Imitative restenosis after percutaneous transluminal coronary angioplasty prevented by buyang huanwu decoction in rabbits

Hou C, He Q, Li S.

OBJECTIVE: To examine the preventive effect of Buyang Huanwu Decoction (BYHWD) on imitative restenosis after percutaneous transluminal coronary angioplasty (PTCA) in diet-induced atherosclerotic rabbits. METHODS: Diet-induced atherosclerotic rabbits were randomly allocated into group 1 (n = 24, fed with BYHWD one week before and 4 weeks after the operation, 2 ml/kg per day, containing herbal drug 8.4 g/ml) and group 2 (n = 20, as control). Balloon angioplasty was performed in the abdominal aorta to mimic coronary angioplasty. RESULTS: Sixty days after operation: (1) Incidence of hyperplasia of the intima was 7/24 (29.2%) in group 1 vs 17/20 (85.0%) in group 2, P < 0.01; (2) Comparison of area of hyperplastic intima was (0.54 +/- 0.21) mm² vs (1.67 +/- 0.75) mm², P < 0.01; (3) Area of hyperplastic intima/area of lumen (limited by the internal elastic membrane was (18.0 +/- 7.2)² vs (56.0 +/- 17.1)%, P < 0.01; (4) Intact lumen/dilated lumen was (0.74 +/- 0.03) vs (0.35 +/- 0.07), P < 0.01; (5) Effect of serum taken from group 1 on cultured smooth muscle cells showed by 3H-TdR method was (4110.14 +/- 1977.01) cpm, which was significantly less than that of serum taken from group 2 [(7960.14 +/- 2802.59) cpm, P < 0.05]. CONCLUSION: BYHWD has significant preventive effect on the imitative post PTCA restenosis in diet–induced atherosclerotic rabbits.
Effects of AGI-1067 and probucol after percutaneous coronary interventions.


BACKGROUND: AGI-1067, a metabolically stable modification of probucol, is an equipotent antioxidant to probucol but is pharmacologically distinct. In a multicenter trial, we studied whether AGI-1067 reduces restenosis assessed by intravascular ultrasound (IVUS) after percutaneous coronary intervention (PCI) compared with placebo and probucol used as a positive control.

METHODS AND RESULTS: Two weeks before PCI, 305 patients were randomly assigned to 1 of 5 treatment groups: placebo, probucol 500 mg BID, or AGI-1067 70, 140, or 280 mg once daily. Patients were treated for 2 weeks before and 4 weeks after PCI. Baseline and 6-month follow-up IVUS were interpreted by a blinded core laboratory. Stents were used in 85% of patients. Luminal area at the PCI site at follow-up was 2.66+/-1.58 mm² for placebo, 3.69+/-2.69 mm² for probucol, 2.75+/-1.76 mm² for AGI-1067 70 mg, 3.17+/-2.26 mm² for AGI-1067 140 mg, and 3.36+/-2.12 mm² for AGI-1067 280 mg (P=0.02 for the dose-response relationship; P< or =0.05 for AGI-1067 280 mg and probucol versus placebo). There was a mean narrowing of 5.3 mm³ of reference segment lumen in the placebo group and an enlargement in the AGI-1067 140- and 280-mg groups at follow-up (P=0.05 for 140 mg). An increase in QTc interval >60 ms occurred in 4.8% of placebo patients, 17.4% of probucol patients, and 4.8%, 2.4%, and 2.5% of patients in the AGI-1067 groups (P=0.02). CONCLUSIONS: AGI-1067 and probucol reduce restenosis after PCI. In contrast to probucol, AGI-1067 did not cause prolongation of the QTc interval and improved lumen dimensions of reference segments, suggestive of a direct effect on atherosclerosis.
Neointimal hyperplasia by luminal cell recruitment and not be transmural migration. The role of Bcl-2 and HSP47 after balloon angioplasty


Restenosis post angioplasty remains the major limitation of several therapeutic interventions including stent implantation. This explains the ongoing interest in its basic pathogenic mechanisms and factors. The aim of the present study was to assess the localization and maximal expression of Bcl-2, a central antiapoptotic protooncogene, and of heat shock protein 47 (HSP47), a marker of early collagen synthesis, in the context with hyperplastic neointima formation as well as concomitant transmural remodeling processes following angioplasty. 0, 4, 24 and 48 hours, 4, 7 and 14 days post balloon traumatization by use of a rat carotid artery model, specific vascular wall compartments were evaluated concerning area, cell density as well as Bcl-2 and HSP47 expression by immunohistochemistry and morphometry, supplemented by electron microscopy (TEM). Neointimal cell accumulation was detected 4 days post angioplasty, characterized by luminal cells adherent to the internal elastic lamina, associated with maximal Bcl-2 and HSP47 expression amounting to 49% and 41%, respectively. With ongoing neointimal formation, a luminal prevalence of both key determinants and a decreasing expression in basal neointimal areas were found. In the media, a temporally reduced cell density was observed significant at 48 hours post trauma. Constitutive HSP47 expression of the media was constant during the entire observation period, whereas sparse Bcl-2 signalling was induced post angioplasty maximal on day 2 with 3% and on day 14 with 5%. The adventitia demonstrated a transient structural separation between day 4 and 7, exhibiting an inner layer with sparse cellularity and an outer layer with extremely high cell density as well as pronounced neovascularization. In this outer adventitia layer, a high frequency of signals for both Bcl-2 and HSP47 were observed amounting to 29% and 57%, respectively. Complementary TEM analysis gave no evidence of transmural migratory events propagated by adventitial cells and thereby supports early neointimal formation by luminal cell recruitment and marked co-expression of anti-apoptotic Bcl-2 and matrix-generating HSP47 as important survival factors. Clinical implications of these findings may be seen in the integration of proapoptotic substances with temporal efficacy in order to prevent restenosis, e.g., by use of coated stents.
A meta-analysis of the angiotensin-converting enzyme gene polymorphism and restenosis after percutaneous transluminal coronary revascularization: evidence for publication bias.

Agema WR, Jukema JW, Zwinderman AH, van der Wall EE.

BACKGROUND: The insertion/deletion polymorphism of the gene encoding angiotensin-converting enzyme is a controversial risk factor for restenosis after percutaneous transluminal coronary revascularization in patients. Genetic association studies addressing this issue are frequently hampered by insufficient power. Therefore, we conducted a meta-analysis of this association, taking into account the possibility of publication bias. METHODS: We used the MEDLINE database and reviewed citations in relevant articles to identify 12 studies. Information on the design of the studies, the detailed genotype distribution, the angiographic follow-up rate, and the restenosis rate were categorized by use of a standardized protocol. RESULTS: Overall, DD (deletion–deletion) homozygotes had a higher restenosis risk than II (insertion–insertion) carriers (odds ratio 1.22, 95% CI 1.04–1.44, P <.05). However, the published studies were significantly heterogeneous, especially those addressing in-stent restenosis. Smaller studies tended to have positive results more frequently, which is characteristic of publication bias. Correcting for publication bias, we estimated the odds ratio to be 1.15 (95% CI 0.98–1.32, not significant). None of the published studies met all rules of genetic epidemiology. CONCLUSION: We conclude that a clinically significant association of the angiotensin-converting enzyme polymorphism with restenosis after percutaneous transluminal coronary revascularization in patients is unlikely. This meta-analysis provides evidence that the pooled estimate based on published literature, which favors an association, is distorted by publication bias. Hence, screening for this mutation in clinical practice is not justified. Future research should preferentially focus on gene–gene interaction and comply with the rules of genetic epidemiology.
Chlamydia pneumoniae seropositivity predicts the risk of restenosis after percutaneous transluminal coronary angioplasty.


This study was done to evaluate whether anti-Chlamydia pneumoniae seropositivity can be a predictor of restenosis after coronary intervention. Recent studies indicate that latent infection with C. pneumoniae is associated with and could possibly cause atherosclerosis. However, it is unknown whether chronic infection with this microorganism is involved in the mechanism of restenosis after percutaneous transluminal coronary angioplasty. We prospectively studied 78 consecutive patients (90 target lesions) with symptomatic coronary artery disease who underwent successful coronary intervention to a de novo lesion (conventional balloon angioplasty to 31 lesions and stent implantation to 59 lesions). At angioplasty, blood samples were collected to measure the serum level of anti-C. pneumoniae IgG to examine whether seropositive patients were prone to restenosis and whether the seropositivity could predict the risk of restenosis determined by follow-up coronary angiography performed within 6 months after the angioplasty. Restenosis, defined as more than 50% stenosis with an increase of 15% or more in the degree of stenosis from that measured on cineangiograms after angioplasty, developed in 36 of 62 seropositive patients and in 4 of 16 seronegative patients (58% vs 25%, P = 0.025). Lesions in the seropositive patients had a greater mean loss index (mean +/- SD 0.75 +/- 0.45 vs 0.35 +/- 0.41, P < 0.001), which was defined as late loss (luminal diameter reduction at follow-up angiography) divided by acute gain (luminal diameter gain by angioplasty), in late loss (1.07 +/- 0.64mm vs 0.65 +/- 0.79mm, P = 0.019), in percentage of diameter stenosis (57% +/- 20% vs 41% +/- 21%, P = 0.003) and a lesser mean in minimal luminal diameter (1.18 +/- 0.58 mm vs 1.67 +/- 0.63 mm, P = 0.002) at follow-up angiography. In a multivariate logistic regression model, anti-C. pneumoniae IgG seropositivity was a strong independent predictor of restenosis compared to the other risk factors (odds ratio = 6.2, P = 0.01). C. pneumoniae could play an important role in the mechanism of restenosis and evaluation of the IgG seropositivity, and may help to identify patients at high risk for restenosis.
Angiotensin converting enzyme insertion or deletion polymorphism and coronary restenosis: meta-analysis of 16 studies.

Bonnici F, Keavney B, Collins R, Danesh J.

OBJECTIVE: To assess the association between genotype at the insertion or deletion polymorphism of the angiotensin converting enzyme gene and risk of coronary restenosis after percutaneous coronary intervention. DESIGN: Meta-analysis of studies before July 2001 that reported on these genotypes and risk of coronary restenosis after a percutaneous coronary intervention, with or without coronary stenting. RESULTS: 16 studies, involving 4631 patients undergoing a percutaneous coronary intervention, yielded 1683 patients with restenosis after a mean weighted follow up of 5.5 months. The combined odds ratio for restenosis in people with the DD genotype was 1.23 (99% confidence interval 1.03 to 1.46). When studies were grouped by size, however, the combined odds ratios for restenosis in people with the DD genotype were 1.94 (1.39 to 2.71) for studies with less than 100 cases, 1.33 (0.92 to 1.93) for studies with 100–200 cases, and 0.92 (0.72 to 1.18) for studies with more than 200 cases (trend P=0.02). Similarly, when studies were grouped by genotyping procedures, significantly larger odds ratios were found in the studies that did not conceal disease status from laboratory staff and in the studies that did not use a second polymerase chain reaction amplification to reduce genetic mistyping. CONCLUSION: Compared with other studies, larger and more rigorous studies show a weaker association between the angiotensin converting enzyme gene DD genotype and restenosis. Publication bias or detection biases can produce artefactual associations at least as large as those that might be expected for common polymorphisms in complex diseases, suggesting the need for larger and more rigorous genetic epidemiological investigations than are now customary.
Intracoronary beta-radiation to reduce restenosis after balloon angioplasty and stenting; the Beta Radiation In Europe (BRIE) study.


AIMS: The BRIE trial is a registry evaluating the safety and performance of (90)Sr delivered locally (Beta-Cath TM system of Novoste) to de-novo and restenotic lesions in patients with up to two discrete lesions in different vessels. METHODS AND RESULTS: In total, 149 patients (175 lesions) were enrolled: 62 treated with balloons and 113 with stents. The restenosis rate, the minimal luminal diameter and the late loss were determined in three regions of interest: (a) in a subsegment of 5mm containing the original minimal luminal diameter pre-intervention termed target segment; (b) the irradiated segment, 28 mm in length, and (c) the entire analysed segment, 42 mm in length, termed the vessel segment. Binary restenosis was 9.9% for the target segment, 28.9% for the irradiated segment, and 33.6% for the vessel segment. These angiographic results include 5.3% total occlusions. Excluding total occlusions binary restenosis was 4.9%, 25% and 29.9%, respectively. At 1 year the incidence of major adverse cardiac events placed in a hierarchical ranking were: death 2%, myocardial infarction 10.1%, CABG 2%, and target vessel revascularization 20.1%. The event–free survival rate was 65.8%. Non-appropriate coverage of the injured segment by the radioactive source termed geographical miss affected 67.9% of the vessels, and increased edge restenosis significantly (16.3% vs 4.3%, P=0.004). It accounted for 40% of the treatment failures. CONCLUSION: The results of this registry reflect the learning process of the practitioner. The full therapeutic potential of this new technology is reflected by the restenosis rate at the site of the target segment. It can only be unravelled once the incidence of late vessel occlusion and geographical miss has been eliminated by the prolonged use of thienopyridine, the appropriate training of the operator applying this new treatment for restenosis prevention, and the use of longer sources.
Clinical and angiographic outcome of patients with mild coronary lesions treated with balloon angioplasty or coronary stenting. Implications for mechanical plaque sealing.

Mercado N, Maier W, Boersma E, Bucher C, de Valk V, O'Neill WW, Gersh BJ, Meier B, Serruys PW, Wijns W.

Aims To investigate the clinical and angiographic outcome of patients with mild coronary lesions treated with balloon angioplasty or coronary stenting (coronary plaque sealing, i.e. dilatation of angiographically non-significant lesions) compared to moderate and severe stenoses.

Methods and results Patients with chronic stable angina and a single de novo lesion in a native coronary vessel scheduled to undergo percutaneous coronary intervention (PCI) were selected from 14 different studies. Off-line analysis of angiographic outcomes was assessed in all patients using identical and standardised methods of data acquisition, analysis and definitions. Clinical endpoints were adjudicated by independent clinical events committees. All quantitative coronary angiographic (QCA) analyses were performed in the same core laboratory. Stenosis severity prior to PCI was categorised into three groups: <50% diameter stenosis (DS), 50–99%DS and >99%DS pre. A total of 3812 patients were included in this study: 1484 patients (39%) were successfully treated with balloon angioplasty (BA) only and stented angioplasty was performed in 2328 patients (61%). One-year mortality and rate of non-fatal myocardial infarction (MI) (Kaplan-Meier) did not differ between BA and stented angioplasty for any of the stenosis severity categories. Following BA, the combined event rate (death and non-fatal MI) was 4.8, 4.6 and 0% in the <50, 50–99 and >99%DS categories, respectively. Following stented angioplasty, the combined event rate was 3.1, 4.4 and 4.8% in the same categories. The need for repeat revascularisation corrected for stenosis severity in the Cox proportional-hazards regression model was reduced by 20% after stented angioplasty (hazard ratio (HR) 0.80, 95%CI 0.69–0.93). Conclusion The concept of plaque sealing is appealing from the theoretical point of view. However, with current technology, plaque sealing cannot prevent death and future non-fatal MIs in the long-term because 1-year event rates after PCI of non-significant stenoses remain unacceptably elevated when compared with the estimated 1-year probability of a non-fatal MI in lesions with a <50%DS. Moreover, major adverse cardiac events at 1-year after PCI are not directly related to the degree of pre-procedural stenosis severity.
Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomised trials.

Keeley EC, Boura JA, Grines CL.

BACKGROUND: Many trials have been done to compare primary percutaneous transluminal coronary angioplasty (PTCA) with thrombolytic therapy for acute ST-segment elevation myocardial infarction (AMI). Our aim was to look at the combined results of these trials and to ascertain which reperfusion therapy is most effective. METHODS: We did a search of published work and identified 23 trials, which together randomly assigned 7739 thrombolytic-eligible patients with ST-segment elevation AMI to primary PTCA (n=3872) or thrombolytic therapy (n=3867). Streptokinase was used in eight trials (n=1837), and fibrin-specific agents in 15 (n=5902). Most patients who received thrombolytic therapy (76%, n=2939) received a fibrin-specific agent. Stents were used in 12 trials, and platelet glycoprotein IIb/IIIa inhibitors were used in eight. We identified short-term and long-term clinical outcomes of death, non-fatal reinfarction, and stroke, and did subgroup analyses to assess the effect of type of thrombolytic agent used and the strategy of emergent hospital transfer for primary PTCA. All analyses were done with and without inclusion of the SHOCK trial data. FINDINGS: Primary PTCA was better than thrombolytic therapy at reducing overall short-term death (7% [n=270] vs 9% [360]; p=0.0002), death excluding the SHOCK trial data (5% [199] vs 7% [276]; p=0.0003), non-fatal reinfarction (3% [80] vs 7% [222]; p<0.0001), stroke (1% [30] vs 2% [64]; p=0.0004), and the combined endpoint of death, non-fatal reinfarction, and stroke (8% [253] vs 14% [442]; p<0.0001). The results seen with primary PTCA remained better than those seen with thrombolytic therapy during long-term follow-up, and were independent of both the type of thrombolytic agent used, and whether or not the patient was transferred for primary PTCA. INTERPRETATION: Primary PTCA is more effective than thrombolytic therapy for the treatment of ST-segment elevation AMI.
Comparative long-term outcomes of balloon angioplasty of uni- or multi-vessel lesions in coronary disease

Asanova AZh, Semitko SP, Ianitskaia MV, Ioseliani DG.

A study has been carried out on long-term results of transluminal balloon angioplasty (TLBAP) in case of mono- and multivascular lesion of coronary bed (CB). During long-term follow-up (16.3 +/- 3.8 months) a high survival rate was observed after treatment procedure both in mono- (97.1%) and multivascular (98.75%) lesion. However, patients with monovascular lesion had lesser probability of being subjected to additional revascularization procedure and greater probability of avoiding angina pectoris in long-term follow-up unlike patients with multivascular lesion of coronary arteries (85.7% vs 63.8%). At the same time a good angiographic angioplastic effect of dilated vessel remained in equal number of patients: 66.7% with monovascular lesion and 68.6% with multivascular lesion. Therefore, it is advantageous to use TLBAP both in mono- and multivascular CB lesion.
Five-year angiographic outcome in patients without restenosis following coronary balloon angioplasty: a comparison between non diabetic and diabetic lesions.


Few studies have investigated the long-term angiographic outcome of successful coronary balloon angioplasty (CBA) among diabetic and nondiabetic dilated lesions. The purpose of this study was to evaluate and compare the long-term (>5 years) outcomes of diabetic and nondiabetic CBA lesions which had remained patent 3–12 months after intervention. Twenty-five patients (45 lesions) with diabetes mellitus and 79 patients (138 lesions) without diabetes mellitus were enrolled as subjects. All patients who underwent CBA without restenosis within 3–12 months of the initial CBA based on follow-up angiographic evaluation were included. Quantitative coronary angiograms performed before, immediately after CBA, during the 3–12-month period (mean 4.1 +/- 1.0 months), and at or after 5 years (mean 6.4 +/- 2.0 years) were compared. There was no significant difference in the reference diameter between nondiabetic and diabetic lesions at any of the four time points studied. The minimum lumen diameter before and immediately after the procedure and at the 3–12-month follow-up did not differ significantly between the two groups. At >5-year follow-up, the minimum lumen diameter was significantly (P = 0.005) decreased in diabetic lesions. Total occlusion occurred in 9% (4/45) of the diabetic lesions compared to only 1%, (1/138) in the nondiabetic lesions (P = 0.007). Diabetic lesions showed significant (P = 0.049) narrowing between the 3–12 month period and >5-year follow-up. Fifty-one percent (18/35) of the nondiseased vessels in the diabetic patients at the time of enrollment had new stenosis during the follow-up periods. In conclusion, compared to nondiabetic lesions, patients with diabetic lesions who underwent CBA were more predisposed to have stenotic progression and total occlusion.
Mechanisms of restenosis after coronary intervention. Difference between plain old balloon angioplasty and stenting.

Nakatani M, Takeyama Y, Shibata M, Yorozuya M, Suzuki H, Koba S, Katagiri T.

BACKGROUND: Restenosis after coronary intervention remains an unsolved and important clinical problem. We histologically examined the mechanism of restenosis after both balloon injury and stenting. METHODS: Coronary arteries of swine were subjected to balloon injury and stenting. Next, just after stenting or at 7, 14, or 28 days, the animals were sacrificed for the evaluation by morphometric analysis, histological observation, and immunostaining. RESULTS: The neointimal area peaked at 14 days in the balloon injury group (BG) and increased linearly up to 28 days in the stent group (SG). At 28 days, the total vascular area in the BG was reduced to 78% of the control values. In the SG, the total vascular area remained enlarged. According to the phenotypic analysis, the vascular smooth muscle cells (VSMCs) in the neointimal area at 28 days were the contractile type in the BG and the synthetic type in the SG. Proliferating cell nuclear antigen (PCNA) and macrophage-positive cells were not observed in neointima in the BG at 28 days, whereas they were observed around the stent struts in the SG. In addition, numerous inflammatory cells, such as neutrophils and eosinophils, were also present in the SG. CONCLUSIONS: Restenosis after balloon injury consisted of arterial remodeling and neointimal hyperplasia, whereas that after stenting consisted mostly of neointimal hyperplasia. The neointimal area in the SG lasted longer than that in the BG. Continuous inflammation may be an important factor in the restenosis of stenting.
Comparison of transthoracic Doppler echocardiography to intracoronary Doppler guidewire measurements for assessment of coronary flow reserve in the left anterior descending artery for detection of restenosis after coronary angioplasty.

Lethen H, Tries HP, Brechtken J, Kersting S, Lambertz H.

Transthoracic Doppler echocardiography (TDE) has been described as a feasible and accurate technique to noninvasively assess coronary flow reserve (CFR) in the left anterior descending artery (LAD). This study was designed to evaluate whether serial assessment of CFR in the LAD using TDE allows detection of restenosis after previously performed angioplasty. Thirty-three consecutive patients with single-vessel coronary artery disease of the LAD scheduled for angioplasty underwent assessment of coronary flow velocity at rest and during adenosine-induced hyperemia in the distal LAD using high-frequency TDE. CFR was calculated as the ratio of hyperemic to basal systolic/diastolic mean velocity. Investigations were performed before and immediately after angioplasty, and at the time of control angiography after 3 months. CFR results by TDE were compared with intracoronary Doppler guide wire measurements. Adequate pulse-wave Doppler signals to measure CFR were obtained in 30 patients (91%) using TDE. There was close correlation between echocardiographically and intracoronary derived CFR results (r = 0.80, 0.79, and 0.87 before angioplasty, early after, and at 3-month control angiography, respectively; p <0.001). Using a cut-off value of CFR $\leq 2.0$ to identify significant coronary artery disease, TDE detected LAD restenosis with a sensitivity of 89% and specificity of 90%. Thus, high-frequency TDE is a feasible technique to noninvasively assess CFR in the LAD with results closely corresponding to invasive measurements. Defining a cut-off value of CFR $\leq 2.0$, the technique has the potential to reliably detect LAD stenosis after coronary intervention.
Balloon angioplasty or medical therapy for hypertensive patients with atherosclerotic renal artery stenosis? A meta-analysis of randomized controlled trials.

Nordmann AJ, Woo K, Parkes R, Logan AG.

PURPOSE: The optimal treatment for hypertensive patients with atherosclerotic renal artery stenosis is controversial. We performed a meta-analysis comparing the effects of balloon angioplasty and medical therapy in these patients. METHODS: We searched MEDLINE, EMBASE, the Science Citation Index, the Cochrane Controlled Trials Registry, and reference lists. Authors of published trials were contacted. RESULTS: We identified three trials involving a total of 210 patients with moderate-to-severe (> or = 50%) unilateral or bilateral atherosclerotic renal artery stenosis and poorly controlled hypertension who were followed for at least 3 months after intervention. Balloon angioplasty was significantly more effective in reducing blood pressure than was medical therapy; the weighted mean difference between the two treatments was -7 mm Hg (95% confidence interval [CI]: -12 to -1 mm Hg) for systolic blood pressure and -3 mm Hg (95% CI: -6 to -1 mm Hg) for diastolic blood pressure. There was no consistent difference in changes in renal function. Patients treated with balloon angioplasty were more likely to have patent renal arteries after 12 months (52% vs. 19%; odds ratio [OR] = 4.2; 95% CI: 1.8 to 9.8), used fewer antihypertensive medications, and appeared to have fewer major cardiovascular and renovascular complications (OR = 0.27; 95% CI: 0.06 to 1.23; P = 0.09). CONCLUSION: Balloon angioplasty has a modest but significant effect on blood pressure and should be considered for patients with atherosclerotic renal artery stenosis and poorly controlled hypertension. There is no evidence supporting its use in improving or preserving renal function, although none of the trials were designed to address this issue.
Balloon angioplasty and stenting of multiple intralobar pulmonary arterial stenoses in adult patients.

Rothman A, Levy DJ, Sklansky MS, Grossfeld PD, Auger WR, Ajami GH, Behling CA.

Balloon angioplasty and stent placement for pulmonary arterial stenoses in children are well-established therapies. In contrast, management of isolated peripheral pulmonary arterial stenoses in adults remains relatively unexplored. Four women (ages 18–63 years) with multiple discrete intralobar pulmonary arterial stenoses were treated with balloon angioplasty. Initially, 4–5 stenoses were dilated in each patient. The mean minimum diameter of the stenoses increased from 1.3 to 3.1 mm (P < 0.001), and the mean ratio of right ventricular to aortic systolic pressure decreased from 0.92 to 0.62 (P < 0.05). Each patient had marked symptomatic improvement. However, three patients developed recurrence of symptoms 4–24 months after angioplasty, and two had angiographic evidence of restenosis at previously dilated sites. These restenoses were treated with repeat angioplasty or stent implantation (three stents in each patient). One of these two patients developed near-occlusive restenosis of the stents and had successful bilateral lung transplantation. The other patient had a third catheterization with successful implantation of three additional stents. The third patient with recurrent symptoms died 2 years later, without further intervention. Transcutaneous catheter therapy for multiple intralobar pulmonary arterial stenoses in adults is highly successful acutely, but restenosis is common within several months. For some patients, balloon angioplasty and stent implantation may provide definitive management, while for others these procedures may serve as a bridge to lung transplantation.
A randomized trial assessing the effect of coumarins started before coronary angioplasty on restenosis: results of the 6-month angiographic substudy of the Balloon Angioplasty and Anticoagulation Study (BAAS).


BACKGROUND: Thrombus formation during coronary angioplasty may play a role in the restenosis process. METHODS: The effect of pretreatment with coumarins on 6-month angiographic outcome was studied. In addition, the effect of "optimal" anticoagulation, defined as an international normalized ratio >70% of the follow-up time in the target range, was studied. A total of 261 patients were assigned to aspirin alone (ASA group) and 270 patients to aspirin plus coumarins started 1 week before the procedure (coumarin group). RESULTS: The mean international normalized ratio was 2.7 +/- 1.2 at the start of the procedure and 3.1 +/- 0.5 during follow up. Quantitative coronary analysis was performed on 301 lesions in the ASA group and of 297 lesions in the coumarin group. At 6 months, the minimal luminal diameter was similar in the ASA and coumarin groups. Optimal anticoagulation, however, was an independent predictor of a larger minimal luminal diameter at follow up (P = .01). CONCLUSION: Overall, coumarins do not improve angiographic outcome 6 months after coronary angioplasty.
Percutaneous transluminal renal artery angioplasty: who benefits most?

Ziakka S, Belli AM, Kong TK, MacGregor GA, Missouris CG.

We set out to assess the long-term benefits of renal percutaneous transluminal angioplasty (PTA) in 107 consecutive hypertensive patients with atheromatous renal artery stenosis. During 12-month follow-up, blood pressure fell to normal levels in 10 (8.8%) patients and improved in 76 (67.3%); renal function improved or remained stable in 74% of patients. In patients with atheromatous disease, renal angioplasty was most successful in those with stenosis in a single functioning kidney, and in nine patients who presented with symptoms and signs of heart failure, in the absence of overt ischaemic or valvular heart disease. In the latter group, renal PTA resulted in a large loss of sodium and water, resolution of the 'apparent' heart failure, and a marked improvement in blood pressure and renal function. It is suggested that all hypertensive patients with haemodynamically significant renal artery stenosis (and/or mild to moderate impairment in renal function), should be considered for renal PTA. Patients with atheromatous stenosis in a single functioning kidney, and those who present with signs of sodium and water retention, are likely to benefit most.
PTCA and RESTENOSIS

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8. Clinical and angiographic outcome of patients with mild coronary lesions treated with balloon angioplasty or coronary stenting. Implications for mechanical plaque sealing.
Mercado N, Maier W, Boersma E, Bucher C, de Valk V, O'Neill WW, Gersh BJ, Meier B, Serruys PW,
10. Comparative long-term outcomes of balloon angioplasty of uni- or multi-vessel lesions in coronary disease
Asanova AZh, Semitko SP, Ianitskaia MV, Ioseliani DG. Klin Med (Mosk) 2002;80(11):24-6
16. A randomized trial assessing the effect of coumarins started before coronary angioplasty on restenosis: results of the 6-month angiographic substudy of the Balloon Angioplasty and Anticoagulation Study (BAAS). ten Berg JM, Kelder JC, Suttrop MJ, Verheugt FW, Plokker HW: Balloon Angioplasty and
OBJECTIVES: The objective of this study was to test the hypothesis that the intracoronary administration of a direct donor of nitric oxide is a safe and effective method to treat impaired blood flow (no-reflow phenomenon) that occurs during percutaneous transluminal coronary interventions (PTCI). BACKGROUND: The absence of blood flow or decreased blood flow in a coronary artery following PTCI despite the presence of a patent epicardial vessel or graft is designated “no-reflow” or “impaired flow.” This alteration in blood flow is a serious complication of percutaneous revascularization strategies that results in an increased incidence of morbidity, myocardial infarction and mortality. METHODS: Nineteen consecutive patients undergoing standard percutaneous revascularization procedures complicated by either no-reflow or impaired flow that received intracoronary nitroprusside treatment were studied. One patient had two procedures performed on two separate grafts on two successive days. Interventions were performed on either saphenous vein grafts or native vessels and utilized angioplasty, stent deployment or rotational atherectomy strategies. Following interventions that were associated with impaired flow, varying total doses (of nitroprusside 50 to 1,000 microg) were administered into the coronary artery or saphenous vein graft. The angiographic archives before and after intracoronary administration of nitroprusside were analyzed for TIMI grade flow and a frame count method was used to quantitate blood flow velocity. RESULTS: Following a PTCI that resulted in either no-reflow or impaired flow, nitroprusside (median dose 200 microg) was found to lead to a highly significant and rapid improvement in both angiographic flow (p < 0.01 compared with pretreatment angiogram) and blood flow velocity (p < 0.01 compared with pretreatment angiogram). No significant hypotension or other adverse clinical events were associated with nitroprusside administration. CONCLUSIONS: The direct nitric oxide donor nitroprusside is an effective, safe treatment of impaired blood flow and no-reflow associated with PTCI. The
use of nitroprusside to treat syndromes secondary to microvascular dysfunction may provide a novel therapeutic strategy for treating no-reflow or impaired blood flow following percutaneous interventions.

