Sirolimus-eluting stent or paclitaxel-eluting stent vs balloon angioplasty for prevention of recurrences in patients with coronary in-stent restenosis: a randomized controlled trial.

CONTEXT: In patients with de novo coronary lesions, drug-eluting stents have drastically reduced restenosis risk compared with bare metal stents and conventional balloon angioplasty. It is less clear whether drug-eluting stents are superior to conventional balloon angioplasty for the treatment of patients with in-stent restenosis.

OBJECTIVES: To assess if drug-eluting stents are a more effective treatment of in-stent restenosis than conventional balloon angioplasty, and to assess the relative merits of 2 drug-eluting stents, a sirolimus-eluting stent and a paclitaxel-eluting stent.

DESIGN, SETTING, AND PARTICIPANTS: Randomized, open-label, active-controlled trial conducted among 300 patients with angiographically significant in-stent restenosis in 2 tertiary German centers from June 1, 2003, to October 20, 2003.

INTERVENTIONS: After pretreatment with 600 mg of clopidogrel for at least 2 hours before intervention, all patients were randomly assigned to 1 of 3 treatment groups: sirolimus stent, paclitaxel stent, or balloon angioplasty (100 patients in each group).

MAIN OUTCOME MEASURES: Primary end point: angiographic restenosis (diameter stenosis $\geq 50\%$) at 6-month follow-up angiography based
on "in-segment" analysis. Primary analysis was comparison between stent groups and balloon angioplasty groups; a secondary analysis compared sirolimus and paclitaxel stents. RESULTS: Follow-up angiography was performed in 275 (92%) of 300 patients. The incidence of angiographic restenosis was 44.6% (41/92) in the balloon angioplasty group, 14.3% (13/91) in the sirolimus stent group (P < .001 vs balloon angioplasty), and 21.7% (20/92) in the paclitaxel stent group (P = .001 vs balloon angioplasty). When compared with balloon angioplasty, receiving a sirolimus stent had a relative risk (RR) of angiographic restenosis of 0.32 (95% confidence interval [CI], 0.18-0.56); a paclitaxel stent had an RR of 0.49 (95% CI, 0.31-0.76). The incidence of target vessel revascularization was 33.0% (33/100) in the balloon angioplasty group, 8.0% (8/100) in the sirolimus stent group (P < .001 vs balloon angioplasty), and 19.0% (19/100) in the paclitaxel stent group (P = .02 vs balloon angioplasty). The secondary analysis showed a trend toward a lower rate of angiographic restenosis (P = .19) and a significantly lower rate of target vessel revascularization (P = .02) among sirolimus stent patients compared with paclitaxel stent patients. CONCLUSIONS: In patients with in-stent restenosis, a strategy based on sirolimus- or paclitaxel-eluting stents is superior to conventional balloon angioplasty for the prevention of recurrent restenosis. Sirolimus-eluting stents may be superior to paclitaxel-eluting stents for treatment of this disorder.

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