for chest pain significantly later than Euro-American women. Once hospitalized, diagnostic evaluation between the two groups is similar.

760 New Devices for Coronary Intervention

Tuesday, March 21, 1995, 4:00 p.m.–5:30 p.m.
Ernest N. Morial Convention Center, La Louisiane A

4:00

760-1 The Precision Guided Directional Laser Atherectomy Catheter: A New Approach to Percutaneous Coronary Revascularisation

Raimund Erbel, Thomas Roth, Lothar Koch, Junbo Ge, Michael Haude. *Department of Cardiology, University Essen, Germany*

Directional coronary atherectomy has been shown to be a successful method of percutaneous coronary revascularisation, particularly in large vessels with eccentric stenoses. The application of laser technology to coronary revascularisation has not been as successful, mainly because of a relatively high rate of vessel wall perforation. We describe a combination endovascular imaging/laser atherectomy catheter (Precision Guided Directional Laser Atherectomy Catheter, PGDLAC) that may overcome these shortcomings by allowing precision guided intervention.

The catheter consists of a laser cutting device with an integrated imaging system (fiberoptic or ultrasound). Fiberoptic imaging allows exact positioning and orientation of the laser tipped catheter within the vessel lumen, and visual control of plaque excision. In the second step, the vessel wall morphology is demonstrated using ultrasound, and the result of the intervention assessed without removing the catheter. Excised plaque fragments are extracted by way of the catheter. Preliminary results of in vitro experimental application of this device in human coronary arteries is promising and confirms the technical feasibility. Such a device potentially offers the advantages of effective, precision guided atherectomy in plaques of variable constitution, with a potential reduction in procedure time and radiation dose.

By combining state of the art imaging and interventional technology, we have developed a precision guided directional laser atherectomy system that may provide more effective percutaneous coronary revascularisation than previously developed techniques.

4:15

760-2 Angiographic Outcome After "Cutting" Balloon Angioplasty

Jeffrey J. Popma, William D. Knopf, Charles Davidson, Robert C. Feldman, Andrew C. Eisenhauer, Sarah A. Johnson, Martin B. Leon, Charles L. Lucore, Ray V. Matthews, Michael Mooney, Andrew Rees, Nagui Sabri, James E. Tcheng, Bonnie H. Weiner, Melvin B. Weiss, Ya Chien Chuang, Anand Desai, Teraza Y. Conway, Peter Barath. *Washington Hospital Center, Washington, DC*

To assess the angiographic outcome after "cutting" balloon (C-Ball) angioplasty, a technique which uses 3–4 longitudinal microtomes to incise atheroma reducing vascular barotrauma, we reviewed the cineangiograms of 86 patients (89 lesions) undergoing this procedure in Phase I and II clinical studies. On-line quantitative angiography (QCA) was used by investigators to approximate a 1:1 balloon artery ratios (BAR). In the Phase II Pilot study, adjunct balloon PTCA was not performed unless a >40% residual diameter stenosis remained after C-Ball. Off-line qualitative morphologic and quantitative angiographic (ImageComm) analyses were performed by independent Core Laboratory review.

	Phase I % (N = 22)	Pilot Phase II % (N = 67)
Vessel (%): RCA/LAD/LCx	41/36/23	37/36/27
Location (%): Ostial/Proximal/Mid-Distal	0/59/41	5/25/70
Eccentricity (%)/Bend ≥ 45° (%)	73/18	54/19
Length ≥ 10 mm (%)/Calcified (%)	9/36	24/25
Irregular (%)/Bifurcation (%)	14/0	8/6
ACC/AHA Class (%): A/B1/B2/C	9/50/41/0	17/40/40/3
Reference Diameter, mm/C-Ball:Artery Ratio	2.83/0.96	2.97/1.00
MLD, mm: Pre/Post C-Ball/Final	0.87/1.59/2.01	1.11/1.63/2.12
% Stenosis: Pre/Post C-Ball/Final	69/45/29	63/48/29
% Adjunct PTCA/% Post-PTCA haziness	64/9.1	30/15
Final NHLBI Dissection (%): Grade B/C/D	0/14/0	16/0/0

Two patients in Phase II required intracoronary stents for dissections after C-Ball and adjunct PTCA. There were no deaths and no patient required emergency CABG. *We conclude that* "cutting" balloon PTCA: (1) can be performed safely without an untoward increase in dissections or other angiographic complications; and (2) results in a residual diameter stenosis (29%) comparable to standard balloon angioplasty. Its effect on reducing late lumen loss (angiographic restenosis) compared with balloon angioplasty is undergoing evaluation in a randomized, Phase II clinical trial.

