

no episode of restenosis either within the stent or at the stent edges. IVUS results (Table) show no difference when SE stent edges were compared to placebo stent edges. To the contrary, there was a tendency for reference lumen areas to be larger and plaque areas to be smaller in SE stents, especially at the distal edge.

	SE stent N=48	Bare stent N=47	Δ	p-value
Proximal edge				
Arterial area, mm ²	14.76±5.05	13.89±3.69	0.87	0.37
Lumen area, mm ²	7.65±3.37	6.84±2.61	0.81	0.22
Plaque area, mm ²	7.11±2.90	7.05±2.52	-0.06	0.91
Distal edge				
Arterial area, mm ²	11.59±4.08	11.46±3.70	0.13	0.88
Lumen area, mm ²	6.68±2.30	5.69±1.91	0.99	0.03
Plaque area, mm ²	4.90±2.53	5.77±2.97	0.86	0.16

Conclusions: Volumetric IVUS analysis shows that there is no "edge effect" when sirolimus-eluting stents are used to treat de novo, native coronary lesions.

9:00 a.m.

880-3 Optimal Endpoint for Drug-Eluting Stent: Predictive Value of Minimum Stent Area for Long-Term Stent Patency

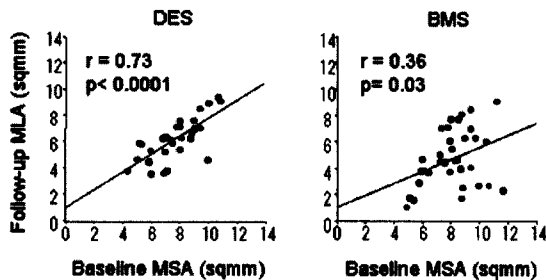
Yasuhiro Honda, Eberhard Grube, Toru Kataoka, Karl E. Hauptmann, Yoshihiro Morino, Seung-Ho Hur, Paul G. Yock, Peter J. Fitzgerald, SCORE investigators group, *Stanford University, Stanford, California, Heart Center Siegburg, Siegburg, Germany.*

Minimum stent area (MSA) has been shown to be a consistent predictor of in-stent restenosis. However, its predictive value is limited because of biologic variability in the restenosis process. Drug-eluting stents (DES) provide a biological effect as well as a mechanical solution to obstructive lesions. The aim of this study was to investigate the relationship between post-procedure MSA and long-term stent patency following the QUANAM QP2-eluting stent (DES) implantation as compared to bare metal stents (BMS).

Methods: SCORE is a randomized trial comparing DES vs. BMS. To date, serial IVUS (baseline and 6-months) studies are available in 64 (DES 30; BMS 34) of 118 enrolled patients. MSA at post-procedure and minimum lumen area (MLA) at follow-up were obtained.

Results: The baseline characteristics were similar in DES and BMS. In BMS, only a weak correlation was observed between post-procedure MSA and follow-up MLA ($r=0.37, p=0.03$), potentially reflecting high variability in biological activity of individual lesion/patients. DES, however, showed a significant positive relationship with a high correlation coefficient between the two parameters ($r=0.73, p<0.0001$).

Conclusions: Preliminary IVUS results suggest that post-procedure MSA may predict long-term stent patency more accurately in DES than in BMS. This finding indicates that post-procedure MSA, a simple mechanical index, can be used as the optimal procedural endpoint for DES, regardless of variable degrees of biological activity in each lesion.



9:15 a.m.

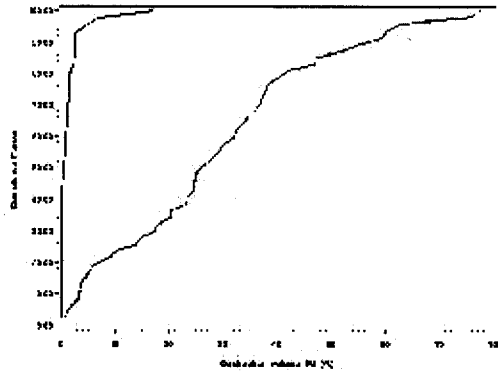
880-4 Total Suppression of Neointimal Proliferation After Implantation of Sirolimus-Eluting Stents: Volumetric Intravascular Ultrasound Results From the Randomized RAVEL Trial

