J Am Coll Cardiol (2004);43:2160-5
Evaluation of the effect of oral verapamil on clinical outcome and angiographic restenosis after percutaneous coronary intervention: the randomized, double-blind, placebo-controlled, multicenter Verapamil Slow-Release for Prevention of Cardiovascular Events After Angioplasty (VESPA) Trial
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OBJECTIVES: We investigated the effect of oral verapamil on clinical outcome and angiographic restenosis after percutaneous coronary intervention (PCI).
BACKGROUND: Thus far, there is no established systemic pharmacologic approach for the prevention of restenosis after PCIs. Five small studies reported encouraging results for calcium channel blockers. METHODS: Our randomized double-blind trial included 700 consecutive patients with successful PCI of a native coronary artery. Patients received the calcium channel blocker verapamil, 240 mg twice daily for six months, or placebo. Primary clinical end point was the composite rate of death, myocardial infarction, and target vessel revascularization (TVR) during one-year follow-up; the angiographic end point was late lumen loss at the six-month follow-up angiography.
RESULTS: We obtained complete clinical follow-up in 95% of the patients, and scheduled angiography was performed in 94%. The proportion of patients treated with stents was 83%. The primary clinical end point was reached in 67 (19.3%) patients on verapamil and in 103 (29.3%) patients on placebo (relative risk [RR] 0.66 [95% confidence interval (CI) 0.48 to 0.89]; p = 0.002). This difference between the groups was driven by TVR (17.5% with verapamil vs. 26.2% with placebo; RR 0.67 [95% CI 0.49 to 0.93]; p = 0.006). Late lumen loss was 0.74 +/- 0.70 mm with verapamil and 0.81 +/- 0.75 mm with placebo (p = 0.11). Compared with placebo, verapamil reduced the rate of restenosis > or =75% (7.8% vs. 13.7%; RR 0.57 [95% CI 0.35 to 0.92]; p = 0.014). CONCLUSIONS: Verapamil compared with placebo improves long-term clinical outcome after PCI of native coronary arteries by reducing the need for TVR. This was caused by a reduction in the rate of high-grade restenosis.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15193674

Catheter Cardiovasc Interv (2004);63:52-6
Contribution of early lumen loss after balloon angioplasty for in-stent restenosis to lumen loss at follow-up
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The treatment of in-stent restenosis using balloon angioplasty alone often produces excellent early results, but is associated with high rate of recurrence. Previous studies have demonstrated significant tissue reintrusion shortly after the treatment of in-stent restenosis with balloon angioplasty. The study was designed to elucidate the contribution of early lumen loss 6 hr after balloon angioplasty to lumen loss at follow-up. We prospectively performed quantitative coronary angiography and intravascular ultrasound in 12 patients with in-stent restenosis before intervention, after the final procedure, 6 hr later (5.6 +/- 1.4 hr), and at follow-up (7.7 +/- 2.3 months). Compared

with immediately after balloon angioplasty, by 6 hr postintervention, the minimum lumen diameter (MLD) and lumen cross-sectional area had decreased significantly (2.48 +/- 0.44 to 2.01 +/- 0.57 mm, P = 0.01, and 7.0 +/- 1.2 to 5.5 +/- 1.4 mm2, P = 0.004, respectively). Furthermore, the MLD decreased further between 6 hr postintervention and long-term follow-up (2.01 +/- 0.57 to 1.55 +/- 0.64 mm; P = 0.001). Patients who showed recurrence of restenosis at follow-up had greater early lumen loss than patients without recurrence of restenosis (0.71 +/- 0.31 vs. 0.23 +/- 0.13 mm; P = 0.006). Diffuse lesions had greater early lumen loss compared to focal lesions (0.75 +/- 0.35 vs. 0.28 +/- 0.13 mm; P = 0.008). Early lumen loss is common after the treatment of in-stent restenosis by balloon angioplasty. Within the first 6 hr postintervention, 32% +/- 29% of acute lumen gain is lost, and early lumen loss contributed to 42% +/- 18% of total lumen loss at follow-up.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15343567

