Single center registries have shown that distal protection with the Medtronic (Percu-Surge) GuardWire balloon occlusion and aspiration system is capable of retrieving embolic particulate debris in a large percentage of patients undergoing primary PCI. Whether this translates into improved reperfusion success and enhanced outcomes has not been determined.

Methods. In the EMERALD trial, 500 pts within 6 hrs onset of chest pain with ≥2 mm ST elevation in 2 or more contiguous leads, or LBBB, undergoing primary or rescue PCI are being prospectively randomized at 40 sites to angioplasty with vs. without distal protection with the 0.028" GuardWire Plus system. The primary endpoints include STR 30 mins post procedure (measured by 24 hour continuous ECG monitoring) and infarct size assessed by tc-99m-sestamibi imaging at day 5-14. The study is powered to show an improvement in complete STR from 50% with control to 65% with distal protection (a 30% relative increase), and a reduction in mean infarct size from 13.1% of the left ventricle to 8.8%. (a 33% relative decrease). Secondary efficacy endpoints include achievement of normal (grade 3) myocardial blush by core lab analysis, and the composite clinical rate of death, new onset sustained hypotension or severe heart failure, and readmission for left ventricular failure within 30 days.

Results. To date, more than 415 pts have been randomized; enrollment will be complete by November 2003.

Conclusions. A large-scale, prospective, randomized multicenter trial has been performed to: 1) Examine whether prevention of distal embolization in patients undergoing primary PCI for AMI improves indices of myocardial reperfusion and resolution of ongoing injury, reduces infarct size and improves clinical outcomes, and 2) Evaluate the safety, feasibility and efficacy of the GuardWire balloon occlusion and aspiration system for this application. The principal results will be reported for the first time in March 2004.

5:15 p.m.

829-6 A Randomized Trial Comparing Rheolytic Thrombectomy Before Infarct Artery Stenting With Stenting Alone in Patients Undergoing Percutaneous Coronary Intervention for Acute Myocardial Infarction

Guido Parodi, Renato Valenti, Angela Migliorini, Gentian Memisha, Emilio V. Dovellini, Giampaolo Cerisano, David Antoniucci, Careggi Hospital, Florence, Italy

Background Macro and microembolization of atherothrombotic debris during percutaneous coronary intervention (PCI) for acute myocardial infarction (AMI) are frequent and may result in the obstruction of the microvessel coronary network and decrease in effectiveness of mechanical reperfusion.

Methods This randomized trial compared rheolytic thrombectomy before direct infarct artery stenting with direct infarct artery stenting alone in 100 patients with a first AMI. The effectiveness of reperfusion was assessed by analysis of ST-segment resolution at 30 min after infarct related artery (IRA) recanalization, by corrected TIMI frame count (cTFC), and by 1-month ^{99m}Tc-Sestamibi scintigraphy infarct size. The primary end point of the study was early ST-segment resolution, and the secondary end points were cTFC, infarct size, and 1-month clinical outcome.

Results There were no significant differences between randomized groups in baseline characteristics. Most patients had abciximab treatment (98%) and IRA stenting (98%). Among direct stenting alone group the cross over to thrombectomy was 8% and was due to residual angiographic evidence of massive thrombosis after stenting. Thrombectomy catheter could successfully cross the lesion before stenting in 96% of patients. The primary end point rate was 90% in the thrombectomy group, and 72% in the direct stenting alone group (p=0.022). At multivariate logistic regression analysis, randomization to thrombectomy was related to the primary end point (OR: 3.56; 95% CI: 1.11-11.42; p = 0.032). cTFC was lower in the thrombectomy group (18.2 ± 7.7 vs 22.5 ± 11.0; p=0.032), and infarct size smaller in the thrombectomy group (13.0 ± 11.6% vs 21.2 ± 18.0%; p=0.010). At 1 month, there were no major cardiac adverse events in both groups.

Conclusions Rheolytic thrombectomy before routine direct IRA stenting is highly feasible and provides a more effective myocardial reperfusion in patients undergoing PCI for AMI.

ORAL CONTRIBUTIONS

833

Adjunctive Medical Therapy for Acute Myocardial Infarction

Tuesday, March 09, 2004, 8:30 a.m.-10:00 a.m.
Morial Convention Center, Room 260

8:30 a.m.

833-1 Use of Angiotensin-Converting Enzyme Inhibitors After Acute Myocardial Infarction Is Associated With a Striking Reduction in 30-Day and One-Year Mortality: Insights From GUSTO V

Deepak P. Vivekananthan, A. Michael Lincoff, Hitinder S. Gurm, Danielle Brennan, Eric J. Topol, Cleveland Clinic Foundation, Cleveland, OH

Background: The use of angiotensin converting enzyme inhibitors (ACE-I) has been shown to provide a reduction in mortality in high-risk patients after myocardial infarction (MI). However, the benefit of routine administration of ACE-I in lower risk MI patients after fibrinolytic therapy has not been well studied.

