

## **Pulmonary hemorrhage after percutaneous coronary intervention with abciximab therapy.**

**Choi RK, Lee NH, Lim DS, Hong S, Hwang HK.**

**A**bciximab has a key role in the treatment of patients with acute coronary syndromes undergoing percutaneous coronary intervention; however, an increased risk of bleeding complications is well recognized. We report a case of serious pulmonary hemorrhage after use of abciximab therapy. A definitive indication and treatment guideline should be available to minimize serious bleeding complications. Additionally, respiratory symptoms should be monitored closely for early detection of serious pulmonary hemorrhage in patients receiving abciximab therapy during percutaneous coronary intervention.

**Coronary flow velocity pattern immediately after percutaneous coronary intervention as a predictor of complications and in-hospital survival after acute myocardial infarction.**

Yamamuro A, Akasaka T, Tamita K, Yamabe K, Katayama M, Takagi T, Morioka S.

**B**ACKGROUND: Recently, it was reported that the degree of microvascular injury and left ventricular functional recovery during the chronic period can be predicted after treatment of the infarct-related artery based on the coronary flow velocity (CFV) pattern assessed using a Doppler guidewire. The aim of this prospective study was to examine whether the CFV pattern may predict complications and in-hospital survival after acute myocardial infarction (AMI). **METHODS AND RESULTS:** The study population consisted of 169 consecutive patients with a first anterior AMI successfully treated with percutaneous coronary intervention (PCI). We examined the CFV pattern immediately after PCI using a Doppler guidewire. In accordance with previous findings, we defined severe microvascular injury as a diastolic deceleration time  $\leq 600$  ms and the presence of systolic flow reversal. Patients were divided into two groups: those without severe microvascular injury (n=118; group 1) and those with severe microvascular injury (n=51; group 2). All of the patients who had cardiac rupture were in group 2. Congestive heart failure (CHF) was observed more frequently in group 2 than in group 1 (53% versus 8%,  $P < 0.001$ ). The in-hospital cardiac mortality rate was significantly higher in group 2 than in group 1 (18% versus 0%,  $P < 0.001$ ). Nine patients in group 2 died, 5 patients because of CHF and 4 patients because of cardiac rupture. **CONCLUSIONS:** These findings suggest that the CFV pattern is an accurate predictor of the presence or absence of complications and of in-hospital survival after AMI.

**Plaque gruel of atheromatous coronary lesion may contribute to the no-reflow phenomenon in patients with acute coronary syndrome.**

Kotani J, Nanto S, Mintz GS, Kitakaze M, Ohara T, Morozumi T, Nagata S, Hori M.

**B**ACKGROUND: No-reflow associated with direct angioplasty (PCI) of patients with acute coronary syndromes (ACS) is associated with unfavorable results. METHODS AND RESULTS: We used a new thrombectomy device to treat 51 lesions in 48 consecutive ACS patients (40 male and 8 female; mean age 63 years) and conducted a microscopic analysis of aspirates and blood samples retrieved from the culprit coronary artery. The first aspirate was collected before PCI and the second was collected separately after percutaneous transluminal coronary angioplasty or stenting, including samples from the no-reflow lumen. Light microscopy showed that the materials obtained from the pre-PCI aspiration consisted of thrombus in 37.5%, thrombus and atheroma in 35.0%, and atheromatous plaque in 27.5%. The materials collected from the post-PCI aspiration were thrombus in 8.3%, thrombus and atheroma in 41.7%, and atheromatous plaque in 50.0%. We then compared the 9 lesions (19.1%) with no-reflow to those without no-reflow. There was no difference in the pre-PCI aspirates. However, after PCI, there was more atheromatous plaque retrieved from patients with no-reflow ( $P < 0.001$ ) as well as significantly more platelet and fibrin complex, macrophages, and cholesterol crystals in the blood aspirated from no-reflow cases. Aspiration of these elements improved the no-reflow in 7 of 9 lesions to TIMI-3 flow. CONCLUSIONS: No-reflow after angioplasty may be caused by gruel that formed from an atheroma attributable to mechanical plaque disruption during intervention.

**Acute cardiogenic shock immediately after successful intervention for failed thrombolysis.**

Constantinides S, Wong P, Shiu MF.

We report the case of a 60-year-old female with a history of hypertension who was admitted with an acute inferior myocardial infarction. She received rescue percutaneous transluminal coronary angioplasty/stenting of an occluded right coronary artery for failed thrombolysis with a good initial result. However, this was immediately complicated by cardiogenic shock characterized by left ventricular outflow tract (LVOT) gradient. She was treated with intravenous fluids and adrenaline. Predischarge echocardiography showed no LVOT gradient and features of left ventricular hypertrophy that mainly affected the septum.

## **Prognostic implication of cardiac troponin T increase following stent implantation.**

**Herrmann J, Von Birgelen C, Haude M, Volbracht L, Malyar N, Eggebrecht H, Konorza TF, Baumgart D, Erbel R.**

**O**BJECTIVE: To identify the incidence and clinical significance of myocardial injury following elective stent implantation. DESIGN: Prospective clinical study with 278 consecutive patients undergoing stenting of de novo coronary or saphenous vein graft lesions. Incidence of periprocedural myocardial injury was assessed by analysis of 12 lead ECG, creatine kinase (CK; upper limit of normal (ULN) 70 IU/l for women, 80 IU/l for men), and cardiac troponin T (cTnT; point of care test; threshold 0.1 ng/ml) before and 6, 12, and 24 hours after the intervention. Major adverse cardiac events (MACE: acute myocardial infarction, bypass surgery, and cardiac death) were recorded during clinical follow up (mean (SD) 7.8 (5.3) months). RESULTS: Following elective stenting, the rate of a positive cTnT status was 17.3%, the rate of CK increase of 1-3x ULN 14.7%, the rate of CK increase of > 3x ULN 1.4%, and the rate of Q wave myocardial infarction 0.4%. Cardiac mortality during follow up was higher in patients with postprocedurally increased CK (7.1% v 1.3%,  $p = 0.01$ , log rank) and cTnT (9.1% v 0.9%,  $p < 0.001$ , log rank). In addition, postprocedurally increased cTnT was associated with a higher overall incidence of MACE (13.1% v 4.0%,  $p < 0.01$ , log rank) and was identified as an independent factor for MACE during follow up (hazard ratio 3.27, 95% confidence interval 1.14 to 9.41,  $p = 0.028$ ). CONCLUSIONS: Following elective stent implantation, a positive cTnT status identified patients at risk of a worse long term outcome. Treatment strategies have to be developed that lead to prognostic improvement by reducing periprocedural myocardial injury.

## **Incidence and prognostic importance of acute renal failure after percutaneous coronary intervention.**

Rihal CS, Textor SC, Grill DE, Berger PB, Ting HH, Best PJ, Singh M, Bell MR, Barsness GW, Mathew V, Garratt KN, Holmes DR Jr.

**B**ACKGROUND: In patients undergoing percutaneous coronary intervention (PCI) in the modern era, the incidence and prognostic implications of acute renal failure (ARF) are unknown. **METHODS AND RESULTS:** With a retrospective analysis of the Mayo Clinic PCI registry, we determined the incidence of, risk factors for, and prognostic implications of ARF (defined as an increase in serum creatinine [Cr] >0.5 mg/dL from baseline) after PCI. Of 7586 patients, 254 (3.3%) experienced ARF. Among patients with baseline Cr <2.0, the risk of ARF was higher among diabetic than nondiabetic patients, whereas among those with a baseline Cr >2.0, all had a significant risk of ARF. In multivariate analysis, ARF was associated with baseline serum Cr, acute myocardial infarction, shock, and volume of contrast medium administered. Twenty-two percent of patients with ARF died during the index hospitalization compared with only 1.4% of patients without ARF ( $P<0.0001$ ). After adjustment, ARF remained strongly associated with death. Among hospital survivors with ARF, 1- and 5-year estimated mortality rates were 12.1% and 44.6%, respectively, much greater than the 3.7% and 14.5% mortality rates in patients without ARF ( $P<0.0001$ ). **CONCLUSIONS:** The overall incidence of ARF after PCI is low. Diabetic patients with baseline Cr values <2.0 mg/dL are at higher risk than nondiabetic patients, whereas all patients with a serum Cr >2.0 are at high risk for ARF. ARF was highly correlated with death during the index hospitalization and after dismissal.

## **Thrombocytopenia associated with c7E3 Fab (abciximab).**

**Schell DA, Ganti AK, Levitt R, Potti A.**

**A**bciximab (c7E3 Fab) inhibits platelet aggregation and is used to prevent complications of percutaneous coronary intervention. Thrombocytopenia is an often-cited complication of abciximab. Pseudothrombocytopenia is due to ethylenediaminetetraacetate (EDTA)-activated platelet agglutination, resulting in a spuriously low platelet count. We have looked at both "true" and pseudothrombocytopenia after infusion of abciximab. Sixty-six patients receiving their first exposure to abciximab after an unstable coronary event/revascularization were eligible. All the patients received a bolus of c7E3 Fab followed by a continuous infusion. Platelets were monitored in all patients at 2, 4, 12, 24, and 48 h, and more frequently if required. The incidence of thrombocytopenia and acute severe thrombocytopenia (platelet count  $\leq$  20,000/microl) was evaluated. A peripheral blood smear was performed on all patients showing thrombocytopenia to evaluate for pseudothrombocytopenia. Seventeen (25.6%) developed thrombocytopenia and nine (13.6%) developed acute severe thrombocytopenia. However, 18 of these patients had pseudothrombocytopenia. The onset of true thrombocytopenia was at 4 h after the infusion, while pseudothrombocytopenia occurred at anytime during the first 24 h. Only two (3.03%) patients required platelet transfusions. No life-threatening hemorrhagic complications were recognized. Five of six subjects with true thrombocytopenia had positive laboratory findings of disseminated intravascular coagulation; however, none had an adverse outcome. Acute severe thrombocytopenia was noted to be a relatively benign adverse effect of abciximab. There is an increasing incidence of pseudothrombocytopenia in this subgroup of patients. It would be worthwhile examining a peripheral blood smear or collecting blood for platelet counts in a heparin-coated tube in order to exclude this phenomenon and thereby prevent inappropriate discontinuation of this drug.

## **Late stent thrombosis in brachytherapy: the role of long-term antiplatelet therapy.**

**Teirstein P, Reilly JP.**

**A**dvances in percutaneous coronary intervention (PCI) have emerged in the past decade. Stenting has improved upon the limitations of angioplasty, acute vessel closure and restenosis by providing mechanical vascular support, resulting in sustained clinical and angiographic benefit. This has led to greater utilization of the technique, although it is associated with a significant incidence of in-stent restenosis. Neointimal hyperplasia is the pathophysiologic process that leads to in-stent restenosis. Brachytherapy can be effective in reducing the occurrence of this process. Unfortunately, brachytherapy trials have identified the phenomenon of late stent thrombosis as a potentially serious complication of this procedure. Late stent thrombosis is thrombosis that occurs > 30 days after PCI. The risk of thrombosis is increased in patients receiving a new stent in addition to brachytherapy. It also appears to be increased when adjunctive antiplatelet therapy with ticlopidine or clopidogrel is discontinued early. Strategies to prevent late stent thrombosis include the prolonged use of combination antiplatelet therapy in addition to limited placement of new stents in patients treated with brachytherapy for in-stent restenosis

## **Predictive elements and prevention of myocardial damage during angioplasty/stenting**

**Bossi I, Savonitto S, Cavallini C, Delgado A, Pirola R, Klugmann S.**

Cardiac enzyme elevation is observed in 5-30% of patients after percutaneous intervention and appears associated with higher subsequent cardiac events and mortality. The cause of myocardial enzyme release could be an obvious angiographic complication of the procedure but, most frequently, is neither clinically nor angiographically clear. Different clinical series have identified clinical, angiographic and procedural risk factors for CK-MB elevation after otherwise successful coronary intervention, including unstable angina, diffuse atherosclerosis and aggressive procedures such as atheroablation. Microembolization of atherothrombotic plaque material appears to be the pathogenetic mechanism. Periprocedural administration of platelet glycoprotein IIb/IIIa inhibitors has been shown to reduce subsequent myocardial infarction and long-term mortality. Beta-blockers may also have a protective effect against post-procedural CK-MB elevations and follow-up cardiac events. New distal protection devices are under investigation and appear promising. The risk of inducing myocardial damage during percutaneous intervention should be considered before attempting the procedure. The use of platelet IIb/IIIa inhibitors and protection devices should be considered in high-risk patients.

**Frequency of abrupt vessel closure and side branch occlusion after percutaneous coronary intervention in a 6.5-year period (1994 to 2000) at a single medical center.**

Almeda FQ, Nathan S, Calvin JE, Parrillo JE, Klein LW.

