Results: The average annualized increase of TP-Vel for the entire study group was small (0.04±0.28m/s/yr) and did not significantly differ between patients receiving statins (0.02±0.29 m/s/yr) and those who did not (0.05±0.28 m/s/yr; p=0.48). However, there was a wide variability of the progression rate. 32 pts had a rapid increase of TP-Vel defined as >0.25 m/s/yr. Such a rapid progression was observed in 17% (14 of 84) of pts treated with statins and 15% (18 of 118) of pts who were not (p=0.79). From these findings it appears unlikely that statins delay hemodynamic deterioration of bioprosthetic valves.
Coronary artery disease, hypertension, age, gender, hypercholesteremia and prosthetic valve type were not related to the progression rate of TP-Vel. However there was a trend towards more rapid increase of TP-Vel in diabetic pts (0.13±0.37 vs. 0.02±0.26 m/s/yr, p=0.06). In particular, rapid hemodynamic deterioration (TP-Vel >0.25 m/s/yr) was observed in 29% (10 of 34) of the diabetic pts compared to 13% (22 of 168) of the non-diabetic pts (p=0.03).
Conclusion: In contrast to calcific aortic stenosis, statins do not appear to affect bioprosthetic valve degeneration. This further underscores the different mechanisms involved in these two disorders.

### 1107-139 Calcium-Phosphorus Product Is Associated With Severity of Aortic Stenosis in Patients With Normal Renal Function

William R. Mills, Douglas Einstadter, Robert S. Finkelhor, Case Western Reserve University, MetroHealth Campus, Cleveland, OH

Background: Recent investigations have shown that acquired aortic stenosis (AS) may result from production of bone matrix proteins by osteoblast-like cells which can mineralize in the presence of phosphorus and other triggers. Elevated serum phosphorus and calcium-phosphorus product (CaxP) have been associated with increased aortic valve calcification in dialysis patients, but it is unknown whether such a relationship exists in patients with normal renal function.
Methods: Between November 2001 and October 2002, 107 consecutive AS patients with a serum creatinine ≤1.5 were identified. Aortic valve area (AVA) was calculated by the echocardiographic continuity equation. Clinical and laboratory data obtained within 3 months of the index echo were determined by chart review.
Results: The study sample included 40 men and 67 women. Mean parameters were as follows: creatinine 0.9±0.3 mg/dl, age 74±12 years, AVA 1.1± 0.35cm$^2$, phosphorus 3.7±0.7mg/dl, CaxP 32.7±7.1, peak gradient 39.6±21.9mmHg, and mean gradient 23.5±12.9mmHg. Both serum phosphorus (R= -0.248, p=0.028) and CaxP (R= -0.303, p=0.007) were inversely related to AVA. CaxP was positively correlated with peak (R=0.227, p=0.044) and mean R=0.235, p=0.039) gradients. Further, in linear regression analysis, a one mg/dl increase in serum phosphorus was associated with a 0.13 cm$^2$ (95% CI of -0.2 to -0.01, p<0.03) decrease in the AVA, and a one unit increase in CaxP was associated with a 0.02cm$^2$ (-0.03 to -0.01, p<0.01) decrease in the AVA.
Conclusions: Higher levels of serum phosphorus and CaxP are associated with more severe AS. These findings support the hypothesis that increased serum phosphorus and CaxP may be important triggers leading to severe AS, even in patients with normal renal function.

### 1107-140 Lack of Association Between Severity of Coronary Artery Disease and Aortic Valve Calcification Determined by Atomic Absorption Spectroscopy in 187 Patients With Aortic Valve Replacement

Jan R. Ortlepp, Fabian Schmitz, Vera Mevissen, Stefan Weiß, Jürgen Huster, Richard Dronskowski, Rüdiger Autschbach, Georg Langebartels, Peter Hanrath, University of Technology Aachen, Aachen, Germany

Background: Coronary artery disease (CAD) and aortic stenosis share many similarities and calcification of the aortic valve is closely linked to CAD. In a previous study we have demonstrated the lack of association of risk factors and valve calcification and the impact of genetic factors. In this analysis we evaluated the relationship between the degree of valve calcification and the degree of angiographic determined CAD.
Methods: The amount of calcification (hexagonal hydroxyapatite) of 187 excised stenotic aortic valves was determined using atomic absorption spectroscopy (mass%). CAD type were defined prior to aortic valve replacement by coronary angiography as (I) angiographically clear coronaries, (II) coronary sclerosis, and (III) stenotic (>50%) CAD. Severity of CAD was defined as the number of needed coronary artery bypass grafts (CABG) per patient (none, 1, 2, 3, more than 3).
Results: 48 patients had clear coronaries, 43 had coronary sclerosis, 96 patients had stenotic CAD. 95 patients underwent CABG (1 CABG: 37 patients; 2 CABG: 27 patients; 3: CABG 20 patients; more than 3 CABG: 11 patients). There was neither an association between the type of CAD (23.4 ± 11.3 vs 25.5 ± 8.8 vs 23.0 ± 8.6; p=0.326) nor the number of CABG (24.2 ± 10.3 vs 23.9 ± 8.1 vs 21.1 ± 9.8 vs 23.2 ± 8.9 vs 25.2 ±6.4; p=0.610) and the exact determined degree of hydroxyapatite in the valve.
Conclusion: At the time of surgery there was no association between the severity of aortic valve calcification and the severity of CAD in patients with relevant aortic valve stenosis who underwent aortic valve replacement. While aortic sclerosis seems to be an excellent marker for CAD, severity of CAD does not have a close link to the extend of severe aortic valve calcification.



