Am J Cardiol (2004);93:474-7
Comparison of diamond-like carbon-coated stents versus uncoated stainless steel stents in coronary artery disease
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Stainless steel (SS) and carbon-coated (CC) stents were randomly compared in 347 patients (520 lesions). No differences were observed in in-hospital major adverse cardiac events: 2.8% in the CC group and 4.5% in the SS group (p = 0.286). The 6-month follow-up showed similar rates of binary restenosis (31.8% in the CC group vs 35.9% in the SS group; p = 0.448) and of cumulative major adverse cardiac events (30.5% in the CC group vs 32.7% in the SS group; p = 0.675). In unselected patients and lesions, carbon coating does not provide significant improvements over SS stents with the same design.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14969628

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Real-world bare metal stenting: identification of patients at low or very low risk of 9-month coronary revascularization
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The high cost of drug-eluting stents (DESs) has made identification of patients who are at low risk for subsequent revascularization after treatment with bare metal stents (BMSs) highly desirable. Previous reports from randomized trials suffer from biases induced by restricted entry criteria and protocol-mandated angiographic follow-up. Between 1994 and 2001, 5,239 consecutive BMS patients, excluding those with coil stents, technical failure, brachytherapy, staged procedure, or stent thrombosis within 30 days, were prospectively identified from a large single-center tertiary-referral-center prospective registry for long-term follow-up. We sought to identify characteristics of patients with very low (< or = 4%) or low (4-10%) likelihood of coronary revascularization 9 months after BMS. Nine-month clinical follow-up was obtained in 98.2% of patients. Coronary revascularization was required in 13.4% and did not differ significantly by stent type. On the basis of multivariate analysis identifying 11 independent correlates and previous reports, 20 potential low-risk patient and lesion groups (228 +/- 356 patients/groups) were identified (e.g, patients with all of the following: native vessel, de novo, reference diameter > or = 3.5 mm, lesion length < 5 mm, no diabetes, not ostial in location). Actual and model-based outcomes were analyzed. No group had both predicted and observed 9-month revascularization < or = 4% (very low risk). Conversely, 19 of 20 groups had a predicted and observed revascularization rate of 4-10% (low risk). In the real-world setting, the need for intermediate-term revascularization after BMS may be lower than expected, but it may be very difficult to identify patients at very low risk. Conversely, if the benefits of DESs are attenuated in routine practice, many groups of patients treated with BMSs may have nearly comparable results.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15390245

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Incidence, mechanism, predictors, and long-term prognosis of late stent malapposition after bare-metal stent implantation
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BACKGROUND: Predictors and long-term prognosis of late stent malapposition (LSM) after bare-metal stent (BMS) implantation are unknown. METHODS AND RESULTS: We evaluated the incidence, mechanisms, predictors, and long-term prognosis of LSM after BMS implantation in 881 patients (992 native lesions) in whom intravascular ultrasound was performed at index and 6-month follow-up. LSM was defined as a separation of stent struts from the intimal surface of the arterial wall that was not presented at stent implantation. LSM occurred in 54 patients with 54 lesions (5.4% overall); the incidence was 10.3% (9 of 87) after directional coronary atherectomy (DCA) before stenting and 11.5% (11 of 96) after primary stenting in acute myocardial infarction (P=0.031 and P=0.007, respectively, versus elective stenting with conventional balloon pre-dilation, 4.3% [30 of 692]). There was an increase of external elastic membrane area (18.9+/-3.9 to 24.5+/-5.1 mm2, P<0.001) that was greater than the increase in plaque area (9.6+/-3.0 to 11.4+/-2.9 mm2, P<0.001). Independent predictors of LSM were primary stenting in acute myocardial infarction (P=0.023, OR=2.55, 95% CI=1.14 to 5.69) and DCA before stenting (P=0.025, OR=3.02, 95% CI=1.15 to 7.96). There were no significant differences in major adverse cardiac events between LSM and non-LSM groups during mean 3-year follow-up (1.9% versus 1.8%, respectively, P=NS). CONCLUSIONS: LSM occurs in approximately 5% after BMS implantation. The predictors of LSM are primary stenting in acute myocardial infarction and DCA before stenting. Compared with complete stent apposition at follow-up, LSM after BMS implantation is not associated with any major adverse cardiac events during a mean 3-year follow-up after detection of LSM.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14967732

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Unrestricted utilization of sirolimus-eluting stents compared with conventional bare stent implantation in the "real world": the Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital (RESEARCH) registry
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BACKGROUND: The effectiveness of sirolimus-eluting stents in unselected patients treated in the daily practice is currently unknown. METHODS AND RESULTS: Sirolimus-eluting stent implantation has been used as the default strategy for all percutaneous procedures in our hospital as part of the Rapamycin-Eluting Stent Evaluated At Rotterdam Cardiology Hospital (RESEARCH) registry. Consecutive patients with de novo lesions (n=508) treated exclusively with sirolimus-eluting stents (SES group) were compared with 450 patients who received bare stents in the period just before (pre-SES group). Patients in the SES group more frequently had multivessel disease, more type C lesions, received more stents, and had more bifurcation stenting. At 1 year, the cumulative rate of major adverse cardiac events (death, myocardial

infarction, or target vessel revascularization) was 9.7% in the SES group and 14.8% in the pre-SES group (hazard ratio [HR], 0.62 [95% CI, 0.44 to 0.89]; P=0.008). The 1-year risk of clinically driven target vessel revascularization in the SES group and in the pre-SES group was 3.7% versus 10.9%, respectively (HR, 0.35 [95% CI, 0.21 to 0.57]; P<0.001). CONCLUSIONS: Unrestricted utilization of sirolimus-eluting stents in the "real world" is safe and effective in reducing both repeat revascularization and major adverse cardiac events at 1 year compared with bare stent implantation.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14691037