The aims of this study were to analyze the contemporary trends in the changing incidence of abrupt vessel closure (AVC) after percutaneous coronary intervention (PCI), to determine the impact of intracoronary stenting and glycoprotein IIb/IIIa inhibitors (GPIs) on complication rates and etiologies, and to determine the incidence of side branch occlusion (SBO) as the etiology of AVC in the stent era, complications occurring during 3,300 consecutive PCIs performed from April 1994 to December 2000 at a single referral institution. In this consecutive patient cohort of PCI cases collected over a 6.5-year period, AVC occurred in 103 of 3,300 cases (3.12%). Linear regression analysis over this time frame documented a steadily decreasing incidence of AVC from 5.9% in 1994 to 1.1% in 2000 ( $-0.76\%$ /per year, 95% confidence interval  $-0.99$  to  $0.52$ ,  $p < 0.05$ ). Analysis using Pearson's correlation showed that the decreasing incidence of AVC was inversely correlated with the increasing percentage of intracoronary stents placed over this time period ( $r = -0.94$ ,  $p < 0.001$ ). Additionally, GPI use increased from 0% in 1995 to 36.0% in 2000 ( $p = 0.009$ ). The absolute incidence of SBO of a major branch vessel remained relatively stable over this 6.5-year period. However, SBO appeared to be increasing as the etiology of AVC, and accounted for 9.0% of AVC in 1995 compared with 28.0% of AVC in 2000. This increasing trend of the percentage of SBO as the etiology of AVC appeared to correlate with the increased use of stents ( $r = 0.85$ ,  $p = 0.015$ ). Thus, the incidence of AVC steadily decreased over the 6.5-year time period, and was associated with the increased use of stents and GPIs; conversely, SBO accounted for an increasing percentage of AVC over this time period.

## **Early and late clinical outcomes following coronary perforation in patients undergoing percutaneous coronary intervention.**

**Fukutomi T, Suzuki T, Popma JJ, Hosokawa H, Yokoya K, Inada T, Hayase M, Kondo H, Ito S, Suzuki S, Itoh M.**

Coronary perforation is a rare but serious complication that occurs during percutaneous coronary intervention (PCI). This study examines the frequency of coronary perforation during PCI, evaluates the management strategies used to treat perforations, and describes the long-term prognosis of patients who have developed coronary perforation during PCI. Coronary perforations were found in 69 (0.93%) of 7,443 consecutive PCI procedures, occurring more often after use of a new device (0.86%) than after use of balloon angioplasty (0.41%) ( $p < 0.05$ ). Coronary perforation was attributable solely to the coronary guidewire in 27 (0.36%) cases. Coronary perforations were divided into 2 types: (1) Those with epicardial staining without a jet of contrast extravasation (type I,  $n = 51$ ), and (2) those with a jet of contrast extravasation (type II,  $n = 18$ ). Patients with type I and type II perforations were managed by observation only (35% and 0%, respectively), reversal of anticoagulation (57% and 94%), pericardiocentesis and drainage (27% and 61%), and prolonged perfusion balloon angioplasty (16% and 100%). Two patients with type II perforations required emergency coronary artery bypass surgery. There were no in-hospital deaths. Late pseudoaneurysms developed in 18 (28.6%) patients during the  $13.4 \pm 11.3$  months' follow-up period, and were more common in patients with type II perforations (72.2% vs 11.1% with type I perforations;  $p < 0.001$ ). During the follow-up period, no patient had evidence of coronary rupture. The results suggest that coronary perforation is uncommon after PCI, and can be managed without cardiac surgery in the majority of cases. Late pseudoaneurysms developed in some patients, particularly in patients with type II perforations, but there were no late consequences of coronary perforation after PCI.

## **Embolism prevention during interventional treatment of aortocoronary bypass stenoses**

**Muller R, Grube E.**

**N**o-reflow is an unpredictable complication after percutaneous intervention in saphenous vein grafts. Plaque embolism, vasoconstriction and thrombosis are mechanisms that lead to poor distal run-off. Treatments with alternative techniques like DCA, TEC and ELCA as well as pharmacological attempts like GP IIb/IIIa inhibitors, vasodilators and calcium-channel blockers do not improve outcome. This is the rationale for the development of mechanical devices to prevent distal embolization. Two concepts of distal protection devices are currently realized: occlusive balloon and filtering devices. The largest experience comes from the PercuSurge GuardWire, an occlusive balloon device. The recently presented data from the SAFER trial showed a significant prevention of distal embolization and improvement in clinical outcome. The second generation of filter devices is under investigation; the advantages of these systems are the preservation of blood flow and precise angiography-guided stent positioning. Another issue of investigation is a broader use of protection devices in carotid stenting, and in interventions in acute MI and acute coronary syndromes.

## **Predictors of length of stay after coronary stenting.**

**Aronow HD, Peyser PA, Eagle KA, Bates ER, Werns SW, Russman PL, Crum MA, Harris K, Moscucci M.**

**B**ACKGROUND: Postprocedure length of stay (LOS) remains an important determinant of medical costs after coronary stenting. Variables that predict LOS in this setting have not been well characterized. METHODS: We evaluated 359 consecutive patients who underwent coronary stenting with antiplatelet therapy. Sequential multiple linear regression (MLR) models were constructed with use of 4 types of variables to predict log-transformed LOS: preprocedure, intraprocedure, and postprocedure factors and adverse outcomes. RESULTS: Preprocedure factors alone explained more than one third of the variability in postprocedure LOS (adjusted  $R(2) = 0.37$ ). The addition of procedural variables added little to the model (adjusted  $R(2) = 0.39$ ). Entering nonoutcome postprocedure variables significantly enhanced the predictive capacity of the model, explaining more than half the variability in postprocedure LOS (adjusted  $R(2) = 0.54$ ). In the final model, addition of outcome variables increased its predictive capacity only slightly (adjusted  $R(2) = 0.61$ ). In this model, significant preprocedure factors included: myocardial infarction (MI) within 24 hours, MI within 1 to 30 days, women with peripheral vascular disease, intravenous heparin, and chronic atrial fibrillation. High-risk intervention was the only significant intraprocedure variable. Significant postprocedure factors included periprocedure ischemia; cerebrovascular accident or transient ischemic attack; treatment with intravenous heparin or nitroglycerin or intra-aortic balloon pump; and need for blood transfusion. Significant adverse outcomes included contrast nephropathy, gastrointestinal bleeding, arrhythmia, vascular complication, and repeat angiography. CONCLUSION: This prediction model identifies a number of potentially reversible factors responsible for prolonging LOS and may enable the development of more accurate risk-adjusted methods with which to improve or compare care.

## **Vascular closure devices and the risk of vascular complications after percutaneous coronary intervention in patients receiving glycoprotein IIb-IIIa inhibitors.**

**Resnic FS, Blake GJ, Ohno-Machado L, Selwyn AP, Popma JJ, Rogers C.**

Vascular closure devices offer advantages over traditional means of obtaining hemostasis after percutaneous coronary intervention (PCI) in terms of patient comfort and time to ambulation. We investigate whether such devices also reduce the risk of vascular complications in selected patient populations. We conducted a retrospective analysis of all patients who underwent PCI at our institution between January 1998 and December 1999. Of 3,151 consecutive patients, 3,027 were eligible to receive vascular closure devices. Of these, 1,485 received a closure device and 1,409 received glycoprotein IIb-IIIa antagonists. The overall vascular complication rate, as defined by the need for surgical repair or transfusion, or the development of arteriovenous fistula, pseudoaneurysm, or large hematoma, was 4.20%. By univariate analysis, the use of closure devices was associated with a lower vascular complication rate (3.03% vs 5.52%;  $p = 0.002$ ) and a shorter length of hospital stay (2.77 vs 3.97 days,  $p < 0.001$ ). Multivariate analysis showed a significant reduction in vascular complications with closure devices (odds ratio 0.59,  $p = 0.007$ ). For the subgroup of patients receiving glycoprotein IIb-IIIa antagonists, the use of closure devices was associated with an even more pronounced reduction in the risk of vascular complications (odds ratio 0.45,  $p < 0.008$ ). Thus, the use of closure devices in selected patients undergoing PCI is associated with a low rate of vascular complications and decreased length of stay. This benefit was most marked for patients receiving glycoprotein IIb-IIIa antagonists.

## **Alveolar hemorrhage as a complication of treatment with abciximab.**

**Kalra S, Bell MR, Rihal CS.**

**STUDY OBJECTIVE:** The use of abciximab, a chimeric monoclonal antibody Fab fragment specific for platelet glycoprotein IIb/IIIa receptors, is associated with improved outcome after angioplasty and stent placement. Major complications include bleeding, but pulmonary hemorrhage has been reported rarely. This study was done to identify patients with pulmonary hemorrhage following abciximab infusion and to define, if possible, any specific risk factors. **DESIGN:** Retrospective review of institutional coronary angiography and bronchoscopy databases to identify patients who received abciximab and developed pulmonary hemorrhage. **SETTING:** Tertiary-care teaching hospital. **PATIENTS:** All patients who underwent coronary angiography and received abciximab between June 1995 and March 2000. **INTERVENTION:** None. **Measurements and results:** Seven of 2,553 patients (0.27%) had documented severe pulmonary hemorrhage associated with chest radiographic abnormalities, impaired oxygenation, and the need for blood product transfusions. The initial symptom was hemoptysis in four of the seven patients. There were two early deaths and one late death. No cases of pulmonary hemorrhage were identified in 5,412 patients who underwent coronary procedures without abciximab infusion. No other risk factors predicting hemorrhage were identified. **CONCLUSIONS:** Severe pulmonary hemorrhage is a complication of abciximab use. Although hemoptysis is an important alerting symptom, it may not be present initially and the diagnosis may be missed or considered late, with the potential for inappropriate treatment until the diagnosis is established. Lesser degrees of bleeding are potentially easily missed, and this report should alert physicians to this complication so that it can be considered early in the evaluation of patients presenting with pulmonary events after abciximab use.

## **Coronary microembolization.**

**Skyschally A, Erbel R, Heusch G.**

**A**therosclerotic plaque rupture is a key event in the pathogenesis of acute coronary syndromes and during coronary interventions. However, it does not always result in complete thrombotic occlusion of the entire epicardial coronary artery with subsequent acute myocardial infarction; in milder forms the result can be embolization of atherosclerotic and thrombotic debris into the coronary microcirculation. This review summarizes the available morphological evidence for coronary microembolization in patients who died from coronary artery disease, most notably from sudden death, and then goes on to address the experimental pathophysiology of coronary microembolization in animal models of acute coronary syndromes and heart failure. Finally, the review presents the available clinical evidence for coronary microembolization in patients, highlights its key features (ie, arrhythmias, contractile dysfunction, infarctlets and reduced coronary reserve) and addresses its prevention by mechanical protection devices and glycoprotein IIb/IIIa antagonism.

## Acute complications after coronary interventions

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11. Early and late clinical outcomes following coronary perforation in patients undergoing percutaneous coronary intervention.

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**Comparison of coronary-artery bypass surgery and stenting for the treatment of multivessel disease.**

**Serruys PW, Unger F, Sousa JE, Jatene A, Bonnier HJ, Schonberger JP, Buller N, Bonser R, van den Brand MJ, van Herwerden LA, Morel MA, van Hout BA; Arterial Revascularization Therapies Study Group.**

**BACKGROUND:** The recent recognition that coronary-artery stenting has improved the short- and long-term outcomes of patients treated with angioplasty has made it necessary to reevaluate the relative benefits of bypass surgery and percutaneous interventions in patients with multivessel disease. **METHODS:** A total of 1205 patients were randomly assigned to undergo stent implantation or bypass surgery when a cardiac surgeon and an interventional cardiologist agreed that the same extent of revascularization could be achieved by either technique. The primary clinical end point was freedom from major adverse cardiac and cerebrovascular events at one year. The costs of hospital resources used were also determined. **RESULTS:** At one year, there was no significant difference between the two groups in terms of the rates of death, stroke, or myocardial infarction. Among patients who survived without a stroke or a myocardial infarction, 16.8 percent of those in the stenting group underwent a second revascularization, as compared with 3.5 percent of those in the surgery group. The rate of event-free survival at one year was 73.8 percent among the patients who received stents and 87.8 percent among those who underwent bypass surgery ( $P < 0.001$  by the log-rank test). The costs for the initial procedure were \$4,212 less for patients assigned to stenting than for those assigned to bypass surgery, but this difference was reduced during follow-up because of the increased need for repeated revascularization; after one year, the net difference in favor of stenting was estimated to be \$2,973 per patient. **CONCLUSION:** As measured one year after the procedure, coronary stenting for multivessel disease is less expensive than bypass surgery and offers the same degree of protection against death, stroke, and myocardial infarction. However, stenting is associated with a greater need for repeated revascularization.

J Am Coll Cardiol ,2001 1;37(7):1877-82

Percutaneous and surgical interventions for in-stent restenosis: long-term outcomes and effect of diabetes mellitus.

Moustapha A, Assali AR, Sdringola S, Vaughn WK, Fish RD, Rosales O, Schroth G, Krajcer Z, Smalling RW.

**OBJECTIVE:** We examined long-term outcomes of patients with in-stent restenosis (ISR) who underwent different percutaneous interventions at the discretion of individual operators: balloon angioplasty (BA), repeat stent or rotational atherectomy (RA). We also examined long-term outcomes of patients with ISR who underwent coronary artery bypass surgery (CABG). **BACKGROUND:** In-stent restenosis remains a challenging problem, and its optimal management is still unknown. **METHODS:** Symptomatic patients ( $n = 510$ ) with ISR were identified using cardiac catheterization laboratory data. Management for ISR included BA (169 patients), repeat stenting (117 patients), RA (107 patients) or CABG (117 patients). Clinical outcome events of interest included death, myocardial infarction, target vessel revascularization (TVR) and a combined end point of these major adverse cardiovascular events (MACE). Mean follow-up was  $19 \pm 12$  months (range = 6 to 61 months).

