Monday, March 4, 1991
2:00PM–3:30PM, Room 314, East Concourse
Atherectomy, Lasers and Balloon Angioplasty: Reports From Large Clinical Trials

2:00

INITIAL CLINICAL RESULTS OF THE RANDOMIZED VA ACME TRIAL OF ANGIOPLASTY VS. MEDICINE FOR SINGLE VESSEL DISEASE

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Of 328 patients randomized to angioplasty (PTCA) vs. medical (M) therapy 212 had single vessel disease with 70% or more subtotal obstructions. Baseline clinical data and exercise test (ET) performance of these patients off all medications are shown below: (all p = N.S.)

	M	PTCA
Number of patients	107	105
Mean age (years)	61.2	59.4
Prior MI	30(28%)	35(33%)
Hypertension	57(53%)	55(52%)
Diabetes	20(19%)	18(17%)
Average % coronary artery stenosis	82.2	81.5
Angina episodes in last 30 days (mean)	15	20
NTG pills in last 30 days (mean)	12	14
Canadian functional class (mean)	1.7	1.7
Angina during ET	83(78%)	81(77%)
Reason for stopping ET		
Angina	55(51%)	59(56%)
Fatigue	30(28%)	26(25%)
Dyspnea	6(6%)	6(6%)
Other	16(15%)	14(13%)
Max double product (mean)	$24.5x10^3$	$24.5x10^3$
Total ET duration (min)	8.8	8.5

A minimum six month follow-up including repeat ET and coronary angiography will be completed by 12/1/90. The relative efficacy of PTCA/M influencing these measures of symptomology and ET performance will be publicly reported for the first time for all data received by 12/31/90.

2:15

INTERIM SAFETY ANALYSIS OF THE BEAUMONT OUTPATIENT ANGIOPLASTY TRIAL

David R. Cragg, M.D., Harold Z. Friedman, M.D., F.A.C.C., Steven L. Almany, M.D., Susan M. Glazier, R.N., William W. O'Neill, M.D., F.A.C.C., William Beaumont Hospital, Royal Oak, MI

The duration of heparin therapy after routine coronary balloon angioplasty (PTCA) varies between institutions and angiographers and often influences the length of hospital stay (LOS). To determine if outpatient, same-day-discharge PTCA, is safe and feasible, elective PTCA pts were prospectively randomized prior to PTCA to receive either no heparin and early hospital discharge or 24 hours of heparin. To date, 200 pts out of a planned 400 have been enrolled. 44 pts were excluded because of intra-procedural complications which prejudiced heparin usage (abrupt closure, complex dissection, unsuccessful PTCA).

	No Heparin	Heparin	P
Number	72	84	
Mean age (yrs)	59.7	61.5	NS
Angina class	2.4	2.4	NS
Hypertension	23 (32%)	30 (36%)	NS
Diabetes	13 (18%)	14 (17%)	NS
Prior MI/PTCA/CABG	32/28/10	32/23/11	NS
Late closure	1 (1%)	0 (0%)	NS
Minor bleeding	4 (6%)	18 (21%)	<0.01
LOS (hrs)	23.1	38.6	<0.0001

16 (22%) pts in the no heparin group were discharged the same day of PTCA and a total of 42 (89%) within 24 hours.

Conclusions: Abbreviated heparin therapy reduces LOS without adversely affecting procedural outcome. Post-PTCA minor bleeding is significantly reduced by avoiding routine 24 hour heparin infusions. Withholding heparin infusion after uncomplicated PTCA is safe and facilitates same-day-discharge. Total enrollment will be completed by December 1990.

2:30

STENT IMPLANTATION IN AORTOCORONARY VEIN GRAFTS: A MULTICENTER REGISTRY REPORT

Martin B. Leon, Augusto D. Pichard, Donald S. Baim, Stephen G. Ellis, Sheldon Goldberg, John W. Hirshfeld, Paul S. Tierstein, Michael W. Cleman, Maurice Buchbinder, Craig Walker, Richard S. Schatz, Washington Hospital Center, Washington, D.C.

Implantation of endovascular stents (S) in aortoconary saphenous vein grafts (VG) may improve PTCA results, reduce procedure-related risks, and increase long-term patency. To determine the efficacy and safety of balloon-expandable S placement in VG, we analyzed 90 consecutive pts (64±10 yrs, 59% prior PTCA, VG age 8.5±3.8 yrs) from a multicenter study. 117 tubular slotted S were deployed in the body of VG immediately after PTCA in 109 lesions (length 5.5±4.0 mm, diameter stenosis 81±15%, expanded S size 3.4±0.6 mm) using a sheath delivery system. RESULTS: 1) S delivery was successful in 116 of 118 placements (98%) and the 2 non-deployed S were retrieved. 2) Diameter stenosis was reduced from 40±16% post-PTCA to 7±9% post-S (p<.00001) and acute flow-limiting dissections were abolished in 3 pts. 3) Complications (definite or possible S-related) included 1 subacute thrombotic closure, 3 distal embolic episodes (1 resulting in massive infarction and death), and 2 other out-of-hospital sudden deaths (10 and 14 dys post-S). There were no abrupt closures or S-related dissections. 4) Early follow-up (average 2.7±1.8 months, 31% eligible for 6 mos angiography) reveals documented restenosis at the S-site in 15 pts (17%), 10 within 3 mos of S placement (all in pts with previous PTCA). In conclusion, S implantation in the body of VG is associated with high delivery success, improved PTCA results with reduced % stenosis, and acceptable complications. Additional angiographic follow-up is required to determine the frequency of restenosis.

2:45

EXIMER LASER CORONARY ANGIOPLASTY:INITIAL RESULTS OF A MULTICENTER INVESTIGATION IN 958 PATIENTS

John F. Bresnahan, Frank Litvack, James Margolis, Donald Rothbaum, Kenneth Kent, William Untereker, Frank Cummins, and the ELCA investigators. Mayo Clinic, Rochester, MN,

Eximer laser coronary angioplasty (ELCA) is currently undergoing clinical investigation to evaluate (1) its safety and effectiveness in treating coronary artery stenoses(s) and (2) its role in interventional cardiology. 1,151 lesions in 958 patients (pts) from 15 centers underwent laser angioplasty using a 308 nm XeCl eximer laser coupled to multifiber over-the-wire catheters (C) of 1.3, 1.6, 2.0, and 2.4 mm diameter. The pt population consisted of 748 males (78%) and 210 females (22%) with a mean age of 61 years. 66% of patients were in CCSFC III or IV, 30% had undergone prior balloon angioplasty (BA), and 26% had previous CABG. Of the 1151 lesions treated, 10% were in vein grafts, 10% were total occlusions, and 22% were greater than 20 mm in length. 41% of the pts were treated with ELCA alone. Laser success (≥20% reduction in S or lumen size approximating C size) was achieved in 85% of lesions; procedural success (<50% residual S) was achieved in 94%. Stenosis severity was reduced from 86±12% to 48±24% post ELCA and 25%±20% post BA. Complications included dissection 12.5%, acute occlusion 5.4%, spasm 2%, thrombus 1.9%, perforation 1.1%, embolism 0.8%, aneurysm 0.5%, CABG 3.5%, MI 1.4%, and death 0.3%. Preliminary follow-up data suggests the restenosis rate is similar to BA. Conclusions: 1) ELCA is a safe and effective treatment for coronary S with early results similar to BA. 2) ELCA may be particularly indicated for long, diffuse lesions. 3) Restenosis remains a significant problem. 4) C design and energy delivery continues to evolve and may effect future results.