Lp(a) is a risk factor of restenosis. Apo E isoform may also contribute to restenosis. The highest rate of restenosis is seen in patients with apoE4, especially in patients with low levels of Lp(a).

922-47 Early Luminal Deterioration After Successful Coronary Balloon Angioplasty: Insights Into the Mechanisms From Coronary Tissue Analysis

Pedro R. Moreno, John T. Fallon, Victor Bernardi, Neil J. Weissman, Valentin Fuster, Alfredo Rodriguez, Igor F. Palacios. *Massachusetts General Hospital, Boston, MA; Mount Sinai Medical Center, New York, NY*

Early loss of minimal luminal diameter (MLD) > 0.3 mm after successful PTCA is associated with a higher incidence of restenosis. The mechanism of early loss is unknown. To test the hypothesis that thrombus plays a significant role in early loss, we performed a prospective study using quantitative computerized planimetry on coronary tissue specimens obtained by directional atherectomy (DCA) of 24 lesions with early loss occurring 22 ± 2 minutes after successful PTCA. MLD and diameter stenosis were (mean ± SEM): 0.6 ± 0.06 mm and 76 ± 2% pre PTCA; 1.9 ± 0.9 mm and 32 ± 2% post-PTCA; 0.98 ± 0.1 mm and 67 ± 3% pre-DCA (time of early loss); and 2.49 ± 0.1 mm and 24 ± 4% post DCA (P = 0.001). Plaque composition included: thrombus: 6 ± 0.4%, sclerotic tissue: 63 ± 6%, fibrocellular tissue: 16 ± 4%, hypercellular tissue: 12 ± 3%, and atheromatous gruel: 3 ± 0.1%. Thrombus was present in only 9/24 (37%) lesions. Furthermore, relative early loss index {(MLD post-PTCA MLD – MLD at early loss/Reference Diameter) × 100} was similar in plaques with or without thrombus, 35 ± 7% vs 26 ± 2% respectively (P = 0.87). Linear regression analysis showed no relation between thrombus and early loss (r = 0.004, P = 0.76).

Conclusion: Histopathologic analysis of lesions with early luminal loss following PTCA showed that thrombus does not play a significant role in this early angiographic phenomenon.

922-48 A Sensitive and Cost-Effective Intravascular Ultrasound Model to Study Anti-Restenosis Strategies *In Vivo*

Gary S. Mintz, Roxana Mehran, Mun K. Hong, Jeffrey J. Popma, Augusto D. Pichard, Lowell F. Satler, Kenneth M. Kent, N. V. Dat, Martin B. Leon. *Washington Hospital Center, Washington, DC*

STRESS and BENESTENT showed that stents reduce restenosis, but required sample sizes in excess of 200 pts per arm to demonstrate a 30% reduction in restenosis rates. To develop a more sensitive model for detecting reductions in restenosis rates, we used volumetric intravascular ultrasound (IVUS: motorized transducer pullback 0.5 mm/sec through a stationary imaging sheath) to analyze instent restenosis 1 month after implantation of single Palma-Schatz stents into 37 porcine coronary arteries and 3.5 ± 1.7 months after implantation of single Palmaz-Schatz stents into 30 native human coronary arteries. Stent and lumen areas were measured in 1 mm axial increaments; intimal hyperplasia (IH = stent – lumen) area; and stent, lumen, and IH volumes (vol, mm^3) were calculated using Simpson's rule. Calculated sample sizes (in each arm) required to demonstrate 25% and a 50% decreases in IH vol (α = 0.05, 80% power) are

	Pigs	Humans	p
Stent volume	106 ± 12	106 ± 40	NS
Lumen volume	67 ± 21	69 ± 43	NS
IH volume	39 ± 17	38 ± 25	NS
# to show a 25% decrease in IH vol	49	112	
# to show a 50% decrease in IH vol	13	28	

We conclude: Quantitative volumetric IVUS results in human and porcine coronary arteries after stent placement are virtually identical. Because smaller sample sizes are required to show effectiveness of strategies to reduce instent cellular proliferation, this volumetric IVUS model should be a sensitive and therefore *cost-effective* method of studying restenosis, particularly in-stent restenosis.