**RESULTS:** Patients with ISR treated with repeat stent had significantly larger average post-procedure minimal lumen diameter compared with BA or RA (3.3±0.4 mm vs. 3.0±0.4 vs. 2.9±0.5, respectively,  $p < 0.05$ ). Incidence of TVR and MACE were similar in the BA, stent and RA groups (39%, 40%, 33% for TVR and 43%, 40%, 33% for MACE,  $p = NS$ ). Patients with diabetes who underwent RA had similar outcomes as patients without diabetes, while patients with diabetes who underwent BA or stent had worse outcomes than patients without diabetes. Patients who underwent CABG for ISR, mainly because of the presence of multivessel disease, had significantly better outcomes than any percutaneous treatment (8% for TVR and 23% for MACE). **CONCLUSIONS:** In this large cohort of patients with ISR and in the subset of patients without diabetes, long-term outcomes were similar in the BA, repeat stent and RA groups. Tissue debulking with RA yielded better results only in diabetic patients. Bypass surgery for patients with multivessel disease and ISR provided the best outcomes.

Heart , 2001 ;85(6):662-6

Outcomes following coronary artery bypass grafting and percutaneous transluminal coronary angioplasty in the stent era: a prospective study of all 9890 consecutive patients operated on in Scotland over a two year period.

Pell JP, Walsh D, Norrie J, Berg G, Colquhoun AD, Davidson K, Eteiba H, Faichney A, Flapan A, Hogg KJ, Jeffrey RR, Jennings K, McArthur J, Mankad P, Oldroyd K, Pell AC, Starkey IR.

**OBJECTIVE:** To determine current outcomes of percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting (CABG). **DESIGN:** The Scottish coronary revascularisation register provided prospectively collected data on case mix and in-hospital complications for all revascularisation procedures between April 1997 and March 1999 (4775 PTCA; 5115 CABG). Linkage to routine hospital discharge and death data provided follow up information on survival and repeat revascularisation. **RESULTS:** Stents were used in 51% of PTCA procedures. CABG patients were older, had more severe coronary disease, and had greater comorbidity. PTCA was more likely to be undertaken as an urgent or emergency procedure. Perioperative death and urgent surgery followed 0.3% and 0.6% of PTCA procedures, respectively. Case fatality rates were higher following CABG, with 6.7% dead within two years compared with 3.4% following PTCA. PTCA was more often followed by readmission for ischaemic heart disease, repeat angiography, or revascularisation: 22.8% of patients had repeat revascularisation within two years, compared with 1.8% following CABG.

**CONCLUSIONS:** The severity of coronary heart disease was greater than in previously published registry studies and randomised trials. Despite this, overall survival figures were comparable and repeat revascularisation rates lower, particularly following PTCA. Perioperative death and urgent surgery following PTCA were also lower. These favourable outcomes may be attributable, in part, to increased use of bail out and elective stenting.

J Am Coll Cardiol, 2001;38(1):41-8

Is early invasive treatment of unstable coronary artery disease equally effective for both women and men?  
FRISC II Study Group Investigators.

Lagerqvist B, Safstrom K, Stahle E, Wallentin L, Swahn E; FRISC II Study Group Investigators.

**BACKGROUND:** The Fragmin and fast Revascularization during InStability in Coronary artery disease (FRISC II) trial compared the effectiveness of an early invasive versus a noninvasive strategy in terms of the incidence of death and myocardial infarction (MI) in patients with unstable coronary artery disease (CAD). **OBJECTIVES:** In this subanalysis, we sought to evaluate gender differences in the effect of these different strategies. **METHODS:** The patients (749 women and 1,708 men) were randomized to early invasive or noninvasive strategies. Coronary angiography was performed within the first 7 days in 96% and 10% of the invasive and noninvasive groups, respectively, and revascularization was performed within the first 10 days in 71% and 9% of the invasive and noninvasive groups, respectively. **RESULTS:** Women presenting with unstable CAD were older, but fewer had previous infarctions, left ventricular dysfunction and elevated troponin T levels. Women had fewer angiographic changes. There was no difference in MI or death at 12 months among women in the invasive and noninvasive groups (12.4% vs. 10.5%, respectively), in contrast to the favorable effect in the invasively treated group of men (9.6% vs. 15.8%,  $p < 0.001$ ). In an interaction analysis, there was a different effect of the early invasive strategy for the two genders ( $p = 0.008$ ). **CONCLUSIONS:** Women with symptoms and/or signs of unstable CAD are older, but still have less severe CAD and a better prognosis compared with men. In contrast to its beneficial effect in men, an early invasive strategy did not reduce the risk of future events among women. Further research is warranted to identify the most appropriate treatment strategy in women with unstable CAD.

J Am Coll Cardiol , 2001;38(1):143-9

Percutaneous coronary intervention versus coronary artery bypass graft surgery for patients with medically refractory myocardial ischemia and risk factors for adverse outcomes with bypass: a multicenter, randomized trial. Investigators of the Department of Veterans Affairs Cooperative Study #385, the Angina With Extremely Serious Operative Mortality Evaluation (AWESOME).

Morrison DA, Sethi G, Sacks J, Henderson W, Grover F, Sedlis S, Esposito R, Ramanathan K, Weiman D, Saucedo J, Antakli T, Paramesh V, Pett S, Vernon S, Birjiniuk V, Welt F, Krucoff M, Wolfe W, Lucke JC, Mediratta S, Booth D, Barbieri C, Lewis D; Angina With Extremely Serious Operative Mortality Evaluation (AWESOME).

**BACKGROUND:** Percutaneous coronary intervention (PCI) and coronary artery bypass graft surgery (CABG) are being applied to high-risk populations, but previous randomized trials comparing revascularization methods have excluded a number of important high-risk groups. **OBJECTIVES:** This five-year, multicenter, randomized clinical trial was designed to compare long-term survival among patients with medically refractory myocardial ischemia and a high risk of adverse outcomes assigned to either a CABG or a PCI strategy, which could include stents. **METHODS:** Patients from 16 Veterans Affairs Medical Centers were screened to identify myocardial ischemia refractory to medical management and the presence of one or more risk factors for adverse outcome with CABG, including prior open-heart surgery, age >70 years, left ventricular ejection fraction <0.35, myocardial infarction within seven days or intraaortic balloon pump required. Clinically eligible patients (n = 2,431) underwent coronary angiography; 781 were angiographically acceptable; 454 (58% of eligible) patients consented to random assignment between CABG and PCI. **RESULTS:** A total of 232 patients was randomized to CABG and 222 to PCI. The 30-day survivals for CABG and PCI were 95% and 97%, respectively. Survival rates for CABG and PCI were 90% versus 94% at six months and 79% versus 80% at 36 months (log-rank test, p = 0.46). **CONCLUSIONS:** Percutaneous coronary intervention is an alternative to CABG for patients with medically refractory myocardial ischemia and a high risk of adverse outcomes with CABG.

Am Heart J, 2001;142(1):190-6

Urgent coronary bypass surgery for failed percutaneous coronary intervention in the stent era: Is backup still

necessary?

Shubrooks SJ Jr, Nesto RW, Leeman D, Waxman S, Lewis SM, Fitzpatrick P, Dib N.

**BACKGROUND:** Current practice guidelines for performance of percutaneous coronary intervention (PCI) in the United States mandate availability of on-site surgical backup. With the decreasing frequency of urgent coronary bypass surgery (UCABG) with newer technologies, it is unclear whether such backup continues to be necessary. **METHODS:** A database of 5655 consecutive patients undergoing PCI at a single center between August 1, 1992, and December 31, 1997, was analyzed. Outcomes were determined as well as clinical, lesion, and procedural characteristics of patients during 4 time periods preceding and during use of coronary stenting. **RESULTS:** Frequency of UCABG for failed PCI decreased from 2.2% to 0.6% in the most recent time period ( $P < .01$ ) with no change in incidence of in-hospital death or myocardial infarction. Incidence of stenting progressively increased to 72% in the latest period. Patients requiring UCABG had a higher prevalence of acute coronary syndromes (95%) and type B lesions (79%), but these characteristics were also common in patients who did not undergo UCABG. Although coronary stents were available during the last 3 periods studied, only 30% of UCABG patients had lesions or complications amenable to stenting, and stenting attempts in these patients were all unsuccessful. Despite stenting and use of perfusion balloons and intra-aortic balloon pumps, only 40% of patients having UCABG were stable and pain free on transfer to the operating room. **CONCLUSIONS:** Although use of UCABG for a failed PCI is currently very low, there are no satisfactory predictors, patients requiring UCABG are frequently clinically unstable, and availability of stenting does not reliably eliminate the need for UCABG or result in a decrease in mortality. This small group of patients continues to require readily available surgical standby.

Am Heart J , 2001;142(4):563-70

Combination of minimally invasive coronary bypass and percutaneous transluminal coronary angioplasty in the treatment of double-vessel coronary disease: Two-year follow-up of a new hybrid procedure compared with ?n-pump?double bypass grafting.

de Canniere D, Jansens JL, Goldschmidt-Clermont P, Barvais L, Decroly P, Stoupe E.

**OBJECTIVE:** Percutaneous transluminal coronary angioplasty (PTCA) or surgery can be chosen as first-line therapies in multiple-vessel coronary disease. A mammary-to-left anterior descending (LAD) graft is the most important statistical determinant of a favorable outcome after coronary artery bypass grafting (CABG) and can be performed with lower morbidity off pump through a minithoracotomy. PTCA and stenting of the ?on-LAD?vessels compete with CABG in terms of patency rates. Our purpose was to compare a combination of minimally invasive direct coronary artery bypass (MIDCAB) and PTCA with double CABG as a treatment for double-vessel coronary artery disease involving the proximal LAD. **METHODS:** Two matched groups of 20 patients with double-vessel coronary disease undergoing either sequential MIDCAB and PTCA (group 1) or double CABG on cardiopulmonary bypass (group 2) were compared. Angiographic control, complications, hospital costs, quality of life, and 2-year follow-up of ischemia are reported. **RESULTS:** All bypasses were patent at early control. Three adverse events were noted in group 1 and 17 in group 2. The hybrid-procedure group exhibited a shorter intensive care unit stay, fewer blood products transfused, less pain, better early quality of life, faster return to work, and similar cost. Three patients required a second PTCA in group 1, one of which for restenosis. At 2 years all the patients are asymptomatic with no residual ischemia. **CONCLUSIONS:** We conclude from this pilot study that the hybrid procedure is feasible and appears to be a safe therapy for double-vessel coronary artery disease and that it appears to generate less perioperative morbidity than classic double CABG does. Therefore we believe that there is room to undertake prospective randomized studies on a larger-scale basis.

J Am Coll Cardiol, 2001;38(3):659-65

Long-term clinical outcome and predictors of major adverse cardiac events after percutaneous interventions on saphenous vein grafts.

Keeley EC, Velez CA, O'eill WW, Safian RD.

**OBJECTIVES:** The purpose of this study was to examine the long-term clinical outcome after percutaneous intervention of saphenous vein grafts (SVG) and to identify the predictors of major adverse cardiac events (MACE). **BACKGROUND:** Percutaneous interventions of SVGs have been associated with more procedural complications and higher restenosis rates compared with interventions on native vessels. **METHODS:** From 1993 to 1997, 1,062 patients underwent percutaneous intervention on 1,142 SVG lesions. Procedural, in-hospital and long-term clinical outcomes were recorded in a database and analyzed. **RESULTS:** In-hospital MACE

occurred in 137 patients (13%) including death (8%), Q-wave myocardial infarction (MI) (2%) and coronary artery bypass surgery (3%). Late MACE occurred in 565 patients (54%) including death (9%), Q-wave MI (9%) and target vessel revascularization (36%). Any MACE occurred in 457 (43%) patients. Follow-up was available in 1,056 (99%) patients at 3 +/- 1 year. Univariate predictors were restenotic lesion (odds ratio [OR]: 2.47, confidence interval [CI]: 1.13 to 3.85, p = 0.0003), unstable angina (OR: 1.99, CI: 1.27 to 2.91, p = 0.04) and congestive heart failure (CHF) (OR: 1.97, CI: 1.14 to 3.24, p = 0.02) for in-hospital MACE, and peripheral vascular disease (PVD) (OR: 2.18, CI: 1.34 to 3.44, p = 0.002), intra-aortic balloon pump placement (OR: 2.08, CI: 1.13 to 3.85, p = 0.02) and previous MI (OR: 1.97, CI: 1.14 to 3.25, p = 0.007) for late MACE. Independent multivariate predictors for late MACE were restenotic lesion (relative risk [RR] 1.33, p = 0.02), PVD (RR: 1.31, p = 0.01), CHF (RR: 1.42, p = 0.01) and multiple stents (RR: 1.47, p = 0.004). Angiographic follow-up was available for 422 patients. Angiographic restenosis occurred in 122 (29%) of stented SVGs and 181 (43%) of nonstented SVGs (p = 0.04). Stent implantation did not confer a survival benefit. CONCLUSIONS: Despite the use of new interventional devices, SVG interventions are associated with significant morbidity and mortality; SVG stenting is not associated with better three-year event-free survival. This may be due to progressive disease at nonstented sites.

J Am Coll Cardiol , 2001;38(5):1440-9

Survival following coronary angioplasty versus coronary artery bypass surgery in anatomic subsets in which coronary artery bypass surgery improves survival compared with medical therapy. Results from the Bypass Angioplasty Revascularization Investigation (BARI).

Berger PB, Velianou JL, Aslanidou Vlachos H, Feit F, Jacobs AK, Faxon DP, Attubato M, Keller N, Stadius ML, Weiner BH, Williams DO, Detre KM; The BARI Investigators.