J Am Coll Cardiol (2004);43:328-36
Myocardial perfusion imaging following percutaneous coronary intervention: the importance of restenosis, disease progression, and directed reintervention
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Percutaneous coronary intervention (PCI) has become a mainstay in the treatment of patients with coronary artery disease. Currently, more than one million coronary angioplasty and stent implantation procedures are performed annually. Although increasingly complex lesions and higher risk patients are being successfully treated percutaneously, restenosis and disease progression continue to cause significant morbidity. Restenosis occurs in approximately one-third of patients, one-half of who remain asymptomatic, while disease progression occurs at rates approaching 7% per year. Despite technological advances, unadjusted mortality rates have actually increased since the mid-1980s, and the current annual risk of a major adverse cardiac event following PCI is 5% to 7%. Although randomized clinical trials are needed to more definitively show a benefit, when performed six or more months following PCI, myocardial perfusion imaging reliably identifies patients most at risk of a poor long-term outcome. Directed reintervention can have a salutary impact on the prognosis of these patients. In view of recent data showing a positive impact of imaging and reintervention in patients after PCI, current guidelines should be reassessed.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15013110

J Am Coll Cardiol (2004);43:513-8
Can we afford to eliminate restenosis? Can we afford not to?
D. Greenberg

and substantial economic burden. Antiproliferative drug-eluting stents (DES) have recently demonstrated dramatic reductions in rates of restenosis, compared with conventional stenting, but important concerns about their costs have been raised. In this article, we summarize current evidence on the economic impact of restenosis and explore the potential benefits and economic outcomes of DES. In addition to examining the long-term costs of this promising technology, we consider the potential cost-effectiveness of DES from a health care system perspective and the impact of specific patient, lesion, and provider characteristics on these parameters.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14975456

Circulation (2004);110:790-5
Randomized, double-blind, placebo-controlled trial of oral sirolimus for restenosis prevention in patients with in-stent restenosis: the Oral Sirolimus to Inhibit Recurrent In-stent Stenosis (OSIRIS) trial
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BACKGROUND: Despite recent advances in interventional cardiology, including the introduction of drug-eluting stents for de novo coronary lesions, the treatment of in-stent restenosis (ISR) remains a challenging clinical issue. Given the efficacy of systemic sirolimus administration to prevent neointimal hyperplasia in animal models and to halt and even reverse the progression of allograft vasculopathy, the aim of the present double-blind, placebo-controlled study was to evaluate the efficacy of a 10-day oral sirolimus treatment with 2 different loading regimens for the prevention of recurrent restenosis in patients with ISR. METHODS AND RESULTS: Three hundred symptomatic patients with ISR were randomly assigned to 1 of 3 treatment arms: placebo or usual-dose or high-dose sirolimus. Patients received a cumulative loading dose of 0, 8, or 24 mg of sirolimus 2 days before and the day of repeat intervention followed by maintenance therapy of 2 mg/d for 7 days. Angiographic restenosis at 6-month angiography was the primary end point of the study. Restenosis was significantly reduced from 42.2% to 38.6% and to 22.1% in the placebo, usual-dose, and high-dose sirolimus groups, respectively (P=0.005). Similarly, the need for target vessel revascularization was reduced from 25.5% to 24.2% and to 15.2% in the placebo, usual-dose, and high-dose groups, respectively (P=0.08). The sirolimus blood concentration on the day of the procedure correlated significantly with the late lumen loss at follow-up (P<0.001). CONCLUSIONS: In patients with ISR, an oral adjunctive sirolimus treatment with an intensified loading regimen before coronary intervention resulted in a significant improvement in the angiographic parameters of restenosis.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15302787

Circulation (2004);109:1366-70
Clinical, angiographic, and procedural predictors of angiographic restenosis after sirolimus-eluting stent implantation in complex patients: an evaluation from the Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital (RESEARCH) study

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BACKGROUND: The factors associated with the occurrence of restenosis after sirolimus-eluting stent (SES) implantation in complex cases are currently unknown. METHODS AND RESULTS: A cohort of consecutive complex patients treated with SES implantation was selected according to the following criteria: (1) treatment of acute myocardial infarction, (2) treatment of in-stent restenosis, (3) 2.25-mm diameter SES, (4) left main coronary stenting, (5) chronic total occlusion, (6) stented segment >36 mm, and (7) bifurcation stenting. The present study population was composed of 238 patients (441 lesions) for whom 6-month angiographic follow-up data were obtained (70% of eligible patients). Significant clinical, angiographic, and procedural predictors of post-SES restenosis were evaluated. Binary in-segment restenosis was diagnosed in 7.9% of lesions (6.3% in-stent, 0.9% at the proximal edge, 0.7% at the distal edge). The following characteristics were identified as independent multivariate predictors: treatment of in-stent restenosis (OR 4.16, 95% CI 1.63 to 11.01; P<0.01), ostial location (OR 4.84, 95% CI 1.81 to 12.07; P<0.01), diabetes (OR 2.63, 95% CI 1.14 to 6.31; P=0.02), total stented length (per 10-mm increase; OR 1.42, 95% CI 1.21 to 1.68; P<0.01), reference diameter (per 1.0-mm increase; OR 0.46, 95% CI 0.24 to 0.87; P=0.03), and left anterior descending artery (OR 0.30, 95% CI 0.10 to 0.69; P<0.01). CONCLUSIONS: Angiographic restenosis after SES implantation in complex patients is an infrequent event, occurring mainly in association with lesion-based characteristics and diabetes mellitus.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14993127

