

eration was less evident than R lesions (grade;  $1.13 \pm 0.35$  vs  $2.17 \pm 0.75$ ;  $P < 0.01$ ). 3) In edge restenosis lesions, extracellular matrices were abundant, and they were composed of coarse collagen fiber and abundant mucinous materials. In contrast, the major component of extracellular matrices in the R lesions were finely fibrillar and dense collagen. 4) Thrombi were not apparent in any edge restenosis or R lesions. **Conclusions:** Edge restenosis following BT consisted of weak proliferation of myofibroblasts and abundant deposition of extracellular matrices such as mucinous materials. It was not accompanied by inflammatory reaction or thrombosis. Edge restenosis following BT may be a pathologically distinct entity.

11:15 a.m.

#### 880-4 Intracoronary Brachytherapy Protects Bifurcation Lesions

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**Background:** Intracoronary brachytherapy frequently involves lesions from which side branches originate. These side branches often contain proximal plaques raising the question whether a bifurcation intervention is required. To date it is not clear whether plaque progression at the origin of the side branch is arrested by the brachytherapy of the main branch. In this study we analyzed the plaque progression in side branches of lesions treated with intracoronary brachytherapy.

**Methods:** One hundred and forty-six patients with in-stent-restenosis  $>70\%$  in diameter were treated with PTCA followed by intracoronary brachytherapy. Brachytherapy was performed with the Betacath system (Novoste). Thirty-three patients had bifurcation lesions involving a side branch of  $1.7 \pm 0.4$  mm in diameter, originating from the irradiated portion of the LAD (n=20), LCX (n=5) or RCA (n=8). Five lesions in side branches were dilated during bifurcation interventions. Brachytherapy was performed with  $18.5 \pm 1.5$  Gy for  $199 \pm 35$  seconds within the main vessel but not in the side branch. The lumen diameter of the side branch was analyzed by quantitative coronary angiography (QCA) at the time of intervention and at follow-up at  $8.6 \pm 3.5$  months.

**Results:** There was one asymptomatic side branch occlusion due to the procedure. There were no in-hospital adverse events such as death, myocardial infarction or reintervention. QCA revealed a side branch minimal lumen diameter of  $1.3 \pm 0.6$  mm at the time of intervention and of  $1.4 \pm 0.7$  mm at follow-up corresponding to mean diameter stenoses of  $25.2 \pm 22.9\%$  and  $24.7 \pm 23.1\%$  ( $p > 0.05$ ). At follow-up none of the dilated side branch lesions had a binary diameter restenosis ( $>50\%$ ). There was no further side branch occlusion and no adverse clinical event related to the side branch lesion.

**Conclusion:** Intracoronary brachytherapy appears to have a protective effect on the progression of lesions in side branch origins even if brachytherapy is only performed in the main branch and not in the side branch.

11:30 a.m.

#### 880-5 Optimizing Dosimetry With High Dose Intracoronary Gamma Radiation 21 Gy for Patients With Diffuse In-Stent Restenosis

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**Background:** The efficacy of coronary gamma radiation in preventing recurrent in-stent restenosis (ISR) is established. Vascular brachytherapy (VBT) may be less effective with the approved dose of 14 Gy. Previously we reported a better outcome with 18 Gy. We sought to examine if escalation of the dose to 21 Gy is safe and improves efficacy.

**Methods:** 35 pts with diffuse ISR in native coronary arteries and saphenous vein grafts (lesion length 20-80mm) underwent PCI, atherectomy, and/or additional stents. Post-intervention pts were treated with gamma VBT using the Checkmate system (Cordis). A ribbon with 14-23 seeds was positioned to cover the treated segment and adequate margins, with a mean length of  $63 \pm 8$  mm. The prescribed dose was 21 Gy at 2mm. All pts were discharged with Clopidogrel for 12 mo. 6-mo clinical outcomes were compared to 120 pts treated with 14 Gy and 120 pts treated with 18 Gy, both groups treated with at least 6 mo of Clopidogrel.

**Results:** High dose of 21 Gy was associated with prolonged dwell time of  $28.6 \pm 2.9$  min, but with absence of procedural or in-hospital complications, when compared with lower doses. At 6 mo there was significant reduction in the need for repeat target lesion revascularization in the pts treated with 21 Gy (Table)

**Conclusions:** High dose of 21 Gy for patients undergoing VBT with gamma radiation is associated with less recurrences compared to the approved radiation dose without increase of adverse events. Thus, optimization of the dose should be considered for pts undergoing VBT for ISR.

	14Gy 1M (N=120)	14Gy 6M (N=120)	18Gy 1M (N=120)	18Gy 6M (N=120)	21Gy 1M (N=31)	21Gy 6M (N=12)
Death, %	0	1.7	0	0	0	0
Q-Wave MI, %	0	0.8	0	0.9	0	0
TLR, %	0.8	20.8	2.5	16.5	0	8.3
TVR, %	16.7	25	4.6	22.9	0	25
Late Thrombosis	0.8	1.7	0.9	6.4	0	0

11:45 a.m.

#### 880-6 Three-Year Follow-Up After Intracoronary Gamma Radiation for In-Stent Restenosis in Saphenous Vein Grafts

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**Background:** The Washington Radiation for In-Stent Restenosis Trial in saphenous vein grafts (SVG WRIST) demonstrated safety and efficacy of intracoronary gamma radiation for the treatment of in-stent restenosis (ISR) in saphenous vein grafts (SVG) at 6 months. The aim of this study was to examine whether the results reported at 6 months continued to be durable at 36 months.

**Methods:** One hundred and twenty patients (pts) with ISR in SVG underwent PTCA, laser ablation, rotational atherectomy, and/or additional stenting (36% of lesions). Pts were randomized to either  $^{192}\text{Ir}$  IRT or placebo, with a prescribed dose of 15 Gy or 18 Gy to a 2 mm radial distance from the center of the source. Pts were followed angiographically at 6 months and clinically up to 36 months.

**Results:** Angiographic restenosis (21% vs. 44%,  $p = 0.005$ ) and target vessel revascularization [TVR, (18% vs. 55%,  $p < 0.001$ )] were dramatically reduced at 6 months in intracoronary radiation therapy (IRT) pts. At 12 months, IRT compared to placebo pts had less target lesion revascularization [TLR, (17% vs. 57%,  $p < 0.001$ )] and TVR (28% vs. 62%,  $p < 0.001$ ). At 36 months clinical follow-up, pts receiving IRT continued to have markedly lower MACE rates when compared with controls (Table).

**Conclusions:** In SVG WRIST, pts with ISR treated with IRT using  $^{192}\text{Ir}$  had a marked reduction in the need for repeat target lesion and vessel revascularization at 6 months, with durability of the clinical benefit at three years.

**Table. Twelve and 36-Month Clinical Outcomes**

	12 Months (%)			36 Months (%)		
<b>Events</b>	Ir-192 (N=60)	Placebo (N=60)	P-Value	Ir-192 (N=60)	Placebo (N=60)	P-Value
<b>Death</b>	7	7	1.0	17	10	0.283
<b>Q-wave MI</b>	2	3	1.0	3	2	0.559
<b>TVR</b>	28	62	$<0.001$	47	65	0.043
<b>TLR</b>	17	57	$<0.001$	33	60	0.003
<b>All MACE</b>	23	57	$<0.001$	38	63	0.006