1155-99 Similar Clinical Outcomes for Sirolimus-Eluting Stent Implantation and Coronary Brachytherapy for the Treatment of In-Stent Restenosis

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Background: Preliminary studies have shown that sirolimus-eluting stent (SES) implantation is safe and effective for the treatment of in-stent restenosis (ISR). However, the clinical efficacy of this new therapeutic approach has not been compared to coronary brachytherapy (CBT), the best treatment currently available for ISR.

Methods: We assessed the incidence of major adverse cardiac events (MACE = death, myocardial infarction, target lesion revascularization) in 43 consecutive patients treated with CBT at our institution for ISR (CBT group) and 44 consecutive patients with ISR, without prior irradiation of the target vessel, treated with SES implantation (SES group). **Results**: Baseline clinical characteristics of the two groups were similar. Relatively more ISR lesions per patient were treated in the SES group (1.2±0.5 versus 1.0±0.2; p=0.02). Angiographically, the prevalence of Mehran class I and II lesions was similar among the two groups (66% CBT versus 63% SES; p=0.7). In the CBT group periprocedural glycoprotein IIb/IIIa inhibitors utilization was more common (33% versus 9%; p=0.007), and clopidogrel prescription longer (7.5±5.5 months vs 5.9±2.6 months; p=0.005). During 9 months of follow-up, 3 patients (7%) died in the CBT group and 0 in the SES group. The incidence of myocardial infarction was 2.3% in both groups. Target lesion revascularization was performed in 11.6% of the CBT patients and 16.3% of the SES patients (p=ns). The 9-month MACE-free survival was similar in both groups (79.1% CBT versus 81.5% SES; p=0.8 by log rank).

Conclusions: This non-randomized study suggests that sirolimus-eluting stent implantation is as effective as vascular brachytherapy in the treatment of in-stent restenosis.

1155-100 Intracoronary Radiation Therapy Using a Novel Beta Emitter for In-Stent Restenosis: Tungsten WRIST

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Background: Tungsten WRIST is a safety and feasibility study of intracoronary radiation therapy utilizing Tungsten (¹⁸⁸W), a beta emitter. In animal studies, ¹⁸⁸W has achieved effective reduction of neointimal proliferation with doses up to 25 Gy at 2mm.

Methods: Thirty patients (pts) with in-stent restenosis (ISR) of native coronary arteries were treated with PCI (balloon angioplasty, rotational atherectomy, laser ablation, or additional stenting) and intracoronary radiation with ¹⁸⁸W. The Tungsten source with an active length of 33mm (total length 40mm, diameter 1mm) was manually delivered over a guidewire. The prescription doses were 18 Gy (n=10), 22 Gy (n=10), and 25 Gy (n=10) at 2mm radial distance from the center of the source. All pts received lifelong aspirin and clopidogrel for at least 6 months.

Results: Pts were: male 67%, diabetics 43%; and age 58 \pm 12 yrs. ISR lesions involved the LAD in 67% of the cases. Preprocedure reference vessel diameter was 2.69 \pm 0.46mm and lesion length was 16.09 \pm 6.91mm. In 7%, an additional stent was used. Balloon angioplasty alone was done in 47% of pts. In all pts radiation was successfully given with no procedural complications. All pts completed 6-month follow-up. There were no differences in angiographic restensis.

Conclusions: Intracoronary delivery of the Tungsten source was feasible and safe. Doses of 18-25 Gy were associated with similar clinical events when compared with other beta and gamma emitters used in clinical practice for the treatment of ISR.

	18 Gy (N=10)	22 Gy (N=10)	25 Gy (N=10)	Total % (n=30)
Binary Restenosis %	11	12.5	10	11
Late Loss (mm)	0.43±0.78	-0.18±0.24	0.18±1.42	0.14±0.88
TLR	1 (10%)	1 (10%)	2 (20%)	4 (13%)
TVR	3 (30%)	1 (10%)	3 (30%)	7 (23%)

1155-101 In Vivo Temperature Measurements of Human Atherosclerotic Plaques With a New Balloon Thermography Catheter: The "Cooling Effect" of Blood Flow

