

## **Effect of preinfarction angina pectoris on ST-segment resolution after primary coronary angioplasty for acute myocardial infarction.**

**Takahashi T, Anzai T, Yoshikawa T, Maekawa Y, Asakura Y, Satoh T, Mitamura H, Ogawa S.**

The presence of preinfarction angina has been shown to exert a favorable effect on left ventricular function after acute myocardial infarction (AMI). Whether or not preinfarction angina is beneficial for myocardial tissue reperfusion, however, remains to be determined. We sought to evaluate the influence of preinfarction angina on resolution of ST-segment elevation, which could be affected by microcirculatory damage after recanalization therapy. We studied 96 patients with a first AMI in whom Thrombolysis In Myocardial Infarction (TIMI)-3 flow in the infarct-related artery was established by primary angioplasty. Percent reduction in the sum of ST elevation from baseline to 1 hour after angioplasty (percent delta summation operator ST) was examined. Poor ST resolution, defined as percent delta summation operator ST <50%, was observed in 25 patients, who had a worse clinical outcome, larger infarct size, and poorer left ventricular function. On multivariate analysis, the absence of preinfarction angina, as well as anterior wall infarction, were major independent predictors of poor ST resolution, whereas age, sex, coronary risk factors, ischemic time, Killip class on admission, multivessel disease, initial TIMI flow grade, and extent of collaterals were not significant. Patients with preinfarction angina had a greater degree of ST-segment resolution than those without angina (71 +/- 21% vs 49 +/- 43%,  $p = 0.02$ ). Additional ST elevation after reperfusion was noted exclusively in patients without preinfarction angina ( $p = 0.02$ ). Preinfarction angina is associated with a greater degree of ST-segment resolution in patients with TIMI-3 flow after primary angioplasty, suggesting a protective effect of preinfarction angina against microcirculatory damage after reperfusion.

**Long-term outcome of primary percutaneous transluminal coronary angioplasty for low-risk acute myocardial infarction in patients older than 80 years: a single-center, open, randomized trial.**

Minai K, Horie H, Takahashi M, Nozawa M, Kinoshita M.

**B**ACKGROUND: Although coronary reperfusion therapy with thrombolytic agents or percutaneous transluminal coronary angioplasty (PTCA) immediately after acute myocardial infarction (AMI) has survival benefits for younger patients, the effect of coronary reperfusion therapy for very elderly (aged 80 years and older) patients with AMI remains controversial. **METHODS AND RESULTS:** We studied 120 patients aged 80 years and older at relatively low risk with AMI. The patients were randomized into a primary PTCA group (n = 61) or a "conservative" no-PTCA group (n = 59). Long-term follow-up examination was conducted with regard to endpoints, which included all causes of death, cardiac death, nonfatal re-MI, the development of congestive heart failure, and cerebral vascular accident. End-diastolic volume index and end-systolic volume index were significantly increased in both groups at follow-up examination 6 months after AMI. However, left ventricular ejection fraction, end-diastolic volume index, and end-systolic volume index were similar between both groups. With endpoints of all causes of death, cardiac death, reinfarction, congestive heart failure, and cerebral vascular accident, a 3-year Kaplan-Meier event-free survival rate analysis revealed no significant benefits in the PTCA group. Anteroseptal MI, multivessel disease, and left ventricular ejection fraction were significantly associated with the combined events with multivariate Cox proportional hazards analysis results. **CONCLUSION:** First, primary PTCA for very elderly patients with AMI appears to have few beneficial effects on combined events during a 3-year period. Second, early PTCA did not prevent left ventricle remodeling after AMI in patients with AMI at relatively low risk.

**Adjunctive platelet glycoprotein IIb/IIIa receptor inhibition with tirofiban before primary angioplasty improves angiographic outcomes: results of the Tirofiban Given in the Emergency Room before Primary Angioplasty (TIGER-PA) pilot trial.**

Lee DP, Herity NA, Hiatt BL, Fearon WF, Rezaee M, Carter AJ, Huston M, Schreiber D, DiBattiste PM, Yeung AC; Tirofiban Given in the Emergency Room before Primary Angioplasty.

**B**ACKGROUND: Previous work has suggested that platelet glycoprotein IIb/IIIa receptor blockade may confer benefit in the treatment of acute myocardial infarction. The TIGER-PA pilot trial was a single-center randomized study to evaluate the safety, feasibility, and utility of early tirofiban administration before planned primary angioplasty in patients presenting with acute myocardial infarction. **METHODS AND RESULTS:** A total of 100 patients presenting with acute myocardial infarction were randomized to either early administration of tirofiban in the emergency room or later administration in the catheterization laboratory. The primary outcome measures were initial TIMI grade flow, corrected TIMI frame counts, and TIMI grade myocardial perfusion ("blush"). Thirty-day major adverse cardiac events were also assessed. Angiographic outcomes demonstrate a significant improvement in initial TIMI grade flow, corrected TIMI frame counts, and TIMI grade myocardial perfusion when patients are given tirofiban in the emergency room before primary angioplasty. The rate of 30-day major adverse cardiac events suggests that early administration may be beneficial. **CONCLUSIONS:** This pilot study suggests that early administration of tirofiban improves angiographic outcomes and is safe and feasible in patients undergoing primary angioplasty for acute myocardial infarction.

## **Clinical practice of primary angioplasty for the treatment of acute myocardial infarction in Germany: results from the MITRA and MIR registries.**

**Zahn R, Schiele R, Schneider S, Gitt AK, Senges J.**

The pooled data of two German AMI registries: the Maximal Individual Therapy in Acute Myocardial Infarction (MITRA) study and the Myocardial Infarction Registry (MIR) were analysed in order to 1) describe current clinical practice of primary angioplasty in Germany, 2) compare the results of primary angioplasty with those of thrombolysis in the "real world" and 3) define subgroups of patients profiting probably most from primary angioplasty. Between 1994 and 1998, 20,306 AMI patients were included in the registries. At the 271 participating hospitals angioplasty facilities were available at 18.5%. Thrombolysis was still the most frequently used reperfusion therapy at hospitals without (96%) as well as hospitals with such facilities (55%). Transfer of AMI patients for angiography was performed in 3.6% of AMI patients admitted to hospitals without angioplasty facilities. A total of 9906 lytic eligible AMI patients with a pre-hospital delay of no more than 12 hours were treated with either primary angioplasty (n = 1327) or thrombolysis (n = 8579). Univariate analysis of hospital mortality showed a more favourable course for patients treated with primary angioplasty: 6.4% versus 11.3%, OR = 0.54, 95% CI: 0.43-0.67, p < 0.0001. This was confirmed by logistic regression analysis: multivariate OR = 0.58, 95% CI: 0.44-0.77, p < 0.0001. Primary angioplasty was associated with a lower mortality in all subgroups analysed. There was a significant correlation between mortality and the absolute risk reduction (r = 0.82, p < 0.0001) in the different subgroups, which showed an increasing absolute benefit of primary angioplasty compared to thrombolysis with increasing mortality risk.

## **Quantitative estimation of myocardial salvage after primary percutaneous transluminal coronary angioplasty in patients with angiographic no reflow.**

**Nakamura S, Takehana K, Sugiura T, Hatada K, Hamada S, Asada J, Yuyama R, Mimura J, Imuro Y, Kurihara H, Fukui M, Baden M, Iwasaka T.**

**A**ngiographic Thrombolysis in Myocardial Infarction (TIMI) flow grade <2 after primary percutaneous transluminal coronary angioplasty (PTCA), defined as angiographic no reflow, predicts poor left ventricular functional recovery and survival in patients with acute myocardial infarction (MI). To determine the relation between angiographic coronary flow and myocardial salvage in the acute phase of MI, serial technetium-99m tetrofosmin imaging was performed before, immediately after and 1 month after PTCA in 117 patients. Angiographic no reflow was observed in 23 patients (20%; group 1), while 94 patients did not have angiographic no reflow (group 2). Although there was no significant difference in the defect score before PTCA between the two groups (group 1, 14.4+/-5.7; group 2, 13.5+/-4.6), the defect score immediately after PTCA in group 1 was significantly higher than that in group 2 (group 1, 12.8+/-5.1; group 2, 8.9+/-4.6; P<0.0001). A significantly smaller change in the defect score after PTCA (before minus immediately after PTCA) was observed in group 1 as compared with group 2 (group 1, 1.7+/-2.0; group 2, 4.5+/-2.9; P<0.0001). Twenty patients in group 1 (87%) had impaired myocardial reperfusion (<4 change in the defect score immediately after PTCA), as compared with 36 patients (38%) in group 2; this difference was significant (chi(2)=17.5, P<0.0001). The sensitivity, specificity and accuracy of angiographic no reflow in estimating impaired myocardial reperfusion were 36%, 95% and 67%, respectively. Thus, angiographic no reflow is a highly specific, although not sensitive, marker of impaired myocardial reperfusion immediately after primary PTCA.

**Angiographic findings, time course of regional and global left ventricular function, and clinical outcome in diabetic patients with acute myocardial infarction treated with primary percutaneous transluminal coronary angioplasty.**

Bolognese L, Carrabba N, Santoro GM, Valenti R, Buonamici P, Antoniucci D.

There is scarce information available about the outcome of diabetic patients with acute myocardial infarction (AMI) treated with percutaneous transluminal coronary angioplasty (PTCA). We sought to compare left ventricular (LV) function, and angiographic and clinical outcomes in diabetics versus nondiabetics with AMI treated with primary PTCA. This study examined 720 consecutive patients with AMI treated with primary PTCA, 102 of whom had diabetes. Six-month follow-up coronary angiography was obtained in 560 patients (88% of eligible patients). In a subgroup of 284 patients, LV function was serially determined by 2-dimensional echocardiography. During 6-month follow-up no significant differences were observed between diabetics and nondiabetics with regard to restenosis rates (31.6% vs 28.2%,  $p = 0.6$ ), recovery of LV function (6-month wall motion score index:  $1.8 \pm 0.7$  vs  $1.8 \pm 0.7$ ,  $p = 0.88$ ; 6-month LV ejection fraction:  $48.5 \pm 12\%$  vs  $51.2 \pm 13\%$ ,  $p = 0.173$ ), nonfatal re-AMI rates (2.9% vs 1.3%,  $p = 0.2$ ), and target vessel revascularization rates (21.6% vs 16.8%,  $p = 0.2$ ). Early and late mortality were higher in diabetics than in nondiabetic patients (8.8% vs 4.2%,  $p = 0.045$  and 11.7% vs 5.5%,  $p = 0.016$ , respectively). By Cox analysis, diabetes was an independent predictor of both early (odds ratio [OR] 2.4, 95% confidence interval [CI] 1.1 to 5.3,  $p = 0.03$ ) and late mortality (OR 2.37, 95% CI 1.16 to 4.84,  $p = 0.017$ ) as well as 6-month major adverse cardiac events (MACEs): death, re-AMI, target vessel revascularization (OR 1.51, 95% CI 1.04 to 2.18,  $p = 0.03$ ). Thus, diabetes is an independent predictor of clinical outcome even if PTCA is used as the primary reperfusion strategy.

## Long distance transport for primary angioplasty vs immediate thrombolysis in acute myocardial infarction. Final results of the randomized national multicentre trial--PRAGUE-2.

Widimsky P, Budesinsky T, Vorac D, Groch L, Zelizko M, Aschermann M, Branny M, St'asek J, Formanek P; 'PRAGUE' Study Group Investigators.

**B**ACKGROUND: Primary percutaneous coronary intervention (PCI) is shown to be the most effective reperfusion strategy in acute myocardial infarction. The aim of this multicentre national randomized mortality trial was to test whether the nationwide change in treatment guidelines (transportation of all patients to PCI centres) was warranted. METHODS: The PRAGUE-2 study randomized 850 patients with acute ST elevation myocardial infarction presenting within <12 h to the nearest community hospital without a catheter laboratory to either thrombolysis in this hospital (TL group, n=421) or immediate transport for primary percutaneous coronary intervention (PCI group, n=429). The primary end-point was 30-day mortality. Secondary end-points were: death/reinfarction/stroke at 30 days (combined end-point) and 30-day mortality among patients treated within 0-3 h and 3-12 h after symptom onset. Maximum transport distance was 120 km. RESULTS: Five complications (1.2%) occurred during the transport. Randomization-balloon time in the PCI group was 97+/-27 min, and randomization-needle time in the TL group was 12+/-10 min. Mortality at 30 days was 10.0% in the TL group compared to 6.8% mortality in the PCI group (P=0.12, intention-to-treat analysis). Mortality of 380 patients who actually underwent PCI was 6.0% vs 10.4% mortality in 424 patients who finally received TL (P<0.05). Among 299 patients randomized >3 h after the onset of symptoms, the mortality of the TL group reached 15.3% compared to 6% in the PCI group (P<0.02). Patients randomized within <3 h of symptom onset (n=551) had no difference in mortality whether treated by TL (7.4%) or transferred to PCI (7.3%). A combined end-point occurred in 15.2% of the TL group vs 8.4% of the PCI group (P<0.003). CONCLUSIONS: Long distance transport from a community hospital to a tertiary PCI centre in the acute phase of AMI is safe. This strategy markedly decreases mortality in patients presenting >3 h after symptom onset. For patients presenting within <3 h of symptoms, TL results are similar results to long distance transport for PCI.

## **Treatment of no-reflow phenomenon with verapamil after primary stent deployment during myocardial infarction.**

**Demir I, Yilmaz H, Ermis C, Sancaktar O.**

No-reflow phenomenon is the absence of myocardial perfusion despite adequate dilatation of the infarct related coronary artery during percutaneous coronary intervention. It predicts severe left ventricular dysfunction and poor prognosis in acute myocardial infarction (AMI). The present case is a 54 year old Turkish female who presented with chest pain that had started 2.5 hours earlier. The clinical and laboratory findings were consistent with AMI and the coronary angiogram performed for primary angioplasty revealed a 95% thrombotic occlusion with a TIMI grade I flow in the left anterior descending (LAD) coronary artery. A TIMI grade III flow was achieved with direct stent deployment. However, after the placement of a second stent for severe ostial stenosis more proximally and adjacent to the first one, the antegrade flow became TIMI grade O. As the intracoronary medications did not improve the flow, a mechanical occlusion was considered and a third stent was deployed covering the first two stents. A control angiogram revealed the persistence of TIMI grade O flow. A severe and persistent vasospasm was considered at this point and accordingly, intracoronary verapamil was administered in high concentrations by an infusion catheter to the distal LAD which was followed by the immediate achievement of TIMI grade III flow. Intracoronary administration of high dose verapamil can be performed to prevent vasospasm in resistant no-reflow cases with no evidence of mechanic occlusion.

**Primary coronary angioplasty compared with intravenous thrombolytic therapy for acute myocardial infarction: six-month follow up and analysis of individual patient data from randomized trials.**

Grines C, Patel A, Zijlstra F, Weaver WD, Granger C, Simes RJ; PCAT Collaborators. Percutaneous transluminal coronary angioplasty.

**B**ACKGROUND: Overviews of trials suggest that percutaneous transluminal coronary angioplasty (PTCA) may be more effective than thrombolysis. However, whether these effects are sustained beyond hospital discharge, and the extent to which the results are applicable to a broad cross section of patients and the wider community are unknown. We compared the effectiveness of primary PTCA and thrombolysis in acute myocardial infarction during a 6-month follow-up period. **METHODS:** Detailed individual patient data were collected from randomized trials commenced from 1989 to 1996 that compared primary PTCA with thrombolysis. Data were combined to produce estimates of relative reduction in events at 30 days and 6 months for the group and for predefined clinical subgroups. Treatment effects were also assessed in relation to several study-related factors. **RESULTS:** Eleven trials were identified. The mortality rate at 30 days was 4.3% for 1348 patients randomized to undergo PTCA, and 6.9% for 1377 patients assigned to thrombolytic therapy (relative risk [RR] 0.62, 95% CI 0.44-0.86,  $P = .004$ ). At 6 months, the mortality rate was 6.2% for PTCA and 8.2% for thrombolysis (RR 0.73, 95% CI 0.55-0.98,  $P = .04$ ). Combined death and reinfarction rates at 30 days were 7.0% for PTCA and 12.9% for thrombolysis, with a sustained effect at 6 months (RR 0.60, 95% CI 0.48-0.75,  $P < .0001$ ). The risk of hemorrhagic stroke at 30 days was lower in the PTCA group (RR 0.06, 95% CI 0.0-0.50,  $P = .009$ ). The relative treatment effect did not vary across clinically important subgroups, but the absolute benefit varied according to baseline risk. The relative treatment effect varied across the trials and according to the thrombolytic comparator used, the delay in performing PTCA, and the recruitment rate. **CONCLUSION:** In the context of these trials, primary PTCA was more effective than thrombolytic therapy in reducing death, reinfarction, and stroke, with the greatest absolute benefit in patients who were at the highest risk. These benefits appear to be sustained for 6 months. The effect of treatment varied significantly across the trials, and this raises issues about how widely the results can be applied.

## **Further insights into the no-reflow phenomenon after primary angioplasty in acute myocardial infarction: The role of microthromboemboli.**

**Sakuma T, Leong-Poi H, Fisher NG, Goodman NC, Kaul S.**

**W**e tested the hypothesis that when acute coronary occlusion is caused by thrombus, part of the no-reflow phenomenon may result from spontaneous or coronary angioplasty-induced microthromboemboli, and that this phenomenon may be partly or wholly reversible. Accordingly, a thrombus was created in the left anterior descending coronary artery of 6 dogs and was labeled in vivo with (99m)Tc-DMP-444 that binds to the IIb/IIIa platelet receptor. Angioplasty was then performed to obtain thrombolysis in myocardial infarction grade-3 flow. Myocardial contrast echocardiography was performed 15 and 60 minutes after recanalization to define perfusion defect size. (99m)Tc-autoradiography and infarct size (IS) measurement were performed postmortem. An additional 5 dogs with coronary artery ligation followed by reperfusion served as control animals. These dogs also underwent myocardial contrast echocardiography and in vivo labeling with (99m)Tc-DMP-44. (99m)Tc uptake was significantly higher in the reperfused bed in dogs with thrombus compared with control dogs ( $2.7 \pm 0.9$  vs  $1.4 \pm 0.3$  counts/pixel(-1)/min(-1),  $P = .01$ ) indicating the presence of microthromboemboli. Perfusion defect size early (15 minutes) after recanalization was smaller than the hot spot on autoradiography and overestimated IS in dogs with thrombus. Perfusion defect size decreased with time and was closer to IS 60 minutes after recanalization. The dogs with thrombi demonstrated larger IS/risk area ratios compared with the 5 control dogs ( $46 \pm 6\%$  vs  $27 \pm 12\%$ ,  $P = .04$ ). We conclude that part of the no-reflow phenomenon seen after angioplasty in acute coronary thrombosis is a result of microthromboemboli and is mostly reversible. No reflow late after reperfusion is a result of tissue necrosis. The thrombus burden also affects ultimate IS.

## **Benefit of an early invasive management strategy in women with acute coronary syndromes.**

**Glaser R, Herrmann HC, Murphy SA, Demopoulos LA, DiBattiste PM, Cannon CP, Braunwald E.**

**C**ONTEXT: Women who present with acute coronary syndromes (ACSs) have different characteristics than men. Reports have conflicted about whether different outcomes exist for women with use of a routine invasive management strategy. However, these studies were performed prior to the widespread use of platelet glycoprotein IIb/IIIa inhibitors and intracoronary stents. **OBJECTIVE:** To determine sex differences in baseline characteristics and outcomes in ACS and whether women benefit from a contemporary early invasive management strategy. **DESIGN AND SETTING:** Prospective analysis of women and men enrolled in the TACTICS-TIMI 18 randomized trial, conducted December 1997 to December 1999 in 169 centers in 9 countries in North America and Europe, with follow-up at 1 and 6 months. **PARTICIPANTS:** A total of 2220 patients (757 women and 1463 men) with ACS. **INTERVENTIONS:** All patients received aspirin, 325 mg/d; intravenous unfractionated heparin; and tirofiban for 48 hours or until revascularization, with tirofiban administered for at least 12 hours after percutaneous coronary revascularization. Patients assigned to the early invasive strategy (n = 1114) underwent coronary angiography 4 to 48 hours after randomization and revascularization when appropriate. Patients assigned to the early conservative strategy (n = 1106) were treated medically and underwent coronary angiography and appropriate revascularization only if they met specified criteria. **MAIN OUTCOME MEASURES:** Baseline characteristics and the primary composite end point of death, myocardial infarction, or rehospitalization for ACS at 6 months in women and men assigned to early invasive vs conservative management. **RESULTS:** Women were older and more frequently had hypertension ( $P < .001$  for both). Women less frequently had previous myocardial infarction, coronary artery bypass grafting, and elevations in cardiac markers ( $P < .001$  for all), but there was no difference in distribution of TIMI risk scores ( $P = .76$ ). Angiography and intervention rates were similar, but women had less severe coronary artery disease, including no critical lesions in 17% of women vs 9% of men ( $P < .001$ ). Women had a 28% odds reduction in the primary end point with an early invasive strategy (adjusted odds ratio [OR], 0.72; 95% confidence interval [CI], 0.47-1.11), similar to the benefit in men (adjusted OR, 0.64; 95% CI, 0.47-0.88;  $P = .60$  for sex interaction). When adjusted for baseline characteristics, the benefit of invasive therapy in women with elevated troponin T levels was further enhanced (adjusted OR, 0.47; 95% CI, 0.26-0.83). **CONCLUSIONS:** Despite differences between women and men in baseline

characteristics, the benefit of an early invasive strategy incorporating tirofiban and intracoronary stents was similar in women and men and was enhanced in women presenting with markers of increased risk.

## **Facilitated Primary Percutaneous Transluminal Coronary Angioplasty for Acute ST Segment Elevation Myocardial Infarction: Rationale for Reuniting Pharmacologic and Mechanical Revascularization Strategies.**

**Keeley EC, Cigarroa JE.**

The primary goal of therapy for acute ST segment elevation myocardial infarction is to preserve left ventricular systolic function and to decrease mortality by achieving rapid, complete, and sustained restoration of blood flow in the infarct-related artery. Early studies assessing the safety and efficacy of combining full-dose thrombolytic therapy with primary percutaneous transluminal coronary angioplasty (PTCA) were disappointing due to an increased incidence of abrupt closure, reinfarction, emergent coronary bypass surgery, and mortality. The observation that the presence of normal coronary blood flow at the time of primary PTCA is an independent predictor of survival coupled with interest in the patency of the downstream microvasculature has prompted investigators to revisit the concept of combining pharmacologic and mechanical strategies. The adjunctive use of pharmacologic therapy with mechanical reperfusion has been coined facilitated primary PTCA and involves the use of reduced-dose thrombolytics, platelet glycoprotein IIb/IIIa inhibitors, or both. The primary goal is to achieve pharmacologic reperfusion before performing definitive mechanical reperfusion. While the preliminary data presented is promising, we must await the results of ongoing large, randomized trials that have been specifically designed to address this question.

## **Procedural characteristics of primary coronary angioplasty in diabetic patients with acute anterior myocardial infarction.**

**Bonnevie L, Stratiev V, Tarragano F, Karillon G, Saidi A, Fressonnet R, Azancot I, Beaufils P, Henry P.**

**B**ACKGROUND: Mortality and morbidity rates are higher in diabetics compared to non-diabetics after acute myocardial infarction (AMI). Previous angiographic studies regarding primary angioplasty for the treatment of AMI found that angioplasty was similarly successful in diabetics and non-diabetics. However, it is noteworthy that patients of "real life" are often far from the population randomised in prospective protocols. The aim of this study was to examine the procedural characteristics of consecutive diabetic patients hospitalised for anterior AMI and treated with primary angioplasty as compared to non-diabetics. **METHOD:** We analysed 28 consecutive diabetics and 74 non-diabetics who underwent primary angioplasty for anterior AMI (< 12 h from the onset of symptoms) during 15 consecutive months between 2000 and 2001 in our institution, depending on the presence or absence of diabetes. **RESULTS:** Among analysed data, we found that in diabetics compared to non diabetics: (i) the delay before arrival in the cath-lab was significantly longer (5.5 +/- 2.7 vs 4.2 +/- 2.8 h); (ii) there was a less important collateral flow coming from the non-culprit arteries towards the culprit artery; (iii) there was a less important rate of recovery of a normal flow (TIMI 3) in the culprit artery after coronary angioplasty (67% vs 91%). **CONCLUSION:** Our study demonstrates that several procedural characteristics could explain the poorer prognosis of AMI treated by primary angioplasty in the diabetic population. The longer delay found in diabetics before arrival in hospital could probably be improved.

## **Comparison of in-hospital outcomes following early or delayed angioplasty for acute myocardial infarction.**

**Srinivas VS, Vakili BA, Brown DL.**

**B**ACKGROUND: Studies of primary angioplasty for treatment of acute myocardial infarction (AMI) have not appeared to demonstrate a reduction in efficacy as a function of time to treatment. We sought to compare the outcomes of patients treated in New York State with primary angioplasty within 6 hours of symptom onset to those treated between 6 and 23 hours after the onset of AMI. METHODS: We used data from the 1995 Coronary Angioplasty Reporting System of the New York State Department of Health to compare the in-hospital outcomes of patients treated with early (within 6 hours) or delayed angioplasty (6-23 hours) for AMI. RESULTS: Early angioplasty (within 6 hours after onset of chest pain) was attempted in 957 patients (71.3%), while 385 patients (28.7%) had a delayed procedure (6-23 hours after the onset of chest pain). Patients who underwent delayed angioplasty were older (mean age, 62.6 years versus 60.4 years in the early group;  $p < 0.01$ ) and more often female (36% vs. 28% in the early treatment group;  $p < 0.001$ ). Patients treated early more frequently demonstrated hemodynamic instability (13.6% versus 9.1% in the late treatment group;  $p = 0.02$ ), malignant ventricular arrhythmia (8.5% versus 2.9% in the late treatment group;  $p < 0.001$ ) and cardiogenic shock (6.6% versus 1.8% in the late treatment group;  $p < 0.001$ ). Overall in-hospital mortality was 63/1,342 (4.7%) with no difference based on early or delayed angioplasty (5.2% versus 3.4%, respectively;  $p = \text{NS}$ ). The composite of the major adverse cardiac events including in-hospital death, reinfarction and emergency bypass surgery did not differ significantly between the early and delayed groups (7.7% versus 5.5%, respectively;  $p = \text{NS}$ ). In multivariable models, delayed angioplasty was not an independent predictor of either in-hospital mortality or major adverse cardiac events. CONCLUSION: Delayed reperfusion does not influence in-hospital clinical outcomes following PTCA for acute myocardial infarction.

## **Comparison of primary angioplasty and conservative treatment on short- and long-term outcome in octogenarian or older patients with acute myocardial infarction.**

Yip HK, Wu CJ, Chang HW, Hang CL, Fang CY, Hsieh YK, Yang CH, Chen CJ, Yeh KH, Chua S, Fu M, Chen MC.

It has long been established that advanced age is not only associated with greater myocardial infarction frequency but also greater mortality and morbidity. The treatment of acute myocardial infarction (AMI) in 80 year old patients remains problematic with conflicting results; in these patients, the risks of conservative treatment are high and the risks and benefits of thrombolytic therapy are still controversial. The purpose of this study was to evaluate whether primary angioplasty can offer an important alternative method to improve short- and long-term outcomes in octogenarian or older patients who experience AMI. Between May 1986 and March 2000, 171 consecutive 80 year old patients hospitalized for AMI were not randomized to be registered and divided into a medical therapy group (group 1: an historical control group, n=11) and a primary angioplasty group (group 2, n=60). In-hospital mortality was markedly increased with advanced Killip scores (Killip 3 or 4) in both groups. Twenty-four hours after admission, group 1 patients had a significantly higher incidence of progression to higher Killip scores than did group 2 patients ( $P=0.006$ ). The 30-day overall mortality of group 2 patients was significantly lower than in group 1 patients (30.0% vs 54.1%,  $P=0.003$ ). Patients without cardiogenic shock treated by primary angioplasty had a significantly lower incidence of overall mortality at 30 days than patients without cardiogenic shock treated conservatively [3.1% vs 24.3%,  $P=0.016$  (Killip 1 and 2); 18.2% vs 52.6%,  $P=0.044$  (Killip 3)]. However, the mortality rate of cardiogenic shock was extremely high and did not differ significantly between groups 1 and 2 (86.1% vs 88.2%,  $P=0.99$ ). The 3-year cumulative survival rate was significantly higher in group 2 than in group 1 patients ( $P=0.0009$ ). In conclusion, primary angioplasty is feasible and effective, and can improve short- and long-term mortalities in octogenarian or older patients with AMI but without cardiogenic shock.

## **Comparison of effectiveness of primary angioplasty for proximal versus distal right coronary artery culprit lesion during acute myocardial infarction.**

Harjai KJ, Boura J, Grines L, Goldstein J, Stone GW, Brodie B, Cox D, O'Neill WW, Grines C.

