POSTER SESSION

1173 Percutaneous Coronary Intervention II

Tuesday, March 19, 2002, Noon-2:00 p.m.
Georgia World Congress Center, Hall G
Presentation Hour: Noon-1:00 p.m.

1173-3 Helical Atherectomy for In-Stent Restenosis: Acute and Long-Term Results From the Helixcision™ EndoLuminal In-Stent Excision (HELIX I) International Feasibility Trial

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Background: The Helixcision™ EndoLuminal In-stent Excision (HELIX I) International Feasibility trial is a prospective multi-center registry to test a new helical atherectomy device for the treatment of in-stent restenosis. The primary endpoint of this study is the safety of this device defined as major adverse cardiac events (MACE) at 30 days. The secondary endpoints are target lesion revascularization (TLR) and angiographic binary restenosis at 6-month follow-up.
Methods: In HELIX I, 32 in-stent restenosis lesions (17.2±11.4 mm in mean lesion length) in 32 patients were treated with Helixcision followed by balloon angioplasty. The debulking efficacy was assessed with serial IVUS (pre, post-Helixcision and post-adjunctive balloon) in a subset of 18 lesions. To further investigate the longitudinal efficacy, 3D analysis was also performed in 12 lesions with automated pullback to calculate average cross-sectional areas across the stent.
Results: At baseline, the angiographic reference diameter was 2.60±0.46 mm. Minimum lumen diameter improved from 0.84±0.33 to 2.19±0.41 mm (p<0.0001). IVUS showed a relative reduction of intimal area (IA) by 39±19% (from 4.99±2.04 to 2.98±1.47 mm^2, p<0.0001) after Helixcision; adjunctive balloon angioplasty resulted in a total reduction of 50±16% (to 2.44±1.09 mm^2) at the site of minimum lumen area. The degrees of IA reduction were closely similar in 3D analysis. To date, 30-day and 6-month clinical follow-up is available in 97% and 72% of the enrolled patients, respectively. At 30-day follow-up, no MACE was reported except for CK elevation in 2 patients (6%) within 1 day after procedure. TLR within 6 months was performed in 6 patients (26%). Angiographic follow-up data will be also presented.
Conclusions: Preliminary results of HELIX I indicate that helical atherectomy is safe and feasible for the treatment of in-stent restenosis. The concordant results between 2D and 3D IVUS analyses suggest that this unique technology can achieve uniform longitudinal debulking throughout the stent. The long-term outcomes appeared to be favorable, considering the relatively diffuse lesion morphology in the small vessels in this trial.

1173-4 The Influence of Diabetes on Long-Term Clinical Outcome Following Percutaneous Coronary Revascularization for Single Vessel Disease

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Background : Diabetics have more often extent of coronary artery disease (CAD) and less favorable outcomes after any form of revascularization. However, in comparison with non diabetic (ND) patients, the long-term survival in diabetic (D) patients type II who underwent percutaneous coronary intervention (PCI) for single vessel disease (SVD) has not been validated.
Methods : Between April 1995 and March 1996, we analyzed a cohort of 533 consecutive patients with SVD who were treated with PCI and divided into ND (n = 437 pts) versus D (n = 87 pts) groups respectively. Clinical and angiographic baseline characteristics were similar between the two groups and global left ventricular(LV) function was sub-normal (54.6 % versus 55.8 %, p = ns).
Mean follow-up interval was 50 ± 13.5 months. The primary end-point of follow-up was death of any cause and secondary end-point was cardiac death, target lesion revascularization (TLR), major adverse cardiac events (MACE) and extent of CAD. Survival rates of the two groups were estimated by the Kaplan-Meier method.

	ND Group (n = 437 pts)	D Group (n = 87 pts)	p
Death	44 (10.1 %)	17 (19.5 %)	0.01
Cardiac Death	22 (5 %)	16 (18.4 %)	< 0.0001
TLR	83 (19 %)	16 (18.4 %)	ns
MACE	139 (31.8 %)	39 (44.8 %)	0.02
Extent of CAD	49 (11.2 %)	18 (20.7 %)	0.009

Conclusion : In comparison with non diabetic patients and in spite of pre-specified CAD (PCI for SVD), diabetes mellitus is associated with worse long-term outcome and 3-fold higher rate of cardiac mortality.

