Comparison of variables in Patients With and Without Major Side Branch at the Restenotic Lesion

Parameter	With SB (Gp1, n=146)	Without SB (Gp 2, n=102)	P value
Usage of Stents	47.3%	30.4%	0.008

Baseline	CPK-MB Normal	96.6%	98.0%	0.49
Post Procedure	CPK-MB X 4	15.3%	7.0%	0.04
	CPK-MB X 5	10.4%	3.0%	0.029
6 month follow up	Restenosis	36.0%	21.5%	0.031
	All MACE	29.3%	17.8%	0.041

1121-56 Earlier Time to Restenosis Predicts Outcomes Following Gamma Vascular Brachytherapy

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Background: A shorter time interval between prior percutaneous coronary intervention and presentation with restenosis is predictive of worse outcomes following therapy for restenosis. Whether this relationship exists following vascular brachytherapy is less clear. We examined the impact of the time to presentation with restenosis (TTR) on outcomes in the GAMMA I & II study cohorts.
Methods: GAMMA I & II enrolled 377 patients with in-stent restenosis (256 treatment with Ir-192 vascular brachytherapy, 121 placebo). TTR was defined as the time interval between the most recent intervention at the index restenotic lesion and subsequent therapy for in-stent restenosis (ISR).
Results: The median TTR for all 377 patients was 7 ± 8 months. The cohort was partitioned at the median into earlier & later TTR groups and baseline characteristics and outcomes compared.

(N=377)	Earlier TTR (<7 months)	Later TTR (≥ 7 months)	
Diabetes	37.8%	28.7%	P = .08
Length (mm)	19.98	18.88	P = .307
Pre-procedure Minimun Lumen Diameter (mm)	0.89	1.03	P = .001
Reference Vessel Diameter (mm)	2.67	2.79	P = .001
6 Month Angiographic Binary Restenosis	41.8%	28.3%	P = .014
Target Lesion Revascularization to 270 days	36.2%	24.5%	P = .018

On multivariate regression, independent predictors for binary restenosis were early TTR (OR = 1.83, P = .019), treatment with vascular brachytherapy (OR = .401, P = .001), lesion length (OR = 1.03, P = .007), and LAD location (OR .541, P = .024).
Conclusions: Patients presenting earlier with ISR were more likely to have smaller reference vessel diameters and minimum lumen diameters. Patients with earlier TTR had higher rates of target lesion revascularization at 270 days & angiographic binary restenosis at 6 months. Earlier TTR was an independent risk factor for recurrent restenosis following gamma vascular brachytherapy.

1121-57 Increasing Brachytherapy Dose Dramatically Improves Outcome in Patients With Long Lesions

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Background: Brachytherapy failure is common in long in-stent restenosis (ISR) lesions. SCRIPPS IV was a double blind randomized trial comparing the currently recomended dose of gamma radiation (14 Gy) to a 21% higher dose. We hypothesized that patients with longer lesions would derive more benefit from an increased radiation dose.
Methods: 358 patients with ISR lesions ≤80 mm in length and between 2.75 and 4.0 mm in diameter were randomized in a double blind fashion to 14 Gy vs 17 Gy of gamma radiation at 2 mm from the source. Clinical and angiographic follow up was obtained at 8 months. Patients with lesions ≥15 mm (long lesion group, LL) were compared to shorter lesions (SL).
Results: Baseline characteristics were similar between LL and SL groups except for a smaller mean lumen diameter in the LL group (0.74 mm vs 0.88 mm). The mean lesion length was 9.9 mm in the SL group compared to 30.3 mm in the LL group. At 8 months, LL patients who received 17 Gy had a 42.5% reduction in target lesion revascularization (TLR) (p=0.04), a 34% reduction in TVR (p=0.06), and 41% reduction in MACE (p=0.04) compared to LL patients receiving 14 Gy. The SL high dose group also had reductions in TLR, TVR, and MACE; however, these did not reach statistical significance.
Conclusion: When treating long ISR lesions, gamma radiation with 17 Gy is more effective than 14 Gy in reducing TLR, TVR, and MACE without increasing adverse events.When treating long, diffuse in-stent restenosis, a dose higher then the currently recommended 14 Gy should be considered .

