Effects of Niacin Extended-Release/Lovastatin in Patients With and Without Metabolic Sundrome

	No Metabolic Syndrome		Metabolic Syndrome	
	Baseline	Week 52 % Change	Baseline	Week 52 % Change
LDL-C mean	201 (2.2)	-45% (0.9)	192 (1.9)	-42% (1.0)
HDL-C mean	52 (0.6)	+32% (1.3)	44	+36% (1.6)*
TG median	140	-32%	210	-47%*
Lp(a) median	24	-26%	23	-22%

Baseline values are in mg/dL (± standard error for mean values). Mean % change (± standard error) for LDL-C and HDL-C. Median % change for TG and Lp(a). $p<0.05$ versus patients without MS.

3:15 p.m.

820-6 **Once-Daily Niacin Extended-Release is Effective and Safe for Treatment of Dyslipidemia Associated With Chronic Kidney Disease**

Mark E. McGovern, Carolin M. Malott, Eric J. Stanek, Phillip D. Simmons, Kos Division of Medical Affairs, Weston, FL

Background: Low levels of high-density lipoprotein cholesterol (HDL-C) and elevated triglycerides (TG) and lipoprotein (a) [Lp(a)] are frequently seen in patients with chronic kidney disease (CKD), who are at 2- to 3-fold elevated risk for coronary heart disease. Niacin is the most potent drug to raise HDL-C. It also reduces TG and Lp(a). However, niacin and its metabolites are primarily excreted in urine. We hypothesized that niacin's lipid effects might be slightly enhanced in patients with CKD.
Methods: This was a retrospective analysis of 458 dyslipidemic patients from an open-label, multicenter, 48-week study of once-daily extended-release niacin dosed up to 3 grams daily (average dose of 2 grams). We defined CKD as estimated baseline creatinine clearance (Cockroft-Gault equation) ≤ 75 mL/min and evaluated lipid efficacy and safety (liver enzymes, fasting glucose, and myopathy) in these patients.
Results: Compared to patients without CKD (N=282), those with CKD (N=176) were older (62 versus 50 years), more often female (57% versus 23%), with lower body mass index (27 versus 30). Mean estimated creatinine clearance (mL/min, ± standard error) was 61±0.7 with CKD versus 93±0.9 without. Lipid results are shown. There were no differences between groups in percent of patients with 3-fold increases in liver tests (<1% in each group) or changes in fasting glucose. No myopathy was reported.
Conclusion: We conclude that once-daily extended-release niacin is effective and safe for patients with CKD.

Effects of Niacin Extended-Release on Lipids in Patients With and Without CKD

	No CKD		CKD	
	Baseline	Week 48 % Change	Baseline	Week 48 % Change
LDL-C mean	191 (1.7)	-17% (1.1)	200 (2.8)	-23%* (1.1)
HDL-C mean	43 (0.5)	+23% (1.4)	49 (0.75)	+29%* (2.1)
TG median	160	-31%	155	-36%
Lp(a) median	21	-36%	32	-33%

LDL-C = low-density lipoprotein cholesterol. Baseline values are in mg/dL (± standard error for mean values). Mean % change (± standard error) for LDL-C and HDL-C. Median % change for TG and Lp(a). *$p<0.05$ versus patients without CKD.

POSTER SESSION

1103

Genomics and Molecular Mechanisms of Atherosclerosis: Clinical Studies

Monday, March 08, 2004, 3:00 p.m.-5:00 p.m.
Morial Convention Center, Hall G
Presentation Hour: 3:00 p.m.-4:00 p.m.

1103-165 **Serum Levels of Angiogenic Growth Factors Predict Long-Term Clinical Outcome After Percutaneous Coronary Revascularization**

Karine Sautiere, Sophie Susen, Francois Cuilleret, Akram Chmait, Arnaud Sudre, Frederic Mouquet, Jean Dallongeville, Christophe Bauters, Jean Marc Lablanche, Brigitte Jude, Eric Van Belle, Hopital Cardiologique, Lille, France

