Influence of stent surface topography on the outcomes of patients undergoing coronary stenting: a randomized double-blind controlled trial.

Abstract: The objective of this study was to examine the relationship between stent surface topography and outcome in patients undergoing implantation of stents with rough and smooth surfaces. Surface topography is considered an important determinant of the bare stent performance. Specifically designed rough surface may increase the drug-storing capacity of stents but its direct impact on the risk of thrombosis and restenosis is not known. A total of 200 patients with significant stenosis in native coronary vessels were randomly assigned in a double-blind way to receive either a rough or a smooth-surface stent. The primary endpoint of the study was late lumen loss. Secondary endpoints included angiographic restenosis and clinical outcomes. The study was designed to test the equivalence of rough-surface stents to smooth-surface stents with respect to late lumen loss based on a noninferiority margin of 0.20 mm. Follow-up angiography was performed in 77% of the patients. Late lumen loss was 1.0 +/- 0.7 mm in the rough-surface stent group and 1.2 +/- 0.7 mm in the smooth stent surface group with a mean difference of -0.20 mm (95% CI = -0.43 to 0.02) between the two stents (P< 0.001 from test for equivalence and P = 0.08 from test for superiority). Angiographic restenosis rates were 25% with rough-surface stents and 35% with smooth-surface stents.
stents (P = 0.19). These results show that a rough stent surface does not increase late lumen loss after stent implantation as compared with a conventional smooth stent surface.