10:45

ENDOVASCULAR INCISIONS WITH A NOVEL DEVICE: A NEW APPROACH TO ANGIOPLASTY

Peter Barath, Michael Fishbein, Sandor Vari, Feixiong Yao, James Forrester, Cedars-Sinai Medical Center, Los Angeles, CA.

We have built a new angioplasty device with cutting edges (cutting balloon, CB) capable of producing radial surgical incisions from the luminal surface of the arteries. Our aim is to overcome elastic recoil, limit tearing injury and localize the reparative response to the incision site. The study goals were: 1) to compare angiography after standard balloons (SB) and CB angioplasty; and 2) to determine the healing response to such incisions. We performed angioplasty on normal peripheral arteries of 18 pigs with SB and CB. Results: The average pressure to gain the nominal angiographic diameter of SB and the CB was 6.8 and 3.4 atm, causing an average increase in angiographic vessel size by 12% and 14%, respectively. At 14 days, the angiographic size of the vessels fell below the original by 5% after SB while it remained 9% above the original after CB dilation. At 14 days, histologically, the incisions were recognized as completely re-endothelialized, shallow crater-like impressions of the luminal surface filled with smooth muscle cells. There was no intimal proliferation outside the incisions after dilatation with the CB as opposed to an average 8.7% proliferation area (intima/media) following dilatation with SB. Conclusions: 1) angioplasty with CB requires less pressure and the original angiographic result is better maintained; 2) surgical cuts heal without intimal proliferation outside the cut region. This method may have implication for human angioplasty.

11:00

TEMPORARY CORONARY "SPLINTING" FOR ABRUPT CLOSURE POST-PTCA: INITIAL IN VIVO STUDIES

David W.M. Muller, Christopher J. White, Harold Z. Friedman, Lloyd Willard, Eric J.Topol. University of Michigan, Ann Arbor, MI

Endoluminal coronary stenting has proven a valuable means of treating abrupt closure due to intimal dissection but is limited by anticoagulation-related bleeding, thrombotic closure, and restenosis. To determine whether a temporary, removable device may be as effective while avoiding these complications, we evaluated an over-the-wire, stainless steel, expandable/retractable, braided mesh catheter in animal models of abrupt closure. The design allows intracoronary antithrombotic or fibrinolytic therapy to be simultaneously delivered through a 0.018" central lumen. Ex vivo testing showed no significant gradient across the device and no evidence of hemolysis.

Nine devices (2-6mm) were deployed in the peripheral (n=3) or coronary (n=6) arteries of 7 animals (2 dogs, 5 pigs). The devices were deployed in normal arteries (group 1; n=6) or after inflation of an oversized balloon (group 2; n=3). Each animal was anticoagulated with iv heparin; 5 were pretreated with aspirin. In group 1, 5 of 6 devices remained widely patent with TIMI 3 flow for 3-6 hours and were easily removed. One animal died from LAD occlusion by a device which was too large (2.5mm in a 1.5 mm vessel) and too long (>4cm deployed length). In group 2, 1 device (2.5mm) remained widely patent following circumflex artery angioplasty but 1 became occluded by thrombus at 2 hours and 1 failed to prevent myocardial ischemia. The latter showed no evidence of thrombus formation and its failure was attributed to the small size of the artery (<2mm).

We conclude that, in its current design, the device is extremely flexible, easily deployed and removed, and remains widely patent in normal vessels. However, in small arteries (<2mm), the stimulus for thrombosis induced by intimal dissection may reduce its efficacy in the absence of concomitant local lytic therapy. A modified design with a markedly reduced metal surface area is currently being evaluated.

11:15

MECHANICAL FEATURES OF THE DUKE BIODEGRADABLE INTRAVASCULAR STENT

Roger S. Gammon, Gregory D. Chapman, GM Agrawal, Robert P. Bauman, Harry R. Phillips, Howard G. Clark, and Richard S. Stack. Duke University Medical Center, Durham, NC.

Self-expanding intravascular stents (IVS) have been constructed braiding 8 polymeric monofilaments (MF) into a tubular configuration. Several biodegradable polymers were examined and found unsuitable as they were plasticized by saline at 40° C. Poly-L-lactide (PLL) retained excellent mechanical stability under these conditions and was investigated further. Performance properties of polymeric materials reflect their thermal and mechanical preparation. After experimentation with PLL at different spinning temperatures, draw ratios, and annealing conditions, a filament with a tensile strength of 4.8×10^4 psi, Young's modulus of 91.7×10^4 psi, and elongation at break of 66% was selected. Filaments of 0.19 mm diameter were used to construct a stent of 4 mm diameter. These stents withstood collapse pressures (CP) ranging from 600-1000 mm Hg. When implanted in dog peripheral arteries, this IVS could resist pharmacologically induced vasospasm. Mechanical analysis shows that as the IVS diameter is decreased, MF diameter may also be decreased (without sacrificing collapse pressure), thereby occupying a similar fraction of the lumen cross section. These IVS maintain their CP for 8 months in 40° C saline and then lose tensile strength, indicating extensive degradation.

In conclusion, this IVS constructed from PLL withstands crush pressures exceeding arterial spasm, will not significantly compromise luminal area, and degrades in approximately 8 months. These characteristics mandate further investigation toward development of a potentially useful clinical prosthetic device.

11:30

TISSUE EFFECTS OF PULSED INFRARED LASERS: IMPLICATIONS FOR LASER ANGIOPLASTY

Robert Bonner, Philippe Douek, Richard Neville, Joseph Pinto, Leon Esterowitz, Martin B. Leon, NIH, Bethesda, MD

Clinical success with the excimer laser has stimulated interest in pulsed infrared (IR) lasers as an alternative for laser angioplasty due to 1) precise tissue ablation, 2) improved silica fiber transmission (for IR lasers ≤2.1um), and 3) convenient, portable, less expensive solid-state instrumentation. However, there remains confusion regarding the variability of tissue effects among different IR lasers which may influence clinical results. Therefore, we performed in vitro tissue studies and in vivo acute/chronic experiments (163 aorta sites from 10 rabbits) using excimer (308nm) and various IR lasers measuring ablation threshold and efficiency, thermal injury (TI), pressure transients caused by acoustic shockwaves (SW), histologic findings, and healing responses.

	XeCl	Tm:YAG	Tm:YAG	Ho:YAG	Er:YAG
W (um)	.308	1.96	2.01	2.10	2.94
TI (um)	50	100	190	440	10
SW (units)	4	0.3	0.6	7	0.1

Larger (>3 units) laser-induced SW were observed to cause clefts in tissue planes and dissections. Of the IR lasers tested, Ho:YAG resulted in the most significant TI and SW damage and may not be suitable for laser angioplasty. Er:YAG elicited superior tissue ablation characteristics but fiber transmission was problematic. Tm:YAG (especially 1.96um) appears most favorable for clinical use, exhibiting tissue ablation with little TI or SW damage, excellent silica fiber transmission, and favorable in vivo healing responses. In conclusion, there are important differences among IR lasers which may critically impact tissue ablation patterns and consequent laser angioplasty results.