**F**rom the cohort of 4,023 patients enrolled in the Primary Angioplasty for Myocardial Infarction (PAMI) trials, we pooled clinical, angiographic, and outcomes data on 1,521 patients with culprit lesions in the right coronary artery (RCA). We compared angiographic results, procedural complications, and in-hospital and 1-year clinical outcomes between patients with proximal RCA (n = 572) versus nonproximal RCA culprit lesions (n = 949). Patients with proximal RCA culprit lesions were older, had lower systolic blood pressure, greater diameter stenosis, and were less likely to have Thrombolysis In Myocardial Infarction (TIMI) 2 or 3 flow (19% vs 31%; p <0.0001) before percutaneous coronary intervention (PCI). After PCI, the incidence of TIMI 3 flow (94% vs 93%) was similar between groups. Patients with proximal RCA lesions were more likely to have bradyarrhythmias (30% vs 23%, p = 0.016) and require an intra-aortic balloon pump (IABP; 4.6% vs 2%, p = 0.034) during PCI. In-hospital complications, including mortality (2.3% vs 2.2%) and reinfarction (1.4% vs 1.1%), and the 1-year incidence of death, reinfarction, ischemia driven target vessel revascularization, and major adverse cardiovascular events were similar between groups. After adjustment for baseline differences, proximal RCA location of the culprit lesion was independently associated with greater IABP use (odds ratio 2.41, 95% confidence interval 1.04 to 5.58) but not with bradyarrhythmias during PCI. Thus, in patients with acute myocardial infarction referred for primary angioplasty, proximal RCA location of the culprit lesion is associated with excellent clinical outcomes that are similar to nonproximal RCA lesions.

**Primary coronary angioplasty in 9,434 patients during acute myocardial infarction: predictors of major in-hospital adverse events from 1996 to 2000 in Brazil.**

Mattos LA, Sousa AG, Pinto IM, Campos Neto Cde M, Labrunie A, Alves CR, Saad J; Central Nacional de Intervencoes Cardiovasculares and Sociedade Brasileira de Hemodinamica e Cardiologia Intervencionista.

**OBJECTIVE:** To verify the results after the performance of primary coronary angioplasty in Brazil in the last 4 years. **METHODS:** During the first 24 hours of acute myocardial infarction onset, 9,434 (12.2%) patients underwent primary PTCA. We analyzed the success and occurrence of major in-hospital events, comparing them over the 4-year period. **RESULTS:** Primary PTCA use increased compared with that of all percutaneous interventions (1996=10.6% vs. 2000=13.1%;  $p<0.001$ ). Coronary stent implantation increased (1996=20% vs. 2000=71.9%;  $p<0.001$ ). Success was greater (1998=89.5% vs. 1999=92.5%;  $p<0.001$ ). Reinfarction decreased (1998=3.9% vs. 99=2.4% vs. 2000=1.5%;  $p<0.001$ ) as did emergency bypass surgery (1996=0.5% vs. 2000=0.2%;  $p=0.01$ ). In-hospital deaths remained unchanged (1996=5.7% vs. 2000=5.1%,  $p=0.53$ ). Balloon PTCA was one of the independent predictors of a higher rate of unsuccessful procedures (odds ratio 12.01 [CI=95%] 1.58-22.94), and stent implantation of lower mortality rates (odds ratio 4.62 [CI=95%] 3.19-6.08). **CONCLUSION:** The success rate has become progressively higher with a significant reduction in reinfarction and urgent bypass surgery, but in-hospital death remains nearly unchanged. Coronary stenting was a predictor of a lower death rate, and balloon PTCA was associated with greater procedural failure.

## **Long-term cardiac function and outcome in patients receiving primary angioplasty for AMI at a community hospital without on-site surgical back-up.**

Gresham J, Mansfield CL, Brush JE Jr.

**B**ACKGROUND: Short- and long-term comparative follow-up studies of patients receiving primary angioplasty or thrombolytic therapy for acute myocardial infarction show higher 30-day survival, and sustained benefits in mortality, reinfarction and ejection fraction in patients treated with primary angioplasty. Long-term benefits of primary angioplasty on cardiac function performed in community hospitals without surgical back-up have not been fully assessed. METHODS: Sixty-one patients who underwent primary angioplasty were compared with patients receiving thrombolytic therapy who were matched for age, gender and location of acute myocardial infarction. Clinical information, reviewed through August 2000, was provided by retrospective analysis of healthcare databases and office and hospital charts. Mortality data were confirmed by the social security death index. RESULTS: Of the original 61 primary angioplasty patients, two died during initial hospitalization. Of the 59 surviving patients, fifty-four (92%) had complete follow-up averaging 57 months. Of the original 61 thrombolytic therapy patients, three died during initial hospitalization. Of the 58 surviving patients, fifty-two (90%) had complete follow-up averaging 46 months. At follow-up, averaging 57 months, ejection fraction was significantly higher in the primary angioplasty group, as compared with the thrombolytic therapy group (51.4% versus 45.8%, respectively;  $p = 0.038$ ). There was no statistical difference between the two groups regarding reinfarction, revascularization at  $\geq 6$  months after the initial presentation or cardiac death. CONCLUSIONS: Primary angioplasty performed in a community hospital without surgical back-up results in improved cardiac function when compared to thrombolytic therapy. These results are similar to those reported from large tertiary centers with on-site surgical back-up, and provide an explanation for the improved long-term outcome that is observed in patients with acute myocardial infarction treated with primary angioplasty.

## **Left ventricular remodeling after primary coronary angioplasty: patterns of left ventricular dilation and long-term prognostic implications.**

**Bolognese L, Neskovic AN, Parodi G, Cerisano G, Buonamici P, Santoro GM, Antoniucci D.**

**B**ACKGROUND: We prospectively evaluated the prevalence, pattern, and prognostic impact of left ventricular (LV) remodeling after acute myocardial infarction (AMI) successfully treated with primary PTCA. The prevalence, course, and prognostic value of LV remodeling after primary PTCA are still to be clarified. **METHODS AND RESULTS:** In 284 consecutive patients with AMI treated with primary PTCA, serial echocardiographic and angiographic studies, within 24 hours (T1), at 1 (T2) and 6 months (T3) after AMI were performed. Long-term (61+/-14 months) clinical follow-up data were collected for 98.6% patients enrolled in the study. Overall, 85 (30%) patients showed LV dilation (>20% end-diastolic volume increase) at T3 as compared with T1. Early (from T1 to T2), late (from T2 to T3), and progressive dilation patterns (from T1 to T2 to T3) were detected in 42 (15%), 41 (14%), and 36 (13%) patients, respectively. Cardiac death and combined events rate was significantly higher among patients with than among those without LV dilation (P=0.005 and P=0.025, respectively). The pattern of LV dilation during 6 months did not significantly affect survival. Cox survival analysis identified end-systolic volume at T1 and age as baseline predictors and end-systolic volume at T3 and age as 6-month predictors of cardiac death, respectively. **CONCLUSIONS:** LV remodeling after successful PTCA occurs despite sustained patency of the infarct-related artery and preservation of regional and global LV function. LV dilation at 6 months after AMI but not the specific pattern of LV dilation is clearly associated with worse long-term clinical outcome.

**Primary stenting versus MIDCAB: preliminary report-comparison of two methods of revascularization in single left anterior descending coronary artery stenosis.**

Cisowski M, Drzewiecki J, Drzewiecka-Gerber A, Jaklik A, Kruczak W, Szczeklik M, Bochenek A.

**B**ACKGROUND: Percutaneous revascularization is a well-accepted method of treatment for a single left anterior descending coronary artery (LAD) stenosis. With the introduction of primary stenting, it has become the treatment of choice for a LAD lesion. In the last few years however, the introduction of minimally invasive cardiac surgery, video-assisted left internal thoracic artery (LITA) harvesting, and robotic surgery have raised the question as to whether minimally invasive surgical revascularization would be competitive with percutaneous coronary interventions in cases of single-vessel stenoses. METHODS: A group of 100 patients with Canadian Cardiovascular Society class II to IV, and angiographically confirmed single critical stenosis of the LAD (type A or B), were treated with direct primary stenting (group 1, n = 50), or with endoscopic atraumatic coronary artery bypass grafting (group 2, n =50). RESULTS: All patients in a group 1, obtained a very good angiographic and clinical effect. No acute postoperative complications were noted at 1 month of follow-up. However, at 1 month of follow-up, 3 patients (6%) developed restenosis of the LAD, and at 6 months follow-up, 6 patients (12%), developed restenosis of the LAD. In these cases, repeated percutaneous coronary interventions of the target vessel were successfully performed. In group 2, very good operative results were observed. In 1 and 6 months of follow-up, all patients remained asymptomatic. Critical stenosis of the left internal thoracic artery-LAD anastomosis was angiographically documented in 1 case (2%). This patient was successfully treated with balloon angioplasty. CONCLUSIONS: The study results document the superiority of endoscopic atraumatic coronary artery bypass grafting over direct primary stenting in LAD revascularization, along with the slightly higher costs of the surgical procedure.

**The effect of blockade of the CD11/CD18 integrin receptor on infarct size in patients with acute myocardial infarction treated with direct angioplasty: the results of the HALT-MI study.**

Faxon DP, Gibbons RJ, Chronos NA, Gurbel PA, Sheehan F; HALT-MI Investigators.

**OBJECTIVE:** The purpose of this study was to determine whether Hu23F2G (LeukoArrest), an antibody to the CD11/CD18 integrin receptors, would reduce infarct size in patients undergoing primary angioplasty for an acute myocardial infarction. **BACKGROUND:** Reperfusion injury in acute myocardial infarction has been shown experimentally to be related to neutrophil accumulation. Inhibitors of the CD11/CD18 or CD18 integrin receptors have been shown to reduce infarct size in experimental models. **METHODS:** Patients within 6 h of onset of chest pain with ST-segment elevation were randomized to receive either 0.3 mg/kg or 1.0 mg/kg of Hu23F2G or placebo just before angioplasty of occluded arteries (Thrombolysis in Myocardial Infarction TIMI flow grade 0 or 1). The primary end point was infarct size as measured by sestamibi single-photon emission computed tomography (SPECT) scan five to nine days later. **RESULTS:** Four-hundred and twenty patients were enrolled and received a placebo or the study drug. The groups did not differ in baseline or angiographic characteristics or angioplasty results. Infarct size was 16%, 17.2% and 16.6%, for placebo, 0.3 mg/kg and 1.0 mg/kg, respectively, of the left ventricle ( $p = \text{NS}$ ). No differences were evident in those patients with anterior myocardial infarction or those presenting within 2 h of onset of chest pain. Corrected TIMI frame count was also not different between groups. Clinical events at 30 days were very low, with a mortality of 0.8%, 1.4% and 3.3%, respectively. The drug was well tolerated, with a slight increase in minor infections in the high dose group. **CONCLUSIONS:** The results of this multicenter, double-blind, placebo-controlled, randomized clinical trial demonstrated that an antibody to CD11/CD18 leukocyte integrin receptor did not reduce infarct size in patients who underwent primary angioplasty.

## **Primary angioplasty versus prehospital fibrinolysis in acute myocardial infarction: a randomised study.**

**Bonnefoy E, Lapostolle F, Leizorovicz A, Steg G, McFadden EP, Dubien PY, Cattan S, Boullenger E, Machecourt J, Lacroute JM, Cassagnes J, Dissait F, Touboul P; Comparison of Angioplasty and Prehospital Thrombolysis in Acute Myocardial Infarction study group.**

**B**ACKGROUND: Although both prehospital fibrinolysis and primary angioplasty provide a clinical benefit over in-hospital fibrinolysis in acute myocardial infarction, they have not been directly compared. Our aim was to find out whether primary angioplasty was better than prehospital fibrinolysis. **METHODS:** We did a randomised multicentre trial of 840 patients (of 1200 planned) who presented within 6 h of acute myocardial infarction with ST-segment elevation, initially managed by mobile emergency-care units. We assigned patients to prehospital fibrinolysis (n=419) with accelerated alteplase or primary angioplasty (n=421), and transferred all to a centre with access to emergency angioplasty. Our primary endpoint was a composite of death, non-fatal reinfarction, and non-fatal disabling stroke at 30 days. Analyses were by intention to treat. **FINDINGS:** The median delay between onset of symptoms and treatment was 130 min in the prehospital-fibrinolysis group and 190 min (time to first balloon inflation) in the primary-angioplasty group. Rescue angioplasty was done in 26% of the patients in the fibrinolysis group. The rate of the primary endpoint was 8.2% (34 patients) in the prehospital-fibrinolysis group and 6.2% (26 patients) in the primary-angioplasty group (risk difference 1.96, 95% CI -1.53 to 5.46). 16 (3.8%) patients assigned prehospital fibrinolysis and 20 (4.8%) assigned primary angioplasty died (p=0.61). **INTERPRETATION:** A strategy of primary angioplasty was not better than a strategy of prehospital fibrinolysis (with transfer to an interventional facility for possible rescue angioplasty) in patients presenting with early myocardial infarction.

## **DANAMI-2: is primary angioplasty superior to thrombolysis in acute MI when the patient has to be transferred to an invasive centre?**

**Moon JC, Kalra PR, Coats AJ.**

**P**Primary angioplasty is superior to thrombolysis in acute myocardial infarction when performed in a timely manner but the benefits are unknown when inter-hospital transfer is required for angioplasty. On the 20th March 2002 at the American College of Cardiology 51st Annual Scientific Session, the results of the Danish Multicentre Randomized Trial on Thrombolytic Therapy versus Acute Coronary Angioplasty in Acute Myocardial Infarction (DANAMI-2) were presented. 1,572 patients were randomized to front loaded tPA or angioplasty on presentation within 12 h of acute myocardial infarction; 1,129 from hospitals requiring transfer for up to 3 h for angioplasty. The trial was stopped early since there was a 40% relative reduction in the composite primary end-point of death, disabling stroke or reinfarction within 30 days (absolute reduction 13.7 to 8%,  $p=0.0003$ ) with primary angioplasty. This appeared to be driven by a significant reduction of reinfarction from 6.3 to 1.6%. Ambulance transfer was shown to be safe but time to angioplasty was approximately 60 min longer than time to thrombolysis. No data are as yet available on the relative infarct sizes or left ventricular function in the two groups. The management of acute myocardial infarction is an area of missed opportunities. Patients present late to hospital, up to 30% of eligible patients do not receive reperfusion therapy and door to needle time is longer than is ideal. Whilst we await the full details of the trial and long term follow-up, we should not forget the challenges of conventional management of acute myocardial infarction.

## **Establishing primary angioplasty as the preferred treatment for acute myocardial infarction.**

**Kaltoft A, Bottcher M, Krusell L, Thuesen L, Kristensen SD, Andersen HR, Nielsen TT.**

**OBJECTIVE:** To report procedural results and mortality rates from the first 4 years after establishing primary angioplasty as the preferred treatment for acute myocardial infarction in a single Scandinavian centre. **DESIGN AND RESULTS:** From August 1995 to October 1999 all patients with the diagnosis of suspected acute myocardial infarction (n = 529, mean age 62 +/- 13 years, 72% men), either transferred (73%) or directly admitted to our institution for coronary angiography with the intention of performing primary percutaneous coronary intervention (primary PCI), were prospectively registered. Procedural success in terms of residual stenosis < or = 30% and a final Thrombolysis in Myocardial Infarction (TIMI) 3 flow was achieved in 94 and 85% of patients treated, respectively. In-hospital delay and procedure times decreased significantly during the 4-year study period. A low in-hospital mortality was observed in each of the 4 years studied (8.7, 8.7, 7.7 and 6.0%). **CONCLUSION:** In a centre with both directly admitted and transferred patients primary angioplasty can be established as the preferred treatment for acute myocardial infarction with an initially low complication and mortality rate. During the first years after implementing the primary angioplasty programme a learning effect can be anticipated with reductions in procedural times.

**Clinical outcomes of patients with diabetes mellitus and acute myocardial infarction treated with primary angioplasty or fibrinolysis.**

Hsu LF, Mak KH, Lau KW, Sim LL, Chan C, Koh TH, Chuah SC, Kam R, Ding ZP, Teo WS, Lim YL.

**O**BJECTIVE: To compare the early and late outcomes of primary percutaneous transluminal coronary angioplasty (PTCA) with fibrinolytic treatment among diabetic patients with acute myocardial infarction (AMI). DESIGN: Retrospective observational study with data obtained from prospective registries. SETTING: Tertiary cardiovascular institution with 24 hour acute interventional facilities. PATIENTS: 202 consecutive diabetic patients with AMI receiving reperfusion treatment within six hours of symptom onset. INTERVENTIONS: Fibrinolytic treatment was administered to 99 patients, and 103 patients underwent primary PTCA. Most patients undergoing PTCA received adjunctive stenting (94.2%) and glycoprotein IIb/IIIa inhibition (63.1%). MAIN OUTCOME MEASURES: Death, non-fatal reinfarction, and target vessel revascularisation at 30 days and one year were assessed. RESULTS: Baseline characteristics were similar in these two treatment groups except that the proportion of patients with Killip class III or IV was considerably higher in those treated with PTCA (15.5% v 6.1%,  $p = 0.03$ ) and time to treatment was significantly longer (103.7 v 68.0 minutes,  $p < 0.001$ ). Among those treated with PTCA, the rates for in-hospital recurrent ischaemia (5.8% v 17.2%,  $p = 0.011$ ) and target vessel revascularisation at one year (19.4% v 36.4%,  $p = 0.007$ ) were lower. Death or reinfarction at one year was also reduced among those treated with PTCA (17.5% v 31.3%,  $p = 0.02$ ), with an adjusted relative risk of 0.29 (95% confidence interval 0.15 to 0.57) compared with fibrinolysis. CONCLUSION: Among diabetic patients with AMI, primary PTCA was associated with reduced early and late adverse events compared with fibrinolytic treatment.

## **Effect of direct stent implantation on minor myocardial injury.**

**Atmaca Y, Ertas F, Gulec S, Dincer I, Oral D.**

**T**his nonrandomized study evaluated the incidence of minor myocardial injury (MMI) in prospectively selected patients with simple lesion morphology and class II stable angina undergoing stenting with or without predilatation. **METHODS:** A total of 154 patients were divided into two arms based on the stenting technique used: direct stenting without predilatation (Group I; n = 78) and stenting with predilatation (Group II; n = 76). Cardiac troponin T (cTnT) was measured immediately before, at 12 hours and 24 hours postprocedure. The primary endpoint was the MMI in-hospital. The secondary endpoint of the study was the major clinical event (MCE) rate in-hospital and up to 6 months. **RESULTS:** The frequency increase in Group I was found to be significantly lower compared with Group II (5.1% vs. 21%, respectively;  $p < 0.007$ ), as was the amount of cTnT release (0.28 0.04 vs. 0.51 0.12 ngr/ml at 12 hours,  $p < 0.001$ ; 0.28 0.06 vs. 0.51 0.10 ngr/ml at 24 hours,  $p < 0.0004$ ). No MCE was seen during the in-hospital period in both groups. Furthermore, no significant differences were found between the 2 groups with respect to MCE (12.8% vs. 18.4%, respectively;  $p > 0.05$ ) at 6 months. The balloon inflation time (BIT) was significantly longer in patients with abnormal cTnT level than in those with normal cTnT level in Group II (120.3 4.7 seconds vs. 118.2 1.3 seconds;  $p < 0.002$ ) but there was not any statistical difference in Group I (32.4 2.1 seconds vs. 30.6 2.4 seconds;  $p > 0.05$ ). Furthermore, there was not any statistical difference with respect to the number of balloon inflations in patients with normal and abnormal cTnT levels in either group (1.2 0.2 inflations vs. 1.3 0.4 inflations in Group I,  $p > 0.05$ ; 3.2 0.9 inflations vs. 3.0 1.4 inflations in Group II,  $p > 0.05$ ). **CONCLUSION:** This study showed that MMI probably occurs less frequently after direct stenting.

**Optimal time for predicting left ventricular remodeling after successful primary coronary angioplasty in acute myocardial infarction using serial myocardial contrast echocardiography and magnetic resonance imaging.**

Sakuma T, Okada T, Hayashi Y, Otsuka M, Hirai Y.

The objective of this study was to determine the optimal time to assess microvascular integrity within the risk area for myocardial infarction in order to predict unfavorable left ventricular remodeling (LVR) after successful primary coronary angioplasty. Fifty-three patients who underwent myocardial contrast echocardiography (MCE) just before recanalization, shortly after and 1 day (Day 2) and 3 weeks after recanalization were studied. The no- and low-reflow ratio (LR ratio) was analyzed at each stage. The wall-thinning ratio within the risk area was determined using magnetic resonance imaging performed 3-4 weeks after the recanalization. Thirteen of the 53 patients showed LVR 3-8 months after recanalization. The optimal time to predict LVR was found to be Day 2 based on the receiver operating characteristic curves. The LR ratio on Day 2 ( $\chi^2=7.39$ ,  $p=0.007$ ) and the collateral circulation before recanalization ( $\chi^2=4.57$ ,  $p=0.03$ ) were chosen as independent variables for predicting LVR. Patients with greater than 0.43 in the LR ratio on Day 2 showed a lower wall-thinning ratio ( $58\pm 19\%$  vs  $72\pm 20\%$ ,  $p=0.05$ ). This study shows that the optimal time to estimate the microvascular integrity for predicting LVR is 1 day after recanalization, which is neither shortly after recanalization nor during the convalescent stage.

## PRIMARY ANGIOPLASTY

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**Eur Heart J ,2001;22(13):1128-35**

**Outcome after combined reperfusion therapy for acute myocardial infarction, combining pre-hospital thrombolysis with immediate percutaneous coronary intervention and stent.**

Loubeyre C, Lefevre T, Louvard Y, Dumas P, Piechaud JF, Lanore JJ, Angellier JF, Le Tarnec JY, Karrillon G, Margenet A, Pougès C, Morice MC.

**BACKGROUND:** Primary therapies in acute myocardial infarction (thrombolysis and angioplasty) have inherent limitations which may be overcome by combining them. So far, no trial has demonstrated a clinical benefit in combining mechanical and pharmacological treatment strategies. **METHODS:** From January 1995 to December 1999, out of 1010 patients admitted to our institution for acute myocardial infarction, 148 had received pre-hospital full dose thrombolysis within 12 h of onset. One hundred and thirty-one patients were included and underwent immediate angioplasty and stenting when suitable, independent of the infarct-artery patency (TIMI grade flow 0-3). In-hospital outcome was assessed and clinical information was collected for a mean (+/-SD) of 2+/-1 years. **RESULTS:** Ninety-minute angiography revealed a patent (TIMI grade 3) infarct artery in 65 patients (49%). Immediate angioplasty was performed in 119 patients (91%) with stent implantation in 114 (96%). Angioplasty achieved TIMI 2, 3 flow in 98%, and complete patency (TIMI 3 flow) in 92%. Six other patients underwent deferred revascularization (surgery in one patient, angioplasty in five) and six received medical treatment. Stent thrombosis and reinfarction occurred in three patients (2.3%). In-hospital death

occurred in six patients (4.6%), including four patients presenting with cardiogenic shock. Major bleeding was observed in 2.3% of cases. No patient had emergency surgery. Freedom from death and reinfarction at 2 years was 90% and freedom from death, reinfarction and target vessel revascularization was 83%. CONCLUSION: A strategy of combined reperfusion using full dose pre-hospital thrombolysis and immediate angioplasty with stent implantation in a non-selected acute myocardial infarction population is safe and achieves high and early patency rates. This preliminary experience suggests that a combined strategy in acute myocardial infarction may have a significant impact on both early and long-term outcomes.

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Comparison of early invasive and conservative strategies in patients with unstable coronary syndromes treated with the glycoprotein IIb/IIIa inhibitor tirofiban.

Cannon CP, Weintraub WS, Demopoulos LA, Vicari R, Frey MJ, Lakkis N, Neumann FJ, Robertson DH, DeLucca PT, DiBattiste PM, Gibson CM, Braunwald E; TACTICS (Treat Angina with Aggrastat and Determine Cost of Therapy with an Invasive or Conservative Strategy)?hrombolysis in Myocardial Infarction 18 Investigators.

**BACKGROUND:** There is continued debate as to whether a routine, early invasive strategy is superior to a conservative strategy for the management of unstable angina and myocardial infarction without ST-segment elevation. **METHODS:** We enrolled 2220 patients with unstable angina and myocardial infarction without ST-segment elevation who had electrocardiographic evidence of changes in the ST segment or T wave, elevated levels of cardiac markers, a history of coronary artery disease, or all three findings. All patients were treated with aspirin, heparin, and the glycoprotein IIb/IIIa inhibitor tirofiban. They were randomly assigned to an early invasive strategy, which included routine catheterization within 4 to 48 hours and revascularization as appropriate, or to a more conservative (selectively invasive) strategy, in which catheterization was performed only if the patient had objective evidence of recurrent ischemia or an abnormal stress test. The primary end point was a composite of death, nonfatal myocardial infarction, and rehospitalization for an acute coronary syndrome at six months. **RESULTS:** At six months, the rate of the primary end point was 15.9 percent with use of the early invasive strategy and 19.4 percent with use of the conservative strategy (odds ratio, 0.78; 95 percent confidence interval, 0.62 to 0.97; P=0.025). The rate of death or nonfatal myocardial infarction at six months was similarly reduced (7.3 percent vs. 9.5 percent; odds ratio, 0.74; 95 percent confidence interval, 0.54 to 1.00;

P<0.05). **CONCLUSIONS:** In patients with unstable angina and myocardial infarction without ST-segment elevation who were treated with the glycoprotein IIb/IIIa inhibitor tirofiban, the use of an early invasive strategy significantly reduced the incidence of major cardiac events. These data support a policy involving broader use of the early inhibition of glycoprotein IIb/IIIa in combination with an early invasive strategy in such patients.

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Primary angioplasty versus intravenous thrombolysis in acute myocardial infarction: can we define subgroups of patients benefiting most from primary angioplasty? Results from the pooled data of the Maximal Individual Therapy in Acute Myocardial Infarction Registry and the Myocardial Infarction Registry.

Zahn R, Schiele R, Schneider S, Gitt AK, Wienbergen H, Seidl K, Voigtlander T, Gottwik M, Berg G, Altmann E, Rosahl W, Senges J.

**OBJECTIVES:** We sought to determine the effectiveness of primary angioplasty compared with thrombolysis in clinical practice. **BACKGROUND:** In clinical practice, primary angioplasty for the treatment of acute myocardial infarction (AMI) has not yet been proven more effective than intravenous thrombolysis, nor have subgroups of patients been identified who would perhaps benefit from primary angioplasty. **METHODS:** The pooled data of two AMI registries—the Maximal Individual Therapy in Acute myocardial infarction (MITRA) study and the Myocardial Infarction Registry (MIR)—were analyzed. A total of 9,906 lytic-eligible patients with AMI, with a pre-hospital delay of  $\leq 12$  h, were treated with either primary angioplasty (n = 1,327) or thrombolysis (n = 8,579). **RESULTS:** Despite differences in the patients' characteristics and concomitant diseases between the two groups, the prevalence of adverse risk factors was balanced. Univariate analysis of hospital mortality showed a more favorable course for patients treated with primary angioplasty: 6.4% versus 11.3% (odds ratio [OR] 0.54, 95% confidence interval [CI] 0.43 to 0.67). This was confirmed by logistic regression analysis (multivariate OR 0.58, 95% CI 0.44 to 0.77). Primary angioplasty was associated with a lower mortality in all subgroups analyzed. We observed a significant correlation between mortality and absolute risk reduction ( $r = 0.82$ ,  $p < 0.0001$ ) in the different subgroups: as mortality increased, there was an increase in absolute benefit of primary angioplasty compared with thrombolysis. **CONCLUSIONS:** These large registry data showed the effect of primary angioplasty to be more favorable than thrombolysis for the treatment of patients with AMI in clinical practice. This effect was not restricted to special subgroups of patients. As mortality increased, the

absolute benefit of primary angioplasty also increased.

Am J Cardiol, 2001 ;88(2):124-8

Predictors and prognosis of suboptimal coronary blood flow after primary coronary angioplasty in patients with acute myocardial infarction.

Cura FA, L'Illyer PL, Kapadia SR, Houghtaling PL, Dipaola LM, Ellis SG, Topol EJ, Brener SJ; The GUSTO IIb and RAPPORT Investigators.

We hypothesized that certain clinical and angiographic characteristics on presentation predict suboptimal infarct artery flow after percutaneous intervention during acute myocardial infarction (AMI). The goal of angioplasty (percutaneous transluminal coronary angioplasty [PTCA]) during AMI is the prompt restoration of normal flow to achieve myocardial reperfusion. However, inadequate epicardial coronary flow is observed in 10% to 20% of patients. From 2 large randomized trials-Global Use of Strategies To open Occluded arteries in Acute Coronary Syndromes-IIb, and Randomized Placebo-Controlled Trial of Platelet glycoprotein IIb/IIIa Blockade With Primary Angioplasty for Acute Myocardial Infarction-patients undergoing primary PTCA during AMI were included in the analysis. A multivariate logistic model was used to identify factors associated with final Thrombolysis In Myocardial Infarction (TIMI) flow grade  $\leq 2$ . The 891 patients were aged (mean  $\pm$  SD) 61  $\pm$  12 years, 75% were men, and 39% had an anterior wall AMI. Patients underwent PTCA within 4.8  $\pm$  3.2 hours from the onset of chest pain. The incidence of final TIMI 3 flow was 81%. TIMI flow grade  $\leq 2$  was independently associated with increasing age (odds ratio [OR] 1.39 for every 10 years, 95% confidence interval [CI] 1.19 to 1.62), increasing heart rate (OR 1.16 for every 10 beats, 95% CI 1.05 to 1.28), and presence of visible thrombus on baseline angiogram (OR 1.89, 95% CI 1.18 to 3.05). Conversely, baseline TIMI 2 or 3 flow grade (OR 0.46, 95% CI 0.28 to 0.75) and left circumflex intervention (OR 0.42, 95% CI 0.23 to 0.79) correlated with normal postprocedural coronary flow. Mortality was significantly higher in patients with TIMI  $\leq 2$  than TIMI 3 flow grade (10.2% vs 1.5%,  $p < 0.001$ , respectively). Thus, angiographic evidence of thrombus and 2 pivotal clinical characteristics, advanced age and elevated heart rate, predict lack of adequate coronary reperfusion. Conversely, the presence of normal or near-normal coronary flow before intervention correlates with a good angiographic result. Mortality risk is increased in patients with postprocedural suboptimal angiographic coronary flow.