OBJECTIVES: We sought to compare survival after coronary artery bypass graft (CABG) and percutaneous transluminal coronary angioplasty (PTCA) in high-risk anatomic subsets. BACKGROUND: Compared with medical therapy, CABG decreases mortality in patients with three-vessel disease and two-vessel disease involving the proximal left anterior descending artery (LAD), particularly if left ventricular (LV) dysfunction is present. How survival after PTCA and CABG compares in these high-risk anatomic subsets is unknown. METHODS: In the Bypass Angioplasty Revascularization Investigation (BARI), 1,829 patients with multivessel disease were randomized to an initial strategy of PTCA or CABG between 1988 and 1991. Stents and Iib/IIIa

inhibitors were not utilized. Since patients in BARI with diabetes mellitus had greater survival with CABG, separate analyses of patients without diabetes were performed. RESULTS: Seven-year survival among patients with three-vessel disease undergoing PTCA and CABG (n = 754) was 79% versus 84% (p = 0.06), respectively, and 85% versus 87% (p = 0.36) when only non-diabetics (n = 592) were analyzed. In patients with three-vessel disease and reduced LV function (ejection fraction <50%), seven-year survival was 70% versus 74% (p = 0.6) in all PTCA and CABG patients (n = 176), and 82% versus 73% (p = 0.29) among non-diabetic patients (n = 124). Seven-year survival was 87% versus 84% (p = 0.9) in all PTCA and CABG patients (including diabetics) with two-vessel disease involving the proximal LAD (n = 352), and 78% versus 71% (p = 0.7) in patients with two-vessel disease involving the proximal LAD with reduced LV function (n = 72). CONCLUSION: In high-risk anatomic subsets in which survival is prolonged by CABG versus medical therapy, revascularization by PTCA and CABG yielded equivalent survival over seven years.

J Am Coll Cardiol , 2002;39(2):266-73

Percutaneous coronary intervention versus coronary bypass graft surgery for patients with medically refractory myocardial ischemia and risk factors for adverse outcomes with bypass: The VA AWESOME multicenter registry: comparison with the randomized clinical trial.

Morrison DA, Sethi G, Sacks J, Henderson W, Grover F, Sedlis S, Esposito R, Ramanathan KB, Weiman D, Talley JD, Saucedo J, Antakli T, Paramesh V, Pett S, Vernon S, Birjiniuk V, Welt F, Krucoff M, Wolfe W, Lucke JC, Mediratta S, Booth D, Barbieri C, Lewis D; The VA AWESOME (Angina With Extremely Serious Operative Mortality Evaluation) Multicenter Registry.

OBJECTIVES: This study was designed to compare the three-year survival after percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG) in physician-directed and patient-choice registries with the Angina With Extremely Serious Operative Mortality Evaluation (AWESOME) randomized trial results. BACKGROUND: The AWESOME multicenter randomized trial and registry compared the long-term survival after PCI and CABG for the treatment of patients with medically refractory myocardial ischemia and at least one additional risk factor for adverse outcome with CABG. The randomized trial demonstrated comparable three-year survival. METHODS: Over a five-year period (1995 to 2000), 2,431 patients with medically refractory myocardial ischemia and at least one of five risk factors (prior heart surgery, myocardial infarction within seven days, left ventricular ejection fraction <0.35, age >70 years, intra-aortic balloon required

to stabilize) were identified. By physician consensus, 1,650 patients formed a physician-directed registry assigned to CABG (692), PCI (651) or further medical therapy (307), and 781 were angiographically eligible for random allocation; 454 of these patients constitute the randomized trial, and the remaining 327 constitute a patient choice registry. Survival for CABG and PCI was compared using Kaplan-Meier curves and log-rank tests. RESULTS: The CABG and PCI 36-month survival rates for randomized patients were 79% and 80%, respectively. The CABG and PCI 36-month survival rates were both 76% for the physician-directed subgroup; comparable survival rates for the patient-choice subgroup were 80% and 89%, respectively. None of the global log-rank tests for survival demonstrated significant differences. CONCLUSIONS: Both registries support the randomized trial conclusion: PCI is an alternative to CABG for some medically refractory high-risk patients.

Am J Cardiol, 2002 ;89(3):251-6

Comparison of event and procedure rates following percutaneous transluminal coronary angioplasty in patients with and without previous coronary artery bypass graft surgery [the ROSETTA (Routine versus Selective Exercise Treadmill Testing after Angioplasty) Registry].

Garzon P, Sheppard R, Eisenberg MJ, Schechter D, Lefkovits J, Goudreau E, Mak KH, Brown DL; The ROSETTA Investigators.

To compare 6-month post-percutaneous transluminal coronary angioplasty (PTCA) outcomes and cardiac procedure use among patients with and without prior coronary artery bypass graft (CABG) surgery, we examined 791 patients who were enrolled in the Routine versus Selective Exercise Treadmill Testing after Angioplasty (ROSETTA) Registry. The ROSETTA Registry is a prospective, multicenter registry that examines the use of functional testing after successful PTCA. Most patients were men (76%, mean age 61 +/- 11 years) who underwent single-vessel PTCA (85%) with stent implantation (58%). Baseline and procedural characteristics differed between patients with a prior CABG (n = 131) and patients with no prior CABG (n = 660), including Canadian Cardiovascular Society angina class III to IV (60% vs 49%, respectively, p = 0.03) and stenosis involving the proximal left anterior descending coronary artery (10% vs 22%, p = 0.004). Event rates among patients with prior CABG were higher than among patients with no prior CABG, including unstable angina (19% vs 11%, p = 0.02), myocardial infarction (2% vs 1%, p = 0.2), death (4% vs 2%, p = 0.08), and composite clinical events (22% vs 12%, p = 0.003). Furthermore, patients with prior CABG had higher rates of follow-up cardiac procedures, including angiography (24% vs 14%, p = 0.008) and PTCA (13% vs 7%, p = 0.04),

but not repeat CABG (2% vs 3%,  $p = 0.8$ ). A multivariate analysis that included baseline clinical and procedural characteristics demonstrated that prior CABG was a significant independent predictor of clinical events and cardiac procedure use (odds ratio 2.3, 95% confidence interval 1.5 to 3.5,  $p = 0.0001$ ). Within the prior CABG group, patients with a PTCA of a bypass graft had a higher composite clinical event rate than patients with a PTCA of a native vessel (32% vs 17%,  $p = 0.05$ ). In contrast, patients with a PTCA of a native vessel had event rates similar to those of patients with no prior CABG (17% vs 12%,  $p = 0.2$ ). Thus, post-CABG patients have an increased risk of developing a cardiac event or needing a follow-up cardiac procedure during the 6 months after PTCA.

The American Journal of Cardiology, 1998;82:4:518-519

Complications associated with combined use of Abciximab and an intracoronary thrombolytic agent (Urokinase or tissue-type plasminogen activator)

Ricardo A. Yaryura, Munir Zaqqa, James J. Ferguson

Intracoronary thrombolytic agents have been used as adjuncts to percutaneous transluminal coronary angioplasty in patients with thrombotic lesions. The recent introduction of potent platelet inhibitors such as the glycoprotein IIb/IIIa integrin inhibitors, which are used for complex lesions, may reduce the use of intracoronary thrombolytic agents. The combination of these 2 agents, however, may be useful in high-risk lesions with refractory thrombus. The complication rates in patients who have received an intracoronary thrombolytic agent plus an intravenous infusion of a glycoprotein IIb/IIIa integrin inhibitor have not been studied. We conducted a retrospective review of in-hospital outcome and complications (with special attention to bleeding complications) in patients who received both types of agents during an interventional coronary procedure.

The American Journal of Cardiology, 82:10:1163-1167

Procedural results and long-term clinical outcomes following coronary stenting in perimyocardial infarction syndromes

Ran Kornowski, Mun K. Hong, Jorge Saucedo, Lowell F. Satler, Augusto D. Pichard, Kenneth M. Kent, Ann Greenberg, Martin B. Leon

Initial experiences with coronary stents in acute coronary syndromes have suggested higher risk of ischemic complications and stent thrombosis. We evaluated in-hospital and 1-year clinical outcomes of coronary stent implantation in perimyocardial infarction (MI) syndromes. We studied 334 consecutive patients undergoing stent interventions in the first week after acute MI. Stenting was performed within 24 hours (n = 31), within 1 to 3 days (n = 95), and within 4 to 7 days (n = 208). Stents were used to improve angioplasty results and to treat dissections and abrupt/threatened closure. Postprocedure anticoagulation regimens were aspirin, ticlopidine, and low molecular weight heparin. Overall procedural success was achieved in 93% of patients. Major in-hospital complications included death (1.0%), recurrent Q-wave MI (0.6%), and emergent bypass surgery (3.0%). Stent thrombosis occurred in 0.6% of patients. At follow-up, cardiac event-free survival was 80%, mortality 2.2%, recurrent MI 3.5%, and target lesion revascularization 11%. We conclude that coronary stenting in periinfarction syndromes was effective in achieving sustained clinical benefit up to 1 year with low morbidity and mortality. Thus, stents seem to be a viable therapeutic strategy in patients sustaining perimyocardial infarction syndromes.

Cathet. Cardiovasc. Diagn. 43:124-129, 1998.

Groin complications associated with collagen plug closure of femoral arterial puncture sites in anticoagulated patients

Ronald G. Carere, John G. Webb, Robert Miyagishima, Ognjenka Djurdev, Tanvir Ahmed, Arthur Dodek

A retrospective study was conducted to determine the frequency and nature of groin complications when the Vasoseal™ (Datascope Corp., NJ) hemostasis device was used on 204 occasions to enable removal of the groin sheath in anticoagulated patients. The patients had undergone balloon angioplasty (53%), coronary stenting (20%), and diagnostic angiography (27%). Complications included vascular surgery in 5% including 2 embolized collagen plugs, failure to achieve hemostasis (2%), late external bleeding (2%), purulent discharge

(1.5%), a minor ooze of blood (7%), hematomas >6 cm (6%), and hematomas 6 cm (7%). One or more complications occurred with 64 of 204 (30.5%) uses. Multivariate analysis identified diagnostic angiography to be associated with a reduced risk of complications [odds ratio (OR) 0.25], while stent procedure (OR 2.7) and female gender (OR 2.5) were associated with increased risk. This complication rate is similar to other reported series except for a higher rate of vascular surgery. The high incidence of anticoagulation in our study patients (94%) may explain this difference. We recommend caution and adherence to the recommended technique when the device is used in anticoagulated patients.

Circulation, 1988,77:372-379

Angiographic and clinical predictors of acute closure after native vessel coronary angioplasty

SG Ellis, GS Roubin, SB King 3d, JS Douglas Jr, WS Weintraub, RG Thomas and WR Cox

To determine predictors of acute coronary closure after PTCA performed with steerable catheter systems, we compared 140 procedures complicated by acute closure and 311 representative successful attempts from 4,772 procedures performed between April 1982 and March 1986. Sixteen clinical, 35 angiographic, and seven procedural variables were analyzed. Multivariate analysis found seven independent preprocedural factors related to closure: stenosis length of 2 or more luminal diameters, female gender, stenosis at a bend point of 45 degrees or more, stenosis at a branch point, stenosis-associated thrombus (filling defect or staining), other stenoses in the same vessel, and multivessel disease. In addition, four procedural factors were found to be associated with closure by univariate analysis: post-PTCA percent stenosis (p less than .001), intimal tear or dissection (p less than .001), use of prolonged heparin infusion (p less than .001), and post-PTCA gradient of 20 mm Hg or more (p = .004). Multivariate analysis of both preprocedural and procedural variables found six factors independently related to closure: post-PTCA percent stenosis, dissection, prolonged post-PTCA use of heparin, branch point location, fixed bend point location, and other stenoses in the vessel dilated. The risk of coronary closure after PTCA has many determinants. While an estimation of risk can be made before performing PTCA, the most powerful predictors of closure can only be assessed during the procedure itself.

#### Summary

1. Independent preprocedural factors related to closure: stenosis length of 2 or more luminal diameters, female gender, stenosis at a bend point of 45 degrees or more, stenosis at a branch point, stenosis-associated thrombus (filling defect or staining), other stenoses in the same vessel, and multivessel disease
2. Independent risk factors of closure: post-PTCA percent stenosis, dissection, prolonged post-PTCA use of

heparin, branch point location, fixed bend point location, and other stenoses in the vessel dilated.

N Engl J Med, 1999;340:1162-8.

### Temporal Trends in Cardiogenic Shock Complicating Acute Myocardial Infarction

Robert J. Goldberg, Navid A. Samad, Jorge Yarzebski, Jerry Gurwitz, Carol Bigelow, Joel M. Gore

**Background.** Limited information is available on trends in the incidence of and mortality due to cardiogenic shock complicating acute myocardial infarction. We studied the incidence of cardiogenic shock complicating acute myocardial infarction and in-hospital death rates among patients with this condition in a single community from 1975 through 1997.

**Methods.** We conducted an observational study of 9076 residents of metropolitan Worcester, Massachusetts, who were hospitalized with confirmed acute myocardial infarction in all local hospitals during 11 one-year periods between 1975 and 1997. Our study included periods before and after the advent of reperfusion therapy.

