

occluded for 30-60 seconds. The measurement is the difference between these two readings.

Results: Temperature measurements were made in 15 lesions from 11 patients with a mean age of 62 years, 90% male, 36% diabetes and 82% with acute coronary syndromes. Measurement were made in all three major coronary arteries. The mean temperature elevation was 0.4 (range 0-2.2°C). Five of the 15 lesions had a mean temperature elevation of 0.9 °C (range 0.3-2.2) over baseline while the rest of lesions (n=10) had no temperature change from baseline. No complications were observed with its clinical application. Conclusion: A thermal sensing catheter that temporarily occludes flow during the measurement is a safe and feasible means to accurately measure lesion temperature. The system used in this trial holds promise as a new diagnostic tool to guide treatment of coronary lesions.

1006-62 Forward Looking Optical Coherence Tomography: A Potential Tool to Visualize the Total Chronic Occlusion

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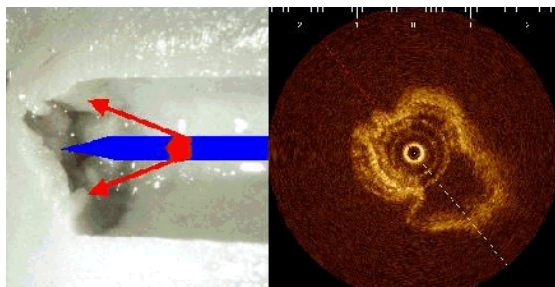
PCI of chronic total occlusion is technically challenging. The direct visualization of the occlusion could help to steer the guidewire and increase the safety and success rate of recanalization procedures. Intravascular Optical Coherence Tomography (OCT) is a new light emitting technique, which provides high resolution cross-sectional images of the vessel wall (~ 15 microns). We hypothesised that OCT is suitable to give forward-looking information on vessel anatomy.

An OCT catheter (Lightlab Inc) was modified to emit near infrared (1340nm) light in an angle of 30° from the axis of the catheter. The catheter is rotating around his axis providing a cone like beam providing images of structures that are located in front of the catheter.

Forward looking OCT was performed in a cryogel (PVA 5%) phantom, which mimics the anatomy of an artery with a total occlusion by introducing the modified catheter into the phantom and advancing the catheter. After image acquisition the phantom was cut open and the morphology was assessed (figure 1).

It was feasible with OCT to detect the total occlusion, the geometry and the size of the phantom. The surface of the occlusion was clearly delineated. Details of the vessel mimicking phantom wall were clearly visible. Comparison with the structure of the phantom showed remarkable agreement between images and details of the vessel wall and the occlusion.

Forward looking OCT is feasible in-vitro and may provide valuable in-vivo information for recanalization of chronic total occlusions.



POSTER SESSION

1024 Drug-Eluting Stents in Complex Anatomy I

Sunday, March 07, 2004, Noon-2:00 p.m.
 Morial Convention Center, Hall G
 Presentation Hour: 1:00 p.m.-2:00 p.m.

1024-47 Sirolimus Versus Plain Old Balloon Angioplasty Small Vessels

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Background: Results of stenting in smaller vessels compared with angioplasty alone have been variable and conflicting particularly in regards to restenosis prevention and follow up events. The Sirolimus-eluting stent may improve the outcome in these vessels.

Purpose: In vessels < 3mm to evaluate effectiveness of the Sirolimus-eluting Bx velocity stent in the randomized SIRIUS Trial and compare it to patients treated in BENESTENT I + II and STRESS with conventional PTCA.

Population: 370 lesions treated with Sirolimus-eluting stent in the SIRIUS Trial and 437 lesions treated with PTCA alone in BENESTENT I (n=120), BENESTENT II (n=209) and STRESS (n=108). All patients had treatment of de novo lesions in vessels with RVD < 3.0mm

Results: Sirolimus stent patients were at higher risk;

- 1) The mean reference RVD was 2.56±0.28 in Sirolimus versus 2.65±0.24mm in the PTCA group
 - 2) Lesion length in Sirolimus was significantly longer 14.0±5.8 versus 7.9±2.6mm
 - 3) Diabetes was more frequent 27% in Sirolimus versus 12.1% in PTCA Group
- Despite these higher risk characteristics, patients treated with Sirolimus had improved outcome at 270 days (table)