>15 mm (n=189)				**<15 mm (n=117)**			
	14 Gy n=158	**17 Gy n=148**	**p value**		**14 Gy n=158**	**17 Gy n=148**	**p value**
TLR	31.6%	17.6%	0.04	TLR	21.7%	14.0%	ns
TVR	36.7%	24.2%	0.06	TVR	26.7%	17.5%	ns
MACE (Death, MI, TLR)	31.6%	18.7%	0.04	MACE (Death, MI, TLR)	25%	15.8%	ns

1121-58 A Double-Blind Randomized Dose Finding Study of Gamma Radiation for In-Stent Restenosis

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Background: While intracoronary gamma radiation has been proven efficacious, the optimal dose is unknown. The object of this study was to determine the safety and efficacy of a 21% increase in the currently recommended dose prescription.
Methods: We randomized 334 patients with in-stent restenosis (ISR) to 14 Gy vs 17 Gy at 2 mm. Patients received aspirin and clopidogrel for 6 months (12 months if a new stents was placed). Clinical and angiographic follow-up was obtained at 8 months.
Results : Baseline clinical and angiographic characteristics were similar with the exception of more diabetics (39.6% vs 29.9%, p=0.06) and more males (79% vs 68%, p=0.03) in the 17 Gy group. The majority of patients had type C diffuse disease and were at very high risk for recurrent ISR. Mean vessel length was 23.3 mm for 14 Gy and 21.8 mm for 17 Gy patients(p=ns). At 8 month angiographic follow-up there was a 36% reduction in restenosis(p=0.01) and a 30% reduction in late loss (p=0.08) for 17 Gy vs 14 Gy patients. At 8 months, there was a 44% reduction in TLR (p=0.008), a 36% reduction in TVR (p=0.06), and a 41% reduction in MACE (p<0.01) for 17 Gy vs 14 Gy patients. There was no significant difference in death, stent thrombosis, or MI.
Conclusions: Gamma brachytherapy using an increased dose of 17 Gy results in significantly reduced restenosis and clinical events without increasing adverse events. Increasing the currently recommended dose prescription from 14 Gy to 17 Gy should be strongly considered.

	14 Gy n=170	**17 Gy n=166**	**p value**
Restenosis	41.8%	26.6%	0.01
Late Loss	0.50 mm	0.35 mm	0.09
TLR	27.2%	15.2%	0.008
TVR	33.1%	21.3%	0.06
MACE	29.0%	17.1%	<0.01
Death	1.2%	2.4%	ns
Thrombosis	1.2%	1.2%	ns

1121-59 Immediate and Mid-Term Results of the Treatment of In-Stent Restenosis With Sirolimus-Eluting Stents

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Background: Restenosis inside the successfully implanted stents is the main limitation of percutaneous coronary interventions. We sought to determine whether Sirolimus eluting stents (SES) can be efficient treatment of in-stent restenosis (ISR).
Methods: The study involves 206 ISR lesions located in native coronary arteries from 159 patients treated with SES implantation from April 2002 to July 2003. Patients with previous brachytherapy were excluded. In the study population 27% had diabetes, 70% hypercholesterolemia and 22% presented as unstable angina. The prevalence of multivessel disease was of 81%.
Results: The mean lesion length was 16.9±11.5mm, mean reference diameter 2.78±0.51mm, minimal lumen diameter (MLD) 0.82±0.52mm, and mean diameter stenosis 70.5±17.7%. After SES implantation MLD increased up to 2.75±0.53mm (acute gain 1.94±0.65mm). Mean number of stents/lesion 1.20±0.48, the average stent length 29.7±13.8mm. Angiographic success was obtained in all cases. In 4 patients (2.5%) in-hospital MI was noted (CK>2 times ULN). All patients were discharged with combined double antiplatelet therapy for at least 6 months. After 30-days clinical follow up (FU) was accomplished in 98% and no adjunctive MACE were recorded. Six months clinical FU was completed for 80%. No patient died, MI occurred in 1 patient. Target lesion revascularization (TLR) was performed in 28/162 (13.8%) lesions from 15/123 (12.2%) patients (repeated PTCA in 26 lesions and CABG in 2 lesions). The type of repeated restenosis at FU was prevalently focal (76.7 vs. 23.3%, p=0.003).
Among all the clinical, angiographic and procedural characteristics, in the multivariable analysis only diabetes was a predictor of TLR (27.3% lesions in diabetics vs. 13.7% non-diabetics; OR: 2.38, 95% CI: 1.00-5.70, p=0.05).**Conclusion**: Our experience with SES treatment of ISR lesions shows good immediate angiographic and clinical results without evidence of acute or sub-acute thrombosis. Angiographic long-term follow up is ongoing to determine the binary restenosis rate and to prove the effectiveness of SES in reducing repeat restenosis. Data will be available for the time of presentation.