1087-61 A Coaxial Catheter System for Prevention of Distal Embolization

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Angioplasty (AP) of aged vein grafts has been substantially hindered by the common occurrence of distal embolization (DE) associated with "no reflow" and myocardial infarction (MI). Carotid Angioplasty (CA) is similarly compromised by the distinct potential for DE with cerebrovascular injury. We have evaluated a coaxial catheter system that utilizes a novel 0.014" guidewire (GW) mounted with an elastomeric distal occlusion balloon (DB) to preclude DE of debris following AP and stenting over this device. The system allows the exchange of virtually all commercially available stent and AP systems over the GW while the DB is inflated. A monorail aspiration catheter evacuates debris prior to deflation of the DB. Eight porcine studies at 4 institutions were conducted to assess the performance of the system during angioplasty and stent deployment in the general vasculature. Occlusion times ranged between 2 and 4 minutes. Evacuation rates averaged 1 cc/sec. All eight animals tolerated the procedure (DB inflation, AP catheter delivery, exchange for stent device, stent delivery, aspiration, DB deflation) and no complications were observed. In three studies, occlusion and aspiration were performed in a vessel without antecedent AP or stenting to determine, by histologic analysis, if any morphologic changes occur after the use of the system. The endothelial loss observed were similar to the changes observed after the passage of wires and angioplasty catheters without inflation and are of no clinical significance.

Conclusion: The safe and efficient application of the technology in this study, shows promise in mitigating the incidence of DE in degenerated and diseased vessels during angioplasty and stenting.

1087-62 An Emboli Containment System for Saphenous Vein Graft Angioplasty

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Background: Distal embolization and "no reflow" are frequent and important complications during PTCA of diseased saphenous vein grafts.

Methods: The Percusurge™ emboli containment system consists of a hollow 0.014" PTCA wire incorporating a compliant inflatable distal occlusion balloon. During occlusion of the distal graft, PTCA can be performed in a standard manner. A monorail aspiration catheter allows removal of potentially embolic debris prior to deflation of the occlusive balloon.

Results: PTCA was performed in 10 saphenous vein grafts (graft age 10 ± 4 yrs). NIH (9), Multilink (3), Be (1) stents measuring 9 to 35 mm in length were implanted. Prophylactic abciximab and/or thrombolytics were not utilized. Minimum lumen diameter increased from 0.4 ± 0.4 to 3.3 ± 0.4 mm. No pt developed new ECG evidence of infarction, required surgery, or died.

The duration of graft occlusion required to allow dilation and aspiration was 173 ± 67 sec, decreasing as experience was gained. Mean aspirate volume was 20 ml.

Initial TIMI flow grade was 0 in 1 pt, 1 in 2 pts, 2 in 2 pts and 3 in 5 pts. TIMI flow post-procedure was grade 3 in all pts. Bulky thrombus visible in 2 pts pre-procedure was not visible post-procedure. In one pt with visible thrombus transient intra-procedural distal occlusion occurred associated with a rise in CK to 432 and CK MB to 32 U/L. In 9 of 10 pts CK and CK-MB remained normal (<260 U/L and <6 ug/L units/ml).

Grossly visible debris was retrieved in all pts. Scanning electron microscopy revealed tissue fragments of mean length 230 um (range 50 to 110 um) and width 80 um (range 16 to 525 um). Plaque material was confirmed by light microscopy and consisted predominantly of cholesterol clefts, lipid-rich macrophages, fibrous caps, necrotic core and fibrin material.

Conclusion: The Percusurge™ emboli containment system is compatible with routine angioplasty procedures, is capable of containing and retrieving atherosclerotic and thrombotic debris, and may aid in the prevention of distal embolization and no reflow in diseased saphenous vein grafts.

1087-63 Intraluminal Low Power red Laser Therapy: Late Follow-up

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Intraluminal low power red laser irradiation (IRLI) accelerates endothelial growth and by modulating smooth muscle cell migration and proliferation, inhibits restenosis in various animal models.

We report long-term results of IRLI in 189 patients. All received IRLI using a laser-balloon (Global Therapeutics, Broomfield, CO) at power of 10 mW for 3 one-minute doses after PTCA and/or stenting procedures. Indications for IRII were: de novo lesions (37 pts), suboptimal PTCA results (57 pts), bail out situation (12 pts), bypass graft (2 pts), recurrent restenosis (40 pts), and in-stent restenosis (41 pts). Angiographic characteristics: mean vessel diameter 3.0 ± 0.7 mm, lesion length 9.3 ± 0.5 mm, type B and C lesions (83.5%), and diffuse disease (32%). We observed no major complications associated with IRLI following interventions and early follow-up.

