Patients with in-stent restenoses: comparison of intracoronary beta-brachytherapy using a rhenium-188 filled balloon catheter with the polymer-based paclitaxel-eluting taxus-express stent.

AIMS: We compared the intracoronary beta-brachytherapy using a liquid rhenium-188 filled balloon with the slow-release, polymer-based, paclitaxel-eluting Taxus-Express stent for treatment of in-stent restenoses. PATIENTS, METHODS: During the same study period, patients with restenoses in bare-metal stents were either treated with Taxus-Express stents (n = 50) or beta-brachytherapy after successful angioplasty (n = 51). For brachytherapy 30 Gy in 0.5 mm tissue depth were administered. The irradiated segment exceeded the traumatized segment 7.5 mm on both sides. Primary endpoint was the minimal lumen diameter (MLD) at the target lesion at six months follow-up. Angiographic follow-up was available in 78% (n = 79/101) and clinical follow-up in all patients. RESULTS: Baseline parameters did not differ statistically. The Taxus-Express stent resulted in a significantly larger MLD and a significantly lower percent diameter stenosis post intervention compared to beta-brachytherapy, which both maintained until angiographic follow-up (primary endpoint 2.44 +/- 0.74 mm versus 1.73 +/- 0.74 mm, p< 0.0001). Therefore, Taxus-Express stents were associated with a lower angiographic restenosis rate compared with beta-brachytherapy, both for the target lesion (6.1% versus 17.4%) and the
total segment (9.1% versus 23.9%). Moreover, use of Taxus-stent was associated with a clinical benefit based on a significantly lower MACE rate compared with beta-brachytherapy (p< 0.05).

CONCLUSIONS: Paclitaxel-eluting Taxus-Express stents resulted in superior clinical and angiographic outcomes compared to intracoronary beta-brachytherapy with a liquid (188)Re filled balloon for treatment of restenosis within a bare-metal stent.