.8% and 0.0%, P < 0.001, respectively). Malapposed struts in the BES group were significantly lower than the SES group (0.2% vs. 2.4%, P < 0.001), whereas they did not differ from the BMS group (0.2% vs. 0.0%, P=0.39). Cross-sectional qualitative analysis of neo-intimal tissue showed that the frequency of lipid-laden neointima was significantly lower in the BES group than the SES group (6.3% vs. 13.9%, P=0.031), and similar to the BMS group (6.3% vs. 5.2%, P=0.83).

Conclusions: Biodegradable polymer BES shows a favorable vascular response compared to SES, but slightly different response from BMS at 5-year follow-up. The observed frequency of in-stent neoatherosclerosis within BES is similar to BMS and significantly lower than SES, which may be due to the difference of polymer between BES and SES.

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Effect of Ezetimibe in addition to Statin Therapy in statin naïve STEMI patients assessed by Optical Coherence Tomography and Intravascular Ultrasound with iMap (The OCTIVUS trial)

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Background: The benefits of statin treatment in ischemic heart disease and its ability to induce plaque regression assessed by intravascular ultrasound (IVUS) are well established. Further reduction in levels of Low Density Lipoproteins (LDL) can be obtained by additional treatment with the cholesterol absorption inhibitor Ezetimibe, but its clinical significance has yet to be determined. The aim of the OCTIVUS study was to examine the optical coherence tomography (OCT) and intravascular ultrasound (IVUS) with iMap changes in plaque composition and volume of atorvastatin, as monotherapy and in combination with Ezetimibe, in patients with ST-segment elevation myocardial infarction.

Methods: The OCTIVUS trial (ClinicalTrials.gov ID: NCT01385631) is a single center prospective double blinded randomized trial designed to determine the change in plaque volume and composition using IVUS with iMap and OCT. Statin naïve patients with STEMI were randomized to receive atorvastatin (80 mg) as monotherapy or atorvastatin 80 mg in combination with Ezetimibe 10 mg, and underwent IVUS with iMap and OCT at baseline (n = 86) and study completion at 12 months (n = 82). Angiographic inclusion criteria was the presence of a >20% and < 50% plaque in a non-culprit vessel.

Results: The overall study cohort is as follows: Mean age: 56.2 years \pm 10.1 years, male gender: n = 74 (86%), Mean BMI: 27.7 \pm 4.5 kg/m2, family history of ischemic heart disease: n = 41 (47.7%), hypertension: n = 19 (22.1%), smokers: n = 48 (55.8%) and diabetes mellitus: n = 2 (82.3%). The distribution between groups cannot be assessed until unblinding. Endpoint results are presented at TCT 2014.

Conclusions: The high resolution of OCT in conjunction with the histologic classification by iMap enables a more detailed assessment of vulnerable plaque features such as fibroartheroma cap thickness, necrotic core and the presence of macrophages and cholesterol crystals. An improvement in these parameters might be a useful indicator of the possible clinical benefits in real world patient treatment.

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Association of Target Lesion Coronary Calcification with Stent Expansion and Eccentricity: An Optical Coherence Tomography Study

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Background: Although target lesion calcification negatively affects stent expansion, previous IVUS studies failed to demonstrate a relationship between stent expansion and the amount of coronary calcium. Optical coherence tomography (OCT) offers better quantitative assessment of coronary calcium than IVUS, and therefore may have potential to predict stent expansion.

Methods: 51 de novo native coronary artery lesions treated by single 2nd generation drug-eluting stent (DES) were enrolled. Prior to intervention, arc and area of calcium at the largest calcification site were measured using OCT. After stent implantation, OCT imaging was repeated to assess minimum stent diameter and area (MSD and MSA). Stent expansion was defined as MSD (or MSA) divided by the values predicted by the compliance charts. Stent eccentricity was also calculated (Figure). Patients were divided into 4 groups according to the median values of arc and area of calcium.

Results: Arc of calcium was associated with stent expansion defined by MSD (p< 0.01) and MSA (p=0.02). Area of calcium was also associated with stent expansion defined by MSD (p=0.01) but not statistically significant with MSA