ORAL CONTRIBUTIONS

## 824FO Featured Oral Session...Percutaneous Approaches to Cardiac Valve Repair and Replacement

Monday, March 08, 2004, 4:00 p.m.-5:30 p.m.
Morial Convention Center, Room 243

4:15 p.m.

### 824-2 The In Vitro Functions of a Percutaneous Heart Valve in the Aortic Position

David Paniagua, Jose M. Cesar, Eduardo Induni, Carolyne Ortiz, Carlos Mejia, Richard T. Schoephoerster, R. David Fish, Endoluminal Technology Research, Miami Beach, FL, Florida Internatrional University, Miami, FL

**Background**
We developed a new folded pericardial valve with a low profile that allows percutaneous implantation. We tested this valve in a validated left heart and systemic circulation simulator (Vivitro Systems, Victoria Canada).
**Methods**
Five 20 mm diameter percutaneous heart valves (PHV) were evaluated in the left heart simulator in the aortic position. This system includes a processor controlled stepper motor that drives a piston cylinder, forcing contraction and relaxation of the left ventricular sac. The aortic valves are mounted in relative anatomical positions. The system is filled with fluid containing 70% water and 30% glycerol to achieve the same density and viscosity as blood. Sodium chloride at 0.9% is added to allow measuring of flow using an electromagnetic probe. The PHV function was evaluated under physiological conditions: cardiac output 5 liters/min, heart rate of 70/min and blood pressure of 180/80 and pathological conditions of hypotension (70/40) and hypertension (320/250). Comparison with the St Jude mechanical heart valve was done for backflow percentage. Echo-Doppler studies of the PHV were performed with a 7.5 MHz transducer in the in-vitro testing model.
**Results**
The PHV had no transvalvular gradient and no backflow (regurgitation) at physiological conditions (graph) compared with a 14% leakage of the St Jude valve.
The opening gradient of the PHV was 5 mmHg. No evidence of prolapsing was seen during extreme hypertension (320/250). The PHV opening and closing characteristics were fully competent even in hypotensive (70/40) conditions. Two-dimensional images showed complete apposition of the leaflets with appreciation of the "Mercedes Benz" sign. Pulse Doppler studies of the PHV in vitro model were performed demonstrating no evidence of regurgitation and physiological forward velocity.
**Conclusion**
Our PHV shows fully competent hemodynamic and Echo-Doppler performance in a validated left heart and systemic circulation simulator (Vivitro Systems). This new PHV design has significantly less backflow than the St Jude mechanical aortic valve.

4:30 p.m.

### 824-3 Percutaneous Implantation of a New Prosthetic Heart Valve in the Descending Aorta in Sheep: Results at Six Weeks in a Model of Severe Aortic Insufficiency

Hélène Eltchaninoff, Danielle Nusimovici, Assaf Bash, Alain Cribier, Charles Nicolle Hospital, Rouen, France, Percutaneous Valve Technologies, Fort Lee, NJ

**Background**: Hufnagel in the 50s, showed that the implantation of a mechanical valve in the descending aorta of patients with aortic insufficiency (AI) decreased the regurgitant flow. In the sheep model, creation of a severe AI consistently leads to early death. The goals of this study were to assess the efficacy on survival and the long-term performance of a percutaneous heart valve (PHV), made of 3 equine pericardial leaflets mounted in a balloon-expandable stent, implanted in the proximal descending aorta of the sheep after creation of a severe AI. Efficacy of this PHV has been previously reported.
**Methods**: AI was created by an original technique using a 7F biotome to extract a small fragment of aortic valve leaflet. Severe AI was defined by massive filling of the left ventricle on supra-aortic angiogram with a fall in aortic diastolic pressure (DBP) ≥ 20 mmHg. Crimped over a 22 mm diameter balloon, the PHV was then introduced through a 24 F sheath in the carotid artery, advanced over a stiff wire and delivered in the descending aorta. PHV function was assessed on hemodynamics, angiography, 2D-and trans-esophageal echocardiography (TEE) and Doppler. TEE and Doppler were repeated at 6 weeks.
**Results**: 13 sheep (8.9 ± 0.7 mths; 41 ± 5 Kg) were studied. Severe AI and accurate PHV delivery were obtained in all cases. Decrease in DPB was 28 ± 11 mm Hg. Three animals died acutely of biotomy related hemorrhagic complications. On echocardiography, post-PHV AI was grade 2 in 2, grade 3 in 7 and grade 4 in 1. PHV valve area was 1.97 ± .06 cm2, with no leak in 8, mild and moderate leaks in 2. Post-PHV treatment was aspirin (150 mg/d) and enoxaparin (40 mg/d). All 10 sheep were alive at 6 weeks. TEE was obtained in 9/10 (poor echogenicity in 1): one PHV had migrated and all other were functioning well. PHV valve area was 1.96 ± .05 cm2 with no leak in one, mild leak in 4, moderate leak in 4. AR on the native valve was unchanged in 3 sheep, and decreased by 1 grade in others.
**Conclusions:** PHV implantation in the descending aorta prevents animal death despite severe AI and shows good immediate and 6-week results. Six-month follow-up is ongoing. In the future, this technique might offer a new therapeutic option to patients with non-operable AI.