Methods: A novel dual-sensor guide wire (Doppler flow and pressure) was used in 12 patients with a single de novo lesion to simultaneously measure distal coronary pressures (Pa) and flow velocity (v), as well as aortic pressure (Pa) after an i.v. bolus of anesthetics. At maximal hyperemia, StV and MRV were calculated as (Pa – Pa) / v and Pa / v, respectively. The results were compared before treatment and after balloon dilatation, stenting and upon starting guide wire intravascular ultrasound. The relative contribution of the decrease in StV to the gain in flow velocity after PCI was estimated using the pre-PCI value of MRV.

Results: Hyperemic StV decreased from 2.5±0.7 CRU (normal PCI ≤ 1 CRU) to 0.016±0.01 CRU (p = 0.01) due to the higher coronary flow originating from 2.5±3.3 CRU to 1.3±0.46 CRU (p = 0.02) after PCI. Compared to the pre-PCI level, the cumulative increase in hyperemic flow velocity was 146±163 %, 68±4x16.5 %, and 22.6±117.2 % at each respective PCI step. The average relative contribution of the reduction in StV to this gain in flow velocity was 48±6x44.5 %.

Conclusion: Distal remodeling of the epicardial coronary lesion by PCI results in a significant reduction in stenosis resistance and a marked decrease in hyperemic coronary microvascular resistance, which accounts for about half of the resulting gain in hyperemic flow velocity. These data suggest that dilation of the epicardial stenosis has a marked effect on coronary perfusion also through the accessory reduction of microvascular resistance.

1197-192 Influence of Diabetic Treatment Status on Survival After Successful Percutaneous Coronary Intervention

Vanghese Mathews, Robert L. Frye, Ryan Lennon, Gregory W. Bansness, David R. Holmes, Jr., Mayo Clinic, Rochester, MN

Background: The influence of diabetic treatment status on long-term outcome after percutaneous coronary intervention (PCI) is unclear. The current study reports analysis that insulin treatment is associated with worse long-term outcome compared to patients not requiring insulin. Whether this is an independent effect of insulin treatment, or whether insulin is merely a marker of more advanced atherosclerosis or other unknown variables is uncertain.

Methods and Results: Patients with diabetes undergoing successful PCI from January 1, 1996, through June 30, 2001, were divided into two groups based on whether or not they required insulin therapy during hospital stay: Insulin patients (n=70) vs. No insulin patients (n=70). Cox proportional hazards models were utilized to estimate the association between diabetes treatment status and long-term survival. Eleven hundred and four eligible diabetic patients were identified and divided into those treated with insulin (418 patients) and those treated with either an oral agent or diet alone (686 patients). Insulin-treated patients were less likely to be male, had more prior coronary revascularization, prior myocardial infarction, and congestive heart failure on presentation. Angiographic and procedural characteristics were comparable. Adjusting for differences in baseline characteristics, insulin treatment did not adversely affect long-term survival (odds ratio (OR) 1.10, 95% confidence interval (CI) 0.71-1.65).

Conclusion: Among diabetic patients undergoing successful PCI, patients treated with insulin have worse long-term survival. However, when adjusting for differences in baseline characteristics, insulin treatment was not independently associated with worse long-term survival, suggesting that the difference observed in the crude survival rates are due primarily to differences in demographic, clinical, and treatment characteristics.

1197-193 Incidence, Management, and Outcomes of Coronary Perforation: An Analysis of 15,298 Patients