1173-5 Impact of Renal Function on Morbidity and Mortality After Percutaneous Saphenous Vein Graft Intervention

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Background: Percutaneous coronary intervention in patients with chronic renal insufficiency (CRI) and native coronary artery disease is often problematic, marred by increased mortality, morbidity and revascularization procedures. Little is known about the effect of CRI on patients who undergo saphenous vein graft (SVG) intervention. **Methods:** We analyzed 1,265 consecutive patients who underwent percutaneous SVG intervention and divided them into four groups based on calculated creatinine clearance (CrCl): Group 1, CrCl>70 ml/min (n=626); Group 2, CrCl=50-69 ml/min (n=357); Group 3, CrCl=30-49 ml/min (n=228) and Group 4 , CrCl<30 ml/min (n=54). Patients on dialysis were excluded from the study. **Results:** Patients with lower CrCl were more often older, female, diabetics and had worse left ventricular function. Overall immediate procedural success was similar for all groups. In-hospital and one-year outcomes are shown in the Table. By multivariate regression analysis, CrCl was an independent predictor of late mortality. **Conclusion:** This study suggests that renal function is a primary determinate in short- and long-term survival in patients undergoing percutaneous SVG intervention and there is a clear relationship between CrCl and cardiovascular outcome.

	Group 1 (n=626)	*Group 2 (n=357)*	*Group 3 (n=228)*	*Group4 (n=54)*	*p*
In-hospital death	0.3 %	1.5 %	2.2 %	7.1 %	<0.001
In-hospital cardiac death	0.1 %	1.1 %	1.5 %	2.4 %	0.002
12-month death	7.1 %	8.0 %	19.0 %	36.7 %	<0.001
12-month cardiac death	66.0 %	80.7 %	63.2 %	54.6 %	<0.001

1173-6 Effect of Postmenopausal Hormone Therapy on Major Adverse Cardiac Events After Percutaneous Coronary Intervention: The HERS Trial

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OBJECTIVES: To determine the effect of post-menopausal hormone therapy (HRT) on coronary heart disease (CHD) events after percutaneous coronary interventions.
BACKGROUND: In observational studies, HRT with estrogen has been associated with a reduced incidence of major adverse cardiac events (MACE) after percutaneous coronary interventions (PCI) in postmenopausal women. No clinical trial has studied the effects of post-menopausal HRT after percutaneous coronary intervention.
METHODS: The Heart and Estrogen/progestin Replacement Study (HERS), was a randomized clinical trial of hormone therapy for CHD prevention in post-menopausal women with known CHD. During HERS follow-up, 357 participants underwent percutaneous coronary intervention, 175 in the HRT arm and 182 on placebo. This study compared the incidence of MACE subsequent to PCI among participants assigned to HRT and placebo.
RESULTS: Among the women who underwent PCI, baseline characteristics were similar between those in the HRT and placebo groups. Mean follow-up duration was 27 months for HRT group and 25 months for placebo group (p=0.50). During follow-up, 70 (40%) women in the HRT group and 72 (40%) women in the placebo group experienced a CHD event (RR=0.97; 95% CI: 0.70 - 1.35). No differences were observed in the incidences of target lesion revascularization (27% vs. 30%; p=0.64), unstable angina (10% vs. 10%; p=0.90), myocardial infarction (7% vs 10%; p=0.31), or CHD death (6% vs. 5%; p=0.75). After multivariate analysis, only diabetes was a significant predictor of CHD events (RR=1.85; 95% CI: (1.26 - 2.72).
CONCLUSION: In contrast to prior observational studies, HRT had no effect on major adverse cardiac events after percutaneous coronary interventions in the HERS trial.

1173-7 Predictors of Contrast Induced Nephropathy After Percutaneous Coronary Intervention in Patients With and Without Chronic Renal Failure

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Background: Contrast induced nephropathy (CIN) has been associated with unfavorable early and late outcome. We determined predictors of CIN in patients with and without chronic renal failure (CRF), defined as baseline serum creatinine >1.5 mg/dl.
Methods and Results: Of a total 8268 consecutive patients who underwent PCI (Jan 1994 to July 1999), 1431 (16.5%) developed CIN (25% rise in serum creatinine compared to pre-PCI). Creatinine clearance was calculated by the Cockcroft formula.
Independent predictors of CIN derived by stepwise logistic regression analysis for both groups (Table).
Conclusions. Baseline clinical characteristics and creatinine clearance (not serum creatinine value) predict CIN development after PCI. Meticulous CIN preventive measures should be targeted in the high-risk patients.

