Jama (2004);292:2727-34
Sirolimus-eluting vs uncoated stents for prevention of restenosis in small coronary arteries: a randomized trial
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CONTEXT: Percutaneous coronary revascularization of small vessels is associated with a high restenosis rate. Sirolimus-eluting stents reduce restenosis in simple and previously untreated lesions of large coronary arteries, but their outcomes in small vessels have not been adequately investigated. OBJECTIVE: To determine whether sirolimus-eluting stents are associated with a reduced 8-month rate of angiographic restenosis in comparison with an uncoated stent. DESIGN, SETTING, AND PATIENTS: This was a randomized, multicenter, single-blind, prospective trial performed with 257 patients undergoing percutaneous coronary revascularization for ischemic heart disease, and who had a previously untreated atherosclerotic lesion located in a small segment with a diameter of 2.75 mm or less, in 20 Italian centers between August 2002 and December 2003. INTERVENTION: Patients were randomly assigned to receive a sirolimus-eluting stent (129 patients) or an uncoated stent having an identical architecture and radiographic appearance (128 patients). MAIN OUTCOME MEASURES: The primary end point was the 8-month binary in-segment restenosis rate; secondary end points included procedural success and the 8-month rate of major adverse cardiac and cerebrovascular events. RESULTS: The mean (SD) reference diameter of the treated segment was 2.2 (0.28) mm; the lesion length, 11.84 (6.15) mm. After 8 months, the binary in-segment restenosis rate was 53.1% (60/113) in the patients receiving an uncoated stent and 9.8% (12/123) in those receiving a sirolimus-eluting stent (relative risk [RR], 0.18; 95% confidence interval [CI], 0.10-0.32; P<.001). Fewer patients randomized to sirolimus-eluting stents experienced major adverse cardiac events (12/129 [9.3%] vs 40/128 [31.3%]; RR, 0.30; 95% CI, 0.15-0.55; P<.001) mainly because of a reduction in target lesion revascularization (9/129 [7%] vs 27/128 [21.1%]; RR, 0.33; 95% CI, 0.14-0.70; P =.002) and myocardial infarction (2/129 [1.6%] vs 10/129 [7.8%]; RR, 0.20; 95% CI, 0.01-0.93; P =.04). CONCLUSION: The use of sirolimus-eluting stents to treat atherosclerotic lesions in small coronary arteries reduces restenosis and may also reduce major adverse cardiac events.
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Am J Cardiol (2004);94:1429-32
Stent implantation in very small coronary arteries: the Tsunami SV International Registry
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The aim of this multicenter registry was to examine the in-hospital and long-term clinical outcomes of patients who underwent Tsunami SV stent implantation for the treatment of lesions involving coronary arteries with a reference diameter of <2.5 mm. The angiographic success rate was 97.5%. No in-hospital or 30-day major adverse cardiac events occurred. During the 6-month follow-up, there was 1 cardiac death (1%), and 5 subjects (4.8%) underwent repeat target lesion revascularization.

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Am J Cardiol (2004);93:633-6
Treatment of very small vessels with 2.25-mm diameter sirolimus-eluting stents (from the RESEARCH registry)
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A total of 91 patients with 112 lesions received 2.25-mm sirolimus-eluting stents (SESs), and these lesions were compared with those treated with SESs of > or =2.5-mm diameter in the same procedure (n = 109). The reference diameters were 1.88 +/- 0.34 and 2.52 +/- 0.57 mm, respectively (p <0.01). At follow-up, the late lumen loss was 0.07 +/- 0.48 mm for the 2.25-mm SES versus 0.03 +/- 0.38 mm for the larger SES (p = 0.5), and the binary restenosis rate was 10.7% versus 3.9%, respectively (p = 0.1). The 12-month target lesion revascularization rate was 5.5%. In conclusion, 2.25-mm SESs were associated with low rates of clinical and angiographic late complications.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14996597