Background: Coronary perforation is a feared complication of percutaneous coronary intervention (PCI). Methods and Results: We performed a retrospective analysis of 15,298 patients’ PCI data at Mayo Clinic database (1990-2001) identifying 95 pts with coronary perforation (0.62%, 95% CI 0.58, 0.71). The incidence was higher in women (12.3%, 95% CI 0.43, 0.88) compared with men (0.56%, 95% CI 0.46, 0.71). The incidence was highest with atherosclerotic plaques (0.71%, 95% CI 0.56, 0.97). The incidence was inversely related to the number of prior PCI procedures (0.76%, 95% CI 0.56, 0.92 vs. 0.52%, 95% CI 0.31-0.76 for <2 vs. >5 PCI procedures, p = 0.0001). Management strategies included covered stents and cardiac surgery (table). Seven pts died (7.4%, 95% CI 3.7, 14.5). Glycoprotein IIb/IIIa inhibitor use (n=33; 34.7%) did not predict the incidence of tamponade (p=0.43) or death (p=0.64). Conclusions: Coronary perforation following laser and atherectomy is a 2 x times more common than after balloon angioplasty or stent placement, respectively; is associated with a significant mortality (7%), but usually does not require surgery or result in tamponade or death.

1197-194 Clinical Outcome After Prehospital Thrombolysis Versus Percutaneous Coronary Intervention for ST Elevation Myocardial Infarction: Results of the START in Berlin Pilot Study

Stefan Hoffmann, Richard Sarn, Iskander A. Motwani, Andreas Diehm, Andreas Breschan, Klinikum am Urban, Berlin, Germany

Purpose: Despite the accepted superiority of PCI over in hospital thrombolysis (TL), there are no data demonstrating a benefit for PCI when compared with prehospital (pTL) therapy. Berlin has a well organized pTL program, previously been proven as a feasible and safe approach for the treatment of AMI. START is a prospective, randomized study evaluating the clinical outcome after pTL compared with direct PCI.

Methods: Patients (pts) with STEMI less than 6 hours, enrolled by MI center physicians, were randomly assigned to pTL with reperfusion or PCI with stenting. Primary endpoint (CEP) is a composite of MACCE during hospital stay (all-cause mortality or recurrent MI or major bleeding or target vessel revascularization or disabling CHF or disabling stroke).

Results: From October 2000 to March 2002, 88 Pts were enrolled (44-pTL, 44-PCI). Median time delay from symptom onset (SO) to MIU arrival was 70 (45-125)min. From SO to balloon balloons of TL 85 (61-137)min and from SO to first balloon 140 (110-195)min. Pts mean age was 60 (49-69) years. 78% were males and 51% had an anterior MI. There were no differences between the two groups regarding baseline characteristics. The CEP was similar for pTL and PCI (13.6% vs. 15.0%). One recurrent MI occurred in the pTL group, one death and one stroke in the PCI group. One major bleed requiring blood transfusion for both treatments (19.6%). The need for urgent PCI was significantly higher in the pTL group (32% vs. 5%, p<0.001).

Conclusion: PCI does not offer clinical benefit over TL, when the administration of thrombolytic is very early in the prehospital setting. However, the 72% rate of urgent PCI after thrombolytic therapy should focus on the need of a complex management strategy for AMI patients (invasive centers).

1197-195 Aqueous Oxygen Therapy for ST-Segment Elevation Myocardial Infarction: AMIHOT Trial Design and Preliminary Results

Jack L. Marin, Simon Daxon, Shuri David, Catherine Penson, Barbara Lindsay, William O'Neil, Main Line Health System, Bryn Mawr, PA, William Beaumont Hospital, Detroit, MI

Background: Although rapid coronary reperfusion in STEMI reduces infarct size and improves recovery of left ventricular function and reduces mortality, percutaneous coronary intervention (PCI) is unfavourable in up to 30% of STEMI patients due to severe epicardial vessel patency. PCI is not feasible in approximately 10% of STEMI patients and mortality rate after PCI is 10%.

Methods: A Phase 2 randomized trial in the US is designed to evaluate the efficacy of rapid reperfusion after STEMI by administering a sub-selective catheter with aerosolized oxygen in 600 patients and a historical control group. The primary endpoint is a composite of death, cardiac arrest, stroke, or persistent Q wave MI at 30 days. The secondary endpoints include persistent Q wave MI at 30 days and ischemic changes during the 30 day follow up period.