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Increased local temperature in human coronary atherosclerotic plaques: an independent predictor of clinical outcome in patients undergoing a percutaneous coronary intervention.

Stefanadis C, Toutouzas K, Tsiamis E, Stratos C, Vavuranakis M, Kallikazaros I, Panagiotakos D, Toutouzas P.

OBJECTIVES: We investigated the midterm clinical significance of human coronary atherosclerotic plaques temperature after a successful percutaneous coronary intervention. BACKGROUND: Previous studies have shown an increased temperature in human atherosclerotic plaques. However, the prognostic significance of atherosclerotic plaque temperature in patients undergoing a successful percutaneous intervention is unknown. METHODS: We prospectively investigated the relation between the temperature difference (deltaT) between the atherosclerotic plaque and the healthy vessel wall and event-free survival among 86 patients undergoing a successful percutaneous intervention. Temperature was measured by a thermography catheter, as previously validated. The study group consisted of patients with effort angina (EA) (34.5%), unstable angina (UA) (34.5%) and acute myocardial infarction (AMI) (30%). RESULTS: The deltaT increased progressively from EA to AMI (0.132 +/- 0.18 degrees C in EA, 0.637 +/- 0.26 degrees C in UA and 0.942 +/- 0.58 degrees C in AMI). The median clinical follow-up period was 17.88 +/- 7.16 months. The deltaT was greater in patients with adverse cardiac events than in patients without events (deltaT: 0.939 +/- 0.49 degrees C vs. 0.428 +/- 0.42 degrees C; p < 0.0001). The deltaT was a strong predictor of adverse cardiac events during the follow-up period (odds ratio 2.14, p = 0.043). The threshold of the deltaT value, above which the risk for an adverse cardiac event was significantly increased, was 0.5 degrees C. The incidence of adverse cardiac events in patients with deltaT > or = 0.5 degrees C was 41%, as compared with 7% in patients with deltaT < 0.5 degrees C (p < 0.001). CONCLUSIONS: Increased local temperature in atherosclerotic plaques is a strong predictor of an unfavorable clinical outcome in patients with coronary artery disease undergoing percutaneous interventions.

Am Heart J 2001 May;141(5):837-46
Use of routine functional testing after percutaneous transluminal coronary angioplasty: results from the ROSETTA Registry.


BACKGROUND: The American College of Cardiology (ACC)/American Heart Association (AHA) guidelines for exercise testing suggest that only selected groups of high-risk patients should undergo routine functional testing after percutaneous transluminal coronary angioplasty (PTCA) for the detection of restenosis. OBJECTIVES: Our purpose was (1) to document the patterns of use of post-PTCA functional testing and (2) to determine whether the choice of functional testing strategy is related to clinical characteristics of patients or whether physicians use a similar strategy for all their patients. METHODS: The Routine Versus Selective Exercise Treadmill Testing After Angioplasty (ROSETTA) Registry is a prospective study examining the use of functional testing among 788 patients at 13 centers in 5 countries. RESULTS: During the 6-month period after a successful PTCA, 49% of patients underwent functional testing (range among centers 10%-81%). Among patients who underwent functional testing, 39% had a clinical indication and 61% had functional testing as a routine follow-up. The first functional test was performed a median of 7 weeks after PTCA, with 13% of patients having second tests at a median of 14 weeks and 4% having additional tests at a median of 20 weeks. Univariate and multivariate analyses demonstrated that the chief determinant of the use of routine functional testing was clinical center. Aside from age (P < .0001), no baseline clinical or procedural characteristics were consistently associated with the use of routine functional testing after PTCA. CONCLUSIONS: Physicians do not appear to be adhering to the ACC/AHA guidelines for exercise testing regarding the routine use of post-PTCA functional testing. None of the clinical characteristics identified by the ACC/AHA guidelines were associated with the routine use of post-PTCA functional testing, and the primary determinant of functional testing was the location of the center at which the patient had the PTCA.


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

Cannon CP, Weintraub WS, Demopoulos LA, Vicari R, Frey MJ, Lakkis N, Neumann FJ, Robertson DH,
BACKGROUND: There is continued debate as to whether a routine, early invasive strategy is superior to a conservative strategy for the management of unstable angina and myocardial infarction without ST-segment elevation. METHODS: We enrolled 2220 patients with unstable angina and myocardial infarction without ST-segment elevation who had electrocardiographic evidence of changes in the ST segment or T wave, elevated levels of cardiac markers, a history of coronary artery disease, or all three findings. All patients were treated with aspirin, heparin, and the glycoprotein IIb/IIIa inhibitor tirofiban. They were randomly assigned to an early invasive strategy, which included routine catheterization within 4 to 48 hours and revascularization as appropriate, or to a more conservative (selectively invasive) strategy, in which catheterization was performed only if the patient had objective evidence of recurrent ischemia or an abnormal stress test. The primary end point was a composite of death, nonfatal myocardial infarction, and rehospitalization for an acute coronary syndrome at six months. RESULTS: At six months, the rate of the primary end point was 15.9 percent with use of the early invasive strategy and 19.4 percent with use of the conservative strategy (odds ratio, 0.78; 95 percent confidence interval, 0.62 to 0.97; P=0.025). The rate of death or nonfatal myocardial infarction at six months was similarly reduced (7.3 percent vs. 9.5 percent; odds ratio, 0.74; 95 percent confidence interval, 0.54 to 1.00; P<0.05). CONCLUSIONS: In patients with unstable angina and myocardial infarction without ST-segment elevation who were treated with the glycoprotein IIb/IIIa inhibitor tirofiban, the use of an early invasive strategy significantly reduced the incidence of major cardiac events. These data support a policy involving broader use of the early inhibition of glycoprotein IIb/IIIa in combination with an early invasive strategy in such patients.
(PTCA) or coronary stenting (CS), the effects on the restenosis rate and the outcome. BACKGROUND: It is unknown whether ET induces beneficial effects after coronary angioplasty. METHODS: We studied 118 consecutive patients with coronary artery disease (mean age 57+/−10 years) who underwent PTCA or CS on one (69%) or two (31%) native epicardial coronary arteries. Patients were randomized into two matched groups. Group T (n = 59) was exercised three times a week for six months at 60% of peak VO2. Group C (n = 59) was the control group. RESULTS: Only trained patients had significant improvements in peak VO2 (26%, p < 0.001) and quality of life (26.8%, p = 0.001 vs. C). The angiographic restenosis rate was unaffected by ET (T: 29%; C: 33%, P = NS) and was not significantly different after PTCA or CS. However, residual diameter stenosis was lower in trained patients (-29.7%, p = 0.045). In patients with angiographic restenosis, thallium uptake improved only in group T (19%; p < 0.001). During the follow-up (33+/−7 months) trained patients had a significantly lower event rate than controls (11.9 vs. 32.2%, RR: 0.71, 95% confidence interval [CI]: 0.60 to 0.91, p = 0.008) and a lower rate of hospital readmission (18.6 vs. 46%, RR: 0.69, 95% CI: 0.55 to 0.93, p < 0.001). CONCLUSIONS: Moderate ET improves functional capacity and QOL after PTCA or CS. During the follow-up, trained patients had fewer events and a lower hospital readmission rate than controls, despite an unchanged restenosis rate.

Am J Cardiol 2001 Jun 1;87(11):1240-5

Comparison of outcomes of coronary stenting versus conventional coronary angioplasty in the department of veterans affairs medical centers.

Maynard C, Wright SM, Every NR, Ritchie JL.

Although the short-term benefits of stent deployment have been established, less is known about long-term outcomes. This study compares short- and long-term outcomes in veterans undergoing stenting and conventional coronary angioplasty. We used Department of Veterans Affairs databases to identify 27,224 veterans who had undergone percutaneous coronary intervention (PCI) in Veterans Affairs medical centers between October 1994 and September 1999. Patients were classified according to whether they had acute myocardial infarction (AMI) as the principal diagnosis. Baseline characteristics were similar in the stent and conventional groups. In AMI, hospital mortality was 2.9% for those with stents and 4.8% for those who underwent conventional coronary angioplasty (p <0.0001), whereas for patients without AMI, hospital mortality was similar (1.2% vs 1.4%, p =0.12). For AMI, same-admission bypass surgery rates were lower in the stent group (0.7% vs 3.2%, p <0.0001) and in the group without AMI (1.2% vs 3.3%, p <0.0001). Two-year
Survival was better for stenting in veterans with (90% vs 88%, p = 0.006) and without (92% vs 91%, p = 0.008) AMI. For AMI, 2-year rehospitalization rates for PCI (10% vs 13%, p < 0.0001), coronary artery bypass surgery (4% vs 6%, p < 0.0001), and unstable angina (17% vs 23%) were lower for those who had stenting. In the no-AMI group, 2-year rehospitalization rates for PCI (14% vs 17%, p < 0.0001), coronary artery bypass surgery (5% vs 8%, p < 0.0001), and unstable angina (22% vs 29%, p < 0.0001) were lower in the stent group. Veterans who underwent stenting had lower hospital mortality, reduced rates of same-admission bypass surgery, marginally better survival, and lower rates of rehospitalization than their counterparts who had conventional coronary angioplasty.

Circulation 2001 Jun 12;103(23):2780-3

Visualization of discrete microinfarction after percutaneous coronary intervention associated with mild creatine kinase-MB elevation.


BACKGROUND: Mild elevations in creatine kinase-MB (CK-MB) are common after successful percutaneous coronary interventions and are associated with future adverse cardiac events. The mechanism for CK-MB release remains unclear. A new contrast-enhanced MRI technique allows direct visualization of myonecrosis.

METHODS AND RESULTS: Fourteen patients without prior infarction underwent cine and contrast-enhanced MRI after successful coronary stenting; 9 patients had procedure-related CK-MB elevation, and 5 did not (negative controls). The mean age of all patients was 61 years, 36% had diabetes, 43% had multivessel coronary artery disease, and all had a normal ejection fraction. Twelve patients (86%) received an intravenous glycoprotein IIb/IIIa inhibitor; none underwent atherectomy, and all had final TIMI 3 flow. Of the 9 patients with CK-MB elevation, 5 had a minor side branch occlusion during stenting, 2 had transient ECG changes, and none developed Q-waves. The median CK-MB was 21 ng/mL (range, 12 to 93 ng/mL), which is 2.3x the upper limit of normal. Contrast-enhanced MRI demonstrated discrete regions of hyperenhancement within the target vessel perfusion territory in all 9 patients. Only one developed a new wall motion abnormality. The median estimated mass of myonecrosis was 2.0 g (range, 0.7 to 12.2 g), or 1.5% of left ventricular mass (range, 0.4% to 6.0%). Hyperenhancement persisted in 5 of the 6 who underwent a repeat MRI at 3 to 12 months. No control patient had hyperenhancement. CONCLUSIONS: Contrast-enhanced MRI provides an anatomical correlate to biochemical evidence of procedure-related myocardial injury, despite the lack of ECG changes or wall motion
abnormalities. Mild elevation of CK-MB after percutaneous coronary intervention is the result of discrete microinfarction.

Eur Heart J 2001 Jun;22(11):934-41

Long-term clinical outcome after coronary balloon angioplasty: identification of a population at low risk of recurrent events during 17 years of follow-up.

van Domburg RT, Foley DP, de Feyter PJ, van der Giessen W, van den Brand MJ, Serruys PW.

AIMS: This study reports the clinical outcome, up to 17 years, of the first 856 consecutive patients treated by coronary angioplasty at a single centre and attempts to identify a subgroup of patients at low risk of adverse events. METHODS AND RESULTS: Follow-up status was established via hospital and general practitioner records and the civil registry. Median follow-up was 16 years. The overall 5-, 10-, 15- and 17-year survival was 90%, 78%, 64% and 58%, respectively and corresponding event-free survival was 53%, 33%, 22% and 19%. After 32% of patients had experienced a major adverse cardiac event in the first year, the annual coronary re-intervention incidence thereafter and, even beyond year 10, remained at 2%-7%. Using multivariable Cox regression, significant independent predictors of mortality were advanced age, diabetes, multivessel disease and impaired left ventricular function at the time of PTCA. A subgroup of 26% of the patients with none of these risk factors had a survival rate similar to the general Dutch population matched for age and gender (at 5 years: 96%, at 10 years: 89% and at 15 years: 83%). CONCLUSION: Although the majority of patients (>80%) experienced a further cardiac event during the 17 years after their first angioplasty procedure, in those non-diabetics under 60 years with single-vessel disease and good left ventricular function, prognosis was similar to the general population.

JAMA 2001 Jul 4;286(1):78-82

Risk of stroke associated with abciximab among patients undergoing percutaneous coronary intervention.

Akkerhuis KM, Deckers JW, Lincoff AM, Tcheng JE, Boersma E, Anderson K, Balog C, Califf RM, Topol EJ,
CONTEXT: Abciximab, a potent inhibitor of the platelet glycoprotein IIb/IIIa receptor, reduces thrombotic complications in patients undergoing percutaneous coronary intervention (PCI). Because of its potent inhibition of platelet aggregation, the effect of abciximab on risk of stroke is a concern. OBJECTIVE: To determine whether abciximab use among patients undergoing PCI is associated with an increased risk of stroke. DESIGN: Combined analysis of data from 4 double-blind, placebo-controlled, randomized trials (EPIC, CAPTURE, EPILOG, and EPISTENT) conducted between November 1991 and October 1997 at a total of 257 academic and community hospitals in the United States and Europe. PATIENTS: A total of 8555 patients undergoing PCI with or without stent deployment for a variety of indications were randomly assigned to receive a bolus and infusion of abciximab (n = 5476) or matching placebo (n = 3079). One treatment group in EPIC received a bolus of abciximab only. MAIN OUTCOME MEASURE: Risk of hemorrhagic and nonhemorrhagic stroke within 30 days of treatment among abciximab and placebo groups. RESULTS: No significant difference in stroke rate was observed between patients assigned abciximab (n = 22 [0.40%]) and those assigned placebo (n = 9 [0.29%]; P = .46). Excluding the EPIC abciximab bolus-only group, there were 9 strokes (0.30%) among 3023 patients who received placebo and 15 (0.32%) in 4680 patients treated with abciximab bolus plus infusion, a difference of 0.02% (95% confidence interval [CI], -0.23% to 0.28%). The rate of nonhemorrhagic stroke was 0.17% in patients treated with abciximab and 0.20% in patients treated with placebo (difference, -0.03%; 95% CI, -0.23% to 0.17%), and the rates of hemorrhagic stroke were 0.15% and 0.10%, respectively (difference, 0.05%; 95% CI, -0.11% to 0.21%). Among patients treated with abciximab, the rate of hemorrhagic stroke in patients receiving standard-dose heparin in EPIC, CAPTURE, and EPILOG was higher than in those receiving low-dose heparin in the EPILOG and EPISTENT trials (0.27% vs 0.04%; P = .057). CONCLUSIONS: Abciximab in addition to aspirin and heparin does not increase the risk of stroke in patients undergoing PCI. Patients undergoing PCI and treated with abciximab should receive low-dose, weight-adjusted heparin.

Incremental prognostic value of elevated baseline C-reactive protein among established markers of risk in percutaneous coronary intervention.

Chew DP, Bhatt DL, Robbins MA, Penn MS, Schneider JP, Lauer MS, Topol EJ, Ellis SG.

Circulation 2001 Aug 28;104(9):992-7
BACKGROUND: Established methods of risk assessment in percutaneous coronary intervention have focused on clinical and anatomical lesion characteristics. Emerging evidence indicates the substantial contribution of inflammatory processes to short-term and long-term outcomes in coronary artery disease. METHODS AND RESULTS: Within a single-center registry of contemporary percutaneous coronary revascularization strategies with postprocedural creatine kinase and clinical events routinely recorded, we assessed the association of baseline C-reactive protein with death or myocardial infarction within the first 30 days. Predictive usefulness of baseline C-reactive protein within the context of established clinical and angiographic predictors of risk was also examined. Among 727 consecutive patients, elevated baseline C-reactive protein before percutaneous coronary intervention was associated with progressive increase in death or myocardial infarction at 30 days (lowest quartile, 3.9%, versus highest quartile, 14.2%; P=0.002). Among clinical and procedural characteristics, baseline C-reactive protein remained independently predictive of adverse events, with the highest quartile of C-reactive protein associated with an odds ratio for excess 30-day death or myocardial infarction of 3.68 (95% CI, 1.51 to 8.99; P=0.004). A predictive model that included baseline C-reactive protein quartiles, American College of Cardiology/American Heart Association lesion score, acute coronary syndrome presentation, and coronary stenting appears strongly predictive of 30-day death or myocardial infarction within this population (C-statistic, 0.735) and among individual patients (Brier score, 0.006). CONCLUSIONS: Elevated baseline C-reactive protein portends heightened risk of 30-day death or myocardial infarction after coronary intervention. Coupled anatomic, clinical, and inflammatory risk stratification demonstrates strong predictive utility among patients undergoing percutaneous coronary intervention and may be useful for guiding future strategies.

Circulation 2001 Aug 7;104(6):642-7

Differential impact on survival of electrocardiographic Q-wave versus enzymatic myocardial infarction after percutaneous intervention: a device-specific analysis of 7147 patients.


BACKGROUND: The relative prognostic importance of ECG myocardial infarction (MI) after intervention compared with varying degrees of enzymatic elevation has not been characterized, and the device-specific
Implications of periprocedural MI are also unknown. METHODS AND RESULTS: Serial creatine phosphokinase (CPK)-MB levels were determined after elective percutaneous intervention of 12,098 lesions in 7,147 consecutive patients at a tertiary referral center. Procedural, in-hospital, and follow-up data were collected by independent research nurses, and clinical and ECG events were adjudicated by a separate committee. Stents were implanted in 50.6% of lesions, atheroablation was performed in 54.8%, and PTCA alone was performed in 9.8%. The peak periprocedural CPK-MB level was >3x the upper limit of normal (ULN) in 17.9% of patients, and Q-wave MI developed in 0.6%. By multivariate analysis, the periprocedural development of new Q waves was the most powerful independent determinant of death (2-year mortality rate, 38.3%; hazard ratio, 9.9; P<0.0001). Non-Q-wave MI with CPK-MB >8x ULN was also a strong predictor of death (2-year mortality rate, 16.3%; hazard ratio, 2.2; P<0.0001); survival was unaffected by lesser degrees of CPK-MB elevation. Though CPK-MB elevation was more common after atheroablation and stenting than PTCA, the rates of Q-wave MI and survival were device-independent. CONCLUSIONS: Myonecrosis after percutaneous intervention is common in a high-risk referral population dominated by atheroablation and stent use. Large periprocedural infarctions (signified by new Q waves and CPK-MB >8xULN) are powerful determinants of death, whereas lesser degrees of CPK-MB release and specific device use do not adversely affect survival.

Circulation 2001 Aug 14;104(7):773-8

Impact of smoking on clinical and angiographic restenosis after percutaneous coronary intervention: another smoker? paradox?

Cohen DJ, Doucet M, Cutlip DE, Ho KK, Popma JJ, Kuntz RE.

BACKGROUND: Recent studies have suggested that smokers may require less frequent repeated revascularization after percutaneous coronary intervention (PCI) compared with nonsmokers. However, the mechanism of this phenomenon is unknown. METHODS AND RESULTS: We examined the association between smoking and restenosis using pooled data from 8,671 patients treated with PCI in 9 multicenter clinical trials. Clinical restenosis was examined in the cohort of 5,682 patients who were assigned to clinical follow-up only. Angiographic restenosis was evaluated in the subset of 2,989 patients who were assigned to mandatory angiographic restudy. Among those patients assigned to clinical follow-up only, target lesion revascularization (TLR) occurred in 6.6% of smokers and 10.1% of nonsmokers (P<0.001). After adjustment for baseline clinical and angiographic differences, the rate of TLR remained significantly lower in smokers with an adjusted relative
risk of 0.69 (95% CI, 0.54 to 0.88). Among the angiographic cohort, there were no differences in the rates of angiographic restenosis or follow-up diameter stenosis in either univariate or multivariate analyses. This dissociation between clinical and angiographic restenosis was explained in part by reduced sensitivity to restenosis on the part of smokers and by the greater reluctance of smokers to seek medical attention despite recurrent angina. CONCLUSIONS: In patients undergoing contemporary PCI, cigarette smoking is associated with a lower rate of subsequent TLR without affecting angiographic restenosis. These findings have important implications for the follow-up of smokers after PCI and suggest that cross-study comparisons of rates of clinical restenosis must account for the potential confounding effect of smoking.

Am J Cardiol 2001 Sep 15;88(6):618-23

Effect on survival of acute myocardial infarction in Killip classes II or III patients undergoing invasive coronary procedures.

Rott D, Behar S, Leor J, Hod H, Boyko V, Mandelzweig L, Gottlieb S

The purpose of the present study was to determine whether patients with acute myocardial infarction (AMI) in Killip class II or III are likely to benefit from catheterization and coronary revascularization performed within 30 days of AMI. The study population was drawn from 2 national surveys performed during 1996 and 1998 in 26 coronary care units operating in Israel. Our analysis included 3,113 patients with AMI who were divided into 2 groups according to their admission Killip class: 2,484 patients (80%) in Killip class I, of whom 1,408 (57%) underwent cardiac catheterization and 1,076 were treated noninvasively; and 629 patients in Killip class II or III, of whom 314 (50%) underwent cardiac catheterization and 315 were managed conservatively. Patients in Killip class II or III who were treated invasively had lower mortality rates than their counterparts who were treated noninvasively at 30 days: 7.6% versus 15.6%, respectively (adjusted odds ratio [OR] 0.52, 95% confidence interval [CI] 0.28 to 0.92), and thereafter from 30 days to 6 months, 4.3% versus 13.6%, respectively (OR 0.34, 95% CI 0.16 to 0.68). In Killip class I patients, an invasive versus noninvasive management was not associated with a better outcome at 30 days: 1.6% versus 3.2%, respectively (OR 0.58, 95% CI 0.32 to 1.05), but with similar mortality rates at 30 days to 6 months, 1.9% versus 2.0%, respectively (OR 1.46, 95% CI 0.79 to 2.74). Thus, the present study suggests that patients with AMI in Killip class II or III on admission may benefit from cardiac catheterization and revascularization performed within 30 days from admission, whereas patients with AMI in Killip class I are less likely to benefit from this approach.
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.
Effect of glycoprotein IIb/IIIa receptor inhibition on angiographic complications during percutaneous coronary intervention in the ESPRIT trial.


OBJECTIVES: We sought to determine whether eptifibatide decreases the incidence of in-laboratory angiographic complications and to determine the relationship of angiographically evident complications to elevations of creatine kinase-MB (CK-MB) enzyme levels during percutaneous coronary intervention.

BACKGROUND: In the Enhanced Suppression of the Platelet IIb/IIIa Receptor with Integrilin Therapy (ESPRIT) trial, eptifibatide during coronary intervention was associated with decreased ischemic complications at 48 h and 30 days.

METHODS: Patients (n = 2,064) were randomized to placebo versus eptifibatide (two 180 microg/kg boluses 10 min apart and as a continuous infusion of 2 microg/kg per min) during percutaneous coronary stenting. Angiographic complications including major dissection, distal embolization, residual thrombus, abrupt closure, residual stenosis >50% and side-branch occlusion were prospectively recorded by the operator. Creatine kinase-MB levels were measured after the procedure and every 6 h thereafter. The incidence of angiographic complications and CK-MB elevation was determined for eptifibatide versus placebo groups.

RESULTS: Eptifibatide-treated patients demonstrated nonsignificant trends toward fewer angiographic complications (10 vs. 12% for placebo patients, p = 0.13) and, for patients with angiographic complications, fewer subsequent CK-MB elevations (43 vs. 50% for placebo patients, p = 0.31). In patients without any angiographic complications, the incidence of CK-MB elevation >3 times the normal was 7% with placebo and 4% with eptifibatide (p = 0.003). CONCLUSIONS: Eptifibatide during nonurgent coronary stent intervention only minimally (and insignificantly) reduces the incidence of angiographic complications and subsequent CK-MB elevations in patients developing an angiographic complication. The greater effect is to reduce myocardial infarction in patients undergoing otherwise uneventful coronary stent implantation as well as in the overall study population.

Clinical and quantitative coronary angiographic predictors of coronary restenosis: a comparative analysis from the balloon-to-stent era.

OBJECTIVES: We sought to assess whether coronary stents have modified the predictive value of demographic, clinical and quantitative coronary angiographic (QCA) predictors of coronary restenosis. BACKGROUND: A systematic analysis in a large cohort of registries and randomized trials of the percutaneous transluminal coronary angioplasty (PTCA) and stent era has never been performed. METHODS: A total of 9,120 treated lesions in 8,156 patients included in nine randomized trials and 10 registries, with baseline, post-procedural and six-month follow-up QCA analyses, were included in this study. Predictors of restenosis were identified with univariate and multivariate logistic regression analyses. Interaction terms were introduced in the regression equation to evaluate whether the predictors of restenosis were common to both eras or specific for either one of the revascularization techniques. RESULTS: The restenosis rate was 35% after PTCA and 19% after angioplasty with additional stenting. In the univariate analysis, favorable predictors were previous coronary artery bypass graft surgery (CABG), stent use, stent length and a large pre-procedural minimal lumen diameter (pre-MLD); unfavorable predictors were weight, body mass index, diabetes mellitus, multi-vessel disease, lesion length and a high residual post-procedural diameter stenosis (post-DS). Predictors specific for the PTCA population were a large post-procedural MLD (post-MLD) as favorable and a severe pre-procedural DS (pre-DS) as unfavorable. Favorable predictors specific for the stent population were a large post-MLD and a large pre-procedural reference diameter (pre-RD). In the multivariate analysis, the best model included the following favorable predictors: stent use, a large post-MLD, previous CABG and the interaction term between stent use and a large post-MLD; unfavorable predictors were lesion length and diabetes mellitus. CONCLUSIONS: There are no major differences in demographic and clinical predictors of coronary restenosis between PTCA and stent populations. In the modern (stent) era, a severe pre-DS is no longer an unfavorable predictor of restenosis. Still important, but more so in the stent population, is a large post-MLD (optimal result). Finally, a larger pre-RD became a favorable predictor with the advent of stenting.

J Am Coll Cardiol 2001 Sep;38(3):624-30

Does the presence of thrombus seen on a coronary angiogram affect the outcome after percutaneous coronary angioplasty? An Angiographic Trials Pool data experience.

Singh M, Reeder GS, Ohman EM, Mathew V, Hillegass WB, Anderson RD, Gallup DS, Garratt KN, Holmes DR
OBJECTIVES: This study aimed to determine whether pre-existing angiographic thrombus was associated with adverse in-hospital and six-month outcomes after percutaneous coronary interventions. BACKGROUND: There are conflicting data about whether pre-existing thrombus is an independent predictor of adverse in-hospital and short-term outcome after coronary interventions. METHODS: The Angiographic Trials Pool, a data set derived from eight prospective randomized trials, was analyzed. The study population consisted of 7,917 patients who underwent coronary interventions between 1986 and 1995. Two trials were excluded because they did not collect information regarding thrombus. Patients from the other six trials were divided on the basis of the presence or absence of thrombus. RESULTS: In patients with (n = 2,752) and without (5,165) thrombus, in-hospital mortality following angioplasty was low (0.8 vs. 0.6%, p = 0.207). Several adverse outcomes were higher in patients with thrombus: death/myocardial infarction (8.4 vs. 5.5%, p ≤ 0.001), in-hospital abrupt closure (5.9 vs. 3.9%, p < or = 0.001) and an in-hospital composite of death, myocardial infarction and/or repeat revascularization (15.4 vs. 11.2%, p < or = 0.001). Six-month mortality was low and comparable between the two groups (2.1 vs. 1.8%, p = 0.34), but the incidence of six-month death/myocardial infarction was higher in patients with thrombus (11.7 vs. 8.7%, p < or = 0.0001). CONCLUSIONS: Percutaneous coronary angioplasty can be performed with low mortality in patients with pre-existing thrombus, although these patients are at higher risk of in-hospital and six-month death/myocardial infarction. Continued efforts are required to optimize the outcome in these high risk patients.