J Am Coll Cardiol (2004);43:1964-72
Coronary stenting versus balloon angioplasty in small vessels: a meta-analysis from 11 randomized studies
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OBJECTIVES: A meta-analysis of 11 randomized trials was done to compare stenting versus balloon angioplasty (BA) in small coronary vessels. BACKGROUND: Randomized studies on coronary stenting (CS) in small vessels have yielded controversial results. METHODS: Eleven randomized trials on CS versus BA in small vessels, including angiographic re-evaluation at six months, were analyzed. RESULTS: The BeStent (Medtronic Instent, Minneapolis, Minnesota) was used in four studies, the Multi-Link (Guidant, Advanced Cardiovascular Systems Inc., Santa Clara, California) in three trials, and the NIR (Boston Scientific Corp., Boston, Massachusetts), JoStent (Jomed International AB, Helsingborg, Sweden), Tenax (Biotronik, Berlin, Germany), and BioDivysio (Abbott Vascular Devices, Redwood City, California) in the remaining four trials. Overall, 3,541 patients were included (1,672 allocated to BA and 1,869 to stent). The rate of cross-over from balloon to stent in the pooled population was 19%, and unsuccessful stent deployment occurred in 2% of the patients allocated to stent. The pooled rates of restenosis were 25.8% and 34.2% in patients allocated to stent and balloon, respectively (p = 0.003) (risk ratio [RR] 0.77; 95% confidence interval [CI] 0.65 to 0.92). A smaller reference vessel diameter at baseline was associated with a higher risk reduction in the restenosis rate (y = -3.551 + 1.826 [x]; p = 0.012). Patients allocated to stent had lower rates of major adverse cardiac events (15.0% vs. 21.8%, p = 0.002; RR 0.70; 95% CI 0.57 to 0.87) and new target vessel revascularizations (12.5% vs. 17.0%, p = 0.004; RR 0.75, 95% CI 0.61 to 0.91). CONCLUSIONS: Elective stenting is superior to provisional stenting in small coronary arteries. This benefit is

more evident in smaller coronary arteries.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15172399

J Am Coll Cardiol (2004);43:1110-5
The Canadian study of the sirolimus-eluting stent in the treatment of patients with long de novo lesions in small native coronary arteries (C-SIRIUS)
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OBJECTIVES: We assessed the safety and effectiveness of the sirolimus-eluting stent (SES) in treating single de novo long lesions in small native coronary arteries compared to an identical bare metal stent (BMS). BACKGROUND: The SES was previously demonstrated to reduce restenosis significantly. However, patients with long lesions in small vessels have not been well studied and may define a group at very high risk. METHODS: The Canadian Study of the Sirolimus-Eluting Stent in the Treatment of Patients With Long De Novo Lesions in Small Native Coronary Arteries (C-SIRIUS) was a multicenter, randomized, double-blind trial comparing SES versus identical BMS. The primary end point was in-stent minimal lumen diameter (MLD) at eight months. Secondary end points included angiographic restenosis at 8 months, target lesion revascularization (TLR), and major adverse cardiac events (MACE) at 270 days. RESULTS: A total of 100 patients were enrolled at eight Canadian sites. The in-stent MLD at eight months was 2.46 +/- 0.37 mm in the SES compared with 1.49 +/- 0.75 mm in the BMS (a 65% increase, $p < 0.001$). Angiographic restenosis occurred in 1 of 44 SES patients (2.3%, with no in-stent restenosis) and in 23 of 44 BMS patients (52.3%, $p < 0.001$). At 270 days, there were two clinically driven TLRs in the SES (4%) and nine in the BMS (18%, $p = 0.05$). The Kaplan-Meier estimate of freedom from MACE at 270 days was 96.0% for SES patients and 81.7% for BMS patients ($p = 0.029$). CONCLUSIONS: Patients with long lesions in small vessels are at very high risk of restenosis. In these patients, the SES dramatically reduces the risk of restenosis at eight months, translating into an excellent clinical outcome at nine months.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15028375

