

to PTCA (n=63) or CABG (n=64). The primary end point of this study was to compare freedom from combined coronary cardiac events (death, myocardial infarction repeat revascularization procedures and angina) and late cost between both groups of patients at 1,3 and 5 years follow up. **Results:** At five years freedom from combined cardiac events was significantly greater in CABG than PTCA group (68% vs. 40% p < 0.001). However there were no differences in overall (9.4% vs. 12.7% p NS) and cardiac (6.8% vs. 6.8% p=NS) mortality and in the incidence of non fatal myocardial infarction (9.4% vs. 11.1% p = NS) between both groups. Patients with CABG had lower incidence of angina (27% vs. 46% p < 0.001), and required less additional reinterventions (6.3 vs. 38% 0 < 0.001) during follow up than patients with PTCA. Nevertheless, the prevalence of angina at the end of follow up was similar between CABG and PTCA patients (9.4% and 6.3% respectively p = NS). Cumulative late cost at 5 years was greater for CABG than for PTCA group (US 832,000 vs. US 491,000 p < 0.01). **Conclusions:** Patients with multiple vessel CAD treated with CABG were more frequently free from angina and need for new revascularization procedures than patients treated with PTCA. However, there were no difference in mortality and incidence of non fatal myocardial infarction between both groups. Cumulative late cost was greater for CABG than PTCA group.

2543

### Final Results in the Balloon vs Optimal Atherectomy Trial (BOAT): 6 Month Angiography and 1 Year Clinical Follow-up

Donald S Balm, Jeffrey J Popma, Samin K Sharma, Richard Fortuna, Theodore L Schreiber, Cynthia Senerchia, Tia DeFeo-Fraulini, Donald E Cullip, Kalon K Ho, Richard E Kuntz, The BOAT Investigators. Beth Israel Hospital, Boston MA USA, Washington Hospital Center, Washington DC USA, Mount Sinai Hospital, New York NY USA, Scripps Memorial Hospital, La Jolla CA USA

Between July 1994 and November 1995, the 38 participating BOAT centers enrolled 1,000 pts with focal de novo native coronary artery lesions, which were randomly assigned to either conventional balloon angioplasty or "optimal" directional atherectomy (in which the goal was to use a 7 Fr AtheroCath, remove as much tissue as safely possible, and perform adjunctive balloon post-dilatation, to achieve a final residual diameter stenosis < 20%). Acute results show that the DCA arm had higher lesion success (residual < 50%, 98.8% vs 96.5%, p < 0.05), lower use of "ballout" catheter treatment (3.8% vs 9.6%, p < 0.001), and higher procedural success (lesion success without a major complication or "ballout" treatment, 93.2% vs 86.6%, p < 0.005). The DCA arm also achieved a larger MLD (2.82 ± 0.50 vs 2.33 ± 0.49 mm, p < 0.001) and a lower residual diameter stenosis (15 ± 13% vs 28 ± 13%, p < 0.001), without an increase in the incidence of major complications (death, Q-MI, EmCABG; 2.8% vs 3.3%, p=NS). As expected from prior trials, however, DCA pts had a higher incidence of CK-MB elevation > 3x normal (14% vs 5%, p < 0.001) in the setting of otherwise uncomplicated procedures. Six month angiographic follow-up is expected to be complete by July 1996 with 1 year clinical follow-up complete by November 1996. This will determine whether the acute results of larger lumens following atherectomy translate into reduced angiographic and/or clinical restenosis (measured as TSR, clinically-driven repeat revascularizations of the target site), whether there is any increase in late mortality risk (as suggested by CAVEAT), and whether there are any late clinical consequences of post-procedural CK elevation in pts with otherwise successful DCA or conventional angioplasty. Full data on these end-points will be presented.