J Am Coll Cardiol 2001 Sep;38(3):653-8

Effect of glycoprotein IIb/IIIa receptor inhibition on angiographic complications during percutaneous coronary intervention in the ESPRIT trial.


OBJECTIVES: We sought to determine whether eptifibatide decreases the incidence of in-laboratory angiographic complications and to determine the relationship of angiographically evident complications to
elevations of creatine kinase-MB (CK-MB) enzyme levels during percutaneous coronary intervention. 

BACKGROUND: In the Enhanced Suppression of the Platelet IIb/IIIa Receptor with Integrilin Therapy (ESPRIT) trial, eptifibatide during coronary intervention was associated with decreased ischemic complications at 48 h and 30 days. METHODS: Patients (n = 2,064) were randomized to placebo versus eptifibatide (two 180 microg/kg boluses 10 min apart and as a continuous infusion of 2 microg/kg per min) during percutaneous coronary stenting. Angiographic complications including major dissection, distal embolization, residual thrombus, abrupt closure, residual stenosis >50% and side-branch occlusion were prospectively recorded by the operator. Creatine kinase-MB levels were measured after the procedure and every 6 h thereafter. The incidence of angiographic complications and CK-MB elevation was determined for eptifibatide versus placebo groups. RESULTS: Eptifibatide-treated patients demonstrated nonsignificant trends toward fewer angiographic complications (10 vs. 12% for placebo patients, p = 0.13) and, for patients with angiographic complications, fewer subsequent CK-MB elevations (43 vs. 50% for placebo patients, p = 0.31). In patients without any angiographic complications, the incidence of CK-MB elevation >3 times the normal was 7% with placebo and 4% with eptifibatide (p = 0.003). CONCLUSIONS: Eptifibatide during nonurgent coronary stent intervention only minimally (and insignificantly) reduces the incidence of angiographic complications and subsequent CK-MB elevations in patients developing an angiographic complication. The greater effect is to reduce myocardial infarction in patients undergoing otherwise uneventful coronary stent implantation as well as in the overall study population.

J Am Coll Cardiol 2001 Sep;38(3):645-52

Clinical and quantitative coronary angiographic predictors of coronary restenosis: a comparative analysis from the balloon-to-stent era.


OBJECTIVES: We sought to assess whether coronary stents have modified the predictive value of demographic, clinical and quantitative coronary angiographic (QCA) predictors of coronary restenosis. BACKGROUND: A systematic analysis in a large cohort of registries and randomized trials of the percutaneous transluminal coronary angioplasty (PTCA) and stent era has never been performed. METHODS: A total of 9,120 treated lesions in 8,156 patients included in nine randomized trials and 10 registries, with baseline, post-procedural and six-month follow-up QCA analyses, were included in this study. Predictors of restenosis were identified
with univariate and multivariate logistic regression analyses. Interaction terms were introduced in the regression equation to evaluate whether the predictors of restenosis were common to both eras or specific for either one of the revascularization techniques. RESULTS: The restenosis rate was 35% after PTCA and 19% after angioplasty with additional stenting. In the univariate analysis, favorable predictors were previous coronary artery bypass graft surgery (CABG), stent use, stent length and a large pre-procedural minimal lumen diameter (pre-MLD); unfavorable predictors were weight, body mass index, diabetes mellitus, multi-vessel disease, lesion length and a high residual post-procedural diameter stenosis (post-DS). Predictors specific for the PTCA population were a large post-procedural MLD (post-MLD) as favorable and a severe pre-procedural DS (pre-DS) as unfavorable. Favorable predictors specific for the stent population were a large post-MLD and a large pre-procedural reference diameter (pre-RD). In the multivariate analysis, the best model included the following favorable predictors: stent use, a large post-MLD, previous CABG and the interaction term between stent use and a large post-MLD; unfavorable predictors were lesion length and diabetes mellitus. CONCLUSIONS: There are no major differences in demographic and clinical predictors of coronary restenosis between PTCA and stent populations. In the modern (stent) era, a severe pre-DS is no longer an unfavorable predictor of restenosis. Still important, but more so in the stent population, is a large post-MLD (optimal result). Finally, a larger pre-RD became a favorable predictor with the advent of stenting.

Lancet 2001 Sep 22;358(9286):951-7

Trial of invasive versus medical therapy in elderly patients with chronic symptomatic coronary-artery disease (TIME): a randomised trial.

The TIME Investigators.

BACKGROUND: Since previous randomised treatment trials in coronary disease have focused on patients younger than 75 years of age, their findings might not apply to the elderly population in whom the cardiac risk profile, risk of intervention, and comorbidities are increased. We aimed to assess quality of life and outcome of elderly patients with coronary disease after medical or revascularisation therapy. METHODS: In this randomised, prospective, multicentre trial, we enrolled patients aged 75 years or older with chronic angina of at least Canadian Cardiac Society class II despite at least two antianginal drugs. Patients were randomly assigned coronary angiography and revascularisation or optimised medical therapy. The primary endpoint was quality of life after 6 months, as assessed by questionnaire and the presence of major adverse cardiac events
(death, non-fatal myocardial infarction, or hospital admission for acute coronary syndrome with or without the need for revascularisation). Analysis was by intention to treat. FINDINGS: 150 patients were assigned medical therapy and 155 invasive therapy. Two protocol violators in each group were not included in the analysis. After 6 months, angina severity decreased and measures of quality of life increased in both treatment groups; however, these improvements were significantly greater after revascularisation. Major adverse cardiac events occurred in 72 (49%) of patients in the medical group and 29 (19%) in the invasive group (p<0.0001).

INTERPRETATION: Patients aged 75 years or older with angina despite standard drug therapy benefit more from revascularisation than from optimised medical therapy in terms of symptom relief and quality of life. Therefore, these patients should be offered invasive assessment despite their high risk profile followed by revascularisation if feasible.

Am J Cardiol 2001 Oct 15;88(8):842-7

Comparison of primary coronary angioplasty versus thrombolysis in patients with ST-segment elevation acute myocardial infarction and grade II and grade III myocardial ischemia on the enrollment electrocardiogram.

Birnbaum Y, Goodman S, Barr A, Gates KB, Barbash GI, Battler A, Barbagelata A, Clemmensen P, Sgarbossa EB, Granger CB, Califf RM, Wagner GS.

We investigated the impact of primary angioplasty compared with thrombolysis in 894 patients with ST elevation acute myocardial infarction and electrocardiographic grades II and III ischemia on enrollment. Patients were divided into 2 groups based on the enrollment electrocardiogram-grade III: (1) absence of an S wave below the isoelectric baseline in leads that usually have a terminal S configuration (leads V(1) to V(3)), or (2) ST J-point amplitude > or =50% of the R-wave amplitude in all other leads. To be included in the grade III group, grade III criteria in > or =2 adjacent leads were required. Patients with ST elevation but without grade III criteria were classified as having grade II. In-hospital mortality was 3.2% and 6.8% in the grade II (n = 616) and grade III (n = 278) groups, respectively (p = 0.016). In the grade II group, in-hospital mortality was similar in the thrombolysis and angioplasty subgroups (3.2% and 3.3%, p = 0.941). In patients with grade III, in-hospital mortality was 6.4% and 7.3%, respectively (p = 0.762). The odds ratio for the grade III group for death with thrombolysis was 2.06 (95% confidence intervals [CI] 0.82 to 5.19; p = 0.125); the odds ratio for primary angioplasty was 2.30 (95% CI 0.93 to 5.66; p = 0.07). In the thrombolysis group, reinfarction occurred in 3.3% and 6.5% of the grade II and grade III subgroups (p = 0.137). In the angioplasty group, reinfarction occurred in
1.3% and 4.4%, respectively (p = 0.239). Grade III ischemia on admission was associated with higher in-hospital and 30-day mortality and a higher rate of reinfarction. There was no difference in mortality between primary angioplasty and thrombolysis in the grade II and grade III ischemia patients.

N Engl J Med 2001 Nov 29;345(22):1593-600

Decreased rate of coronary restenosis after lowering of plasma homocysteine levels.


BACKGROUND: We have previously demonstrated an association between elevated total plasma homocysteine levels and restenosis after percutaneous coronary angioplasty. We designed this study to evaluate the effect of lowering plasma homocysteine levels on restenosis after coronary angioplasty.

METHODS: A combination of folic acid (1 mg), vitamin B12 (400 microg), and pyridoxine (10 mg) referred to as folate treatment or placebo was administered to 205 patients (mean [+/SD] age, 61+/11 years) for six months after successful coronary angioplasty in a prospective, double-blind, randomized trial. The primary end point was restenosis within six months as assessed by quantitative coronary angiography. The secondary end point was a composite of major adverse cardiac events.

RESULTS: Baseline characteristics and initial angiographic results after coronary angioplasty were similar in the two study groups. Folate treatment significantly lowered plasma homocysteine levels from 11.1+/4.3 to 7.2+/2.4 micromol per liter (P<0.001). At follow-up, the minimal luminal diameter was significantly larger in the group assigned to folate treatment (1.72+/0.76 vs. 1.45+/0.88 mm, P=0.02), and the degree of stenosis was less severe (39.9+/20.3 vs. 48.2+/28.3 percent, P=0.01). The rate of restenosis was significantly lower in patients assigned to folate treatment (19.6 vs. 37.6 percent, P=0.01), as was the need for revascularization of the target lesion (10.8 vs. 22.3 percent, P=0.047). CONCLUSIONS: Treatment with a combination of folic acid, vitamin B12, and pyridoxine significantly reduces homocysteine levels and decreases the rate of restenosis and the need for revascularization of the target lesion after coronary angioplasty. This inexpensive treatment, which has minimal side effects, should be considered as adjunctive therapy for patients undergoing coronary angioplasty.

J Am Coll Cardiol 2001 Nov 15;38(6):1614-21
Quality of life after balloon angioplasty or stenting for acute myocardial infarction. One-year results from the Stent-PAMI trial.


OBJECTIVES: The goal of this study was to compare the impact of primary stenting or percutaneous transluminal coronary angioplasty (PTCA) on health-related quality of life (HRQOL) in patients undergoing direct angioplasty for acute myocardial infarction (AMI). BACKGROUND: Previous studies have demonstrated that coronary stenting reduces clinical and angiographic restenosis compared with PTCA. However, the impact of stenting on HRQOL from the patient's perspective remains unknown. METHODS: We administered the Seattle Angina Questionnaire and the Medical Outcomes Study Short-form Survey at 1, 6 and 12 months after initial treatment to all North American patients in the Stent-Primary Angioplasty for Myocardial Infarction trial (Stent-PAMI) (n = 509)-a randomized trial comparing primary stenting to conventional PTCA for patients with AMI. RESULTS: At one month, most HRQOL measures were similar for the two groups, but stent patients reported less bodily pain than PTCA patients (p = 0.03). At six-month follow-up, stenting resulted in significant improvements in several dimensions of HRQOL including reduced anginal frequency and bodily pain as well as improved disease perception (all p < 0.03) and a trend towards better anginal stability (p = 0.056). By 12-month follow-up, however, none of these differences remained statistically significant. These differences in HRQOL were largely explained by the greater need for ischemia-driven target-vessel repeat revascularization procedures in PTCA patients during the first six months (16.0% vs. 6.2%, p < 0.001). CONCLUSIONS: In patients undergoing revascularization for AMI, initial stent placement is associated with improvements in several dimensions of health status during the first six months of follow-up. In the absence of differences in mortality, these findings add to the overall argument in favor of initial stenting in patients treated with mechanical reperfusion for myocardial infarction.

Am J Cardiol 2001 Nov 15;88(10):1120-4

Association of a CD18 gene polymorphism with a reduced risk of restenosis after coronary stenting.

Inflammatory mechanisms play an important role in the process of restenosis after percutaneous coronary interventions, with cell adhesion molecules, including Mac-1 (CD11b, CD18), as key mediators. A single nucleotide polymorphism, 1323C/T, located in exon 11 of the CD18 gene has been previously described, but its functional and clinical significances have not yet been studied. We assessed whether an association exists between this polymorphism and restenosis after coronary stenting. Clinical and angiographic measures of restenosis were evaluated over 1 year after coronary stent placement in 1,207 consecutive patients. Angiographic restenosis was defined as a > or =50% diameter stenosis at follow-up angiography. Determination of the CD18 1323C/T genotype was based on the polymerase chain reaction technique. The frequency of the T allele was 0.34 and its presence reduced the 1-year risk of a major adverse cardiac event (death, myocardial infarction, target vessel revascularization) by 29% (p = 0.011). Carriers of the T allele had a significantly lower risk of angiographic restenosis compared with noncarriers (odds ratio 0.71, 95% confidence interval 0.55 to 0.92). The incidence of restenosis decreased as a function of the number of T alleles: 38.1% in patients with genotype CC, 31.7% in patients with genotype CT, and 26.0% in patients with genotype TT (p = 0.004). Thus, the 1323T allele of the CD18 gene is associated, in a gene dose-dependent manner, with a lower incidence of angiographic restenosis after coronary stenting. This finding suggests that Mac-1 is involved in the development of restenosis after coronary stent placement.

Am J Cardiol 2001 Nov 15;88(10):1108-13

Effect of pravastatin on myocardial protection during coronary angioplasty and the role of adenosine.

Lee TM, Su SF, Chou TF, Tsai CH.

Pravastatin has been shown, in an experimental model of ischemia reperfusion, to increase adenosine levels, which exert a potent and protective effect on the heart. The purpose of this study was to investigate whether pravastatin can provide cardioprotection by increased production of adenosine in patients undergoing coronary angioplasty, a clinical model of ischemia reperfusion. Thirty-five hyperlipidemic patients who underwent elective angioplasty for a major epicardial coronary artery were randomly allocated to either 3-month pravastatin or placebo before catheterization. In the placebo group, the mean ST-segment shift during
the second balloon inflation was similar that observed during the first inflation, whereas in the preconditioned patients, the shift was significantly less, which is consistent with ischemic preconditioning. In the pravastatin-treated patients, the changes of ST-segment shift were similar between the first and second balloon inflations. In contrast, the patients who received aminophylline developed higher ST-segment shifts during the first and second inflations than those in the pravastatin-treated group alone. Measurements of chest pain score and myocardial lactate extraction ratios during inflation mirrored those of the ST-segment shift. The present study demonstrates that administration of pravastatin results in a significant gain in tolerance to ischemia during angioplasty. The effect of pravastatin was abolished by aminophylline, suggesting that the cardioprotective effect of pravastatin may result from activation of adenosine receptors.

Am J Cardiol 2001 Nov 15;88(10):1091-6

Influence of coronary thrombus on outcome of percutaneous coronary angioplasty in the current era (the Mayo Clinic experience).


Earlier studies documented an increased risk of percutaneous coronary intervention (PCI) in patients with angiographic evidence of thrombus. With newer antiplatelet agents and stents, it is not known whether thrombus is a risk factor after PCI. This study examines whether outcome of PCI in patients with thrombus has improved, and whether thrombus is associated with adverse outcome after PCI in the current era. This single-institution retrospective analysis of PCI in 7,184 patients was divided into 2 periods: group I, 1990 to 1995 (n = 3,640), and group II, 1996 to 1999 (n = 3,544). The groups were subdivided according to the presence or absence of angiographic thrombus before PCI. We compared the outcome of PCI for patients with and without thrombus in group II. A comparison was made in the 2 groups in patients with angiographic thrombus. Procedural success improved in group II compared with group I patients with thrombus (93% vs 88%, p <0.001). There was significant reduction in abrupt closure in the recent era in patients with thrombus (4% vs 7%, p = 0.01). In group II, procedural success remained lower in patients with (93% vs 96%) than without thrombus (p <0.001). After adjusting for the significant univariate characteristics of group II patients, thrombus remained an independent predictor of Q-wave infarction (odds ratio 3.78; 95% confidence interval [CI], 1.8 to 8.0; p <0.0013) and the composite end point of death, Q-wave infarction, and emergency bypass surgery (odds ratio 2.37; 95% CI 1.4 to 4.1; p = 0.002). There was a trend toward increased in-hospital death among patients with thrombus (odds ratio 2.06; 95% CI 0.9 to 4.8; p = 0.09). The 1-year outcome after successful PCI was similar for those with
and without thrombus. Despite improvement in the outcome of patients with thrombus undergoing PCI in recent years, thrombus is still an independent predictor of adverse in-hospital outcomes after PCI.

Circulation 2001 Nov 6;104(19):2289-94

Clinical and angiographic factors associated with asymptomatic restenosis after percutaneous coronary intervention.

Ruygrok PN, Webster MW, de Valk V, van Es GA, Ormiston JA, Morel MA, Serruys PW.

BACKGROUND: Angiographic restenosis after percutaneous coronary interventional procedures is more common than recurrent angina. Clinical and angiographic factors associated with asymptomatic versus symptomatic restenosis after percutaneous coronary intervention were compared. METHODS AND RESULTS: All patients with angiographic restenosis from the BENESTENT I, BENESTENT II pilot, BENESTENT II, MUSIC, WEST 1, DUET, FINESSE 2, FLARE, SOPHOS, and ROSE studies were analyzed. Multivariate analysis evaluated 46 clinical and angiographic variables, comparing those with and without angina. The 10 studies recruited 2690 patients who underwent percutaneous revascularization and 6-month follow-up angiography (86% of those eligible). Restenosis (≥50% diameter stenosis) occurred in 607 patients and was clinically silent in 335 (55%). Male sex (P=0.008), absence of antianginal therapy with nitrates (P=0.0002) and calcium channel blockers (P=0.02) at 6 months, greater reference diameter after the procedure (P=0.04), greater reference diameter at follow-up (P=0.004), and lesser lesion severity (percent stenosis) at 6 months (P=0.0004) were univariate predictors of asymptomatic restenosis. By multivariate analysis, only male sex (P=0.04), greater reference diameter at follow-up (P=0.002), and lesser lesion severity at 6 months (P=0.0001) were associated with restenosis without angina. CONCLUSIONS: Approximately half of patients with angiographic restenosis have no symptoms. The only multivariate predictors of silent restenosis at 6 months were male sex, greater reference diameter at follow-up, and lesser lesion severity on follow-up angiography.

J Invasive Cardiol 2001 Nov;13(11):723-8

A randomized trial of the low-molecular-weight heparin certoparin to prevent restenosis following coronary
OBJECTIVES: The objectives of this study were to evaluate the effectiveness and safety of the low-molecular-weight heparin (LMWH) certoparin in preventing restenosis following balloon coronary angioplasty.

BACKGROUND: Restenosis following coronary angioplasty continues to limit the long-term efficacy of this procedure. Animal studies have indicated a potential role for LMWH in reducing restenosis by limiting smooth muscle proliferation.

METHODS: This study tested the effects of certoparin, self-administered for 3 months, in reducing restenosis following balloon coronary angioplasty. One hundred and eighteen patients with 158 lesions treated with angioplasty were enrolled in this randomized, placebo-controlled trial. One hundred and two patients completed the study. The endpoint was relative loss measured with quantitative coronary angiography.

RESULTS: The relative loss for placebo was 0.19 +/- 0.23 compared to 0.14 +/- 0.21 for LMWH (p = NS). The minimum lumen diameter (MLD) was 1.47 +/- 0.66 for placebo and 1.40 +/- 0.57 for the LMWH (p = NS). There was a reduction (31% for LMWH; 49% for placebo PSDP) in the percent of patients having binary restenosis (MLD < 50% of reference diameter). At the end of the study 77% of the placebo patients and 76% of the LMWH group were asymptomatic (p = NS). There was a low rate of bleeding complications and these were minor. Bone density scans showed that there was no significant occurrence of osteoporosis with 3 months of LMWH.

CONCLUSIONS: Administration of certoparin for 3 months is safe, but appears ineffective in reducing post-PTCA restenosis.

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

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

Ammann P, Straumann E, Naegeli B, Schuiki E, Frielingsdorf J, Gerber A, Bertel O.
cardiogenic shock. This involved a follow-up study from a prospectively conducted patient registry in a tertiary referral center. A total of 59 patients (10 female/49 male; median age 62 years (32?1)) with percutaneous transluminal cardiac interventions in primary cardiogenic shock were identified between January 1995 and January 2000. Twenty-two patients (37%) had been resuscitated successfully before intervention. The in-hospital mortality of shock patients was 36% (n=21, median age 68 (47?4)). The median follow-up of survivors was 18.1 (7?7.3) months, during which three further patients died (8%; two because of sudden cardiac deaths, one because of acute reinfarction). Achievement of thrombolysis in myocardial infarction (TIMI) flow III after acute PTCA (84% in survivors vs. 38% in non-survivors; P<0.001) and the absence of the left main coronary artery (3% survivors vs. 29% non-survivors; P=0.003) as culprit lesion in patients with cardiogenic shock was strongly associated with an improved survival rate. A second cardiac intervention was performed in seven patients (18%). Overall functional capacity of shock survivors was good. At final follow-up, 80% of the survivors were completely asymptomatic. One patient had angina pectoris NYHA II, five patients dyspnoea NYHA class II. Exercise stress-test was performed in 24 of the 38 surviving patients, median exercise capacity was 100% (range 55?13%) of the age adjusted predicted value. In unselected patients with cardiogenic shock due to AMI, treatment with acute PTCA resulted in an in-hospital mortality of 36%, low late mortality and good functional capacity in long-term survivors. TIMI flow grade III after acute PTCA in patients with acute myocardial infarction complicated by cardiogenic shock was strongly associated with an improved survival rate whereas the left main coronary artery as culprit lesion was associated with worse outcome.

Circulation 2002 Feb 12;105(6):691-6

Early and sustained survival benefit associated with statin therapy at the time of percutaneous coronary intervention.

Chan AW, Bhatt DL, Chew DP, Quinn MJ, Moliterno DJ, Topol EJ, Ellis SG.

BACKGROUND: Long-term administration of statin therapy has been shown to reduce major coronary events and cardiac mortality within randomized clinical trials. In addition to lowering lipids, statins favorably affect platelet adhesion, thrombosis, endothelial function, inflammation, and plaque stability, which may potentially
improve outcome after percutaneous coronary intervention (PCI). Therefore, we hypothesized that statin therapy has an early beneficial effect among patients undergoing PCI. METHODS AND RESULTS: Each year from 1993 to 1999, we prospectively collected data among the first 1000 patients undergoing PCI. Patients who presented with acute or recent myocardial infarction or cardiogenic shock were excluded from the analysis. Baseline, procedural, and 6-month data of statin-treated and non-statin-treated patients were compared. Propensity score and multivariate survival analysis were used to adjust for heterogeneity between the two groups. Of 5052 patients who completed follow-up, 26.5% were treated with statin at the time of the procedure. Statin therapy was associated with a mortality reduction at 30 days (0.8% versus 1.5%; hazard ratio, 0.53; P=0.048) and at 6 months (2.4% versus 3.6%; hazard ratio, 0.67; P=0.046). After adjusting for the propensity to receive statin therapy before the procedure and other confounders, statin therapy remained an independent predictor for survival at 6 months after coronary intervention (hazard ratio, 0.65; 95% CI, 0.42 to 0.99; P=0.045). CONCLUSIONS: In this large study cohort, statin therapy among PCI patients seems to be associated with a significant mortality advantage at early and intermediate-term follow-up.


Transradial approach for coronary angioplasty in the setting of acute myocardial infarction: a dual-center registry.


Although transradial angioplasty has been shown to have no major entry site-related complications, its clinical applicability for balloon angioplasty and stenting in acute myocardial infarction (AMI) is unclear. In order to assess the feasibility, safety, and clinical outcome of transradial access for coronary angioplasty (PTCA) and stenting during AMI, transradial angioplasty for AMI was registered on a prospective database at two European sites (A and B) with experience in the radial approach (RA); 6 Fr catheters with an inner lumen of at least 0.064?and low-profile rapid-exchange balloons were used. Primary success rates and procedural complications of 6 Fr RA were determined and compared to 6 Fr femoral approach (FA) procedures. A total of 1,224 AMI patients entered the registry. Study site A enrolled 185 RA patients (13.6% AMI) and study site B 92 RA patients (63.4%). Patient baseline demographics were similar in both study centers and showed no differences between RA and FA patients, except a more frequent use of abciximab in study site B compared to A. PTCA was successful in >95% of both RA and FA patients. Total procedural time did not differ between RA and
FA patients. Severe access site-related bleeding complications, however, were observed in FA patients only: study site A used closure devices routinely and found 2% severe bleedings; study site B used no closure device for FA patients and observed 7% severe bleedings. In selected patients and in experienced hands, transradial PTCA in AMI has a high success rate, is clinically safe, and could become an attractive alternative access site for patients being at high or even low risk for bleeding complications. Copyright 2002 Wiley-Liss, Inc

Minor myocardial damage and prognosis: are spontaneous and percutaneous coronary intervention-related events different?

Akkerhuis KM, Alexander JH, Tardiff BE, Boersma E, Harrington RA, Lincoff AM, Simoons ML.

BACKGROUND: The relevance of the adverse prognostic implications of CK-MB elevation after percutaneous coronary intervention (PCI) remains controversial. Therefore, we compared the relationship between the level of postprocedural CK-MB elevation and 6-month mortality in patients undergoing PCI with the relationship between the level of spontaneous, non-PCI-related CK-MB elevation and 6-month mortality in patients with acute coronary syndromes (ACS) treated medically. METHODS AND RESULTS: In the PURSUIT trial, 5583 of 9461 patients who presented with a non-ST-elevation ACS did not undergo PCI or CABG and had at least 1 CK-MB sample collected during index-hospitalization. There was a gradual increase in 6-month mortality with higher CK-MB levels: 4.1%, 8.6%, 9.0%, 14.3%, 15.5% for CK-MB ratios 0 to 1, >1 to 3, >3 to 5, >5 to 10, and >10 times the upper limit of normal. A combined analysis in 8838 patients undergoing PCI in 5 large, clinical trials revealed a proportional relationship between postprocedural CK-MB levels (<= 48 hours after PCI) and 6-month mortality. In patients with CK-MB ratios 0 to 1, >1 to 3, >3 to 5, >5 to 10, and >10, the risk of death was 1.3%, 2.0%, 2.3%, 4.3%, and 7.4%, respectively. The absolute mortality rates were lower after procedure-related infarcts compared with spontaneous infarcts. Yet, the relative increase in 6-month mortality with each increase in peak CK-MB level was similar for PCI-related myocardial necrosis and spontaneous myocardial necrosis, as all tests for heterogeneity of the odds ratios were nonsignificant. CONCLUSIONS: The present analysis indicates that the adverse prognostic implications of periprocedural myocardial necrosis should be considered similar to the adverse consequences of spontaneous myocardial necrosis.
Initial experience with hyperoxemic reperfusion after primary angioplasty for acute myocardial infarction: results of a pilot study utilizing intracoronary aqueous oxygen therapy.

Dixon SR, Bartorelli AL, Marcovitz PA, Spears R, David S, Grinberg I, Qureshi MA, Pepi M, Trabattoni D, Fabbiocchi F, Montorsi P, O’eill WW.

OBJECTIVES: The purpose of this study was to evaluate the feasibility and safety of intracoronary hyperoxemic reperfusion after primary angioplasty for acute myocardial infarction (MI). BACKGROUND: Hyperoxemic therapy with aqueous oxygen (AO) attenuates reperfusion injury and preserves left ventricular (LV) function in experimental models of MI. METHODS: In a multi-center study of patients with acute MI undergoing primary angioplasty (PTCA), hyperoxemic blood (pO(2): 600 to 800 mm Hg) was infused into the infarct-related artery for 60 to 90 min after intervention. The primary end points were clinical, electrical and hemodynamic stability during hyperoxemic reperfusion and in-hospital major adverse cardiac events. Global and regional LV function was evaluated by serial echocardiography after PTCA, after AO infusion, at 24 h and at one and three months. RESULTS: Twenty-nine patients were enrolled (mean age: 58.9+/−12.6 years). Hyperoxemic reperfusion was performed successfully in all cases (mean infusion time: 80.8+/−18.2 min; mean coronary perfusate pO(2): 631+/−235 mm Hg). There were no adverse events during hyperoxemic reperfusion or the in-hospital period. Compared with baseline, a significant improvement in global wall motion score index was observed at 24 h (1.68+/−0.24 vs. 1.48+/−0.24, p < 0.001) with a trend toward an increase in ejection fraction (48.6+/−7.3% vs. 51.8+/−6.8%, p = 0.08). Progressive improvement in LV function was observed at one and three months, primarily due to recovery of infarct zone function. CONCLUSIONS: Intracoronary hyperoxemic reperfusion is safe and well tolerated after primary PTCA. These preliminary data support the need for a randomized controlled trial to determine if hyperoxemic reperfusion enhances myocardial salvage or improves long-term outcome.
PURPOSE: We sought to assess whether stenting is a better treatment strategy than percutaneous transluminal coronary angioplasty (PTCA) for lesions in small coronary vessels of diabetic patients. METHODS: We studied the 100 diabetic patients who were enrolled in the Intracoronary Stenting or Angioplasty for Restenosis Reduction in Small Arteries trial; 51 patients were randomly assigned to receive a stent and 49 to PTCA alone. Small vessels were considered those with a reference diameter of 2.0 to 2.8 mm. The primary endpoint of the study was the incidence of restenosis, defined as 50% or greater diameter stenosis at follow-up angiography (performed in 83 of the 100 patients). The secondary endpoint was clinical restenosis, defined as the need for target vessel revascularization within 1 year. RESULTS: Angiographic restenosis occurred in 18 (44%) of the patients who received a stent and in 19 (45%) of the PTCA patients (P = 0.90). Target vessel revascularization was needed in 13 (25%) of the stent patients and 10 (20%) of the PTCA patients (P = 0.55). During the 1-year follow-up, 5 (10%) of the stent patients died or incurred myocardial infarction, compared with 3 (6%) of the PTCA patients (P = 0.50). CONCLUSIONS: Patients with diabetes who undergo percutaneous coronary interventions for lesions in small vessels have an especially high risk of restenosis that does not appear to be attenuated by stenting.