J Am Coll Cardiol, 2001; 38(2):464-71

Time course and determinants of left ventricular function recovery after primary angioplasty in patients with acute myocardial infarction.

Sheiban I, Fragasso G, Rosano GM, Dharmadhikari A, Tzifos V, Pagnotta P, Chierchia SL, Trevisan G.

**OBJECTIVES:** We sought to evaluate the importance of time in relation to treatment, time course and determinants of recovery of left ventricular (LV) function in patients with acute myocardial infarction (AMI) undergoing primary percutaneous transluminal coronary angioplasty (PTCA). **BACKGROUND:** Myocardial salvage has been shown to be dependent on the time elapsed from the onset of AMI to reperfusion. **METHODS:** Left ventricular function was evaluated at hospital admission, after angioplasty, at 24 h and 6 months by both echocardiography and angiography and at 1, 7, 30, 90 and 180 days by echocardiography in 101 consecutive patients. **RESULTS:** Patients were allocated to three groups according to interval between symptom onset and angioplasty: <2 h (group A), 2 to 4 h (group B) and >4 h (group C). Patients in groups A and B showed a progressive improvement of LV function between day 7 and day 90, which became statistically significant at day 30 ( $p < 0.01$ ). No LV function changes were noted in group C patients. Thrombolysis In Myocardial Infarction (TIMI) flow grade <3 at 24 h was not associated with any significant change in LV volume and function during the six-month follow-up period. Restenosis, when associated with TIMI flow grade 3 in the infarct-related vessel, did not influence LV function. Flow grade <3 of the infarct-related artery was not associated with any improvement of cardiac events independently from the time to treatment at the initial procedure. **CONCLUSIONS:** Patients undergoing primary PTCA for AMI have a good recovery of LV function if TIMI flow grade 3 is restored within 4 h. Coronary angioplasty limits further remodeling of the LV in patients treated after 4 h.

Circulation, 2001;104(6):636-41

Normal flow (TIMI-3) before mechanical reperfusion therapy is an independent determinant of survival in acute myocardial infarction: analysis from the primary angioplasty in myocardial infarction trials.

Stone GW, Cox D, Garcia E, Brodie BR, Morice MC, Griffin J, Mattos L, Lansky AJ, O'Neill WW, Grines CL.

**BACKGROUND:** Whereas survival after lytic therapy for myocardial infarction is strongly dependent on early administration, it is unknown whether the otherwise excellent outcomes in patients undergoing primary PTCA for acute myocardial infarction, in whom TIMI-3 flow rates of >90% may be achieved, can be further improved by early reperfusion. **METHODS AND RESULTS:** Among 2507 patients enrolled in 4 PAMI trials undergoing primary PTCA, spontaneous reperfusion (TIMI-3 flow) was present in 16% at initial angiography. Compared with patients without TIMI-3 flow, those with TIMI-3 flow before PTCA had greater left ventricular ejection fraction (57+/-10% versus 53+/-11%, P=0.003) and were less likely to present in heart failure (7.0% versus 11.6%, P=0.009). Patients with initial TIMI-3 flow had significantly lower in-hospital rates of mortality, new-onset heart failure, and hypotension and had a shorter hospital stay. Cumulative 6-month mortality was 0.5% in patients with initial TIMI-3 flow, 2.8% with TIMI-2 flow, and 4.4% with initial TIMI-0/1 flow (P=0.009). By multivariate analysis, TIMI-3 flow before PTCA was an independent determinant of survival (odds ratio 2.1, P=0.04), even when corrected for by postprocedural TIMI-3 flow. **CONCLUSIONS:** Patients undergoing primary PTCA in whom TIMI-3 flow is present before angioplasty present with greater clinical and angiographic evidence of myocardial salvage, are less likely to develop complications related to left ventricular failure, and have improved early and late survival. These data warrant prospective randomized trials of pharmacological strategies to promote early reperfusion before definitive mechanical intervention in acute myocardial infarction.

Am Heart J, 2001;142(3):452-9

Primary percutaneous coronary interventions in patients with acute myocardial infarction and prior coronary artery bypass grafting.

Al Suwaidi J, Velianou JL, Berger PB, Mathew V, Garratt KN, Reeder GS, Grill DE, Holmes DR Jr.

**BACKGROUND:** The outcome of patients with previous coronary artery bypass grafting (CABG) undergoing primary percutaneous coronary intervention (PCI) for the treatment of acute myocardial infarction (AMI) is unclear. We sought to assess the outcome of patients with prior CABG undergoing primary PCI for the treatment of AMI. **METHODS AND RESULTS:** Between 1991 and 1997, 1072 patients with AMI underwent

primary PCI without antecedent thrombolytic therapy at the Mayo Clinic. There were 128 patients with previous CABG and 944 without previous CABG. Patients with previous CABG were further subdivided according to the treated vessel: native vessels (n = 65) and bypass graft (n = 63). Clinical and angiographic characteristics and 30-day and 1-year outcomes were evaluated. Patients with previous CABG were significantly older and had a higher incidence of diabetes, hypertension, and hypercholesterolemia. They had a lower left ventricular ejection fraction and were also more likely to have congestive heart failure. After 1 year of follow-up, adverse cardiac events (death, MI, CABG, or repeat PCI) were significantly greater in patients with prior CABG (49.2% vs 35.9%, P =.04). With use of multivariate logistic regression analysis to adjust for differences in baseline characteristics, the treatment of vein graft was independently associated with adverse cardiac events (relative risk 1.48 [95% confidence interval 1.07-2.03], P =.02), but a history of prior CABG itself was not (relative risk 1.22 [95% confidence interval 0.96-1.56], P =.11). CONCLUSIONS: Primary PCI for AMI in patients with previous CABG is associated with higher adverse events largely attributable to adverse baseline clinical characteristics and the treatment of a vein graft.

J Am Coll Cardiol , 2001;38(3):666-71

TIMI frame count immediately after primary coronary angioplasty as a predictor of functional recovery in patients with TIMI 3 reperfused acute myocardial infarction.

Hamada S, Nishiue T, Nakamura S, Sugiura T, Kamihata H, Miyoshi H, Imuro Y, Iwasaka T.

**OBJECTIVES:** The purpose of this study was to evaluate whether higher coronary blood flow, estimated by the corrected Thrombolysis In Myocardial Infarction (TIMI) frame count (CTFC), is related to better functional and clinical outcome after successful percutaneous transluminal coronary angioplasty (PTCA) in patients with acute myocardial infarction (AMI). **BACKGROUND:** Experimental studies have found that functional recovery of the infarcted myocardium was associated with increased blood flow (reactive hyperemia) to the infarcted bed shortly after reperfusion. **METHODS:** We measured CTFC immediately after successful (TIMI 3) primary PTCA in 104 consecutive patients with their first AMI. Wall motion score index (WMSI) and the presence of pericardial effusion were assessed by two-dimensional echocardiography before and one month after PTCA. **RESULTS:** The patients were divided into two groups according to mean CTFC for corresponding coronary artery of the control group: TIMI 3 slow group (45 patients,  $40 > \text{CTFC} \geq 23$ ) and TIMI 3 fast group (59 patients,  $\text{CTFC} < 23$ ). There were no significant differences in the baseline characteristics and WMSI before

reperfusion between the two groups. Improvement of WMSI in the TIMI 3 fast group was significantly greater than that of the TIMI 3 slow group (1.33 +/- 0.52 vs. 0.60 +/- 0.34,  $p < 0.001$ ). Pericardial effusion and intractable heart failure were observed more frequently in the TIMI 3 slow group than in the TIMI 3 fast group (27 vs. 10%;  $p < 0.05$ , 36 vs. 17%;  $p < 0.05$ ). Corrected TIMI frame count, assessed as a continuous variable, had a significant correlation with the change in WMSI ( $r = 0.60$ ,  $p < 0.001$ ) after adjusting for age, gender, history of hypertension, history of diabetes, elapsed time to PTCA, collateral grade, presence of antegrade flow before PTCA and number of diseased vessels. CONCLUSIONS: Lower CTFC of the infarct-related artery immediately after PTCA was associated with greater functional recovery; and hence, CTFC can predict clinical and functional outcome in patients with successful PTCA.

Am J Cardiol , 2001 ;88(10):1103-7

Predictors of long-term outcomes following direct percutaneous coronary intervention for acute myocardial infarction.

Beohar N, Davidson CJ, Weigold G, Goodreau L, Benzuly KH, Bonow RO.

To determine predictors of a long-term major adverse cardiac event (MACE) in unselected patients undergoing direct percutaneous coronary intervention (PCI), 274 consecutive patients presenting within 12 hours of ST-segment elevation acute myocardial infarction (AMI) were evaluated. No patient with ST-segment elevation AMI received intravenous thrombolytic drugs. Chest pain to balloon time was 3.8 hours (range 2.5 to 6.9). percutaneous transluminal coronary angioplasty was successful in 95% of patients. Abciximab was administered to 69% of patients, stents were deployed in 53%, and 17% underwent only catheterization. In-hospital events were death (7%), abrupt closure (2%), emergent coronary artery bypass grafting (CABG) (5%), repeat PCI (3%), and recurrent myocardial infarction (1%). In patients undergoing direct PCI ( $n = 227$ ), the in-hospital event rate was death 5.3%, abrupt closure 2.2%, emergency CABG 0.9%, repeat PCI 3.1%, and repeat myocardial infarction 1.3%. Median time to last follow-up or death was 20 months (range 11 to 34), and to any event, 0.3 months (range 0.03 to 24.0). Postdischarge MACE included death (5%), AMI (4%), repeat PCI (8%), CABG (9%), and stroke (0.7%). Among those undergoing direct PCI ( $n = 227$ ), 10% died, 3.5% had a repeat AMI, 9% had a repeat PCI, 5% had CABG, and 1% had a stroke at long-term follow-up. At long-term follow-up, 75% were event free. Multivariate predictors were (hazard ratio [95% confidence interval (CI)]): abciximab use 0.6 (95% CI 0.43 to 0.95), Killip class 2.2 (95% CI 1.1 to 4.4), and number of narrowed coronary arteries 1.7 (95% CI 1.4 to 2.2). In this unselected consecutive series of patients presenting with ST-segment elevation AMI, direct PCI was associated with sustained long-term efficacy. Outcomes were predicted by cardiac impairment at

presentation and number of narrowed coronary arteries. MACE is not related to device selection but is significantly improved with abciximab.

Am J Cardiol , 2001 ;88(10):1085-90

Importance of time to reperfusion on outcomes with primary coronary angioplasty for acute myocardial infarction (results from the Stent Primary Angioplasty in Myocardial Infarction Trial).

Brodie BR, Stone GW, Morice MC, Cox DA, Garcia E, Mattos LA, Boura J, O'Neill WW, Stuckey TD, Milks S, Lansky AJ, Grines CL; Stent Primary Angioplasty in Myocardial Infarction Study Group

The mortality benefit of thrombolytic therapy for acute myocardial infarction (AMI) is strongly dependent on time to treatment. Recent observations suggest that time to treatment may be less important with primary percutaneous transluminal coronary angioplasty (PTCA). Patients with AMI of <12 hours duration, without cardiogenic shock, who were treated with primary PTCA from the Stent PAMI Trial (n = 1,232) were evaluated to assess the effect of time to reperfusion on outcomes. Thrombolysis In Myocardial Infarction grade 3 flow was achieved in a high proportion of patients regardless of time to treatment. Improvement in ejection fraction from baseline to 6 months was substantial with reperfusion at <2 hours but was modest and relatively independent of time to reperfusion after 2 hours (<2 hours, 12.3% vs ≥2 hours, 4.2%, p = 0.004). There were no differences in 1- or 6-month mortality by time to reperfusion (6-month mortality: <2 hours [5.5%], 2 to <4 hours [4.6%], 4 to <6 hours [4.5%], ≥6 hours [4.2%], p = 0.97). There were also no differences in other clinical outcomes by time to reperfusion, except that reinfarction and infarct artery reocclusion at 6 months were more frequent with later reperfusion. The lack of correlation between time to treatment and mortality in patients without cardiogenic shock suggests that the survival benefit of primary PTCA may be related principally to factors other than myocardial salvage. These data may also have implications regarding the triage of patients with AMI for primary PTCA.

Circulation, 2001 ;104(25):3039-45

Cost-effectiveness of coronary stenting in acute myocardial infarction: results from the stent primary

angioplasty in myocardial infarction (stent-PAMI) trial.

Cohen DJ, Taira DA, Berezin R, Cox DA, Morice MC, Stone GW, Grines CL.

**BACKGROUND:** Although several randomized trials have demonstrated that coronary stenting improves angiographic and clinical outcomes for patients with acute myocardial infarction (AMI), the cost-effectiveness of this practice is unknown. The objective of the present study was to evaluate the long-term costs and cost-effectiveness (C/E) of coronary stenting compared with primary balloon angioplasty as treatment for AMI. **Methods and Results-** Between December 1996 and November 1997, 900 patients with AMI were randomized to undergo balloon angioplasty (PTCA, n=448) or coronary stenting (n=452). Detailed resource utilization and cost data were collected for each patient? initial hospitalization and for 1 year after randomization. Compared with conventional PTCA, stenting increased procedural costs by approximately \$2000 per patient (\$6538+/-1778 versus \$4561+/-1598, P<0.001). During the 1-year follow-up period, stenting was associated with significant reductions in the need for repeat revascularization and rehospitalization. Although follow-up costs were significantly lower with stenting (\$3613+/-7743 versus \$4592+/-8198, P=0.03), overall 1-year costs remained approximately \$1000/patient higher with stenting than with PTCA (\$20 571+/-10 693 versus 19 595+/-10 990, P=0.02). The C/E ratio for stenting compared with PTCA was \$10 550 per repeat revascularization avoided. In analyses that incorporated recent changes in stent technology and pricing, the 1-year cost differential fell to <\$350/patient, and the C/E ratio improved to \$3753 per repeat revascularization avoided. The cost-utility ratio for primary stenting was <\$50 000 per quality-adjusted life year gained only if stenting did not increase 1-year mortality by >0.2% compared with PTCA. **CONCLUSIONS:** As performed in Stent-PAMI, primary stenting for AMI increased 1-year medical care costs compared with primary PTCA. The overall cost-effectiveness of primary stenting depends on the societal value attributed to avoidance of symptomatic restenosis, as well as on the relative mortality rates of primary PTCA and stenting.

Chest, 2001 ;120(6):1959-63

Clinical significance of coronary flow to the infarct zone before successful primary percutaneous transluminal coronary angioplasty in acute myocardial infarction.

Hatada K, Sugiura T, Kamihata H, Nakamura S, Takahashi N, Yuasa F, Iwasaka T.

**STUDY OBJECTIVE:** To assess the effect of coronary flow to the infarct zone before primary coronary angioplasty on hospital complications in patients with acute myocardial infarction (MI). **DESIGN:** Consecutive case series analysis. **SETTING:** Coronary-care unit in a university hospital. **PATIENTS:** Two hundred sixty-four consecutive patients with ST-elevation acute MIs who had successful primary percutaneous transluminal coronary angioplasty. **INTERVENTIONS:** Coronary angiography on hospital admission and serial echocardiography. **MEASUREMENTS AND RESULTS:** The status of infarct-related artery flow before primary angioplasty was evaluated on hospital admission. Left ventricular wall motion and pericardial effusions were studied by echocardiography. One hundred ninety patients had total occlusions (Thrombolysis in Myocardial Infarction [TIMI] flow grade, 0 to 1) in the infarct-related artery (group 1), and 74 patients had antegrade flow (TIMI flow grade, 2 to 3) [group 2] before undergoing primary angioplasty procedures. When group 1 was subdivided into two groups (for the presence and absence of collateral flow), the patients with total occlusions and no collateral flow had a higher incidence of left ventricular aneurysmal wall motion (11% vs 1%, respectively;  $p = 0.03$ ) and pericardial friction rub (15% vs 3%, respectively;  $p = 0.03$ ) than did those in group 2. Moreover, those patients with total occlusions and no collateral flow had higher incidences of pericardial effusion (34% vs 17%, respectively;  $p = 0.02$ ; and 34% vs 9%, respectively;  $p < 0.01$ ) and in-hospital mortality (8% vs 1%, respectively;  $p = 0.04$ ; and 8% vs 1%, respectively;  $p = 0.06$ ) than did those patients in the other two groups. **CONCLUSIONS:** Despite successful primary angioplasty, the absence of antegrade flow in the infarct-related artery and collateral flow to the infarct zone before angioplasty resulted in a higher incidence of in-hospital complications.

Am J Cardiol , 2002 ;89(2):126-31

Results of primary percutaneous transluminal coronary angioplasty plus abciximab with or without stenting for acute myocardial infarction complicated by cardiogenic shock.

Giri S, Mitchel J, Azar RR, Kiernan FJ, Fram DB, McKay RG, Mennett R, Clive J, Hirst JA.

This study examines the effects of abciximab as adjunctive therapy in primary percutaneous transluminal coronary angioplasty (PTCA) for acute myocardial infarction (AMI) complicated by cardiogenic shock. Abciximab improves the outcome of primary PTCA for AMI, but its efficacy in cardiogenic shock remains

unknown. Case report forms were completed in-hospital and follow-up was obtained by telephone, outpatient visit, and review of hospital readmission records. A total of 113 patients with cardiogenic shock from AMI were included. All underwent emergency PTCA during which abciximab was administered to 54 patients (48%). The 2 groups of patients who received and did not receive abciximab were similar at baseline. Coronary stents were implanted slightly more often in the abciximab group (59% vs 42%;  $p = 0.1$ ). A significantly improved final TIMI flow, less no-reflow, and a decrease in vessel residual diameter stenosis occurred in the abciximab group. At 30-day follow-up, the composite event rate of death, myocardial reinfarction, and target vessel revascularization was better in the abciximab group (31% vs 63%;  $p = 0.002$ ). The combination of abciximab and stents was synergistic and resulted in improvement of all components of the composite end point beyond that seen with each therapy alone. Thus, abciximab therapy improves the 30-day outcome of primary PTCA in cardiogenic shock, especially when combined with coronary stenting.

J Am Coll Cardiol ,2002 ;39(1):15-21

A randomized comparison of direct stenting with conventional stent implantation in selected patients with acute myocardial infarction.

Loubeyre C, Morice MC, Lefevre T, Piechaud JF, Louvard Y, Dumas P.

**OBJECTIVES:** We sought to determine whether direct stenting might prevent the adverse events associated with stent implantation during primary angioplasty and to compare it with conventional stent implantation in patients with acute myocardial infarction (AMI). **BACKGROUND:** No trial has demonstrated that stents favorably influence mortality rate. Recent studies have even suggested a negative impact of stents on coronary blood flow and clinical outcome. **METHODS:** Of 409 patients treated by primary angioplasty with stent implantation in our center, 206 (50%) were enrolled in this randomized, single-center trial and allocated to direct stent implantation ( $n = 102$ ) or stent implantation after balloon pre-dilation ( $n = 104$ ). The study end points included angiographic results (final corrected Thrombolysis In Myocardial Infarction [TIMI] frame count and a composite end point of slow and no-reflow or distal embolization), an electrocardiogram marker of myocardial reperfusion assessment (ST-segment resolution) and in-hospital clinical outcome (death and recurrent infarction). **RESULTS:** Direct stent implantation failed in eight patients but succeeded after pre-dilation in all. A non-significant increase in TIMI flow grade 3 was achieved after direct stenting (95.1% vs. 93.3%,  $p = 0.74$ ) without significant difference in the corrected TIMI frame count (31.5 +/- 17 and 35.2 +/- 20

frames after direct and conventional stent, respectively,  $p = 0.42$ ). The composite angiographic end point was significantly reduced by direct stent implantation (11.7% vs. 26.9%,  $p = 0.01$ ). ST-segment resolution was also significantly improved after direct stent (no ST-segment resolution in 20.2% vs. 38.1% after direct and conventional stent, respectively,  $p = 0.01$ ). Death and/or recurrent infarction occurred in six patients after conventional stent implantation and in two patients after direct stenting ( $p = 0.28$ ). CONCLUSIONS: In selected patients with AMI, direct stenting can be applied safely and effectively. This strategy may result in a significant reduction of microvascular injury, as suggested by improved ST-segment resolution after reperfusion with major potential clinical consequences.

Int J Cardiol ,2002 ;82(2):127-31

Long-term results after acute percutaneous transluminal coronary angioplasty in acute myocardial infarction and cardiogenic shock.

Ammann P, Straumann E, Naegeli B, Schuiki E, Frielingsdorf J, Gerber A, Bertel O.

The aim of this study was to determine the long-term outcome in unselected, consecutive patients after acute percutaneous transluminal angioplasty (PTCA) for acute myocardial infarction (AMI) complicated by cardiogenic shock. This involved a follow-up study from a prospectively conducted patient registry in a tertiary referral center. A total of 59 patients (10 female/49 male; median age 62 years (32?1)) with percutaneous transluminal cardiac interventions in primary cardiogenic shock were identified between January 1995 and January 2000. Twenty-two patients (37%) had been resuscitated successfully before intervention. The in-hospital mortality of shock patients was 36% ( $n=21$ , median age 68 (47?4)). The median follow-up of survivors was 18.1 (7?7.3) months, during which three further patients died (8%; two because of sudden cardiac deaths, one because of acute reinfarction). Achievement of thrombolysis in myocardial infarction (TIMI) flow III after acute PTCA (84% in survivors vs. 38% in non-survivors;  $P<0.001$ ) and the absence of the left main coronary artery (3% survivors vs. 29% non-survivors;  $P=0.003$ ) as culprit lesion in patients with cardiogenic shock was strongly associated with an improved survival rate. A second cardiac intervention was performed in seven patients (18%). Overall functional capacity of shock survivors was good. At final follow-up, 80% of the survivors were completely asymptomatic. One patient had angina pectoris NYHA II, five patients dyspnoea

NYHA class II. Exercise stress-test was performed in 24 of the 38 surviving patients, median exercise capacity was 100% (range 55-133%) of the age adjusted predicted value. In unselected patients with cardiogenic shock due to AMI, treatment with acute PTCA resulted in an in-hospital mortality of 36%, low late mortality and good functional capacity in long-term survivors. TIMI flow grade III after acute PTCA in patients with acute myocardial infarction complicated by cardiogenic shock was strongly associated with an improved survival rate whereas the left main coronary artery as culprit lesion was associated with worse outcome.

J Am Coll Cardiol , 2002 ;39(4):598-603

Primary angioplasty reduces the risk of left ventricular free wall rupture compared with thrombolysis in patients with acute myocardial infarction.

Moreno R, Lopez-Sendon J, Garcia E, Perez de Isla L, Lopez de Sa E, Ortega A, Moreno M, Rubio R, Soriano J, Abeytua M, Garcia-Fernandez MA.

**OBJECTIVES:** This study aimed to evaluate the effect of primary angioplasty (PA) over the risk of free wall rupture (FWR) in reperfused acute myocardial infarction (AMI). **BACKGROUND:** It has been suggested that PA reduces the risk of FWR compared with thrombolysis. However, few studies have evaluated this issue, and there are no data demonstrating this hypothesis. **METHODS:** A total of 1,375 patients with AMI treated with PA (n = 762, 55.4%) or thrombolysis (n = 613, 44.6%) within 12 h after symptoms onset were included. The diagnosis of FWR was made either in the presence of sudden death due to electromechanical dissociation with large pericardial effusion on an echocardiogram or when demonstrated post mortem or at surgery. A multivariable analysis was performed including type of reperfusion strategy. **RESULTS:** The overall incidence of FWR was 2.5% (n = 34): 1.8% and 3.3% in patients treated with PA and with thrombolysis, respectively (p = 0.686). The following characteristics were associated with a higher rate of FWR in the univariable analysis: age >70 (5.2% vs. 1.2%, p < 0.001), female gender (5.1% vs. 1.8%, p = 0.006), anterior location (3.3% vs. 1.4%, p = 0.020) and treatment >2 h after symptoms onset (3.6% vs. 1.7%, p = 0.043). In the multivariable analysis, age >70 (odds ratio [OR]: 4.12, 95% confidence interval [CI]: 2.04 to 8.62, p < 0.001) and anterior location (OR: 2.91, 95% CI: 1.36 to 6.63, p = 0.008) were independent risk factors of FWR, whereas treatment with PA was an independent protective factor (OR: 0.46, 95% CI: 0.22 to 0.96, p = 0.0371). **CONCLUSIONS:** In patients with AMI, PA reduces the risk of FWR in comparison with thrombolysis.

Am Heart J , 2002 ;143(3):497-505

Long-term outcome of primary percutaneous transluminal coronary angioplasty for low-risk acute myocardial infarction in patients older than 80 years: A single-center, open, randomized trial.

Minai K, Horie H, Takahashi M, Nozawa M, Kinoshita M.

**BACKGROUND:** Although coronary reperfusion therapy with thrombolytic agents or percutaneous transluminal coronary angioplasty (PTCA) immediately after acute myocardial infarction (AMI) has survival benefits for younger patients, the effect of coronary reperfusion therapy for very elderly (aged 80 years and older) patients with AMI remains controversial. **METHODS AND RESULTS:** We studied 120 patients aged 80 years and older at relatively low risk with AMI. The patients were randomized into a primary PTCA group (n = 61) or a ?onservative?no-PTCA group (n = 59). Long-term follow-up examination was conducted with regard to endpoints, which included all causes of death, cardiac death, nonfatal re-MI, the development of congestive heart failure, and cerebral vascular accident. End-diastolic volume index and end-systolic volume index were significantly increased in both groups at follow-up examination 6 months after AMI. However, left ventricular ejection fraction, end-diastolic volume index, and end-systolic volume index were similar between both groups. With endpoints of all causes of death, cardiac death, reinfarction, congestive heart failure, and cerebral vascular accident, a 3-year Kaplan-Meier event-free survival rate analysis revealed no significant benefits in the PTCA group. Anteroseptal MI, multivessel disease, and left ventricular ejection fraction were significantly associated with the combined events with multivariate Cox proportional hazards analysis results. **CONCLUSION:** First, primary PTCA for very elderly patients with AMI appears to have few beneficial effects on combined events during a 3-year period. Second, early PTCA did not prevent left ventricle remodeling after AMI in patients with AMI at relatively low risk.

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Use of Intraaortic Balloon Counterpulsation in Patients Presenting With Cardiogenic Shock: Observations From the GUSTO-I Study

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**Objectives.** We sought to examine the use, complications and outcomes with early intraaortic balloon counterpulsation (IABP) in patients presenting with cardiogenic shock complicating acute myocardial infarction and treated with thrombolytic therapy.

**Background.** The use of IABP in patients with cardiogenic shock is widely accepted; however, there is a paucity of information on the use of this technique in patients with cardiogenic shock who are treated with thrombolytic therapy.

**Methods.** Patients who presented within 6 h of chest pain onset were randomized to one of four thrombolytic regimens. Cardiogenic shock was not an exclusion criterion, and data for these patients were prospectively collected. Patients presenting with shock were classified into early IABP (insertion within one calendar day of enrollment) or no IABP (insertion on or after day 2 or never).

**Results.** There were 68 (22%) IABP placements in 310 patients presenting with shock. Early IABP use occurred in 62 patients (20%) and none in 248 (80%). Most IABP use occurred in the United States (59 of 68 IABP placements) involving 32% of U.S. patients presenting with shock. Despite more adverse events in the early IABP group and more episodes of moderate bleeding, this cohort showed a trend toward lower 30-day and 1-year mortality rates.

**Conclusions.** IABP appears to be underutilized in patients presenting with cardiogenic shock, both within and outside the United States. Early IABP institution is associated with an increased risk of bleeding and adverse events but a trend toward lower 30-day and 1-year all-cause mortality.

Journal of the American College of Cardiology, 30:201-208

Predictors of Success and Major Complications for Primary Percutaneous Transluminal Coronary Angioplasty in Acute Myocardial Infarction : An Analysis of the 1990 to 1994 Society for Cardiac Angiography and Interventions Registries

Eric D. Grassman, MD, FACC, Sarah A. Johnson, MD, FACC, Ronald J. Krone, MD, FACC

**Objectives.** The purpose of this study was to determine predictors of successful coronary angioplasty for acute myocardial infarction (MI) and associated predictors of the major complications of in-hospital mortality and emergency coronary artery bypass graft surgery.

**Background.** Primary angioplasty is being increasingly used to treat acute MI, but factors affecting the success and major complications have not been well studied. Forty laboratories have been contributing clinical and procedural data to the Society of Cardiac Angiography and Interventions (SCA&I) on primary angioplasty for acute MI.

**Methods.** Univariable and stepwise multivariable logistic regression analysis of clinical and procedural variables was used to calculate predictors of success and major complications.