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Comparison of early and late results of a Carbofilm-coated stent versus a pure high-grade stainless steel stent (the Carbostent-Trial)
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The long-term success of coronary interventions with stents is largely determined by the development of restenosis. The aim of this study was to compare a Carbofilm-coated and a pure stainless steel stent with regard to early and late adverse events. In this prospective, randomized trial, the Carbofilm-coated Carbostent and Sirius stent (same stent design, newly developed delivery system) were compared with the stainless steel stents S660, S670, and S7 (newly developed delivery system, same principal stent design with a few changes). The primary end point was relative late luminal loss, and secondary end points were diameter stenosis at 6 months, rate of restenosis, and major adverse cardiac events (MACEs) (myocardial infarction, reintervention, and death). From March 2000 to June 2002 at 18 centers in Canada and Europe, 420 patients were randomized. Relative late luminal loss (Carbofilm 28.9 +/- 23.0% vs stainless steel 26.7 +/- 20.2%, p = 0.95) as the primary end point, absolute late luminal loss (1.00 +/- 0.72 vs 0.93 +/- 0.62 mm, p = 0.95), net gain (1.32 +/- 0.82 vs 1.40 +/- 0.74 mm, p = 0.75), and the degree of stenosis (40.7 +/- 22.9% vs 38.0 +/- 20.1%, p = 0.92), as well as restenosis rates (23.5% vs 15.9%, p = 0.09) and MACEs (20.1% vs 13.7%, p = 0.11) were not significantly different. Thus, the Carbofilm coating of stents does not lead to an improvement in angiographic results or a reduction of restenosis rate and MACEs. These results agree with other trials using inactive coatings on stents, which also could not demonstrate any advantage over pure stainless steel stents.

symptomatic ischemic heart disease attributable to de novo or restenotic nonstented native lesions of a single vessel amenable to percutaneous stenting. The primary composite end point was the incidence of major adverse cardiac events (death, myocardial infarction, emergency bypass surgery, or target lesion revascularization) 180 days after enrollment. Quantitative coronary angiography was performed before and after the index stent deployment and repeated at 6 months in 83 patients. Mean patient age was 62.6 years, mean reference vessel diameter was 3.07 mm before the procedure, and mean lesion length was 11.04 mm. Fifty-one patients received multiple stents. Angiographic success rate was 100% and procedural success rate was 98.3%. Cumulative incidence of major adverse cardiac events was 5.7% and target lesion revascularization was 3.4% at 180 days. In-stent late loss was 0.94 mm at 180 days, and no subacute stent thromboses were observed. This registry demonstrated the safety and efficacy of this novel coronary stent platform.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15619386

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Chronic arterial responses to polymer-controlled paclitaxel-eluting stents: comparison with bare metal stents by serial intravascular ultrasound analyses: data from the randomized TAXUS-II trial
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BACKGROUND: Polymer-controlled paclitaxel-eluting stents have shown a pronounced reduction in neointimal hyperplasia compared with bare metal stents (BMS). The aim of this substudy was to evaluate local arterial responses through the use of serial quantitative intravascular ultrasound (IVUS) analyses in the TAXUS II trial. METHODS AND RESULTS: TAXUS II was a randomized, double-blind study with 536 patients in 2 consecutive cohorts comparing slow-release (SR; 131 patients) and moderate-release (MR; 135 patients) paclitaxel-eluting stents with BMS (270 patients). This IVUS substudy included patients treated with one study stent who underwent serial IVUS examination after the procedure and at 6-month follow-up (BMS, 152 patients; SR, 81; MR, 81). The analyzed stented segment (15 mm) was divided into 5 subsegments in which mean vessel area (VA), stent area (SA), lumen area (LA), intrastent neointimal hyperplasia area (NIHA), and peristent area (VA-SA) were measured. NIHA was significantly reduced in SR (0.7+/-0.9 mm2, P<0.001) and MR (0.6+/-0.8 mm2, P<0.001) compared with BMS (1.9+/-1.5 mm2), with no differences between the two paclitaxel-eluting release formulations. Longitudinal distribution of neointimal hyperplasia throughout the paclitaxel-eluting stent was uniform. Neointimal growth was independent of peristent area at postprocedure examination in all groups. There were progressive increases in peristent area from BMS to SR to MR (0.5+/-1.7, 1.0+/-1.8, and 1.4+/-2.0 mm2, respectively; P<0.001). The increase in peristent area was directly correlated with increases in VA. CONCLUSIONS: Both SR and MR paclitaxel-eluting stents prevent neointimal formation to the same degree compared with BMS. However, the difference in peristent remodeling suggests a release-dependent effect between SR and MR.
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