Circulation (2004);109:2500-2
Post-sirolimus-eluting stent restenosis treated with repeat percutaneous intervention: late angiographic and clinical outcomes
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BACKGROUND: We evaluated the clinical and angiographic outcomes of patients presenting with restenosis after sirolimus-eluting stent (SES) implantation treated with repeated percutaneous intervention. METHODS AND RESULTS: A total of 24 consecutive patients have undergone repeated percutaneous intervention to treat post-SES restenosis (27 lesions). The restenosis was located within the stent in 93% of lesions. From the 27 lesions, 1 (4%) was re-treated with a bare stent, 3 (11%) were treated with balloon dilatation, and the remaining 23 lesions (85%) were treated with repeated drug-eluting stent implantation (SES in 12 lesions [44%], paclitaxel-eluting stents in 11 lesions [41%]). The event-free survival rate was 70.8% after a median follow-up of 279 days from the post-SES treatment. The overall recurrent restenosis rate was 42.9%. The risk of recurrent restenosis was increased for patients with hypercholesterolemia, previous angioplasty, failed brachytherapy, post-SES restenosis needing early (<6 months) treatment, and post-SES restenosis treated with balloon dilatation. The recurrent restenosis rate of originally de novo lesions re-treated with drug-eluting stents was 18.2%. CONCLUSIONS: Even though de novo lesions treated with SES at baseline and re-treated with drug-eluting stents had reasonably better outcomes than other lesion types and strategies, our study shows that the treatment of

post-SES restenosis is currently suboptimal and warrants further investigation.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15148279

Circulation (2004);109:476-80
Outcomes in patients with diabetes mellitus undergoing percutaneous coronary intervention in the current era: a report from the Prevention of RESt enosis with Tranilast and its Outcomes (PRESTO) trial
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BACKGROUND: Diabetes portends an adverse prognosis in patients undergoing percutaneous coronary intervention (PCI). Whether improvements in current clinical practice (stents, IIb/IIIa antagonists) have resulted in substantial improvement of these outcomes remains an issue. The aim of this study was to determine the influence of diabetes on 9-month outcomes of patients undergoing PCI in the current era.
METHODS AND RESULTS: The 11 482 patients enrolled in the Prevention of RESt enosis with Tranilast and its Outcomes (PRESTO) Trial were stratified according to the presence (n=2694) or absence (n=8798) of diabetes. Diabetic patients were older; were more likely to be female; had a higher proportion of congestive failure, hypertension, prior CABG, and unstable angina; and had higher body mass index and lower ejection fraction than nondiabetic patients (P<0.01 for all comparisons). The degree of multivessel disease was similar between the two groups. American College of Cardiology/American Heart Association type C lesions were more common in diabetic patients (17% versus 15%, P<0.01). Angiographic and procedural success rates and in-hospital events were similar between the two groups. The primary end point of death, myocardial infarction, or target vessel revascularization (TVR) was analyzed as time-to-first event within 9 months of the index PCI. After adjusting for certain baseline characteristics, diabetes was independently associated with death at 9 months (relative risk [RR], 1.87; 95% CI, 1.31 to 2.68, P<0.01) and with an increased likelihood of TVR (RR, 1.27; 95% CI, 1.14 to 1.42, P<0.01), as well as the composite end point of

by soluble VEGF receptor 1 (sFlt-1) gene transfer attenuated neointimal formation after intraluminal injury in rabbits, rats, and mice. sFlt-1 gene transfer markedly attenuated the early vascular inflammation and proliferation and later neointimal formation. sFlt-1 gene transfer also inhibited increased expression of inflammatory factors such as monocyte chemoattractant protein-1 and VEGF. Intravascular VEGF gene transfer enhanced angiogenesis in the adventitia but did not reduce neointimal formation. CONCLUSIONS: Increased expression and activity of VEGF are essential in the development of experimental restenosis after intraluminal injury by recruiting monocyte-lineage cells.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15477409