2544

### Outcomes and Their Predictors after PTCA in Patients with Type II Diabetes Mellitus

Nancy L Hassinger, Diane E Grill, David R Holmes, Jr.. Mayo Clinic, Rochester MN USA

Diabetic patients (DPs) frequently present for revascularization and account for 12-25% of patients in published clinical trials. Mortality may be higher in DPs after PTCA than CABG as seen in subgroup analysis of the BARI trial. This study examined 225 Type II (nonketotic) DPs who underwent PTCA between 1984-1994 at the Mayo Clinic matched to nonDPs for age, gender, degree of disease, and date of procedure. **Results:** DPs had a significantly higher prevalence of prior CABG (25 vs 14%), HTN (66 vs 46%), CHF (23 vs 8%), and had lower ejection fractions (59 vs 63%) compared to nonDPs; unstable angina and history of MI were not different. Technical success (95 vs 93%) and early (in hospital) complications of death and emergent CABG were similar. After mean follow-up of 4 years there was no significant difference between DPs and nonDPs for myocardial infarction, repeat intervention, or CABG. Mortality in DPs was higher: 17% vs 12% (p=0.048). Degree of control assessed as glycosylated hemoglobin (HA1C) at the time of intervention, correlated with late outcome. The relative risk of the combined endpoint death, MI, or severe angina was 1.6 for HA1C values > 8.5 (p=0.038), there was no additional predictive strength when higher HA1C values were analyzed. Among DPs, those with a prior CABG were 2.1 times more likely to have a repeat intervention on a restenotic lesion; restenosis was lowest in those DPs taking an ACE inhibitor as part of their overall therapy (odds ratio=0.32) **Conclusions:** 1) Despite having more co-morbidities, percutaneous revascularization in DPs can achieve similar outcomes to nonDPs when age, gender, and degree of disease are considered. 2) Overall survival is lower in diabetics. 3) Better diabetic control is associated with improved outcome. 4) ACE inhibitor therapy may favorably influence restenosis in DPs.

2545

### The Role of Diabetes in Long-Term Survival After Coronary Bypass and Angioplasty

Gregory W Barsness, Eric D Peterson, E Magnus Ohman, Charlotte L Nelson, Robert M Callif. Duke University Medical Center, Durham NC USA

Randomized trials have suggested that PTCA in diabetic patients with multivessel coronary disease results in higher mortality than CABG. To evaluate the effect of diabetes on outcome following revascularization in a large prospective cohort, we analyzed data on 3220 patients with symptomatic 2- or 3-vessel coronary disease undergoing PTCA or CABG at Duke from 1984 to 1990. This group consisted of 704 PTCA patients, including 144 with diabetes (20.5%), and 2516 CABG patients, including 625 diabetics (24.8%). Patients with acute infarction, prior revascularization, valvular or congenital disease, or significant left main disease were excluded. The mean followup

was 6.1 ± 2.1 years. At 5 years, unadjusted survival in patients undergoing CABG was 74.3% in diabetics and 86.3% in non-diabetics. Likewise, 5-year survival in PTCA patients was 76.4% in diabetics and 88.3% in patients without diabetes. After adjusting for baseline risk factors including age, gender, coronary anatomy, LVEF, mitral regurgitation and comorbidity, diabetic patients receiving either PTCA or CABG had significantly lower survival than non-diabetics (p < 0.0001). In contrast to previous studies, however, there was no significant differential effect of diabetes on outcome in patients treated with either PTCA or CABG (p > 0.3). **Conclusion:** While diabetes was a risk factor for worse long-term outcome in patients with multivessel coronary artery disease, the effect was similar in the PTCA and CABG groups. These results do not support earlier conclusions that diabetes status should determine the choice of revascularization strategy.