Am Heart J 2002 Jan;143(1):111-7

Revascularization improves survival in ischemic cardiomyopathy regardless of electrocardiographic criteria for prior small-to-medium myocardial infarcts.

Shah BR, Velazquez E, Shaw LK, Bart B, O?onnor C, Wagner GS.

BACKGROUND: The purpose of the current study was to determine whether survival after revascularization (coronary artery bypass grafting or percutaneous transluminal coronary angioplasty) is influenced by the extent of electrocardiographic (ECG) evidence of previous myocardial infarction (MI) in patients with ischemic cardiomyopathy by use of the 50-criteria, 31-point Selvester QRS scoring system. METHODS: Patients with ischemic cardiomyopathy documented by a left ventricular ejection fraction (LVEF) < or =30% undergoing coronary angiography between January 1984 and July 1996, with no acute MI within the last 30 days, follow-up
through 1996, and > or =75% occlusion in at least 1 major coronary artery at catheterization were included. These patients were subdivided on the basis of subsequent treatment: revascularization or no revascularization. The complete Selvester QRS system was applied to each patient? ECG and the subgroups were further subdivided by QRS score. RESULTS: The 141 patients receiving revascularization had better survival at 5 years compared with the 298 patients receiving no revascularization (adjusted 5-year survival rate 73% vs 47%, P =.0001). No significant treatment differences were observed for low (< or =3 points) versus high (≥3 points) QRS levels in either of the 2 treatment groups (revascularized patients: P =.215, patients without revascularization: P =.126) between the 2 treatment groups. Although all patients had LVEF < or =30%, only 8% of patients had QRS scores >10 points, the level that would be expected if the decrease in LVEF could be attributed entirely to infarcted myocardium. CONCLUSIONS: Hibernating myocardium may contribute significantly to the decreased function in patients with ischemic cardiomyopathy, and the QRS score cannot be used as an independent predictor of survival in those patients with a marked decrease in LVEF but small to moderate infarct sizes.

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Impact of normalized myocardial perfusion after successful angioplasty in acute myocardial infarction.


We sought to evaluate and validate the ability of the angiographic myocardial blush grade to risk stratify patients after successful angioplasty in acute myocardial infarction (AMI). Although epicardial Thrombolysis In Myocardial Infarction (TIMI)-3 flow is restored in >90% of patients undergoing primary percutaneous coronary intervention (PCI), normal myocardial perfusion may be present less frequently and may detrimentally impact survival. A cohort of 173 consecutive patients undergoing intervention within 24 h of AMI onset were studied. High-risk features of this population included failed intervention in 39%, cardiogenic shock in 17% and saphenous vein graft culprit in 11% of patients. Despite the restoration of TIMI-3 flow in 163 (94.2%) patients, myocardial perfusion, as evidenced by normal contrast opacification of the myocardial bed subtended by the infarct artery (myocardial blush), was normal in only 29.4% of patients with TIMI-3 flow following PCI, and in no patient with TIMI 0 to 2 flow. In patients in whom TIMI-3 flow was restored, survival was strongly dependent on the myocardial perfusion grade; one-year cumulative mortality was 6.8% with normal myocardial blush, 13.2% with reduced myocardial blush and 18.3% in patients with absent myocardial blush (p
Abnormal myocardial perfusion is present in most patients following primary or rescue PCI in AMI, despite restoration of brisk epicardial coronary flow. In high risk patients achieving TIMI-3 flow after intervention, the myocardial blush score may be used to stratify prognosis into excellent, intermediate and poor survival. Further study is warranted to examine whether adjunctive mechanical or pharmacologic strategies can further improve myocardial perfusion and survival of patients with acute myocardial infarction undergoing intervention.

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Prognostic value of coronary blood flow velocity and myocardial perfusion in intermediate coronary narrowings and multivessel disease.


This study aimed to investigate the roles of intracoronary derived coronary flow velocity reserve (CFVR) and myocardial perfusion scintigraphy (single photon emission computed tomography, or SPECT) for management of an intermediate lesion in patients with multivessel coronary artery disease. Evaluation of the functional significance of intermediate coronary narrowings (40% to 70% diameter stenosis) is important for clinical decision making and risk stratification. In a prospective, multicenter study, SPECT was performed in 191 patients with stable angina and multivessel disease and scheduled for angioplasty (percutaneous transluminal coronary angioplasty, or PTCA) of a severe coronary narrowing. Coronary flow velocity reserve was determined selectively distal to an intermediate lesion in another artery using a Doppler guidewire. Percutaneous transluminal coronary angioplasty of the intermediate lesion was deferred when SPECT was negative or CFVR greater-than-or-equal2.0. Patients were followed for one year to document major cardiac events (death, infarction, revascularization), related to the intermediate lesion. Reversible perfusion defects were documented in the area of the intermediate lesion in 30 (16%) patients; CFVR was positive in 46 (24%) patients. Percutaneous transluminal coronary angioplasty of the intermediate lesion was deferred in 182 patients. During follow-up, 19 events occurred (3 myocardial infarctions, 16 revascularizations). Coronary flow velocity reserve was a more accurate predictor of cardiac events than was SPECT; relative risk: CFVR 3.9 (1.7 to 9.1), p < 0.05; SPECT 0.5 (0.1 to 3.2), p = NS. Multivariate analysis revealed CFVR as the only significant predictor for cardiac events. Deferral of PTCA of intermediate lesions in multivessel disease is safe when CFVR
greater-than-or-equal2.0 (event rate 6%). This selective evaluation of coronary lesion severity during cardiac catheterization allows a more accurate risk stratification than does SPECT, which is important for clinical decision making in this patient cohort.

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The impact of tranilast on restenosis after coronary angioplasty: The second tranilast restenosis following angioplasty trial (TREAT-2).


BACKGROUND: The Tranilast Restenosis Following Angioplasty Trial showed that oral administration of 600 mg/day of tranilast for 3 months markedly reduced the restenosis rate after percutaneous transluminal coronary angioplasty (PTCA) for de novo lesions. METHODS: We conducted the second multicenter, randomized, double-blinded placebo-controlled trial. A total of 297 patients with 329 lesions were randomly assigned to treatment with tranilast or a placebo for 3 months after successful PTCA for both de novo and restenotic lesions. Angiographic follow-up examination was done at 3 months, and angiograms were interpreted with a quantitative approach. RESULTS: Two hundred thirty-nine lesions (72.6%) in 216 of the patients (72.7%) met the criteria and were included in the assessment of restenosis. Lesion restenosis was defined as a loss of 50% or more of the initial gain, and the restenosis rates were 18.8% in the tranilast group (n = 112) and 44.1% in the placebo group (n = 127; P =.00005). The restenosis rate, defined as a percent stenosis of greater-than-or-equal50% at follow-up examination, was also significantly lower in the tranilast group (25.9% versus 41.9%; P =.012). The numbers of restenotic lesions were 38 (33.9% of 112) in the tranilast group and 30 (23.6% of 127) in the placebo group. In restenotic lesions, the lesion restenosis rate was significantly lower in the tranilast subgroup (18.4% versus 53.3% with the first restenosis criterion; P =.004). CONCLUSION: The oral administration of tranilast for 3 months markedly reduced the restenosis rate after PTCA, even in restenotic lesions.

Journal of the American College of Cardiology, 31:2:252-258
Objectives. We report the acute results and midterm clinical course after percutaneous transluminal septal myocardial ablation (PTSMA) in symptomatic patients with hypertrophic obstructive cardiomyopathy (HOCM).

Background. In the treatment of HOCM, surgical myectomy and DDD pacemaker therapy are considered the standard procedural extensions to drug therapy with negatively inotropic drugs. As an alternative nonsurgical procedure for reducing the left ventricular outflow tract (LVOT) gradient, PTSMA by alcohol-induced septal branch occlusion was introduced. However, clinical follow-up has not been sufficiently described.

Methods. In 25 patients (13 women, 12 men; mean ±SD age 54.7 ± 15.0 years) who were symptomatic despite sufficient drug therapy, 1.4 ± 0.6 septal branches were occluded with an injection of 4.1 ± 2.6 ml of alcohol (96%) to ablate the hypertrophied interventricular septum. After 3-months, follow-up results of LVOT gradients and clinical course were determined.

Results. The invasively determined LVOT gradients could be reduced in 22 patients (88%), with a mean reduction from 61.8 ± 29.8 mm Hg (range 4 to 152) to 19.4 ± 20.8 mm Hg (range 0 to 74) at rest (p < 0.0001) and from 141.4 ± 45.3 mm Hg (range 76 to 240) to 61.1 ± 40.1 mm Hg (range 0 to 135) after extrasystole. All patients had angina pectoris for 24 h. The maximal creatine kinase increase was 780 ± 436 U/liter (range 305 to 1,810) after 11.1 ± 6.0 h (range 4 to 24). Thirteen patients (52%) developed a trifascicular block for 5 min to 8 days requiring temporary (n = 8 [32%]) or permanent (DDD) pacemaker implantation (n = 5 [20%]). An 86-year old woman died 8 days after successful intervention of uncontrollable ventricular fibrillation in conjunction with beta-sympathomimetics in chronically obstructive pulmonary disease. The remaining patients were discharged after 11.3 ± 5.4 days (range 5 to 24), after an uncomplicated hospital course. Clinical and echocardiographic follow-up was achieved in all 24 surviving patients after 3 months. No cardiac
complications occurred. Twenty-one patients (88%) showed clinical improvement, with a New York Heart Association functional class of 1.4 ± 1.1. A further reduction in LVOT gradient was shown in 14 patients (58%).

Conclusions. PTSMA of HOCM is a promising nonsurgical technique for septal myocardial reduction, with a consecutive reduction in LVOT gradient. Possible complications are trifascicular blocks, requiring permanent pacemaker implantation, and tachycardiac rhythm disturbances. Clinical long-term observations of larger patient series and a comparison with conventional forms of therapy are necessary to determine the conclusive therapeutic significance.

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Long-Term Angiographic Follow-Up of Coronary Balloon Angioplasty in Patients With Diabetes Mellitus: A Clue to the Explanation of the Results of the BARI Study

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Objectives. We sought to compare the angiographic outcome of diabetic patients (treated with insulin or oral hypoglycemic agents) after successful coronary angioplasty with that in nondiabetic patients. The analysis included the outcome of the dilated (restenosis) and nondilated narrowings (disease progression).

Background. Recent data have confirmed that diabetes mellitus is an important risk factor for long-term adverse events. These adverse events are more common after balloon angioplasty than after bypass surgery (Bypass Angioplasty Revascularization Investigation [BARI]).

Methods. We examined retrospectively 353 coronary angiograms of 248 patients (55 diabetic, 193 nondiabetic) who were referred for diagnostic angiography >1 month after successful angioplasty (1.4 ± 0.6 [mean ± SD] repeat angiograms/patient). Restenosis and disease progression/regression were compared between groups by means of quantitative angiography.
Results. Baseline clinical and angiographic characteristics were similar in both groups. There was a nonsignificant trend for a higher restenosis rate of dilated narrowings in diabetic patients. There were no significant changes between diabetic and nondiabetic patients in the rates of progression and regression of narrowings that were not dilated during the initial angioplasty. The main difference was in the rate of appearance of new narrowings: There was a 22% increase in the number of narrowings on the follow-up angiogram in diabetic patients (38 new, 174 preexisting narrowings) compared with 12% (86 new, 734 preexisting narrowings) in nondiabetic patients (p < 0.004). Diabetes mellitus and the performance of angioplasty in the artery had an additive risk for development of new narrowings, which were identified in 15 (16.9%) of 89 arteries with and 16 (13.2%) of 121 without angioplasty in diabetic patients and in 42 (12.7%) of 331 arteries with and 38 (7.3%) of 518 without angioplasty in nondiabetic patients (p = 0.009).

Conclusions. The combination of diabetes mellitus and an artery that was instrumented during balloon angioplasty is additive and increases the risk of formation of new narrowing in that artery. This finding may explain the high adverse event rates observed in diabetic patients in the angioplasty arm of the BARI study, most of whom had angioplasty performed in at least two arteries.


Sheath pulling immediately after PTCA: Comparison of two different deployment techniques for the hemostatic puncture closure device: A prospective, randomized study

Sigmund Silber, Rolf Dorr, Holger Muhling, Uwe Konig

Sheath pulling immediately after percutaneous transluminal coronary angioplasty (PTCA) increases patients’ comfort, decreases burden for the medical staff, and may reduce hospital costs by shortening the length of stay. Immediate sheath pulling in anticoagulated patients with a low risk of bleeding complications is feasible using hemostatic devices. For the hemostatic puncture closing device (HPCD), published data regarding sheath pulling in patients immediately after PTCA is limited. Furthermore, no study addressed the question whether the recommended deployment time (DT) of 30 min can be reduced to a few minutes. We, therefore, performed a prospective study, randomizing 140 patients to a DT of 5 and 30 min, respectively. There were no statistical differences in gender, age, height, weight, or cardiovascular risk factors between the two groups. Blood pressures measured invasively immediately before sheath removal were comparable. Activated coagulation time just prior to sheath removal was 227 ± 52 sec in the DT-5 group and 223 ± 37 sec in the DT-30 group.
After deployment, 74% of the DT-5 patients and 71% of the DT-30 patients showed immediate and complete hemostasis. The remaining patients showed only little oozing with complete hemostasis at the time of the final device removal. Hematoma size after 24 hr was $6.2 \pm 4.4$ cm² for DT-5 and $6.8 \pm 8.2$ cm² for DT-30 patients. There was no statistical difference between both groups. No severe bleeding or major complications were observed in either group. Thus, the use of a collagen system with an intra-arterial anchor (HPCD) is effective and safe when sheaths are pulled immediately after PTCA. The reduction of deployment time from 30 to 5 min is not related to an increased risk of bleeding or other vascular complications; patients can be transferred much faster to the ward, therefore reducing the burden on the personnel in the catheterization laboratory and increasing patients’ comfort by allowing them to return to their rooms without a sheath.

Keywords
coronary artery disease; interventional cardiology; collagen; patient comfort


Late Regression of the Dilated Site After Coronary Angioplasty: A 5-Year Quantitative Angiographic Study

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Background Limited data are available on the changes that occur at the dilated site late after coronary angioplasty. The aim of this study was to evaluate with quantitative angiography the natural history of changes that occur in the dilated segment between “early” (6 months) and “late” (5 years) follow-up after angioplasty.

Methods and Results Of 127 consecutive patients (174 lesions) with successful angioplasty, 125 underwent early angiography. Three patients subsequently died, and 24 underwent revascularization surgery or repeated angioplasty, giving a study-eligible population of 98 patients. Quantitative angiographic analysis was performed before and immediately after angioplasty and at early and late follow-up in the study population of 84 patients (115 lesions), which was 86% of study-eligible patients. Mean lesion diameter stenosis decreased from $36.3\pm14.2\%$ at early to $29.6\pm13.5\%$ at late follow-up ($P<0.001$). No lesion developed late restenosis by the 50% diameter loss criterion. Late regression was related to stenosis severity at early angiography ($r=-.58$, $P<0.001$). Subgroups at early angiography of 40% to 49% stenosis and 50% stenosis showed significant regression at late angiography.

Conclusions Lesion regression at the dilated site is common late after angioplasty. The more severe a stenosis is
at early angiography, the more likely the chance that there will be late regression. A strategy of watchful waiting may be appropriate for patients with restenotic lesions of borderline severity.

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A Randomized Comparison of Percutaneous Transluminal Coronary Angioplasty by the Radial, Brachial and Femoral Approaches: The Access Study

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Objectives.
This study sought to compare procedural and clinical outcomes of percutaneous transluminal coronary angioplasty (PTCA) performed with 6F guiding catheters introduced through the radial, brachial or femoral arteries.

Background.
Transradial PTCA has been demonstrated to be an effective and safe alternative to transfemoral PTCA; however, no randomized data are currently available.

Methods. A randomized comparison between transradial, transbrachial and transfemoral PTCA with 6F guiding catheters was performed in 900 patients. Primary end points were entry site and angioplasty related. Secondary end points were quantitative coronary analysis after PTCA, procedural and fluoroscopy times, consumption of angioplasty equipment and length of hospital stay.

Results.
Successful coronary cannulation was achieved in 279 (93.0%), 287 (95.7%) and 299 (99.7%) patients randomized to undergo PTCA by the radial, brachial and femoral approaches, respectively. PTCA success was achieved in 91.7%, 90.7% and 90.7% (p = NS) of patients, with 88.0%, 87.7% and 90.0% event free at 1-month follow-up, respectively (p = NS). Major entry site complications were encountered in seven patients (2.3%) in the transbrachial group, six (2.0%) in the transfemoral group and none in the transradial group (p = 0.035). Transradial PTCA led to asymptomatic loss of radial pulsations in nine patients (3%). Procedural and fluoroscopy times were similar, as were consumption of guiding and balloon catheters and length of hospital stay ([mean ± SD] 1.5 ± 2.5, 1.8 ± 3.8 and 1.8 ± 4.2 days, respectively).

Conclusions.
With experience, procedural and clinical outcomes of PTCA were similar for the three subgroups, but access
failure is more common during transradial PTCA. Major access site complications were more frequently encountered after transbrachial and transfemoral PTCA.


Effect of Reperfusion on Biventricular Function and Survival after Right Ventricular Infarction

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Background. Although the salutary effects of reperfusion in patients with left ventricular infarction are well documented, the benefits in patients with acute right ventricular infarction are less clear.

Methods. To determine whether primary angioplasty improves right ventricular function and the clinical outcome in patients with right ventricular infarction, we performed echocardiographic studies before and after angioplasty in 53 patients with acute right ventricular infarction.

Results. Complete reperfusion, defined as normal flow in the right main coronary artery and its major right ventricular branches, was achieved in 41 patients (77 percent), leading to prompt and striking recovery of right ventricular function (mean [±SE] score for free-wall motion, 3.0±0.4 at base line and 1.4±0.1 at three days; P<0.001). Twelve patients (23 percent) had unsuccessful reperfusion, defined as the failure to restore right ventricular branch flow, with or without patency of the right main coronary artery. Unsuccessful reperfusion was associated with lack of recovery of right ventricular function (score for free-wall motion, 3.2±0.6 at base line and 3.0±0.9 at three days; P = 0.55), as well as persistent hypotension and low cardiac output (in 83 percent of the patients, vs. 12 percent of those with successful reperfusion; P = 0.002) and a high mortality rate (58 percent, vs. 2 percent for those with successful reperfusion; P = 0.001).

Conclusions. In patients with right ventricular infarction, complete reperfusion of the right coronary artery by angioplasty results in the dramatic recovery of right ventricular performance and an excellent clinical outcome. In contrast, unsuccessful reperfusion is associated with impaired recovery of right ventricular function, persistent hemodynamic compromise, and a high mortality rate.

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Percutaneous Interventions Alter the Hemostatic Profile of Patients With Unstable Versus Stable Angina

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Objectives. The objectives of this study were to define the hemostatic profiles of patients with unstable angina compared with patients with stable angina and to investigate the effect of percutaneous interventions on the follow-up hemostatic profiles of these patients.

Background. Disturbances in hemostatic factors have been shown to be present in various clinical syndromes involving coronary artery disease. However, their role in stable angina versus unstable angina is less well defined.

Methods. We studied 61 patients with either stable or unstable angina undergoing percutaneous coronary interventions. Blood samples were drawn immediately before the intervention and at 1-month follow-up. Plasma levels of tissue-type plasminogen activator (t-PA), plasminogen activator inhibitor-1 (PAI-1) and von Willebrand factor (vWF) were measured by enzyme-linked immunosorbent assays.

Results. Patients with unstable angina had significantly higher t-PA levels (mean ± SE 23.7 ± 3.4 vs. 14.3 ± 1.4 ng/ml, respectively, p = 0.02) and vWF antigen concentrations (2,231 ± 157 vs. 1,792 ± 108 mU/ml, respectively, p = 0.03) than patients with stable angina. No statistically significant differences were observed in the PAI-1 levels between the two groups (27.9 ± 5.5 vs. 21.4 ± 2.5 ng/ml, respectively, p = 0.25). At 1-month follow-up, there were no longer any significant differences in the t-PA or vWF levels between the two groups (15.7 ± 1.2 vs. 13.6 ± 0.6 ng/ml, p = 0.13; 1,962 ± 170 vs. 1,809 ± 88 mU/ml, p = 0.39, respectively). There were no significant differences between the hemostatic profiles of patients undergoing percutaneous transluminal coronary angioplasty or coronary stenting initially and at 1-month follow-up.

Conclusions. These data suggest that elevated plasma levels of t-PA and vWF may correlate with instability of atheromatous plaques, and that their decrease after coronary interventions may reflect plaque reendothelialization and stabilization.

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Clinical Investigation and Reports
Prediction of Restenosis After Coronary Balloon Angioplasty

Results of PICTURE (Post-IntraCoronary Treatment Ultrasound Result Evaluation), a Prospective Multicenter Intracoronary Ultrasound Imaging Study

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Background. Intracoronary ultrasound (ICUS) imaging is potentially suitable to identify lesions at high risk of restenosis after percutaneous transluminal coronary angioplasty (PTCA), but it has not been studied systematically.

Methods and Results. We Recruited 200 patients in whom ICUS studies were performed after successful PTCA and related their ICUS parameters to 6-month follow-up quantitative coronary angiography. This was performed in 164 patients (82%), yielding 170 lesions for analysis. The overall incidence of a ≥50% diameter stenosis at follow-up (categorical restenosis) was 29.4%. Quantitative ICUS parameters were weakly but significantly relate to follow-up minimal luminal diameter on quantitative coronary angiography (lumen area: R2=.36, P=.0001; vessel area: R2=.29, P=.0002; plaque area: R2=.18, P=.021; percent obstruction: R2=.15; P=.05), but categorical restenosis was not significantly related to these parameters (P=.63, .77, .38, and .08, respectively).

There were no significant predictors of restenosis in ICUS parameters of plaque morphology: eccentric versus concentric (P=1.0), plaque type (hard, soft, or calcific, P=.98), or the number of calcified quadrants (P=.41).

There were no significant predictors of restenosis in two predefined types of vessel-wall disruptions: (1) rupture: presence (p=.79), depth (partial versus complete, P=.85), or extent in quadrants (P=.6), and (2) dissection: presence (P=.31), depth (P=.82), or extent (P=.38).

Conclusions. Qualitative ICUS parameters after PTCA did not predict restenosis. A larger lumen and vessel area and a smaller plaque area by ICUS were associated with a larger angiographic minimal lumen diameter at follow-up, but these parameters were not significantly related to categorical restenosis.

Effect of Nadroparin, a Low-Molecular-Weight Heparin, on Clinical and Angiographic Restenosis After Coronary Balloon Angioplasty

The FACT Study

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Background. Experimental studies suggest that the antiproliferative effect of heparin after arterial injury is maximized by pretreatment. No previous studies of restenosis have sued a pretreatment strategy. We designed this study to determine whether treatment with nadroparin, a low-molecular-weight heparin, started 3 days before the procedure and continued for 3 months affected angiographic restenosis or clinical outcome after coronary angioplasty.

Methods and Results. In a prospective multicenter, doubleblind, randomized trial, elective coronary angioplasty was performed on 354 patients who were treated with daily subcutaneous nadroparin (0.6 mL of 10 250 anti-Xa IU/mL) of placebo injections started 3 days before angioplasty and continued for 3 months. Angiography was performed just before and immediately after angioplasty and at follow-up. The primary study end point was angiographic restenosis, assessed by quantitative coronary angiography 3 months after balloon angioplasty. Clinical follow-up was continued up to 6 months. Clinical and procedural variables and the occurrence of periprocedural complications did not differ between groups. At angiographic follow-up, the mean minimal lumen diameter and the mean residual stenosis in the nadroparin group (1.37±0.66 mm, 51.9±21.0%) did not differ from the corresponding values in the control group (1.48±0.59 mm, 48.8±18.9%). Combined major cardiac-related clinical events (death, myocardial infarction, target lesion revascularization) did not differ between groups (30.3% versus 29.6%).

Conclusions. Pretreatment with the low-molecular-weight heparin nadroparin continued for 3 months after balloon angioplasty had no beneficial effect on angiographic restenosis or on adverse clinical outcomes.

Summary

Femoral artery hemostasis using an implantable device (Angio-SealTM) after coronary angioplasty

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Coronary catheter interventional procedures are associated with risk of access site complications. We report our experience with Angio-SealTM, an implantable hemostasis device, when used in the femoral artery after coronary angioplasty procedures. Sixty-eight patients were studied. Their average age was 63 years; 84% of the patients were male. All had 8 French access sheaths and received bolus heparin (mean dose 12,690 U). The arterial sheaths were removed an average of 455 min after the conclusion of the procedure, when the activated clotting time was 220 ± 94 sec (range 97-503 sec).

The hemostasis device was successfully deployed in 63 patients (93%). The average time to achieve complete arterial hemostasis was 4.4 ± 8.9 min (range 0-45). Immediate, total hemostasis without requiring any form of external pressure was obtained in 37 of these patients (54%).

The incidence of complications was as follows: significant bleeding occurred in 9 patients (13%); there were 2 hematomas (3%); there were no vascular or infectious complications. One device embolization occurred when the connecting suture broke and the intravascular anchor was lost; no clinical sequelae resulted, and manual hemostasis was successful. In four other patients, the device did not deploy and was removed entirely, followed by uneventful manual hemostasis. Follow-up for 2 months revealed no late sequelae in any patient, and complete absorption of the device was documented by ultrasound study in all cases.

We conclude that this implantable device can achieve arterial hemostasis quickly and safely when used in anticoagulated patients after coronary interventional procedures.


Percutaneous Transluminal Coronary Angioplasty Reverses Vasoconstriction of Stenotic Coronary Arteries in Hypertensive Patients

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Background-Endothelial dysfunction of coronary arteries with impaired vasodilation has been reported in patients with arterial hypertension. However, the effect of dynamic exercise on coronary vasmotion of a stenotic vessel segment before and after PTCA has not yet been evaluated in these patients.
Methods and Results—Coronary vasomotion of a normal and a stenotic vessel segment was studied in 39 patients with coronary artery disease during supine bicycle exercise before and 9 ± 3 months after PTCA. Luminal area changes were determined by biplane quantitative coronary arteriography. There were 21 normotensive and 18 hypertensive patients who did not differ with regard to clinical characteristics. Percent area stenosis decreased after PTCA from 90% to 39% (P < 0.001) in normotensive and from 86% to 33% (P < 0.001) in hypertensive patients. Exercise-induced vasomotion of the normal vessel segment was significantly different between normotensives and hypertensives before (+19% versus +1%, P < 0.01) and after (+16% versus +3%, P < 0.01) PTCA. In contrast, stenotic vessel segments showed vasoconstriction in both normotensive and hypertensive patients (exercise, -11% versus -20%, P = NS), which was reversed after PTCA (+3% versus +2%, P = NS).

Conclusions—Normal coronary arteries show reduced vasodilation during exercise in hypertensive patients that may be explained by the presence of endothelial dysfunction. Stenotic vessels demonstrate paradoxical vasoconstriction during exercise in both normotensive and hypertensive patients. PTCA reverses vasoconstriction by elimination of the flow-limiting stenosis and prevention of coronary stenosis narrowing during exercise in normotensive and hypertensive patients.

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Six-month angiographic and clinical follow-up of patients prospectively randomized to receive either tirofiban or placebo during angioplasty in the RESTORE trial

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Objectives. This study sought to investigate the effects of tirofiban versus placebo on the incidence of adverse cardiac outcomes and coronary artery restenosis at 6 months.

Background. Tirofiban is a highly selective, short-acting inhibitor of fibrinogen binding to platelet glycoprotein IIb/IIIa. In a recent clinical study, tirofiban reduced the incidence of adverse cardiovascular events at both 2 and 7 days after coronary angioplasty or directional coronary atherectomy. This reduction persisted but was no longer statistically significant at 30 days.
Methods. The Randomized Efficacy Study of Tirofiban for Outcomes and Restenosis (RESTORE) trial was a randomized, double-blind, placebo-controlled trial of tirofiban in patients undergoing balloon angioplasty or directional atherectomy within 72 h of presentation with either unstable angina pectoris or acute myocardial infarction. All patients received an initial bolus (10 g/kg body weight over 3 min), followed by a 36-h infusion (0.15 g/kg per min) of either tirofiban or placebo.