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Background: Ex vivo and in vivo temperature measurements of the human atherosclerotic plaques present a mismatch. This may be due to the 'cooling effect' of blood flow. In order to test this hypothesis we designed a new balloon-thermogaphy catheter for temperature measurements during coronary flow interruption. Method: A thermistor probe is positioned at the distal segment of the catheter. Exactly opposite is placed a balloon. During balloon inflation coronary flow is progressively interrupted. We studied 10 patients with effort angina. Coronary flow velocity was continuously recorded. Temperature was recorded at the proximal vessel wall and at the lesion before, during and after complete interruption of blood flow. TDb was assigned as the difference between the background and the maximal temperature during and after balloon inflation. TDI was assigned as the difference between the atherosclerotic lesion and the proximal vessel wall. **Results**: TDb during and after balloon inflation was 0.01±0.01 and -0.003±-0.01°C (p<0.001) respectively. TDI was 0.07±0.04°C at baseline, 0.17±0.06°C (59.3±11.8% increase) during and 0.07±0.05°C after flow interruption (p<0.001)(Figure). TDI was greater than TDb during and after obstruction of flow (p<0.001). **Conclusions:** In vivo atherosclerotic plaque temperature recording with this new balloon-thermography catheter introduces a new method for the detection of thermal heterogeneity in plaques and possibly resolves the issue of 'cooling effect' of blood flow.



POSTER SESSION

1156

Carotid Stenting: Immediate and Late Outcomes

Tuesday, March 09, 2004, 3:00 p.m.-5:00 p.m. Morial Convention Center, Hall G Presentation Hour: 3:00 p.m.-4:00 p.m.

1156-59 Comparison of Interventional Versus Conservative Treatment of Isolated Ostial Lesions of Coronary Diagonal Branch Vessels: Results of a Prospective Single Center Trial

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Background. Percutaneous coronary intervention (PCI) of ostial stenosis of coronary artery side branches are associated with reduced success and increased complications. Therefore, it was the aim of the study to compare PCI with medical treatment of isolated ostial stenosis of diagonal branches for reducing the incidence of ischemic events.

Methods. The study group comprised 302 patients with ostial stenosis > 75 % of the diagonal branch and a vessel diameter \geq 2 mm of the diagonal branch without further significant (< 50 %) coronary artery stenoses. The decision of medical or interventional treatment was left to the discretion of the operator. 233 patients (77 %) were treated medically (Group I), and 69 patients (23 %) underwent PCI (Group II). All patients went into a database looking for death, myocardial infarction, recatheterization or angina at 12 months either by clinical examination or telephone call.

Results. Successful dilation of the ostial branch stenosis was obtained in 65 of 69 patients of Group II (94 %). In-hospital clinical outcome (death, acute myocardial infarction, refractory angina) were not different between both strategies. At 12 months follow-up, 51 of 233 patients of Group I (22 %) were rehospitalized due to cardiac complaints compared to 38 of 59 patients (55 %) of Group II (p < 0.001). 45 patients of Group I (19 %) and 32 of Group II (46 %) underwent recatheterization (p < 0.001). In 19 patients of Group II (8 %) and 16 of Group II (23 %) (re-)PCI was necessary (p = 0.001). There were no significant differences concerning death and myocardial infarction between both groups after 12 months. Interventional treatment did not result in a higher incidence of freedom of angina (41 %) compared with medical treatment (56 %; p = 0.255).

Conclusion. Medical treatment of isolated ostial stenosis of diagonal branches is an alternative to percutaneous intervention without higher incidence of death or myocardial infarction at 12 months follow-up. Interestingly, patients with isolated ostial stenosis of diagonal branches treated by PCI showed a significantly higher probability of rehospitalization, recatheterization and re-PCI compared to medically treated patients.

1156-60 Predilatation Before Distal Protection Device Placement in Stenting Carotid Arteries Is Successful and Not Associated With Adverse Outcome

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Background: The use of distal protection devices (DPD) is gaining growing acceptance as standard therapy to prevent distal embolization during carotid artery stenting (CAS). It is optimal to have the device deployed during all phases of intervention, but this may not be possible in tight and complex lesions, in which device crossing may be difficult. We therefore examined whether the need for balloon pre-dilatation prior to lesion crossing