**Results.** There were 4,366 primary angioplasty procedures reported from 1990 through 1994, with an overall success rate of 91.5%, an in-hospital mortality rate of 2.5% and a rate of emergency surgery of 4.3%. Higher laboratory primary angioplasty volume and lower age were predictive of success. An intraaortic balloon pump in place, cardiogenic shock and a moribund condition had negative predictive effects. Unsuccessful angioplasty, cardiogenic shock or a moribund state were predictive of in-hospital death. Unsuccessful angioplasty, the absence of a history of hypertension and the absence of congestive heart failure were predictive of emergency surgery.

**Conclusions.** The rates of success and major complications in the SCA&I Registry are similar to other series. Predictors of success and major complications can be assessed and may be useful for risk stratifying candidates for primary angioplasty in acute MI.

Circulation,1997;96:122-127

Impact of an Aggressive Invasive Catheterization and Revascularization Strategy on Mortality in Patients With Cardiogenic Shock in the Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries (GUSTO-I) Trial  
An Observational Study

Peter B. Berger, MD; David R. Holmes, Jr, MS; Amanda L. Stebbins, MD; Eric R. Bates, MD; Robert M. Califf, MD; Eric J. Topol, MD; ; for the GUSTO-I Investigators

Background

Although retrospective analyses have revealed an association between survival and coronary angiography and angioplasty in patients with acute myocardial infarction complicated by cardiogenic shock, the degree to which bias in the selection of patients to undergo these procedures contributes to this observation remains unclear.

#### Methods and Results

We studied 2200 patients in the Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries (GUSTO-I) trial with acute myocardial infarction complicated by cardiogenic shock (systolic blood pressure <90 mm Hg for  $\geq 1$  hour) who survived  $\geq 1$  hour after the onset of shock to determine the influence of an aggressive strategy of early angiography (within 24 hours of shock onset) and coronary angioplasty or bypass surgery, if appropriate, on survival. Revascularization was not protocol mandated but was selected by the attending physicians. Shock was present on admission in 11% and developed after admission in 89% of shock patients. The 30-day mortality was 38% in the 406 patients who underwent early angiography and were referred within 24 hours for angioplasty (n=175), bypass surgery (n=36), angioplasty and bypass surgery (n=22), or neither (late or no revascularization, n=173) compared with 62% in the 1794 patients who did not (P=.0001). However, there were important differences in the baseline characteristics of the two groups, including younger age (63 versus 68 years, P=.0001), less prior infarction (19% versus 27%, P=.001), and a shorter time to thrombolytic therapy (2.9 versus 3.2 hours, P=.0001) in patients treated with an aggressive strategy. Using multivariate logistic regression analysis to adjust for differences in baseline characteristics, an aggressive strategy was independently associated with reduced 30-day mortality (odds ratio, 0.43 [confidence interval, 0.34 to 0.54], P=.0001).

#### Conclusions

An aggressive strategy of early angiography (and revascularization when appropriate) is associated with a reduction in mortality in patients with acute myocardial infarction and cardiogenic shock who receive thrombolytic therapy.

J Am Coll Cardiol , 1997;29:28-34

Coronary Stent Placement in Patients With Acute Myocardial Infarction: Comparison of Clinical and Angiographic Outcome After Randomization to Antiplatelet or Anticoagulant Therapy

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**Objectives.** The Intracoronary Stenting and Antithrombotic Regimen (ISAR) trial is a randomized comparison of combined antiplatelet with anticoagulant therapy after coronary Palmaz-Schatz stent placement. The objective of this study was to compare early and late clinical and angiographic outcome in a subgroup of patients with stent placement for acute myocardial infarction.

**Background.** Stenting has become a treatment option for acute myocardial infarction, but it is not known which antithrombotic regimen is more adequate after stent implantation.

**Methods.** One hundred twenty-three patients with successful stenting after acute myocardial infarction were randomized to receive aspirin plus ticlopidine (n = 61) or intense anticoagulant therapy (n=62). Six-month repeat angiography was performed in 101 (86.3%) eligible patients.

**Results.** During the first 30 days after stenting, patients with antiplatelet therapy had a significantly lower clinical event rate (3.3% vs. 21.0%, p=0.005) and stent vessel occlusion rate (0%vs.9.7%, p = 0.03) and a trend to fewer cardiac events (1.6% vs. 9.7%, p = 0.12). After 6 months, the survival rate free of recurrent myocardial infarction was higher in patients with antiplatelet therapy (100% vs. 90.3%, p = 0.03), and the rate of stent vessel occlusion was lower (1.6%vs. 14.5%, p = 0.02). Both groups had comparable restenosis rates (26.5%vs. 26.9%, p = 0.87).

**Conclusions.** This study demonstrates that combined antiplatelet therapy after stent placement in patients with acute myocardial infarction is associated with an overall better clinical and angiographic outcome than anticoagulant therapy.

SVO: Stent vessel occlusion

## Summary

Journal of the American College of Cardiology, 32:1351-1357

Optimal coronary balloon angioplasty with provisional stenting versus primary stent (OCBAS) : Immediate and long-term follow-up results

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**Objective.** This study sought to compare two strategies of revascularization in patients obtaining a good immediate angiographic result after percutaneous transluminal coronary angioplasty (PTCA): elective stenting versus optimal PTCA. A good immediate angiographic result with provisional stenting was considered to occur only if early loss in minimal luminal diameter (MLD) was documented at 30 min post-PTCA angiography. **Background.** Coronary stenting reduces restenosis in lesions exhibiting early deterioration ( $>0.3$  mm) in MLD within the first 24 hours (early loss) after successful PTCA. Lesions with no early loss after PTCA have a low restenosis rate.

**Methods.** To compare angiographic restenosis and target vessel revascularization (TVR) of lesions treated with coronary stenting versus those treated with optimal PTCA, 116 patients were randomized to stent ( $n = 57$ ) or to optimal PTCA ( $n = 59$ ). After randomization in the PTCA group, 13.5% of the patients crossed over to stent due to early loss (provisional stenting).

**Results.** Baseline demographic and angiographic characteristics were similar in both groups of patients. At 7.6 months, 96.6% of the entire population had a follow-up angiographic study: 98.2% in the stent and 94.9% in the PTCA group. Immediate and follow-up angiographic data showed that acute gain was significantly higher in the stent than in the PTCA group (1.95 vs. 1.5 mm;  $p < 0.03$ ). However, late loss was significantly higher in the stent than the PTCA group ( $0.63 \pm 0.59$  vs.  $0.26 \pm 0.44$ , respectively;  $p = 0.01$ ). Hence, net gain with both techniques was similar ( $1.32 \pm 0.3$  vs.  $1.24 \pm 0.29$  mm for the stent and the PTCA groups, respectively;  $p = \text{NS}$ ). Angiographic restenosis rate at follow-up (19.2% in stent vs. 16.4% in PTCA;  $p = \text{NS}$ ) and TVR (17.5% in stent vs. 13.5% in PTCA;  $p = \text{NS}$ ) were similar. Furthermore, event-free survival was 80.8% in the stent versus 83.1% in the PTCA group ( $p = \text{NS}$ ). Overall costs (hospital and follow-up) were US \$591,740 in the stent versus US \$398,480 in the PTCA group ( $p < 0.02$ ).

**Conclusions.** The strategy of PTCA with delay angiogram and provisional stent if early loss occurs had similar restenosis rate and TVR, but lower cost than primary stenting after PTCA.

Journal of the American College of Cardiology, 1998;32:629-633

Influence of treatment delay on infarct size and clinical outcome in patients with acute myocardial infarction treated with primary angioplasty

Aylee L. Liem, Arnoud W.J. van 't Hof, Jan C.A. Hoorntje, Menko-Jan de Boer, Harry Suryapranata, Felix Zijlstra

**Objectives.** The purpose of this analysis was to determine the influence of an additional treatment delay inherent in transfer to an angioplasty center for primary angioplasty of patients with acute myocardial infarction who are first admitted to hospitals without angioplasty facilities.

**Background.** Several randomized trials have demonstrated the benefits of primary angioplasty in acute myocardial infarction. In recent years, increasing numbers of patients with myocardial infarction, initially admitted to hospitals without angioplasty facilities are transported to our hospital for primary angioplasty. However, the additional delay due to the transport may have a deleterious effect on infarct size and clinical outcome.

**Methods.** In a three-year period (December 1993 to November 1996), 207 consecutive patients who were transferred for primary angioplasty were analyzed in a matched comparison with nontransferred patients. Matching criteria were age, sex, infarct location, presentation delay and Killip class.

**Results.** Patients who were transferred had an additional median delay of 43 min. This resulted in a more extensive enzymatic infarct size and a lower ejection fraction measured at 6 months. The rate of angioplasty success defined as TIMI grade 3 flow, and the 6-month mortality rate (7%) were comparable in both groups.

**Conclusions.** The additional delay had a deleterious effect on myocardial salvage, reflected by a larger infarct size and a lower left ventricular function. However, the patency rate and 6-month clinical outcome were not affected by this delay.

The American Journal of Cardiology, 82:8:938-942

Procoagulant inflammatory responses of monocytes after direct balloon angioplasty in acute myocardial infarction

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This study sought to investigate monocyte procoagulant activity and Mac-1 expression after successful percutaneous transluminal coronary angioplasty (PTCA) in acute myocardial infarction (AMI). An increased leukocyte count is an important risk factor for subsequent adverse cardiac events in AMI. Cellular procoagulant responses may contribute to the risk of thrombotic events after AMI. In 20 patients with AMI serial venous blood samples were obtained before, 4, 8 hours, and daily after direct PTCA. Twenty patients with elective PTCA served as a control group. We measured leukocyte procoagulant activity with a 1-stage clotting assay, Mac-1 expression of monocytes by flow cytometry, concentrations of tumor necrosis factor-,

interleukin (IL)-1 $\beta$ , IL-6, and IL-8 using immunoassays. Forty-eight hours after PTCA in patients with AMI, an increase in systemic IL-6 and C-reactive concentrations was found ( $p = 0.001$ ,  $p = 0.008$ ) associated with an increase in monocyte Mac-1 expression by  $49 \pm 18\%$  ( $p = 0.04$ ) and followed by an increase in monocyte procoagulant activity by  $140 \pm 63\%$  72 hours after PTCA ( $p = 0.01$ ). None of these changes were detectable in the control group. No changes in the concentrations of the cytokines IL-1 $\beta$ , tumor necrosis factor- $\alpha$ , or IL-8 were found. The present study demonstrates an increase in procoagulant activity along with an increase in Mac-1 expression on circulating monocytes after successful PTCA in AMI associated with an increase in systemic IL-6. These cellular procoagulant responses may limit the clinical benefit from timely reperfusion.

Circulation, 1998 ;97: 2302-2306

#### Angiographic Assessment of Myocardial Reperfusion in Patients Treated With Primary Angioplasty for Acute Myocardial Infarction : Myocardial Blush Grade

Arnoud W.J. van 't Hof, Aylee Liem, Harry Suryapranata, Jan C.A. Hoorntje, Menko-Jan de Boer, and Felix Zijlstra

**Background-**The primary objective of reperfusion therapies for acute myocardial infarction is not only restoration of blood flow in the epicardial coronary artery but also complete and sustained reperfusion of the infarcted part of the myocardium.

**Methods and Results-**We studied 777 patients who underwent primary coronary angioplasty during a 6-year period and investigated the value of angiographic evidence of myocardial reperfusion (myocardial blush grade) in relation to the extent of ST-segment elevation resolution, enzymatic infarct size, left ventricular function, and long-term mortality. The myocardial blush immediately after the angioplasty procedure was graded by two experienced investigators, who were otherwise blinded to all clinical data: 0, no myocardial blush; 1, minimal myocardial blush; 2, moderate myocardial blush; and 3, normal myocardial blush. The myocardial blush was related to the extent of the early ST-segment elevation resolution on the 12-lead ECG. Patients with blush grades 3, 2, and 0/1 had enzymatic infarct sizes of 757, 1143, and 1623 ( $P < 0.0001$ ), respectively, and ejection fractions of 50%, 46%, and 39%, respectively ( $P < 0.0001$ ). After a mean  $\pm$  SD follow-up of  $1.9 \pm 1.7$  years, mortality rates of patients with myocardial blush grades 3, 2, and 0/1 were 3%, 6%, and 23% ( $P < 0.0001$ ), respectively. Multivariate analysis showed that the myocardial blush grade was a predictor of long-term mortality, independent of Killip class, Thrombolysis In Myocardial Infarction grade flow, left ventricular

ejection fraction (LVEF), and other clinical variables.

**Conclusions**-In patients after reperfusion therapy, the myocardial blush grade as seen on the coronary angiogram can be used to describe the effectiveness of myocardial reperfusion and is an independent predictor of long-term mortality.

**Key Words:** myocardial infarction ; angioplasty ; angiography

Journal of the American College of Cardiology, 32:5:1320-1325

**Long-term follow-up after direct percutaneous transluminal coronary angioplasty for acute myocardial infarction**

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**Objectives.** The purpose of this study was to analyze long-term follow-up information over several years from consecutive, unselected patients treated with direct percutaneous transluminal coronary angioplasty (PTCA) for acute myocardial infarction (MI).

**Background.** Direct PTCA is often used in patients with acute MI. Short-term results are favorable. However, there is less information available on long-term observations over several years in these patients.

**Methods.** A total of 416 consecutive and unselected patients with acute MI underwent direct PTCA. Survival of the acute infarct phase was 94.2%; the remaining 392 patients-the study population-were discharged and followed for  $3.3 \pm 1.4$  years. Mortality as well as cardiac events and reinterventions are reported. Clinical variables assessed at the time of discharge are submitted to statistical analysis to detect potential risk factors.

**Results.** Total cumulative mortality in the first year was 10% for the entire group and 6% for patients not presenting in cardiogenic shock. Mortality after discharge was 4.6% in the first year and dropped to <4% per year thereafter. Reinterventions after discharge were required in 16% in the first year and in <4% per year in years 2 to 4. Poor left ventricular ejection fraction (<35%), three-vessel disease and advanced age ( $\geq 75$  years) were long-term risk factors for total mortality after direct PTCA.

**Conclusions.** The clinical benefit of direct PTCA for acute MI is maintained during follow-up with respect to mortality. However, reinterventions for restenosis or de novo stenosis are often required (10% to 20%). Although few in number (<10%), patients with severely impaired left ventricular function continue to have a poor prognosis.

Journal of the American College of Cardiology, 32:1312-1319

Importance of time to reperfusion for 30-day and late survival and recovery of left ventricular function after primary angioplasty for acute myocardial infarction

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**Objectives.** The purpose of this study was to evaluate the importance of time to reperfusion for outcomes after primary angioplasty for acute myocardial infarction.

**Background.** Survival benefit of thrombolytic therapy for acute myocardial infarction is strongly dependent on time to treatment. Recent observations suggest that time to treatment may be less important for survival with primary angioplasty.

**Methods.** Consecutive patients (n = 1,352) with acute myocardial infarction treated with primary angioplasty were followed for up to 13 years. Paired acute and follow-up ejection fraction data were obtained at cardiac catheterization in 606 patients.

**Results.** Reperfusion was achieved within 2h in 164 patients (12%). Thirty-day mortality was lowest with early reperfusion (4.3% at <2 h vs. 9.2% at  $\geq$ 2 h, p = 0.04) and was relatively independent of time to reperfusion after 2 h (9.0% at 2 to 4 h, 9.3% at 4 to 6 h, 9.5% at >6 h). Thirty-day-plus late cardiac mortality was also lowest with early reperfusion (9.1% at <2 h vs. 16.3% at  $\geq$ 2 h, p = 0.02) and relatively independent at time to reperfusion after 2 h (16.4% at 2 to 4 h, 16.9% at 4 to 6 h, 15.6% at >6 h). Improvement in left ventricular ejection fraction was greatest in the early reperfusion group and relatively modest after 2 h (6.9% at <2 h vs. 3.1% at  $\geq$  2 h, p = 0.007).

**Conclusions.** Time to reperfusion, up to 2 h, is important for survival and recovery of left ventricular function. After 2 h, recovery of left ventricular function is modest and survival is relatively independent of time to reperfusion. These data suggest that factors other than myocardial salvage may be responsible for survival benefit in patients treated with primary angioplasty after 2 h.

Journal of the American College of Cardiology, 1998;31:1234-1239

A Clinical Trial Comparing Primary Stenting of the Infarct-Related Artery With Optimal Primary Angioplasty

for Acute Myocardial Infarction : Results From the Florence Randomized Elective Stenting in Acute Coronary Occlusions (FRESCO) Trial

David Antoniucci, MD, Giovanni M. Santoro, MD, Leonardo Bolognese, MD, Renato Valenti, MD, Maurizio Trapani, MD, Pier Filippo Fazzini, MD

**Objectives.** This study sought to compare stenting of the primary infarct-related artery (IRA) with optimal primary percutaneous transluminal coronary angioplasty (PTCA) with respect to clinical and angiographic outcomes of patients with an acute myocardial infarction.

**Background.** Early and late restenosis or reocclusion of the IRA after successful primary PTCA significantly contributes to increased patient morbidity and mortality. Coronary stenting results in a lower rate of angiographic and clinical restenosis than standard PTCA in patients with angina and with previously untreated, noncomplex lesions.

**Methods.** After successful primary PTCA, 150 patients were randomly assigned to elective stenting or no further intervention. The primary end point of the trial was a composite end point, defined as death, reinfarction or repeat target vessel revascularization as a consequence of recurrent ischemia within 6 months of randomization. The secondary end point was angiographic evidence of restenosis or reocclusion at 6 months after randomization.

**Results.** Stenting of the IRA was successful in all patients randomized to stent treatment. At 6 months, the incidence of the primary end point was 9% in the stent group and 28% in the PTCA group ( $p = 0.003$ ); the incidence of restenosis or reocclusion was 17% in the stent group and 43% in the PTCA group ( $p = 0.001$ ).

**Conclusions.** Primary stenting of the IRA, compared with optimal primary angioplasty, results in a lower rate of major adverse events related to recurrent ischemia and a lower rate of angiographically detected restenosis or reocclusion of the IRA.

Journal of the American College of Cardiology, 1998;31:1260-1266

Elevated Plasma Lipoprotein(a) Is Associated With Coronary Artery Disease in Patients With Chronic Stable Angina Pectoris

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**Objectives.** We sought to assess the relation between plasma lipoprotein(a) [Lp(a)] levels, clinical variables and angiographic coronary artery disease (CAD) in patients with chronic stable angina.

**Background.** The relation between plasma Lp(a) levels and the severity and extent of angiographic CAD has not been studied in well characterized patients with stable angina pectoris.

**Methods.** We investigated clinical variables, lipid variables and angiographic scores in 129 consecutive white patients (43 women) undergoing coronary angiography for chronic stable angina.

**Results.** Plasma Lp(a) levels were significantly higher in patients with than in those without significant angiographic stenoses ( $\geq 70\%$ ) (372 mg/liter [interquartile range 87 to 884] vs. 105 mg/liter [interquartile range 56 to 366], respectively,  $p = 0.002$ ). This difference remained significant when patients with mild or severe angiographic disease were compared with those with completely normal coronary arteries (312 mg/liter [interquartile range 64 to 864] vs. 116 mg/liter [interquartile range 63 to 366], respectively,  $p = 0.02$ ). However, subset analysis indicated that this difference achieved statistical significance only in women. Multiple logistic regression analysis indicated that Lp(a) concentration was independently predictive of significant angiographic stenoses (adjusted odds ratio [OR] 9.1, 95% confidence interval [CI] 2.0 to 42.1,  $p = 0.006$ ) and remained true even after exclusion of patients receiving lipid-lowering treatment ( $n = 27$ ) (OR 10.4, 95% CI 1.1 to 102.9,  $p = 0.05$ ). Lp(a) also had independent predictive value in a similar analysis using mild or severe angiographic disease as the outcome variable (OR 11.8, 95% CI 1.5 to 90.8,  $p = 0.02$ ).

**Conclusions.** Our results indicate that elevated plasma Lp(a) is an independent risk factor for angiographic CAD in chronic stable angina and may have particular significance in women.

The American Journal of Cardiology, 1998;82:7:839-844

Intracoronary aspiration thrombectomy for acute myocardial infarction

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To investigate the pathogenesis of acute myocardial infarction (AMI) and values of intracoronary aspiration thrombectomy (ICAT), we applied ICAT to reperfusion therapy using generally available intracoronary

catheters to aspirate intracoronary occlusive tissues. We assigned ICAT or primary percutaneous transluminal coronary angioplasty (PTCA) to patients with evolving AMI (Thrombolysis In Myocardial Infarction (TIMI) trial grade 0), and investigated primary histopathologic, clinical, and angiographic outcomes in 43 patients treated with ICAT alone or followed by PTCA, and compared the outcomes with those in 48 patients treated with primary PTCA. No major complications (procedural death, emergent bypass graft surgery) occurred. Recanalization (TIMI grade 3 and 2) was achieved in 25 patients (58%) with ICAT alone and in 39 patients (91%) with ICAT alone or followed by PTCA. Aspirated thrombi were defined as recent thrombi in 21 cases (49%), atheroma in 6 (14%), no thrombi in 13 (30%), and organized thrombi in 1 case. In cases of recent thrombi, ICAT alone provided recanalization more frequently than in those of atheroma or no thrombi (18 of 21 [86%], 3 of 6 [50%], 4 of 13 [31%], respectively;  $p < 0.05$ ; recent thrombi vs atheroma or no thrombi). There were no significant differences in primary recanalization rate (ICAT alone or followed by PTCA vs primary PTCA; 91% vs 92%) or incidence of complications between the 2 strategies. These results indicate that although the pathogenesis of AMI is heterogeneous in each individual case, intracoronary thrombus contributes little to the pathogenesis of average AMI, and therefore mechanical approaches may be feasible to maximize reperfusion therapies for AMI.

Journal of the American College of Cardiology, 1998;31:2:294-300

### Systematic Direct Angioplasty and Stent-Supported Direct Angioplasty Therapy for Cardiogenic Shock Complicating Acute Myocardial Infarction: In-Hospital and Long-Term Survival

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**Objectives.** This prospective observational study was conducted to examine the apparent impact of a systematic direct percutaneous transluminal coronary angioplasty (PTCA) strategy on mortality in a series of 66 consecutive patients with acute myocardial infarction (AMI) complicated by cardiogenic shock, and to analyze the predictors of outcome after successful direct PTCA.

**Background.** Previous studies have reported encouraging results with PTCA in patients with AMI complicated by cardiogenic shock, but a biased case selection for PTCA may have heavily influenced the observed outcomes. **Methods.** All patients admitted with AMI were considered eligible for direct PTCA, including those with the most profound shock, and no upper age limit was used. The treatment protocol also included stenting of the

infarct-related artery for a poor or suboptimal angiographic result after conventional PTCA.

**Results.** Between January 1995 and March 1997, 364 consecutive patients underwent direct PTCA, and in 66 patients AMI was complicated by cardiogenic shock. In patients with cardiogenic shock, direct PTCA had a success rate of 94%; an optimal angiographic result was achieved in 85%; primary stenting of the infarct-related artery was accomplished in 47%; and the in-hospital mortality rate was 26%. Univariate analysis showed that patient age, chronic coronary occlusion and completeness of revascularization were significantly related to in-hospital mortality. The mean follow-up period was  $16 \pm 8$  months. Survival rate at 6 months was 71%. Comparison of event-free survival in patients with a stented or nonstented infarct-related artery suggests an initial and long-term benefit of primary stenting.

**Conclusions.** Systematic direct PTCA, including stent-supported PTCA, can establish a Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow in the great majority of patients presenting with AMI and early cardiogenic shock. High performance criteria, including new devices such as coronary stents, should be considered in randomized trials where mechanical revascularization therapy is being tested.

J Am Coll Cardiol 1998;31:23-30

**Prospective, Multicenter Study of the Safety and Feasibility of Primary Stenting in Acute Myocardial Infarction: In-Hospital and 30-Day Results of the PAMI Stent Pilot Trial**

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For the Primary Angioplasty in Myocardial Infarction (PAMI) Stent Pilot Trial Investigators

**Objectives.** The goals of this study were to examine the safety and feasibility of a routine (Primary) stent strategy in acute myocardial infarction (AMI).

**Background.** Limitations of reperfusion by primary percutaneous transluminal coronary angioplasty (PTCA) in AMI include in-hospital recurrent ischemia or reinfarction in 10% to 15% of patients, restenosis in 37% to 49% and late infarct-related artery reocclusion in 9% to 14%. By lowering the residual stenosis and sealing dissection planes created by PTCA, primary stenting may further improve short- and long-term outcomes after mechanical reperfusion.

**Methods.** Three hundred twelve consecutive patients treated with primary PTCA for AMI at nine international centers were prospectively enrolled. After PTCA, stenting was attempted in all eligible lesions (vessel size 3.0 to 4.0 mm; lesion length  $\leq$ 2 stents; and the absence of giant thrombus burden after PTCA, major side branch jeopardy or excessive proximal tortuosity or calcification). Patients with stents were treated with aspirin, ticlopidine and a 60-h tapering heparin regimen.

**Results.** Stenting was attempted in 240 (77%) of 312 patients, successfully in 236 (98%), with Thrombolysis in Myocardial Infarction grade 3 flow restored in 230 patients (96%). Patients with stents had low rates of in-hospital death (0.8%), reinfarction (1.7%), recurrent ischemia (3.8%) and predischage target vessel revascularization for ischemia (1.3%). At 30-day follow-up, no additional deaths or reinfarctions occurred among patients with stents, and target vessel revascularization was required in only one additional patient (0.4%).

**Conclusions.** Primary stenting is safe and feasible in the majority of patients with AMI and results in excellent short-term outcomes.

#### Summary

1. Successful stenting: 98%, TIMI grade 3 flow: 96%
2. In-hospital death (0.8%), reinfarction (1.7%), recurrent ischemia (3.8%) and predischage target vessel revascularization for ischemia (1.3%).
3. At 30-day follow-up: no additional deaths or reinfarctions , TLR(0.4%).

Circulation, 1998;98:734-741

Randomized, Placebo-Controlled Trial of Platelet Glycoprotein IIb/IIIa Blockade With Primary Angioplasty for Acute Myocardial Infarction

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**Background-**The benefit of catheter-based reperfusion for acute myocardial infarction (MI) is limited by a 5% to 15% incidence of in-hospital major ischemic events, usually caused by infarct artery reocclusion, and a 20% to 40% need for repeat percutaneous or surgical revascularization. Platelets play a key role in the process of early infarct artery reocclusion, but inhibition of aggregation via the glycoprotein IIb/IIIa receptor has not been prospectively evaluated in the setting of acute MI.

**Methods and Results-**Patients with acute MI of <12 hours' duration were randomized, on a double-blind basis, to placebo or abciximab if they were deemed candidates for primary PTCA. The primary efficacy end point was death, reinfarction, or any (urgent or elective) target vessel revascularization (TVR) at 6 months by intention-to-treat (ITT) analysis. Other key prespecified end points were early (7 and 30 days) death, reinfarction, or urgent TVR. The baseline clinical and angiographic variables of the 483 (242 placebo and 241 abciximab) patients were balanced. There was no difference in the incidence of the primary 6-month end point (ITT analysis) in the 2 groups (28.1% and 28.2%,  $P=0.97$ , of the placebo and abciximab patients, respectively). However, abciximab significantly reduced the incidence of death, reinfarction, or urgent TVR at all time points assessed (9.9% versus 3.3%,  $P=0.003$ , at 7 days; 11.2% versus 5.8%,  $P=0.03$ , at 30 days; and 17.8% versus 11.6%,  $P=0.05$ , at 6 months). Analysis by actual treatment with PTCA and study drug demonstrated a considerable effect of abciximab with respect to death or reinfarction: 4.7% versus 1.4%,  $P=0.047$ , at 7 days; 5.8% versus 3.2%,  $P=0.20$ , at 30 days; and 12.0% versus 6.9%,  $P=0.07$ , at 6 months. The need for unplanned, "bail-out" stenting was reduced by 42% in the abciximab group (20.4% versus 11.9%,  $P=0.008$ ). Major bleeding occurred significantly more frequently in the abciximab group (16.6% versus 9.5%,  $P=0.02$ ), mostly at the arterial access site. There was no intracranial hemorrhage in either group.

**Conclusions-**Aggressive platelet inhibition with abciximab during primary PTCA for acute MI yielded a substantial reduction in the acute (30-day) phase for death, reinfarction, and urgent target vessel revascularization. However, the bleeding rates were excessive, and the 6-month primary end point, which included elective revascularization, was not favorably affected.

## Summary

Circulation, 1998;98:2695-2701

Effect of Glycoprotein IIb/IIIa Receptor Blockade on Recovery of Coronary Flow and Left Ventricular Function After the Placement of Coronary-Artery Stents in Acute Myocardial Infarction

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Meinrad Gawaz, MD; Adnan Kastrati, MD; Albert Schomig, MD

**Background-**Apart from its established effects on vessel patency after percutaneous coronary revascularization, glycoprotein IIb/IIIa receptor blockade by abciximab may improve myocardial perfusion by inhibition of the interaction of platelets and platelet aggregates with the microvasculature. We investigated the effect of abciximab with stent placement in acute myocardial infarction.