Results. At 6 months the composite end point (either death from any cause, new myocardial infarction, bypass surgery for angioplasty failure or recurrent ischemia, repeat target vessel angioplasty or stent insertion for actual or threatened abrupt closure) occurred in 1,070 placebo group patients (27.1%) and 1,071 tirofiban group patients (24.1%, p = 0.11). Analysis of 6-month coronary arteriograms by means of quantitative coronary arteriography showed no significant difference between placebo- and tirofiban-treated patients in either the incidence of a 50% diameter stenosis (57% vs. 51%, p = NS), a loss of 50% of lumen diameter gained (50% vs. 50%, p =NS) or a loss of 0.72 mm of lumen diameter (44% vs. 42%, p =NS).

Conclusions. The 3% absolute reduction in the incidence of the composite end point at 6 months (27.1% placebo vs. 24.1% tirofiban) was similar to that previously reported at 2 days (8.7% vs. 5.4%, p < 0.005), and there does not appear to be any late effect of tirofiban on clinical end points between day 2 and 6 months. Tirofiban did not reduce the incidence of restenosis at 6 months when defined in a number of ways.

The American Journal of Cardiology, 82:2:135-139

Results of percutaneous coronary angioplasty in patients <40 years of age

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Study examined factors influencing the outcome of percutaneous transluminal coronary angioplasty (PTCA) in patients <40 years of age. We followed 86 patients (mean age 37 years) treated from 1982 to 1994. The primary procedural success was 90%. At follow-up of 83 patients (97%) at a mean of 48 ± 33 months (range 5 to 147), there had been 3 late deaths. Actuarial survival at 5 and 10 years was 95% and 91%, respectively. At review only 5% of patients had class III angina and no patient had class IV angina. Repeat revascularization (PTCA alone in 21 [25%], surgery in 8 [10%], or both in 10 [12%] patients) was performed for restenosis in 29 patients (35%) and for disease progression at other sites in 10 patients (12%). On multivariate analysis, a history of diabetes mellitus (p <0.02) was the only factor associated with death or a subsequent cardiovascular event (myocardial
infarction, stroke, or hospital admission with unstable angina). At follow-up, 20 patients (24%) still smoked, 64 (77%) had a total cholesterol level 200 mg/dl, 20 (24%) had a body mass index 30, and 15 (18%) were not taking aspirin. In conclusion, PTCA in adults <40 years of age has excellent early results with a low morbidity and mortality. The medium-term prognosis and control of symptoms was good, although by 5 years, further revascularization was required in almost half of the patients.

The American Journal of Cardiology, 82:12:1451-1456

Increased intensity of contrast material immediately after late angioplasty of infarct-related coronary artery is associated with reduced ventricular volumes at six months

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To assess the contribution of residual muscle perfusion in the infarcted territory to prevent ventricular remodeling, 24 patients with 1-vessel disease underwent coronary angiography and angioplasty of a critical left anterior descending coronary stenosis 18 ± 11 days after a first anterior myocardial infarction. The degree of stenosis was assessed using biplane quantitative angiography, whereas ventricular volumes, together with regional wall motion, were computed from single-plane ventriculography. Patients were reevaluated at 6 months after they had been subdivided according to the videointensity of the territory of the culprit vessel, as assessed from images obtained during main stem dye contrast injections before and immediately after angioplasty using a subtraction technique (group A, increased intensity [n = 15]; group B, no change [n = 9]), assuming that higher peak intensities reflect greater myocardial blood volume. There was a significant time - group interaction for ventricular volumes (diastolic, -13 ± 12% for group A vs +20 ± 24% for group B, p = 0.008; systolic, -15 ± 19% for group A vs +18 ± 36% for group B, p = 0.017), although no interaction was evident for the degree of resolution of coronary stenosis or the extent of recovery of regional dysfunction. The effects on volumes were paralleled by changes in ventricular end-diastolic pressure (-3 ± 7 mm Hg in group A vs +5 ± 6 mm Hg in group B, p = 0.006), although baseline clinical characteristics and medical regimen over the 6-month period were quite comparable between the 2 groups. In conclusion, despite late angioplasty of the culprit vessel, ventricular remodeling is prevented mainly when the procedure guarantees improved perfusion at the muscular level. The result is not necessarily mediated by recovery of regional systolic function.
Time dependence of left ventricular recovery after delayed recanalization of an occluded infarct-related
coronary artery: findings of a pilot study

Matthias E. Pfusterer, Peter Buser, Stefan Osswald, Philipp Weiss, Jens Bremerich, Felix Burkart

Objectives. We sought to test the hypothesis that late recanalization of infarct-related coronary arteries (IRAs)
improves long-term left ventricular (LV) function.

Background. Reperfusion within 24 h of an acute myocardial infarction (MI) has been shown to improve
myocardial healing and to reduce infarct expansion. Uncontrolled data suggest that there may be a time
window of several weeks for such an effect.

Methods. Sixteen asymptomatic patients 10 ± 4 days after a first Q wave anterior wall MI with persistent left
antero descending coronary artery occlusion and infarct-zone akinesia were randomized to immediate (2
weeks) or delayed (3 months) angioplasty. Repeat catheterization and cardiac magnetic resonance imaging
(MRI) were performed after 3 and 12 months.

Results. Angiography 3 months after MI revealed that LV ejection fraction (LVEF) had increased ([mean ± SD]
54.4 ± 4.3% vs. 63.9 ± 7.4%, p < 0.01) as a result of improved regional function (p < 0.01) and LV end-systolic
volume had decreased (p < 0.002), whereas LV end-diastolic volume remained unchanged. With delayed
angioplasty, LVEF, infarct zone wall motion and LV volumes did not improve. Cardiac MRI at baseline and at 3
and 12 months confirmed these findings and extended them up to 1 year, indicating that delayed angioplasty
could no longer improve LV function because of marked LV dilation (p < 0.01). Immediate angioplasty had a
high success rate, but restenosis (50%) was accompanied by new severe angina as a clinical indicator of
salvaged myocardium, which did not occur after delayed angioplasty.

Conclusions. This pilot study in selected patients supports the hypothesis that myocardial viability persists
(hibernation? for 2 to 3 weeks but not for 3 months after MI, during which time it may be worthwhile to restore
blood flow to a large myocardial territory, even in asymptomatic patients, to improve long-term LV function.

Effects of Probucol on Vascular Remodeling After Coronary Angioplasty

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Gosselin, Michel Joyal, Jean-Francois Tanguay, Stanley Nattel, Richard Gallo, and Jacques Crepeau
Background-We have shown that probucol reduces restenosis after balloon angioplasty. Whether probucol acted via prevention of neointimal formation or improvement in vascular remodeling could not be addressed by angiography and required the use of intravascular ultrasound (IVUS).

Methods and Results-Beginning 30 days before angioplasty, 317 patients were randomly assigned to receive probucol, multivitamins, combined treatment, or placebo. Patients were then treated for 6 months after angioplasty. IVUS examination was performed immediately after angioplasty and at follow-up in 94 patients (111 segments). The cross section selected for serial analysis was the one at the angioplasty site with the smallest lumen area at follow-up. In the placebo group, lumen area decreased by -1.21±1.88 mm² at follow-up, and wall area and external elastic membrane (EEM) area increased by 1.50±2.50 and 0.29±2.93 mm², respectively. Change in lumen area, however, correlated more strongly with the change in EEM area (r=0.53, P=0.002) than with the change in wall area (r=0.13, P=0.49). Lumen loss was -1.21±1.88 mm² for placebo, -0.83±1.22 mm² for vitamins, -0.25±1.17 mm² for combined treatment, and -0.15±1.70 mm² for probucol alone (P=0.002 for probucol, P=0.84 for vitamins). Change in wall area was similar for all groups. EEM area increased by 0.29±2.93 mm² for placebo, 0.09±2.33 mm² for vitamins only, 1.17±1.61 mm² for combined treatment, and 1.74±1.80 mm² for probucol only (P=0.005 for probucol).

Conclusions-Lumen loss after balloon angioplasty is due to inadequate vessel remodeling in response to neointimal formation. Probucol exerts its antirestenotic effects by improving vascular remodeling after angioplasty.

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Early Noninvasive Identification of Failed Reperfusion After Intravenous Thrombolytic Therapy in Acute Myocardial Infarction

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Objectives. This study sought to evaluate a biochemical approach to the early noninvasive assessment of reperfusion.
Background. In patients with an acute myocardial infarction, a rapid noninvasive method of detecting failure of intravenous thrombolytic therapy to restore early Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow in the infarct-related artery (IRA) is needed.

Methods. Serial blood samples were collected to assay creatine kinase-MB fraction (CKMB mass), cardiac troponin T and myoglobin concentrations in 105 patients with a myocardial infarction who underwent early angiography after intravenous streptokinase. The ratios of the 60- and 90-min concentrations to prethrombolytic values were used to determine an index that could identify failure to achieve TIMI grade 3 flow in the IRA at 90 min.

Results. Significant increases in serum concentrations of markers at 60 min were more likely with TIMI grade 3 flow (59 patients) than with TIMI grade 0 to 2 flow (46 patients). Ratios ≤5 at 60 min after thrombolysis detected failure to achieve 90-min TIMI grade 3 flow with 92% to 97% sensitivity, 43% to 60% specificity and 63% to 76% positive and 86% to 94% negative predictive values. Ratios 10 at 90 min showed 88% to 95% sensitivity, 49% to 65% specificity and 61% to 69% positive and 86% to 94% negative predictive values for TIMI flow grade <3. The overall predictive values were thus similar for all three markers.

Conclusions. In acute myocardial infarction treated with intravenous streptokinase, a simple measurement of increased serum concentrations of CKMB mass, cardiac troponin T or myoglobin at 60 and 90 min can accurately predict failure to achieve TIMI grade 3 flow in the IRA at 90 min.

Journal of the American College of Cardiology, 32:3:590-595

Long-term analysis of conventional coronary balloon angioplasty and an initial “stent-like” result : The NHLBI PTCA registry

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Objectives. We examined the influence of an initial “stent-like” result on long-term outcome in patients in the 1985-86 NHLBI PTCA Registry.

Background. Stent use in selected patients is associated with improved angiographic and short-term clinical outcome; however, due to potential for in-stent restenosis and high costs of stents, there is interest in a strategy of more optimal dilatation to achieve a “stent-like” result without a stent. The long-term outcome of patients with a “stent-like” percutaneous transluminal coronary angioplasty (PTCA) remains unknown.
Methods. Ten-year outcome was compared between 225 successfully treated patients with and 1,764 successfully treated patients without an initial “stent-like” result (1 lesion dilated to 10% stenosis). The sample had 75% and 80% power, respectively, to detect an absolute difference of 8% in the 10-year rate of death and myocardial infarction (MI) between the two groups.

Results. Ten-year rates of death and MI were similar between the stent-like and non-stent-like groups (22.3% vs. 22.2%, 17.6% vs. 17.9%), however, there was less target lesion revascularization in the stent-like group (30.2% vs. 36.8%). In subgroup analysis of patients with multivessel disease, those with a stent-like result had less follow-up bypass surgery (25.2% vs. 32.7%), yet more repeat PTCA (53.8% vs. 42.7%). These findings were unaffected by adjustment for differences in baseline characteristics between the two patient groups.

Conclusions. Achievement of an initial stent-like result via balloon angioplasty alone may not appreciably reduce the long-term risk of death or MI, nor confer equivalent clinical benefit as achieving a stent-like result with a stent.

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Stenting in acute coronary syndromes: a comparison of radial versus femoral access sites

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Background. Aggressive anticoagulation in patients with acute coronary syndromes increases the risk of femoral vascular complications. The transradial approach has the potential to significantly reduce the incidence of access site bleeding complications in this group of patients.

Methods. One hundred forty-two patients with acute coronary syndromes undergoing coronary stenting were prospectively randomized to have their procedure performed from either the radial or femoral access site and the results compared.

Results. Nine of 74 patients randomized to the radial group crossed over to the femoral group (6 negative Allen tests, 3 access failures). Patient demographics were the same in both groups. Primary success was identical: 96% radial, 96% femoral, ns. There were no procedural myocardial infarctions or deaths, and no patient was referred for emergency bypass surgery. There were no access site bleeding complications in the radial group as opposed to 3 (4%) in the femoral group, p < 0.01. Postprocedure length of stay, days (1.4 ± 0.2 radial vs. 2.3 ± 0.4 femoral, p < 0.01) as well as total hospital length of stay (3.0 ± 0.3 radial vs. 4.5 ± 0.5 femoral, p < 0.01)
were significantly reduced in the radial group. Total hospital charge was also significantly lower in the radial group ($20,476 ± 811 radial versus $23,389 ± 1,180 femoral, p < 0.01).

Conclusion. Coronary stenting from the radial approach is efficacious in patients with acute coronary syndromes. Access site bleeding complications are less, and early ambulation results in a shorter hospital length of stay. There was a 15% reduction in total hospital charge in the radial group.


Final Results of the Balloon vs Optimal Atherectomy Trial (BOAT)


Background-Previous directional coronary atherectomy (DCA) trials have shown no significant reduction in angiographic restenosis, more in-hospital complications, and higher 1-year mortality than conventional balloon angioplasty (percutaneous transluminal coronary angioplasty [PTCA]). DCA, however, has subsequently evolved toward a more “optimal” technique (larger devices, more extensive tissue removal, and routine postdilation to obtain diameter stenosis <20%).

Methods and Results-The Balloon vs Optimal Atherectomy Trial (BOAT) was conducted to evaluate whether optimal DCA provides short- and long-term benefits compared with balloon angioplasty. One thousand patients with single de novo, native vessel lesions were randomized to either DCA or PTCA at 37 participating centers. Lesion success was obtained in 99% versus 97% (P=.02) of patients to a final residual diameter stenosis of 15% versus 28% (P<.0001) for DCA and PTCA, respectively, the latter including stents in 9.3% of the patients. There was no increase in major complications (death, Q-wave myocardial infarction, or emergent coronary artery bypass graft surgery [2.8% versus 3.3%]), although creatine kinase-MB ≥3x normal was more common with DCA (16% versus 6%; P<.0001). Angiographic restudy (in 79.6% of eligible patients at 7.2±2.6 [median, 6.9] months) showed a significant reduction in the prespecified primary end point of angiographic restenosis by DCA (31.4% versus 39.8%; P=.016). Clinical follow-up to 1 year showed nonsignificant 13% to 17% reductions in the DCA arm of the study for mortality rate (0.6% versus 1.6%; P=.14), target-vessel revascularization (17.1% versus 19.7%; P=.33), target-site revascularization (15.3% versus 18.3%; P=.23), and target-vessel failure (death, Q-wave myocardial infarction, or target-vessel revascularization, 21.1% versus
Conclusions—Optimal DCA provides significantly higher short-term success, lower residual stenosis, and lower angiographic restenosis than conventional PTCA, despite failing to reach statistical significance for reducing late clinical events compared with PTCA with stent backup.

Journal of the American College of Cardiology, 1998;32:3:629-633

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

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

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

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

Results. Patients who were transferred had an additional median delay of 43 min. This resulted in a more extensive enzymatic infarct size and a lower ejection fraction measured at 6 months. The rate of angioplasty success defined as TIMI grade 3 flow, and the 6-month mortality rate (7%) were comparable in both groups. Conclusions. The additional delay had a deleterious effect on myocardial salvage, reflected by a larger infarct size and a lower left ventricular function. However, the patency rate and 6-month clinical outcome were not affected by this delay.
Long-Term Beneficial Effect of Late Reperfusion for Acute Anterior Myocardial Infarction With Percutaneous Transluminal Coronary Angioplasty

Hajime Horie, Masayuki Takahashi, Kazuo Minai, Masafumi Izumi, Atsushi Takaoka, Masato Nozawa, Hiroshi Yokohama, Tamotsu Fujita, Taizo Sakamoto, Osamu Kito, Hiroshi Okamura, and Masahiko Kinoshita

Background—Although the short-term and long-term beneficial effects of early coronary revascularization by primary PTCA or thrombolytic therapy have been established for acute myocardial infarction, thrombolytic therapy >24 hours after the onset of acute myocardial infarction has not been shown to improve clinical outcome. The purpose of this study was to assess the effect of late revascularization by primary PTCA over a 5-year period.

Methods and Results—Eighty-three patients with initial Q-wave anterior myocardial infarction >24 hours after onset were randomized into a PTCA group (n=44) and a no-PTCA group (n=39). Long-term follow-up was conducted with regard to end points, which included cardiac death, nonfatal recurrence of myocardial infarction, and development of congestive heart failure. Left ventricular ejection fraction and regional wall motion at 6 months after myocardial infarction were similar in the 2 groups. Left ventricular end-diastolic and end-systolic volume indexes were significantly smaller in the PTCA group than in the no-PTCA group (P<0.0001). With cardiac events as end points, a 5-year Kaplan-Meier event-free survival analysis revealed that the no-PTCA group had a worse prognosis than the PTCA group (P<0.0001). Patency of the infarct-related artery, left ventricular ejection fraction, end-diastolic volume index, and end-systolic volume index were significantly associated with cardiac events by a Cox proportional hazards analysis (hazard ratios 0.120, 0.845, 1.065, and 1.164, respectively).

Conclusions—In initial Q-wave anterior myocardial infarction, we conclude that even with late reperfusion, PTCA had beneficial effects on cardiac events over the 5-year period after myocardial infarction, with the prevention of left ventricular dilation after myocardial infarction being a possible mechanism.
Objectives. We sought to determine whether there is a relation between operator volume and outcomes for percutaneous coronary interventions (PCIs).

Background. A 1993 American College of Cardiology/American Heart Association task force stated that cardiologists should perform 75 procedures/year to maintain competency in PCIs; however, there were limited data available to support this statement.

Methods. Data were collected from 1990 through 1993 on 12,988 PCIs (12,118 consecutive hospital admissions) performed by 31 cardiologists at two hospitals in New Hampshire and two in Maine and one hospital in Massachusetts supporting these procedures. Operators were categorized into terciles based on annualized volume of procedures. Univariate and multivariate regression analyses were used to control for case-mix. Successful outcomes included angiographic success (all lesions attempted dilated to <50% residual stenosis) and clinical success (at least one lesion dilated to <50% residual stenosis and no adverse outcomes). In-hospital adverse outcomes included coronary artery bypass graft surgery (CABG), myocardial infarction (MI) and death.

Results. After adjustment for case-mix, higher angiographic (low, middle and high terciles: 84.7%, 86.1% and 90.3%, p-trend 0.006) and clinical success rates (85.8%, 88.0% and 90.7%, p-trend 0.025), with fewer referrals to CABG (4.54%, 3.75% and 2.49%, p-trend <0.001), were seen as operator volume increased. There was a trend toward higher MI rates for high volume operators (2.00%, 1.98% and 2.57%, p-trend 0.06); all terciles had similar in-hospital mortality rates (1.09%, 0.96% and 1.05%, p-trend 0.8).

Conclusions. There is a significant relation between operator volume and outcomes in PCIs. Efforts should be directed toward understanding why high volume operators are more successful and encounter fewer adverse outcomes.

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Metabolic changes in hibernating myocardium after percutaneous transluminal coronary angioplasty and the relation between recovery in left ventricular function and free fatty acid metabolism
To elucidate the changes in oxidative metabolism in hibernating myocardium after coronary revascularization, we performed myocardial single-photon emission computed tomography with a free fatty acid analog, I-123-methylidophenylpentadecanoic acid (BMIPP), and thallium-201 before and 1 month after percutaneous transluminal coronary angioplasty (PTCA) in 11 patients with angina pectoris caused by single artery stenosis. All patients had improvement in wall motion after PTCA at the region with coronary stenosis; the wall motion abnormality score evaluated by left ventriculography decreased from 5.5 ± 0.8 (mean ± SE) to 2.1 ± 0.9, p <0.01) after PTCA. The defect score of I-123 BMIPP images was significantly larger than that of thallium-201 images either before (14 ± 1.3 vs 8.9 ± 1.1, p <0.01) or 1 month after (7.4 ± 1.5 vs 3.7 ± 0.8, p <0.01) PTCA. The decrease in the defect score of both images was significant (p <0.01). Changes in the wall motion abnormality score showed a significant correlation with both the change in the defect score of thallium-201 images (r = 0.58, p <0.01) and that of I-123 BMIPP images (r = 0.75, p <0.01). These results indicate that the metabolism of free fatty acid is impaired in hibernating myocardium, and that improvement in left ventricular function after successful PTCA is strongly associated with the recovery of oxidative metabolism.

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Intensive Medical Therapy Versus Coronary Angioplasty for Suppression of Myocardial Ischemia in Survivors of Acute Myocardial Infarction: A Prospective, Randomized Pilot Study

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Background-Patients who have inducible ischemia after acute myocardial infarction (AMI) generally undergo coronary angiography with the intent to revascularize. Whether this approach is superior to intensive treatment with anti-ischemic medications is unknown.

Methods and Results-We performed a prospective, randomized pilot study comparing intensive medical
therapy with coronary angioplasty (PTCA) for suppression of myocardial ischemia in 44 stable survivors of AMI. Myocardial ischemia was quantified with adenosine 201Tl tomography (SPECT) performed 4.5±2.9 days after AMI. All patients at baseline had a large total (20%) and ischemic (10%) left ventricular perfusion defect size (PDS). SPECT was repeated at 43±26 days after therapy was optimized. The total stress-induced PDS was comparably reduced with medical therapy (from 38±13% to 26±16%; P<0.0001) and PTCA (from 35±12% to 20±16%; P<0.0001). The reduction in ischemic PDS was also similar (P=NS) in both groups. Cardiac events occurred in 7 of 44 patients over 12±5 months. Patients who remained clinically stable had a greater reduction in ischemic PDS (-13±9%) than those who had a recurrent cardiac event (-5±7%; P<0.02). Event-free survival was superior in the 24 patients who had a significant (9%) reduction in PDS (96%) compared with those who did not (65%; P=0.009).

Conclusions-In this small pilot study, intensive medical therapy and PTCA were comparable at suppressing ischemia in stable patients after AMI. Sequential imaging with adenosine SPECT can track changes in PDS after anti-ischemic therapies and thereby predict subsequent outcome. Corroboration of these preliminary findings in a larger cardiac-event trial is warranted.

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Clinical Investigation and Reports
Prevention of Restenosis After Angioplasty in Small Coronary Arteries With Probucol

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Background- Restenosis remains the major limitation of coronary angioplasty. Coronary stents have reduced the incidence of restenosis in selected patients with relative large vessels. No strategies to date have demonstrated a beneficial effect in vessels <3.0 mm in diameter. We have shown in the MultiVitamines and Probucol (MVP) Trial that probucol, a potent antioxydant, reduces restenosis after balloon angioplasty. The purpose of this study was to determine whether the benefit of probucol therapy is maintained in the subgroup of patients with smaller coronary vessels.

Methods and Results-We studied a subgroup of 189 patients included in the MVP trial who underwent successful balloon angioplasty of at least one coronary segment with a reference diameter <3.0 mm. One month before angioplasty, patients were randomly assigned to one of four treatments: placebo, probucol (500mg),
multivitamins (beta-carotene 30,000 IU, vitamin C 500mg, and vitamin E 700 IU), or probucol plus multivitamins twice daily. The treatment was maintained until follow-up angiography was performed at 6 months. The mean reference diameter of this study population was 2.49±0.34 mm. Lumen loss was 0.12±0.34 mm for probucol, 0.25±0.43 mm for the combined treatment, 0.35±0.56 mm for vitamins, and 0.38±0.51 mm for placebo (P=.005 for probucol). Restenosis rates per segment were 20.0% for probucol, 28.6% for the combined treatment, 45.1% for vitamins, and 37.3% for placebo (P=.006 for probucol).

Conclusions-Probucol reduces lumen loss and restenosis rate after balloon angioplasty in small coronary arteries.

Summary
Journal of the American College of Cardiology, 33:2:403-411

A prospective randomized trial of prevention measures in patients at high risk for contrast nephropathy: Results of the P.R.I.N.C.E. study

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Objectives
This study was done to test the hypothesis that a forced diuresis with maintenance of intravascular volume after contrast exposure would reduce the rate of contrast-induced renal injury.

Background
We have previously shown a graded relationship with the degree of postprocedure renal failure and the probability of in-hospital death in patients undergoing percutaneous coronary intervention. Earlier studies of singular prevention strategies (atrial natriuretic factor, loop diuretics, dopamine, mannitol) have shown no clear benefit across a spectrum of patients at risk.

Methods
A prospective, randomized, controlled, single-blind trial was conducted where 98 participants were randomized to forced diuresis with intravenous crystalloid, furosemide, mannitol (if pulmonary capillary wedge pressure <20 mm Hg), and low-dose dopamine (n = 43) versus intravenous crystalloid and matching placebos (n = 55).

Results
The groups were similar with respect to baseline serum creatinine (2.44 ± 0.80 and 2.55 ± 0.91 mg/dl), age, weight, diabetic status, left ventricular function, degree of prehydration, contrast volume and ionicity, and
extent of peripheral vascular disease. The forced diuresis resulted in higher urine flow rate (163.26 ± 54.47 vs. 122.57 ± 54.27 ml/h) over the 24 h after contrast exposure (p = 0.001). Two participants in the experimental arm versus five in the control arm required dialysis, with all seven cases having measured flow rates <145 ml/h in the 24 h after the procedure. The mean individual change in serum creatinine at 48 h, the primary end point, was 0.48 ± 0.86 versus 0.51 ± 0.87, in the experimental and control arms, respectively, p = 0.87. There were no differences in the rates of renal failure across six definitions of renal failure by intent-to-treat analysis. However, in all participants combined, the rise in serum creatinine was related to the degree of induced diuresis after controlling for baseline renal function, r = -0.36, p = 0.005. The rates of renal failure in those with urine flow rates greater than 150 ml/h in the postprocedure period were significantly lower, 8/37 (21.6%) versus 28/61 (45.9%), p = 0.03.

Conclusions
Forced diuresis with intravenous crystalloid, furosemide, and mannitol if hemodynamics permit, beginning at the start of angiography provides a modest benefit against contrast-induced nephropathy provided a high urine flow rate can be achieved.

Journal of the American College of Cardiology, 34:1:55-61

Factors correlating with risk of mortality after transmyocardial revascularization

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OBJECTIVES
The purpose of this study was to determine factors correlating with the risk of postoperative mortality after transmyocardial laser revascularization (TMR).

BACKGROUND
Clinical studies have indicated that TMR reduces angina by an average of two classes in patients with medically refractory symptoms not treatable by coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty. Factors which correlate with mortality after TMR, however, have not been extensively investigated.

METHODS
One hundred thirty-two patients with severe angina underwent TMR as sole therapy with a CO2 laser. Age, gender, ejection fraction, prior CABG, unstable angina and the severity of coronary artery disease (graded on
the basis of a newly proposed Anatomic Myocardial Perfusion index, AMP) were each determined. Each vascular territory (left anterior descending artery [LAD] left circumflex artery and posterior descending artery [PDA]) was graded as either having (AMP = 1) or not having (AMP = 0) blood flow through an unobstructed major vessel in the territory. Univariate and multivariate analysis determined which factors correlated with mortality.

**RESULTS**

Patients with at least one AMP = 1 vascular territory (overall AMP = 1) had a 5% (4/82) postoperative mortality rate (POM), compared with 25% (12/49) with overall AMP 0 (p = 0.002). Left anterior descending artery AMP (p = 0.03) and previous CABG (p = 0.04) each correlated with the risk of POM. However, multivariate analysis indicated that no factor improved the correlation obtained with overall AMP by itself. With regard to overall mortality (Kaplan-Meier curves), univariate analysis also revealed correlations with overall AMP (p < 0.001), LAD AMP (p = 0.005), previous CABG (p = 0.003) and PDA AMP (p = 0.05) each individually correlated with mortality. Multivariate analysis indicated that overall AMP = 1, female gender and previous CABG together correlated best with lower postoperative mortality.

**CONCLUSIONS**

Patients with good blood flow to at least one region of the heart through a native artery or a patent vascular graft have a markedly reduced risk of perioperative and longer term mortality.

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Restenosis Following Angioplasty in the Swine Coronary Artery Is Inhibited By an Orally Active PDGF-Receptor Tyrosine Kinase Inhibitor, RPR101511A

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Background-Platelet-derived growth factor (PDGF), a purported mediator of arterial response to injury, stimulates proliferation, chemotaxis, and matrix production by activation of its membrane receptor tyrosine kinase. Because these activities underlie restenosis, inhibition of the PDGF-receptor tyrosine kinase (PDGFR-TK) is postulated to decrease restenosis.

Methods and Results-RPR101511A is a novel compound which selectively and potently inhibits the cell-free and in situ PDGFR-TK and PDGFR-dependent proliferation and chemotaxis in vascular smooth muscle cells (VSMC). To evaluate the effect of RPR101511A (30 mg · kg⁻¹ · d⁻¹ BID for 28 days following PTCA) on
coronary restenosis, PTCA was performed in hypercholesterolemic minipigs whose left anterior descending (LAD) coronary artery had been injured by overdilation and denudation, yielding a previously existing lesion. Angiographically determined prePTCA minimal lumen diameters (MLD) were similar in vehicle and RPR101511A-treated pigs (1.98±0.09 versus 2.01±0.08 mm) and increased to the same extent in the 2 groups following successful PTCA (2.30±0.06 versus 2.52±0.13). At termination, there was an average 50% loss of gain in the vehicle-treated group but no loss of gain with RPR101511A (2.16±0.05 versus 2.59±0.11, P<0.001). Morphometric analysis of the LAD showed that RPR101511A caused a significant decrease in total intimal/medial ratio (0.96±0.58 versus 0.67±0.09, P<0.05).