Safety Measures (Events up to 270 days)	Sirolimus-Eluting Bx VELOCITY(TM) (n=370 patients n=370 lesions)	Historical Control Balloon (n=429 patients n=437 lesions)	Difference (95% CI)
MACE (Any Death, MI, TLR)	8.4% (31/370)	24.7% (106/429)	-16.3%{-21.3%,-11.4%}
Death	1.1% (4/370)	0.0% (0/429)	1.1% {0.0%, 2.1%}
Any MI	3.0% (11/370)	3.3% (14/429)	-0.3% {-2.7%, 2.1%}
Target Lesion Revasc	5.1% (19/370)	24.0% (105/437)	-18.9% {-23.5%, -14.3%}
(Sub)acute Occlusion	0.3% (1/370)	1.4% (6/429)	-1.1% {-2.4%, 0.1%}

>Conclusions: Implantation of Sirolimus-eluting stents in small vessels < 3.0mm results in markedly improved outcome compared with conventional PTCA alone.

1024-48 Intraprocedural Stent Thrombosis: A Potentially New Emerging Complication With Usage of Long Stents in the Drug-Eluting Stent Era

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Background Intraprocedural stent thrombosis (IPST) is an unheard event outside specific settings such as acute myocardial infarction, thrombus containing lesions or dissections. Some concerns have been raised due to the implantation of long stent required by sirolimus-eluting stents (SES). The aim of our study was to investigate the frequency and the predictors of IPST in drug-eluting stent era.

Methods and Results Between April 2002 and August 2003, 683 patients (pts) were treated with Cypher (Cordis, Johnson and Johnson Company, Warren, NJ) Sirolimus-Eluting Stent (SES) implantation in San Raffaele Hospital and EMO Centro Cuore Columbus. 146 (21%) patients were diabetics, 161 (23%) had unstable angina. 239pts (35%) were pretreated with glycoprotein IIb/IIIa inhibitors (IIb/IIIa). Maximum stent length per vessel (per patient) was 43.2±28.4mm. IPST occurred in 5 (0.7%) patients. None of the patients with IPST was pretreated with IIb/IIIa. Multivariate analysis using exact test for logistic regression modelling showed that maximum stent length per vessel (exact odds ratio [OR]=1.039 , 95% confidence interval [CI]= 1.016-1.067; p=0.001) and the lack of use of elective IIb/IIIa (OR=11.6, CI=1.5 -∞, p=0.016) were independent correlates of IPST.

Conclusions Stent length and no pretreatment with IIb/IIIa are independently correlated with occurrence of IPST. Particular attention will need to be paid to this new emerging complication when long stents are being used.

1024-49 Impact of Sirolimus-Eluting Stents on the Outcome of Patients With Chronic Total Occlusions: Multicenter Registry in Asia

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Background: Although previous clinical studies utilizing sirolimus-eluting stents (SES) in simple coronary lesions demonstrated an impressive reduction in intimal hyperplasia and restenosis, long-term efficacy of SES in treating patients with chronic total occlusion is still unknown. A prospective Asian multicenter registry was set up in 5 high volume Asian centers to evaluate the efficacy of SES in the treatment of chronic total occlusions.

Method: A total of 88 patients with 102 chronic total occlusions (male 70.5% mean age 69.2) (defined as TIMI flow grade 0 and the age of occlusion was more than 3 months: LAD=42.1% LCX=27.3% RCA=30.6%) were treated with SES after successful lesion crossing and dilating the lesions. We evaluate immediate and long-term clinical results by 6 months and 12 months angiography. Results: See table for clinical results. The 12 months QCA results will be available at the time of presentation. Conclusion: These results showed utilizing the SES can dramatic suppress the restenosis rate with chronic total occlusive lesions.

Number of patients	88
Procedural success (%)	100
MACE at 30 days (%)	0
Reference diameter (mm)	2.86±0.66
MLD post (mm)	2.65±0.55
MLD at 6 months (mm)	2.54±0.44
Restenosis rate (%)	3.4
TVR (%)	4.5
MACE at 6 months (%)	4.5