**Methods and Results-**In a prospective randomized trial, patients undergoing stenting in acute myocardial infarction within 48 hours after onset of symptoms were randomly assigned to receive either standard-dose heparin or abciximab plus low-dose heparin. Immediately after the procedure and at 14-day angiographic follow-up, we assessed flow velocity in the recanalized vessel with the Doppler wire and regional wall motion by the centerline method. End points were changes in papaverine-induced peak flow velocities and in wall motion indices. We assigned 98 patients to standard heparin and 102 to abciximab. We obtained 152 paired flow measurements and 151 paired left ventricular function studies. Residual stenoses of the treated lesions did not differ between the 2 groups. Improvement of peak flow velocity (mean [95% CI]: 18.1 cm/s [13.6 to 22.6 cm/s], n=80, versus 10.4 cm/s [5.4 to 15.4 cm/s], n=72, P=0.024) and wall motion index (0.44 SD/chord [0.29 to 0.59 SD/chord], n=79 versus 0.15 SD/chord [0.00 to 0.30 SD/chord], n=72, P=0.007) was significantly greater in patients assigned to abciximab than in those on heparin alone. At follow-up, the abciximab group had a higher global left ventricular ejection fraction than the heparin group (62% [59% to 65%] versus 56% [53% to 59%], P=0.003).

**Conclusions-**Abciximab had important effects beyond the maintenance of large-vessel patency. It improved the recovery of microvascular perfusion and concomitantly enhanced the recovery of contractile function in the area at risk.

## Summary

Circulation ,1999 ;99: 2486-2491

Meeting Highlights : Highlights of the 71st Scientific Sessions of the American Heart Association

James J. Ferguson Acute MI

The Trial: STENT-PAMI

Presenter: Cindy Grines, Beaumont Hospital, Royal Oak, Mich.

The study: A randomized trial comparing PTCA and stents for the treatment of acute myocardial infarction (MI). A total of 900 patients presenting within 12 hours of the onset of acute MI were randomized to either primary PTCA or implantation of a heparin-coated stent (Palmaz-Schatz, Cordis). The primary end point of the study was the 6-month composite of death, recurrent MI, disabling stroke, or ischemia-driven target-vessel revascularization.

The results: Acute procedural success was high (>99%) in both groups, although the incidence of postprocedure TIMI grade III flow was somewhat lower in the stent group (89% versus 92% by core laboratory analysis). Stented patients had significantly lower residual stenosis and significantly higher minimum lumen diameters (MLDs). There were 67 PTCA patients (15.1%) who crossed over to a stent because of suboptimal results. At 6-month follow-up angiography, stented patients continued to have significantly larger MLDs, resulting in a significantly lower binary angiographic restenosis rate (20.3% versus 32.5% with PTCA). Primary composite end-point events at 6 months were significantly lower in the stent group (12.4% versus 20.1% with PTCA), as was total target-lesion revascularization (12.8% versus 21.4% with PTCA) and ischemia-driven target-vessel revascularization (7.5% versus 17% with PTCA).

Summary: Coronary stent implantation for acute MI results in an initially better angiographic result although with slightly lower TIMI 3 flow rates. Longer-term follow-up strongly supports the superiority of stenting in reducing restenosis, target-vessel revascularization, ischemia-driven revascularization, and composite events.

The American Journal of Cardiology, 83:305-310

A matched comparison of the combination of prehospital thrombolysis and standby rescue angioplasty with primary angioplasty

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This study sought to assess the rate of acute Thrombolysis In Myocardial Infarction (TIMI) trial grade 3 patency that can be achieved with the combination of prehospital thrombolysis and standby rescue angioplasty in acute myocardial infarction. No large angiographic study has been performed after prehospital thrombolysis to

determine the 90-minute TIMI 3 patency rate in the infarct-related artery. Hospital outcome and artery patency were compared to 170 matched patients treated with primary angioplasty. Prehospital thrombolysis was applied  $151 \pm 61$  minutes after the onset of pain in 170 patients ( $56 \pm 12$  years, 86% men), using recombinant tissue-type plasminogen activator, streptokinase, or eminease. Emergency 90-minute angiography was performed in every case. All patients in whom thrombolysis failed underwent rescue angioplasty. After thrombolysis alone, TIMI grade 3 flow in the infarct-related artery was observed in 108 patients (64%), TIMI grade 2 in 12 (7%), and TIMI grade 0 or 1 in 50 (29%). Rescue angioplasty was successful in 47 of 50 attempts. Overall, TIMI 3 patency was achieved in 91%, and additionally TIMI 2 flow in 7% of patients, an average of  $113 \pm 39$  minutes after thrombolysis and  $55 \pm 19$  minutes after admission. Therefore, <2 hours after thrombolysis, only 2% of patients had persistent occlusion (TIMI 0 or 1) of the infarct-related artery. In-hospital mortality was 4% overall (7 of 170), and 3% in the 155 patients in whom TIMI 3 was obtained during the acute phase. Severe hemorrhagic complications occurred in 14 patients (8%) with 2 fatal cerebral hemorrhages (7% of patients required transfusions). The matched comparison with primary PTCA showed no significant difference in hospital outcome. Combined prehospital thrombolysis, 90-minute angiography, and rescue angioplasty yield a high rate of acute TIMI 3 patency rate early after thrombolysis and hospital admission. A randomized, prospective comparison between these 2 reperfusion strategies may be now warranted.

The American Journal of Cardiology, 83:1314-1319

Primary percutaneous transluminal coronary angioplasty for Acute Myocardial Infarction in patients not included in randomized studies

Ralf Zahn, Rudolf Schiele, Karlheinz Seidl, Caroline Bergmeier, Karl K. Haase, Hans G. Glunz, Karl E. Hauptmann, Thomas Voigtlander, Martin Gottwik, Jochen Senges for the Maximal Individual Therapy in Acute Myocardial Infarction (MITRA) Study Group

Patients with acute myocardial infarction included in randomized trials comparing primary percutaneous transluminal coronary angioplasty (pPTCA) with thrombolysis represent a special subgroup of patients with a low event rate. Patients excluded from these trials represent a variety of different subgroups, with different patient characteristics and possibly different clinical event rates. Primary PTCA was performed in 491

consecutive patients with acute myocardial infarction in the prospective multicenter observational Maximal Individual Therapy in Acute Myocardial Infarction trial. They were divided into the following groups: group I, patients fulfilling the inclusion criteria of the randomized trials (284 of 491, 58%); group II, patients not included in these trials (207 of 491, 42%). Of group II the following subgroups were defined: group IIa, patients in cardiogenic shock (20 of 491, 4.1%); group IIb, patients with a left bundle branch block (12 of 491, 2.4%); group IIc, patients with contraindications for thrombolysis (42 of 491, 8.6%); group IId, patients with a nondiagnostic first electrocardiogram (95 of 491, 19.3%); group IIe, patients with a prehospital delay of >12 hours (72 of 491, 14.7%); group II f, patients with an unknown prehospital delay (30 of 491, 6.1%). A comparison of groups I and II showed similar baseline characteristics but a higher clinical event rate during hospitalization was seen in group II: combined end point of death, reinfarction, heart failure equal to or greater than NYHA class III, any stroke or postinfarction angina, 26.6% versus 18%;  $p = 0.022$ . Hospital deaths were nearly twice as high in these patients, without reaching statistical significance (10.6% vs 6%;  $p = 0.06$ ). The subgroups of group II showed quite different rates of clinical events. In-hospital death rates were: IIa, 40% (8 of 20); IIb, 8% (1 of 12); IIc, 12% (5 of 42); IId, 5% (5 of 95); IIe, 6% (4 of 72); and II f, 13% (4 of 30). The incidence of the combined end point was 60% (12 of 20) in IIa, 33% (4 of 12) in IIb, 29% (12 of 42) in IIc, 16% (15 of 95) in IId, 26% (19 of 72) in IIe, and 33% (10 of 30) in II f. Thus, in clinical practice, about half of the patients treated with pPTCA would not have been included in randomized trials comparing pPTCA with thrombolysis. These patients represent a population at higher risk for in hospital clinical events. However, they do represent very different nonhomogenous subgroups with different clinical event rates.

Journal of the American College of Cardiology, 33:640-646

Long-term outcome after primary angioplasty: report from the Primary Angioplasty in Myocardial Infarction (PAMI-I) trial

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#### OBJECTIVES

This study sought to compare the two-year outcome after primary percutaneous coronary angioplasty or thrombolytic therapy for acute myocardial infarction.

## BACKGROUND

Primary angioplasty, that is, angioplasty without antecedent thrombolytic therapy, has been shown to be an effective reperfusion modality for patients suffering an acute myocardial infarction. This report reviews the two-year clinical outcome of patients randomized in the Primary Angioplasty in Myocardial Infarction trial.

## METHODS

At 12 clinical centers, 395 patients who presented within 12 h of the onset of myocardial infarction were randomized to undergo primary angioplasty (195 patients) or to receive tissue-type plasminogen activator (t-PA) (200 patients) followed by conservative care. Patients were followed by physician visits, phone call, letter and review of hospital records for any hospital admission at one month, six months, one year and two years.

## RESULTS

At two years, patients undergoing primary angioplasty had less recurrent ischemia (36.4% vs. 48% for t-PA,  $p = 0.026$ ), lower reintervention rates (27.2% vs. 46.5% for t-PA,  $p < 0.0001$ ) and reduced hospital readmission rates (58.5% vs. 69.0% for t-PA,  $p = 0.035$ ). The combined end point of death or reinfarction was 14.9% for angioplasty versus 23% for t-PA,  $p = 0.034$ . Multivariate analysis found angioplasty to be independently predictive of a reduction in death, reinfarction or target vessel revascularization ( $p = 0.0001$ ).

## CONCLUSIONS

The initial benefit of primary angioplasty performed by experienced operators is maintained over a two-year follow-up period with improved infarct-free survival and reduced rate of reintervention.

The American Journal of Cardiology, 83:7:989-993

Efficacy of invasive strategy for the management of acute myocardial infarction complicated by cardiogenic shock

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This retrospective study evaluates the influence of an invasive strategy of urgent coronary revascularization on the in-hospital mortality of patients with acute myocardial infarction (AMI) complicated early by cardiogenic shock. Among 1,981 patients with AMI admitted to our institution from 1994 to 1997, 162 patients (8.2%) developed cardiogenic shock unrelated to mechanical complications. The strategy of management was considered invasive if an urgent coronary angiography was indicated within 24 hours of symptom onset. Every

other strategy was considered conservative. Fifty-seven patients who developed the shock late or after a revascularization procedure, or who died on admission, were excluded. The strategy was invasive in 73 patients (70%). Five of them died before angiography could be performed and 65 underwent angioplasty (success rate 72%). By univariate analysis the invasive strategy was associated with a lower mortality than conservative strategy (71% vs 91%,  $p = 0.03$ ), but this association disappeared after adjustment for baseline characteristics. Older age, nonsmoking, and previous ischemic heart disease were independent predictors of mortality. In conclusion, we have failed to demonstrate that a strategy of urgent coronary revascularization within 24 hours of symptom onset for patients with AMI complicated by cardiogenic shock is independently associated with a lower in-hospital mortality. This strategy was limited by the high mortality within 1 hour of admission in patients with cardiogenic shock, the modest success rate of angioplasty in this setting, and the powerful influence of some adverse baseline characteristics on prognosis.

Journal of the American College of Cardiology, 1999;34:2:486-493

Changes of hemostasis, endogenous fibrinolysis, platelet activation and endothelins after percutaneous transluminal coronary angioplasty in patients with stable angina

Markus Borries, Michael Heins, Yuriko Fischer, Hugo Stiegler, Ansgar Peters, Hans Reinauer, Frank C. Schoebel, Bodo E. Strauer, Matthias Leschke

#### OBJECTIVES

This study investigated parameters of endogenous fibrinolysis, activation of coagulation and platelets, and endothelin levels before and after elective percutaneous transluminal coronary angioplasty (PTCA) in patients with stable coronary artery disease (CAD).

#### BACKGROUND

Abrupt vessel closure is a serious short-term complication after PTCA and is often unforeseeable. Detailed insight into the effect of PTCA on hemostasis, platelets and the release of vasoconstrictive substances, which are among the mainly discussed mechanisms of abrupt vessel closure, is needed to enhance the safety of coronary intervention.

#### METHODS

Plasma levels of markers of platelet activity, coagulation, endogenous fibrinolysis and endothelins were determined in 20 patients with stable CAD undergoing elective PTCA. The blood specimens were drawn

before, immediately after, 1 h after intervention and on the next morning.

## RESULTS

All patients showed an initially uncomplicated PTCA. Regarding the efficacy of anticoagulation after receiving 15.000 IU heparin during PTCA, two groups were compared. In eight patients with ineffective anticoagulation production of thrombin and platelet activation directly after and 1 h after PTCA was significantly higher compared with 12 patients with effective anticoagulation. Despite the strong activation of coagulation, only a low fibrinolytic response could be observed. Endothelins rose significantly after PTCA in both groups but stayed longer on higher levels in patients with distinct thrombin generation. Three of the eight patients without sufficient heparin treatment suffered abrupt vessel closure.

## CONCLUSIONS

Initially uncomplicated dilation of coronary arteries leads to systemically measurable activation of coagulation and platelets in patients with ineffective doses of heparin and release of endothelins in all patients. Therefore, individual adjustment of anticoagulation and platelet inhibition in combination with effective antivasospastic substances are needed in every patient before, during and after initially uncomplicated PTCA to prevent this serious complication.

Circulation 1999 99: 2639-2644.

Treatment of Acute Myocardial Infarction by Primary Coronary Angioplasty or Intravenous Thrombolysis in the "Real World" : One-Year Results From a Nationwide French Survey

Nicolas Danchin, Laurent Vaur, Nathalie Genes, Sylvie Etienne, Michael Angioi, Jean Ferrieres, and Jean-Pierre Cambou

**Background-**Recent randomized trials comparing primary coronary angioplasty and intravenous thrombolysis at the acute stage of myocardial infarction have shown a limited but definite advantage for primary angioplasty. The aim of this study was to document 1-year outcome in patients receiving either thrombolysis or primary angioplasty for acute myocardial infarction in the "real world."

**Methods and Results-**We used a nationwide prospective registry of all patients admitted for acute myocardial infarction in French intensive care units in November 1995. Of the 721 patients who received reperfusion therapy, 152 were treated with primary angioplasty and 569 received intravenous thrombolysis. The two groups were remarkably similar with respect to all baseline descriptors, except that a higher proportion of patients in the angioplasty group had a history of cerebrovascular accident (10% versus 2%,  $P<0.01$ ). In-hospital outcome was not different in the 2 groups. One-year survival was 85.5% in the angioplasty group and 89.5% in

the thrombolysis group (P=0.18). Multivariate analysis showed that older age, anterior location of infarction, female sex, and history of heart failure were related to 1-year mortality. In patients alive on day 5, the use of primary angioplasty and higher Killip class were additional adverse prognostic indicators.

Conclusions-The results of this large registry of real-world practice indicate no survival benefit for patients treated with primary angioplasty compared with those who received thrombolytic therapy.

The American Journal of Cardiology, 1999;83:9:1326-1329

Differences in TIMI frame count following successful reperfusion with stenting or percutaneous transluminal coronary angioplasty for Acute Myocardial Infarction

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The Thrombolysis In Myocardial Infarction (TIMI) flow grade achieved in the infarct-related artery (IRA) during reperfusion therapy for acute myocardial infarction (AMI) is directly related to myocardial salvage. Recently, several series have demonstrated the safety of stenting in AMI and documented a larger postprocedure luminal diameter than that found at angioplasty, although no study has compared the effect of PTCA and stenting in AMI on flow characteristics of the IRA. The residual stenosis and the number of frames required to opacify standardized angiographic landmarks normalized for vessel length (corrected TIMI frame count) or compared with flow in a corresponding normal coronary artery (TIMI frame count index) were determined for the IRA of 39 patients who underwent angioplasty or stenting for AMI. Baseline characteristics were similar for the 20 patients who underwent stenting and the 19 patients who underwent percutaneous transluminal coronary angioplasty. After intervention, the luminal diameter was greater (3.24 vs 2.09 mm,  $p < 0.0001$ ) and the residual stenosis was less (-9.4% vs. 26.7%,  $p < 0.0001$ ) after stenting than after percutaneous transluminal coronary angioplasty. These changes in vessel geometry were associated with a lower corrected TIMI frame count (16.1 vs 30.7,  $p < 0.002$ ) and a lower TIMI frame count index (0.68 vs 1.3,  $p < 0.002$ ). Thus, stenting in AMI is associated with a greater postprocedure luminal diameter and improvement in coronary blood flow as measured by the TIMI frame count method.

Circulation, 2000 ;101: 2368-2374

## Assessment of Myocardial Reperfusion by Intravenous Myocardial Contrast Echocardiography and Coronary Flow Reserve After Primary Percutaneous Transluminal Coronary Angiography in Patients With Acute Myocardial Infarction

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**Background-**This study investigated whether the extent of perfusion defect determined by intravenous myocardial contrast echocardiography (MCE) in patients with acute myocardial infarction (AMI) treated by primary percutaneous transluminal coronary angioplasty (PTCA) relates to coronary flow reserve (CFR) for assessment of myocardial reperfusion and is predictive for left ventricular recovery.

**Methods and Results-**Twenty-five patients with first AMI underwent intravenous MCE with NC100100 with intermittent harmonic imaging before PTCA and after 24 hours. MCE before PTCA defined the risk region and MCE at 24 hours the “no-reflow” region. The no-reflow region divided by the risk region determined the ratio to the risk region. CFR was assessed immediately after PTCA and 24 hours later. Left ventricular wall motion score indexes were calculated before PTCA and after 4 weeks. CFR at 24 hours defined a recovery (CFR  $\geq 1.6$ ; n=17) and a nonrecovery group (CFR  $< 1.6$ ; n=8). Baseline CFR did not differ between groups. MCE ratio to the risk region was smaller in the recovery group compared with the nonrecovery group ( $34 \pm 49\%$  vs  $81 \pm 46\%$ , P=0.009). A ratio to the risk region of  $\leq 50\%$  defined an MCE reperfusion group. It was associated with improvement of CFR from  $1.67 \pm 0.47$  at baseline to  $2.15 \pm 0.53$  at 24 hours (P<0.001) and of regional wall motion score index from  $2.6 \pm 0.5$  to  $1.9 \pm 0.5$  at 4 weeks (P<0.001).

**Conclusions-**Intravenous MCE can be used to define perfusion defects after AMI. Assessment of microcirculation by MCE corresponds to evaluation by CFR. Serial intravenous MCE has the potential to identify patients likely to have improved left ventricular function after AMI.

Journal of the American College of Cardiology, 1999;33:412-419

Effect of age on outcome with primary angioplasty versus thrombolysis

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## Objectives

The purpose of this study was to determine how risks associated with increasing age differed in patients treated with percutaneous transluminal coronary angioplasty versus thrombolysis.

## Background

Advancing age is a risk factor for adverse outcome in patients with acute myocardial infarction. Primary angioplasty has been thought to be particularly beneficial in higher risk patients including the elderly. There is, however, limited data on any differential incremental benefit of angioplasty compared with thrombolysis in candidates for either treatment.

## Methods

In the GUSTO-IIb angioplasty substudy, 1,138 patients were randomized to receive primary angioplasty or accelerated tissue-type plasminogen activator (t-PA). The effect of age on outcome was assessed as a discrete and continuous variable for each treatment group. Models using age as a linear factor as well as cubic spline transformations were used for the major end points of 30-day death or disabling stroke; death or reinfarction; and death, reinfarction or disabling stroke.

## Results

For each 10-year patient group, outcome was improved with angioplasty (n = 565) compared with t-PA (n = 573). Irrespective of treatment, however, risk increased with age. After adjusting for baseline characteristics, each increment of 10 years of age increased the risk of death or myocardial infarction by 1.32 (95% confidence interval 1.04 to 1.76, p = 0.022). For all adverse outcomes, this incremental effect of increasing age was constant.

## Conclusions

Advancing age is associated with worse outcomes, and the risks increase in proportion to age. Although primary angioplasty improves outcomes over thrombolysis, it does not appear to be more beneficial in older than in younger patient groups. The incremental adverse effect of age does not vary by treatment strategy.

The American Journal of Cardiology, 1999;83:994-999

Thrombectomy with AngioJet catheter in native coronary arteries for patients with acute or recent myocardial infarction

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The AngioJet thrombectomy catheter removes thrombi by rheolytic fragmentation and suction. The purpose of this study was to identify the efficacy and safety of this new device. Myocardial infarction (MI) is associated with intracoronary thrombus. Intracoronary thrombus has been identified as a risk factor of unfavorable outcome after percutaneous transluminal coronary angioplasty. To what extent the AngioJet is applicable or effective for acute or recent MI in native coronary artery is not clear. Thrombectomy with the AngioJet was attempted in 31 patients with 31 native coronary arteries selected from 304 patients with acute or recent MI. Follow-up angiography was performed at 3 to 6 months. Procedure success was achieved in 29 patients (94%). Adjunctive balloon angioplasty was performed after AngioJet thrombectomy in 30 patients (97%), and in only 1 patient (3%) AngioJet thrombectomy was the sole procedure. Subsequent stenting after balloon angioplasty was attempted successfully in 12 patients (40%) without thrombotic complications. Thrombolysis In Myocardial Infarction trial flow grading increased from  $0.70 \pm 0.97$  before to  $2.61 \pm 0.88$  after AngioJet thrombectomy ( $p < 0.0001$ ), to  $2.84 \pm 0.64$  after adjunctive procedures ( $p = 0.070$ ). At follow-up angiography restenosis rate was 21% but Thrombolysis In Myocardial Infarction flow 3 was present in all patients. The restenosis rate of stented patients was 8%. There were no major events during in-hospital and follow-up. The AngioJet can be used safely and successfully to remove thrombus from the native coronary artery of patients with MI. Thrombus removal makes subsequent stenting safe and uncomplicated. The restenosis rate was considered to be acceptable.

Circulation ,1999; 100: 2067-2073

#### Cardiogenic Shock in Patients With Acute Ischemic Syndromes With and Without ST-Segment Elevation

David R. Holmes, Jr, Peter B. Berger, Judith S. Hochman, Christopher B. Granger, Trevor D. Thompson, Robert M. Califf, Alec Vahanian, Eric R. Bates, and Eric J. Topol

Background-Cardiogenic shock is usually considered a sequela of ST-segment elevation myocardial infarction. There are limited prospective data on the incidence and significance of shock in non-ST-segment elevation patients. This study assessed the incidence and outcomes of cardiogenic shock developing after enrollment among patients with and without ST-segment elevation in the Global Use of Strategies To Open Occluded Coronary Arteries (GUSTO)-IIb trial.

Methods and Results-Among 12 084 patients in GUSTO-IIb who did not present with cardiogenic shock, 4092

(34%) had and 7991 (66%) did not have ST-segment elevation on the enrollment ECG. Cardiogenic shock developed in 4.2% of ST-segment elevation patients compared with 2.5% of patients without ST-segment elevation (odds ratio, 0.581; 95% CI, 0.472 to 0.715;  $P < 0.001$ ). Shock developed significantly later among patients without ST-segment elevation. There were significant differences in baseline characteristics between shock patients with and without ST-segment elevation: Patients without ST-segment elevation were older, more frequently had diabetes mellitus and 3-vessel disease, but had less TIMI grade 0 flow at angiography. Regardless of the initial ECG, mortality was high: 63% among patients with ST-segment elevation and 73% in those without ST-segment elevation.

**Conclusions**-Cardiogenic shock occurs in the setting of acute ischemic syndromes regardless of whether ST-segment elevation is present. The incidence, patient characteristics, timing, clinical course, and angiographic findings differ between the 2 groups. Mortality from cardiogenic shock is similarly high among patients with and without ST-segment elevation.

Circulation 1999 99: 1548-1554

#### Clinical and Angiographic Follow-Up After Primary Stenting in Acute Myocardial Infarction : The Primary Angioplasty in Myocardial Infarction (PAMI) Stent Pilot Trial

Gregg W. Stone, Bruce R. Brodie, John J. Griffin, Costantino Costantini, Marie Claude Morice, Frederick G. St. Goar, Paul A. Overlie, Jeffrey J. Popma, JoAnn McDonnell, Denise Jones, William W. O'Neill, and Cindy L. Grines

**Background**-Restenosis has been reported in as many as 50% of patients within 6 months after PTCA in acute myocardial infarction (AMI), which necessitates repeat target-vessel revascularization (TVR) in 20% of patients during this time period. Routine (primary) stent implantation after PTCA has the potential to further improve late outcomes.

**Methods and Results**-Primary stenting was performed as part of a prospective study in 236 consecutive patients without contraindications who presented with AMI of <12 hours' duration at 9 international centers. A mean of  $1.4 \pm 0.7$  stents were implanted per patient (97% Palmaz-Schatz) at  $17.3 \pm 2.4$  atm. During a clinical follow-up period of  $7.4 \pm 2.6$  months, death occurred in 4 patients (1.7%), reinfarction occurred in 5 patients (2.1%), and TVR was required in 26 patients (11.1%). By Cox regression analysis, small reference-vessel diameter and the number of stents implanted were the strongest determinants of TVR. Angiographic restenosis

occurred in 27.5% of lesions. By multiple logistic regression analysis, the number of stents implanted and the absence of thrombus on the baseline angiogram were independent determinants of binary restenosis.

Conclusions-A strategy of routine stent implantation during mechanical reperfusion of AMI is safe and is associated with favorable event-free survival and low rates of restenosis compared with primary PTCA alone.

N Engl J Med ,1999 ;341(26):1949-56

Coronary angioplasty with or without stent implantation for acute myocardial infarction. Stent Primary Angioplasty in Myocardial Infarction Study Group.

Grines CL, Cox DA, Stone GW, Garcia E, Mattos LA, Giambartolomei A, Brodie BR, Madonna O, Eijgelshoven M, Lansky AJ, O'Neill WW, Morice MC

**BACKGROUND:** Coronary-stent implantation is frequently performed for treatment of acute myocardial infarction. However, few studies have compared stent implantation with primary angioplasty alone. **METHODS:** We designed a multicenter study to compare primary angioplasty with angioplasty accompanied by implantation of a heparin-coated Palmaz-Schatz stent. Patients with acute myocardial infarction underwent emergency catheterization and angioplasty. Those with vessels suitable for stenting were randomly assigned to undergo angioplasty with stenting (452 patients) or angioplasty alone (448 patients). **RESULTS:** The mean (+/-SD) minimal luminal diameter was larger after stenting than after angioplasty alone (2.56+/-0.44 mm vs. 2.12+/-0.45 mm,  $P<0.001$ ), although fewer patients assigned to stenting had grade 3 blood flow (according to the classification of the Thrombolysis in Myocardial Infarction trial) (89.4 percent, vs. 92.7 percent in the angioplasty group;  $P=0.10$ ). After six months, fewer patients in the stent group than in the angioplasty group had angina (11.3 percent vs. 16.9 percent,  $P=0.02$ ) or needed target-vessel revascularization because of ischemia (7.7 percent vs. 17.0 percent,  $P<0.001$ ). In addition, the combined primary end point of death, reinfarction, disabling stroke, or target-vessel revascularization because of ischemia occurred in fewer patients in the stent group than in the angioplasty group (12.6 percent vs. 20.1 percent,  $P<0.01$ ). The decrease in the combined end point was due entirely to the decreased need for target-vessel revascularization. The six-month mortality rates were 4.2 percent in the stent group and 2.7 percent in the angioplasty group ( $P=0.27$ ). Angiographic follow-up at 6.5 months demonstrated a lower incidence of restenosis in the stent group than in the angioplasty group (20.3 percent vs. 33.5 percent,  $P<0.001$ ). **CONCLUSIONS:** In patients with acute myocardial infarction, routine implantation of a stent has clinical benefits beyond those of primary coronary angioplasty alone.

## Summary

J Am Coll Cardiol, 1999 ;34(7):1954-62

A randomized trial comparing primary angioplasty with a strategy of short-acting thrombolysis and immediate planned rescue angioplasty in acute myocardial infarction: the PACT trial. PACT investigators. Plasminogen-activator Angioplasty Compatibility Trial.

Ross AM, Coyne KS, Reiner JS, Greenhouse SW, Fink C, Frey A, Moreyra E, Traboulsi M, Racine N, Riba AL, Thompson MA, Rohrbeck S, Lundergan CF

**OBJECTIVES:** The study evaluated the efficacy and safety of a short-acting reduced-dose fibrinolytic regimen to promote early infarct-related artery (IRA) patency during the inherent delay experienced by infarct patients referred for angioplasty as the principal recanalization modality. **BACKGROUND:** Previous approaches using long-acting, full-dose thrombolytic infusions rarely showed benefit, but they did increase adverse event rates. **METHODS:** Following aspirin and heparin, 606 patients were randomized to a 50-mg bolus of recombinant tissue-type plasminogen activator (rt-PA) (alpha half-life 4.5 min) or to placebo followed by immediate angiography with angioplasty if needed. The end points included patency rates on catheterization laboratory (cath lab) arrival, technical results when PTCA (percutaneous transluminal coronary angioplasty) was performed, complication rates, and left ventricular (LV) function by treatment assignment and time to restored patency following angioplasty. **RESULTS:** Patency on cath lab arrival was 61% with rt-PA (28% Thrombolysis in Myocardial Infarction trial [TIMI]-2, 33% TIMI-3), and 34% with placebo (19% TIMI-2, 15% TIMI-3) ( $p = 0.001$ ). Rescue and primary PTCA restored TIMI-3 in closed arteries equally (77%, 79%). No differences were observed in stroke or major bleeding. Left ventricular function was similar in both treatment groups, but convalescent ejection fraction (EF) was highest with a patent IRA (TIMI-3) on cath lab arrival (62.4%) or when produced by angioplasty within an hour of bolus (62.5%). However, in 88% of angioplasties, the delay exceeded 1 h: convalescent EF 57.3%. **CONCLUSIONS:** Tailored thrombolytic regimens compatible with subsequent interventions lead to more frequent early recanalization (before cath arrival), which facilitates greater LV function preservation with no augmentation of adverse events.

