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


Background: The Helixcision™ EndoLuminal In-Stent Excision (HELIX™) International Feasibility trial is a prospective multicenter 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±11.4 mm in mean lesion length) in 23 patients were treated with Helixcision followed by balloon angioplasty. The debulking efficacy was assessed with serial IVUS (pre-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 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 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 (8%) 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 dense 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: Diabetes 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, p = 0.87) and D (n = 87) 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 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.

Conclusions: 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


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 1,285 consecutive patients who underwent percutaneous SVG intervention and divided them into four groups based on calculated creatinine clearance (C Cr): Group 1, C Cr > 70 ml/min (n = 626); Group 2, C Cr = 50-70 ml/min (n = 357); Group 3, C Cr = 30-49 ml/min (n = 228) and Group 4, C Cr ≤ 30 ml/min (n = 54). Patients on dialysis were excluded from the study. Results: Patients with lower C Cr 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. Multivariate regression analysis, C Cr was an independent predictor of late mortality. Conclusions: This study suggests that renal function is a primary determinant in short- and long-term survival in patients undergoing percutaneous SVG intervention and there is a clear relationship between C Cr and cardiovascular outcome.

<table>
<thead>
<tr>
<th>Group</th>
<th>1 (n=626)</th>
<th>2 (n=357)</th>
<th>3 (n=228)</th>
<th>4 (n=54)</th>
<th>p</th>
</tr>
</thead>
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<td>In-hospital death</td>
<td>0.3 %</td>
<td>1.5 %</td>
<td>2.2 %</td>
<td>7.1 %</td>
<td>&lt;.001</td>
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<tr>
<td>In-hospital cardiac death</td>
<td>0.1 %</td>
<td>1.1 %</td>
<td>1.5 %</td>
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<tr>
<td>12-month death</td>
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<td>63.2 %</td>
<td>54.6 %</td>
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</table>

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 postmenopausal 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, 376 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=0.98; 95% CI=0.70 - 1.35). No differences were observed in the incidences of any major adverse cardiac event (CAD) endpoints (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=1.28 - 2.66).

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


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 8608 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). 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.

Table. By multivariate regression analysis, C Cr was an independent predictor of late mortality. Conclusions: This study suggests that renal function is a primary determinant in short- and long-term survival in patients undergoing percutaneous SVG intervention and there is a clear relationship between C Cr and cardiovascular outcome.
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. 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 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 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 fuse native coronary ISR treated with a stepping technique using a 30, 40, or 60mm radiation 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 diabetes 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 and 1 year could be demonstrated. No significant loss of lumen diameter or increment of wall area was 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 12.6% in the placebo group (p<0.0001). Conclusion: 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.

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

Background: The effectiveness of intracoronary radiation diffusion of tissue 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-CathTM system. Results: 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 diabetes 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 and 1 year could be demonstrated. No significant loss of lumen diameter or increment of wall area was 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 12.6% in the placebo group (p<0.0001). Conclusion: 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.