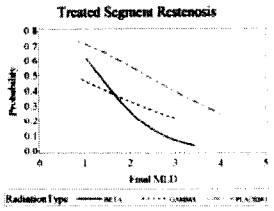

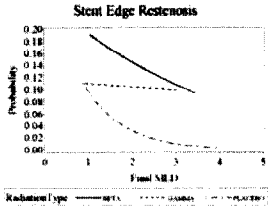

4:30 p.m.

0032-3

Late (Two-Year) Follow-Up From the First-in-Man (FIM) Experience After Implantation of Sirolimus-Eluting Stents

Jose Eduardo Sousa, Alexandre Abizaid, Andrea Abizaid, Jeffrey Popma, Plm de Feyter, Fausto Feres, Marco Costa, Judith Jaeger, Luiz F. Tanajura, Ana C. Seixas, Ibraim Pinto, Luiz A. Mattos, Robert Falotico, Martin Leon, Patrick Serruys, Amanda Sousa, *Institute Dante Pazzanese of Cardiology, Sao Paulo, Brazil.*

Background: Exciting short-term (4-months) and intermediate-term (1-year) results after implantation of sirolimus-eluting (Cypher™) stent in human coronary arteries have been reported. Between 4 to 12 months clinical and angiographic restenosis was still 0%, follow-up MLD showed minimal changes from 2.62±0.18mm at 4 months to 2.43±0.19mm at 12 months, and IVUS percent obstruction volume increased minimally from 0.3±0.8% to 2.2±3.4%. The aim of this study is to determine if deleterious pathobiologic responses are present after a long (2-year) follow-up. **Methods:** Thirty patients treated with Cypher™ stents for single de novo coronary lesions (15 fast-release and 15 slow-release formulation) will complete 2-year follow-up in February, 2002. Repeat quantitative angiography, clinical outcomes assessments, and volumetric IVUS analysis will be performed. **Results:** At present (21±2 months) there has been one MACE (3.3%) at 14 months due to non-target site coronary occlusion proximal to the Cypher™ stent resulting in acute MI. Serial IVUS interrogation of this MI culprit lesion demonstrated plaque progression with echo-lucent zones suggesting plaque instability. For the entire patient cohort, there was no deaths and no target lesion revascularization events. **Conclusion:** Thusfar, in the FIM experience, the sirolimus-eluting Cypher™ stent has demonstrated striking safety and efficacy up to one-year follow-up, with no restenosis or repeat revascularization events, and complete elimination of stent associated neointimal hyperplasia. The 2-year follow-up results (available for presentation) should definitively establish sustained suppression of the restenosis process and long-term safety.

4:45 p.m.

0032-4

Beta Versus Gamma Radiation for Treatment of In-Stent Restenosis: Angiographic Predictors and Outcomes in 630 Patients

Kazuyuki Shirai, Alexandra J. Lansky, Roxana Mehran, Kartik Desai, Costantino Costantini-Ortiz, Brian Proctor, Teraza Conway, Martin Fahy, Nishe Dave, Izat Hjazi, George Dangas, Gregg W. Stone, Paul Teirstein, Jeffrey Moses, Martin B. Leon, *Cardiovascular Research Foundation, New York.*

Background: Randomized trials have demonstrated striking efficacy of Gamma and Beta radiation compared to placebo in the treatment of in-stent restenosis (ISR). Methods: To compare the outcomes of Gamma vs Beta radiation we reviewed the angiographic results of 630 pts (N=227 Gamma; N=177 Beta; N=226 placebo) with native coronary ISR matched for ACC/AHA lesion complexity, lesion length and vessel size. QCA was performed prospectively by analysts blinded to treatment allocation, using standardized methodology. Results: The mean lesion length was 15.54+/-6.81mm and the vessel size 2.49+/-0.33mm. Final QCA results were similar in the 3 groups (final MLD 1.87+/-0.36 and final %DS 28%). Follow-up results in table. By multivariable analysis, independent angiographic predictors of treated segment restenosis among radiation pts included lesion length (OR 1.024, p=0.008) and vessel size (OR 0.494, p=0.001). Conclusion: In pts with matched lesion characteristics, gamma and beta radiation achieve a similar reduction in treated segment restenosis compared to placebo. Given the current isotope dosimetries, the relative reduction after Beta radiation is greatest within the stent at the expense of more stent edge restenosis, whereas with Gamma radiation the relative reduction within the stent is less pronounced, but stent edge restenosis is also less frequent.