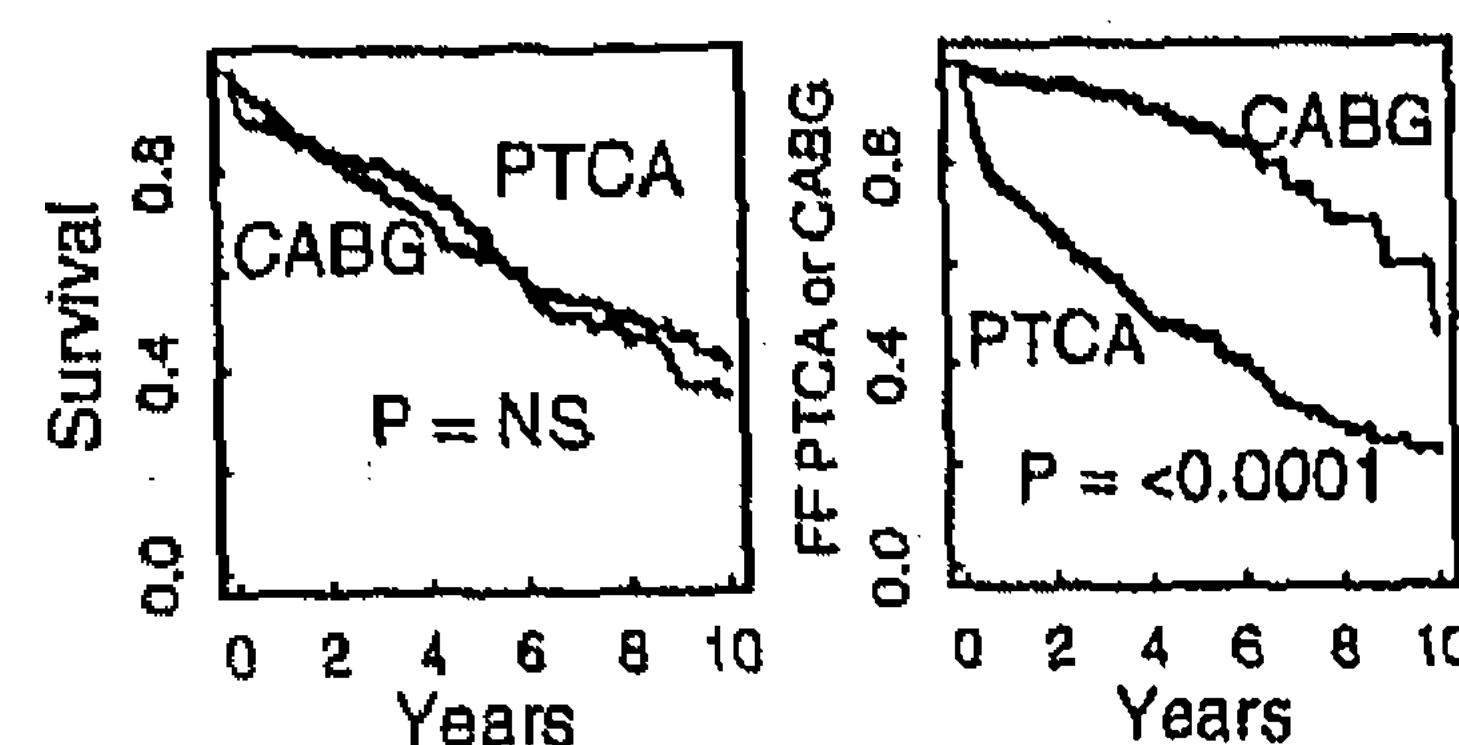
2546

### The Choice of Repeat CABG or PTCA in Diabetics Who Have had Previous CABG

William S Weintraub, Ellis L Jones, Joseph M Craver, Robert A Guyton, Douglas C Morris. Emory University, Atlanta GA USA

Outcome in 1041 diabetics with previous CABG was studied after repeat CABG (n=439) or PTCA (n=602). The PTCA group had more women (26% vs 21%), fewer prior MIs (56% vs 68), less 3 vessel or left main disease (65% vs 81%) & higher EFs (51 vs 49). The groups were otherwise similar. Hospital Q wave MIs occurred more often after (p) CABG (4.8% vs 2.2%), as did death (7.5% vs 2.0%). 5 & 10 year survival was 63% & 41% p PTCA & 68% & 34% p CABG (left figure, p=NS). 5 & 10 year freedom from (FF) MI was 71% & 56% p PTCA & 83% & 60% p CABG (p=0.01). 5 & 10 year FF CABG was 70% & 53% p PTCA & 96% & 79% p CABG (p < 0.0001). 5 & 10 year FF PTCA or CABG was 46% & 23% p PTCA & 91% & 47% p CABG (right figure, p < 0.0001). Any survival difference between groups could be accounted for by the covariates age (OR 1.04 per year), ejection fraction (OR 0.98 per % increase), time from prior CABG (OR 1.05 per year), heart failure (OR 1.71), hypertension (OR 1.40) and emergent or urgent procedure (OR 1.43 and 2.05). Characteristics, in-hospital and followup results and covariates in 284 PTCA & 262 CABG IR patients

were similar. This study reveals that both long term death and non-fatal MI rates are high with either PTCA or repeat CABG. Thus, revascularization choice in diabetics with previous CABG must be made without data to support a survival advantage for either therapy, but rather on clinical, angiographic and patient preference grounds.