Multivariate Predictors of CIN	Patients without CRF OR (95%CI), p-value	Patients with CRF OR (95%CI), p-value
Diabetes	1.45 (1.26-1.67) p<0.0001	1.78 (1.34-2.37) p<0.0001
Severe CHF	3.44 (2.54-4.65) p<0.0001	2.41 (1.55-3.73) p<0.0001
Contrast/BSA ratio	1.02 (1.01=1.02) p<0.0001	1.01 (1.00-1.01) p<0.0001
Creatinine Clearance	1.02 (1.01-1.02) p<0.0001	0.98 (0.98-0.99) p=0.0003
Female Gender	1.25 (1.08-1.43) p=0.0047	p=NS
Age	1.04 (1.03-1.05) p<0.0001	p=NS

1173-8 Intracoronary Beta-Radiation Therapy for Long Lesions in Native Coronary Vessels

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Background: This study evaluates early and late clinical and angiographic outcome of patients with long (>20mm) de novo or in-stent restenotic lesions in native coronary vessels treated with beta radiation for restenosis prevention.
Methods and results: Between April 1999 and December 2000, 84 consecutive patients, with 117 lesions longer than 20mm in native coronary vessels, were successfully treated using 90-Strontium/Yttrium radiation source. The reference vessel size was 2.49±0.5 mm, and the mean lesion length 28.7±8.6 mm. Stents were implanted in 43.6% of the lesions. Radiation dose delivered was 18.5±3.3 Gy at 2 mm from the center of the source, with a mean dwell time of 269±122 sec, and using manual pullback technique in 21% of lesions. Ticlopidine was prescribed for 3 months in the first 29 patients, subsequently for 6 months without stenting or for 1 year with stent implantation. Clinical follow-up was obtained for all patients after 16.4±6.7 months. Major adverse cardiac events, a composite of death, Q-wave myocardial infarction and target lesion revascularization, occurred in 19 patients (22.6%). Late thrombosis occurred in 2 patients (2.4%) treated with stents at the time of radiation, and after discontinuation of ticlopidine.
Follow-up angiography was performed in 74 patients (88%). Angiographic restenosis (>50% diameter stenosis of the analysis segment) was present in 27/103 lesions (26.2%). Target lesion and target vessel revascularization rates were 21.4% and 30.8%, respectively.
Conclusion: Intracoronary beta radiation can be safely and effectively used to treat long coronary lesions. Long term combined antiplatelet therapy is necessary for patients who receive new stents at the time of the radiation treatment.

1173-9 Efficacy of Long Radiation Treatment in Native In-Stent Restenosis: A Subanalysis From the RENO Registry

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Background: The effectiveness of intracoronary radiation therapy of diffuse in-stent restenosis (ISR) with Strontium-90 Beta sources is unknown.
Methods: The RENO registry is a post market prospective surveillance study enrolling consecutive patients with ISR at 46 European centers using the Novoste Beta-Cath™ system. Patients were treated with approved interventional devices, followed by Strontium-90 Beta-radiation treatment. Of the 1098 patients enrolled in the trial, 139 had diffuse native coronary ISR treated with a stepping technique using a 30, 40, or 60mm source train or a single 60mm source train. The historical control group was the placebo arm of the WRIST and LONG WRIST studies (N=94).
Results: Baseline characteristics were similar between two groups except for more diabetics in placebo. Brachytherapy success (<50% residual stenosis and successful delivery of the radiation device) was 99.3% in the RENO group. Clinical follow-up at 6 months was available in >96%. The results are shown in the table.
Conclusion: Beta-radiation with Sr-90 using either a stepping (pullback) technique or a single 60mm source train to treat patients with diffuse, long native ISR lesions is effective and results in significant reductions in TVR by 75% and MACE by 72% without any increase in the late thrombosis rates compared to historical controls .