**Results.** The incidence of cardiogenic shock remained relatively stable over time, averaging 7.1 percent among patients with acute myocardial infarction. The results of a multivariable regression analysis indicated that the patients hospitalized during recent study years were not at a substantially lower risk for shock than patients hospitalized in the mid-to-late 1970s. Patients in whom cardiogenic shock developed had a significantly greater risk of dying during hospitalization (71.7 percent) than those who did not have cardiogenic shock (12.0 percent,  $P < 0.001$ ). A significant trend toward an increase in in-hospital survival among patients with cardiogenic shock in the mid-to-late 1990s was found in crude and adjusted analyses.

**Conclusions.** Our findings indicate no significant change in the incidence of cardiogenic shock complicating acute myocardial infarction over a 23-year period. However, the short-term survival rate has increased in recent years at the same time as the use of coronary reperfusion strategies has increased.

Circulation , 1999 ;99: 2371-2377.

Stroke in Patients With Acute Coronary Syndromes : Incidence and Outcomes in the Platelet Glycoprotein IIb/IIIa in Unstable Angina: Receptor Suppression Using Integrilin Therapy (PURSUIT) Trial

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**Background-**The incidence of stroke in patients with acute coronary syndromes has not been clearly defined because few trials in this patient population have been large enough to provide stable estimates of stroke rates. **Methods and Results-**We studied the 10 948 patients with acute coronary syndromes without persistent ST-segment elevation who were randomly assigned to placebo or the platelet glycoprotein IIb/IIIa receptor inhibitor eptifibatide in the Platelet Glycoprotein IIb/IIIa in Unstable Angina: Receptor Suppression Using Integrilin Therapy (PURSUIT) trial to determine stroke rates, stroke types, clinical outcomes in patients with stroke, and independent baseline clinical predictors for nonhemorrhagic stroke. Stroke occurred in 79 (0.7%) patients, with 66 (0.6%) nonhemorrhagic, 6 intracranial hemorrhages, 3 cerebral infarctions with hemorrhagic conversion, and 4 of uncertain cause. There were no differences in stroke rates between patients who received placebo and those assigned high-dose eptifibatide (odds ratios and 95% confidence intervals 0.82 [0.59, 1.14] and 0.70 [0.49, 0.99], respectively). Of the 79 patients with stroke, 17 (22%) died within 30 days, and another 26 (32%) were disabled by hospital discharge or 30 days, whichever came first. Higher heart rate was the most important baseline clinical predictor of nonhemorrhagic stroke, followed by older age, prior anterior myocardial infarction, prior stroke or transient ischemic attack, and diabetes mellitus. These factors were used to develop a simple scoring nomogram that can predict the risk of nonhemorrhagic stroke.

**Conclusions-**Stroke was an uncommon event in patients with acute coronary syndromes in the PURSUIT trial. These strokes are, however, associated with substantial morbidity and mortality rates. The majority of strokes were of nonhemorrhagic causes. Eptifibatide was not associated with an increase in intracranial hemorrhage, and no significant effect on nonhemorrhagic stroke was observed. We developed a useful nomogram for assigning baseline nonhemorrhagic stroke risk in this patient population.

Circulation , 1998 ;98: 2030-2036.

Nonsustained Ventricular Tachycardia in the Setting of Acute Myocardial Infarction : Tachycardia Characteristics and Their Prognostic Implications

Asim N. Cheema, Kathleen Sheu, Michele Parker, Alan H. Kadish, and Jeffrey J. Goldberger

Background-Nonsustained ventricular tachycardia (NSVT) has significant prognostic implications in the setting of healing and healed myocardial infarction (MI), but only limited information is available on its importance in the setting of acute MI. We evaluated the prognostic significance of NSVT characteristics in the setting of acute MI.

Methods and Results-A prospective database was used to identify 112 patients with NSVT within 72 hours of acute MI. A control group was identified matched for age, sex, type of MI, and thrombolytic treatment. Mean age was 64 to 65 years in the 2 groups with 71% to 72% men. Q-wave MI was noted in 52% to 53%, and thrombolytic therapy was administered to 31% to 32% of patients in each group. In-hospital ventricular fibrillation occurred more frequently in the NSVT group (9% versus 0% in the control group;  $P<0.001$ ), but total in-hospital (10% versus 4%) and follow-up mortality (10% versus 17%) did not differ between the 2 groups. With a Cox regression model, specific NSVT characteristics were predictive of mortality. The strongest predictor was time from presentation to occurrence of NSVT. Shortest RR interval during NSVT was also a univariate predictor of mortality. Multivariate analysis identified time from presentation to occurrence of NSVT as the strongest predictor of mortality ( $P<0.0001$ ). The increased relative risk of NSVT was first significant when it occurred 13 hours from presentation and continued to increase as the time from presentation to occurrence of NSVT increased, plateauing at 24 hours with a relative risk of 7.5.

Conclusions-Contrary to prevailing clinical opinion, NSVT that occurs in the setting of acute MI does have important prognostic significance. Specifically, the currently accepted notion that NSVT that occurs within 48 hours of acute MI has no prognostic significance needs to be adjusted. Although NSVT that occurs within the first several hours of presentation does not have an associated adverse prognosis, NSVT that occurs beyond the first several hours after presentation is associated with significant increases in relative risk.

Journal of the American College of Cardiology, 34:3:716-721

Prognostic importance of lower extremity arterial disease in patients undergoing coronary revascularization in the bypass angioplasty revascularization investigation (BARI)

Karen A. Burek, Kim Sutton-Tyrrell, Maria Mori Brooks, Barbara Naydeck, Norma Keller, Mary Ann Sellers, Gary Roubin, Rena Jandova, Charanjit S. Rihal

## OBJECTIVES

The purpose of this study was to evaluate the prevalence and prognostic importance of lower extremity arterial disease (LEAD) in patients with multivessel coronary artery disease.

## BACKGROUND

The presence of clinically evident LEAD increases the risk of death in patients with known coronary artery disease. Because studies have lacked noninvasive measures of subclinical LEAD, the true prognostic importance of lower extremity atherosclerosis in this population has probably been underestimated.

## METHODS

Ankle blood pressures were measured in 405 consecutive patients with angiographically documented multivessel coronary disease from seven Bypass Angioplasty Revascularization Investigation (BARI) sites and a parallel study site within 3 years of enrollment. Lower extremity arterial disease was defined as an ankle/arm systolic blood pressure ratio of 0.90 or less.

## RESULTS

Among patients studied, 69 (17%) had LEAD. These patients were more likely to be current smokers, treated for diabetes, older and present with unstable angina compared with patients without LEAD. Among patients who underwent coronary arterial bypass grafting, major complications occurred in 2.8% of those without LEAD compared with 20.7% of those with LEAD ( $p = 0.002$ ). Five-year mortality rates were similar for symptomatic LEAD (14%) and asymptomatic LEAD (14%). Patients without LEAD had a 3% mortality. After adjusting for baseline differences, the relative risk of death was 4.9 times greater for patients with LEAD compared with those without (95% confidence interval [CI]: 1.8, 13.4,  $p < 0.01$ ).

## CONCLUSIONS

Patients with LEAD have a significantly higher risk of death than patients without LEAD, regardless of the presence of symptoms. An abnormal ankle/arm index is a strong predictor of mortality and can be used to further stratify risk among patients with multivessel coronary artery disease.

Circulation ,1999 ;100: 2400-2405.

Creatine Kinase-MB Enzyme Elevation Following Successful Saphenous Vein Graft Intervention Is Associated With Late Mortality

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**Background-**Although the risk for development of creatine kinase (CK-MB) elevation after saphenous vein graft (SVG) intervention is high, its prognostic significance remains unknown. This study evaluated the impact of periprocedural CK-MB elevation on late clinical events following successful SVG angioplasty.

**Methods and Results-**We studied 1056 consecutive patients with successful (defined by angiographic success and absence of major complications) intervention of 1693 SVG lesions. These patients were grouped as normal CK-MB (n=556), minor CK-MB rise (CK-MB 1 to 5 times normal, n=339), and major CK-MB rise (CK-MB >5 times normal, n=161). There were no differences in major clinical events at 30-day follow-up among the 3 groups. However, 1-year mortality was 4.8%, 6.5%, and 11.7%, respectively,  $P < 0.05$  (ANOVA). Even within a population without any intraprocedure or in-hospital complications (n=727, 69% of the overall cohort), 1-year mortality remained significantly higher with CK-MB elevation: 2.4%, 5.5%, and 10.7%, respectively,  $P < 0.05$  (ANOVA). Multivariate analysis revealed major CK-MB elevation as the strongest independent predictor of late mortality (odds ratio 3.3, with 95% CI 1.7 to 6.2), followed by diabetes mellitus (odds ratio 2.6, with 95% CI 1.5 to 4.5).

**Conclusions-**Major CK-MB elevation occurs after 15% of otherwise successful SVG interventions and is associated with increased late mortality.

Circulation ,1999 ;99: 36-43.

**Functional Recovery of Subepicardial Myocardial Tissue in Transmural Myocardial Infarction After Successful Reperfusion : An Important Contribution to the Improvement of Regional and Global Left Ventricular Function**

Jan Bogaert, Alex Maes, Frans Van de Werf, Hilde Bosmans, Marie-Christine Herregods, Johan Nuyts, Walter Desmet, Luc Mortelmans, Guy Marchal, and Frank E. Rademakers

**Background-**The transmural extent of myocardial necrosis after an acute coronary artery occlusion can vary considerably. The contribution of residual subepicardial viable myocardium to global left ventricular function is largely unknown.

**Methods and Results-**We studied 12 patients with single-vessel disease 1 week after successful reperfusion of a first transmural anterior myocardial infarction (MI). With PET, myocardial blood flow (MBF) and glucose metabolism were measured regionally, and the viability was graded as normal, mismatch, or match with severely (<50% of normal) or intermediately (50% to 80% of normal) impaired MBF. Magnetic resonance

tagging was used to regionally quantify fiber strains, wall thickening, and ejection fraction in patients 1 week and 3 months after the MI and in age-matched healthy volunteers. From 1 week to 3 months, subepicardial fiber shortening improved significantly in the match region (MBF <50%,  $-5.1\pm 7.0\%$  to  $-9.9\pm 8.7\%$ ; MBF of 50% to 80%,  $-7.1\pm 7.6\%$  to  $-14.9\pm 7.9\%$ ). This was associated with an improvement in regional ejection fraction in the infarcted myocardium ( $29.6\pm 21.8\%$  to  $43.5\pm 15.5\%$ ,  $P<0.0001$ ) and in normal regions ( $54.3\pm 15.1\%$  to  $56.5\pm 13.1\%$ ,  $P=0.013$ ), contributing to an increase in global ejection fraction from  $44.2\pm 22.2\%$  to  $49.3\pm 17.9\%$  ( $P<0.0001$ ).

Conclusions-Functional recovery of viable subepicardial regions is a mechanism of late improvement in regional and global ejection fraction after a so-called transmural MI.

Circulation, 1999 ;99: 873-878.

One-Year Survival Among Patients With Acute Myocardial Infarction Complicated by Cardiogenic Shock, and its Relation to Early Revascularization : Results From the GUSTO-I Trial

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Background-Although 30-day survival is increased in patients with acute myocardial infarction complicated by cardiogenic shock who undergo coronary revascularization, the longer-term outcome in such patients and the duration of benefit from revascularization are unknown.

Methods and Results-We analyzed 30-day survivors of acute myocardial infarction in the Global Utilization of Streptokinase and Tissue-Plasminogen Activator for Occluded Coronary Arteries (GUSTO-I) trial and identified 36 333 who had not had cardiogenic shock (systolic blood pressure <90 mm Hg for  $\geq 1$  hour, group 1) and 1321 patients who had shock (group 2). Group 2 patients were older and sicker. At 1 year, 97.4% of group 1 patients were alive versus 88.0% of group 2 ( $P=0.0001$ ). Among group 2 patients, 578 (44%) had undergone revascularization within 30 days (group 2A) and 728 (56%) had not (group 2B). Revascularization was not required by protocol but was selected by the attending physicians. At 1 year, 91.7% of group 2A patients were alive versus 85.3% of group 2B ( $P=0.0003$ ). With the use of multivariable logistic regression analysis to adjust for differences in baseline characteristics of shock patients alive at 30 days, revascularization within 30 days was independently associated with reduced 1-year mortality (odds ratio 0.6, [95% confidence interval 0.4, 0.9],  $P=0.007$ ).

Conclusions-Most patients (88%) with acute myocardial infarction complicated by cardiogenic shock who are

alive at 30 days survived at least 1 year. Shock patients who underwent revascularization within 30 days had improved survival at 1 year compared with shock patients who did not receive revascularization, even after adjustment for differences in baseline characteristics between the 2 groups.

Key Words: revascularization ? shock ? acute myocardial infarction ? thrombolysis ? mortality

Circulation , 1999 ;100: 171-177.

### Increased Incidence of Periprocedural Complications Among Patients With Peripheral Vascular Disease Undergoing Myocardial Revascularization in the Bypass Angioplasty Revascularization Investigation

Charanjit S. Rihal, Kim Sutton-Tyrrell, Ping Guo, Norma M. Keller, Ruzena Jandova, Mary Ann Sellers, Hartzell V. Schaff, and David R. Holmes, Jr

**Background-**Risks of coronary artery bypass graft surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA) may be different in the presence of peripheral vascular disease (PVD).

