Intracoronary beta-brachytherapy using a rhenium-188 filled balloon catheter in restenotic lesions of native coronary arteries and venous bypass grafts.

Abstract:

PURPOSE: We have previously demonstrated the efficacy of intracoronary beta-brachytherapy using a liquid(188)Re-filled balloon in a randomised trial including de novo lesions. Percutaneous coronary interventions in restenotic lesions and in stenoses of venous bypass grafts are characterised by a high recurrence rate for restenosis and re-interventions. Against this background, we wanted to assess the impact of intracoronary beta-brachytherapy using a liquid(188)Re-filled balloon in restenotic lesions in native coronary arteries and venous bypass grafts. METHODS: In 243 patients, beta-brachytherapy with 22.5 Gy was applied at a tissue depth of 0.5 mm. Patients were followed up angiographically after 6 months and clinically for 12 months. The primary clinical endpoint was the incidence of MACE (death, myocardial infarction, target vessel revascularisation). Secondary angiographic endpoints were late loss and binary restenosis rate in the total segment. RESULTS: All irradiation procedures were successfully performed. A total of 222 lesions were in native coronary arteries; 21 were bypass lesions. Mean irradiation length was 41.6 +/- 17.3 mm (range 20-150 mm) in native coronary arteries and 48.1 +/- 33.9 mm (range 30-180 mm) in bypass lesions; the reference diameter
was 2.57±0.52 mm and 2.83±0.76 mm, respectively. There was no vessel thrombosis during antiplatelet therapy. Angiographic/clinical follow-up rate was 84%/100%. MACE rate was 17.6% in the native coronary artery group and 38.1% in the CABG group (p<0.03). Binary restenosis rate was 22.5% and 55.6% (p<0.01), and late loss was 0.38±0.72 mm and 1.33±1.11 mm (p<0.001), respectively. CONCLUSIONS: We conclude that intracoronary beta-brachytherapy with a liquid(188)Re-filled balloon using 22.5 Gy at a tissue depth of 0.5 mm in restenotic lesions is safe. It is associated with a low binary restenosis rate, resulting in a low occurrence rate of MACE within 12 months in restenotic lesions in native coronary arteries but not in vein grafts.