4:30

760-3 Vibrational Coronary Angioplasty; Challenging Chronic Total Occlusions. Preliminary Clinical Data

Michael R. Rees, Lampros K. Michalis. *Department of Postgraduate Medicine, University of Keele, UK*

Vibrational angioplasty is a novel method of angioplasty which is particularly suitable for the treatment of chronic total occlusions. Vibrational angioplasty utilises a hand held motor which is attached to a conventional catheter and guide wire. This device consists of a motor and gearing system producing a fine rapid reciprocation and random motion in a flexible guide wire. In vitro studies have shown that this system generates reciprocal motion in a guide wire with random oscillations of 2 times the reciprocating frequency. The range of movement of the wire is dependant on the frequency of vibration and degree of flexibility of the wire together with the lateral motion of the vibrating 'shuttle' in the device. We present the first 18 cases (12 male 6 female, mean age 59.8 yrs range 40–73) of chronic total occlusion treated with the new version of this device. All patients had symptoms of stable angina. Arteries treated were left anterior descending:8, left circumflex:4, right coronary artery:6. In all 18 cases there was a failure to cross the lesion with conventional techniques and wires. The mean duration of the occlusions was 17.03 months (range:4–60 months). In 16/18 cases successful crossing was achieved with vibration In 2/18 cases where a wire managed to cross the lesion no balloon could subsequently cross the lesion. In 14/18 cases lesions were crossed successfully by a balloon and PTCA was performed with pressure ranging between 2.5–6 Atm. The post procedural result was: uncomplicated in 9/18, complicated by moderate dissection treated conservatively in 1/18 cases, by major dissection needed stenting in 2/18, compromised by the evidence of severe diffuse disease distally in 2/18 and regarded as unsuccessful in 4/18. The total procedural and screening times (mean ± SD) were 73.2 ± 31.3 and 41.2 ± 16.4 min respectively. *In conclusion* "vibrational angioplasty" appears to achieve high primary success rates in the recanalisation of totally occluded arteries. Further studies are needed to clarify its mechanism of action, the vessel wall changes due to vibrational energy and their impact on restenosis.

4:45

760-4 Initial Multicenter Experience with Therapeutic Ultrasonic Coronary Angioplasty in Patients

Christian W. Hamm, Michel E. Bertrand, Ivan de Scheerder, Julian Gunn, Jean-Marc Lablanche, Jan Piessens, Jacobus Reimers, David C. Cumberland, CRUSADE investigators. *Dept. of Cardiology, University Hospital Hamburg, Germany*

Therapeutic ultrasonic (19.5 kHz) catheters with 1.2 or 1.7 mm ball tips for coronary angioplasty have recently been developed. During the first phase of a multi-center European trial (CRUSADE) this system was evaluated in 100 patients (86% male, mean age 57 years) with symptomatic coronary artery disease or acute myocardial infarction. Lesions were located in the LAD (n = 61), CX (n = 17), and RCA (n = 22); 62% were type B or C; 11 lesions were restenotic, 19 occlusive, 9 longer than 20 mm, 37 calcified, 18 thrombotic, and 15 collateralised.

Results: The ultrasound catheter crossed 82/100 lesions, adjunctive balloon angioplasty was needed in 98 lesions. There was no death and myocardial infarction, or CABG in the first 24 hours. There was no perforation, but 2 acute vessel closures; intimal cleft or dissection was seen in 17 lesions of which 1 required stenting. Procedural success was obtained in 93%. At 24 hours 11/100 vessels were reoccluded. At 6 months angiographic follow-up in 51 patients restenosis (>50% stenosis) occured in 33%.

Conclusions: Therapeutic ultrasound angioplasty is a feasible and safe new treatment modality. Adjunctive balloon angioplasty is regularly necessary. Preliminary experience suggests usefulness in lesions with visible thrombus, and undilatable or uncrossable lesions.

5:15

760-6 Initial In-Vivo and In-Vitro Testing of an Ultrasound-Guided Directional Coronary Atherectomy Catheter

Andrew I. MacIsaac, Paul G. Yock, Peter J. Fitzgerald, Stephen N. Oesterle, Robert S. Schwartz, Stuart T. Higano, Joseph P. Carrozza, Donald S. Baim, James Vetter, Tomoaki Hinohara. *Stanford University, Stanford, CA*

We report the results of initial in-vitro and in-vivo testing of a new, ultrasound-guided directional coronary atherectomy (GDCA) catheter (DVI, Redwood City, CA) which is being developed as a potential first-generation clinical prod-