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TAXUS IV: Results From the Intravascular Ultrasound Substudy

Neil J. Weissman, Stephen Ellis, Mark Turco, Joel Greenberg, James Tift Mann, Michael Kutcher, S. Chiu Wong, Charles O'Shaughnessy, Mary Russell, Gregg W. Stone, Washington Hospital Center, Washington, DC

Background: The TAXUS IV multicenter, randomized, double-blind clinical trial demonstrated that the TAXUS stent decreases clinical events and angiographic restenosis.

Methods: In order to enhance our understanding of the relative efficacy and safety of the TAXUS stent, a pre-specified IVUS substudy was conducted at 27 sites in 268 patients. Consecutive patients enrolled into the TAXUS IV study at these sites were mandated to use IVUS at implantation and follow-up. Standard IVUS imaging methods (IC nitroglycerine, motorized pullback) and core lab volumetric analysis was performed throughout the stent and edges.

Results: Of the 199 patients returning for a 9-month follow-up IVUS, 178 (90%) were technically adequate for subsequent analysis (87 control, 91 TAXUS). Baseline IVUS volumes (vessel, stent and lumen volume) at implantation were similar in each group. Follow up volumes are below (table):

	CONTROL	TAXUS	p-value
Vessel vol (mm ³)	286	288	0.92
Stent vol (mm ³)	147	150	0.66
Lumen vol (mm ³)	106	131	0.001
Neointima vol (mm ³)	41	18	<0.001
% vol obstruction	29.4%	12.2%	<0.001

The neointima reduction was uniform throughout the stent. In addition, there was no difference in the lumen loss at the margins beyond the stent edges except for a reduction of the lumen loss for the first mm at the distal edge in the TAXUS group (p=0.004). Late incomplete stent apposition only occurred in 2 control patients and 1 TAXUS patient (p=0.62).

Conclusion: The TAXUS stent decreased neointima volume uniformly throughout the stent without any negative edge effects and without any increase in late incomplete apposition.

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Longitudinal Vessel Remodeling Pattern Following Sirolimus-Eluting Stent Implantation: Analysis of Vessel Integrity Throughout Target Segment

Hideaki Kaneda, Junya Ako, Yasuhiro Honda, Ryota Sakurai, Mitsuyasu Terashima, Shinjo Sonoda, Yoshihisa Shimada, Yoshihiro Morino, Paul G. Yock, Martin B. Leon, Jeffrey W. Moses, Peter J. Fitzgerald, The SIRIUS Investigators, Stanford University, Stanford, CA, Lenox Hill Hospital, New York, NY

Background: Previous studies of drug-eluting stents have shown asymmetric effect on neointimal hyperplasia (i.e., greater neointima at proximal vs distal stent edge). These results may be caused by longitudinally asymmetric drug diffusion, delivery technique and/or margin injury. Our study objective was to assess whether vessel remodeling following sirolimus-eluting stent (SES) implantation is longitudinally asymmetric.

Methods: Thirty-six patients who underwent single 18 mm stent implantation (23 SES and 13 control Bx VELOCITY) and serial (baseline and 8 month follow-up) three-dimensional IVUS were enrolled in this study from the overall SIRIUS population. Five 2 mm-subsegments were chosen from each patient: proximal/ distal adjacent or in-stent edge segments within 2 mm from the stent edge and at the center of stent. Vessel (inside the external elastic membrane) and plaque plus neointima (vessel-lumen) volume were calculated and divided by length to create an average area. Serial change was calculated as follow up - baseline measurements.

Results: The amount and pattern of plaque plus neointima area change was significantly different between SES and control (Left Fig.). However, there was no significant difference in remodeling between the two treatment groups nor among different segments using two-way ANOVA (Right Fig.).

Conclusion: There was no detectable difference in the remodeling pattern of SES and control stents, despite significant difference in plaque plus neointima distribution.