**Methods and Results-**We analyzed outcomes of 550 patients with PVD enrolled in the Bypass Angioplasty Revascularization Investigation randomized trial and registry. Compared with 1770 patients without PVD, those with PVD were older and had a greater prevalence of medical comorbid conditions. No significant differences in coronary anatomy or PTCA success rates were found. The risk of any major complication (death, myocardial infarction, stroke, coma, or emergency revascularization) after PTCA was significantly higher among patients with PVD (11.7% versus 7.8%,  $P=0.027$ ). In multivariate analysis, this represented a 50% increase in the odds of having any major complication (multivariate odds ratio, 1.5;  $P=0.032$ ). Among patients undergoing CABG, the risk of major complications was found to be markedly higher for patients with PVD (12%) than those without (6.1%,  $P=0.003$ ) even after controlling for baseline differences (multivariate odds ratio, 1.8;  $P=0.018$ ). Major differences between the PTCA and CABG groups were related primarily to a higher risk of neurological complications in PVD patients who had CABG (multivariate odds ratio, 2.8;  $P<0.001$ ).

**Conclusions-**We conclude that patients with PVD are at high risk for periprocedural complications after myocardial revascularization, in particular neurological events.

Journal of the American College of Cardiology, 33:3:647-653

## The relationship between periprocedural myocardial infarction and subsequent target vessel revascularization following percutaneous coronary revascularization : Insights from the EPIC trial

Craig R. Narins, Dave P. Miller, Robert M. Califf, Eric J. Topol

### OBJECTIVES

We sought to determine whether periprocedural myocardial infarction complicating percutaneous coronary revascularization is associated with subsequent clinical restenosis, as judged by the need for target vessel revascularization.

### BACKGROUND

Although myocardial enzyme elevation following angioplasty is associated with increased late mortality, its effect on subsequent clinical restenosis, as assessed by the need for late target vessel revascularization (TVR), is unknown.

### METHODS

Serial myocardial enzyme determinations were performed on 2,099 patients who underwent angioplasty or atherectomy in the Evaluation of IIb/IIIa platelet receptor antagonist 7E3 in Preventing Ischemic Complications (EPIC) trial. Thirty-day survivors were prospectively followed for three years for adverse clinical events including death and need for TVR.

### RESULTS

Within the study population, periprocedural creatine kinase (CK) elevation was a predictor of late mortality. Among patients with elevated CK, however, a paradoxical decrease in the need for late TVR was present. This relationship became progressively more profound as the magnitude of CK release increased. Late TVR occurred in 29.8% of patients with no CK elevation, 24.8% with CK elevation to >3 times normal, and 16.9% with >10 times elevation (hazard ratio 0.51, 95% CI 0.29, 0.91).

### CONCLUSIONS

In the EPIC study, patients with periprocedural MI were less likely to develop clinical restenosis as measured by the need for TVR. Mechanistically, although it is unlikely that CK elevation prevents vascular renarrowing per se, myocardial necrosis impairs the clinical manifestation of restenosis, thereby reducing the need for ischemia-driven TVR. This novel finding 1) highlights the potential discordance between angiographic and clinical measures of restenosis, and 2) has implications for clinical trials, as therapies that reduce periprocedural MI may be associated with a perceived excess of restenosis when measured by the need for TVR.

JAMA. 1999;281:172-179

## Management of Ventricular Arrhythmias

### Detection, Drugs, and Devices

David S. Cannom; Eric N. Prystowsky

**Objective.** To review evaluation and treatment of patients with ventricular arrhythmias, based on recent studies, with an emphasis on randomized controlled trials.

**Data Sources.** MEDLINE search of English-language publications of ventricular arrhythmias and their references from 1966 through April 27, 1998. References to articles were also scanned to broaden the search.

**Study Selection.** Randomized controlled trials and all large nonrandomized trials of arrhythmias and arrhythmia therapy were reviewed. In addition, studies that led to changes in approach to patients with arrhythmias were reviewed.

**Data Extraction** We reviewed articles jointly for pertinent studies and information.

**Data Synthesis.** The goals of treatment of the patient with ventricular arrhythmias are to suppress symptoms and prevent a fatal event. The steps in providing such therapy include defining the cardiac anatomy, assessing arrhythmia risk through noninvasive or invasive testing, and prescribing treatment based on these results. Patients may be separated into high- and low-risk groups to help identify appropriate treatment. While low-risk groups may benefit from reassurance or medications such as  $\beta$ blockers or verapamil, high-risk groups have been more difficult to treat. Recent randomized trials of implantable cardioverter defibrillators for ventricular arrhythmias suggest that they may provide better protection for high-risk patients than do antiarrhythmic medications.

**Conclusions.** Treatment and understanding of risk from ventricular arrhythmias have advanced substantially in recent years. Classifying patients as being at high or low risk for fatal arrhythmias allows the physician to identify appropriate treatments for the high-risk patient without exposing the low-risk patient to unnecessary treatment-related risks.

Journal of the American College of Cardiology, 33:1895-1902

Prevalence, characteristics and prognostic value during long-term follow-up of nonsustained ventricular

tachycardia after myocardial infarction in the thrombolytic era

Stefan H. Hohnloser, Thomas Klingenhöben, Markus Zabel, Matthias Schöpperl, Oliver Mauß

**OBJECTIVES** The purpose of this study was to determine the prevalence, characteristics and the predictive value of nonsustained ventricular tachycardia (VT) for subsequent death and arrhythmic events after acute myocardial infarction (AMI).

**BACKGROUND** Nonsustained VT has been linked to an increased risk for sudden death in coronary patients. It is unknown whether this parameter can be used for selection of high-risk patients to receive an implantable defibrillator for primary prevention of sudden death in patients shortly after AMI.

**METHODS** In 325 consecutive infarct survivors, 24-h Holter monitoring was performed  $10 \pm 6$  days after AMI. All patients underwent coronary angiography, determination of left ventricular function and assessment of heart rate variability (HRV). Mean follow-up was  $30 \pm 22$  months.

**RESULTS** There was a low prevalence (9%) of nonsustained VT shortly after AMI. Nonsustained VT together with depressed left ventricular ejection fraction (LVEF) was found in only 2.4% of patients. During follow-up, 25 patients reached one of the prospectively defined end points (primary composite end point of cardiac death, sustained VT or resuscitated ventricular fibrillation; secondary end point: arrhythmic events). Kaplan Meier event probability analyses revealed that only HRV, LVEF and status of the infarct-related artery were univariate predictors of death or arrhythmic events. The presence of nonsustained VT carried a relative risk of 2.6 for the primary study end point but was not a significant predictor if only arrhythmic events were considered. On multivariate analysis, only HRV, LVEF and the status of the infarct artery were found to be independently related to the primary study end point.

**CONCLUSIONS** There is a low prevalence of nonsustained VT shortly after AMI. Only 2% to 3% of all infarct survivors treated according to contemporary guidelines demonstrate both depressed LVEF and nonsustained VT. The predictive value of nonsustained VT for subsequent mortality and arrhythmic events is inferior to that of impaired autonomic tone, LVEF or infarct-related artery patency. Accordingly, the use of nonsustained VT to select patients for primary implantable cardioverter/defibrillator prevention trials shortly after AMI appears to be limited.

Circulation, 1999;99: 1972-1977.

Determinants and Prognostic Implications of Persistent ST-Segment Elevation After Primary Angioplasty for

## Acute Myocardial Infarction : Importance of Microvascular Reperfusion Injury on Clinical Outcome

Marc J. Claeys, Johan Bosmans, Leonard Veenstra, Philippe Jorens, Herbert De Raedt, and Chris J. Vrints

**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 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.

Circulation, 1999;99:2243-2250.

## Angiographically Documented Late Reocclusion After Successful Coronary Angioplasty of an Infarct-Related Lesion Is a Powerful Predictor of Long-Term Mortality

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### Background

Late reocclusion of an infarct-related artery (IRA) that was patent in the early days after acute myocardial infarction (MI) is a frequent event; the reocclusion rate may be as high as 30%. Few studies have been designed to analyze the impact of late reocclusion of the IRA on late survival.

## Methods and Results

We studied 528 patients who all had a patent IRA after a successful PTCA procedure  $10 \pm 6$  days after MI and who underwent systematic 6-month angiographic follow-up to assess late patency of the IRA. We compared long-term survival of patients with and without late reocclusion. Based on the results of 6-month follow-up angiography, 2 groups of patients were defined: (1) 90 patients (17%) with reocclusion (Thrombolysis In Myocardial Infarction [TIMI] flow 0 or 1) and (2) 438 patients (83%) without reocclusion. Long-term clinical follow-up was obtained for all 528 patients at a median of 5.7 years after follow-up angiography (6.4 years after PTCA). The overall actuarial 8-year total mortality rate was 13%. At the end of follow-up, there were 35 deaths (8%) among the 438 patients without reocclusion and 18 deaths (20%) among the 90 patients with reocclusion ( $P=0.002$ ). The actuarial 8-year total mortality rate was 10% in patients without reocclusion and 28% in patients with reocclusion ( $P=0.0003$ ). The actuarial cardiovascular mortality rate was 7% in patients without reocclusion and 25% in patients with reocclusion ( $P<0.0001$ ). The impact of reocclusion on long-term mortality was greater in patients with anterior MI.

## Conclusions

Late IRA patency is strongly associated with long-term survival after MI. These observations should encourage prospective studies to evaluate the impact of strategies designed to prevent late reocclusion in postinfarction patients.

Journal of the American College of Cardiology, 1999;33:1:88-96

Clinical outcomes after detection of elevated cardiac enzymes in patients undergoing percutaneous intervention

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**Objectives.** We examined the relations of elevated creatine kinase (CK) and its myocardial band isoenzyme (CK-MB) to clinical outcomes after percutaneous coronary intervention (PCI) in patients enrolled in Integrilin (eptifibatide) to Minimize Platelet Aggregation and Coronary Thrombosis-II (trial) (IMPACT-II), a trial of the platelet glycoprotein IIb/IIIa inhibitor eptifibatide.

**Background.** Elevation of cardiac enzymes often occurs after PCI, but its clinical implications are uncertain.

**Methods.** Patients undergoing elective, scheduled PCI for any indication were analyzed. Parallel analyses investigated CK (n = 3,535) and CK-MB (n = 2,341) levels after PCI (within 4 to 20 h). Clinical outcomes at 30 days and 6 months were stratified by postprocedure CK and CK-MB (multiple of the site's upper normal limit). **Results.** Overall, 1,779 patients (76%) had no CK-MB elevation; CK-MB levels were elevated to 1 to 3 times the upper normal limit in 323 patients (13.8%), to 3 to 5 times normal in 84 (3.6%), to 5 to 10 times normal in 86 (3.7%), and to >10 times normal in 69 patients (2.9%). Elevated CK-MB was associated with an increased risk of death, reinfarction, or emergency revascularization at 30 days, and of death, reinfarction, or surgical revascularization at 6 months. Elevated total CK to above three times normal was less frequent, but its prognostic significance paralleled that seen for CK-MB. The degree of risk correlated with the rise in CK or CK-MB, even for patients with successful procedures not complicated by abrupt closure.

**Conclusions.** Elevations in cardiac enzymes, including small increases (between one and three times normal) often not considered an infarction, are associated with an increased risk for short-term adverse clinical outcomes after successful or unsuccessful PCI.

Journal of the American College of Cardiology, 1999;34:3:663-671

Creatine kinase-MB elevation after coronary intervention correlates with diffuse atherosclerosis, and low-to-medium level elevation has a benign clinical course : Implications for early discharge after coronary intervention

Annapoorna Kini, Jonathan D. Marmur, Subhash Kini, George Dangas, Thomas P. Cocks, Sylvan Wallenstein, Eppie Brown, John A. Ambrose, Samin K. Sharma

#### OBJECTIVES

The study evaluated the incidence and predictors of creatine kinase-MB isoenzyme (CK-MB) elevation after successful coronary intervention using current devices, and assessed the influence on in-hospital course and midterm survival.

#### BACKGROUND

The CK-MB elevation after coronary intervention predominantly using balloon angioplasty correlates with late cardiac events of myocardial infarction (MI) and death. Whether CK-MB elevation after nonballoon devices is associated with an adverse short and midterm prognosis is unknown.

#### METHODS

The incidence and predictors of CK-MB elevation after coronary intervention were prospectively studied in 1,675 consecutive patients and were followed for in-hospital events and survival.

#### RESULTS

CK-MB elevation was detected in 313 patients (18.7%), with 1-3 $\times$  in 12.8%, 3-5 $\times$  in 3.5% and >5 $\times$  normal in 2.4% of patients. Procedural complications or electrocardiogram changes occurred in only 49% of the CK-MB-elevation cases; CK-MB elevation was more common after nonballoon devices (19.5% vs. 11.5% after percutaneous transluminal coronary angioplasty;  $p < 0.01$ ). Predictors of CK-MB elevation on multivariate analysis were diffuse coronary disease ( $p = 0.02$ ), systemic atherosclerosis ( $p = 0.002$ ), stent use ( $p = 0.04$ ) and absence of beta-blocker therapy ( $p = 0.001$ ). Adverse in-hospital cardiac events were more frequent in patients with >5 $\times$  CK-MB elevation, with no significant difference between 1-5 $\times$  CK-MB elevation versus normal CK-MB group. During a mean follow-up of  $13 \pm 3$  months, the incidence of death in the CK-MB-elevation group was 1.6% versus 1.3% in the normal CK-MB group ( $p = \text{NS}$ ).