Catheter Cardiovasc Interv (2004);63:44-51
Balloon angioplasty plus cilostazol administration versus primary stenting of small coronary artery disease: final results of COMPASS
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months after BA. Ticlopidine was given for 1 month when bailout stent was implanted. Serial quantitative angiography was performed at the procedure and 6 months. The primary endpoint was 6-month angiographic restenosis. Clinical event rates at 1 year were also assessed. Baseline characteristics were similar. All procedures were successful. Bailout stenting was performed in three lesions in the BA-cilostazol group. No side effects of cilostazol were observed. Postprocedural lumen diameter was significantly larger (2.69 vs. 2.03 mm; P < 0.0001) in the stenting group. However, the follow-up lumen diameter was not different (1.76 vs. 1.85 mm, stenting vs. BA-cilostazol). Although the difference was not statistically significant, restenosis rate was lower in the BA-cilostazol group (13.2% vs. 24.5%; P = 0.11). Subacute thrombosis occurred in one patient and target revascularization rate was higher in the stenting group (22.0% vs. 10.7%; P = 0.10). BA plus cilostazol administration seems to be a favorable strategy for small coronary artery disease.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15343566

Am Heart J (2004);147:E4
Promising efficacy of primary gradual and prolonged balloon angioplasty in small coronary arteries: a randomized comparison with cutting balloon angioplasty and conventional balloon angioplasty
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BACKGROUND: Small vessel size represents a critical risk factor for an adverse outcome after both conventional balloon angioplasty (POBA) and stenting. Gradual and prolonged balloon angioplasty (GPBA) has been shown to cause less arterial trauma, which results in higher procedural success rates and fewer in-hospital complications than POBA. The aim of this study was to assess the clinical and angiographic benefits of primary GPBA with a perfusion balloon in small coronary arteries, as compared with cutting balloon angioplasty (CBA) and POBA. METHODS: A total of 263 patients with symptoms and reference diameters <3.0 mm were randomly assigned to undergo GPBA (n = 85), CBA (n = 88), or POBA (n = 90). The cumulative inflation time must be >10 minutes in GPBA. Crossover to stent was allowed for inadequate results. Follow-up angiography was performed after 6 months. The primary end point was angiographic restenosis at follow-up. RESULTS: Compared with POBA, GPBA resulted in a lower final residual diameter stenosis (27.3% vs 34.2%, P =.01) and decreased the need for stent placement (8.0% vs 22.2%, P =.031). At follow-up, the restenosis rates were lower with GPBA (31.3%, P =.034) and CBA (32.9%, P =.059) than POBA (50.6%). Target lesion revascularization was less frequently needed with GPBA (20.5%, P =.043) and CBA (20.0%, P =.033) than POBA (37.6%). Additionally, the event-free survival rate was higher with GPBA (77.1%, P =.033) and CBA (76.4%, P =.047) than POBA (58.8%). CONCLUSIONS: In small coronary arteries, both GPBA and CBA resulted in favorable angiographic and clinical outcomes. With a lower restenosis rate and target lesion revascularization rate, GPBA may be a superior strategy for small vessels compared with POBA.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=14691442

Catheter Cardiovasc Interv (2004);62:425-9
Effect of stents in reducing restenosis in small coronary arteries: A meta-analysis
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The ability of stents to reduce restenosis was established in larger coronary arteries. Clinical trials of stenting in smaller vessels have yielded conflicting results due in part to their sample sizes. The aim of this meta-analysis was to increase the statistical power by pooling data from these clinical trials. Trials were identified from Medline search, review of recent cardiology meetings' abstracts, and manual review of bibliographies. Studies were included if they were prospective randomized controlled trials. Endpoints examined included a dichotomized definition of angiographic restenosis, target lesion revascularization (TLR), target vessel revascularization (TVR), or any repeat revascularization. Pooling of data was performed by calculating a Mantel-Haenszel odds ratio (OR). The analysis included 2,598 patients enrolled in eight clinical trials. Stenting significantly reduced restenosis (OR = 0.62; 95% CI = 0.61-0.63). Concordantly, stenting reduced TLR (OR = 0.49), TVR (OR = 0.90), and any revascularization (OR = 0.48). This meta-analysis supports the hypothesis that stenting reduces restenosis in small coronary arteries as well as in larger coronary arteries. The apparent discordant result of individual clinical trials was due in part to underpowering related to small sample sizes. Catheter Cardiovasc Interv 2004;62:425-429. Copyright 2004 Wiley-Liss, Inc.