Conclusions-RPR101511A, which acts by inhibition of the PDGFr-TK, completely prevented angiographic loss of gain following PTCA and significantly reduced histological intimal hyperplasia.


Preintervention Arterial Remodeling as an Independent Predictor of Target-Lesion Revascularization After Nonstent Coronary Intervention : An Analysis of 777 Lesions With Intravascular Ultrasound Imaging

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Background—Pathological and intravascular ultrasound (IVUS) studies have documented arterial remodeling during atherogenesis. However, the impact of this remodeling process on the long-term outcome after percutaneous intervention is unknown.

Methods and Results—We used preintervention IVUS to define positive and negative/intermediate remodeling in a total of 777 lesions in 715 patients treated with nonstent techniques. Positive remodeling (lesion external elastic membrane area greater than average reference) was present in 313 lesions; intermediate, negative remodeling (lesion external elastic membrane area less than or equal to reference) was present in the other 464. Baseline clinical and angiographic characteristics were similar, except for a slightly higher percentage of insulin-dependent diabetic patients (10.2% versus 6.1%; P=0.054) in the negative/intermediate-remodeling group. Angiographic success and in-hospital and short-term complications were comparable in the 2 groups. There was no significant correlation between remodeling (as a continuous variable) and final lumen area (r=0.06) or final lesion plaque burden (r=0.17). At 18±13 months of clinical follow-up, both groups had similar rates of death and Q-wave myocardial infarction: 3.4% and 2.5% for the negative/intermediate-remodeling
group versus 2.7% and 2.7% for the positive-remodeling group. However, the target-lesion revascularization (TLR) rate was 20.2% for the negative/intermediate-remodeling group versus 31.2% for the positive-remodeling group (P=0.007), and remodeling, as a continuous variable, was strongly correlated with probability of TLR (P=0.0001). By multivariable logistic regression analysis, diabetes (OR=2.3), left anterior descending artery location (OR=1.8), and remodeling (OR=5.9) were independent predictors of TLR.

Conclusions-Positive lesion-site remodeling is associated with a higher long-term TLR after a nonstent interventional procedure. Thus, long-term clinical outcome appears to be determined in part by preintervention lesion characteristics.

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

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


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 uncomplicated 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 uncomplicated closure require

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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.

The American Journal of Cardiology, 83:5:675-680

Comparison of slow oscillating versus fast balloon inflation strategies for coronary angioplasty


Previous studies suggest that slow and/or oscillating balloon inflation during coronary angioplasty may decrease the incidence of coronary dissection and improve clinical outcomes. To compare the effect of slow oscillating versus conventional fast inflation techniques on the incidence of severe coronary dissection during angioplasty, 622 patients were randomized to slow oscillation inflation versus fast inflation. Angiographic outcomes of the procedures and in-hospital clinical events were recorded. The primary end point of severe (type C, D, E, F) dissection occurred in 7.7% of patients undergoing slow oscillation and 6.6% of patients undergoing fast inflation (p = 0.87). Major complications (death, urgent coronary artery bypass graft surgery, stroke, abrupt closure, or Q-wave myocardial infarction) occurred in 4.7% of patients undergoing slow oscillation and 3.5% of patients undergoing fast inflation (p = 0.45). The 2 inflation strategies did not differ in the pressure at which the balloon achieved full expansion, angiographic success rate, residual stenosis, and incidence of all minor and/or major complications. We conclude that there is no benefit of slow oscillating inflation over routine fast inflation in angioplasty. Slow oscillating inflation did not dilate lesions at lower pressures, decrease the incidence of dissection or severe dissection, or reduce the incidence of adverse clinical outcomes.
Outcome of target sites escaping high-grade (>70%) restenosis after percutaneous transluminal coronary angioplasty

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This study examined the fate of target sites that escaped high-grade restenosis (70% diameter narrowing) after percutaneous transluminal coronary angioplasty. Although favorable long-term prognosis after successful percutaneous transluminal coronary angioplasty is well documented, little is known about the stability of target sites. Long-term follow-up (mean 6.5 years, range 1.0 to 12.0) was performed in 693 patients with 948 narrowings (stenosis <70% in diameter at follow-up coronary angiography). Among them, 249 patients (36%) with 303 target sites received late follow-up coronary angiography. The relation of target sites to the culprit lesions for coronary events or newly developed angina was angiographically reviewed and progression/regression was also examined, focusing on the target sites. Regression was observed in 16 of 255 target sites in subjects with <50% stenosis and in 21 of 48 sites in the group with midgrade stenosis of 50% to 69% luminal narrowing (16 of 255, 6.3% vs 21 of 48, 43.8%, p <0.001). Progression was observed in 33 and 4 sites (33 of 255, 12.9% vs 4 of 48, 8.3%; p = NS) in each group, respectively. The rest remained within the same range of stenosis. Culprit lesions for 2 acute myocardial infarctions, 7 unstable anginas, and 17 newly developed anginas were related to the original target sites. Three lesions developed in the midgrade stenosis group. Those 26 lesions were a component of 8.6% of 303 angiographically confirmed sites and 2.7% of total target sites. Target sites that escape high-grade restenosis frequently regress and become stable plaques and rarely trigger coronary events.

Procedural results and early clinical outcome of percutaneous transluminal myocardial revascularization

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A substantial number of patients present with medically refractory angina who are not candidates for angioplasty or bypass surgery. The creation of channels between the myocardium and the ventricular blood pool has been performed after thoracotomy with excellent relief of symptoms but has been associated with high perioperative mortality. We investigated the safety of a nonoperative, percutaneous technique for channel creation. Twenty-seven patients with angina and coronary anatomy not amenable to revascularization with coronary angioplasty or bypass surgery underwent percutaneous transluminal myocardial revascularization (PTMR). Energy from a Holmium:yttrium-aluminum-garnet (YAG) laser was directed through a fiber enclosed in a catheter to the ventricular myocardium creating channels between the blood pool and the myocardium. On average, 17 ± 4 channels were formed per patient. There were no procedure-related deaths, episodes of tamponade, or other complications except for an increase in creatine phosphokinase in 1 patient. Immediately after the procedure, there was no worsening of regional wall motion function in any patient, but rather improvement in some. All patients were discharged alive after a hospital stay of 1.8 ± 1.5 days. Mean Canadian Cardiovascular Society functional class declined from 3.6 ± 0.5 before the procedure to 0.65 ± 0.8 at 30 days after the procedure (p < 0.01). For 12 patients eligible for 6-month follow-up, mean functional class was 0.94 ± 0.97. At 6-month stress testing, 9 of these 12 had no electrocardiographic evidence of ischemia. Thus, PTMR can be performed safely in the cardiac catheterization laboratory with a complication rate lower than that reported in surgical series and with excellent near-term symptomatic relief. The long-term effect of PTMR on mortality and relief of angina as well as its safety and effectiveness compared with the surgical approach remains to be defined.

Journal of the American College of Cardiology, 34:1:70-82

Long-term (three-year) prognosis of patients treated with reperfusion or conservatively after acute myocardial infarction

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OBJECTIVES
This survey sought to assess the frequency of the use of thrombolytic therapy, invasive coronary procedures (ICP) (angiography, percutaneous transluminal coronary angioplasty and coronary artery bypass grafting [CABG]), variables associated with their use, and their impact on early (30-day) and long-term (3-year) mortality after acute myocardial infarction (AMI).

BACKGROUND
Few data are available regarding the implementation in daily practice of the results of clinical trials of treatments for AMI and their impact on early and long-term prognosis in unselected patients after AMI.

METHODS
A prospective community-based national survey was conducted during January-February 1994 in all 25 coronary care units operating in Israel.

RESULTS
Among 999 consecutive patients with an AMI (72% men; mean age 63 ± 12 years) acute reperfusion therapy (ART) was used in 455 patients (46%; thrombolysis in 435 patients [44%] and primary angioplasty in 20 [2%]). Its use was independently associated with anterior AMI location and hospitals with on-site angioplasty facilities, whereas advancing age, prior myocardial infarction (MI) and prior angioplasty or CABG were independently associated with its lower use. The three-year mortality of patients treated with ART was lower than in counterpart patients (22.0% vs. 31.4%, p = 0.0008), mainly as the result of 30-day to 3-year outcome (12.4% vs. 21.1%; hazard ratio = 0.73, 95% confidence interval [CI] 0.52 to 1.03). Independent predictors of long-term mortality were: age, heart failure on admission or during the hospitalization, ventricular tachycardia or fibrillation and diabetes. The outcome of patients not treated with ART differed according to the reason for the exclusion, where patients with contraindications experienced the highest three-year (50%) mortality rate. After ART, coronary angiography, angioplasty and CABG were performed in-hospital in 28%, 12% and 5% of patients, respectively. Their use was independently associated with recurrent infarction or ischemia, on-site catheterization or CABG facilities, non-Q-wave AMI and anterior infarct location. In the entire study population, and in patients with a non-Q-wave AMI, performance of ICP was associated with lower 30-day mortality (odds ratio [OR] = 0.53, 95% CI 0.25 to 0.98, and OR = 0.21, 0.03 to 0.84, respectively), but not thereafter.

CONCLUSIONS
This survey demonstrates the extent of implementation in daily practice of ART and ICP and their impact on early and long-term prognosis in an unselected population after AMI.

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

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

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

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

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

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

Circulation 1999;100: 256-261

Long-Term Follow-Up After Percutaneous Transluminal Coronary Angioplasty Was Not Performed Based on Intravascular Ultrasound Findings: Importance of Lumen Dimensions

Background-Angiography is limited in determining the anatomic severity of coronary artery stenoses. Clinical decision-making in patients with symptoms and intermediate lesions remains challenging.

Methods and Results-The current analysis included 300 patients (357 intermediate native artery lesions) in whom intervention was deferred based on intravascular ultrasound (IVUS) findings. Standard clinical, angiographic, and IVUS parameters were collected. Patients were followed for >1 year. Events occurred in 24 patients (8%). They included 2 cardiac deaths, 4 myocardial infarctions, and 18 target-lesion revascularizations (TLR; 12 percutaneous transluminal coronary angiographies and 6 coronary artery bypass grafts; only 3 TLRs occurred within 6 months after the IVUS study). All significant univariate clinical, angiographic, and IVUS parameters (P<0.05) were tested in multivariate models. These included diabetes mellitus, IVUS lesion lumen area, maximum lumen diameter, minimum lumen diameter, plaque area, plaque burden, and area stenosis (AS). No angiographic measurement was significant at P<0.05. The only independent predictors of an event (death, myocardial infarction, or TLR) were IVUS minimum lumen area and AS. The only independent predictors of TLR were diabetes mellitus, IVUS minimum lumen area, and AS. In 248 lesions with a minimum lumen area 4.0 mm2, the event rate was only 4.4% and the TLR rate 2.8%.

Conclusions-Long-term follow-up after IVUS-guided deferred interventions in patients with de novo intermediate native artery lesions showed a low event rate. In patients with a minimum lumen area 4.0 mm2, the event rate was especially low. IVUS imaging is an acceptable alternative to physiological assessment in these patients.

Circulation 1999;100: 14-20

Relationship Between Delay in Performing Direct Coronary Angioplasty and Early Clinical Outcome in Patients With Acute Myocardial Infarction : Results From the Global Use of Strategies to Open Occluded Arteries in Acute Coronary Syndromes (GUSTO-IIb) Trial

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Background-Time to treatment with thrombolytic therapy is a critical determinant of mortality in acute myocardial infarction. Little is known about the relationship between the time to treatment with direct coronary angioplasty and clinical outcome. The objectives of this study were to determine both the time
required to perform direct coronary angioplasty in the Global Use of Strategies to Open Occluded Arteries in Acute Coronary Syndromes (GUSTO-IIb) trial and its relationship to clinical outcome.

Methods and Results—Patients randomized to direct coronary angioplasty (n=565) were divided into groups based on the time between study enrollment and first balloon inflation. Patients randomized to angioplasty who did not undergo the procedure were also analyzed. The median time from study enrollment to first balloon inflation was 76 minutes; 19% of patients assigned to angioplasty did not undergo an angioplasty procedure. The 30-day mortality rate of patients who underwent balloon inflation 60 minutes after study enrollment was 1.0%; 61 to 75 minutes after enrollment, 3.7%; 76 to 90 minutes after enrollment, 4.0%; and ≥91 minutes after enrollment, 6.4%. The mortality rate of patients assigned to angioplasty who never underwent the procedure was 14.1% (P=0.001). Logistic regression analysis revealed that the time from enrollment to first balloon inflation was a significant predictor of mortality within 30 days; after adjustment for differences in baseline characteristics, the odds of death increased 1.6 times (P=0.008) for a movement from each time interval to the next.

Conclusions—The time to treatment with direct PTCA, as with thrombolytic therapy, is a critical determinant of mortality.

Key Words: reperfusion, myocardial infarction, angioplasty, mortality, survival

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Clinical and sequential angiographic follow-up six months and 10 years after successful percutaneous transluminal coronary angioplasty

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Sequential angiographic follow-up is needed for interpreting coronary events that occur after successful percutaneous transluminal coronary angioplasty (PTCA). One hundred eight consecutive patients who had undergone successful dilatation were followed for 10 years, and quantitative sequential angiograms were recorded at 6 months (n = 101) and 10 years (n = 68). The 10-year event rate was: 5.8 ± 2.4% for cardiac death, 9.7 ± 3.3% for Q-wave acute myocardial infarction, 18.3 ± 4.5% for additional surgery, and 22.4 ± 4.9% for repeated angioplasty. Using Cox’s proportional-hazards regression, multivessel coronary artery disease (CAD) (RR 5.6; 95% confidence intervals [CI] 1.2 to 24.7; p = 0.02), restenosis within 6 months (RR 7.8; 95% CI 3.1 to 20.0; p = 0.001), and CAD progression over 10 years (RR 10.6; 95% CI 1.3 to 87.1; p = 0.004) were the strongest predictors of all-cause death, repeated PTCA, and additional surgery, respectively, after controlling for age and
coronary risk factors. The minimal luminal diameter of 48 narrowings with complete sequential angiographic follow-up and without restenosis remained stable from 6 months (2.13 ± 0.60 mm) to 10 years (2.18 ± 0.61 mm). Disease progression was similar in nondilated arteries and dilated arteries (32% vs 30%). The 10-year risk of coronary events was higher in patients with baseline multivessel CAD than in those with 1-vessel CAD because of more frequent progression of CAD (RR 3.8; 95% CI 1.6 to 6.8; p = 0.001). Thus, early cardiac events after successful PTCA were related to restenosis, and late events to CAD progression. Nevertheless, after the restenosis period, the target lesion remained stable for the next 10 years. Coronary disease progression was not related to the angioplasty procedure.

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Impact of Cilostazol on Restenosis After Percutaneous Coronary Balloon Angioplasty

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Background-Restenosis after percutaneous transluminal coronary (balloon) angioplasty (PTCA) remains a major drawback of the procedure. We previously reported that cilostazol, a platelet aggregation inhibitor, inhibited intimal proliferation after directional coronary atherectomy and reduced the restenosis rate in humans. The present study aimed to determine the effect of cilostazol on restenosis after PTCA.

Methods and Results-Two hundred eleven patients with 273 lesions who underwent successful PTCA were randomly assigned to the cilostazol (200 mg/d) group or the aspirin (250 mg/d) control group. Administration of cilostazol was initiated immediately after PTCA and continued for 3 months of follow-up. Quantitative coronary angiography was performed before PTCA and after PTCA and at follow-up. Reference diameter, minimal lumen diameter, and percent diameter stenosis (DS) were measured by quantitative coronary angiography. Angiographic restenosis was defined as DS at follow-up >50%. Eligible follow-up angiography was performed in 94 patients with 123 lesions in the cilostazol group and in 99 patients with 129 lesions in the control group. The baseline characteristics and results of PTCA showed no significant difference between the 2 groups. However, minimal lumen diameter at follow-up was significantly larger (1.65±0.55 vs 1.37±0.58 mm; P<0.0001) and DS was significantly lower (34.1±17.8% vs 45.6±19.3%; P<0.0001) in the cilostazol group. Restenosis and target lesion revascularization rates were also significantly lower in the cilostazol group (17.9% vs 39.5%; P<0.001 and 11.4% vs 28.7%; P<0.001).
Conclusions-Cilostazol significantly reduces restenosis and target lesion revascularization rates after successful PTCA.

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Invasive versus conservative strategies in unstable angina and NQ-wave myocardial infarction following treatment with tirofiban: rationale and study design of the international TACTICS-TIMI 18 trial

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In the management of unstable angina and non-Q-wave acute myocardial infarction (AMI), there is considerable debate regarding the use of invasive strategy versus conservative strategy. The Thrombolysis In Myocardial Infarction (TIMI) III B trial found similar clinical outcomes for the 2 strategies, but the Veterans Administration Non-Q-Wave Infarction Strategies in-Hospital trial found a higher mortality with the invasive strategy. Both these trials were conducted before platelet glycoprotein IIb/IIIa inhibition and coronary stenting, both of which improve clinical outcome. Thus, there is a need to reexamine the question of which management strategy is optimal in the current era of platelet glycoprotein IIb/IIIa inhibition and new coronary interventions. The Treat Angina with Aggrastat and determine Cost of Therapy with an Invasive or Conservative Strategy (TACTICS-TIMI 18) trial is an international, multicenter, randomized trial that is evaluating the clinical efficacy of early invasive and early conservative treatment strategies in patients with unstable angina or non-Q-wave AMI treated with tirofiban, heparin, and aspirin. Patients are randomized to an invasive strategy, involving cardiac catheterization within 4 to 48 hours and revascularization with angioplasty or bypass surgery if feasible, versus a conservative strategy, where patients are referred for catheterization only for recurrent pain at rest or provokable ischemia. The primary end point is death, MI, or rehospitalization for acute coronary syndromes through a 6-month follow-up. The trial is also testing the “troponin hypothesis,” that baseline troponins T and I will be useful in selecting an optimal management strategy.

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Prevention of Restenosis After Angioplasty in Small Coronary Arteries With Probucol

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Background-Restenosis remains the major limitation of coronary angioplasty. Coronary stents have reduced the incidence of restenosis in selected patients with relatively large vessels. No strategies to date have demonstrated a beneficial effect in vessels < 3.0 mm in diameter. We have shown in the MultiVitamins and Probucol (MVP) Trial that probucol, a potent antioxidant, reduces restenosis after balloon angioplasty. The purpose of this study was to determine whether the benefit of probucol therapy is maintained in the subgroup of patients with smaller coronary vessels.

Methods and Results-We studied a subgroup of 189 patients included in the MVP trial who underwent successful balloon angioplasty of at least one coronary segment with a reference diameter < 3.0 mm. One month before angioplasty, patients were randomly assigned to one of four treatments: placebo, probucol (500 mg), multivitamins (beta-carotene 30 000 IU, vitamin C 500 mg, and vitamin E 700 IU), or probucol plus multivitamins twice daily. The treatment was maintained until follow-up angiography was performed at 6 months. The mean reference diameter of this study population was 2.49±0.34 mm. Lumen loss was 0.12±0.34 mm for probucol, 0.25±0.43 mm for the combined treatment, 0.35±0.56 mm for vitamins, and 0.38±0.51 mm for placebo (P=.005 for probucol). Restenosis rates per segment were 20.0% for probucol, 28.6% for the combined treatment, 45.1% for vitamins, and 37.3% for placebo (P=.006 for probucol).

Conclusions-Probucol reduces lumen loss and restenosis rate after balloon angioplasty in small coronary arteries.

Effects of Octreotide Treatment on Restenosis After Coronary Angioplasty: Results of the VERAS Study

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Circulation 1997;96: 1482-1487
Background The VERAS study (VErringerung der Re- stenoserate nach Angioplastie durch ein Somatostatinanalogon [Prevention of Restenosis Following Angioplasty With a Somatostatin Analogue]) was a placebo-controlled trial to evaluate the effects of octreotide for the prevention of restenosis after coronary angioplasty. Octreotide is a somatostatin analogue with antiproliferative properties on smooth muscle cell growth in vitro that limits myointimal thickening of arteries in balloon injury models.

Methods and Results Patients received either octreotide or placebo, starting 1 hour before angioplasty and continued for 3 weeks. The minimal luminal diameters before and after angioplasty and at 6-month follow-up were analyzed with a digital quantitative algorithm. Of the initial 274 patients recruited, 217 (108 in the octreotide group and 109 in the placebo group) could be analyzed after a complete 6-month evaluation: the minimal luminal diameters were $1.67 \pm 0.57$ mm in the octreotide-treated group and $1.66 \pm 0.64$ mm in the placebo group (two-paired $P = .70$), and the relative losses were $0.16 \pm 0.22$ and $0.13 \pm 0.21$ (two-paired $P = .27$). The restenosis rates were also identical in both treatment groups: final diameter stenosis $\geq 50\%$ (34.3\% versus 33.9\%, two-paired $P = 1.0$), loss of 50\% of the initial gain (34.3\% versus 33.9\%, two-paired $P = 1.0$), and absolute reduction of minimal luminal diameter $>0.72$ mm (29.6\% versus 24.8\%, two-paired $P = .45$). Likewise, there was no difference with regard to the incidence of clinical events (death, myocardial infarction, bypass operations, reintervention). Octreotide was well tolerated, with the exception of gastrointestinal side effects, which were three times more common than in the placebo group.

Conclusions Octreotide did not reduce the angiographically determined restenosis rate or the incidence of major clinical events after coronary angioplasty.

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Prevention of Distal Embolization During Saphenous Vein Graft Lesion Angioplasty: Experience With a New Temporary Occlusion and Aspiration System

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Background—Repeat coronary artery bypass graft surgery (CABG) is associated with a high morbidity and mortality, rendering percutaneous treatment of saphenous vein graft (SVG) lesions an attractive alternative. However, percutaneous interventions of degenerated SVGs carries high risk of distal embolization.

Methods and Results—This study reports our initial experience with the PercuSurge GuardWire, a new device
developed to prevent embolization during treatment of degenerated SVG. This device consists of a 190-cm-long, hollow 0.014-in guidewire with a central lumen connected to a distal occlusion balloon. A dedicated inflation device (the MicroSeal Adapter) was used to inflate the distal balloon and maintain complete lumen occlusion during balloon dilatation and stent implantation. A monorail aspiration catheter, connected to a vacuum syringe, was used to evacuate atherosclerotic and thrombotic debris. Angioplasty with stent implantation was performed in 15 degenerated SVGs (18 lesions). Procedural success was achieved in all patients with normal postprocedure flow (Thrombolysis in Myocardial Infarction grade 3). No distal embolization was observed. There were no major in-hospital adverse clinical events, including Q-wave or non-Q-wave myocardial infarction, emergency CABG, or death. All patients were asymptomatic at discharge.

Conclusions-This preliminary series supports the feasible use of the PercuSurge GuardWire for retrieval of plaque debris and prevention of embolization in degenerated SVGs. The good tolerance of temporary occlusions without angiographic or clinical evidence of distal embolization represents encouraging early findings.

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A randomized trial of elective stenting after balloon recanalization of chronic total occlusions.

Hoher M, Wohrle J, Grebe OC, Kochs M, Osterhues HH, Hombach V, Buchwald AB

OBJECTIVES: The aim of this study was to assess the role of Wiktor stent implantation after recanalization of chronic total coronary occlusions with regard to the clinical and angiographic outcome after six months. BACKGROUND: Beside the common use of stents in clinical practice, the number of stent indications proven by randomized trials is still limited. METHODS: Eighty-five patients with a thrombolysis in myocardial infarction grade 0 chronic coronary occlusion were examined. After standard balloon angioplasty, the patients were randomly assigned to stent implantation, or percutaneous transluminal coronary angioplasty (PTCA) alone (no further intervention). Quantitative coronary angiography was performed at baseline and after six months. RESULTS: The minimal lumen diameter did not differ immediately after recanalization (stent group 1.61 +/- 0.30 mm vs. PTCA group 1.65 +/- 0.36 mm), and increased after stent implantation to 2.51 +/- 0.41 mm. After six months, the stent group still had a significantly greater lumen (1.57 +/- 0.59 vs. 1.06 +/- 0.90 mm; p < 0.01) and a significantly lower restenosis and reocclusion rate (32% and 3%) compared with the PTCA group (64% and 24%); restenosis analysis according to treatment was 72% (PTCA) versus 29% (stent, p < 0.01). Late
loss was equal in both groups. At follow-up, the stent patients had a better angina class (p < 0.01), and fewer cardiac events (p < 0.03). A meta-analysis including this trial and three other controlled trials with the Palmaz-Schatz stent showed concordant results. CONCLUSIONS: Stent implantation after reopening of a chronic total occlusion provides a better angiographic result, corresponding to a better clinical outcome with fewer recurrence of symptoms and reinterventions after six months.

Summary

Am J Cardiol 1999 Apr 15;83(8):1164-9

Determinants of stent restenosis in chronic coronary occlusions assessed by intracoronary ultrasound.

Werner GS, Gastmann O, Ferrari M, Scholz KH, Schunemann S, Figulla HR

Chronic coronary occlusions have a high recurrence rate that can be reduced by stenting, but this rate remains higher than in nonocclusive lesions. To analyze possible determinants of restenosis in these lesions, intracoronary ultrasound was performed during the recanalization procedure. A chronic coronary occlusion of > or = 1 month duration (range 1 to 33 months; median 3.3) was successfully recanalized in 41 patients. Quantitative ultrasound analysis was performed before and after stent placement, with measurement of the luminal area, the extent of the plaque burden at the site proximal and distal to the occlusion, and within the occlusion and the subsequent stent. The degree of compensatory enlargement of the coronary artery within the occlusion was determined by comparing the average of the total vessel area of the proximal and distal reference with the lesion site. Early reocclusion (subacute stent thrombosis) was observed in 1 patient (2.4%). The angiographic control after 6 months showed restenosis in 9 patients with 1 late reocclusion. The overall recurrence rate was 24%. There was no difference in clinical and procedural characteristics between lesions with restenosis and without restenosis. The latter had a larger minimum stent area (7.59 +/- 1.96 mm2 vs 5.71 +/- 0.90 mm2; p <0.01), and there was evidence for more compensatory vessel enlargement in lesions without restenosis. Thus, intracoronary ultrasound showed that a smaller minimum stent area was a major predictor of angiographic restenosis, and it occurred more often in occlusions without compensatory vessel enlargement.

Summary
Percutaneous transluminal coronary angioplasty of chronic total occlusions. determinants of primary success and long-term clinical outcome

Teruo Noguchi, Shunichi Miyazaki MD, Isao Morii, Satoshi Daikoku, Yoichi Goto, Hiroshi Nonogi

This study was conducted to assess the determinants of the procedural success and long-term clinical benefits of percutaneous transluminal balloon angioplasty (PTCA) of chronic total occlusion (CTO) in recent years. Two hundred and twenty-six consecutive patients who underwent PTCA of CTO were divided into two groups according to the procedural success (n = 134) or failure (n = 92). Both groups were analyzed in terms of the initial success, predictors of procedural failure, and clinical outcome. The procedural success rate was noted to have improved to more than 70% since 1995. A multiple logistic regression analysis revealed that the presence of calcification, the length of the occlusion and the presence of multivessel disease were independent predictors of procedural failure. Cardiac death and the need for coronary surgery were significantly less frequent in patients with procedural success than in those with procedural failure. In properly selected cases, the success rate of PTCA of CTO is acceptable. Long-term clinical benefit is suggested by the high rate of freedom from coronary surgery and the low cardiac death rate in the patients who underwent successful revascularization.


The Volume of Primary Angioplasty Procedures and Survival after Acute Myocardial Infarction


Background. There is an inverse relation between mortality from cardiovascular causes and the number of elective cardiac procedures (coronary angioplasty, stenting, or coronary bypass surgery) performed by
individual practitioners or hospitals. However, it is not known whether patients with acute myocardial infarction fare better at centers where more patients undergo primary angioplasty or thrombolytic therapy than at centers with lower volumes.

Methods. We analyzed data from the National Registry of Myocardial Infarction to determine the relation between the number of patients receiving reperfusion therapy (primary angioplasty or thrombolytic therapy) and subsequent in-hospital mortality. A total of 450 hospitals were divided into quartiles according to the volume of primary angioplasty. Multiple logistic-regression models were used to determine whether the volume of primary angioplasty procedures was an independent predictor of in-hospital mortality among patients undergoing this procedure. Similar analyses were performed for patients receiving thrombolytic therapy at 516 hospitals.

Results. In-hospital mortality was 28 percent lower among patients who underwent primary angioplasty at hospitals with the highest volume than among those who underwent angioplasty at hospitals with the lowest volume (adjusted relative risk, 0.72; 95 percent confidence interval, 0.60 to 0.87; P<0.001). This lower rate, which represented 2.0 fewer deaths per 100 patients treated, was independent of the total volume of patients with myocardial infarction at each hospital, year of admission, and use or nonuse of adjunctive pharmacologic therapies. There was no significant relation between the volume of thrombolytic interventions and in-hospital mortality among patients who received thrombolytic therapy (7.0 percent for patients in the highest-volume hospitals vs. 6.9 percent for those in the lowest-volume hospitals, P=0.36).