Follow-up results	Gamma	Beta	Placebo	P Value
Treated Segment Restenosis, %	33.5	30.0	53.9	<0.0001
In-Stent Restenosis, %	24.7	18.9*	50.0	<0.0001
Stent Edge Restenosis, %	9.3	17.1**	4.4	0.0001

*p=0.164 and ** p=0.018 for gamma versus beta.

5:00 p.m.

0032-5

Quantitative Angiographic Findings of the PREDICT Trial: A Randomized Clinical Trial Comparing a Strategy of Predilatation Prior to Stent Placement Versus Direct Stenting

Ross Prpic, Jeffrey J. Popma, Nicholas Cox, Michelle Fitzpatrick, Azin Parhizgar, Richard E. Kuntz, Donald S. Baim, *Harvard Clinical Research Institute, Boston, Massachusetts.*

Background: High pressure direct stenting has potential advantages over traditional deployment strategies (predilatation, stent deployment +/- post dilatation), including reductions in consumable costs, radiation exposure, contrast load and procedure time. **Methods:** Four hundred patients were randomized to either direct stenting with the AVE S670™ stent or predilatation followed by S670™ deployment in native coronary artery lesions. Baseline angiographic and clinical data were collected, with clinical follow-up at 14 and 30 days and 6 months, and angiographic follow-up at 6 months. **Findings:** Primary Device Success (<50% residual stenosis at target site using assigned treatment strategy) was achieved in 92.6% of patients undergoing direct stenting compared with 96.0% in those with lesion predilatation (P=0.056). Quantitative angiographic findings are demonstrated below. There were no significant differences at baseline, post procedure or follow up, and the restenosis rate was similar in both groups (20.4% in direct stenting group versus 20.9% in controls P=1.0). Incidence of major complications including abrupt and subacute closure and stent thrombosis was low in both groups, as was significant dissection (Type C or greater, 1.5% both groups).

Lesion Characteristics (Mean±SD)	Direct Stenting (N=198 Patients, N=201 Lesions)	Pre-Dilatation (N=201 Patients, N=203 Lesions)	P-value
Baseline			
ACC/AHA Lesion Class			
A	8.1%	11.0%	0.594
B1	44.2%	35.6%	0.331
B2	40.7%	45.2%	0.630
C	7.0%	8.2%	0.773
Lesion Length (mm)	11.98±4.87	11.41±4.10	0.425
Reference Vessel Diameter (mm)	2.91±0.60	2.90±0.52	0.862
Minimal Lumen Diameter (mm)	0.94±0.46	0.90±0.45	0.367
% Diameter Stenosis	67.6%±14.0%	69.2%±12.9%	0.216
Post-Procedure			
Reference Vessel Diameter (mm)	3.13±0.55	3.15±0.55	0.771
Minimal Lumen Diameter (mm)	2.92±0.43	2.98±0.42	0.185
% Diameter Stenosis	5.9%±9.4%	4.5%±9.3%	0.150
Acute Gain (mm)	1.98±0.53	2.08±0.52	0.056
Follow-Up			
Reference Vessel Diameter (mm)	2.85±0.54	2.84±0.46	0.811
Minimal Lumen Diameter (mm)	1.95±0.71	1.93±0.73	0.717
% Diameter Stenosis	31.6%±22.1%	32.5%±22.2%	0.714
Late Loss	0.98±0.61	1.06±0.66	0.240
Late Loss Index	0.51±0.35	0.52±0.32	0.755
Binary Restenosis Rate	20.4% (33 / 162)	20.9% (34 / 163)	1.000
Abrupt Closure to 180 days	0.0%	1.5%	0.248
Subacute Closure to 180 days	0.0%	0.5%	1.000
Stent Thrombosis to 180 days	0.5%	0.5%	1.000

Conclusions: Direct stenting using the AVE S670™ is associated with high acute procedural success and low rates of angiographic complications and binary restenosis, equivalent to those seen with conventional predilatation and stenting.

5:15 p.m.