repeat-PCI (1% vs 2.7 %, p = 0.005), need for urgent CABG (0.1% vs 1.3 %, p = 0.03), seven months MACE (1% vs 3.1 %, p = 0.029), seven months TVR (11 % vs 19.9%, p = 0.001), combined MACE /TVR at seven months (14.9 % vs 26.9 %, p = 0.001) and death at seven months (1 % vs 3.1 %, p = 0.029).
Conclusion: Analysis of our large database of bifurcation lesions shows that provisional T stenting is the sole modifiable predictor associated with a reduction in target vessel revascularization as well as MACE and should be the preferred strategy for coronary bifurcation lesion PCI.

11:45 a.m.

878-6 **Stenting Under Intravascular Ultrasound Guidance of Coronary Bifurcation Lesions With a New Device Allowing Provisional Side Branch Treatment**

Wim J. Vander Giessen, Jurgen R. Ligthart, Pieter C. Smits, Pim J. de Feyter, George Sianos, Thierry Lefèvre, Patrick W. Serruys, Thoraxcenter, Erasmus MC, Rotterdam, The Netherlands

Background: A new stent (MULTI-LINK FRONTIER) was developed for coronary bifurcation lesions. It is an 18 mm stent premounted on a delivery system with 2 balloons. The device is positioned by pushing it up to the carina of the bifurcation. Simultaneous inflation of the balloons deploys the main branch (MB) stent and opens up a portal to the side branch (SB). We studied intravascular ultrasound (IVUS) parameters and their relation to procedural success and 6-month outcome.
Methods: Patients with (un)stable angina pectoris and de novo or restenotic (no previous stent) bifurcation lesion between 2.5 and 4 mm in diameter for the main branch and >2.0mm for the side branch were eligible. Exclusion criteria were angiographic severe calcification, thrombus or left main lesion. Pre-, post-, and at follow-up IVUS was performed in MB and SB using a 30 MHz catheter and automated pull-back.
Results: 18 patients were included: male 14, age 62 (13) year. The LAD/diag bifurcation was the target lesion in 17/18. After IVUS and mandatory predilatation stent implantation was successful in 16 (89%). Failure to wire the SB or to position the catheter in phase with the SB were the cause. Implantation at the carina succeeded in 12/16 (75%). The cases with "carina failure" had longer segments with calcified plaque proximal to the carina than cases with "carina success" (25 (14) vs 11 (11) mm; P<0.05) as assessed by IVUS. The presence of calcium per se, or its circumferential angle or whether superficial or deep was not associated with carina failure. Carina failure resulted in (partial) overlap of the stent with the ostium of the SB in 75%. Carina failure or SB overlap was not associated with SB restenosis. MLA by IVUS pre-, post-, and at 6 months FU was 2.3 (1.2) mm2, 7.3 (2.2) mm2, and 4.2 (1.0) mm2, resp. (P<0.05). At FU there were no deaths or MI's. Target vessel revascularization occurred in 3 patients (16.6%). Angiographic restenosis (>50% DS) occurred in 18.8% in the Frontier stent MB and in 12.5% in the SB, overall 31.3%.
Conclusion: This bifurcation stent can be implanted in about 90% of lesions, with promising 6 months adverse event rate. Longer proximal calcified segment is associated with less favorable implantation results.

ORAL CONTRIBUTIONS

880

Intracoronary Brachytherapy

Wednesday, March 10, 2004, 10:30 a.m.-Noon
Morial Convention Center, Hall E-1

10:30 a.m.

880-1 **Repeat Intracoronary Gamma Radiation for Patients With In-Stent Restenosis Who Failed Radiation Therapy: Results From the Re-WRIST Clinical Trial**

Ron Waksman, Andrew E. Ajani, Rebecca Torguson, Donna J. Whitman, Daniel A. Canos, Regina Deible, Lowell F. Satler, William O. Suddath, Augusto D. Pichard, Kenneth M. Kent, Joseph Lindsay, Washington Hospital Center, Washington, DC

Background: Intracoronary radiation (IR) is an effective therapy for preventing the recurrence of in-stent restenosis (ISR). However, nearly 20% of patients enrolled in radiation studies required repeat revascularization to the irradiated site. Re-WRIST is a registry evaluating the safety and efficacy of retreatment with IR.
Methods: Thirty pts (31 lesions) with ISR at the previously irradiated segment and who failed a subsequent angioplasty without radiation were eligible for retreatment with IR. The Checkmate radiation system using Ir-192 seeds was udes, and the repeat was prescribed dose was 15 Gy at 2 mm. The antiplatlet regimen post procedure was lifelong aspirin and at least 6 months of clopidogrel.
Results: Pts mean age was 65±7.9 yrs, 67% were males, 52% were diabetic, and 90% had CABG. Lesions were in native coronaries 67.7%, saphenous vein grafts 29.0%, and the left internal mammary 3.3%. Time between radiation treatments was 16.4±8.7 mos and the number of interventions to the target lesion was 5.2±3.5 (range 3-20). The lesion length was 21.74±14.25 mm. At 9 mos, the major adverse cardiac events rate was 36%, target lesion revascularization 32%, MI 0%, and deaths 4%. QCA at 9 months demonstrated a restenosis rate of 35%. There was one late total occlusion and no angiographic complications (evidence of aneurysm, fibrosis, perforation) in any of the pts.
Conclusions: Repeat radiation to the same site using Ir-192 for refractory ISR is safe and should be considered an option in this difficult patient subset.