922-49 A Preliminary Report of Local Alcohol Delivery for Treatment of Restenosis Within Stented Segments After Successful Coronary Angioplasty. The Safety Study of *Local Alcohol and Stent Against Restenosis* (LASAR) Trial

Ming W. Liu, Gary S. Roubin, William A. Baxley, Larry S. Dean, Srirum Iyer, J. Michael Parks, Ronald Sutor. *Interventional Cardiology, Division of Cardiovascular Disease, University of Alabama at Birmingham, Birmingham AL*

Local delivery of pharmacological agents into the vessel wall with specially designed delivery catheters to prevent restenosis is being extensively investigated. We have observed that local delivery alcohol solution into balloon injured arterial segments may significantly reduce intimal hyperplasia in two animal study models, i.e., rabbit iliac arteries and pig coronary arteries. Patients who had successful coronary stenting and developed restenosis within the stented segments were enrolled in the study. The restenotic lesions are first completely dilated and then received 3 ml alcohol solution delivered by a Dispatch Catheter over 3 minutes. In our first phase (safety study), 8 patients were enrolled. The first 2 patients received 3 ml 2% alcohol solution, the 3rd and 4th patients received 3 ml 5% alcohol solution, the 5th and 6th patients received 3 ml 10% alcohol solution and the last 2 patients received 3 ml 15% alcohol solution. Lesions treated were in left anterior descending artery (n = 1), left circumflex artery (n = 1), right coronary artery (n = 4), and vein graft (n = 2). Symptoms, 12 leads EKG and cardiac rhythms were closely monitored during, immediately and 24 hr. after the procedure. Cardiac enzyme was also followed every 8 hr. for 24 hr. There were no symptoms related to local alcohol delivery. No EKG or rhythm change was noted. Cardiac enzymes revealed no significant rise. Clinical follow-up up to 2 months has not shown recurrence. Coronary angiogram will be performed at 4 to 6 months in all patients. We have now started the second phase of the study in which patients will be treated with 3 ml 15% alcohol solution with a Dispatch catheter after angioplasty.

922-50 Effect of Tranilast on Restenosis After Coronary Angioplasty

Tomoya Onodera, Akinori Takizawa, Man-Sok Kim, Hiroyuki Fukita, Akihiko Uehara, Tsuyoshi Urushida, Masaki Matsunaga, Takeshi Yoneda, Shinzo Miyamoto, Tomoyuki Kubota. *Shizuoka City Hospital, Shizuoka, Japan*

The effect of Tranilast (an inhibitor of fibroblast proliferation and collagen accumulation) on restenosis after coronary angioplasty is still controversial. In this trial, 100 patients who received Tranilast (600 mg/day) after successful balloon angioplasty till follow-up angiography were compared with 100 control patients. Coronary angiograms before angioplasty, after angioplasty and at follow-up at 4 ± 1 months were quantitatively analyzed and minimal luminal diameter (MLD) was obtained. Restenosis was defined as > 50% diameter stenosis at follow-up angiogram. Baseline characteristics including age, gender, risk factors and lesion characteristics were similar in both groups. *Results:* Follow-up angiography was performed in 88 patients with Tranilast and in 85 control patients.

	Tranilast	Control	p
MLD pre (mm)	0.72 ± 0.32	0.70 ± 0.33	NS
MLD post (mm)	1.80 ± 0.42	1.82 ± 0.48	NS
MLD follow-up (mm)	1.34 ± 0.65	1.39 ± 0.62	NS
% Stenosis pre	72.1 ± 10.4	73.1 ± 13.4	NS
% Stenosis post	29.4 ± 16.5	29.7 ± 18.3	NS
% Stenosis follow-up	47.6 ± 25.3	46.3 ± 24.2	NS
Restenosis rate	55% (49/88)	51% (43/85)	NS

Conclusion: Tranilast at this trial failed to reduce the incidence of restenosis. Further study is needed before using Tranilast as an adjunctive treatment for the prevention of restenosis after coronary angioplasty.

922-51 Low Expression of Calponin in Smooth Muscle Cells of Coronary Artery Lesions Identifies the High Risk for Restenosis After Directional Coronary Atherectomy

Hidemasa Oh, Masanobu Funamoto, Etsuo Tsuchikane, Nobuyuki Negoro, Toru Kobayashi, Katsuhito Takahashi, Nobuhisa Awata. *The Center for Adult Diseases, Osaka, Osaka, Japan*

The process of coronary restenosis after angioplasty is accompanied by neointimal formation. We have reported that local delivery of the recombinant human calponin (CN) gene inhibits myointimal hyperplasia in animals. Low levels of CN expression have been correlated with a proliferating smooth muscle cells (SMC) phenotype *in vitro*. To elucidate its role in human coronary arteries, we investigated 108 consecutive atherosclerotic lesions (53 de novo and 55 restenosis) retrieved by directional coronary atherectomy (DCA) for the expression of CN using immunohistochemistry. The CN expression was quantified by calculating the relative abundance of CN positive cells among the α-actin positive cells in more than 100 nuclei in three high power fields (×100). Seventy out of 108 DCA specimens were subjected to analyze and divided into two groups based on the ratio of CN positive cells to that of α-actin (C/A ratio); Gr-H (n = 42): C/A ratio ≥ 0.6, Gr-L (n = 28): C/A ratio < 0.6. Coronary quantitative analysis was performed at 6 months follow-up, and loss index were calculated. Significant negative correlation was found between the levels of CN expression and loss index at 6 months follow-up (y = 0.936–0.698 ×, r = –0.62, p < 0.0001).

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