	RENO Long Radiation (N=139)	WRIST Placebo (N=94)	p-Value
Diabetes (%)	21.9%	37.2%	0.02
Lesion length (mm)	35.33 ± 17.89	27.97 ± 11.84	0.0003
TVR at 6 months	14.9%	60.6%	<0.0001
MACE at 6 months	17.9%	64.9%	<0.0001
Total occlusion at 6 months	12.2%	9.9%	NS

1173-10 Feasibility and Safety of a Novel Cryoangioplasty System

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Background: Previous cryosurgical studies have indicated that freezing arterial tissues *in vivo* is followed by a benign healing process largely devoid of neointimal proliferation, suggesting a potential beneficial impact on restenosis following intervention. This study is designed to evaluate feasibility and safety of a newly developed cryoangioplasty (CP) system in a porcine coronary model.
Methods: The cryoangioplasty system (CryoPlasty™, CryoVascular Systems, Inc.) consists of a balloon-based catheter and an inflation unit, which delivers liquid nitrous oxide through the catheter and inflates the balloon to a predetermined pressure and temperature. We assessed the safety and performance characteristics of CP system at a subzero treatment temperature, compared with those of a control treatment (conventional PTCA) using a similar balloon to artery ratio and pressure conditions. Twelve animals were assigned to 3-day or 28-day follow-up (6 animals per group). Each animal underwent PTCA in one of the coronary arteries and CP in up to two of the remaining arteries (6 vessels with PTCA in both groups, 9 vessels and 12 vessels with CP in 3-day and 28-day follow-up, respectively). Angiography was performed at baseline, following treatment, and follow-up, and changes in lumen diameter and % diameter stenosis were analyzed by quantitative coronary angiography.
Results: No adverse events (including side branch occlusion or distal coronary flow limitation) were observed in any group. No significant loss of lumen diameter or increment of % diameter stenosis was found at either 3-day or 28-day follow-up in the CP group. At 28-day follow-up, mean % diameter stenosis in the CP group was 4.6%, compared with 12.5% in the PTCA group (p<0.05).
Conclusions: This study demonstrates the feasibility and safety of the cryoangioplasty system for use in the coronary arteries and a possible beneficial effect on chronic vascular reaction following intervention.

1173-11 Are Older Women, Compared to Older Men, at Higher Risk During Percutaneous Coronary Intervention? Results From the Danish PTCA Registry

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BackgroundOlder patients are at higher risk during percutaneous coronary intervention (PCI). Whether this increased risk is gender related is not known. In order to evaluate this issue further, data from the Danish PTCA Registry were analysed for the 3-year period 1996-1998. During this period data from all PCI procedures in Denmark were prospectively recorded in a central database.
Methods Angiographic baseline characteristics, outcome of PCI and procedural complications were analysed in a total of 8.187 consecutive procedures (6.896 patients, 11.472 lesions dilated).
Results In patients ≤ 70 year women were significantly older than men (58.0 vs. 56.5; p < 0.0001), but no significant gender difference in age was seen in patients > 70 year.

	≤ 70 year		> 70 year		p
	men	women	men	women	
Number of patients	5.242	1.654	822	469	
Age (Year)	56.5	58.0	74.8	75.0	
Left ventricle ejection fraction (%)	60.3	62.1	56.5	61.1	*
Coronary narrowing severity (%)	84.6	83.2	84.8	84.2	*
Number of 1 vessel disease (%)	60.1	69.2	45.5	53.9	**
Angiographic primary success rate (%)	87.8	89.2	87.1	85.8	*
Rate of stenting (%)	58.1	56.2	58.6	57.8	
MACE (%)	4.2	4.9	8.4	10.4	*
Emergency CABG (%)	0.9	1.0	1.0	1.3	
Myocardial infarction (%)	2.9	3.7	5.8	6.6	*
Death (%)	0.4	0.2	1.6	2.6	*

M = men, W = women; MACE = major adverse coronary events (emergency CABG, non-fatal myocardial infarction (q-wave and non-q-wave myocardial infarction), and death) within 24 hours after index procedure.
*age but not gender as independent predictor, p < 0.0001
**age and gender as independent predictor, p < 0.0001
Logistic regression analysis showed, that age, but not gender, was an independent predictor of angiographic primary success rate, MACE, myocardial infarction and death.
ConclusionOlder patients had significant more complications after PCI, however no significant gender difference with regard to complications after PCI, neither in patients ≤ 70 year nor in patients > 70 year could be demonstrated.