Conclusions. Among hospitals in the United States that have full interventional capabilities, a higher volume of angioplasty procedures is associated with a lower mortality rate among patients undergoing primary angioplasty, but there is no association between volume and mortality for thrombolytic therapy.

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Percutaneous revascularization of the internal mammary artery graft: short- and long-term outcomes

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OBJECTIVES
We evaluated the short- and long-term clinical outcomes after percutaneous revascularization of the internal mammary artery (IMA) graft.
BACKGROUND
Previous reports in a relatively small number of patients have indicated the safety of balloon angioplasty for the treatment of stenoses in the IMA graft. However, the use of alternative interventional techniques and their long-term results have not yet been evaluated.

METHODS
We analyzed the in-hospital and one-year clinical outcomes of 174 consecutive patients who underwent percutaneous revascularization of 202 lesions located in the IMA graft, by either balloon angioplasty or stenting.

RESULTS
Anastomotic lesions were evident in 128 cases (63%), and they were more commonly treated with balloon angioplasty (116/128, 91%), whereas lesions located at the ostium (n = 16, 8%) were more frequently treated with stents (11/16, 69%). Procedural success was 97% with excellent in-hospital outcome: 0.6% mortality rate, no Q-wave myocardial infarction (MI) and 0.6% rate of urgent bypass surgery. Cumulative one-year rates were: mortality 4.4%, MI 2.9% and target lesion revascularization (TLR) 7.4%.

CONCLUSIONS
Revascularization of the IMA graft can be performed safely, with high procedural success and a low rate of in-hospital complications. Long-term follow-up showed very low TLR rate.


Review of immediate angioplasty after fibrinolytic therapy for acute myocardial infarction: Insights from the RESCUE I, RESCUE II, and other contemporary clinical experience

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Background Prompt restoration of Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow improves survival in patients with acute ST-segment elevation myocardial infarction (MI). Fibrinolytic therapy fails to restore TIMI 3 flow within 90 minutes in 40% to 50% of patients. Because the results of percutaneous coronary intervention (PCI) for MI seem to be improving, a reevaluation of the role of PCI after fibrinolytic therapy for MI appears to be warranted.

Methods and Results Data from all 9 randomized controlled trials (including new data from 4 trials) of rescue
percutaneous transluminal coronary angioplasty (PTCA) versus conservative therapy after fibrinolytic therapy (1456 patients), 4 contemporary registries of PCI in this setting (977 patients), and other germane studies are reviewed. PTCA after failed fibrinolysis (TIMI 0 to 1 flow) appears to reduce early severe heart failure (3.8% vs 11.7%, P = .04) and improve survival over 1 year in patients with moderate to large MI (92% vs 87%, P = .001) and possibly reduces early repeat MI (4.3% vs 11.3%, P = .08). Assessment of the possible benefit of PTCA for TIMI 2 flow is hampered by the small number of patients randomly assigned. Repeat MI may be decreased and left ventricular functional recovery enhanced. PTCA early after successful fibrinolysis is nearly always technically successful and may reduce repeat MI and hospital length of stay. However, it must be recalled that randomized trials from the 1980s suggested increased mortality rates with PTCA after restoration of TIMI 2 to 3 flow with fibrinolysis. Data from contemporary randomized studies of stents and glycoprotein IIb/IIIa inhibitors suggest that PCI as performed today may yield better results than those reviewed.

Conclusions These data suggest a probable benefit of rescue PTCA in several distinct scenarios and that the pivotal mid-1980s studies suggesting no benefit or harm for PTCA after fibrinolytic therapy may no longer be relevant. The role of mechanical intervention in the treatment of patients treated in these settings should be reassessed.

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Risk Stratification in Patients With Inferior Acute Myocardial Infarction Treated by Percutaneous Coronary Interventions : The Role of Admission Troponin T

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Background-Cardiac troponin T (cTnT) elevations on admission indicate a high-risk subgroup of patients with ST-segment elevation acute myocardial infarction (AMI). This finding has been attributed to less effective reperfusion after thrombolytic therapy. The aim of this study was to determine the role of admission cTnT on the efficacy of percutaneous coronary interventions (PCIs) in inferior AMI.

Methods and Results-One hundred fifty-nine consecutive patients with inferior ST-segment AMI were enrolled and followed up for a mean of 448 days. Patients were stratified by cTnT on admission. A cTnT ≥0.1 μg/L was found in 58% of patients. These patients had longer time intervals from onset of symptoms to therapy (P<0.001) and higher 30-day (10.8% versus 1.5%, P=0.027) and long-term (17.2% versus 4.5%, P=0.023) cardiac mortalities. Rates of the combined end point of death, nonfatal reinfarction, and need for repeated target vessel
revascularization procedures were not different in cTnT groups (log rank, 0.69; \( P=0.41 \)). PCI was attempted in 93.3% of cTnT-positive and 98.5% cTnT-negative patients \( (P=0.24) \) but was less frequently successful in patients with cTnT \( \geq 0.1 \ \mu g/L \) (77.9% versus 96.9%, \( P<0.001 \)). Coronary stenting reduced 30-day and long-term cardiac mortality, particularly among cTnT-positive patients. In a multivariate analysis, cTnT indicated an 5-fold-higher risk (adjusted OR, 4.6; 95% CI, 0.79 to 27.11; \( P=0.089 \)) and was a strong albeit not independent risk predictor.

Conclusions-In inferior AMI, a positive admission cTnT is associated with lower success rates of direct PCI and higher rates of cardiac events over the short and long term. These patients benefit from coronary stenting.

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Randomized Trial Comparing Intravenous Nitroglycerin and Heparin for Treatment of Unstable Angina Secondary to Restenosis After Coronary Artery Angioplasty

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Background-The treatment of unstable angina targets the specific pathophysiological thrombotic process at the site of the active culprit lesion. In unstable angina due to a restenotic lesion, smooth muscle cell proliferation and increased vasoreactivity may play a more important role than thrombus formation. Therefore, the relative benefits of nitroglycerin and heparin might differ in unstable angina associated with restenosis compared with classic unstable angina.

Methods and Results-We randomized 200 patients hospitalized for unstable angina within 6 months after angioplasty (excluding those with intracoronary stents) to double-blind administration of intravenous nitroglycerin, heparin, their combination, or placebo for 63±30 hours. Recurrent angina occurred in 75% of patients in the placebo and heparin-alone groups, compared with 42.6% of patients in the nitroglycerin-alone group and 41.7% of patients in the nitroglycerin-plus-heparin group \( (P<0.003) \). Refractory angina requiring angiography occurred in 22.9%, 29.2%, 4.3%, and 4.2% of patients, respectively \( (P<0.002) \). The odds ratios for being event free were 0.24 (95% CI, 0.13 to 0.45, \( P=0.0001 \)) for nitroglycerin versus no nitroglycerin and 0.98 (95% CI, 0.55 to 1.73, \( P=NS \)) for heparin versus no heparin. No patient died or suffered myocardial infarction.

Conclusions-Intravenous nitroglycerin is highly effective in preventing adverse ischemic events (recurrent or refractory angina) in patients with unstable angina secondary to restenosis, whereas heparin has no effect.
Objectives. This study was designed to determine the incidence and to quantitate aortic debris retrieved during placement of guiding catheters in patients undergoing percutaneous interventions.

Background. Studies have shown that atherosclerotic aortic debris predisposes patients to spontaneous or procedurally related ischemic events.

Methods. In 1,000 consecutive percutaneous interventions, the amount of visible atheromatous material from large-lumen-guiding catheters was recorded. Clinical characteristics and in-hospital complications were prospectively collected and associated with debris production.

Results. Visible aortic debris (1+ to 3+) occurred more frequently with the Judkins left (JL) catheter, followed by the multipurpose (Multi) catheter compared to any other type of guiding catheter (65%, p = 0.001 and 60%, p = 0.01, respectively). Large debris (2+ and 3+) was observed most frequently with the Multi (odds ratio 3.79, C.I. = 2.32 to 6.21, p = 0.001), JL (odds ratio 2.83, C.I. = 1.98 to 4.05, p = 0.001) and voda left (VL) (odds ratio 2.73, C.I. = 1.51 to 4.95, p = 0.001) catheters. The Judkins right (JR) catheter type was least likely to produce any debris (24%, p = 0.001). A history of unstable angina (p = 0.05) or myocardial infarction (p = 0.003) was associated with a decreased incidence of debris production. The presence of debris was not found to be associated with in-hospital ischemic complications.

Conclusions. Studies have shown that atherosclerosis of the aorta is a potential source of systemic embolism in patients undergoing cardiac catheterization. Our study shows that in more than 50% of percutaneous revascularization procedures, guiding catheter placement is associated with scraping debris from the aorta. Design characteristics of the JL, Multi and VL guiding catheters make them most likely to produce such debris. Meticulous attention to allow the debris to exit the back of the catheter is essential to prevent injecting atheromatous debris into the vascular bed.
Serial quantitative coronary angiography and coronary events

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Background. Although assessment of progression of atherosclerosis by quantitative coronary angiography (QCA) is used as a surrogate for coronary events, no validation study has compared the several QCA measures used.

Methods and Results. The Cholesterol Lowering Atherosclerosis Study was a clinical trial testing the efficacy of colestipol-niacin on the progression of coronary atherosclerosis. Baseline/2-year coronary angiograms were obtained on 156 men with prior coronary artery bypass graft surgery. Changes in percent diameter stenosis and minimum lumen diameter (both measured in coronary lesions and segments) and coronary segment measures of average diameter, percent involvement, and vessel edge roughness were measured by QCA. Coronary events ascertained over 12 years of follow-up included myocardial infarction (MI), coronary death, and coronary artery revascularizations. Proportional hazards models evaluated the relation between QCA change measures and coronary events. Changes in percent diameter stenosis and minimum lumen diameter of coronary artery lesions were significantly related to the risk of MI/coronary death. All QCA measures were significantly related to the risk of any coronary event. Relative risks for each QCA measure were of similar magnitude when estimated separately within each treatment group. Change in minimum lumen diameter of lesions was the only measure independently associated with the risk of coronary events.

Conclusions. All QCA measures of progression of coronary artery disease were related to all coronary events (including revascularizations). Only QCA measures of lesion progression were related to MI/coronary death. QCA measures of lesion change may be better surrogate end points for “hard” coronary events than measures of change in coronary segments.

Improving outcome over time of percutaneous coronary interventions in unstable angina

OBJECTIVE
This study was performed to evaluate the recent changes in the outcome of coronary interventions in patients with unstable angina (UA).

BACKGROUND
An early invasive strategy has not been shown to be superior to conservative treatment in patients with UA. Earlier studies had utilized older technology. Interventional approaches have changed in the recent past, but to our knowledge, no large studies have addressed the impact of these changes on the outcome of coronary interventions.

METHODS
We analyzed the in-hospital and intermediate-term outcome in 7,632 patients with UA who underwent coronary interventions in the last two decades. The study population was divided into three groups: group 1, n = 2,209 who had coronary intervention from 1979 to 1989; group 2, n = 2,212 with interventions from 1990 to 1993; and group 3, n = 3,211 treated from 1994 to 1998.

RESULTS
Group 2 and 3 patients were older and sicker compared with group 1 patients. The clinical success improved significantly in group 3 (94.1%) compared with group 2 (87%) and group 1 (76.5%) (p < 0.001). There was a significant reduction in in-hospital mortality, Q-wave myocardial infarction and need for emergency bypass surgery in group 3 compared with the earlier groups. One-year event-free survival was also significantly higher in the recent group compared with the earlier groups: 77% in group 3, 70% in group 2 and 74% in group 1 (p < 0.001). With the use of multivariate models to adjust for clinical and angiographic variables, treatment during the most recent era was found to be independently associated with improved in-hospital and intermediate-term outcomes.

CONCLUSIONS
There has been significant improvement in the in-hospital and intermediate-term outcome of coronary interventions in patients with UA in recent years; newer trials comparing conservative and invasive strategies are therefore needed.

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A Randomized Trial Comparing Stenting With Balloon Angioplasty in Small Vessels in Patients With Symptomatic Coronary Artery Disease
Background
More than 30% of the lesions currently treated with interventional approaches are situated in vessels smaller in size than those representing an established indication for stenting. The objective of this randomized trial was to assess whether compared with PTCA, stenting of small coronary vessels is associated with a reduction of restenosis.

Methods and Results
Patients with symptomatic coronary artery disease with lesions situated in native coronary vessels between 2 and 2.8 mm in size were randomly assigned to be treated with either stenting (n=204) or PTCA (n=200). Adjunct therapy consisted of abciximab, ticlopidine, and aspirin. Repeat angiography at 6-month follow-up was performed in 83% of the patients. The primary end point of the study was the incidence of angiographic restenosis (≥50% diameter stenosis) at follow-up; adverse clinical events, such as death, myocardial infarction, stroke, or target vessel revascularization, were assessed as secondary end points. After 7 months, there were no significant differences in the infarct-free survival rates between the 2 study groups: 96.6% for stent patients, and 97.0% for PTCA patients (P=0.80). Target vessel revascularization was needed in 20.1% of the stent patients and 16.5% of the PTCA patients (P=0.35). The primary end point of angiographic restenosis was found in 35.7% of the stent patients and 37.4% of the PTCA patients (P=0.74). The net lumen gain observed at follow-up was identical (0.76±0.78 in the stent group versus 0.76±0.63 mm in the PTCA group, P=0.93).

Conclusions
Stenting and PTCA are associated with equally favorable results when used for treating lesions in small coronary vessels.
results of a nonrandomized single-center investigation using a hydrophilic-coated guidewire (Terumo Crosswire). Between September 1996 and September 1998, 107 chronic occlusions in 106 patients were approached when previous attempts with conventional guidewires failed. Median occlusion duration in these cases was 4 months (range, 0.5-122); mean occlusion length was 19 +/- 11 mm (range, 5-60). Forty-five (42%) of these attempts were successful. Attempts were successful in 42% in the left anterior descending artery, in 30% in the left circumflex artery, in 48% in the right coronary artery, and in 43% in coronary artery bypass grafts. Success rates ranged from 56% for occlusions of less than 4-month duration to 18% for occlusions of more than 36-month duration. The success rate in TIMI 1-flow lesions was significantly higher than in TIMI 0 flow lesions, 85% vs. 36%. In a multivariate regression analysis, TIMI flow grade and occlusion age were independent predictors of success. There were no deaths or Q-wave myocardial infarctions; two cases of hemopericardium were treated successfully. In five cases, pericardial contrast staining due to vessel perforation occurred. Our results indicate that the Crosswire is an effective tool in the treatment of chronic coronary occlusions, even when recanalization attempts with conventional guidewires fail.

1. Success rate:
   - LAD: 42%, LCX: 30%, RCA: 48%, bypass grafts: 43%
   - Less than 4 months: 56%, more than 36 months: 18%
   - TIMI 1 flow lesions: 85%, TIMI 0 flow lesions: 36%

2. Predictors of success: TIMI flow grade and occlusion age

3. Complications: no deaths or Q-wave MI, 2 cases of hemopericardium, 5 cases of pericardial contrast staining due to vessel perforation

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Balloon optimization versus stent study (BOSS): provisional stenting and early recoil after balloon angioplasty

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perfusion balloon inflation \((n = 66)\) versus elective stenting \((n = 31)\). Recoil after PTCA was assessed by routine delayed angiograms (5 and 20 minutes). Cross over to stent was allowed for an inadequate result; there was no on-line quantitative angiography. An independent core angiographic laboratory assessed all results and evaluated the adequacy of the subjective interpretation. Within the PTCA arm, there were 24 (36%) crossovers to stenting \((5 \text{ of } 24 [21\%]\) due to recoil), whereas 2 stents could not be delivered to the lesion and crossed over to PTCA. As assessed by quantitative angiography, baseline reference vessel diameters were similar between the PTCA and stent groups. The immediate lumen diameter achieved with PTCA was smaller than that achieved with stenting \((2.18 \pm 0.49 \text{ vs } 2.44 \pm 0.38 \text{ mm}, \text{ respectively}, \ p = 0.01)\). There were no differences in angiographic results between elective and crossover stenting and there were no in-hospital complications in any patient. Target lesion revascularization at 8 months was 19% \((n = 6)\) in the elective stent arm versus 21% \((n = 14)\) in the PTCA arm, \(p = \text{NS}\); respective rates in PTCA alone and crossed over-to-stent subsets were 23% \((n = 10)\) versus 17% \((n = 4)\), \(p = \text{NS}\). Angiographic restenosis was 47% after elective stenting versus 38% after PTCA \(\text{(intention to treat)}\), \(p = \text{NS}\). By received treatment, it was 41% \((11 \text{ of } 27)\) in the group treated with the PTCA versus 33% \((5 \text{ of } 15)\) in the crossover-to-stent arm \(p = \text{NS}\). Thus, provisional stenting can be safely performed in the treatment of discrete, native de novo lesions. Early recoil after PTCA cannot be reliably assessed without quantitative angiography.

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Assessment of coagulation and platelet activation in coronary sinus blood induced by transcatheter coronary intervention for narrowing of the left anterior descending coronary artery

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Influences of recently developed methods for coronary intervention on hemostasis in the coronary circulation are unclear. The objective of this study was to investigate changes in coagulation and platelet activation in the coronary circulation induced by percutaneous transluminal coronary angioplasty (PTCA). We studied 35 patients with coronary heart disease who underwent elective PTCA to isolated stenotic narrowing of left coronary arteries. Seven patients received only PTCA, 12 underwent percutaneous transluminal rotational atherectomy (PTRA), and 16 underwent stent implantation. Blood samples were drawn from the coronary sinus immediately before and after as well as 4 and 24 hours after PTCA. Plasma levels of tissue factor (TF),
thrombin-antithrombin III complex, plasminogen activator inhibitor (PAI)-1, tissue plasminogen activator (t-PA), -thromboglobulin, and platelet factor 4 were measured by enzyme-linked immunosorbent assay. In all patients, TF levels in the coronary sinus blood showed significant increases 4 and 24 hours after PTCA and thrombin-antithrombin III complex levels showed significant increases 24 hours after PTCA. PAI-1 showed significant increases 24 hours after PTCA and t-PA showed significant increases 4 and 24 hours after PTCA. Changes in levels of these markers by PTCA were similar among the 3 groups. In PTRA, levels of -thromboglobulin and platelet factor 4, markers of platelet activation, increased immediately after the procedure and returned to baseline levels after 4 hours. PTCA induced increases in blood coagulation and fibrinolysis in the coronary circulation. PTRA caused a marked but transient activation of platelets. These changes may contribute to acute complications during the procedure.

Figure 1. Changes in markers for blood coagulation, fibrinolysis, platelet activation with time. A: after PTCA, B: after PTRA.

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Minimal heparinization in coronary angioplasty—how much heparin is really warranted?

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The purpose of the study was to assess the results of percutaneous transluminal coronary angioplasty (PTCA), performed with a single intravenous bolus of 2,500 U of heparin, in a nonemergency PTCA cohort. Three hundred of 341 consecutive patients (87.9%) undergoing PTCA were prospectively enrolled in the study. They received heparin, 2,500-U intravenous bolus, before PTCA, with intention of no additional heparin administration. Patient and lesion characteristics as well as PTCA results were evaluated independently by 2 physicians. Patients were followed up by structured telephone questionnaires at 1 and 6 months after PTCA. Mean activated clotting time obtained 5 minutes after heparin administration was 185 ± 19 seconds (range 157 to 238). There were 3 (1%) in-hospital major adverse cardiovascular events: 2 deaths (0.66%), 1 (0.33%) Q-wave myocardial infarction. Emergency coronary surgery and stroke were not reported. Six patients (2%) experienced abrupt coronary occlusion within 14 days after PTCA, warranting repeat target vessel revascularization. Angiographic and clinical success were achieved in 96% and 93.3%, respectively. No bleeding or vascular complications were recorded. Six-month follow-up (184 patients) revealed 3 cardiac deaths (1 arrhythmic, 2 after cardiac surgery), 1 Q-wave myocardial infarction, and 9.7% repeat target vessel revascularization. This study suggests that very low doses of heparin and reduced activated clotting time target values are safe in non-emergency PTCA, and can reduce bleeding complications, hospital stay, and costs.
Larger, randomized, double-blind heparin dose optimization studies need to confirm this notion.

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Quality of life after coronary angioplasty or continued medical treatment for angina: three-year follow-up in the RITA-2 trial

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OBJECTIVES: We sought to evaluate the impact of percutaneous transluminal coronary angioplasty (PTCA) and medical treatment on self-perceived quality of life among patients with angina.

BACKGROUND: The second Randomized Intervention Treatment of Angina trial (RITA-2) implemented initial policies of PTCA or continued medical treatment in patients with angina, allowing assessment of long-term health consequences.

METHODS: A total of 1,018 patients were randomly assigned (504 to PTCA and 514 to medical treatment). The short form 36 (SF-36) self-administered quality-of-life questionnaire was completed at randomization and three months, one year and three years later. To date, 98% of patients reached one year and 67% reached three years.

RESULTS: The PTCA group had significantly greater improvements in physical functioning, vitality and general health at both three months and one year, but not at three years. These quality-of-life scores were strongly related to breathlessness, angina grade and treadmill exercise time both at baseline and at one year. The treatment differences in quality of life are explained by the PTCA group’s improvements in breathlessness, angina and exercise time. The attenuation of treatment difference at three years is partly attributed to 27% of medically treated patients receiving nonrandomized interventions in the interim. For both groups, there were also improvements in ratings of physical role functioning, emotional role functioning, social functioning, pain and mental health, but for these the superiority of PTCA over medical treatment was less pronounced. After one year, 33% and 22% of the PTCA and medical groups, respectively, rated their health much better.

CONCLUSIONS: Coronary angioplasty substantially improves patient-perceived quality of life, especially physical functioning and vitality, as compared with continued medical treatment. These differences are attributed to alleviation of cardiac symptoms (specifically, breathlessness and angina), but must be balanced against the small procedure-related risks of PTCA.
Association between new electrocardiographic abnormalities after coronary revascularization and five-year cardiac mortality in BARI randomized and registry patients

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There are few data comparing the relative frequency of new electrocardiographic (ECG) abnormalities after coronary artery bypass grafting (CABG) compared with percutaneous transluminal coronary angioplasty (PTCA) and their association with long-term cardiac mortality. The study population consisted of 3,373 patients who were either randomized or eligible to be randomized to CABG or PTCA in the BARI trial. The frequency of new postprocedural ECG abnormalities was significantly greater after a CABG procedure than after PTCA. The incidence of new postprocedural major Q waves, ST-segment elevation, and T-wave abnormalities were significantly more frequent after CABG. After PTCA (n = 1,869), the 5-year cardiac mortality rates associated with the new development of major Q waves, ST-segment elevation, ST-segment depression, T-wave abnormalities, or no abnormality was 18.1%, 8.5%, 8.9%, 6.0%, and 5.4%, respectively. After CABG (n = 1,427), 5-year cardiac mortality rates were 8.0%, 4.2%, 3.8%, 2.8%, and 3.7%, respectively. The adjusted relative risk of 5-year cardiac mortality for new Q-wave abnormalities was 2.6 after CABG (p <0.04) and 4.6 after PTCA (p <0.01). Thus, patients who undergo CABG have more postinitial procedural ECG abnormalities than patients who undergo PTCA. Cardiac mortality is significantly increased by the new development of postprocedural Minnesota code Q-wave abnormalities regardless of whether patients undergo CABG or PTCA.

Detection of coronary restenosis by exercise electrocardiography thallium-201 perfusion imaging and coronary angiography in asymptomatic patients after percutaneous transluminal coronary angioplasty

Farzin Beygui, Claude Le Feuvre, Christophe Maunoury, Gerard Helft, Thierry Antonietti, Jean Philippe Metzger, Andre Vacheron
Noninvasive detection of restenosis in patients remaining asymptomatic after percutaneous transluminal coronary angioplasty (PTCA) remains a major clinical problem. The value of exercise electrocardiography (ECG) and exercise-redistribution thallium-201 single-photon emission computed tomography (SPECT) in detecting restenosis in such patients remains uncertain. Discordances between these tests and coronary angiography is a common situation. We studied 179 consecutive patients remaining asymptomatic after successful PTCA (208 vessels), who underwent 6 ± 2 months of exercise ECG, SPECT, and coronary angiography. We sought to assess the diagnostic value of the noninvasive tests compared with coronary angiography, and identify the determinants of discordances between the tests. Restenosis (diameter stenosis >50%) was detected in 39% of patients and in 37% of vessels. The overall sensitivity, specificity, and accuracy for exercise ECG and SPECT in detecting restenosis in individual vessels were, respectively, 53% versus 63% (p = 0.06), 59% versus 77% (p = 0.0001), and 57% versus 72% (p = 0.0001). On multivariate analysis, positive exercise ECG was associated with higher heart rate response (p = 0.02), incomplete revascularization (p = 0.004), and angiographic restenosis (p = 0.03), whereas positive SPECT was associated with incomplete revascularization (p = 0.02), infarct-related artery PTCA (p = 0.01), and angiographic restenosis (p = 0.0001). Accuracies of the 2 tests were not significantly different in patients with incomplete revascularization or PTCA of an infarct-related vessel. Overall, SPECT is more accurate than exercise ECG in detecting asymptomatic restenosis. Nevertheless, incomplete revascularization and PTCA of an infarct-related artery could cause reversible perfusion defects regardless of restenosis, reducing the diagnostic value of SPECT in such patients.

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Application of a continuous regression model of restenosis to saphenous vein grafts after successful percutaneous transluminal coronary angioplasty or directional coronary atherectomy


OBJECTIVES. To evaluate a quantitative model of restenosis in patients with vein graft disease undergoing percutaneous transluminal coronary angioplasty (PTCA) or directional coronary atherectomy (DCA).

BACKGROUND. A quantitative relationship between acute gain and late loss has been developed to describe the late changes in lumen dimension after native vessel coronary intervention. This same relationship may also be seen after treatment of saphenous vein graft disease.

METHODS. Patients with native coronary artery stenoses (CAVEAT-I) or saphenous vein graft lesions
(CAVEAT-II) were randomized to either DCA or PTCA, and data from these trials were analyzed retrospectively. Angiographic results of the target lesions were reviewed, and each lesion was assessed for vessel caliber and reference diameter, absolute minimal lumen diameter, percent diameter stenosis, percent stenosis of the cross-sectional area, acute gain and late loss. Linear regression models were used to determine late loss and to detect differences in angiographic outcomes.

RESULTS. Vein grafts had significantly larger reference vessel diameters than native coronary arteries; they also had significantly more acute gain and more late loss. Directional coronary atherectomy was associated with a larger acute gain in both studies. Patients undergoing DCA also experienced greater late loss although the effect was statistically significant only in the CAVEAT-I study. After adjusting for the acute gain, the treatment effect on late loss became nonsignificant in both studies.

CONCLUSIONS. In patients undergoing DCA or PTCA of saphenous vein graft narrowings, the relationship between late loss and acute gain is also demonstrated, similar to the device-independent relationships seen in native coronary lesions. In CAVEAT-II, larger degrees of acute gain were also associated with higher degrees of late lumen loss.

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Platelets and restenosis

Baskaran Chandrasekar, Jean-Francois Tanguay

Restenosis is currently the major limitation of percutaneous transluminal coronary angioplasty (PTCA). Factors such as elastic recoil, migration of vascular smooth muscle cells from media to intima, neointimal proliferation and vascular remodeling underly the restenotic process. Presently there is no effective therapy available for restenosis. The role of platelets in the development of thrombosis and abrupt closure after PTCA is well recognized. However, the effects of platelets in PTCA extend well beyond the early phase. Although antiplatelet agents such as glycoprotein IIb/IIIa antagonists have been reported to reduce target vessel revascularization, major unresolved controversies still exist. This report reviews the potential role of platelets in restenosis. Various drugs, successfully tested in experimental studies and in a small number of human studies, that inhibit the effect of platelets on the restenotic process are also reviewed.

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.


Coronary angioplasty using 5 French guiding catheters: preliminary experience

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In a retrospective study of 40 patients, we evaluated the effectiveness of the new 5 Fr 0.058” lumen diameter guiding catheter in routine PTCA. A total of 54 balloon angioplasties were performed. The mean age was 62.1+/−12.8 years, with 71% men. The artery dilated was the LAD in 50%, the RCA in 37%, and the circumflex in 13%. Sixty percent of the lesions dilated were proximal lesions, with only 25% defined as distal lesions. Significant calcifications were present in 20% of the lesions. Stents were implanted in 96%, and mean stent length was 14.0 mm, ranging from 8 to 24 mm. Mean balloon diameter was 2.7 mm, ranging from 2.0 to 3.5 mm. The procedure was a success in 95%, with only two failures. No other complications occurred. We concluded that the 0.058” 5 Fr guiding catheter could be suitable in the majority of noncomplex, selected PTCA cases. However, limitations and advantages over the standard 6 Fr technique are yet to be defined.
Angiographic and clinical follow-up of percutaneous revascularization for transplant coronary artery disease


BACKGROUND. There are limited data on the use of percutaneous revascularization techniques for transplant coronary artery disease (CAD).

METHODS. Medical records and angiographic results for cardiac transplant patients undergoing percutaneous revascularization at Emory University Hospital were reviewed. Procedural results, results of angiography 4Eth 6 months after intervention, and clinical follow-up were recorded.

