

	CB (n=450)	Rota (n=432)	p
In-hospital			
Procedural success (%)	98.7	99.1	NS
MACE at 30 days (%)	0	0	
Lesion Length (mean: mm)	22.6	24.5	NS
Reference diameter (mean: mm)	2.72	2.83	NS
Post MLD (mean: mm)	2.20	2.73	p<0.05
Angiographic follow-up at 6 months			
Follow-upMLD (mean: mm)	1.55	2.03	p<0.05
Restenosis (%)	41.8	27.8	p<0.05
TLR (%)	32.8	20.6	p<0.05
Event free survival (12 months) (%)	56.9	71.5	p<0.05

MACE: Major Adverse Cardiac Event (death / CABG / MI: Myocardial Infarction)
MLD: Minimum Lumen Diameter
TLR: Target Lesion Revascularization

1099-190 Stenting After Cutting Balloon Versus Plain Old Balloon Angioplasty: Interim Results of the REDUCE III Trial

Tetsu Yamaguchi, Takahiko Suzuki, Michihiko Kitayama, Hideo Nishikawa, Teruo Inoue, Masami Sakurada, Kazuhiro Hara, Fumihiko Usuba, Kojiro Awano, Tetsuo Matsubara, Osamu Kato, Shinichi Momomura, Tatsuya Yasukawa, Yukio Ozaki, Toranomon Hospital, Tokyo, Japan, Various Centers, Japan

In-stent restenosis remains a major problem after coronary stenting. The Cutting Balloon™ (CB) is a new device which has shown promise in the reduction of in-stent restenosis. We report here interim results of the REDUCE III study; a prospective, randomized, multi-center trial to investigate the safety and effectiveness of CB angioplasty followed by stenting, compared to Plain Old Balloon Angioplasty (POBA) followed by stenting, for the reduction of in-stent restenosis. Method: A total of 523 patients were randomized to either CB angioplasty or POBA, followed by stenting. Patients underwent follow-up angiograms at 6 months. Primary endpoint was TLR at 6 month follow-up. Results: Analysis for the initial 281 patients has been completed (CB: 135 pts, POBA: 146 pts). There were no differences in patient or lesion characteristics; coronary risk factors, including diabetes mellitus (CB: 71/260, 27.3%; POBA: 87/262, 33.2%); or in procedural success rates (CB 99.2% vs. POBA 98.4%). The preliminary analysis for the initial 281 patients shows no significant difference as yet for TLR (CB: 14/135, 10%; POBA: 20/146, 17%; p = 0.07); however, TLR tends to be higher for POBA than CB. Conclusion: CB angioplasty followed by stenting seems to decrease TLR. The final QCA data results will be presented at the next meeting.

1099-191 Adventitial Response and Expansive Remodeling After Intravascular Brachytherapy in a Rabbit Model of Restenosis

Paul Wexberg, Konrad Mueck, Ursula Windberger, Susanna Lang, Martin Osraneck, Franz Weidinger, Gerald Maurer, Michael Gottsauner-Wolf, University of Vienna, Vienna, Austria, Austrian Research Centre Seibersdorf, Seibersdorf, Austria

Background: The incidence of late major adverse cardiac events after vascular brachytherapy is higher than in controls. Because expansive remodeling has been shown to correlate with a poor clinical outcome after vascular interventions, we studied adventitial changes and arterial remodeling after intravascular irradiation in an animal model of restenosis.

Methods: Twenty normolipidemic rabbits underwent balloon injury in both external iliac arteries. One artery was randomly assigned for subsequent irradiation with an 90Y source (15 Gy or 30 Gy at 0.5 mm in the vessel wall). After 4 weeks morphometric measurements were performed and cell density, collagen amount, and the extent of arterial remodeling were determined. Staining for Ki67 identified proliferating cells; apoptotic cells were identified by in situ end-labeling of fragmented DNA, and indices were calculated as positive cells/total cell count x100.

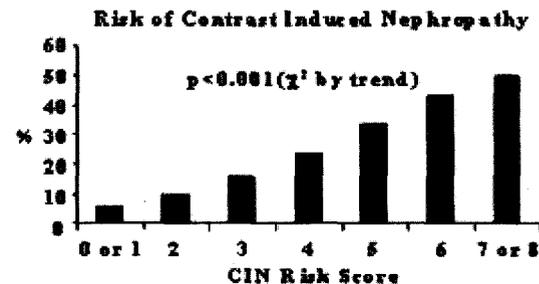
Results: The neointimal area decreased to $0.27 \pm 0.3 \text{ mm}^2$ after irradiation vs. $0.55 \pm 0.2 \text{ mm}^2$ in controls (p=0.007), whereas the adventitia increased from $0.62 \pm 0.3 \text{ mm}^2$ to $0.87 \pm 0.3 \text{ mm}^2$ (p=0.02). The expansive remodeling observed after irradiation correlated directly with the adventitial area (p<0.0001, r=0.83) and inversely with neointimal area (p=0.0001, r=0.57). Irradiation reduced the proliferative (0.95 ± 2.6 vs. 3.73 ± 4.7 , p=0.026) and the apoptotic index (0.006 ± 0.02 vs. 0.107 ± 0.2 , p=0.03) in the neointima, but not in the other arterial wall layers. There was no difference between 15 and 30Gy in any of the parameters, although adventitial thickening was more pronounced in the high-dose group.