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Background: We previously showed, in a non-randomized study, that Sirolimus-Eluting (SE) stents inhibit neointimal proliferation. These preliminary results were tested in RAVEL, a double-blinded, randomized, placebo-controlled multicenter trial that compared SE BX Velocity stents (n=120) vs bare BX Velocity stents (BS, n=118). **Methods:** The intravascular ultrasound (IVUS) sub-study included 95 pts (SE=48 and BS=47). **Results:**

6-Month IVUS FU	Sirolimus-eluting	Bare stent	P values
Stent volume (mm ³)	130.6±33.9	132±1±35.6	0.842
Lumen volume (mm ³)	128.9±33.9	94.9±40.9	< 0.0001
Intimal hyperplasia volume (mm ³)	1.97±4.87	37.2±27.8	< 0.0001
Intimal hyperplasia (% of stent volume)	1.45±2.83	28.8±19.7	< 0.0001

The cumulative frequency distribution curve of percent obstruction shows that 90% of the SE group had less than 2% of the stent occupied by neointima (left curve, Figure). **Conclusions:** In the RAVEL trial, IVUS analysis shows a striking inhibition of intimal hyperplasia 6 months after sirolimus eluting stent implantation.



9:30 a.m.

880-5 Intravascular Ultrasound Assessment Five Years After Intracoronary Gamma Radiation Therapy

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BACKGROUND: Late effects of intracoronary gamma radiation remain unknown, as most long-term studies of efficacy and potential side effects have been initiated within the past 3 years. We report five-year intravascular ultrasound (IVUS) findings from the initial cohort of patients treated with intracoronary brachytherapy in Venezuela.

METHOD: IVUS examinations were performed in 14 patients (15 lesions) 5 years after they were treated with non-centered 192Ir in doses of 19-55 Gy after PTCA. IVUS interrogations were performed by manual pullback using a dynamic aperture catheter system (In-Vision, EndoSonics Corp., Rancho Cordova, CA) and were analyzed off-line using quantitative methods (QCU) by a commercially available software package (Quant32, Sanders Data Systems, Palo Alto, CA).

RESULTS: At 5 years, the mean minimum lumen area (MLA) at the treated segment was 3.6±1.9 mm² (range, 0 to 8 mm), and the mean % area stenosis (%AS) at the irradiated segment was 50.5±22.9 (range, 19.4 to 100 %). IVUS defined (%AS >70%) restenosis was present in 4 arteries (26.7%), two of which occurred at edges. Positive remodeling was observed in 9 arteries (60%), and three true coronary aneurysms were observed (2 focal, 1 fusiform) without evidence of thrombus. Increased echo intensity of adventitia, presumably due to fibrosis, of moderate or greater degree occurred in 11 arteries (73.3%). Calcification was observed in 9 arteries (60%), mostly as >90 degree arcs and of deep or mixed location.

CONCLUSIONS: In this five-year IVUS cohort, gamma radiation was associated with modest plaque/neointima accumulation. Positive remodeling was common and there were three aneurysms (previously detected by angio). The most striking new finding was fibrosis of the adventitia and extensive deep and mixed calcification in the majority of the treated segments.

9:45 a.m.

880-6 Peri-Stent Remodeling and Neointimal Response Following Intracoronary Radiation Therapy: A Volumetric Intravascular Ultrasound Study

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A recent volumetric IVUS study has suggested the role of peri-stent remodeling in subsequent neointimal response. The aim of this study was to investigate the potential relationship between peri-stent remodeling and neointimal proliferation following intracoronary brachytherapy with a beta source wire (³²P).

Methods: Serial (baseline and follow-up) volumetric IVUS analyses were performed in 23 stented lesions treated with intracoronary beta radiation enrolled in the PREVENT study. Vessel (VV), stent (SV) and lumen volumes (LV) were obtained using Simpson's method. The volumes of plaque and neointima outside the stent (peri-stent volume, PSV) and neointima within the stent (intra-stent volume, ISV) were computed. Peri-stent remodeling was defined present if ΔVV > 0 (Group P) and absent if ΔVV ≤ 0 (Group N). **Results:** At baseline, VV, LV, SV, PSV and ISV were similar between Group P (n=12)