Angiographic follow-up at 6 months (71 pts) revealed restenosis (stenosis >50% luminal diameter) rate in all groups of 16.9%. Moreover, restenosis rate was only 7.8% in arteries (n = 38) diameter ≥3.0 mm (late loss index = 0.27 ± 0.1 mm). In arteries (n = 33) diameter <3.0 mm, restenosis occurred in 26% (late loss index = 0.35 ± 0.15 mm). Restenosis in 44 pts with recurrent and in-stent restenosis was 22%.

We conclude IRLI reduces luminal renarrowing in pts following coronary interventions.

1087-64 AngioJet Thrombectomy Catheter for Acute Myocardial Infarction

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Background: Acute Myocardial Infarction (AMI) is associated with intracoronary thrombus. Intracoronary thrombus has been identified as a predictor of unfavorable outcome after PTCA, and also has been considered to be a contraindication for stenting. AngioJet thrombectomy catheter (AJ) removes thrombus by rheolytic suction.

Method: Between Nov. 96 and Aug. 97,240 AMI patients (pts) were admitted, and 26 pts (11%) received AJ, (mean age 61 ± 11, male 88%). Infarction arteries were 18 RCA (69%), 5 LAD (19%), 1 LCX (4%) and 2 SVG (8%).

Results: Of the 26 pts, 24 pts (92%) received AJ as a planned treatment according to initial angiogram suggesting presence of massive thrombus and all of them were successful, and other 2 pts (8%) received AJ as a bailout treatment for distal embolism after direct balloon angioplasty and these 2 cases were failed. Of the 24 successful AJ, 23 pts (96%) received adjunctive balloon and 9 pts (38%) received subsequent stenting and one pt (4%) finished with AJ alone. One pt (4%) received adjunctive t-PA infusion for minor distal embolism. There was no in-hospital death and no AJ related MI. One pt (4%) received CABG due to balloon rupture of adjunctive PTCA. There was no acute or subacute thrombosis after stenting. Quantitative angiography data (CMS system) showed significant improvement of TIMI flow grade and reduction of thrombus length after AJ.

	Initial	Post AJ	Final	P-value
TIMI grade	0.50 ± 0.19	2.88 ± 0.92	2.88 ± 0.92	< 0.0001
Reference (mm)	3.82 ± 0.86	3.83 ± 0.80	3.95 ± 0.74	NS
MLD (mm)	0.23 ± 0.38	1.16 ± 0.59	2.79 ± 0.65	< 0.0001
%Diameter stenosis	93.0 ± 12.0	57.1 ± 14.8	28.9 ± 12.5	< 0.0001
Thrombus length (mm)	21.6 ± 13.6	3.6 ± 6.7	0	< 0.0001

Conclusion: 1) AJ could be used successfully in removing thrombus in pt with AMI. 2) AJ seems to have no bailout effect for distal embolism after balloon angioplasty. 3) Thrombus removal makes subsequent stenting safe and uncomplicated. Angiographic follow-up study is ongoing.

1088 Observations on Use of Abciximab in Interventional Procedures

Tuesday, March 31, 1998, 9:00 a.m.–11:00 a.m.
Georgia World Congress Center, West Exhibit Hall Level
Presentation Hour: 9:00 a.m.–10:00 a.m.

1088-98 Abciximab Can Freely Redistribute Between GPIIb/IIIa and $\alpha_v\beta_3$

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In addition to acute inhibition of platelet (PLT) function during infusion, abciximab (c7E3 Fab, ReoPro™) has a prolonged PLT-bound half-life after termination of the infusion which is associated with a slow recovery of PLT aggregation. This is attributable to the continuous redistribution of abciximab among PLTs as measured by *in vitro* and *ex vivo* FACS analysis. Abciximab binds and blocks not only PLT GPIIb/IIIa but also the related integrin $\alpha_v\beta_3$ which mediates vascular cell proliferation and PLT thrombin generation. The objective of this study was to determine if abciximab could redistribute from GPIIb/IIIa to $\alpha_v\beta_3$. FITC-abciximab-boundHEL cells (expressing GPIIb/IIIa) were mixed with unlabeled $\alpha_v\beta_3$-expressing M21 cells and samples were fixed at various times for FACS analysis. Data are representative of 4 separate experiments. Abciximab redistributed *in vitro* from GPIIb/IIIa to $\alpha_v\beta_3$ with redistribution complete by 2 hours. Equivalent redistribution occurred

TUESDAY POSTER