## Summary

1. Patency on cath lab arrival: 61% with rt-PA, 34% with placebo ( $p = 0.001$ ).
2. Rescue and primary PTCA restored TIMI-3 in closed arteries equally (77%, 79%).
3. No differences were observed in stroke, major bleeding and LV function.
4. Convalescent EF: highest with a patent IRA (TIMI-3) on cath lab arrival (62.4%) or when produced by angioplasty within an hour of bolus (62.5%).

J Am Coll Cardiol, 1999 ;34(7):1932-8

The significance of persistent ST elevation versus early resolution of ST segment elevation after primary PTCA.

Matetzky S, Novikov M, Gruberg L, Freimark D, Feinberg M, Elian D, Novikov I, Di Segni E, Agranat O, Har-Zahav Y, Rabinowitz B, Kaplinsky E, Hod H

**OBJECTIVES:** To determine the prevalence and clinical significance of early ST segment elevation resolution after primary percutaneous transluminal coronary angioplasty (PTCA) for acute myocardial infarction (AMI). **BACKGROUND:** Despite angiographically successful restoration of coronary flow early during AMI, adequate myocardial reperfusion might not occur in a substantial portion of the jeopardized myocardium due to microvascular damage. This phenomenon comprises the potentially beneficial effect of early recanalization of the infarct related artery (IRA). **METHODS:** Included in the study were 117 consecutive patients who underwent angiographically successful [Thrombolysis in Myocardial Infarction (TIMI III)] primary PTCA. The patients were classified based on the presence or absence of reduction  $>$  or  $=50\%$  in ST segment elevation in an ECG performed immediately upon return to the intensive cardiac care unit after the PTCA in comparison with ECG before the intervention. **RESULTS:** Eighty-nine patients (76%) had early ST segment elevation resolution (Group A) and 28 patients (24%) did not (Group B). Group A and B had similar clinical and hemodynamic features before referring to primary PTCA, as well as similar angiographic results. Despite this, ST segment elevation resolution was associated with better predischarge left ventricular ejection fraction (LVEF) ( $44.7 \pm 8.0$  vs.  $38.2 \pm 8.5$ ,  $p < 0.01$ ). Group B patients, as compared with those of Group A, had a higher incidence of in-hospital mortality (11% vs. 2%,  $p = 0.088$ ), congestive heart failure (CHF) [28% vs. 19%, odds ratio (OR) = 4, 95% confidence interval (CI) 1 to 15,  $p = 0.04$ ], higher long-term mortality (OR = 7.3, 95% CI 1.9 to 28,  $p = 0.004$  with Cox proportional hazard regression analysis) and long-term CHF rate (OR = 6.5, 95% CI 1.3 to 33,  $p = 0.016$  with logistic regression). **CONCLUSIONS:** Absence of early ST segment elevation resolution after angiographically successful primary PTCA identifies patients who are less likely to benefit from the early restoration of flow in

the IRA, probably because of microvascular damage and subsequently less myocardial salvage.

Figure. Prevalence of in-hospital adverse events in patients with (group A) and without (group B) early ST segment elevation resolution. \*p = NS; \*\*p = 0.088.

Figure. Comparison of in-hospital mortality and CHF in patients with (group A) and without (group B) early ST segment elevation resolution according to Killip classification on admission.

Am J Cardiol ,1999 ;84(9):1074-6

Impact of cilostazol on clinical and angiographic outcome after primary stenting for acute myocardial infarction.

Ochiai M, Eto K, Takeshita S, Yokoyama N, Oshima A, Kondo K, Sato T, Isshiki T

Cilostazol, an antiplatelet drug that also may inhibit smooth muscle proliferation, was given together with aspirin after primary stenting to treat patients with acute myocardial infarction. In a randomized controlled trials of 50 patients, clinical and angiographic outcome at 6 months was significantly improved with cilostazol, depicting a significantly smaller late loss and/or loss index.

Summary

N Engl J Med , 1999 ;341(19):1413-9

Long-term benefit of primary angioplasty as compared with thrombolytic therapy for acute myocardial infarction.

Zijlstra F, Hoorntje JC, de Boer MJ, Reiffers S, Miedema K, Ottervanger JP, van'T Hof AW, Suryapranata H

BACKGROUND: As compared with thrombolytic therapy, primary coronary angioplasty results in a higher rate of patency of the infarct-related coronary artery, lower rates of stroke and reinfarction, and higher in-

hospital or 30-day survival rates. However, the comparative long-term efficacy of these two approaches has not been carefully studied. **METHODS:** We randomly assigned a total of 395 patients with acute myocardial infarction to treatment with angioplasty or intravenous streptokinase. Clinical information was collected for a mean ( $\pm$ -SD) of 5 $\pm$ 2 years, and medical charges associated with the two treatments were compared. **RESULTS:** A total of 194 patients were assigned to undergo primary angioplasty, and 201 to receive streptokinase. Mortality was 13 percent in the angioplasty group, as compared with 24 percent in the streptokinase group (relative risk, 0.54; 95 percent confidence interval, 0.36 to 0.87). Nonfatal reinfarction occurred in 6 percent and 22 percent of the two groups, respectively (relative risk, 0.27; 95 percent confidence interval, 0.15 to 0.52). The combined incidence of death and nonfatal reinfarction was also lower among patients assigned to angioplasty than among those assigned to streptokinase, with a relative risk of 0.13 (95 percent confidence interval, 0.05 to 0.37) for early events (within the first 30 days) and a relative risk of 0.62 (95 percent confidence interval, 0.43 to 0.91) for late events (after 30 days). The rates of readmission for heart failure and ischemia were also lower among patients in the angioplasty group than among patients in the streptokinase group. Total medical charges per patient were lower in the angioplasty group (16,090 dollars) than in the streptokinase group (16,813 dollars,  $P=0.05$ ). **CONCLUSIONS:** During five years of follow-up, primary coronary angioplasty for acute myocardial infarction was associated with lower rates of early and late death and nonfatal reinfarction, fewer hospital readmissions for ischemia or heart failure, and lower total medical charges than treatment with intravenous streptokinase.

Catheter Cardiovasc Interv 1999 Nov;48(3):262-8

Primary stent implantation is superior to balloon angioplasty in acute myocardial infarction: final results of the primary angioplasty versus stent implantation in acute myocardial infarction (PASTA) trial. PASTA Trial Investigators.

Saito S, Hosokawa G, Tanaka S, Nakamura S

Several studies have shown that stent implantations in acute myocardial infarction (AMI) result in better short- and long-term outcomes than primary balloon angioplasty. These results, however, have not been ascertained in randomized trials. We randomized 136 patients out of 208 patients with AMI within 12 hr from onset into two groups: 69 patients with primary balloon angioplasty (POBA group) and 67 patients with primary stent implantation (STENT group). We compared the incidences of major cardiac events (repeat MI, target lesion revascularization, and cardiac death) and angiographic parameters during hospitalization and follow-up periods up to 12 months in these two groups. There was no significant difference in the reperfusion success rates. The incidences of major cardiac events were lower in the STENT group than in the POBA group during hospitalization, the first 6 months and 12 months (6% vs. 19%,  $P = 0.023$ ; 21% vs. 46%,  $P < 0.0001$ ; 22% vs. 49%,  $P = 0.0011$ ). Minimum lumen diameters were significantly bigger in the STENT group than the POBA group at predischARGE angiogram and 6-month follow-up (2.85 +/- 0.62 vs. 2.08 +/- 0.82 mm,  $P < 0.0001$ ; 2.24 +/- 0.64 vs. 1.72 +/- 0.76,  $P = 0.002$ ). Restenosis rates at 6-month follow-up were significantly lower in the STENT group than in the POBA group (17% vs. 37.5%,  $P = 0.02$ ). In selected patients with AMI, primary stent implantation results in a lower incidence of major cardiac events during the first 12 months, postprocedure, and less frequent 6-month restenosis than primary balloon angioplasty.

#### Summary

\* Death, MI, TLR

Am J Cardiol , 1999 ;84(6):621-5

Comparison of protective effects of preinfarction angina pectoris in acute myocardial infarction treated by thrombolysis versus by primary coronary angioplasty with stenting.

Tomoda H, Aoki N

The protective effects of preinfarction angina were evaluated in acute myocardial infarction (AMI) treated by primary percutaneous transluminal coronary angioplasty (PTCA) and stenting. We studied 613 patients with

AMI. Group 1 (n = 306) was treated by conventional medical therapies and coronary thrombolysis and group 2 (n = 307) was treated by primary PTCA supported by stenting. Each group was subdivided into those with and without preinfarction angina within 24 hours before the onset of AMI. There was no significant difference in clinical characteristics between the subgroups of groups 1 and 2. In group 1, there were differences between patients with preinfarction angina (n = 84) and those without (n = 222) in in-hospital mortality (11% vs 18%), pump failure (Killip classes 3 and 4) (11% vs 21%, p <0.05), left ventricular ejection fraction at discharge (52 +/- 13% vs 48 +/- 14%, p <0.05), and peak creatine kinase (2,106 +/- 1,637 vs 2,764 +/- 2,154 U/L, p <0.02). In group 2, however, there was no significant difference between those with preinfarction angina (n = 82) and those without (n = 225) in mortality (6% vs 6%), pump failure (12% vs 12%), left ventricular ejection fraction (50 +/- 13% vs 50 +/- 13%) and peak creatine kinase (3,285 +/- 2,306 vs 3,291 +/- 2,262 U/L). Multivariate analysis indicated that preinfarction angina was an independent determinant of in-hospital death and pump failure in group 1, but not in group 2. We conclude that the protective effects of preinfarction angina in AMI are not evident in those treated by primary PTCA and stenting, possibly because of the overwhelming protective effects of complete coronary revascularization provided by primary PTCA and stenting.

## Summary

Heart ,1999 ;82(4):426-31

Prospective randomised comparison between thrombolysis, rescue PTCA, and primary PTCA in patients with extensive myocardial infarction admitted to a hospital without PTCA facilities: a safety and feasibility study.

Vermeer F, Oude Ophuis AJ, vd Berg EJ, Brunninkhuis LG, Werter CJ, Boehmer AG, Lousberg AH, Dassen WR, Bar FW

**OBJECTIVE:** To assess the safety and feasibility of acute transport followed by rescue percutaneous transluminal coronary angioplasty (PTCA) or primary PTCA in patients with acute myocardial infarction initially admitted to a hospital without PTCA facilities. **DESIGN:** In a multicentre randomised open trial, three regimens of treatment of acute large myocardial infarction were compared for patients admitted to hospitals without angioplasty facilities: thrombolytic treatment with alteplase (75 patients), alteplase followed by transfer to the PTCA centre and (if indicated) rescue PTCA (74 patients), or transfer for primary PTCA (75 patients). **RESULTS:** Between 1995 and 1997 224 patients were included. Baseline characteristics were

distributed evenly. Transport to the PTCA centre was without severe complications in all patients. Mean (SD) delay from onset of symptoms to randomisation was 130 (75) minutes and from randomisation to angiography 90 (25) minutes. Death or recurrent infarction within 42 days occurred in 12 patients in the thrombolysis group, in 10 patients in the rescue PTCA group, and in six patients in the primary PTCA group. These differences were not significant. CONCLUSIONS: Acute transfer for rescue PTCA or primary PTCA in patients with extensive myocardial infarction is feasible and safe. Efficacy of rescue PTCA or primary PTCA in this setting will have to be tested in larger series before this approach can be implemented as “routine treatment” for patients with extensive myocardial infarction.

### Summary

1. Transport to the PTCA centre was without severe complications in all patients.
2. Mean (SD) delay from onset of symptoms to randomization: 130 (75) minutes, from randomisation to angiography :90 (25) minutes.
3. Death or recurrent infarction within 42 days: 12 patients in the thrombolysis group, 10 patients in the rescue PTCA group, 6 patients in the primary PTCA group(p=NS)

JAMA ,1999 ;282(4):341-8

Primary coronary angioplasty vs thrombolysis for the management of acute myocardial infarction in elderly patients.

Berger AK, Schulman KA, Gersh BJ, Pirzada S, Breall JA, Johnson AE, Every NR

CONTEXT: Despite evidence from randomized trials that, compared with early thrombolysis, primary percutaneous transluminal coronary angioplasty (PTCA) after acute myocardial infarction (AMI) reduces mortality in middle-aged adults, whether elderly patients with AMI are more likely to benefit from PTCA or early thrombolysis is not known. OBJECTIVE: To determine survival after primary PTCA vs thrombolysis in elderly patients. DESIGN: The Cooperative Cardiovascular Project, a retrospective cohort study using data from medical charts and administrative files. SETTING: Acute care hospitals in the United States. PATIENTS: A total of 20683 Medicare beneficiaries, who arrived within 12 hours of the onset of symptoms, were admitted between January 1994 and February 1996 with a principal discharge diagnosis of AMI, and were eligible for reperfusion therapy. MAIN OUTCOME MEASURES: Thirty-day and 1-year survival. RESULTS: A total of

80356 eligible patients had an AMI at hospital arrival and met the inclusion criteria, of whom 23.2% received thrombolysis and 2.5% underwent primary PTCA within 6 hours of hospital arrival. Patients undergoing primary PTCA had lower 30-day (8.7% vs 11.9%,  $P=0.001$ ) and 1-year mortality (14.4% vs 17.6%,  $P=0.001$ ). After adjusting for baseline cardiac risk factors and admission and hospital characteristics, primary PTCA was associated with improved 30-day (hazard ratio [HR] of death, 0.74; 95% confidence interval [CI], 0.63-0.88) and 1-year (HR, 0.88; 95% CI, 0.73-0.94) survival. The benefits of primary coronary angioplasty persisted when stratified by hospitals' AMI volume and the presence of on-site angiography. In patients classified as ideal for reperfusion therapy, the mortality benefit of primary PTCA was not significant at 1-year follow-up (HR, 0.92; 95% CI, 0.78-1.08). CONCLUSION: In elderly patients who present with AMI, primary PTCA is associated with modestly lower short- and long-term mortality rates. In the subgroup of patients who were classified as ideal for reperfusion therapy, the observed benefit of primary PTCA was no longer significant.

## Summary

Circulation ,1999 ;100(3):236-42

Primary stenting versus balloon angioplasty in occluded coronary arteries: the Total Occlusion Study of Canada (TOSCA).

Buller CE, Dzavik V, Carere RG, Mancini GB, Barbeau G, Lazzam C, Anderson TJ, Knudtson ML, Marquis JF, Suzuki T, Cohen EA, Fox RS, Teo KK

**BACKGROUND:** Balloon angioplasty (PTCA) of occluded coronary arteries is limited by high rates of restenosis and reocclusion. Although stenting improves results in anatomically simple occlusions, its effect on patency and clinical outcome in a broadly selected population with occluded coronary arteries is unknown. **METHODS AND RESULTS:** Eighteen centers randomized 410 patients with nonacute native coronary occlusions to PTCA or primary stenting with the heparin-coated Palmaz-Schatz stent. The primary end point, failure of sustained patency, was determined at 6-month angiography. Repeat target-vessel revascularization, adverse cardiovascular events, and angiographic restenosis (>50% diameter stenosis) constituted secondary end points. Sixty percent of patients had occlusions of >6 weeks' duration, baseline flow was TIMI grade 0 in 64%, and median treated segment length was 30.5 mm. With 95.6% angiographic follow-up, primary stenting resulted in a 44% reduction in failed patency (10.9% versus 19.5%,  $P=0.024$ ) and a 45% reduction in clinically

driven target-vessel revascularization at 6 months (15.4% versus 8.4%,  $P=0.03$ ). The incidence of adverse cardiovascular events was similar for both strategies (PTCA, 23.6%; stent, 23.3%;  $P=NS$ ). Stenting resulted in a larger mean 6-month minimum lumen dimension (1.48 versus 1.23 mm,  $P<0.01$ ) and a reduced binary restenosis rate (55% versus 70%,  $P<0.01$ ). CONCLUSIONS: Primary stenting of broadly selected nonacute coronary occlusions is superior to PTCA alone, improving late patency and reducing restenosis and target-vessel revascularization.

## Summary

Circulation, 1999 ;100(1):14-20

Relationship between delay in performing direct coronary angioplasty and early clinical outcome in patients with acute myocardial infarction: results from the global use of strategies to open occluded arteries in Acute Coronary Syndromes (GUSTO-IIb) trial.

Berger PB, Ellis SG, Holmes DR Jr, Granger CB, Criger DA, Betriu A, Topol EJ, Califf RM

**BACKGROUND:** Time to treatment with thrombolytic therapy is a critical determinant of mortality in acute myocardial infarction. Little is known about the relationship between the time to treatment with direct coronary angioplasty and clinical outcome. The objectives of this study were to determine both the time required to perform direct coronary angioplasty in the Global Use of Strategies to Open Occluded Arteries in Acute Coronary Syndromes (GUSTO-IIb) trial and its relationship to clinical outcome. **METHODS AND RESULTS:** Patients randomized to direct coronary angioplasty ( $n=565$ ) were divided into groups based on the time between study enrollment and first balloon inflation. Patients randomized to angioplasty who did not undergo the procedure were also analyzed. The median time from study enrollment to first balloon inflation was 76 minutes; 19% of patients assigned to angioplasty did not undergo an angioplasty procedure. The 30-day mortality rate of patients who underwent balloon inflation  $\leq 60$  minutes after study enrollment was 1.0%; 61 to 75 minutes after enrollment, 3.7%; 76 to 90 minutes after enrollment, 4.0%; and  $\geq 91$  minutes after enrollment, 6.4%. The mortality rate of patients assigned to angioplasty who never underwent the procedure was 14.1% ( $P=0.001$ ). Logistic regression analysis revealed that the time from enrollment to first balloon inflation was a significant predictor of mortality within 30 days; after adjustment for differences in baseline characteristics, the odds of death increased 1.6 times ( $P=0.008$ ) for a movement from each time interval to the

next. **CONCLUSIONS:** The time to treatment with direct PTCA, as with thrombolytic therapy, is a critical determinant of mortality.

#### Summary

1. The 30-day mortality rate:  $\leq 60$  min - 1.0%; 61 to 75 min - 3.7%; 76 to 90 min - 4.0%;  $\geq 91$  min - 6.4% (P=0.001).
2. Logistic regression analysis: time from enrollment to first balloon inflation - significant predictor of mortality within 30 days (OR 1.6, p=0.008)

J Am Coll Cardiol ,1999 ;33(6):1528-32

Abciximab in the treatment of acute myocardial infarction eligible for primary percutaneous transluminal coronary angioplasty. Results of the Glycoprotein Receptor Antagonist Patency Evaluation (GRAPE) pilot study.

van den Merkhof LF, Zijlstra F, Olsson H, Grip L, Veen G, Bar FW, van den Brand MJ, Simoons ML, Verheugt FW

**OBJECTIVES:** We sought to study the effect of early infusion of abciximab on coronary patency before primary angioplasty in patients with acute myocardial infarction. **BACKGROUND:** Glycoprotein IIb/IIIa antagonists have proved to be effective in reducing ischemic events associated with coronary angioplasty. The present study explores whether abciximab alone, without administration of thrombolytic therapy, may induce reperfusion in patients with acute myocardial infarction. **METHODS:** In the Glycoprotein Receptor Antagonist Patency Evaluation pilot study 60 patients with less than 6 h signs and symptoms of acute myocardial infarction eligible for primary angioplasty received in the emergency room a bolus of abciximab 250 microg/kg followed by a 12-h infusion of 10 microg/min. All patients were also treated with an oral dose of 160 mg aspirin and 5,000 IU of heparin intravenously. As soon as possible a diagnostic angiography was performed to evaluate the patency of the infarct-related artery. **RESULTS:** The median time between onset of symptoms and the administration of the abciximab bolus was 150 min (range 45 to 345), and the median time between abciximab bolus and first contrast injection in the infarct-related artery was 45 min (range 10 to 150). In 24 patients (40%, 95% confidence interval 28% to 52%) Thrombolysis in Myocardial Infarction (TIMI) flow grade 2 or 3 was observed at a median time of 45 min (range 10 to 150) after abciximab bolus; TIMI flow grade 3 was observed in 11 patients (18%, 95% confidence interval 9% to 28%). There was no difference in percentage of TIMI flow

grade 2 or 3 between patients who received abciximab within 2.5 h after onset of symptoms or thereafter. CONCLUSIONS: Abciximab therapy given in the emergency room in patients awaiting primary angioplasty is associated with full reperfusion (TIMI flow grade 3) in about 20% and with TIMI flow grade 2 or 3 in about 40% of the patients at a median time of 45 min. These figures are higher than those in primary angioplasty trials without such pretreatment. Randomized controlled trials of very early infusion of abciximab, either prehospital or in-hospital, in patients eligible for angioplasty are warranted.

### Summary

1. TIMI 2 or 3 flow: 40%(95% confidence interval 28% to 52%) at a median time of 45 min
2. TIMI 3 flow: 18%(95% confidence interval 9% to 28%)
3. No difference in % of TIMI flow grade 2 or 3 between patients who received abciximab within 2.5 h after onset of symptoms or thereafter.

Circulation ,1999 ;99(15):1972-7

Determinants and prognostic implications of persistent ST-segment elevation after primary angioplasty for acute myocardial infarction: importance of microvascular reperfusion injury on clinical outcome.

Claeys MJ, Bosmans J, Veenstra L, Jorens P, De Raedt H, Vrints CJ

BACKGROUND: Despite early recanalization of an occluded infarct artery, reperfusion at the level of the microcirculation may remain impaired owing to a process of microvascular reperfusion injury. METHODS AND RESULTS: Microvascular reperfusion injury was studied in 91 patients with acute myocardial infarction (AMI) by evaluation of the resolution of ST-segment elevation after successful PTCA. Impaired microvascular reperfusion, defined as the presence of persistent ( $\geq 50\%$  of initial value) ST-segment elevation (ST  $\geq 50\%$ ) at the end of coronary intervention, was observed in 33 patients (36%) and was independently correlated with low systolic pressure on admission and high age. Patients  $\geq 55$  years of age with systolic pressures  $\leq 120$  mm Hg were at high risk for development of impaired reperfusion compared with patients not meeting these criteria (72% versus 14%,  $P < 0.001$ ). Impaired microvascular reperfusion was associated with a more extensive infarction and worse clinical outcome at the 1-year follow-up: cardiac death rate, 15% versus 2% (ST  $\geq 50\%$  versus ST  $< 50\%$ ,  $P = 0.01$ ); nonfatal MI rate, 9% versus 2% ( $P = 0.1$ ); and total major adverse cardiac event (MACE) rate, 45% versus 15% ( $P < 0.005$ ). ST  $\geq 50\%$  was the most important independent determinant of MACE with an

adjusted risk ratio of 3.4. CONCLUSIONS: Impaired microvascular reperfusion, as evidenced by ST  $\geq$ 50% after successful recanalization, occurs in more than one third of our AMI patients, especially in older patients with low systolic pressure. Its detrimental implications on clinical outcome reinforce the need to develop adjunctive agents that attenuate the process of reperfusion injury.

#### Summary

J Am Coll Cardiol, 1999 ;33(3):605-11

Primary angioplasty versus systemic thrombolysis in anterior myocardial infarction.

Garcia E, Elizaga J, Perez-Castellano N, Serrano JA, Soriano J, Abeytua M, Botas J, Rubio R, Lopez de Sa E, Lopez-Sendon JL, Delcan JL

**OBJECTIVES:** This study compares the efficacy of primary angioplasty and systemic thrombolysis with t-PA in reducing the in-hospital mortality of patients with anterior AMI. **BACKGROUND:** Controversy still exists about the relative benefit of primary angioplasty over thrombolysis as treatment for AMI. **METHODS:** Two-hundred and twenty patients with anterior AMI were randomly assigned in our institution to primary angioplasty (109 patients) or systemic thrombolysis with accelerated t-PA (111 patients) within the first five hours from the onset of symptoms. **RESULTS:** Baseline characteristics were similar in both groups. Primary angioplasty was independently associated with a lower in-hospital mortality (2.8% vs. 10.8%,  $p = 0.02$ , adjusted odds ratio 0.23, 95% confidence interval 0.06 to 0.85). During hospitalization, patients treated by angioplasty had a lower frequency of postinfarction angina or positive stress test (11.9% vs. 25.2%,  $p = 0.01$ ) and less frequently underwent percutaneous or surgical revascularization after the initial treatment (22.0% vs. 47.7%,  $p < 0.001$ ) than did patients treated by t-PA. At six month follow-up, patients treated by angioplasty had a lower cumulative rate of death (4.6% vs. 11.7%,  $p = 0.05$ ) and revascularization (31.2% vs. 55.9%,  $p < 0.001$ ) than those treated by t-PA. **CONCLUSIONS:** In centers with an experienced and readily available interventional team, primary angioplasty is superior to t-PA for the treatment of anterior AMI.

#### Summary

Journal of the American College of Cardiology, 33:1:119-124

## Sulfonylurea drugs increase early mortality in patients with diabetes mellitus after direct angioplasty for acute myocardial infarction

Kirk N. Garratt, Peter A. Brady, Nancy L. Hassinger, Diane E. Grill, Andre Terzic, David R. Holmes, Jr.

The purpose of this study was to examine the impact of sulfonylurea drug use on outcome in diabetic patients undergoing direct coronary angioplasty for acute myocardial infarction.

**Background.** Sulfonylurea drugs impair ischemic preconditioning. Whether sulfonylurea drugs affect outcome adversely in diabetic patients undergoing direct angioplasty for acute myocardial infarction is unknown.

**Methods.** Clinical outcomes after direct balloon angioplasty for acute myocardial infarction were evaluated in 67 diabetic patients taking oral sulfonylurea drugs and 118 diabetic patients not taking these drugs.

**Results.** Hospital mortality was significantly higher among diabetics treated with sulfonylurea drugs at the time of myocardial infarction (24% vs. 11%). Univariate analysis identified sulfonylurea drug, age, ventricular function, ejection fraction less than 40%, prior bypass surgery and congestive heart failure as correlates of increased in-hospital mortality. Logistic regression found sulfonylurea drug use (odds ratio 2.77,  $p = 0.017$ ) to be independently associated with early mortality. Congestive heart failure, but not sulfonylurea drug use, was associated with an increased incidence of in-hospital ventricular arrhythmias. Congestive heart failure, prior bypass surgery and female gender, but not sulfonylurea drug use, were associated with late adverse events.

**Conclusions.** Sulfonylurea drug use is associated with an increased risk of in-hospital mortality among diabetic patients undergoing coronary angioplasty for acute myocardial infarction. This early risk is not explained by an increase in ventricular arrhythmias, but may reflect deleterious effects of sulfonylurea drugs on myocardial tolerance for ischemia and reperfusion. For surviving patients sulfonylurea drug use is not associated with an increased risk of serious late adverse events.

Journal of the American College of Cardiology, 36:1194-1201

## Short- and long-term mortality for patients undergoing primary angioplasty for acute myocardial infarction

Edward L. Hannan, Michael J. Racz, Djavad T. Arani, Thomas J. Ryan, Gary Walford, Ben D. McCallister

### OBJECTIVES

The goal of this study was to learn more about the risk factors and short- and long-term outcomes for primary angioplasty.

## BACKGROUND

Primary angioplasty (direct angioplasty without antecedent thrombolytic therapy) has been an effective alternative to thrombolytic therapy for patients with acute myocardial infarction (AMI). However, most reported studies have been compromised by small sample sizes and short observation times.

## METHODS

New York's coronary angioplasty registry was used to identify New York patients undergoing angioplasty within 6 h of AMI between January 1, 1993 and December 31, 1996. Statistical models were used to identify significant risk factors for in-patient and long-term survival and to estimate long-term survival for all patients as well as various subsets of patients undergoing primary angioplasty.

## RESULTS

The in-hospital mortality rate for all primary angioplasty patients was 5.81%. When patients in preprocedural shock (who had a mortality rate of 45%) were excluded, the in-hospital mortality rate dropped to 2.60%. Mortality rates for all primary angioplasty patients at one year, two years and three years were 9.3%, 11.3% and 12.6%, respectively. Patients treated with stent placement did not have significantly lower risk-adjusted in-patient or two-year mortality rates.

## CONCLUSIONS

Primary angioplasty is a highly effective option for AMI.

Cathet. Cardiovasc. Intervent. 49:237-243, 2000

Outcome of patients with acute myocardial infarction who are ineligible for primary angioplasty trials

Harold L. Dauerman, Duane S. Pinto, Kalon K.L. Ho, C. Michael Gibson, Richard E. Kuntz, David J. Cohen, Donald S. Baim, Joseph P. Carrozza Jr.

We determined acute outcome in 148 consecutive patients with ST segment elevation myocardial infarction undergoing angioplasty including 72 patients (48.7%) considered ineligible for primary angioplasty trials. Overall, in-hospital mortality for acute infarct angioplasty was 12%, with fivefold higher mortality in the trial-ineligible group (21% vs. 4%,  $P = 0.003$ ). Thus, primary angioplasty trials continue to exclude nearly 50% of acute infarction patients and reported mortality rates of primary angioplasty trials are likely to be significantly lower than the unselected in-hospital mortality rates.

