Randomized comparison of a titanium-nitride-oxide-coated stent with a stainless steel stent for coronary revascularization: the TiNOX trial.

BACKGROUND: Stent coating with titanium-nitride-oxide has been shown to reduce neointimal hyperplasia in the porcine restenosis model. We designed a prospective, randomized, clinical study to investigate the safety and efficacy of titanium-nitride-oxide-coated stents compared with stainless steel stents.

METHODS AND RESULTS: Ninety-two patients with de novo lesions were randomly assigned to treatment with titanium-nitride-oxide-coated stents (n=45) or stainless steel stents of otherwise identical design (n=47; control). Baseline characteristics were similar in both groups. At 30 days, no stent thromboses or other adverse events had occurred in either group. Quantitative coronary angiography at 6 months revealed lower late loss (0.55 +/- 0.63 versus 0.90 +/- 0.76 mm, P=0.03) and percent diameter stenosis (26 +/- 17% versus 36 +/- 24%, P=0.04) in lesions treated with titanium-nitride oxide-coated than in control stents. Binary restenosis was reduced from 33% in the control group to 15% in the titanium-nitride oxide-coated stent group (P=0.07). Intravascular ultrasound studies at 6 months showed smaller neointimal volume in titanium-nitride-oxide-coated stents than in control stents (18 +/- 21 versus 26 +/- 21 mm³, P=0.04).
48+/-28 mm3, P<0.0001). Major adverse cardiac events at 6 months were less frequent in

titanium-nitride-oxide-coated stents than in control stent-treated patients (7% versus 27%, P=0.02),
largely driven by a reduced need for target-lesion revascularization (7% versus 23%, P=0.07).

CONCLUSIONS: Revascularization with titanium-nitride-oxide-coated stents is safe and effective in

patients with de novo native coronary artery lesions. Titanium-nitride-oxide-coated stents reduce

restenosis and major adverse cardiac events compared with stainless steel stents of otherwise

identical design.