	Baseline (post procedure)	Follow up (9 months)
RVD, mm	2.66+/-0.57	2.62+/-0.58
MLD, mm	2.07+/-0.66	1.61+/-0.98
DS, %	23.53+/-10.5	38.4+/-36.33
In-stent MLD, mm	1.99+/-0.56	1.23+/-0.76
In-stent DS, %	27.75+/-8.48	51.66+/-33.2
In-lesion late loss, mm		0.51+/-0.99
Binary Restenosis, %		35

10:45 a.m.

880-2 **Randomized Comparison of Rotational Atherectomy and Cutting Balloon Angioplasty Followed by Radiation Therapy With a ^{188}Re-MAG$_3$-Filled Balloon in the Treatment of Diffuse In-Stent Restenosis**

Seong-Wook Park, Seung-Whan Lee, Young-Hak Kim, Ki-Hoon Han, Cheol Whan Lee, Myeong-Ki Hong, Jae-Joong Kim, Seung-Jung Park, Asan Medical Center, Seoul, South Korea

Background: Randomized comparison of rotablation atherectomy (RA) and cutting balloon angioplasty (CB), followed by beta-radiation for in-stent restenosis (ISR) has not been reported.
Methods: This randomized controlled study was conducted to compare the efficacy of RA (n=58) with CB (n=55) prior to beta-radiation therapy with a rhenium-188-mercaptoacetyltriglycine (^{188}Re-MAG$_3$)-filled balloon for diffuse in-stent restenosis (ISR). The radiation dose was 18 Gy at a depth of 1.0 mm into the vessel wall.
Results: The baseline clinical and angiographic characteristics were similar between the 2 groups. The lesion length was 21.0±11.2 mm in the RA group and 20.8±10.2 mm in the CB group (p=0.77). Radiation was delivered successfully to all patients. Adverse events including myocardial infarction, death, or stent thrombosis did not occurred during the 9-month follow-up period. Six months angiographic follow-up was obtained in 88 patients (78%) and the rates of angiographic restenosis was not statistically different between the RA group (13%, 6/46) and the CB group (12%, 5/42)(p=0.87). The risk of a target lesion revascularization or a major adverse cardiac event was similar between two groups (RA group vs CB group: 3.4% vs 3.6%, p=0.94) during 9-month follow-up period.
Conclusions: Concomitant treatment of RA or CB with beta-irradiation using a ^{188}Re-MAG$_3$-filled balloon for diffuse ISR was safe and had a similarly favorable angiographic and clinical outcomes.

MLD:minimal lumen diameter

	RA group	CB group	P value
Pre MLD (mm)	0.76±0.37	0.84±0.41	0.30
Post MLD (mm)	2.59±0.39	2.69±0.53	0.30
Follow-up MLD (mm)	2.01±0.66	2.22±0.68	0.15
Acute gain (mm)	1.79±0.54	1.85±0.60	0.58
Late loss (mm)	0.35±0.52	0.54±0.60	0.25
Loss index	0.19±0.36	0.29±0.36	0.34

11:00 a.m.

880-3 **Histopathological Characteristics of Edge Restenosis After Intracoronary Brachytherapy for In-Stent Restenosis**

Masaharu Okada, Hideo Tamai, Eisho Kyo, Kunihiko Kosuga, Tatsuhiko Hata, Takuji Nakamura, Shinya Fujita, Takafumi Tsuji, Shinsaku Takeda, Nobutoyo Masunaga, Katsuyuki Hasegawa, Seiichiro Motohara, Hiromu Uehata, Shiga Medical Center for Adults, Moriyama, Japan

Background: Histopathology of edge restenosis following intracoronary brachytherapy (BT) has not been fully evaluated in humans. The purpose of this study was to clarify the histopathological characteristics of edge restenosis following BT by examining the specimens obtained from directional coronary atherectomy (DCA). **Methods**: Eight edge restenosis lesions which developed in native coronary arteries after BT with the beta-emitting ^{32}P source wire were obtained by DCA and were compared with the restenosis lesion which developed after ordinary balloon angioplasty without BT (R, 6 lesions). Edge restenosis was defined as a lesion which developed 5 mm proximal or distal to either edge of ^{32}P source wire. Mean interval from BT to edge restenosis was 242±28 days. Specimens retrieved by DCA were immediately placed in 10% buffered formalin, processed for paraffin embedding and stained with hematoxylin and eosin. To assess the proliferation of myofibroblast, we categorized the severity as grade 0, 1, 2, and 3 by estimating the cell density and analyzed by Mann-Whitney U test. **Results**: 1) Invasion of inflammatory cells and evidence of vasculitis were not apparent in any of the edge restenosis lesions or R lesions. 2) In edge restenosis lesions, myofibroblasts were more scarce and active prolif-