2547

### The Association Between a History of Diabetes and Outcome in Patients Undergoing Percutaneous Interventions

R. David Anderson, Nancy W. Wildermann, Robert A. Harrington, Gregory W. Barsness, David P. Faxon, E. Magnus Ohman. Duke University, Durham NC USA, Univ. of Southern California, Los Angeles CA USA

To study the relative importance of diabetes compared with other risk factors for adverse outcomes (death, MI, re-PTCA, CABG) after percutaneous intervention (PCI) we pooled data from 7 multicenter trials. A total of 6338 pts with 6 to 9 mo clinical and angiographic follow-up were included. Diabetics were older (median age 62 v 59), less often male (63 v 78%), smoked less (64 v 74%), had more hypertension (68 v 45%), 3-vessel disease (11 v 6%), prior MI (48 v 45%), prior PTCA (20 v 15%), and prior CABG (23 v 14%). Diabetics and non-diabetics had similar pre-procedure stenosis (69 v 68%) and TIMI 3 flow (71 v 73%). Angiographic success (QCA ≤ 50%) and abrupt closure rates were similar between groups. Diabetics had higher 6 mo restenosis rates (49 v 44% p=0.04). Outcomes are shown in the table. Multivariable regression revealed that a history of diabetes was associated with higher 9 mo composite outcomes after adjusting for base-

	No Diabetes (n=5108)	Diabetes (n=1230)
Death (30d)	27(0.5%)	14(1.2%)
Composite (30d)	586(12%)	138(11%)
Death (9mo)	82(1.6%)	33(2.7%)
Composite (9mo)	1600(33%)	439(38%)

line variables ( $\chi^2=4.05$  p=0.05) but prior MI, pre-procedure stenosis, and # diseased vessels were more predictive ( $\chi^2=69$  p < .001). **Conclusion:** Intermediate outcomes after PCI are best predicted by # diseased vessels, prior MI, and pre-procedure stenosis. Although diabetes predicts composite outcomes, the effect is mild and mostly due to higher restenosis rates.

