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

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) at 6-month follow-up.

Methods: In HELIX I, 32 in-stent restenosis lesions (17.2±1.4 mm in mean lesion length) in 22 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 16 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 2.68±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 internal area (IA) by 39±19% (from 4.99±2.04 to 2.98±1.47 mm², p<0.0001) after Helixcision; adjunctive balloon angioplasty resulted in a total reduction of 55±16% (to 2.44±1.06 mm²) at the site of minimum lumen area. The degree 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 1999, we analyzed a cohort of 533 consecutive patients with SVD who were treated with PCI and divided into ND (n = 427 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.

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.