Quantitative Angioscopy: A New Technique for Evaluation of Residual Lumen Area

Gérald R. Barbeau MD, Stephan E. Friedl MEE, George S. Abela MD., F.A.C.C., University of Florida, Gainesville, FL

Quantitative angiography [QAG] has improved the reliability of standard angiographic techniques for evaluation of residual lumen area. A new technique for the measurement of intravascular dimensions using quantitative angioscopy [QAS] has been developed. To determine the accuracy of QAS for measurement of residual lumen area, QAG and QAS were compared to residual lumen area measured by surface planimetry. Each of five eccentric stenoses, induced in human post-mortem vessels was measured 1) four times by monoplane [MP] QAG using four different views (0°, 90°, 180°, 270°), 2) twice by biplane [BP] QAG using combinations of two orthogonal views (0° & 90°, 180° & 270°), and 3) four times by QAS from four different intra-luminal locations. Following QAG and QAS measurements the vessels were cut proximal to the stenotic section for measurement by surface planimetry . Area of the residual lumen was derived using 1) QAG from the angiographic radius of the patent lumen as determined by computerized vascular edge detection, 2) QAS, by digitization and analysis of multiple angioscopic views of the same stenosis and 3) computerized surface planimetry.

Results: Using all data points, BP QAG and QAS were highly correlated to surface planimetry, but MP QAG was least correlated (r=0.81, 0.79 & 0.38 respectively). Pooling all measurements of each residual lumen area by the same technique, QAS and BP QAG were best correlated with surface planimetry, while MP QAG was least correlated (r=0.92, r=0.87 & r=0.68, respectively).

Conclusion: In addition to the qualitative diagnostic advantages of angioscopy which provides data on the nature of a vascular obstruction, these preliminary results suggest that QAS may provide another method for precise measurement of residual lumen area.

A NEW, BIOCOMPATIBLE POLYMERIC CORONARY STENT: DESIGN AND EARLY RESULTS IN A PIG MODEL

Joseph G. Murphy MD, Robert S. Schwartz MD FACC, Kelley Kennedy MD, William D. Edwards MD FACC, Steven J. Reiter MD FACC, Ronald E. Vlietstra MD FACC, David R. Holmes MD FACC

Mayo Clinic and Foundation, Rochester, Minnesota.

Implantation of metallic intracoronary stents to maintain vessel patency after balloon angioplasty has been complicated by issues of mechanical flexibility, thrombogenicity, and restenosis. The use of non-metallic polymeric materials has recently been advocated as a potential solution to these difficulties. Thus, a flexible, self-expanding, dual helical polyethylene terephthalate (PET) stent and delivery system for implantation in porcine coronary arteries is being developed and tested.

Five domestic crossbred swine underwent right carotid artery cutdown, and the left main coronary artery was intubated using standard techniques. PET stents 3.0 mm in diameter were placed without difficulty in the left anterior descending (4 animals) and in the circumflex (1 animal) coronary arteries, using the specially designed delivery catheter. Intravenous heparin (400 units/kg) was given at the time of implant only, and no other anticoagulant or anti-platelet agents were utilized at any time during the procedure or followup period.

Coronary arteriography performed at 20 minutes post stent implantation revealed patent coronary vessels in all cases, and no coronary artery spasm was noted in any vessel. At four weeks of followup, all animals remained well without evidence of coronary artery occlusion.

Successful *in vivo* deployment of non-metallic, PET stents in coronary arteries is thus practical and safe, with early results indicating that these stents are comparatively non-thrombogenic in this animal model.

IN VITRO ANALYSIS OF CORONARY ANGIOPLASTY BALLOONS: CHARACTERISTICS AFFECTING FUNCTIONAL PROFILE

M. Chang, MD, M. Plant, P. Moon, PhD, G. Vetrovec, MD, FACC, Medical College of Virginia, Richmond, Virginia

Coronary angioplasty balloon characteristics affecting the force required to cross an in vitro stenosis model was analyzed for 8 different commercially available 2 mm catheters. The force required for each balloon to traverse an artificial 1.1 mm diameter stenosis was measured in a water bath at body temperature over the length of each balloon using an Instron force velocity analyzer. To exclude differential effects of balloon and stenosis material interaction, stenoses were made from 2 different elastomeric dental impression materials; polyvinyl siloxane and polyether urothane dimethacrylate, both 2.3 mms thick. The mean peak force required to traverse either stenosis material was similar (50±15 [SEM] vs 64±10 grams, P=NS). The peak force required to traverse the stenosis was seen at the metal ring marker distal and mid in 6 of 8 balloons. Mean force required at the ring was 57±7 grams, 86% > than the mean force (31±10 grams) recorded at the proximal segment of the balloons ($p < 0.05$). Furthermore, there was no difference in peak force between balloons "out of the box" vs balloons "prepped" with 50% contrast (60±4 vs 63±9 grams, P=NS). Finally, there was a significant linear relationship between manufacturer profile and peak force required to cross the stenosis (R=0.7, $p \leq 0.05$). In conclusion, prepping appears to have little effect on functional profile while marker rings provide the major impediment in crossing a stenosis. Thus, an in vitro stenosis model appears useful to assess functional balloon profiles characteristics. Based on these findings, changes in marker construction and/or placement could potentially reduce balloon profiles.

Tuesday, March 20, 1990
2:00PM–3:30PM, Room 37
Intravascular Ultrasound Imaging

INITIAL TRIALS OF A COMBINED ULTRASOUND IMAGING/ MECHANICAL ATHERECTOMY CATHETER

Paul G. Yock MD, FACC, Peter J. Fitzgerald MD, PhD, Yue-Teh Jang PhD, John McKenzie BS, Martin Belef, Neil Starksen MD, Neal W. White MD, David T. Linker MD, John B. Simpson MD, FACC. University of California, San Francisco.

Although acute results with directional mechanical atherectomy are excellent, early clinical studies suggest that restenosis continues to be a problem under certain circumstances. More aggressive debulking may reduce restenosis, but with an increased risk of damaging normal vessel wall or causing frank perforation.

We have developed and tested a prototype, combined ultrasound imaging and atherectomy catheter. Initial tests were performed with a 9 French catheter similar in design to the Simpson Atherocath (TM), with a 20MHz transducer incorporated behind the cutting element. Rotation of the transducer provides a scan of the vessel wall through the opening in the atherectomy housing, in a plane perpendicular to the axis of the catheter.

In-vitro studies were performed using 9 human freshly excised pathologic iliac and femoral artery specimens with various degrees of atherosclerotic disease (Ath). High-resolution images were obtained in all cases, clearly defining the extent and depth of Ath. These images were used to direct the housing toward accumulations of Ath and away from more normal segments. With inflation of the balloon on the housing device, the Ath was visualized moving into the cutting field. The images provided clear orientation and guidance for progressive debulking of the Ath segments with multiple passes of the catheter.

In-vivo feasibility was assessed in a normal canine preparation, where imaging without atherectomy was performed using the combined device. Full access to all quadrants was obtained by torquing of the device, with clear images of the vessel wall and periadventitial structures.

We conclude that combined ultrasound imaging/atherectomy appears to be a technically feasible approach which may enhance the efficacy and safety of mechanical atherectomy in some applications.