Conclusion: The occurrence of adventitial thickening and expansive remodeling after intravascular irradiation might explain the increased incidence of late MACE after coronary brachytherapy.

1099-192 A Risk Score for Prediction of Contrast Induced Nephropathy After Percutaneous Coronary Intervention

Roxana Mehran, Eve D. Aymong, George Dangas, Andrea S. Abizaid, Alexandre A. Abizaid, Gary S. Mintz, Milena G. Adamian, Issam Moussa, Alexandra J. Lansky, Gregg W. Stone, Jeffrey W. Moses, Martin B. Leon, Lenox Hill Heart and Vascular Institute, Cardiovascular Research Foundation, New York, NY

Background: Contrast induced nephropathy (CIN) is a common cause of renal failure and correlates with higher in-hospital and late mortality after percutaneous coronary intervention (PCI). **Objective:** To develop a simple risk score that has broad applicability, is easily calculated at presentation, and identifies pts with different responses to contrast exposure. **Methods:** The Cardiovascular Research Foundation (CRF) prospective database was probed to identify 9726 consecutive pts undergoing PCI. Univariate predictors for CIN (defined as 25% rise in baseline creatinine) were identified. The risk score was derived by selection of independent prognostic variables using multivariate logistic regression. Assignment of value of 1 when a factor was present and 0 when it was absent, and summing the number of factors present to categorize patients into risk strata. **Results:** The eight risk score predictor variables were: Chronic renal failure (Cr₂≥2.0 mg/dl, or creatinine clearance <40cc/min), age > 70 yrs, diabetes mellitus, female gender, left ventricular ejection fraction < 40%, acute coronary syndrome presentation, contrast volume >150cc, and IABP use. Incidence of CIN increased significantly as the risk score increased in this cohort. (Figure). **Conclusion:** In pts undergoing PCI, the CRF risk score is a simple prognostic scheme that categorizes a pt's risk of CIN and provides a basis for important modifications in the procedural related factors which are controlled by the operator (ie: contrast volume).



1099-193 Totally Occluded In-Stent Restenotic Lesions Treated With Gamma Intracoronary Radiation: Six-Month Clinical and Angiographic Outcomes

Arvind K. Sharma, **Andrew E. Ajani**, Robert Lew, Augusto D. Pichard, Lowell F. Satler, Kenneth M. Kent, Ellen Pinnow, Regina Deible, George Aggrey, Ron Waksman, Washington Hospital Center, Washington, DC

Background: Intracoronary radiation therapy (IRT) has become the treatment strategy of choice for in-stent restenosis (ISR). However, its role in totally occluded ISR lesions has been poorly characterized. The objective of this study was to evaluate the safety and long-term efficacy of gamma IRT in patients with totally occluded ISR lesions. **Methods and Results:** Six hundred and sixty nine consecutive patients (pts) were selected from the WRIST (Washington Radiation for In-Stent Restenosis Trial) series of gamma IRT trials designed to assess the role of IRT for ISR. Of the total cohort, 86 (12.9%) pts had totally occluded (TO) ISR and had similar demographic and procedural characteristics to 587 pts with non-total occlusion (NTO) ISR. Six-month clinical and angiographic outcomes were equivalent in both groups (Table). Eighty-two (95%) patients with TO ISR had successful recanalization with conventional percutaneous coronary intervention.

	TO ISR (N=82)	NTO ISR (N=587)	P
Late Loss, mm	0.6 ± 0.9	0.4 ± 0.7	0.12
Angiographic Binary Restenosis, %	32	21	0.12
Death, %	4	3	0.71
Q-wave Myocardial Infarction, %	3	1	0.36
Target Lesion Revascularization, %	20	20	0.95
Target Vessel Revascularization, %	24	28	0.41
Late Thrombosis, %	8	4	0.13
Major Adverse Cardiac Events, %	21	22	0.92

Conclusions: Gamma IRT for ISR with total occlusion is feasible, safe, and associated with comparable outcomes as non-occlusive ISR. Totally occluded ISR lesions should become an important indication for gamma intracoronary radiation.