Results: Twenty patients have been randomized. Nine of 10 patients assigned to AO therapy completed the 90 minute infusion without hemodynamic or electrophysiologic instability. One patient could not cooperate due to noncardiac factors and received only 60 minutes of infusion. Repeat angiography following AO therapy showed that 8 patients were in the perfusion catheter and maintenance of TIMI 3 flow was in all subjects. The majority of the planned 250 patients are anticipated to be enrolled by March 2003.

Conclusion: Preliminary results suggest that rapid administration of oxygen by AO therapy appears to be safe and can be readily applied in institutions performing primary angioplasty for STEMI. Conclusions regarding the promise of this new mode of therapy to improve recovery of left ventricular function requires longer-term follow up.

1197-196 Effect of a Novel Pharmacological Strategy to Counteract Shivering During Endovascular Cooling for Acute Myocardial Infarction


Background: Mild hypothermia significantly reduces infarct size in experimental models of acute myocardial infarction (AMI), however, hypothermia triggers shivering, which is metabolically stressful, increases blood pressures and heart rate, and often prevents successful PCI. Methods: One hundred and thirteen patients with acute ST-elevation MI (69 hours from symptom-onset) underwent primary PCI with adjunctive cooling. Hypothermia was induced using the SoftPlex® Temperature Management System (Redford Medical, Inc, Redwood City, CA) to a target core temperature of 33°C for a hours after repertu- lation. The SetPoint system uses an endovascular heat exchange catheter that is placed in the interior vena cava via the femoral vein. Skin warming, oral buspirone and intravenous meperidine were used to suppress shivering.

Results: Seventy-eight (69%) patients had no evidence of shivering during cooling at an average of 36°C (n=2). Of the 32 patients that were shivering, 12 patients (38%) were successfully treated with oral buspirone (n=5) or intravenous meperidine (n=7). Skin warming, oral buspirone and intravenous meperidine were used to suppress shivering.

Results: Seventy-eight (69%) patients had no evidence of shivering during cooling at an average of 36°C (n=2). Of the 32 patients that were shivering, 12 patients (38%) were successfully treated with oral buspirone (n=5) or intravenous meperidine (n=7). Skin warming, oral buspirone and intravenous meperidine were used to suppress shivering.
required a small increase in core temperature to 33.6 ± 0.15°C. Meperidine and buspirone did not cause respiratory depression or other complications. Patients with shivering were younger (54 ± 10 years vs. 59 ± 12 years, p = 0.04), and received a higher total blood dose of meperidine than those without shivering (156 ± 66 mg vs. 120 ± 66 mg, p < 0.01). Mean patient weight and body surface area were similar in both groups and no other demographic, clinical or hemodynamic predictors of shivering were identified. Results: Clinical (90 months) and angiographic (89 months) outcomes were comparable in the SES and CS LAD subgroups (see table).

Conclusions: The SIRIUS LAD substudy indicates striking improvement after SES in all clinical and angiographic efficacy parameters compared with CS. These SES results are similar to those reported after LIMA surgery, and thus, SES should be considered the new standard of care for single vessel LAD therapy.

Follow-up parameter SES (n=234) CS (n=228) p-value
TLR (%) 5.4 21.2 <0.001
TVR (%) 7.6 23.0 <0.001
MACE (%) 8.8 22.9 <0.001
Res (%): in-stent 2.0 41.6 <0.001
Res (%): In-lesion 10.1 41.6 <0.001
TLR+target lesion revascularization TVR+target vessel revascularization MACE = major adverse cardiac events (death, MI, and repeat revascularization)

1198-180 Effects of Sirolimus-Eluting Stents in Diabetic Patients: Volumetric Intravascular Ultrasound Analysis From the SIRIUS Trial

Jung Ahn, Yasuhiko Morino, Yasuhiko Honda, Shinjiro Seroda, Masayuki Takashima, Ah Hassan, Judith J. Jaeger, Charles A. Simonot, David K. Roberts, Michael W. Cleman, Martin B. Leon, Jeffrey W. Moses, Paul G. Yock, Peter J. Fitzgerald, the SIRIUS Investigators, Stanford University, Stanford, CA, Lenox Hill Hospital, New York, NY

Background: Exaggerated intimal hyperplasia has been reported to contribute to increased restenosis after percutaneous coronary interventions in diabetic patients. The effects of drug-eluting stents in diabetic patients have not been well investigated.