Context : angiogenic growth factors are important in tissue and vascular repair and it has been suggested that serum levels could reflect the degree of vascular injury in patients with atherosclerosis. The predictive value of serum levels of angiogenic growth factors in the context of percutaneous coronary revascularization (PCR) is unclear. Our objective was to clarify this issue.
Methods: A total of 262 consecutive patients who underwent coronary angioplasty had blood sample for measurement of CRP, IL6, hepatocyte Results : growth factor (HGF) and vascular endothelial growth factor (VEGF) levels immediately before PCR. Patients who underwent primary or rescue PCR for an acute myocardial infarction were excluded. The primary endpoint, a composite of death and myocardial infarction at 1 year, occurred in 33 patients (12.5%).
Before PCR, mean HGF level was 2582±2322 pg/mL and mean VEGF level was 604±471 pg/mL. By univariate analysis, baseline HGF and VEGF levels were significantly higher in patients reaching a clinical endpoint (3463±2671 pg/mL vs 2455±2264 pg/mL, p=0.004 and 895+774 pg/mL vs 562+395 pg/mL, p=0.007; respectively).
For multivariate analysis, the population was dichotomized in 2 groups : low versus high levels according to the median value. By multivariate analysis 4 predictors of clinical events were identified: Diabetes mellitus (Hazard ratio (HR) = 2.82, 95% confidence interval (CI) = 1.42-5.62; p=0.003), "high" HGF levels (HR = 2.93, 95% CI = 1.32-6.54; p=0.008), "high" VEGF level (HR = 2.37, 95% CI = 1.12-5.00; p=0.02) and CRP > 4 mg/L (HR = 2.39, 95% CI = 1.04-5.49; p=0.04).
When HGF and VEGF data were combined, the HR for patients with combined high HGF and High VEGF levels was 4.00 (95% CI: 1.97-7.87; p=0.0001).
Conclusion : Our results demonstrate that in patients referred for PCR, high serum levels of VEGF and HGF are associated with an increased rate of clinical major events during the first year of follow up. The predictive value of VEGF and HGF levels is mutually additive and is independent of other known clinical and biological risk factors.

1103-166 **Brachial Artery Intima-Media Thickness Is Closely Related to Long-Term Cardiovascular Events**

Alois Suessenbacher, Matthias Frick, Hannes Alber, Otmar Pachinger, Franz Weidinger, University of Innsbruck, Innsbruck, Austria

Background: We have recently demonstrated that brachial artery intima-media thickness (BA-IMT) is associated with cardiovascular risk factors and coronary artery disease (CAD). The prognostic value of BA-IMT has not been investigated. The aim of this study was to determine the relation of BA-IMT with late cardiovascular events in patients admitted for stable angina.
Methods: In 294 patients (age 54±10 years) undergoing coronary angiography (CA), BA-IMT was measured using high-resolution ultrasound (13 MHz) by an observer blinded to CA diagnosis. 211 patients (72%) had CAD (≥30% diameter stenosis in ≥1 major vessel) and 83 patients (28%) had smooth coronaries (non-CAD). All patients underwent brachial artery ultrasound examination for measurements of IMT of the far wall. Patients were divided into 2 groups: BA-IMT above the median of 0.37mm (group 1) and BA-IMT<0.37mm (group 2). After a mean follow-up of 38±16 months, cardiovascular events (hospitalization due to angina pectoris, CA, revascularization, myocardial infarction, cardiac death) were documented by direct patient contact and confirmed by review of hospital records.
Results: At baseline age (58±9 vs. 51±9years; <0.001), body mass index (28±4 vs. 26±3kg/m^2; p<0.001) and the proportion of CAD-patients (82 vs. 63%; p<0.001) were greater in group 1, whereas the number of risk factors (1.9±0.9 vs. 1.8±1.0; NS) was comparable between groups. Cardiovascular events (n=52) were more frequent in group 1 than in group 2 patients (34 vs. 18; p=0.01 in the log-rank test). On multivariate Cox regression analysis, BA-IMT >0.37mm (odds ratio=1.96; p=0.03), number of risk factors (odds ratio=1.51; p=0.01) and presence of CAD (odds ratio=3.09; p=0.02) remained significantly associated with cardiovascular events.
Conclusion: In patients with stable angina brachial artery-IMT is independently associated with long-term cardiovascular events. This easily measurable parameter may become useful in the noninvasive assessment of cardiovascular risk.