March 23, 2000 -- Vol. 342, No. 12

## Primary Angioplasty versus Thrombolysis for Acute Myocardial Infarction

Eric Boersma, Ph.D. Martijn Akkerhuis, M.D. Maarten L. Simoons, M.D., Ph.D.

In the November 4 issue, Zijlstra et al. (1) report a better long-term outcome after primary angioplasty than after thrombolysis in patients with acute myocardial infarction. Should the debate about the relative merits of angioplasty and thrombolytic therapy now be closed, as Faxon and Heger suggest in the accompanying editorial? (2) We do not think so, since the discussion to date has focused on in-hospital thrombolysis, and the role of prehospital thrombolysis has been underestimated.

The time from the onset of symptoms to the initiation of treatment is a major determinant of the outcome after thrombolytic therapy. (3) The delay in treatment can be reduced if the diagnosis of myocardial infarction and the subsequent initiation of therapy occur in the patient's home rather than in the hospital. When the data from all randomized trials of prehospital thrombolysis as compared with in-hospital thrombolysis, involving a total of 6607 patients, were combined, prehospital thrombolysis was associated with a gain of 1 hour (125 minutes vs. 186 minutes) (Figure 1). As a result, prehospital treatment was associated with a significant absolute reduction of 1.7 percent in the mortality rate at 30 days or at discharge, and an 18 percent reduction in the odds of death (odds ratio, 0.82; 95 percent confidence interval, 0.70 to 0.97;  $P=0.02$ ).

The benefit of prehospital over in-hospital thrombolytic therapy is strikingly similar to the benefit of primary angioplasty over in-hospital thrombolysis. A recent meta-analysis of randomized trials, involving a total of 2606 patients, showed that primary angioplasty was associated with an absolute reduction of 2.1 percent in the mortality rate at 30 days or at discharge. (4) The observed 34 percent reduction in the odds of death (odds ratio, 0.66; 95 percent confidence interval, 0.46 to 0.94;  $P=0.02$ ) does not differ significantly from the reduction in the odds of death in the trials of prehospital thrombolysis ( $P=0.26$  by the Breslow-Day test for the homogeneity of the two odds ratios).

Data on the long-term outcome of prehospital thrombolytic therapy as compared with in-hospital thrombolytic therapy are available only from the Grampian Region Early Anistreplase Trial. In this trial, the mortality rate at five years was 25.2 percent in the prehospital group and 35.8 percent in the in-hospital group ( $P=0.04$ ). (5) The reduction in the mortality rate with prehospital thrombolysis (odds ratio, 0.60; 95 percent confidence interval, 0.37 to 0.98) is similar to the reduction at five years with primary angioplasty, as reported by Zijlstra et al. ( $P=0.50$  by the Breslow-Day test for the homogeneity of the two odds ratios).

In view of the excellent outcome after primary angioplasty, it should be considered the treatment of choice for acute myocardial infarction in well-equipped and experienced centers. The vast majority of patients, however, have no access to such facilities and will benefit more from on-site diagnosis and immediate thrombolytic therapy. Sophisticated portable electrocardiographic devices and easy-to-use thrombolytic agents (with bolus injections) are available to facilitate diagnosis and treatment in the patient's home.

Journal of the American College of Cardiology, 2000;35:3:600-604

High dose heparin as pretreatment for primary angioplasty in acute myocardial infarction: the Heparin in Early Patency (HEAP) randomized trial

Aylee Liem, Felix Zijlstra, Jan Paul Ottervanger, Jan C.A. Hoorntje, Harry Suryapranata, Menko-Jan de Boer, Freek W.A. Verheugt

#### OBJECTIVES

In the Heparin in Early Patency (HEAP) pilot study a beneficial effect of high-dose heparin on early patency in acute myocardial infarction (MI) was observed in a matched-control study.

#### BACKGROUND

High dose bolus intravenous injection of heparin may achieve lysis of coronary thrombi and could enhance early patency of the infarct related vessel in patients with MI scheduled for primary angioplasty.

#### METHODS

Before primary angioplasty, 584 patients with MI entered an open randomized trial of high dose (300 IU/kg) or low dose (0 or 5,000 IU) heparin. Of the 584 patients, 299 were randomized to high dose and 285 patients to low dose heparin.

#### RESULTS

Thrombolysis In Myocardial Infarction (TIMI) flow grade 2 or 3 was observed before primary angioplasty in 65 patients (22%) in the high dose group and 60 patients (21%) in the low dose heparin group ( $p > 0.1$ ), whereas TIMI flow grade 3 was observed in 38 (13%) and 24 patients (9%), respectively ( $p = 0.11$ ). There were no differences in the clinical end points between the two groups. There were no hemorrhagic strokes, while 10% of the patients in the high dose group required blood transfusion versus 6% in the low dose/no heparin group ( $p = 0.07$ ). No subsets of patients showed beneficial effects of high dose heparin, such as patients with longer delay

between heparin administration and diagnostic angiogram or patients with short delay between symptom onset and admission.

#### CONCLUSIONS

There is no benefit of high dose bolus heparin on early patency compared with no or low dose heparin.

Journal of the American College of Cardiology, 2000;35:6:1502-1512

Diabetes mellitus and outcome after primary coronary angioplasty for acute myocardial infarction: lessons from the GUSTO-IIb angioplasty substudy

David Hasdai, Christopher B. Granger, S. Sanjay Srivatsa, Douglas A. Criger, Stephen G. Ellis, Robert M. Califf, Eric J. Topol, David R. Holmes, Jr.

#### OBJECTIVES

We sought to compare the efficacy of primary angioplasty in diabetics versus nondiabetics and to evaluate the relative benefits of angioplasty over thrombolytic therapy among diabetics.

#### BACKGROUND

Primary angioplasty for myocardial infarction is at least as effective as thrombolytic therapy in the general population. However, the influence of diabetic status on outcome after primary angioplasty versus thrombolysis remains unknown.

#### METHODS

Patients in the Global Use of Strategies To Open Occluded Arteries in Acute Coronary Syndromes (GUSTO-IIb) Angioplasty Substudy were randomized to receive either primary angioplasty or accelerated alteplase. The interaction of diabetic status (diabetics n = 177, nondiabetics n = 961) and treatment strategy with the occurrence of the primary end point (death, nonfatal reinfarction or nonfatal, disabling stroke at 30 days) was analyzed (power to detect a 40% relative reduction in the primary end point with alpha = 0.05 and beta = 0.20). Among patients who were randomized to and underwent primary angioplasty, procedural success (defined as residual stenosis <50% and TIMI grade 3 flow) was assessed based on diabetic status.

#### RESULTS

Compared with nondiabetics, diabetics had worse baseline clinical and angiographic profiles. Despite more severe stenosis and poorer flow in the culprit artery, procedural success with angioplasty was similar for diabetics (n = 81; 70.4%) and nondiabetics (n = 391; 72.4%). Outcome at 30 days was better for nondiabetics randomized to angioplasty versus alteplase (adjusted odds ratio, 0.62; 95% confidence interval, 0.41-0.96) with a

similar trend for diabetics (0.70, [0.29-1.72]). We noted no interaction between diabetic status and treatment strategy on outcome (p = 0.88).

## CONCLUSIONS

Primary angioplasty was similarly successful in diabetics and nondiabetics and appeared to be more effective than thrombolytic therapy among diabetics with acute infarction.

Journal of the American College of Cardiology, 2000;36:5:1489-1496

Facilitation of early percutaneous coronary intervention after reteplase with or without abciximab in acute myocardial infarction : Results from the SPEED (GUSTO-4 Pilot) trial

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## OBJECTIVES

We examined the utility of early percutaneous coronary intervention (PCI) in a trial that encouraged its use after thrombolysis and glycoprotein IIb/IIIa inhibition for acute myocardial infarction (MI).

## BACKGROUND

Early PCI has shown no benefit when performed early after thrombolysis alone.

## METHODS

We studied 323 patients (61%) who underwent PCI with planned initial angiography, at a median 63 min after reperfusion therapy began. A blinded core laboratory reviewed cineangiograms. Ischemic events, bleeding, angiographic results, and clinical outcomes were compared between early PCI and no-PCI patients (n = 162), between patients with Thrombolysis in Myocardial Infarction (TIMI) flow grade 0 or 1 before PCI versus flow grade 2 or 3, and among three treatment regimens.

## RESULTS

Early PCI patients showed a procedural success (<50% residual stenosis and TIMI flow grade 3) rate of 88% and a 30-day composite incidence of death, reinfarction, or urgent revascularization of 5.6%. These patients had fewer ischemic events and bleeding complications (15%) than did patients not undergoing early PCI (30%, P =

0.001). Early PCI was used more often in patients with initial TIMI flow grade 0 or 1 versus flow grade 2 or 3 (83% vs. 60%,  $p < 0.0001$ ). Patients receiving abciximab with reduced-dose reteplase (5 U double bolus) showed an 86% incidence of TIMI grade 3 flow at ~90 min and a trend toward improved outcomes.

#### CONCLUSIONS

In this analysis, early PCI facilitated by a combination of abciximab and reduced-dose reteplase was safe and effective. This approach has several advantages for acute MI patients, which should be confirmed in a dedicated, randomized trial.

Journal of the American College of Cardiology, 2000;35:605-611

Clinical and angiographic outcomes in patients with previous coronary artery bypass graft surgery treated with primary balloon angioplasty for acute myocardial infarction

Gregg W. Stone, Bruce R. Brodie, John J. Griffin, Lorelei Grines, Judith Boura, William W. O'Neill, Cindy L. Grines for the Second Primary Angioplasty in Myocardial Infarction Trial (PAMI-2) Investigators

#### OBJECTIVES

We sought to characterize the presenting characteristics of patients with previous coronary artery bypass graft surgery (CABG) and acute myocardial infarction (AMI) and to determine the angiographic success rate and clinical outcomes of a primary percutaneous transluminal coronary angioplasty (PTCA) strategy.

#### BACKGROUND

Patients who have had previous CABG and AMI comprise a high risk group with decreased reperfusion success and increased mortality after thrombolytic therapy. Little is known about the efficacy of primary PTCA in AMI.

#### METHODS

Early cardiac catheterization was performed in 1,100 patients within 12 h of onset of AMI at 34 centers in the prospective, controlled Second Primary Angioplasty in Myocardial Infarction trial (PAMI-2), followed by primary PTCA when appropriate. Data were collected by independent study monitors, end points were adjudicated and films were read at an independent core laboratory.

#### RESULTS

Of 1,100 patients with AMI, 58 (5.3%) had undergone previous CABG. The infarct-related vessel in these patients was a bypass graft in 32 patients (55%) and a native coronary artery in 26 patients. Compared with

patients without previous CABG, patients with previous CABG were older and more frequently had a previous myocardial infarction and triple-vessel disease. Coronary angioplasty was less likely to be performed when the infarct-related vessel was a bypass graft rather than a native coronary artery (71.9% vs. 89.8%,  $p = 0.001$ ); Thrombolysis in Myocardial Infarction trial (TIMI) flow grade 3 was less frequently achieved (70.2% vs. 94.3%,  $p < 0.0001$ ); and in-hospital mortality was increased (9.4% vs. 2.6%,  $p = 0.02$ ). As a result, mortality at six months was 14.3% versus 4.1% in patients with versus without previous CABG ( $p = 0.001$ ). By multivariate analysis, independent determinants of late mortality in the entire study group were advanced age, triple-vessel disease, Killip class and post-PTCA TIMI flow grade  $<3$ .

#### CONCLUSIONS

Reperfusion success of a primary PTCA strategy in patients with previous CABG, although favorable with respect to historic control studies, is reduced as compared with that in patients without previous CABG. New approaches are required to treat patients with previous CABG and AMI, especially when the infarct-related vessel is a diseased saphenous vein graft.

JACC , 2000;35:1729-36

A comparison of systematic stenting and conventional balloon angioplasty during primary percutaneous transluminal coronary angioplasty for acute myocardial infarction

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#### OBJECTIVES

In a multicenter, randomized trial, systematic stenting using the Wiktor stent was compared to conventional balloon angioplasty with provisional stenting for the treatment of acute myocardial infarction (AMI).

#### BACKGROUND

Primary angioplasty in AMI is limited by in-hospital recurrent ischemia and a high restenosis rate.

#### METHODS

A total of 211 patients with AMI  $<12$  h from symptom onset, with an occluded native coronary artery, were randomly assigned to systematic stenting ( $n = 101$ ) or balloon angioplasty ( $n = 110$ ). The primary end point was the binary six-month restenosis rate determined by core laboratory quantitative angiographic analysis.

## RESULTS

Angiographic success (Thrombolysis in Myocardial Infarction [TIMI] flow grade 3 and residual diameter stenosis <50%) was achieved in 86% of the patients in the stent group and in 82.7% of those in the balloon angioplasty group ( $p = 0.5$ ). Compared with the 3% cross-over in the stent group, cross-over to stenting was required in 36.4% of patients in the balloon angioplasty group ( $p = 0.0001$ ). Six-month binary restenosis ( $\geq 50\%$  residual stenosis) rates were 25.3% in the stent group and 39.6% in the balloon angioplasty group ( $p = 0.04$ ). At six months, the event-free survival rates were 81.2% in the stent group and 72.7% in the balloon angioplasty group ( $p = 0.14$ ), and the repeat revascularization rates were 16.8% and 26.4%, respectively ( $p = 0.1$ ). At one year, the event-free survival rates were 80.2% in the stent group and 71.8% in the balloon angioplasty group ( $p = 0.16$ ), and the repeat revascularization rates were 17.8% and 28.2%, respectively ( $p = 0.1$ ).

## CONCLUSIONS

In the setting of primary angioplasty for AMI, as compared with a strategy of conventional balloon angioplasty, systematic stenting using the Wiktor stent results in lower rates of angiographic restenosis.

Am Heart J, 2000 139(3):476-481

Predictors of death and reinfarction at 30 days after primary angioplasty: The GUSTO IIB and RAPPORT trials.

Brener SJ, Ellis SG, Sapp SK, Betriu A, Granger CB, Burchenal JE, Moliterno DJ, Califf RM, Topol EJ

**BACKGROUND:** Thirty-day death among recipients of fibrinolytic therapy for acute myocardial infarction (MI) is tightly correlated with easily obtainable key demographic and clinical parameters such as age, blood pressure, heart rate, and infarct location. Similar data for primary angioplasty are not available. **METHODS AND RESULTS:** Data from 2 large, contemporary, primary angioplasty trials were formally combined and analyzed with respect to death and death/repeat MI at 30 days through the use of multivariate logistic regression models. The 1048 patients had a median age of 62 years, and 26% were women. Thirty-eight percent had an anterior infarction. The patients underwent angioplasty at a median delay from symptom onset of 3.8 hours. Death was independently predicted by increasing age (adjusted odds ratio [OR] per decade 2.32, 95% confidence interval [CI] 1.60 to 3.42), whereas a history of smoking (OR 0.29, CI 0.13 to 0.64), Thrombolysis in Myocardial Infarction (TIMI) flow grade 3 after angioplasty (OR vs TIMI <3 0.21, CI 0.10 to 0.45) and higher systolic blood pressure (OR per 10 mm Hg 0.73, CI 0.62 to 0.87) were associated with lower mortality rates. Death or repeat MI was independently associated with increasing age (OR per decade 1.40, CI 1.13 to 1.76) and

anterior location of the index MI (OR 1.89, CI 1.12 to 3.20). TIMI grade 3 flow (OR vs TIMI <3 0.40, CI 0.23 to 0.68) and higher systolic blood pressure (OR per 10 mm Hg 0.79, CI 0.71 to 0.89) were associated with a lower incidence of death/repeat MI. Time to angioplasty, heart rate, extent of coronary artery disease, participation in 1 of the 2 trials, and all common coronary risk factors did not significantly predict outcome. CONCLUSIONS: Death and reinfarction after primary angioplasty are predominantly predicted by age, hemodynamic instability, and the attainment of TIMI 3 flow in the infarct artery.

### Summary

Odds ratio of independent predictors of adverse events at 30days

Am Heart J, 2000 ;139(2 Pt 1):208-16

Primary intracoronary stenting in acute myocardial infarction: long-term clinical and angiographic follow-up and risk factor analysis.

Kastrati A, Pache J, Dirschinger J, Neumann FJ, Walter H, Schmitt C, Schomig A

**BACKGROUND:** Coronary stent placement may be an effective primary intervention in acute myocardial infarction. Recently published or reported data indicate that primary stenting may be superior to primary plain balloon angioplasty in this setting. The aim of this study was to analyze the long-term clinical and angiographic follow-up of patients treated with primary intracoronary stenting and to identify the predictive factors of an adverse outcome. **METHODS:** The study population was composed of 519 consecutive patients with acute myocardial infarction (43 in cardiogenic shock) and attempted primary stent implantation. Adverse clinical events such as death, recurrent infarction, and target vessel revascularization were recorded. Six-month follow-up angiography was performed in 78.2% of the eligible patients, and coronary dimensions were assessed with an automated quantitative system. **RESULTS:** Procedural success was achieved in 500 patients (96.3%). The incidence of reocclusion was 3.2%. Thirty-day mortality rate was 5.4% (2.5% in patients without shock); adverse clinical events were encountered in 10.4% of the patients. Independent risk factors for an adverse outcome were longer time to treatment, Killip class, reduced left ventricular function, overlapping stents, and residual dissection. The incidence of angiographic restenosis was 30.6%. One-year survival rate was 89.0%; 86.5% of the patients did not have a myocardial infarction and 71.7% did not have any major adverse event. **CONCLUSIONS:** Primary intracoronary stenting in patients with acute myocardial infarction is associated with a favorable early and long-term outcome. This is the result of low reocclusion and restenosis rates achieved by stenting.

## Summary

1. Procedural success: 96.3%, incidence of reocclusion: 3.2%.
2. Thirty-day mortality rate: 5.4%, adverse clinical events: 10.4%
3. Independent risk factors for an adverse outcome: longer time to treatment, Killip class, reduced left ventricular function, overlapping stents, and residual dissection.
4. The incidence of angiographic restenosis: 30.6%.
5. One-year survival rate: 89.0%

Am J Cardiol , 2000; 85:11:1292-1296

## Role of cardiac surgery in the hospital phase management of patients treated with primary angioplasty for acute myocardial infarction

Gregg W. Stone, Bruce R. Brodie, John J. Griffin, Lorelei Grines, Judith Boura, William W. O'Neill, Cindy L. Grines for the Primary Angioplasty in Myocardial Infarction Trial-2 (PAMI-2) Investigators

Although cardiac surgery is performed in ~10% of acute myocardial infarction (AMI) patients undergoing a primary percutaneous transluminal coronary angioplasty (PTCA) reperfusion strategy before discharge, the indications for and timing of operative revascularization, and the short- and long-term outcomes after surgery have not been characterized. In the prospective, controlled Primary Angioplasty in Myocardial Infarction-2 trial, cardiac catheterization was performed in 1,100 patients within 12 hours of onset of AMI at 34 centers, followed by primary PTCA when appropriate. Cardiac surgery was performed before hospital discharge in 120 patients (10.9%), electively in 42.6%, and on an urgent or emergent basis in 57.4%. Surgery was performed in 6.1% of 982 patients after primary PTCA (although emergently for failed PTCA in only 4 cases [0.4%]), and in 53 of 118 patients (44.9%) not undergoing primary PTCA. Patients requiring surgery were older, and more frequently had diabetes and 3-vessel disease than those managed nonoperatively. Internal mammary artery grafts were placed in only 31% of patients. In-hospital mortality was 6.4% in patients undergoing urgent/emergent surgery, 2.0% after elective surgery, and 2.6% in patients not undergoing surgery ( $p = \text{NS}$ ). After multivariate correction for baseline risk factors, early and late survival free of reinfarction were similar in patients undergoing versus not undergoing in-hospital cardiac surgery. Thus, the appropriate use of coronary artery bypass graft surgery in the peri-infarction period is an integral component of the primary PTCA approach, and is frequently used to optimize the prognosis of a high-risk AMI cohort with unfavorable baseline features. The implications for the

performance of primary PTCA in AMI at centers without on-site surgical facilities are discussed.

TABLE III. In-Hospital Major Adverse Events

Figure 2. Kaplan-Meier survival curves demonstrating freedom from death, reinfarction, and death or reinfarction in patients undergoing (bottom bold lines) and not undergoing (top thin lines) in-hospital cardiac surgery.

TABLE IV. Multivariate Correlates of Late Death or Reinfarction

Am J Cardiol 2000; 86:3:269-274

Synergy between intracoronary stenting and abciximab in improving angiographic and clinical outcomes of primary angioplasty in acute myocardial infarction

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This study examined 650 consecutive patients who presented with an acute myocardial infarction and were treated with primary angioplasty within 12 hours of symptom onset between August 1995 and December 1998. Patients were placed into 4 treatment groups depending on the adjunctive therapy they received: group 1, percutaneous transluminal coronary angioplasty (PTCA) (?alloon PTCA alone?; n = 220); group 2, PTCA plus

intracoronary stent placement (?tent? n = 128); group 3, PTCA plus abciximab therapy ('abciximab? n = 104); and group 4, PTCA plus intracoronary stent placement plus abciximab therapy (?tent/abciximab? n = 198). The patients' clinical characteristics, severity of disease, and total ischemia time on presentation were similar. At baseline, abciximab and stent/abciximab groups had a higher incidence of thrombus on coronary angiography. Postprocedural quantitative coronary analysis showed a significantly larger minimum luminal diameter in the stent and stent/abciximab groups than PTCA alone. Overall, stents were most efficacious in reducing target vessel revascularization rate, whereas abciximab was associated with a higher postprocedural Thrombolysis In Myocardial Infarction-3 trial flow and less ?o reflow.?The best angiographic result was achieved in the stent/abciximab group. Similarly, the primary combined end point of death, myocardial infarction, and target vessel revascularization at 30 days was the lowest (6.1%) in the stent/abciximab group. The combination of abciximab and stenting in primary angioplasty for acute myocardial infarction is thus synergistic and is associated with improved angiographic and clinical results at 30-day follow-up.

TABLE V. Clinical Outcome in the Treatment Groups

Figure 1. Kaplan-Meier event-free survival curves for the composite end point of death, recurrent myocardial infarction, and target vessel revascularization over 30 days.

Figure 2. Risk adjusted OR with 95% CI for individual adjunctive strategies.

Am J Cardiol 2000; 86:4:400-405

Reappraising the role of immediate intervention following thrombolytic recanalization in acute myocardial infarction

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Early studies indicated that after successful thrombolytic recanalization, adjunctive percutaneous transluminal coronary angioplasty (PTCA) was not appropriate, even when a significant residual stenosis was present. The aim of this study was to assess in-hospital clinical outcomes of patients with acute myocardial infarction (AMI) who underwent successful recanalization after thrombolytic therapy. The relation between repeat AMI/unstable angina and the severity of the stenosis, as well as other angiographic and clinical features was also examined. One hundred patients with AMI of <10 hours underwent coronary angiography 2 hours after receiving thrombolytic therapy. Salvage PTCA  $\pm$  stenting was performed if recanalization was unsuccessful

(Thrombolysis In Myocardial Infarction [TIMI] trial grade 0 to 2), and no PTCA was undertaken if there was brisk anterograde flow (TIMI 3). Angiographic analysis was performed to assess the severity of the residual lesion, as well as the presence or absence of thrombus. Forty patients had unsuccessful recanalization, and of these, 36 underwent attempted PTCA. Of the 60 patients with TIMI 3 flow, 15 required repeat angiography and PTCA after repeat AMI (n = 13) or unstable angina (n = 2) within 5 days. Receiver-operating characteristic analysis indicated an optimum percent diameter stenosis predictor of 85% for repeat AMI/unstable angina. There was no additional relation to age, gender, time to thrombolysis, the infarct-related artery, or the presence of culprit lesion thrombus. After recanalization, a high-grade stenosis >85% is common (n = 25, 42.4%). This is associated with a 54% repeat AMI/unstable angina risk—a ninefold increase in the incidence of such events than in patients with lesions <85%. Thus, patients with narrowings >85% may benefit from early intervention rather than a conservative approach. Narrowings <85% have a 94% probability of no repeat AMI/unstable angina and do not require early intervention.

Figure 4. ROC curve for model:  $\log(p/1-p) = 0.173 (\% \text{ diameter stenosis}) - 15.79$ , used to predict reinfarction or unstable angina.

TABLE II. Sensitivity, Specificity, and Negative and Positive Predictive Values for Various Cutoff Points of Percent Diameter Stenosis

TABLE III. Significance Levels of Reocclusion/Unstable Angina With Age, Gender, Chest Pain Onset to Initiation of Streptokinase Time Interval, Presence of Visible Culprit Lesion Thrombus, and Infarct-Related Vessel

J Am Coll Cardiol 2000; 35:5:1162-1169

Reperfusion syndrome: relationship of coronary blood flow reserve to left ventricular function and infarct size

Laurent J. Feldman, Dominique Himbert, Jean-Michel Juliard, Gaetan J. Karrillon, Hakim Benamer, Pierre Aubry, Olivier Boudvillain, Patrick Seknadji, Marc Faraggi, Ph Gabriel Steg

OBJECTIVES: We tested the hypothesis that the reperfusion syndrome (RS), defined as an additional elevation of the ST segment upon reperfusion, may be a marker of microcirculatory reperfusion injury during acute myocardial infarction (AMI).

**BACKGROUND:** The pathophysiology of the RS is unknown, and its prognostic implications are controversial.

**METHODS:** Twenty-one patients with an anterior AMI treated  $\leq 12$  h after onset by primary coronary angioplasty (PTCA) were studied. Coronary velocity reserve (CVR), an index of microcirculatory function, was measured using a Doppler guidewire. Left ventricular (LV) ejection fraction, infarct size (percent defect) and LV end-systolic volume index (LVESVi) were evaluated by radionuclide ventriculography,  $^{201}\text{Tl}$  single-photon emission computed tomography and contrast ventriculography, respectively.

**RESULTS:** Baseline ST elevation and pain-to-TIMI 3 time were similar in patients with and without RS. Patients with RS (10/21) had a lower post-PTCA CVR than patients without RS (median [95% confidence interval]: 1.2 [1-1.3] vs. 1.6 [1.5-1.7],  $p < 0.005$ ). Even though predischage CVR was similar in the two groups, infarct size at six weeks (26 [21 to 37] vs. 14 [10-17] %  $^{201}\text{Tl}$  defect,  $p = 0.001$ ) and predischage LVESVi (45% [40 to 52] vs. 30% [29 to 38] mL/m<sup>2</sup>,  $p = 0.001$ ) were larger, and LV ejection fraction at six weeks (40% [37 to 46] vs. 55% [50 to 60],  $p = 0.004$ ) was lower in patients with RS than in patients without RS.

**CONCLUSIONS:** Patients with RS during primary PTCA for an anterior AMI have a transiently lower CVR than patients without RS, but sustained LV dysfunction and larger infarct size, suggesting that RS is a marker of microcirculatory reperfusion injury.

J Am Coll Cardiol 2000; 36:4:1202-1209

Angiographic no-reflow phenomenon as a predictor of adverse long-term outcome in patients treated with percutaneous transluminal coronary angioplasty for first acute myocardial infarction

Itsuro Morishima, Takahito Sone, Kenji Okumura, Hideyuki Tsuboi, Junichiro Kondo, Hiroaki Mukawa, Hideo Matsui, Yukio Toki, Takayuki Ito, Tetsuo Hayakawa

**OBJECTIVES:** We sought to elucidate the long-term prognostic importance of angiographic no-reflow phenomenon after percutaneous transluminal coronary angioplasty (PTCA) for acute myocardial infarction (AMI).

**BACKGROUND:** Angiographic no-reflow phenomenon, a reduced coronary antegrade flow (Thrombolysis in Myocardial Infarction [TIMI] flow grade 2012) without mechanical obstruction after recanalization, predicts poor left ventricular (LV) functional recovery and survival in the early phase of AMI. We hypothesized that angiographic no-reflow phenomenon also predicts long-term clinical outcome.

**METHODS:** We studied 120 consecutive patients with their first AMI treated by PTCA without flow-restricting lesions. The patients were classified as either no-reflow ( $n = 30$ ) or reflow (TIMI-3) ( $n = 90$ ) based on post-PTCA

cineangiograms to follow up ( $5.8 \pm 1.2$  years) for cardiac death and nonfatal events.

**RESULTS:** Patients with no-reflow had congestive heart failure ( $p < 0.0001$ ), malignant arrhythmia ( $p = 0.038$ ), and cardiac death ( $p = 0.002$ ) more often than did those with reflow. Kaplan-Meier curves showed lower cardiac survival and cardiac event-free survival ( $p < 0.0001$ ) in patients with no-reflow than in those with reflow. Multivariate analyses disclosed that no-reflow phenomenon was an independent predictor of long-term cardiac death (relative risk [RR] 5.25, 95% confidence interval [CI] 1.85 to 14.9,  $p = 0.002$ ) and cardiac events (RR 3.71, 95% CI 1.79 to 7.69,  $p = 0.0004$ ). At follow-up, survivors with no-reflow had higher end-diastolic and end-systolic LV volume indices and plasma brain natriuretic peptide levels, and lower LV ejection fractions ( $p = 0.0002$ ,  $p < 0.0001$ ,  $p = 0.002$ ,  $p < 0.0001$ , respectively) than did those with reflow, indicating that no-reflow may be involved in LV remodeling.