Methods: IVUS data were obtained from SIRIUS, a prospective, randomized, multicenter trial comparing sirolimus-eluting Bx Velocity stents (SES) vs. bare metal Bx Velocity stents (BMS). Eight-month follow-up 3-D IVUS analysis was available in 90 cases (BMS 44; SES 51). Mean lumens (LA), stent (SA), and neointimal areas (NIA) were obtained by dividing each volume with stent length. Cross sectional narrowing (CSN) was calculated as NIA divided by SA. The variables were compared by stent types (CCTV/ BMS), presence of diabetes, and their interactions.

Results: There were 25 diabetic patients (BMS 13, SES 12). BMS showed a trend toward decreased LA in diabetic patients compared to non diabetic patients (p=0.09). SES significantly suppressed neointimal hyperplasia in both diabetic and non-diabetic patients. There was no significant interaction effect between stent types and diabetes, indicating that the extent of neointimal suppression by SES was not affected by the presence of diabetes.

Conclusions: Volumetric IVUS results of the SIRIUS trial suggest that sirolimus-eluting stents can provide suppression of neointimal hyperplasia that is as substantial in diabetic as in non-diabetic patients.

Table (*p=0.08 vs. DM(-), BMS)

<table>
<thead>
<tr>
<th>Variable</th>
<th>BMS (n=44)</th>
<th>SES (n=51)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIA (mm^3/mm)</td>
<td>DM(-)</td>
<td>2.5±1.3</td>
<td>0.18±0.3</td>
</tr>
<tr>
<td></td>
<td>DM(+)</td>
<td>2.4±1.2</td>
<td>0.01±0.13</td>
</tr>
<tr>
<td>LA (mm^3/mm)</td>
<td>DM(-)</td>
<td>5.3±1.7</td>
<td>6.7±2.0</td>
</tr>
<tr>
<td></td>
<td>DM(+)</td>
<td>4.3±1.7</td>
<td>6.2±1.8</td>
</tr>
<tr>
<td>%CSN</td>
<td>DM(-)</td>
<td>31±12.8</td>
<td>2.6±1.1</td>
</tr>
<tr>
<td></td>
<td>DM(+)</td>
<td>36±16.8</td>
<td>1.7±2.1</td>
</tr>
<tr>
<td>Minimum lumen area (mm^2)</td>
<td>DM(-)</td>
<td>3±1.3</td>
<td>5±1.4</td>
</tr>
<tr>
<td></td>
<td>DM(+)</td>
<td>3±1.2</td>
<td>4.5±1.7</td>
</tr>
</tbody>
</table>

1198-181 About the Use of the ACHIEVE™ Paclitaxel Eluting Stent in Treatment of Restenotic Lesions: A Subanalysis of the 30-Day Safety Data of DELIVER II

Antonio L. Bartorelli, Eberhard Grube, Didier Blanchard, Anthony Gershick, Carlos Mosooy, Sophie Horney, Christian Horney, on behalf of the DELIVER II Investigators, Centro Cardiologico Monzino, Milano, Italy, GUIDANT Europe, Diegem, Belgium

Background: Many interventional cardiologists believe that restenosis following angioplasty or stenting is the most significant and pressing problem in the field of cardiology today. Stenting of coronary arteries resulted in a reduction of restenosis to 15-30% following treatment of de novo lesions. But when restenosis of a stent does occur, recurrence of in-stent restenosis treated with repeat PTCA ranges from 30% to as high as 80% for diffuse in-stent restenosis. The DELIVER II study is a 1500 patients prospective, non-randomized, multi-center evaluation of the ACHIEVE™ paclitaxel eluting Coronary Stent System in the treatment of lesions with high risk of revascularization due to restenosis. Such lesions include Chronic Total and Sub-Total Occlusions (CTO), lesions...