J Am Coll Cardiol (2004);43:950-7
Heme oxygenase-1 genotype and restenosis after balloon angioplasty: a novel vascular protective factor
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OBJECTIVES: We investigated the association of the heme oxygenase-1 (HO-1) promoter genotype with the inflammatory response and restenosis after balloon angioplasty. BACKGROUND: Heme oxygenase-1, which is induced by balloon angioplasty, can inhibit neointima formation and vascular remodeling. A dinucleotide repeat in the HO-1 gene promoter shows a length polymorphism that modulates HO-1 gene transcription. Short (<25 guanosine thymidine [GT]) repeats are associated with a 10-fold greater up-regulation of HO-1 than are longer repeats. METHODS: We studied 381 consecutive patients who underwent femoropopliteal balloon angioplasty (n = 210) and comparison groups with femoropopliteal stenting (n = 68) and lower limb angiography (n = 103). C-reactive protein (CRP) was measured at baseline, 24, and 48 h. We evaluated patency at six months by duplex sonography and assessed the association of the length of GT repeats in the HO-1 gene promoter with postintervention CRP and restenosis. RESULTS: Restenosis within six months was found in 74 patients (35%) after balloon angioplasty and in 21 patients (31%) after stenting. After balloon angioplasty, carriers of the short length (<25 GT) dinucleotide repeats had a lower postintervention CRP at 24 h ($p = 0.009$) and 48 h ($p < 0.001$) and a reduced risk for restenosis (adjusted relative risk 0.43, 95% confidence interval: 0.24 to 0.71, $p < 0.001$) compared with patients with longer alleles. After stenting or angiography, we found no association between the HO-1 genotype with CRP or restenosis. CONCLUSIONS: The HO-1 promoter genotype that controls the degree of HO-1 up-regulation in response to stress stimuli is associated with the postintervention inflammatory response and the restenosis risk after balloon angioplasty.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15028349

Eur Heart J (2004);25:1029-35
Pre-procedural plasma levels of C-reactive protein and interleukin-6 do not predict late coronary angiographic restenosis after elective stenting
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AIMS: Inflammatory markers may serve as an important prognostic predictor in patients with coronary heart diseases. In patients undergoing coronary interventions, it has been shown that baseline C-reactive protein (CRP) could predict late clinical restenosis. Only a few small studies have examined the possible relationship with angiographic restenosis. In patients with stable angina pectoris,we examined whether baseline CRP and IL-6 predict late coronary angiographic restenosis after stenting. METHODS AND RESULTS: Pre-procedural plasma levels of CRP and IL-6 were measured in 216 patients with stable angina pectoris undergoing elective coronary stenting. Angiographic follow-up was performed in all patients at 6 months. Baseline CRP levels were 6.15 +/- 0.78 mg/L versus 5.24 +/- 1.17 mg/L in the patent and restenosis groups, respectively (P=0.64). IL-6 levels were 0.46 +/- 0.03 ng/L versus 0.40 +/- 0.07 ng/L in the patent and restenosis groups, respectively (P=0.50). CRP levels were obtained again at the time of angiographic follow-up and were found to be similar in both groups (2.89 +/- 0.29 mg/L versus 2.61 +/- 0.63 mg/L, P=0.72). Moreover, in a sub-group of 43 patients, serial blood samples were obtained at several time points after the procedure up to 6 months. Both CRP and IL-6 plasma levels increased significantly in response to the procedure. CRP levels peaked at 3 days (11.27 +/- 1.53 mg/L versus 4.26 +/- 0.72 mg/L at baseline, P<0.0001). IL-6 levels reached maximum values after 24 h (1.08 +/- 0.14 ng/L versus 0.53 +/- 0.08 ng/L at baseline, P<0.0001). However, in this sub-group of patients, neither peak CRP nor IL-6 levels were found to predict late angiographic restenosis. CONCLUSIONS: Coronary stenting is associated with transient increases in both CRP and IL-6 levels. However, pre-procedural CRP and IL-6 levels do not predict late coronary angiographic restenosis.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15191773