RESULTS. Nineteen patients underwent 51 interventions. Thirty-eight lesions (75%) were de novo and 13 (25%) were restenotic. All patients had hypertension, 37% had diabetes, 79% had elevated lipid levels, and 53% had at least one episode of moderate to severe allograft rejection (grade 3A or greater). The primary procedural success rate was 100% with no major complications. Six-month restenosis rate (defined as > 50%) was 49%. At 23+/17 months follow-up, 6 patients were dead or retransplanted (31%). Thirteen patients were alive without retransplantation (9 New York Heart Association class I, 3 class II, 1 class III).

CONCLUSION. Percutaneous revascularization is safe and has a high initial procedural success rate in patients with transplant CAD. However, the restenosis rate in this population remains higher than reported for atherosclerotic coronary disease and the long-term prognosis remains poor.

Left internal mammary artery intervention: the left radial approach with a new guide catheter.

Mann T, Cubeddu G, Schneider J, Arrowood M

Coronary intervention involving left internal mammary bypass grafts is an increasingly common challenge for the interventionalist. Although successful in a high percentage of patients, the femoral approach may be technically challenging. The shorter, more direct approach from the left radial artery has potential advantages in these cases. The present study evaluated our experience using a new left transradial internal mammary guide catheter. Angiography alone was successfully performed with the catheter in 40 patients. In an additional
10 patients, internal mammary artery interventional procedures were performed. Angioplasty alone was performed in five patients. Five patients underwent coronary stenting within the internal mammary artery or native left anterior descending artery. Guide catheter backup was satisfactory and angioplasty catheters and, or stents could be advanced to the target lesion with minimal difficulty. No procedural complications occurred. The left radial artery access site is an excellent approach for left internal mammary intervention.

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Angiographic and clinical outcome of mild to moderate nonocclusive unstented coronary artery dissection and the influence on coronary flow velocity reserve. The Debate I Study Group.

Albertal M. Van Langenhove G. Kay IP. Costa MA. Kozuma K. Serruys PW.

Limited data are available regarding the angiographic healing rate and physiologic impact of coronary artery dissections. Therefore, we studied the impact of coronary dissections on coronary flow velocity and outcome as well as their healing rate at 6-month follow-up balloon angioplasty. Of 297 patients who underwent balloon angioplasty, 225 underwent intracoronary Doppler measurements and 184 had Doppler and angiographic assessment at 6-month follow-up. Dissections were scored by an independent core lab (Cardialysis BV) and divided in 4 groups: mild (types A to B), moderate (type C), severe (D to F), and patients without dissections. Severe dissections (types D to F) were excluded from the analysis. Clinical, angiographic, and Doppler data were compared among the remaining 3 patient groups. From the 67 dissections detected after balloon angioplasty, only 3 (4.5%) remained unhealed at follow-up. Immediately after balloon angioplasty, the moderate dissection group was associated with a lower coronary flow velocity reserve than the patients with mild (2.16 +/- 0.60 vs 2.82 +/- 1.00, p = 0.037) or no dissections (2.16 +/- 0.60 vs 2.71 +/- 0.88, p = 0.046), respectively. In addition, higher recurrence of angina at 30 days was observed in the moderate group rather than in the mild group (5 [50%] vs 8 [16%), p = 0.0160) and in the patients without dissections (11 [12%], p = 0.007). After standard balloon angioplasty, the occurrence of unhealed dissections is a rare phenomenon. An impaired coronary flow reserve was observed after the development of nonocclusive type C dissections, which was associated with a worse short-term outcome.

OBJECTIVES: We sought to define the risks facing octogenarians undergoing contemporary percutaneous coronary interventions (PCIs).

BACKGROUND: The procedural risks of PCI for octogenarians have not been well established.

METHODS: We compared the clinical characteristics and in-hospital outcomes of 7,472 octogenarians (mean age 83 years) with those of 102,236 younger patients (mean age 62 years) who underwent PCI at 22 National Cardiovascular Network (NCN) hospitals from 1994 through 1997.

RESULTS: Octogenarians had more comorbidities, more extensive coronary disease and a two- to fourfold increased risk of complications, including death (3.8% vs. 1.1%), Q-wave myocardial infarction (1.9% vs. 1.3%), stroke (0.58% vs. 0.23%), renal failure (3.2% vs. 1.0%) and vascular complications (6.7% vs. 3.3%) (p < 0.001 for all comparisons). Independent predictors of procedural mortality in octogenarians included shock (odds ratio [OR] 5.4, 95% confidence interval [CI] 3.3 to 8.8), acute myocardial infarction (OR 3.2, 95% CI 2.3 to 4.4), left ventricular ejection fraction (LVEF) <35% (OR 2.9, 95% CI 2.1 to 3.9), renal insufficiency (OR 2.8, 95% CI 2.0 to 3.8), first PCI (OR 2.3, 95% CI 1.7 to 3.3), age >85 years (OR 2.1, 95% CI 1.5 to 2.7) and diabetes mellitus (OR 1.5, 95% CI 1.1 to 2.0). For elective procedures, octogenarian mortality varied nearly 10-fold, and was strongly influenced by comorbidities (0.79% mortality with no risk factors vs. 7.2% with renal insufficiency or LVEF <35%). Despite similar case-mix, PCI outcomes in octogenarians improved significantly over the four years of observation (OR of 0.61 for death/myocardial infarction/stroke in 1997 vs. 1994; 95% CI 0.45 to 0.85).

CONCLUSIONS: Risks to octogenarians undergoing PCI are two- to fourfold higher than those of younger patients, strongly influenced by comorbidities, and have decreased in the stent era.
The recent publication of the Atorvastatin Versus Revascularization Treatment (AVERT) trial has renewed debate on the optimal management strategy for relatively stable patients with coronary artery disease. Currently, coronary angiography and percutaneous coronary intervention are often performed in stable patients with good exercise tolerance who have not been treated with proven medications such as aspirin, statins and beta-adrenergic blocking agents in conjunction with comprehensive lifestyle modification. We review the results of prior trials comparing medical therapy with angioplasty and assess their strengths and limitations and then make conclusions about the aggregate data. Next, we describe the ongoing Clinical Outcome Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial, which will be the largest of the studies comparing optimal medical therapy and percutaneous revascularization. This study will employ intensive medical management in all patients with coronary disease, and the incremental benefit of state of the art revascularization techniques in terms of clinical event reduction, quality of life issues and cost-effectiveness will be addressed. For now, aggressive medical therapy and revascularization should be viewed as complementary rather than opposing strategies. All patients with coronary heart disease should receive proven medical and lifestyle prescriptions to favorably alter the atherosclerotic process. Percutaneous revascularization without comprehensive risk factor modification is a suboptimal therapeutic strategy.


Coronary stenting versus balloon angioplasty in small coronary artery with complex lesions

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The impact of stenting on small vessels (<3.0 mm) with complex lesions (B2-C) is still controversial. Restenosis rate in this population is high (>40%). We compared early and late outcome of patients with complex coronary lesions in small vessel treated with traditional coronary angioplasty (angioplasty group) and with elective stent implantation (stent group). Angioplasty group (n = 97) and stent group (n = 112) were comparable for all clinical and angiographic characteristics. All patients in the two groups had clinical and angiographic follow-up. Major adverse cardiac events (MACE) and restenosis rate were evaluated. No patients in the two groups experienced in-hospital death or bypass surgery. Myocardial infarction occurred in four patients in the
angioplasty group and in seven patients in the stent group (P = 0.36). No patients in either the angioplasty or the stent group had acute stent thrombosis, whereas subacute stent thrombosis occurred in only one patient of the stent group (0.9%). Long-term MACEs (20 +/- 4 month) were not different in the two groups (angioplasty group 39% vs. stent group 44%, P = 0.35). Target lesion revascularization rate was 33% in the angioplasty group and 34% in the stent group (P = 0.50). Restenosis rate was not statistically different in the two groups (stent group 41% vs. angioplasty group 38%, P = 0.41). In conclusion, compared to balloon angioplasty, elective stent implantation in small vessels with complex lesions does not improve early and late outcome.

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Cardioprotective effect of prior beta-blocker therapy in reducing creatine kinase-MB elevation after coronary intervention: benefit is extended to improvement in intermediate-term survival

Sharma SK, Kini A, Marmur JD, Fuster V

BACKGROUND: Both retrospective studies and prospective randomized trials have shown that beta-blockers improve survival and reduce the risk of reinfarction in patients with myocardial infarction. To evaluate whether beta-blockers exert similar protective benefits during and after coronary intervention, we studied the incidence of postprocedure creatine kinase (CK)-MB elevation in patients with or without prior beta-blocker therapy and its effect on intermediate-term (approximately 1 year) survival.

METHODS AND RESULTS: We prospectively analyzed 1675 consecutive patients undergoing coronary intervention; of these patients, 643 (38.4%) were on beta-blocker therapy before the intervention. The incidence of CK-MB elevation after coronary intervention was 13.2% in patients on beta-blocker therapy before intervention and 22.1% in patients who were not on beta-blockers (P<0.001). Patients with prior beta-blocker therapy had lower persistent/recurrent postprocedure chest pain and lower preprocedure and postprocedure heart rates and mean blood pressures compared with patients who were not on beta-blockers (P<0.001). Multiple linear regression analysis revealed prior beta-blocker therapy as the sole independent factor for lower CK-MB release after coronary intervention. During intermediate-term follow-up at 15+/3 months, patients on beta-blocker therapy before intervention had lower mortality rates compared with those not on beta-blockers (0.78% versus 1.96%; P=0.04), although the benefit was independent of the reduction in CK-MB release.

CONCLUSIONS: Our nonrandomized, prospective analysis suggests that prior beta-blocker therapy has a cardioprotective effect in limiting CK-MB release after coronary intervention and that it is associated with a
lower mortality at intermediate-term follow-up.

Lancet 2000 Jun; 355(9222):2199-203

Optimum percutaneous transluminal coronary angioplasty compared with routine stent strategy trial (OPUS-1): a randomised trial

Weaver WD. Reisman MA. Griffin JJ. Buller CE. Leimgruber PP. Henry T. D’Haem C. Clark VL. Martin JS. Cohen DJ. Neil N. Every NR

BACKGROUND: Whether routine implantation of coronary stents is the best strategy to treat flow-limiting coronary stenoses is unclear. An alternative approach is to do balloon angioplasty and provisionally use stents only to treat suboptimum results. We did a multicentre trial to compare the outcomes of patients treated with these strategies.

METHODS: We randomly assigned 479 patients undergoing single-vessel coronary angioplasty routine stent implantation or initial balloon angioplasty and provisional stenting. We followed up patients for 6 months to determine the composite rate of death, myocardial infarction, cardiac surgery, and target-vessel revascularisation.

RESULTS: Stents were implanted in 227 (98.7%) of the patients assigned routine stenting. 93 (37%) patients assigned balloon angioplasty had at least one stent placed because of suboptimum angioplasty results. At 6 months the composite endpoint was significantly lower in the routine stent strategy (14 events, 6.1%) than with the strategy of balloon angioplasty with provisional stenting (37 events, 14.9%, p=0.003). The cost of the initial revascularisation procedure was higher than when a routine stent strategy was used (US$389 vs $339, p<0.001) but at 6 months, average per-patient hospital costs did not differ ($10,206 vs $10,490). Bootstrap replication of 6-month cost data showed continued economic benefit of the routine stent strategy.

INTERPRETATION: Routine stent implantation leads to better acute and long-term clinical outcomes at a cost similar to that of initial balloon angioplasty with provisional stenting.

Circulation 2000 Jun; 101(24):2795-802
Long-term clinical outcome in the Bypass Angioplasty Revascularization Investigation Registry: comparison with the randomized trial. BARI Investigators


BACKGROUND: The Bypass Angioplasty Revascularization Investigation (BARI) included 4039 patients with multivessel coronary artery disease; 1829 consented to randomization, and 2010 did not but were followed up in a registry. Thus, we can evaluate the outcome of physician-guided versus random assignment of percutaneous transluminal coronary angioplasty (PTCA) versus coronary artery bypass graft surgery (CABG).

METHODS AND RESULTS: We compared the baseline features and outcomes for PTCA and CABG in the overall registry and its predesignated subgroups. We assessed the impact of treatment by choice versus random assignment by comparing the results in the registry with those of the randomized trial. Statistical adjustments for differences in baseline characteristics were made. Within the registry, nearly twice as many patients were selected for PTCA (1189) as CABG (625); mortality at 7 years was similar for PTCA (13.9%) and CABG (14.2%) (P=0.66) before and after adjustment for baseline differences between patients selected for PTCA versus CABG (adjusted RR, 1.02; P=0.86). In contrast to the randomized trial, the 7-year mortality rate of treated diabetics in the registry was equally high (26%) with PTCA or CABG. Seven-year mortality was higher for patients undergoing PTCA in the randomized trial than in the registry (19.1% versus 13.9%, P<0.01) but not for those undergoing CABG (15.6% versus 14.2%, P=0.57). The adjusted relative mortality risk for PTCA in the randomized versus registry population was 1.17 (P=0.16).

CONCLUSIONS: BARI physicians were able to select PTCA rather than CABG for 65% of registry patients who underwent revascularization without compromising long-term survival either in the overall population or in treated diabetics.

Am Heart J 2000 May; 139(5):830-9

Clinical and angiographic outcome after angiography-guided stent placement in small coronary vessels

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BACKGROUND: Although it is widely accepted that stenting confers favorable angiographic and clinical results in coronary arteries \( \geq 3.0 \) mm in diameter, the outcome of stent placement in smaller vessels remains largely unclear.

METHODS AND RESULTS: We sought to specifically determine the early and long-term clinical outcomes in a large series of 197 consecutive patients who underwent stent placement in 207 vessels <3.0 mm in diameter. Procedural success, accomplished in 97.3%, was accompanied by a significant reduction in lesion severity from 85% +/- 9% before to 3% +/- 7% diameter stenosis after the procedure (\( P = .0001 \)) and a 0.5% incidence of subacute stent thrombosis. At 1 and 2 years of follow-up, survival rate without major target lesion-driven events was observed in 77.3% and 73.9% of patients, respectively. Repeat revascularization procedures accounted for most of these events; cardiac deaths (including those related to subacute stent thrombosis) and late (>30 days) myocardial infarctions were infrequent (2.4% and 1.0%, respectively). The 6-month angiographic binary instent restenosis rate was 30.1%. On multivariate analysis, diabetes mellitus (\( P = .0275 \)), small baseline reference vessel size (\( P = .0300 \)), and stent size.

CONCLUSIONS: Optimal angiography-guided coronary stenting of vessels <3.0 mm in diameter in association with the stringent use of a poststent combined aspirin-ticlopidine antiplatelet regimen confers a low risk of stent thrombosis, an acceptable incidence of angiographic instent restenosis, and a favorable long-term clinical outcome.

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Unprotected left main coronary artery stenting: immediate and medium-term outcomes of 140 elective procedures

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OBJECTIVES: We sought to evaluate immediate and late outcomes after stenting for left main coronary artery (LMCA) stenosis.

BACKGROUND: Conventional percutaneous transluminal coronary angioplasty (PTCA), for which coronary artery bypass grafting (CABG) has been the gold standard therapy for years, has yielded poor results in unprotected LMCA lesions. The development of coronary stents, together with their dramatic patency improvement provided by new antiplatelet regimens and their validation against restenosis, warrants a
reappraisal of angioplasty in LMCA stenosis.

METHODS: From January 1993 to September 1998, 140 consecutive unselected patients with unprotected LMCA stenosis underwent elective stenting. Group I included 47 high-CABG-risk patients, and group II included 93 low-CABG-risk patients. Ticlopidine without aspirin was routinely started at least 72 h before the procedure and continued for one month. Patients were reevaluated monthly. A follow-up angiography was requested after six months.

RESULTS: The procedure success rate was 100%. One-month mortality was 9% (4/47) in group I and 0% in group II. A follow-up angiography was obtained in 82% of cases, and target lesion revascularization was required in 17.4%. One-year actuarial survival was 89% in the first 29 group I patients and 97.5% in the first 63 group II patients.

CONCLUSIONS: Stenting of unprotected LMCA stenosis provided excellent immediate results, particularly in good CABG candidates. Medium-term results were good, with a restenosis rate of 23%, similar to that seen after stenting at other coronary sites. Stenting deserves to be considered a safe and effective alternative to CABG in institutions performing large numbers of PTCAs.

Catheter Cardiovasc Interv 2000 Apr 49(4):410-4

Influence of residual stenosis in determining restenosis after cutting balloon angioplasty

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The cutting balloon is a new device for coronary angioplasty, which, by the combination of incision and dilatation of the plaque, is believed to minimize arterial wall trauma, the neoproliferative response, and subsequent restenosis. In this study, we sought to determine predictors of the restenosis using this technique. Seventy-seven patients underwent successful coronary angioplasty with cutting balloon alone. In 67 of these patients (87%), we performed a control angiogram at 6-month follow-up. Pre-, post-, and late angiographic results were evaluated by quantitative coronary analysis. Clinical and angiographic variables were correlated with restenosis as a binary variable and a continuous variable (late loss and late minimum luminal diameter). Univariate analysis showed that the immediate postprocedure minimum luminal diameter (MLD) was smaller in the restenotic group (defined as MLD > 50% by quantitative coronary angiography) than in the nonrestenotic group (1.90 +/- 0.47 mm vs. 2.19 +/- 0.56 mm, P < 0.05). In addition, the immediate percentage of stenosis was higher in the restenotic group than in the nonrestenotic group (37% +/- 10% vs. 27% +/- 11%, P < 0.003).
Multivariate analysis identified the immediate postcutting balloon percentage of stenosis as an independent determinant of binary restenosis (P < 0.008). When restenosis was defined as a continuous variable, the immediate postprocedure MLD was an independent predictor of late loss (P < 0.02) and of late MLD (P < 0.0002). No clinical, preprocedure angiographic, or technical variables tested were associated with restenosis. The degree of postprocedural residual stenosis after cutting balloon angioplasty is predictive of late restenosis.

Catheter Cardiovasc Interv 2000 Apr; 49(4):401-7

Angiographic and clinical outcome of a new self-expanding intracoronary stent (RADIUS): results from multicenter experience in Japan


The RADIUS coronary stent featuring a multisegmented slotted tube design and self-expanding nitinol delivery system has a high radial force and flexibility, uniform expansion, and contours to the shape of the vessel. Successful stent deployment was achieved in 104 stable angina patients (106 lesions; 44% LAD, 19% circumflex, and 37% RCA). Mean minimal lumen diameter (MLD) increased from 0.77 +/- 0.46 mm to 2.88 +/- 0.61 mm and mean percent diameter stenosis (% DS) decreased from 73 +/- 14% to 6 +/- 13% immediately after the procedure. At 6-month follow-up, two patients (2%) underwent urgent target revascularization, and cerebral bleeding occurred in one patient (1%). Angiographic follow-up was performed in 94 lesions (89%) and mean MLD and mean % DS were 2.08 +/- 0.92 mm and 30% +/- 24%, respectively. Stent restenosis (>50% diameter stenosis at follow-up) was observed in 16 (17%) of all lesions. The high success rate for stent deployment, low incidence of major adverse cardiac event, and lower restenosis rate after stent implantation indicate that the RADIUS stent is useful for coronary intervention.

J Am Coll Cardiol 2000 Apr; 35(5):1145-51

Bifurcation lesions: two stents versus one stent-immediate and follow-up results

OBJECTIVES: The purpose of this study was to evaluate two different techniques of stent placement in bifurcation lesions.

BACKGROUND: Although stent placement with dedicated techniques has been suggested to be a useful therapeutic modality for bifurcation lesions, limited information is available if stent placement on the side branch and on the parent branch provides any advantage over a simpler strategy of stenting the parent vessel and balloon angioplasty of the side branch.

METHODS: Between March 1993 and April 1999, we treated a total of 92 patients with bifurcation lesions with two strategies: stenting both vessels (group B, n = 53) or stenting the parent vessel and balloon angioplasty of the side branch (group P, n = 39). Paired angiograms were analyzed by quantitative angiography, and clinical follow-up was obtained.

RESULTS: Stent placement on both branches resulted in a lower residual stenosis (7.4 +/- 10.9% vs. 23.4% +/- 18.7%, p < 0.001) in the side branch. Acute procedural success was similar in the two groups (group B: 87% vs. Group P: 92%). In-hospital major adverse cardiac events (MACE) occurred only in group B (13% vs. 0%, p < 0.05). At the six-month follow-up, the angiographic restenosis rate (group B: 62% vs. Group P: 48%) and the target lesion revascularization rate (38% vs. 36%, respectively) were similar in the two groups. There was no difference in the incidence of six-month total MACE (51% vs. 38%).

CONCLUSIONS: For the treatment of true bifurcation lesions, a complex strategy of stenting both vessels provided no advantage in terms of procedural success and late outcome versus a simpler strategy of stenting only the parent vessel.

J Am Coll Cardiol 2000 Apr; 35(5):1134-41

Long-term clinical events following creatine kinase--myocardial band isoenzyme elevation after successful coronary stenting

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OBJECTIVE: We sought to evaluate the impact of intermediate creatine kinase-myocardial band isoenzyme (CK-MB) elevation on late clinical outcomes in patients undergoing successful stent implantation in native coronary arteries.

BACKGROUND: Elevations of CK-MB after percutaneous coronary interventions are frequent. An association
between high level of CK-MB elevation (>5 times normal) and late mortality after balloon and new device angioplasty has been reported previously. However, significant controversy remains on the long-term clinical importance of lower CK-MB elevations (one to five times normal) after percutaneous coronary revascularization. Moreover, the incidence and prognostic importance of cardiac enzyme elevation after coronary stenting have not been well established.

METHODS: Prospectively collected data from 900 consecutive patients (1,213 lesions) undergoing successful stenting in native vessels were analyzed. Based on the CK-MB levels after coronary stenting, patients were classified into three groups: normal group 1 (n = 585), elevation of >1 to 5 times normal group 2 (n = 238) and elevation of >5 times normal group 3 (n = 77).

RESULTS: Patients in group 3 had more in-hospital recurrent ischemia (p = 0.001) and pulmonary edema (p = 0.01) than patients in groups 1 and 2. Long-term clinical end points were similar between groups 1 and 2. However, patients in group 3 had an increased incidence of late mortality compared with patients in groups 2 and 1 (6.9%, 1.2% and 1.7%, respectively, p = 0.01). Multivariate analysis showed that patients with CK-MB >5 times normal after coronary stenting had an increased risk of major adverse clinical events (relative risk: 1.70, p < 0.05) and death (relative risk: 3.25, p < 0.05) that was not observed in patients with lower CK-MB rise.

CONCLUSIONS: Patients with CK-MB elevation >5 times normal had higher late mortality and more unfavorable event-free survival than those patients with normal or lower CK-MB rise after coronary stenting. While intermediate CK-MB elevation (>1 to 5 times normal) is frequent after coronary stenting (26%), this was not associated with an increased risk of late mortality or major adverse clinical events.

Catheter Cardiovasc Interv 2000 Mar; 49(3):258-64

Percutaneous transluminal coronary angioplasty of chronic total occlusions. Determinants of primary success and long-term clinical outcome

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This study was conducted to assess the determinants of the procedural success and long-term clinical benefits of percutaneous transluminal balloon angioplasty (PTCA) of chronic total occlusion (CTO) in recent years. Two hundred and twenty-six consecutive patients who underwent PTCA of CTO were divided into two groups according to the procedural success (n = 134) or failure (n = 92). Both groups were analyzed in terms of the initial success, predictors of procedural failure, and clinical outcome. The procedural success rate was noted to have improved to more than 70% since 1995. A multiple logistic regression analysis revealed that the presence
of calcification, the length of the occlusion and the presence of multivessel disease were independent predictors of procedural failure. Cardiac death and the need for coronary surgery were significantly less frequent in patients with procedural success than in those with procedural failure. In properly selected cases, the success rate of PTCA of CTO is acceptable. Long-term clinical benefit is suggested by the high rate of freedom from coronary surgery and the low cardiac death rate in the patients who underwent successful revascularization.

Circulation 2000 Feb; 101(5):470-2

Pulsatility of ascending aortic pressure waveform is a powerful predictor of restenosis after percutaneous transluminal coronary angioplasty

Nakayama Y. Tsumura K. Yamashita N. Yoshimaru K. Hayashi T

BACKGROUND: Because ascending aortic pressure has a greater effect on coronary perfusion during diastole than systole, we hypothesized that a high coronary diastolic-to-systolic pressure ratio prevents coronary lesions from restenosing after percutaneous transluminal coronary angioplasty (PTCA) and that ascending aortic pulsatility relative to mean pressure is higher in patients with restenosis than in those without restenosis. The purpose of this study was to evaluate prospectively whether the morphology of the ascending aortic pressure wave can be used to predict restenosis after PTCA.

METHODS AND RESULTS: We measured the coronary artery diameter and the aortic pressure before PTCA. To quantify the relative magnitude of the pulsatile-to-mean aortic pressure, we normalized the pulse pressure to mean pressure and referred to this value as the fractional pulse pressure (PPf). We prospectively investigated the effect of PPf in relation to subsequent risk of restenosis after PTCA in patients with coronary artery disease. PPf was a powerful predictor of restenosis. Crude cumulative incidence rates of restenosis were 17.6% for the lowest, 33.3% for the middle, and 77.8% for the highest tertile of PPf levels. After adjustments for age, smoking habits, systolic blood pressure, type 2 diabetes, hypercholesterolemia, old myocardial infarction, vessel location, vessel size, and sex, the odds ratio of restenosis was 33.5 (95% confidence interval, 2.04 to 550.6) for the highest tertile of the PPf level compared with the lowest tertile level.

CONCLUSIONS: Pulsatility of the ascending aortic pressure is a predictive factor for restenosis after PTCA.
Effect of plaque debulking and stenting on short- and long-term outcomes after revascularization of chronic total occlusions


OBJECTIVES: We evaluated the effect of plaque burden modification (debulking) on the short- and long-term clinical outcomes of patients with a totally occluded native coronary artery undergoing successful stent deployment.

BACKGROUND: Although the primary success rate of crossing a chronic totally occluded coronary artery has improved with the development of new interventional devices and guidewires, the rate of acute reocclusion and restenosis remains high.

METHODS: The in-hospital and late clinical outcomes of 150 patients who had undergone successful stenting of 176 chronic total occlusions were analyzed. After successful crossing of the lesion, 44 patients with 50 lesions underwent debulking by laser angioplasty, rotational or directional atherectomy followed by stenting, whereas 106 patients with 126 lesions underwent stent implantation without prior debulking.

RESULTS: Baseline clinical and angiographic characteristics were similar for the two groups, except for a higher incidence of left anterior descending coronary artery location and longer lesions in the group of patients who underwent debulking prior to stenting. In-hospital mortality, myocardial infarction and repeat angioplasty rates were similar for the two groups. At a mean 14 +/- 8 months follow-up time, there were no deaths in either group, and target lesion revascularization rates were the same (16.3% in the debulking plus stent group vs. 14.4% in the stent alone group, p = NS).

CONCLUSIONS: Treatment of chronic total native coronary artery occlusions with stent deployment with and without lesion modification (debulking) results in a favorable in-hospital outcome, with relatively low long-term target lesion revascularization rates.

Circulation 2001; 103: 658-663

Percutaneous Coronary Intervention After Subcutaneous Enoxaparin Pretreatment in Patients With Unstable Angina Pectoris
Background-Subcutaneous low-molecular-weight (LMW) heparins can effectively replace unfractionated heparin in patients with unstable angina or non-Q-wave myocardial infarction. However, the optimal anticoagulation strategy for these patients when they require cardiac catheterization is still unclear. Therefore, we evaluated a new and simple strategy of anticoagulation in these patients.

Methods and Results-A total of 451 consecutive patients with unstable angina/non-Q-wave myocardial infarction were treated for at least 48 hours with subcutaneous injections of enoxaparin (1 mg [100 IU]/kg every 12 hours, cycled at 6 AM and 6 PM). Of this unselected population, 293 patients (65%) underwent a coronary angiography within 8 hours of the morning LMW heparin injection, followed by immediate percutaneous coronary intervention (PCI) in 132 patients (28%). PCI was performed without any additional bolus of unfractionated/LMW heparin and without coagulation monitoring. Anti-Xa activity at the time of catheterization was 0.98±0.03 IU/mL, was >0.5 IU/mL in 97.6% of patients, and did not relate to the LMW heparin injection-to-catheterization time. There were no in-hospital abrupt closures or urgent revascularizations after PCI. The death/myocardial infarction rate at 30 days was 3.0% in the PCI group (n=132) but 6.2% in the whole population (n=451) and 10.8% in the patients not undergoing catheterization (n=158). The 30-day major bleeding rate was 0.8% in the PCI group, which was comparable to that of patients without catheterization (1.3%).

Conclusions-PCI within 8 hours of the last enoxaparin subcutaneous injection seems to be safe and effective. The safety of subcutaneous LMW heparin in combination with platelet glycoprotein IIb/IIIa blockade awaits further study.

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C. Michael Gibson, Mukesh Goel, David J. Cohen, Robert N. Piana, Lawrence I. Deckelbaum, Katherine E. Harris, Spencer B. King, III for the RESTORE Investigators

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66. Prevention of Restenosis After Angioplasty in Small Coronary Arteries With Probucol

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