#### CONCLUSIONS

The CK-MB elevation after coronary intervention was observed even in the absence of discernible procedural complications and was more common in patients with diffuse atherosclerosis. In-hospital clinical events requiring prolonged monitoring were higher in >5 $\times$  CK-MB-elevation patients only. Midterm survival of CK-MB-elevation patients was similar to those with normal CK-MB. Our prospective analysis shows a lack of adverse in-hospital cardiac events and suggests that early discharge of stable 1-5 $\times$  normal CK-MB-elevation patients after successful coronary intervention is safe.

Journal of the American College of Cardiology, 1999;33:1:73-78

Effect of transient abrupt vessel closure during otherwise successful angioplasty for unstable angina on clinical outcome at six months

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**Objectives.** The objective of this study was to identify predictors of major adverse cardiac events after successful coronary angioplasty.

**Background.** The acute complications of angioplasty are related to baseline clinical and angiographic variables, and early complications adversely affect long-term outcome. However, the predictors of enduring success after

uncomplicated angioplasty are less well defined.

**Methods.** Of 4,098 patients undergoing angioplasty in the Hirulog Angioplasty Study, 3,899 (95%) had a successful procedure without in-hospital death, emergent bypass surgery or clinical evidence of myocardial infarction. Baseline and procedural variables for these 3,899 patients were examined.

**Results.** Major adverse cardiac events occurred in 22% of the patients with initially successful procedures at 6 months: death in 1%, myocardial infarction in 2% and repeat revascularization in 21%. Univariable predictors of increased events included successful salvage from abrupt vessel closure ( $p < 0.001$ ), emergency stenting ( $p < 0.001$ ), multilesion angioplasty ( $p < 0.001$ ), diabetes ( $p = 0.02$ ), target lesion in the left anterior descending artery ( $p = 0.02$ ), unstable angina ( $p = 0.03$ ) and smaller final luminal diameter ( $p = 0.04$ ). There was a trend toward increased events among patients with prior angioplasty ( $p = 0.08$ ), but asymptomatic elevation of the creatine kinase was not predictive ( $p = 0.5$ ). In a multivariable model, abrupt vessel closure was the strongest independent predictor of major adverse cardiac events at 6 months ( $p < 0.001$ ; odds ratio [95% confidence interval] = 3.6 [2.5 to 5.1]), while multivessel angioplasty, target lesion in the left anterior descending artery and diabetes also remained independent predictors (all  $p < 0.02$ ).

**Conclusions.** This analysis suggests that ?ncomplicated? abrupt vessel closure is a powerful predictor of adverse clinical outcome following successful angioplasty. Improved techniques to reduce abrupt closure during angioplasty are thus urgently needed, and patients who experience ?ncomplicated? closure require closer surveillance during follow-up.

JACC, 1999;33:395-402

A randomized trial comparing the impact of a nonionic (iomeprol) versus an ionic (ioxaglate) low osmolar contrast medium on abrupt vessel closure and ischemic complications after coronary angioplasty

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#### Objectives

To assess the effect of nonionic versus ionic contrast media on abrupt vessel closure and major ischemic complications after coronary angioplasty.

#### Background

There is a continuous debate about the ?thrombogenic potential? of nonionic contrast media. The results of both

in vitro and in vivo investigations are incongruent.

#### Methods

We prospectively evaluated the outcomes of 2,000 patients undergoing percutaneous transluminal coronary angioplasty (PTCA). According to a randomized, double-blind protocol, they received either iomeprol (nonionic; n = 1,001) or ioxaglate (ionic; n = 999). Intracoronary thrombus before PTCA was found more often in the iomeprol group (4.2% vs 2.7%, p = 0.04). No other significant differences between both groups were observed with regard to pre-PTCA clinical and angiographic characteristics.

#### Results

The frequency of reocclusions necessitating repeat angioplasty occurring either in laboratory (2.9% with iomeprol and 3.0% with ioxaglate) or out of laboratory (3.1% vs 4.1%) was not significantly different. The rate of major ischemic complications was also comparable after both contrast media (emergency bypass surgery: 0.8% vs 0.7%, myocardial infarction: 1.8 vs 2.0%, cardiac death during hospital stay: 0.2% vs 0.2%). In the iomeprol group, more patients had dissections post-PTCA (30.2% vs 25.0%, p = 0.01) and more patients received intracoronary stents (31.6% vs 25.7%, p = 0.004). Allergic reactions requiring treatment occurred only in the ioxaglate group (0.0% vs 0.9%, p = 0.002).

#### Conclusions

The nonionic contrast medium was not associated with a higher rate of abrupt vessel closure requiring repeat angioplasty, or major ischemic events. These data suggest that nonionic contrast media do not increase the risk of thrombotic complications in patients undergoing coronary interventions.

J Am Coll Cardiol, 1999;34(5):1484-8

Short- and long-term evolution of unstented nonocclusive coronary dissection after coronary angioplasty.

appelletti A, Margonato A, Rosano G, Mailhac A, Veglia F, Colombo A, Chierchia SL

**OBJECTIVES:** We assessed the short- and long-term clinical and angiographic outcome of nonocclusive unstented dissection after percutaneous transluminal coronary angioplasty (PTCA) and its correlation with restenosis. **BACKGROUND:** The use of stents has dramatically increased both the number and the cost of coronary revascularization procedures. However, this technique is not completely risk free, and its benefits have not been fully demonstrated in uncomplicated dissections. **METHODS:** We studied 129 consecutive patients with 49 nonocclusive dissections after PTCA (grades A to D of National Heart, Lung, and Blood Institute classification) and good distal flow (TIMI [Thrombolysis in Myocardial Infarction] flow grade 3). All patients underwent coronary angiography at 24 h and at six months post-PTCA. Clinical status was assessed every three months in the outpatient clinic. Study subjects were matched with 60 other patients in whom

stenting was performed for the presence of dissection. RESULTS: In the former group, all but two patients (with type E dissection, which evolved to coronary occlusion and myocardial infarction) improved their dissection score during follow-up: at six months only 18 dissections were still angiographically visible, and no clinical adverse events were recorded. In the dissected vessels, the restenosis rate was significantly lower than in those without dissection (12% vs. 44%,  $p < 0.001$ ); in the stented vessels, the restenosis rate was 25% (15/60). CONCLUSIONS: In the presence of TIMI flow grade 3, coronary dissection is associated with a favorable outcome and predicts a low restenosis rate. These results caution against the indiscriminate use of intravascular prostheses in the event of nonocclusive coronary dissection.

### Summary

1. Only 18 dissections were still angiographically visible at six months.
2. No clinical adverse events were recorded.
3. In the dissected vessels, the restenosis rate was significantly lower than in those without dissection (12% vs. 44%,  $p < 0.001$ )

Figure. Evolution of the dissections during the first 24 h and at six-month follow-up. A, B, C, D = degree of dissection.

Am J Cardiol, 1999 ;83(7):1006-11

Timing of coronary stent thrombosis in patients treated with ticlopidine and aspirin.

Wilson SH, Rihal CS, Bell MR, Velianou JL, Holmes DR Jr, Berger PB

In patients receiving coronary stents treated with aspirin and coumadin, the peak incidence of stent thrombosis occurs on the fifth and sixth days following the implantation procedure. Little is known about the timing of stent thrombosis in patients treated with aspirin and ticlopidine. We compared the timing of coronary stent thrombosis in patients treated with ticlopidine and aspirin with the timing in those receiving coumadin and aspirin. A retrospective databank analysis was performed and 39 patients were identified who experienced stent thrombosis after successful coronary stent implantation. Of these, 21 had been treated with ticlopidine and aspirin and 18 with coumadin and aspirin therapy. The median time from stent implantation to stent thrombosis in the ticlopidine and aspirin group was 12 hours (interquartile range 6 to 72 hours) compared with 4 days in the coumadin and aspirin group (interquartile range 21 to 68 hours) ( $p < 0.0001$ ). There was no

significant difference between the timing of stent thrombosis in patients treated with abciximab in addition to ticlopidine and aspirin (median 17 hours, interquartile range 6 to 29) versus ticlopidine and aspirin patients who did not receive abciximab (median 11 hours, interquartile range 9 to 12,  $p = 0.57$ ). Thus, in patients who receive coronary stents, stent thrombosis occurs much earlier after the procedure in patients treated with ticlopidine and aspirin than in patients treated with anticoagulation therapy.

Figure. Timing of stent thrombosis in the aspirin and ticlopidine versus aspirin and coumadin groups.

Am J Cardiol, 1999;83(2):180-6

Ultrasonic assessment of vascular complications in coronary angiography and angioplasty after transradial approach.

Nagai S, Abe S, Sato T, Hozawa K, Yuki K, Hanashima K, Tomoike H

The transradial approach has currently been accepted as an alternative entry method for coronary angiography and angioplasty. Vascular complications of this method were evaluated by 2-dimensional echo and color Doppler ultrasonic studies in 162 patients before, early ( $2 \pm 2$  [mean  $\pm$  SD] days), and late ( $95 \pm 29$  days) after catheterization. Mean age was  $64 \pm 10$  years, and 103 were men. Coronary angioplasty was performed in 59 patients (79 lesions) with angiographic success in 92%. Early after the procedure, segmental stenosis was noted in 35 patients (22%) and no flow in 15 patients (9%). Late after the procedure, segmental stenosis was noted in 2, diffuse stenosis in 36 (22%), and no flow in 8 (5%) patients. The cessation of radial artery pulse was unpalpable in only 2% of cases, whereas radial flow by color Doppler was undetectable in 9% early after the procedure. Late after the procedure, recanalization was observed in 60% of these occluded cases. Thirty-three of 86 patients (38%) with no flow or diffuse stenosis had radial artery diameters smaller than the sheath diameter, and 11 of 76 patients (14%) had radial artery diameters larger than the sheath diameter ( $p < 0.01$ ). Multivariate analysis revealed risk factors for vascular complications: (1) Radial artery diameter before the procedure was one of the significant and independent determinants of no flow both early ( $p = 0.06$ ) and late ( $p = 0.004$ ) after the procedure. (2) The difference in radial artery diameter and sheath size was related to the occurrence of diffuse stenosis late after the procedure ( $p = 0.003$ ). (3) Diabetes mellitus was related to no flow ( $p = 0.05$ ) or diffuse stenosis ( $p = 0.11$ ) late after the procedure. Thus, ultrasonic evaluation of the radial artery was useful in selecting both an access route and an appropriate size of the sheath to determine early and late vascular complications.

## Summary

1. Early after the procedure - segmental stenosis: 22%, no flow: 9%
2. Late after the procedure - segmental stenosis: 1.3%, diffuse stenosis: 22%, no flow: 5%
3. Multivariate analysis revealed risk factors for vascular complications: (1) Radial artery diameter before the procedure: determinants of no flow both early ( $p = 0.06$ ) and late ( $p = 0.004$ ) after the procedure. (2) The difference in radial artery diameter and sheath size: related to the occurrence of diffuse stenosis late after the procedure ( $p = 0.003$ ). (3) Diabetes mellitus: related to no flow ( $p = 0.05$ ) or diffuse stenosis ( $p = 0.11$ ) late after the procedure.

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Vascular complications and clinical outcome after coronary angioplasty with platelet IIb/IIIa receptor blockade. Comparison of transradial vs transfemoral arterial access

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**Aims** Vascular complications associated with femoral artery access for interventional cardiological procedures may increase morbidity especially in patients receiving anticoagulants, aspirin, ticlopidine and platelet glycoprotein IIb/IIIa receptor inhibitors. The use of radial arterial access has the potential to reduce the incidence of access site bleeding complications. The purpose of this study was to compare outcomes after the radial and femoral approaches in patients treated with the platelet IIb/IIIa inhibitor, abciximab.

**Methods and Results** One hundred and fifty consecutive patients treated by abciximab underwent angioplasty by the radial or femoral approach in 83 and 67 cases, respectively. Outcome variables were major cardiac events and major access site bleeding at 1-month follow-up. Freedom from major cardiac events at 1-month follow-up occurred in 78 (93.9%) and 63 (94.0%) patients in the radial and femoral groups, respectively ( $P=0.99$ ). There were no major access site bleeding complications in the radial group, as opposed to five (7.4%) in the femoral group,  $P=0.04$ . Postprocedure length of stay, days ( $3.7 \pm 6.0$  radial vs  $3.7 \pm 2.6$  femoral,  $P=0.96$ ) as well as total hospital length of stay ( $5.0 \pm 4.3$  radial vs  $4.9 \pm 3.0$  femoral,  $P=0.72$ ) were similar in both groups.

**Conclusion** Coronary angioplasty in patients treated by abciximab using the transradial approach is efficacious with fewer major access site complications than with the transfemoral approach.

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

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Cleveland, Ohio; Barcelona, Spain; Durham, NC; and Denver, Colo

**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.

Circulation, 2000 ;102: 1245-1251

## Relationship of Infarct Artery Patency and Left Ventricular Ejection Fraction to Health-Related Quality of Life After Myocardial Infarction : The GUSTO-I Angiographic Study Experience

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**Background-**Post-myocardial infarction global ejection fraction and infarct-related artery patency might be expected to be associated with health-related quality-of-life (HRQOL) outcomes, but this association has not been previously shown. The GUSTO-I Angiographic Study cohort 2-year follow-up afforded an examination of such potential relationships.