**CONCLUSIONS:** Angiographic no-reflow phenomenon strongly predicts long-term cardiac complications after AMI; these complications are possibly associated with LV remodeling.

Am J Cardiol 2000; 85:7:815-820

Heart rate variability in patients with acute myocardial infarction undergoing primary coronary angioplasty

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Depressed heart rate variability (HRV) has been associated with adverse outcome during and after acute myocardial infarction (AMI). The effects of reperfusion in AMI on the course of HRV have not been well characterized as yet. We analyzed 123 consecutive patients with a first AMI who underwent successful reperfusion (Thrombolysis In Myocardial Infarction grades 2 and 3) by primary percutaneous transluminal coronary angioplasty (PTCA). Time- and frequency-domain HRV was measured from 24-hour Holter monitoring, which began at hospital admission. Mean RR interval increased significantly after successful PTCA. Reperfusion immediately caused an immediate transient depression of HRV, which was followed by a significant increase of HRV. Quantitative markers of sympathetic activity and sympathovagal balance, such as SD of the averages of NN intervals in all 5-minute segments, and low- and/or high-frequency ratio continuously decreased within the observation period. Patients with anterior AMI exhibited the same pattern of temporal changes of HRV, with, however, lower absolute values for HRV and mean RR interval than patients with non-anterior AMI. Subgroup analysis in 21 patients with reperfusion  $> 12$  hours after onset of pain showed that the biphasic profile of HRV and the marked increase of mean RR interval was absent. Furthermore,

in patients with late reperfusion, HRV was significantly lower compared with those with early reperfusion. Thus, timely reperfusion in AMI leads to a biphasic effect on autonomic tone, characterized by a transient suppression, followed by a significant activation of the vagal tone, as well as an attenuation of sympathetic activity. Recovery of HRV may contribute to the benefits of early reperfusion in AMI.

Coronary Artery Dis 2000 Jun; 11(4):305-13

Primary angioplasty for acute myocardial infarction in the elderly

Lane GE. Holmes DR Jr.

Elderly patients with acute myocardial infarction present a formidable therapeutic challenge. Although there appears to be a survival benefit from thrombolytic therapy for the eligible elderly patient, persistent concerns regarding the risk of intracranial hemorrhage impedes utilization in this age group. Primary or direct angioplasty of the infarct artery has been proven to be an effective modality for reperfusion. Randomized comparisons suggest an advantage over thrombolysis in terms of achieving superior patency and mitigating recurrent ischemic events. Primary angioplasty expands the reperfusion population by including many patients ineligible for thrombolysis and is more effective for treating patients at high risk, such as those with cardiogenic shock. Acute angiography accumulates important prognostic and decision-facilitating information. The benefits of primary angioplasty are more impressive for the aging patient. The survival gain and reduction in intracranial hemorrhage may combine to magnify the advantages of performing angioplasty on patients in this group. Emerging evidence concerning the aging population validates continued examination of this invasive reperfusion approach.

Catheter Cardiovasc Interv 2000 Sep; 51(1):27-31

Intracoronary adenosine administered during percutaneous intervention in acute myocardial infarction and reduction in the incidence of "no reflow" phenomenon

Assali AR. Sdringola S. Ghani M. Denkats AE. Yepes A. Hanna GP. Schroth G. Fujise K. Anderson HV. Smalling RW. Rosales OR

Percutaneous intervention in acute myocardial infarction has been associated with a high incidence of “no reflow,” ranging from 11% to 30%, with an increased risk of complications. The role of intracoronary adenosine for the prevention of this phenomenon has not been evaluated fully. We studied the procedural outcomes of 79 patients who underwent percutaneous intervention in the context of acute myocardial infarction. Twenty-eight patients received no intracoronary adenosine, and 51 received intracoronary adenosine boluses (24-48 microg before and after each balloon inflation). Eight patients who were not given adenosine experienced no reflow (28.6%) and higher rates of in-hospital death, while only three of 51 patients (5.9%;  $P = 0.014$ ) in the adenosine group experienced no reflow. No untoward complications were noted during adenosine infusion. Intracoronary adenosine bolus administration during percutaneous intervention in the context of acute myocardial infarction is easy and safe and may significantly lessen the incidence of no reflow, which may improve the outcome of this procedure.

J Invasive Cardiol 2000 Jun; 12(6):292-6

Primary stenting for acute myocardial infarction via the transradial approach: a safe and useful alternative to the transfemoral approach

Kim MH. Cha KS. Kim HJ. Kim SG. Kim JS

**BACKGROUND:** Primary stenting in acute myocardial infarction (AMI) has been demonstrated to reduce recurrent ischemic events. However, transradial stenting in AMI has not been well established. Therefore, we sought to investigate the feasibility and utility of transradial coronary stenting in patients with AMI.

**METHODS:** From April 1998 to April 1999, 56 patients (43 male; mean age of 57 years) who arrived within 6 hours of pain onset with culprit vessel size > 2.5 mm constituted this study. The transradial approach (Group 1) was used in 30 patients with hemodynamically stable and palpable right radial pulse. The transfemoral approach (Group 2) was used for vascular access in the remainder of patients (26) who might have required a second vascular access site for intraaortic balloon pumping (in cardiogenic shock) and/or a transvenous temporary pacemaker.

**RESULTS:** Overall success rate was achieved in 54 of 56 patients (96%). The success rate was 90% (27/30) in Group 1 and 96% (25/26) in Group 2. The cannulation time (from patient arrival at the catheterization room to the time of arterial cannulation) and the total procedure time (from patient arrival at the catheterization room

to the completion of the procedure) were not significantly different between Group 1 and Group 2 (9.2+/-5.3 versus 8.9+/-5.8 minutes,  $p>0.05$ ; 53.7+/-19.4 versus 57.5 +/-26.8 minutes,  $p>0.05$ , respectively). In the Group 1 patients, there was no forearm ischemia or loss of radial pulse during the 30-day follow-up period.

**CONCLUSION:** Primary coronary stenting for acute myocardial infarction via the transradial approach is a safe and feasible alternative to the conventional transfemoral approach, and is especially useful for hemodynamically stable patients who do not require a second vascular access site.

Angiology 2000 Aug; 51(8):659-66

Changing features of stent-supported primary angioplasty for acute myocardial infarction: impact of new flexible stents

Tomoda H. Aoki N.

Although primary coronary stenting for acute myocardial infarction (AMI) has been reported to be superior to primary percutaneous transluminal coronary angioplasty (PTCA), cautious entry criteria resulted in low-risk populations in these studies. This study was undertaken to delineate factors that have not been clarified by randomized multicenter studies and is based on the results of stent-supported primary PTCA for AMI using second-generation new stents. In 1994-1998, 355 AMI patients were studied < 12 hours after onset. The patients were divided into two groups: group 1 (n = 175) was treated in 1994-1996 and group 2 (n = 180) in 1997-1998. In group 1, bailout stenting was performed in 17% of the patients for acute coronary dissection or occlusion with use of Palmaz-Schatz stents. In group 2, stenting was performed in 62% of the patients for suboptimal coronary dilatation and dissection or occlusion, using second-generation flexible stents with excellent radial force in 65% of them (Multilink, GFX, and NIR). In-hospital death and reinfarction occurred in 7.4% of group 1 and 5.0% of group 2 patients, and follow-up death and reinfarction in 4.0% of group 1 and 0.6% of group 2 patients ( $p < 0.05$ ). In-hospital target vessel revascularization was performed in 8.6% of group 1 and 3.3% of group 2 patients ( $p < 0.05$ ), and follow-up target vessel revascularization in 21.1% of group 1 and 11.7% of group 2 patients ( $p<0.02$ ). Thus, the total adverse clinical event rates were 36.0% in group 1 and 18.3% in group 2 ( $p < 0.01$ ). In conclusion, outcomes of stent-supported coronary intervention in nonselected AMI patients have improved along with the availability of second-generation flexible stents, approaching the outcomes of primary stent studies in highly selected patients.

Catheter Cardiovasc Interv 2000 Jul; 50(3):362-70

Adjunctive thrombus aspiration and mechanical protection from distal embolization in primary percutaneous intervention for acute myocardial infarction

Belli G. Pezzano A. De Biase AM. Bonacina E. Silva P. Salvade P. Piccalo G. Klugmann S

Primary percutaneous intervention for acute occlusion of a native coronary artery may be complicated by distal embolization of plaque or thrombotic debris, with infarct extension. We tested the clinical application of a new therapeutic strategy combining maximal antiplatelet therapy, with glycoprotein IIb/IIIa inhibition, and adjunctive mechanical protection from distal embolization and direct aspiration of thrombus with a new balloon and catheter system (PercuSurge trade mark). Successful aspiration of thrombus could be obtained in 7 out of 8 attempted procedures, with inability to negotiate the angulated take-off of the circumflex coronary artery in one patient. The current mechanical characteristics of the device, primarily developed for use in larger saphenous vein grafts, and certain caveats and limitations are discussed. New dedicated systems should be available in the near future for the native coronary circulation. Excellent immediate angiographic results were obtained in all treated patients, without evidence of loss of distal branches and no intraprocedural complications.

Catheter Cardiovasc Interv 2000 Jul; 50(3):269-75

Angiographic and clinical outcomes after rescue coronary stenting

Dauerman HL. Prpic R. Andreou C. Vu MA. Popma JJ

The role of coronary stenting in improving outcomes after failed thrombolysis has not been well described. This study represents a registry of rescue coronary interventions performed during a 3 year period in which interventional treatment was changing for this high risk population. We analyzed acute angiographic results and clinical outcomes in 108 consecutive patients treated for thrombolytic failure with either balloon angioplasty (n = 63) or coronary stenting (n = 45). The overall in-hospital mortality rate was 5.5%, and there was no increase in complications in the stent group. Coronary stenting was associated with improved angiographic results including lower residual stenosis in the culprit artery (15 +/- 10% vs. 31 +/- 22%, P < 0.001) without

increasing bleeding complications. The rate of in-hospital and long term target vessel revascularization in the stent group was significantly lower than in the unmatched PTCA group. Rescue coronary stenting is safe, improves acute angiographic results compared to PTCA alone and leads to excellent in-hospital and long term outcomes.

Circulation 2000 Jun; 101(25):2902-8

Cardioprotective effects of the Na(+)/H(+) exchange inhibitor cariporide in patients with acute anterior myocardial infarction undergoing direct PTCA

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**BACKGROUND:** Activation of Na(+)/H(+) exchange in myocardial ischemia and/or reperfusion leads to calcium overload and myocardial injury. Experimental studies have shown that Na(+)/H(+) exchange inhibitors can attenuate Ca(2+) influx into cardiomyocytes. We therefore performed a multicenter, randomized, placebo-controlled clinical trial to test the hypothesis that inhibition of Na(+)/H(+) exchange limits infarct size and improves myocardial function in patients with acute anterior myocardial infarction (MI) treated with direct PTCA.

**METHODS AND RESULTS:** One hundred patients were randomized to receive placebo (n=51) or a 40-mg intravenous bolus of the Na(+)/H(+) exchange inhibitor cariporide (HOE 642) (n=49) before reperfusion. Global and regional left ventricular functions were analyzed by use of paired contrast left ventriculograms performed before and 21 days after PTCA and myocardial enzymes (ie, creatine kinase :CK, CK-MB, and LDH) as markers for myocardial tissue injury were evaluated. At follow-up, the ejection fraction was higher (50% versus 40%;  $P<0.05$ ) and the end-systolic volume was lower (69.0 versus 97.0 mL;  $P<0.05$ ) in the cariporide group. Significant improvements in some indices of regional wall motion abnormalities were observed, such as the percentage of chords with hypokinesis  $< -2$  SD ( $P=0.045$ ) and the severity of hypokinesis in the border zone of the infarct region ( $P=0.052$ ). In addition, CK, CK-MB, or LDH release was significantly reduced in the cariporide patients. **CONCLUSIONS:** Our findings suggest that inhibition of Na(+)/H(+) exchange by cariporide may attenuate reperfusion injury and thereby improve the recovery from left ventricular dysfunction after MI.

Figure 1. LV function at baseline and after 3 weeks in placebo- and cariporide-treated patients. A, End-systolic volume (mL); B, end-diastolic volume (mL); C, ejection fraction (%). Data are given as mean $\pm$ SEM. Significance

between treatment groups refers to change in values from baseline to follow-up.

Figure 4. Enzyme activity at baseline and 4,12,24,36 and 72hours after ptca in patients treated with placebo (black up pointing small triangle) and cariporide(·).A,CK;B,CK-MB;C,LDH.Significance between treatment groups refers to peak concentration(Cmax), area under curve (AUC),or time until peak concentration (tmax)

JAMA 2000 Jun; 283(22):2941-7

Relationship of symptom-onset-to-balloon time and door-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction

Cannon CP. Gibson CM. Lambrew CT. Shoultz DA. Levy D. French WJ. Gore JM. Weaver WD. Rogers WJ. Tiefenbrunn AJ.

**CONTEXT:** Rapid time to treatment with thrombolytic therapy is associated with lower mortality in patients with acute myocardial infarction (MI). However, data on time to primary angioplasty and its relationship to mortality are inconclusive. **OBJECTIVE:** To test the hypothesis that more rapid time to reperfusion results in lower mortality in the strategy of primary angioplasty. **DESIGN:** Prospective observational study of data collected from the Second National Registry of Myocardial Infarction between June 1994 and March 1998. **SETTING:** A total of 661 community and tertiary care hospitals in the United States. **SUBJECTS:** A cohort of 27,080 consecutive patients with acute MI associated with ST-segment elevation or left bundle-branch block who were treated with primary angioplasty. **MAIN OUTCOME MEASURE:** In-hospital mortality, compared by time from acute MI symptom onset to first balloon inflation and by time from hospital arrival to first balloon inflation (door-to-balloon time). **RESULTS:** Using a multivariate logistic regression model, the adjusted odds of in-hospital mortality did not increase significantly with increasing delay from MI symptom onset to first balloon inflation. However, for door-to-balloon time (median time 1 hour 56 minutes), the adjusted odds of mortality were significantly increased by 41% to 62% for patients with door-to-balloon times longer than 2 hours (for 121-150 minutes: odds ratio [OR], 1.41; 95% confidence interval [CI], 1.08-1.84; P=.01; for 151-180 minutes: OR, 1.62; 95% CI, 1.23-2.14; P<.001; and for >180 minutes: OR, 1.61; 95% CI, 1.25-2.08; P<.001). **CONCLUSIONS:** The relationship in our study between increased mortality and delay in door-to-balloon time longer than 2 hours (present in nearly 50% of this cohort) suggests that physicians and health care systems should work to minimize door-to-balloon times and that door-to-balloon time should be considered when

choosing a reperfusion strategy. Door-to-balloon time also appears to be a valid quality-of-care indicator.

Eur Heart J 2000 May; 21(10):823-31

Multicentre randomized trial comparing transport to primary angioplasty vs immediate thrombolysis vs combined strategy for patients with acute myocardial infarction presenting to a community hospital without a catheterization laboratory. The PRAGUE study

Widimsky P. Groch L. Zelizko M. Aschermann M. Bednar F. Suryapranata H.

**BACKGROUND:** Primary coronary angioplasty is an effective reperfusion strategy in acute myocardial infarction. However, its availability is limited, and transporting patients to an angioplasty centre in the acute phase of myocardial infarction has not yet been proved safe.

**METHODS:** The PRAGUE study (PRimary Angioplasty in patients transferred from General community hospitals to specialized PTCA Units with or without Emergency thrombolysis) compared three reperfusion strategies in patients with acute myocardial infarction, presenting within 6 h of symptom onset at community hospitals without a catheterization laboratory: group A - thrombolytic therapy in community hospitals (n=99), group B - thrombolytic therapy during transportation to angioplasty (n=100), group C - immediate transportation for primary angioplasty without pre-treatment with thrombolysis (n=101).

**RESULTS:** No complications occurred during transportation in group C. Two ventricular fibrillations occurred during transportation in group B. Median admission-reperfusion time in transported patients (group B 106 min, group C 96 min) compared favourably with the anticipated >90 min in group A. The combined primary end-point (death/reinfarction/stroke at 30 days) was less frequent in group C (8%) compared to groups B (15%) and A (23%,  $P<0.02$ ). The incidence of reinfarction was markedly reduced by transport to primary angioplasty (1% in group C vs 7% in group B vs 10% in group A,  $P<0.03$ ).

**CONCLUSIONS:** Transferring patients from community hospitals to a tertiary angioplasty centre in the acute phase of myocardial infarction is feasible and safe. This strategy is associated with a significant reduction in the incidence of reinfarction and the combined clinical end-point of death/reinfarction/stroke at 30 days when compared to standard thrombolytic therapy at the community hospital.

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Relation of phasic coronary flow velocity characteristics with TIMI perfusion grade and myocardial recovery after primary percutaneous transluminal coronary angioplasty and rescue stenting

Akasaka T. Yoshida K. Kawamoto T. Kaji S. Ueda Y. Yamamuro A. Takagi T. Hozumi T

**BACKGROUND:** A residual stenosis and/or microvascular damage have been proposed as mechanisms of TIMI 2 flow for acute myocardial infarction. Coronary flow dynamics were assessed in patients with TIMI 2 flow to predict whether additional intervention would improve TIMI grade.

**METHODS AND RESULTS:** In 35 patients who had a successfully recanalized anterior acute myocardial infarction using angioplasty or rescue stenting, coronary flow patterns were compared with corresponding TIMI grade and regional left ventricular wall motion (LVWM) 1 month after the intervention. After angioplasty, the time-averaged peak velocity (APV) was lower in patients with TIMI 2 flow (n=22) than in those with TIMI 3 flow (n=13;  $7.9\pm 3.9$  versus  $20.6\pm 5.1$  cm/s;  $P<0.001$ ). Two different flow patterns were recorded in patients with TIMI 2 flow (versus TIMI 3,  $P<0.001$ ); patients with type 1 TIMI 2 flow (n=15) had a reduced diastolic APV ( $8.3\pm 4.8$  versus  $24.2\pm 7.4$  cm/s), prolonged diastolic deceleration time ( $1176\pm 455$  versus  $728\pm 205$  ms), and a small diastolic/systolic APV ratio ( $1.3\pm 0.6$  versus  $2.1\pm 0.7$ ); patients with type 2 TIMI 2 flow (n=7) had systolic flow reversal (systolic APV,  $-7.9\pm 4.6$  versus  $11.7\pm 4.5$  cm/s), a rapid diastolic deceleration time ( $221\pm 84$  versus  $728\pm 205$  ms), and a negative diastolic/systolic APV ratio ( $-2.1\pm 1.4$  versus  $2.1\pm 0.7$ ). A significantly lower mean chord LVWM ( $-3.0\pm 0.2$  versus  $-1.9\pm 0.8$ ;  $P<0.001$ ) and a greater number of chords  $<-2SD$  ( $50\pm 2$  versus  $28\pm 18$ ;  $P<0.001$ ) were present in patients with type 2 versus type 1 TIMI 2 flow. Stenting increased TIMI 2 flow to TIMI 3 flow more in patients with type 1 than type 2 flow (67% versus 0%;  $P=0.003$ ). Patients with TIMI 2 flow after stenting continued to demonstrate a type 2 pattern, and they had poor LVWM recovery.

**CONCLUSIONS:** The differentiation between 2 types of TIMI 2 flow can predict the improvement of TIMI grade and LVWM recovery after additional stenting.

J Invasive Cardiol 2000 Jan; 12(1):13-9

Influence of vessel size on early and late outcomes after primary angioplasty for acute myocardial infarction

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Small vessel size is associated with worse outcomes after elective angioplasty, but the effect of vessel size on outcomes after primary angioplasty for acute myocardial infarction has not been studied. We evaluated outcomes in 1,490 consecutive patients treated with primary angioplasty comparing patients with small (< 3.0 mm) versus large (3.0 mm) vessels. Outcomes were worse in patients with small vessels with lower procedural success rates (92% versus 96%;  $p = 0.002$ ), higher rates of reinfarction (5.5% vs. 3.4%;  $p = 0.07$ ), more late reocclusion (12.5% vs. 4.1%;  $p = 0.002$ ), less improvement in ejection fraction (1.8% vs. 4.2%;  $p = 0.04$ ), lower follow-up ejection fraction (53.7% vs. 56.5%;  $p = 0.03$ ), and higher 30-day and late mortality (12.5% vs. 6.4%;  $p = 0.0002$ ). The higher mortality can be explained by a higher baseline risk profile combined with worse procedural results and higher rates of reocclusion and reinfarction. These data stress the importance of developing new strategies to improve procedural and late outcomes after primary angioplasty in patients with small vessels.

Circulation 2000 May; 101(18):2154-9

Beneficial effects of intracoronary adenosine as an adjunct to primary angioplasty in acute myocardial infarction

Marzilli M. Orsini E. Marraccini P. Testa R

**BACKGROUND:** The benefits of vessel recanalization in acute myocardial infarction (AMI) are limited by reperfusion damage. In animal models, adenosine limits reperfusion injury, reducing infarct size and improving ventricular function. The aim of this study was to evaluate the safety and feasibility of adenosine adjunct to primary PTCA in AMI.

**METHODS AND RESULTS:** Fifty-four AMI patients undergoing primary PTCA were randomized to intracoronary adenosine or saline. The 2 groups were similar for age, sex, and infarct location. Adenosine administration was feasible and well tolerated. PTCA was successful in all patients and resulted in TIMI 3 flow in all patients given adenosine and in 19 given saline ( $P < 0.05$ ). The no-reflow phenomenon occurred in 1 adenosine patient and in 7 saline patients ( $P = 0.02$ ). Creatine kinase was lower in the adenosine group, and a Q-wave MI developed in 16 adenosine patients and in 23 saline patients ( $P = 0.04$ ). Sixty-four percent of dyssynergic segments improved in the adenosine group and 36% in the saline group ( $P = 0.001$ ). Function worsened in 2% of dysynergic segments in the adenosine group and in 20% in the saline group ( $P = 0.0001$ ). Adverse cardiac events occurred in 5 patients in the adenosine group and in 13 patients in the saline group ( $P = 0.03$ ).

**CONCLUSIONS:** Intracoronary adenosine administration is feasible and well tolerated in AMI. Adenosine adjunct to primary PTCA ameliorates flow, prevents the no-reflow phenomenon, improves ventricular function, and is associated with a more favorable clinical course.

Figure 1. Effect of adenosine (ADO) on coronary blood flow. Intracoronary adenosine was associated with TIMI 3 flow and with a significant reduction in prevalence of no-reflow phenomenon.

Figure 2. Effect of adenosine (ADO) on clinical course. In adenosine group, a significant reduction of death, Q-wave MI, and major adverse cardiac events (MACE) was observed.

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The volume of primary angioplasty procedures and survival after acute myocardial infarction. National Registry of Myocardial Infarction 2 Investigators

Canto JG. Every NR. Magid DJ. Rogers WJ. Malmgren JA. Frederick PD. French WJ. Tiefenbrunn AJ. Misra VK. Kiefe CI. Barron HV.

**BACKGROUND:** There is an inverse relation between mortality from cardiovascular causes and the number of elective cardiac procedures (coronary angioplasty, stenting, or coronary bypass surgery) performed by individual practitioners or hospitals. However, it is not known whether patients with acute myocardial infarction fare better at centers where more patients undergo primary angioplasty or thrombolytic therapy than at centers with lower volumes. **METHODS:** We analyzed data from the National Registry of Myocardial Infarction to determine the relation between the number of patients receiving reperfusion therapy (primary angioplasty or thrombolytic therapy) and subsequent in-hospital mortality. A total of 450 hospitals were divided into quartiles according to the volume of primary angioplasty. Multiple logistic-regression models were used to determine whether the volume of primary angioplasty procedures was an independent predictor of in-hospital mortality among patients undergoing this procedure. Similar analyses were performed for patients receiving thrombolytic therapy at 516 hospitals. **RESULTS:** In-hospital mortality was 28 percent lower among patients who underwent primary angioplasty at hospitals with the highest volume than among those who underwent angioplasty at hospitals with the lowest volume (adjusted relative risk, 0.72; 95 percent confidence interval, 0.60 to 0.87;  $P < 0.001$ ). This lower rate, which represented 2.0 fewer deaths per 100 patients treated, was independent of the total volume of patients with myocardial infarction at each hospital, year of admission, and use or nonuse of adjunctive pharmacologic therapies. There was no significant relation between the volume of thrombolytic interventions and in-hospital mortality among patients who received thrombolytic

therapy (7.0 percent for patients in the highest-volume hospitals vs. 6.9 percent for those in the lowest-volume hospitals,  $P=0.36$ ). CONCLUSIONS: Among hospitals in the United States that have full interventional capabilities, a higher volume of angioplasty procedures is associated with a lower mortality rate among patients undergoing primary angioplasty, but there is no association between volume and mortality for thrombolytic therapy.

Arch Int Med 2000 Apr; 160(7):947-52

Are beta-blockers effective in elderly patients who undergo coronary revascularization after acute myocardial infarction?

Chen J. Radford MJ. Wang Y. Marciniak TA. Krumholz HM

**BACKGROUND:** Although randomized clinical trials have demonstrated that beta-blocker therapy is effective in reducing mortality after acute myocardial infarction (AMI), many of these studies excluded patients who undergo coronary revascularization. However, the clinical practice guidelines established by the American College of Cardiology and the American Heart Association recommend that beta-blocker therapy be considered for patients who underwent successful revascularization after AMI.

**METHODS:** Using data from the Cooperative Cardiovascular Project, we compared the initiation of beta-blocker therapy at discharge in patients aged 65 years or older who underwent coronary artery bypass surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA) during their hospitalization for AMI with that of patients who did not undergo revascularization. We then examined whether beta-blocker therapy was associated with lower 1-year mortality between revascularized and nonrevascularized groups.

**RESULTS:** After excluding patients with contraindications to beta-blocker therapy, 84 457 patients remained in the study sample. Of these, 8482 patients underwent CABG, and 13 997 patients underwent PTCA. After adjusting for demographic and clinical factors, we found that these patients were less likely to initiate beta-blocker therapy after CABG (odds ratio [OR], 0.44; 95% confidence interval [CI], 0.41-0.47) or PTCA (OR, 0.89; 95% CI, 0.85-0.93) relative to the nonrevascularized group. After adjusting for potential confounders, beta-blockers were significantly associated with lower 1-year mortality in patients who underwent CABG (hazard ratio [HR], 0.70; 95% CI, 0.55-0.89) or PTCA (HR, 0.86; 95% CI, 0.74-1.00), similar to that of the nonrevascularized group (HR, 0.83; 95% CI, 0.80-0.87).

**CONCLUSIONS:** Therapy after AMI with beta-blockers appears to be as effective in reducing 1-year mortality for elderly patients who have undergone CABG or PTCA as for a nonrevascularized group. Our findings

suggest that routine use of beta-blockers should be considered for patients who undergo revascularization after AMI.

Circulation 2000 102: 1611-1616.

### Elevated Troponin I Level on Admission Is Associated With Adverse Outcome of Primary Angioplasty in Acute Myocardial Infarction

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**Background**-In patients with acute myocardial infarction (AMI) undergoing thrombolytic therapy, an elevated troponin level on admission is associated with a lower reperfusion rate and a complicated clinical course. Whether an elevated troponin level on admission similarly predicts an adverse outcome in patients undergoing primary angioplasty is currently unknown and was investigated in the present study.

**Methods and Results**-Cardiac troponin I (cTnI) was determined on admission in 110 consecutive patients with AMI associated with ST-segment elevation or left bundle branch block who underwent primary angioplasty. Fifty-four patients (49%) had an elevated cTnI (0.4 ng/mL) on admission. In patients with elevated cTnI, primary angioplasty was less likely to achieve TIMI 3 flow (as classified by the Thrombolysis in Myocardial Infarction trial) in univariate (76% versus 96%,  $P=0.03$ ) or in multivariate (odds ratio 0.1, 95% CI 0.02 to 0.54) analysis. Patients with elevated cTnI were more likely to develop congestive heart failure (23% versus 9%,  $P<0.05$ ) and death, heart failure, or shock (30% versus 9%,  $P=0.006$ ). Elevated cTnI remained a significant predictor of the composite end point after controlling for other clinical data that were available early in the course, including time to presentation and angiographic results (relative risk 5.2, 95% CI 1.03 to 26.3). During a follow-up of  $426\pm 50$  days, elevated admission cTnI was a predictor of cardiac mortality (11% versus 0%,  $P=0.012$ ), adverse cardiac events (cardiac mortality or nonfatal reinfarction; 19% versus 5.4%,  $P=0.04$ ), and adverse cardiac events plus target vessel revascularization (32% versus 14%,  $P=0.054$ ).

**Conclusions**-In patients with ST-segment elevation AMI, an elevated cTnI on admission is associated with an increased risk of primary angioplasty failure and a more complicated clinical course.

Figure 2. Long-term ( $425\pm 50$ -day) adverse event rate according to admission cTnI level. Cardiac event indicates death or nonfatal myocardial infarction; TVR, target-vessel revascularization; and Pt, patient.

Figure 3. Kaplan-Meier curves of event-free survival in patients with elevated cTnI ( $\geq 0.4$  ng/mL) compared with patients with normal cTnI on admission.

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