Methods: We used data from the GUSTO V trial to compare all-cause mortality among patients who received ACE-I (n=9352) between 24 hours of trial enrollment and hospital discharge and those who did not receive ACE inhibitors (n=6867) within this time frame. Use of ACE-I was left to discretion of the treating physician. We performed a propensity analysis to fully adjust for selection bias in the prescription of ACE-I.

Results: Patients prescribed ACE-I tended to be older and had a higher percentage of diabetes, anterior wall MI, and history of hypertension. The incidence of prior congestive heart failure (CHF) was low in both groups (<4%). Over 96% of patients in both groups were Killip 1 or 2. There were 587 deaths (3.5%) at 30 days and 1021 deaths (6.3%) at one year. Despite a higher risk factor profile, patients prescribed ACE-I had a lower mortality at 30-days (2.8% vs. 4.8%, p<0.001) and one-year (5.7% vs. 7.1%, p<0.001). After adjusting for the propensity to receive ACE-I and known confounders, the prescription of ACE-I was associated with a significant decrease in 30-day mortality (OR 0.43; 95% CI 0.34 - 0.53, p<0.001).

Conclusions: In-hospital initiation of ACE-I after fibrinolytic therapy for acute MI, even in lower-risk patients, is associated with a dramatic reduction in short-term and long-term mortality. This study adds to the growing evidence supporting the routine use of ACE-I in all patients with acute myocardial infarction.

8:45 a.m.

833-2 Long-Term Effects of Statin Therapy in Patients With Acute ST-Elevation Myocardial Infarction and Moderate or Severe Left Ventricular Dysfunction: Reduction of Mortality but Not of Nonfatal Major Adverse Coronary and Cerebrovascular Events

Thomas Kleemann, Rudolf Schiele, Anselm Gitt, Claus Jünger, Harm Wienbergen, Jochen Senges, Bernhard Rauch, The MITRA PLUS Study Group, Herzzentrum Ludwigshafen, Ludwigshafen, Germany

Background: Different randomized clinical trials have shown that statins reduce mortality and major adverse coronary and cerebrovascular events (MACCE) in the setting of acute myocardial infarction. These trials had focused mainly on patients (P) with preserved or slightly reduced left ventricular function. **Aim of the study** was to evaluate the prognostic impact of statin therapy in P with ST elevation acute myocardial infarction (STEMI) and moderate or severe left ventricular dysfunction (LVD). **Patients and methods:** 1402 consecutive P with acute STEMI and a LVD (ejection fraction < 40%) of the prospective multicenter registry Maximal Individual Therapy of Acute Myocardial Infarction PLUS (MITRA PLUS) were analyzed. 1034 (74%) P received statin therapy. **Results:** After a median follow-up time of 399 [353-574] days, the all-cause mortality of P not receiving statin therapy was more than twice as high as in P receiving statin therapy (26.9% versus 12.6%, p< 0.0001).

Conclusion: 1. In P with acute STEMI and moderate or severe LVD statin therapy was associated with a 36% reduction of long-term mortality. 2. In contrast to previous clinical trials performed in P with preserved or slightly decreased LVD, statins did not reduce nonfatal MACCE in P with moderate or severe LVD.

Multiple logistic regression of outcome: statin versus no statin in acute STEMI and LVD

	Odds ratio	95% Confidence interval
Long-term mortality	0.64	0.45 - 0.90
Nonfatal reinfarction	1.15	0.52 - 2.55
Nonfatal stroke	0.53	0.19 - 1.44
CABG	1.07	0.62 - 1.83
PTCA	0.88	0.50 - 1.53

9:00 a.m.

833-3 Statin Therapy and Mortality in Patients With Acute Myocardial Infarction Treated With Primary Angioplasty

Giuseppe De Luca, Harry Suryapranata, Jan Paul Ottervanger, Arnoud JW van't Hof, Jan CA Hoorntje, AT Marcel Gosselink, Jan-Henk E Dambrink, Felix Zijlstra, Menko-Jan de Boer, De Weezenlanden Hospital, Zwolle, The Netherlands

Background. Previous studies have shown that statin therapy can reduce long-term mortality in patients with significant risk factors for coronary artery disease or stable angina. However the benefits of statins in patients with ST-segment elevation myocardial infarction (STEMI) have yet to be established. Thus the aim of the current study was to determine whether statin therapy is associated with a reduction in mortality in patients with STEMI treated with primary angioplasty.

Methods. A total of 1513 consecutive in-hospital survivors treated with primary angioplasty for STEMI between April 1997 and October 2001 represent the population of the current study. All clinical, angiographic and 1-year follow-up data were prospectively collected.

Results. A total of 893 (59%) patients were on statins at discharge. At 1 year follow-up statins therapy was associated with a significantly lower mortality (1.2% vs 7.1%, RR [95% CI] = 0.16 [0.09-0.32], p < 0.0001). In almost all groups of patients identified by the propensity score analysis, statin therapy was associated with a significant reduction in mortality. Furthermore, statin therapy was an independent predictor of mortality at multivariate analysis (adjusted RR [95% CI] = 0.24 [0.12-0.47], p < 0.0001).

Conclusions: Statin therapy at discharge is associated with a significant reduction in 1-