Circulation (2004);109:2727-31
Clinical and angiographic predictors of restenosis after percutaneous coronary

corresponding variability for each possible level of the resultant risk score were obtained via bootstrapping techniques. The area under the receiver-operator characteristic (ROC) curve was 0.63, indicating modest discriminatory ability to predict restenosis. The second approach constructed a multiple logistic regression model considering significant univariate clinical and angiographic predictors of restenosis identified from the PRESTO database (treated diabetes mellitus, nonsmoker, vessel size, lesion length, American College of Cardiology/American Heart Association type C lesion, ostial location, and previous PCI). The area under the ROC curve for this risk score was also 0.63. CONCLUSIONS: The preprocedural clinical and angiographic variables from available studies and from the PRESTO trial have only modest predictive ability for restenosis after PCI.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15173022

J Am Coll Cardiol (2004);43:1959-63
Impact of final stent dimensions on long-term results following sirolimus-eluting stent implantation: serial intravascular ultrasound analysis from the sirius trial
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OBJECTIVES: We assessed the predictive value of minimum stent area (MSA) for long-term patency of sirolimus-eluting stents (SES) implantation compared to bare metal stents (BMS). BACKGROUND: Although MSA is a consistent predictor of in-stent restenosis, its predictive value in BMS is still limited because of biologic variability in the restenosis process. METHODS: From the SIRolImUS (SIRIUS) trial, 122 cases (SES: 72; BMS: 50) with complete serial intravascular ultrasound (IVUS) (baseline and 8-month follow-up) were analyzed. Postprocedure MSA and follow-up minimum lumen area (MLA) were obtained. Based on previous physiologic studies, adequate stent patency at follow-up was defined as MLA >4 mm(2). RESULTS: In both groups, a significant positive correlation was observed between baseline MSA and follow-up MLA (SES: $p < 0.0001$, BMS: $p < 0.0001$). However, SES showed higher correlation than BMS (0.8 vs. 0.65) with a higher regression coefficient (0.92 vs. 0.59). The sensitivity and specificity curves identified different optimal thresholds of MSA to predict adequate follow-up MLA: 5 mm(2) for SES and 6.5 mm(2) for BMS. The positive predictive values with these cutoff points were 90% and 56%, respectively. CONCLUSIONS: In this SIRIUS IVUS substudy, SES reduced both biologic variability and restenosis, resulting in increased predictability of long-term stent patency with postprocedure MSA. In addition, SES had a considerably lower optimal MSA threshold compared to BMS.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15172398

J Am Coll Cardiol (2004);44:1386-92
Oral rapamycin to inhibit restenosis after stenting of de novo coronary lesions: the Oral Rapamune to Inhibit Restenosis (ORBIT) study
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OBJECTIVES: The aim of this study was to establish safety and feasibility of oral

Rapamycin at two doses-2 mg and 5 mg-in achieving low rates of repeat target lesion revascularization (TLR) in de novo native coronary artery lesions. BACKGROUND: Drug-eluting stents have shown the ability to limit restenosis. Oral Rapamycin is an alternative strategy that can target multiple coronary lesions suitable for treatment with any approved metal stent and at potentially lower cost. METHODS: The Oral Rapamune to Inhibit Restenosis (ORBIT) study is an open-label study of 60 patients with de novo lesions treated with bare metal stents in up to two vessels. After a loading dose of 5 mg, patients received a daily dose of 2 mg (n = 30) and 5 mg (n = 30) for 30 days. Six-month angiographic, intravascular ultrasound (IVUS), and clinical follow-up were conducted. RESULTS: Baseline clinical and procedural characteristics were similar: 10% of patients in the 2-mg group and 30% in the 5-mg group did not complete the course; 43% in the 2-mg group and 66% in the 5-mg group had side effects. At six-month follow-up, late loss (0.6 +/- 0.5 mm vs. 0.7 +/- 0.5 mm; p = NS), in-stent binary restenosis (7.1% vs. 6.9%; p = NS), in-stent percent volume obstruction by IVUS (29% vs. 24%; p = NS), and clinically driven TLR (14.3% vs. 6.9%; p = NS) were similar in 2-mg and 5-mg groups. CONCLUSIONS: Oral Rapamycin for the prevention of restenosis is safe, feasible, and associated with low rates of repeat revascularization. Although associated with certain side effects, it may be considered for patients undergoing multivessel stents if proven in larger randomized studies. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15464317