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Effect of Everolimus-Eluting Stents in Preventing Neointimal Hyperplasia: An Intravascular Ultrasound Analysis From the FUTURE II Trial

Shinjo Sonoda, Eberhard Grube, Yoshihisa Shimada, Ali H.M Hassan, Yasuhiro Honda, Paul G. Yock, Charles Chan, Hidehiko Honda, Saibal Kar, Karl E. Hauptmann, Hans Storger, Alexandra J. Lansky, Peter J. Fitzgerald, The FUTURE II Investigators, Stanford University Medical Center, Stanford, CA, Heart Center Siegburg, Siegburg, Germany

Background: FUTURE II is a prospective, randomized, multicenter, double-blind trial comparing everolimus-eluting stents (EES), coated with a bioabsorbable polymer, to conventional metallic stents (MS). This study includes a more restenosis-prone lesion subset than FUTURE I. The purpose of this IVUS substudy was to investigate the antiproliferative efficacy of EES compared to MS in this more complex lesion subset.

Methods and Results: To date, serial 3-D IVUS analyses (baseline and 6 months follow-up) are available in 41 patients. To adjust volume data to different stent lengths, volume index was calculated as volume divided by stent length (VVI: vessel volume index, SVI: stent volume index, LVI: lumen volume index). Percent neointimal volume (%NV) was defined as neointimal volume divided by stent volume. At baseline, EES achieved stent expansion similar to MS. VVI within the stented segment and SVI were not different between groups either at baseline or at follow-up. LVI was also comparable between groups at baseline. However, LVI at follow-up was significantly larger in EES than in MS (P<0.05) and %NV was significantly lower in EES than in MS (P<0.0001, 95% reduction). There was no evidence of unhealed dissections or late stent malapposition in either group.

Conclusion: Everolimus-eluting stents demonstrated marked antiproliferative efficacy compared to MS with no evidence of IVUS-detected adverse effects.

	EES	MS	P-value
Baseline			
VVI, mm ³ /mm	15.6 ± 5.8	16.6 ± 4.7	0.53
SVI, mm ³ /mm	7.5 ± 2.2	7.9 ± 2.2	0.60
6 months follow-up			
VVI, mm ³ /mm	15.7 ± 5.7	17.0 ± 4.9	0.46
SVI, mm ³ /mm	7.7 ± 2.1	7.8 ± 2.2	0.82
LVI, mm ³ /mm	7.6 ± 2.1	6.2 ± 2.3	< 0.05
%NV, %	1.2 ± 1.9	22.0 ± 16.0	<0.0001

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Contribution of Stent Underexpansion to Target Lesion Revascularization After Sirolimus-Eluting Stenting for In-Stent Restenosis

Kenichi Fujii, Yoshio Kobayashi, Gary S. Mintz, Hideo Takebayashi, Takenori Yasuda, David Jacoboff, Issam Moussa, Roxana Mehran, George Dangas, Alexandra Lansky, Edward Kreps, Michael Collins, Gregg W. Stone, Martin B. Leon, Jeffrey W. Moses, Cardiovascular Research Foundation, New York, NY

Background: Sirolimus-eluting stents (SES) strongly suppresses neointimal hyperplasia and prevents target lesion revascularization (TLR) in de novo lesions. However, the efficacy of SES in the treatment of in-stent restenosis (ISR) is less certain. Minimum stent area (MSA) after stenting is a predictor of TLR. We investigated the relationship between stent underexpansion and TLR after SES treatment of ISR.

Methods: In 40 ISR lesions treated with SES, 3-D intravascular ultrasound (IVUS) analysis was performed. Stent and reference segments were measured every 1mm, and volumes were calculated using Simpson's rule. Stent underexpansion was MSA <5.0 mm² and <80% of the average reference lumen. A residual edge lesion was stent edge plaque burden (plaque/external elastic membrane [EEM]) >50%. Eight lesions required TLR; 32 did not.

Results: Stent underexpansion was observed in 6 TLR lesions (75%) and 11 non-TLR lesions (34%, p=0.04). A gap between stents was detected in 3 TLR lesions (38%) and 1 non-TLR lesion (3%, p=0.01). Multivariate analysis identified stent underexpansion as the only independent predictor of TLR (p=0.04).

Conclusions: SES fail in 25% of patients after treatment of ISR. IVUS analysis shows that stent underexpansion, in particular, is associated with failure after SES implantation to treat ISR.