**Methods and Results-**A total of 1848 patients (87.7% response rate) who were enrolled in the GUSTO-I Angiographic Study were contacted for a telephone interview regarding their current HRQOL (physical function, psychological well-being, perceived health status, and social function) 2 years after MI. In multivariable models, left ventricular ejection fraction (EF) was significantly related to physical ( $P=0.021$ ) and social ( $P=0.014$ ) function, psychological well-being ( $P=0.042$ ), and perceived health status ( $P=0.024$ ). Infarct-related artery patency was not directly related to any HRQOL outcome. A decreasing EF was predictive of poorer outcomes in each HRQOL dimension. Men consistently had better outcomes in all HRQOL dimension with the exception of perceived health status. Increasing age was predictive of poorer outcomes in all dimensions of HRQOL except for psychological well-being where the inverse occurred; younger patients experienced greater depression, anxiety and worry than their older counterparts. The presence of comorbidities increased the likelihood of worse outcomes in all dimensions.

**Conclusions-**This is the first study to demonstrate a significant relationship between EF and long-term HRQOL outcomes. This advantage in left ventricular function preservation should be added to the mortality advantage when considering the impact of treatment strategies for myocardial infarction.

Journal of the American College of Cardiology, 35:6:1453-1461

Regional myocardial blood flow in patients with sick sinus syndrome randomized to long-term single chamber atrial or dual chamber pacing-effect of pacing mode and rate

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## OBJECTIVES

This study aimed to evaluate regional myocardial blood flow (MBF) and global left ventricular ejection fraction (LVEF) during chronic pacing in patients with sick sinus syndrome (SSS) randomized to either single chamber atrial (AAI) or dual chamber (DDD) pacing.

## BACKGROUND

Experimental studies indicate that chronic pacing in the right ventricular apex changes regional MBF, thereby compromising left ventricular function.

## METHODS

Thirty patients (age  $74 \pm 10$  years) were randomized to AAI ( $n = 15$ ) or DDD ( $n = 15$ ) pacemakers. After  $22 \pm 7$  months of pacing, MBF was quantified with  $^{13}\text{N}$ -labeled ammonia positron emission tomography scanning at 60 beats per min and 90 beats per min. Patients in the DDD group furthermore underwent MBF measurement at temporary AAI pacing, 60 beats per min. Myocardial blood flow was assessed in the anterior, lateral, inferior and septal regions, and the global mean MBF was calculated. Left ventricular ejection fraction was determined by echocardiography at pacemaker implantation and at the time of MBF measurements.

## RESULTS

Myocardial blood flow at rates 60 and 90 beats per min did not differ between the AAI and DDD groups. During temporary AAI pacing in the DDD group, MBF was significantly higher than during DDD pacing in both the inferior ( $p = 0.001$ ) and septal ( $p = 0.004$ ) regions and also globally ( $0.61 \pm 0.15$  vs.  $0.53 \pm 0.13$  mL·g<sup>-1</sup>·min<sup>-1</sup>,  $p = 0.005$ ). In the DDD group, LVEF decreased from pacemaker implantation to time of MBF measurements ( $0.61 \pm 0.09$  vs.  $0.56 \pm 0.07$ ,  $p = 0.013$ ). Left ventricular ejection fraction during temporary AAI pacing at time of MBF measurements was not different from LVEF at pacemaker implantation.

## CONCLUSIONS

In patients with SSS, chronic DDD pacing reduced inferior, septal and global mean MBF as well as LVEF, as compared with temporary AAI pacing. The LVEF reversed to baseline level during temporary AAI pacing despite 22 months of permanent ventricular pacing preceding it. Augmenting pace rate to 90 beats per min increased MBF equally in the two treatment groups

Circulation, 2000 ;102: 1358-1363

Physical Activity and Mortality in Older Men With Diagnosed Coronary Heart Disease

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**Background-**We have studied the relations between physical activity, types of physical activity, and changes in physical activity and all-cause mortality in men with established coronary heart disease (CHD).

**Methods and Results-**In 1992, 12 to 14 years after the initial screening (Q1) of 7735 men 40 to 59 years of age from general practices in 24 British towns, 5934 (91% of available survivors, mean age 63 years) provided further information on physical activity (Q2) and were followed up for 5 years; 963 had a physician's diagnosis of CHD (myocardial infarction or angina). After exclusions, there were 772 men with established CHD, 131 of whom died of all causes. The lowest risks for all-cause and cardiovascular mortality were seen in light and moderate activity groups (adjusted relative risk compared with inactive/occasionally active: light, 0.42 (0.25, 0.71); moderate, 0.47 (0.24, 0.92); and moderately vigorous/vigorous, 0.63 (0.39, 1.03). Recreational activity of  $\geq 4$  hours per weekend, moderate or heavy gardening, and regular walking ( $>40$  min/d) were all associated with a significant reduction in all-cause mortality. Nonsporting activity was more beneficial than sporting activities. Men sedentary at Q1 who began at least light activity by Q2 showed lower mortality rates on follow-up than those who remained sedentary (relative risk 0.58, 95% CI 0.33 to 1.03;  $P=0.06$ ).

**Conclusions-**Light or moderate activity in men with established CHD is associated with a significantly lower risk of all-cause mortality. Regular walking and moderate or heavy gardening were sufficient to achieve this benefit.

The American Journal of Cardiology, 2000;85:1179-1184

A simplified lesion classification for predicting success and complications of coronary angioplasty

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In 1988, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures presented a classification of coronary lesions utilizing 26 lesion features to predict the success and complications of balloon angioplasty. Using data from the Registry of the Society for Cardiac Angiography and Interventions (SCAI) we evaluated the ability of this classification to predict success and complications. Lesion success, death in hospital, emergency cardiac bypass surgery, and major adverse events were evaluated in 41,071 patients who underwent single-vessel

angioplasty from January 1993 to June 1996. Logistic models using the ACC/AHA lesion classification, vessel patency, or both, were compared. A new classification based on the interaction of the ACC/AHA classification plus lesion patency was compared with the existing ACC/AHA classification. Vessel patency, added to the ACC/AHA classification, improved prediction of lesion success (p 0.0001). Class A and patent B lesions had similar success and complication rates, so a simplified classification (SCAI) using only 7 lesion characteristics could be created. This system (I: non-C patent, II: C patent, III: non-C occluded, and IV: C occluded) improved prediction of lesion success compared with the ACC/AHA classification (Bayesian Information Criterion statistic: ACC/AHA 16539, SCAI 15956; and area under the receiver- operating characteristics curve 0.659, 0.693, respectively). The SCAI classification was preferred for predicting major complications and in-hospital death and was similar to the ACC/AHA classification for predicting emergency bypass surgery.

Figure 1. A lesion success rates according to the ACC/AHA lesion classification.  
B. lesion success rates according to patency and ACC/AHA lesion classification.  
C. success rates according to the proposed SCAI classification. The 4 classes provide separation of success from 96.8% to 75%

Figure 3. Complications in patients subgrouped by presence or absence of an acute myocardial infarction within 24 hours and by the SCAI lesion classification. When patency of the vessel is taken into consideration, the complication rates shown for the B or the C lesions are seen to be quite different for the patent or occluded vessels in the same ACC/AHA class.

The American Journal of Cardiology, 2000;86:6:680-682

Incidence, management, and outcome of coronary artery perforation during percutaneous coronary intervention

Luis Gruberg , Ellen Pinnow, Roy Flood , Yvonne Bonnet , Mihaela Tebeica, Ron Waksman , Lowell F. Satler , Augusto D. Pichard , Kenneth M. Kent , Martin B. Leon and Joseph Lindsay Jr.

Coronary artery perforation is a rare but dreaded complication of percutaneous coronary intervention (PCI). It has been reported to occur in 0.2% to 0.6% of all patients who undergo percutaneous transluminal coronary angioplasty, and to have a higher incidence with the use of new atheroablative devices that cut, vaporize, or drill the vessel wall. This study was designed to analyze the incidence, management, and outcome of a large consecutive series of unselected patients who had a coronary artery perforation during PCI during a 9-year period in a single center. In our experience, patients who underwent emergency surgery with either pericardial window and/or bypass surgery had a worse outcome, with a higher in-hospital mortality than patients who were treated medically or with emergency pericardiocentesis, reflecting the severity of the perforation and rapid hemodynamic deterioration that required drastic measures. Although the likelihood of coronary artery perforation during PCI is low, it is more frequent in female patients and in patients who undergo lesion modification with atheroablative devices.

TABLE 3 Clinical Outcome (n = 84)

TABLE 4 Comparison According to Outcome

*The American Journal of Cardiology, 2000;85:6:757-760*

Frequency of left ventricular free-wall rupture in patients with acute myocardial infarction treated with primary angioplasty

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The main advantage of primary percutaneous transluminal coronary angioplasty (PTCA) over thrombolytic therapy for the treatment of acute myocardial infarction (AMI) is the achievement of a higher rate of coronary patency with a lower risk of intracranial bleeding, which includes lower mortality and a reduction of the

reinfarction rate, especially in high-risk patients. Free-wall rupture (FWR) constitutes the second most common cause of in-hospital death in patients with AMI, ranging from 0.8% to 6%. It has been suggested and even widely accepted that primary PTCA reduces the risk of FWR, especially when a successful result is achieved. However, the risk of FWR in patients with AMI treated with primary angioplasty has not been studied in detail. This study was conducted to assess the incidence of FWR in patients with AMI treated with primary angioplasty, as well as to investigate the clinical and angiographic variables associated with a higher risk of FWR in this setting. The frequency of FWR in our series of 590 patients with AMI treated with primary PTCA was 2.2%, which is not different from that reported in series of patients treated with thrombolysis. This incidence was higher in patients >65 years old, women, nonsmokers, as well as in those with anterior location and an initial TIMI grade 0 flow, but it was similar in patients with a successful or unsuccessful angiographic result.

TABLE III Incidence of Free-Wall Rupture in Different Subgroups of Patients.

The American Journal of Medicine, 2000;108:4:309-316

Ischemic complications after percutaneous transluminal coronary angioplasty

Eric R. Bates

The ischemic complications of percutaneous transluminal coronary angioplasty (PTCA) include abrupt closure, which occurs in 2% to 10% of patients and is associated with increased morbidity and mortality. Periprocedural myocardial infarction due to side branch occlusion or embolization of platelet aggregates or thrombus occurs in 5% to 20% of patients. Patients with acute coronary syndromes, older age, and complex lesions are at greater risk of periprocedural complications. Technical advances, primarily stenting, are useful in the prevention and management of acute closure, but are also accompanied by thrombotic complications. It remains to be seen whether the new antithrombin agents reduce the rate of periprocedural complications if used in combination with aspirin and new antiplatelet therapies. These new antiplatelet agents (ticlopidine, clopidogrel, abciximab, eptifibatide, and tirofiban) reduce the rate of ischemic complications and have become standard adjunctive therapy for patients who undergo PTCA.

Figure 3. Development of preprocedural and periprocedural myocardial infarction (MI) during treatment with abciximab or placebo in the CAPTURE (c7E3 Fab Antiplatelet Therapy in Unstable Refractory Angina) study. PTCA = percutaneous transluminal coronary angioplasty. From the CAPTURE study report, with permission.

Figure 4. Incidence of the composite endpoint (death, myocardial infarction, or revascularization) 24 hours after randomization in the IMPACT II (Integrilin to Minimize Platelet Aggregation and Coronary Thrombosis II) study. Results are shown for patients who actually received therapy and for the total sample.

Figure 5. Incidence of the composite endpoint (death and nonfatal myocardial infarction [MI]) in patients who underwent percutaneous coronary interventions in the PURSUIT (Platelet Glycoprotein IIb/IIIa in Unstable Angina: Receptor Suppression Using Integrilin Therapy) trial, before the intervention and at 96 hours, 7 days, and 30 days after the procedure. PTCA = percutaneous transluminal coronary angioplasty.

Journal of the American College of Cardiology, 2000;36:5:1520-1525

Reduced procedural risk for coronary catheter interventions in carriers of the coagulation factor VII-Gln353 gene

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**OBJECTIVES:** We have focused on the role of coagulation factor VII (FVII) Arg353Gln polymorphism as a risk predictor of complications following percutaneous transluminal coronary angioplasty (PTCA), directional coronary atherectomy (DCA), and stenting.

**BACKGROUND:** The FVII Arg353Gln mutation decreases FVII activity, and presence of the Arg353 allele could be protective against thrombus formation during catheter interventions. **METHODS:** A total of 666 consecutive patients with coronary artery disease who had undergone PTCA (n = 280), DCA (n = 104), or stenting (n = 282) were followed up for a 30-day composite end point, which included need for target vessel revascularization, myocardial infarction, and death. The Arg353Gln polymorphism of FVII was determined by PCR/RFLP assay.

**RESULTS:** Carriers of the Gln353 allele had significantly lower levels of total FVII activity (FVIIc, -20.7%, p < 0.001) and of activated circulating FVII (FVIIa, -32.7%, P = 0.03) compared with Arg353/Arg353. The composite end point occurred in 43 patients: 4 were heterozygous Arg353/Gln353, and 39 were homozygous Arg353/Arg353. The incidence of the composite end point was 2.5% in carriers of the Gln353 allele and 7.7% in Arg353/Arg353 homozygotes (p = 0.013). This corresponds to a 72% risk reduction in carriers of the Gln353 allele (relative risk: 0.28; 95% confidence interval: 0.09-0.81; P = 0.02). **CONCLUSIONS:**

The Gln353 allele of FVII is associated with substantial risk reduction in adverse events that complicate coronary catheter interventions. With the perspective of active site-blocked activated FVII (FVIIai) as conjunctive medication, the results suggest that the FVII genotype should be taken into due consideration in

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