## Clinical Cardiology:

Coronary Angiography and Diagnostic Imaging

Tuesday Afternoon

Ballroom D2

Abstracts 2548-2557

2548

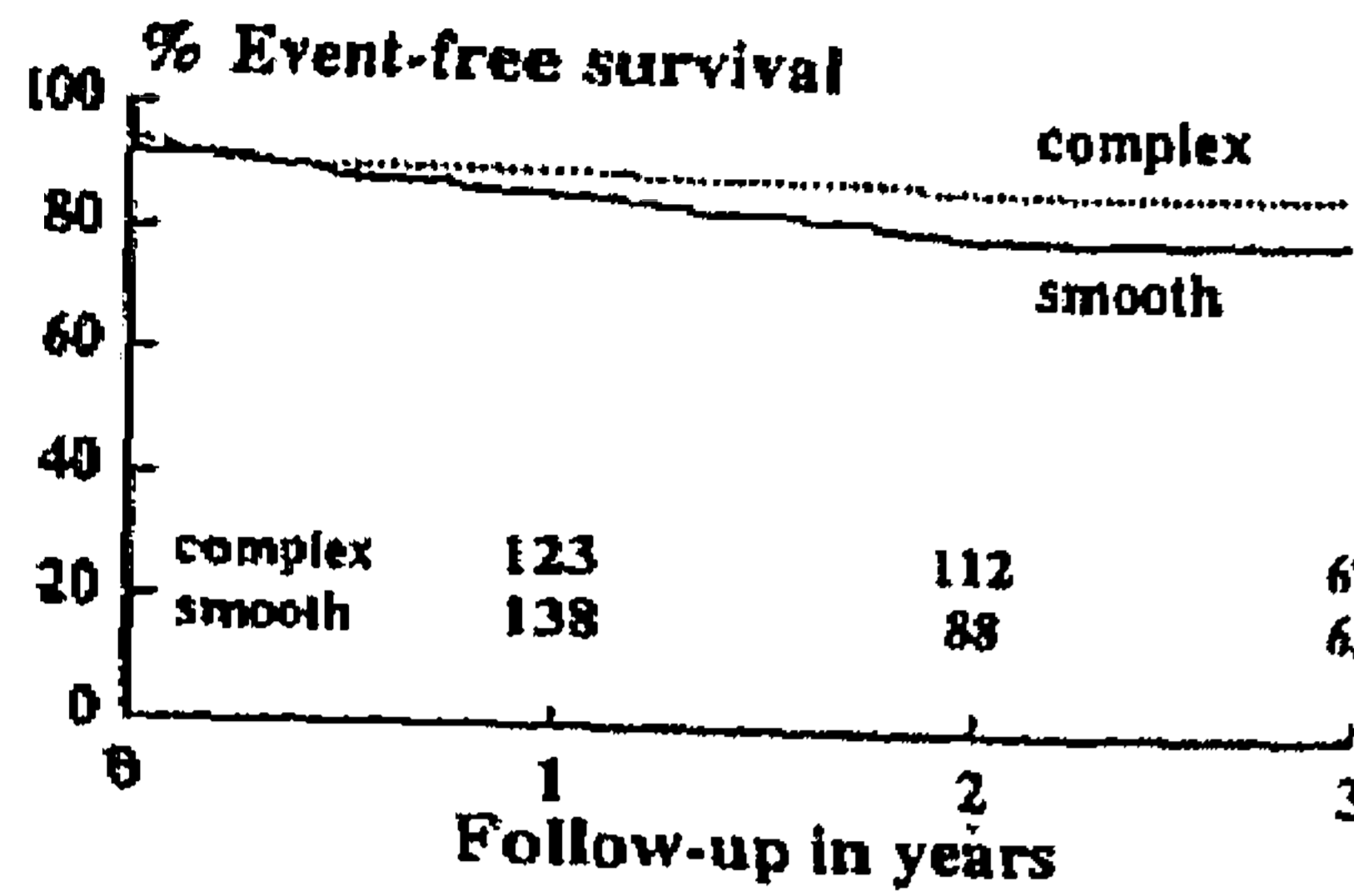
### After Successful Thrombolysis for Acute Myocardial Infarction Culprit Lesion Morphology does Not Predict Early and Long-term Outcome.

Gerrit Veen, Carel C de Cock, Freek WA Verheugt. Free University Hospital, Amsterdam The Netherlands, University Hospital Radboud, Nijmegen The Netherlands

In the APRICOT-study we performed coronary angiography in 284 patients (pts) within 48 (mean 24) hours after successful thrombolysis for acute myocardial infarction (AMI). Culprit lesion morphology was scored as complex or smooth. After 3 months a second angiogram was performed in



249 pts. Follow-up was done up to 3 years. Results: At baseline 161 pts had a smooth and 123 had a complex lesion. There were no differences in age, male/female ratio and quantitative angiographic parameters between these two groups. Complex lesions were more often present in the right coronary artery (55% vs 33%;  $p < 0.005$ ). Reocclusion rate of complex lesions was lower at 3 months (23% vs 34%;  $p < 0.05$ ). Pts with complex morphology had more often multivessel disease (50% vs 37%;  $p < 0.05$ ). The figure shows the 3-years follow-up for the combined endpoint of death and recurrent MI, showing no difference in outcome in relation to culprit lesion morphology. Conclusion: Complex morphology of a culprit coronary lesion early after successful thrombolysis for AMI is not associated with adverse outcome. Possibly related factors are lower reocclusion rate and higher incidence of right coronary involvement.



2549

### Fusion of Intracoronary Ultrasound and Biplane Angiography Images for Accurate 3D Reconstruction of Coronary Arteries

Robert M Colhoun, Raj Shekhar, D G Vince, J F Cornhill. Cleveland Clinic Foundation, Cleveland OH USA, Ohio State University, Columbus OH USA

3D visualization of coronary morphology using intravascular ultrasound (IVUS) may aid in evaluating atheroma progression and treatment efficacy. A method for accurate reconstruction of coronary anatomy using IVUS and biplane fluoroscopy has been developed which depicts true arterial curvature and orientation. The IVUS transducer was tracked in time by back-projection of biplane fluoroscopy during unassisted pullback in perfused non-atherosclerotic LADs *ex vivo*.

The luminal borders from simultaneously acquired IVUS images were placed perpendicular to the transducer path at each time point. Rotational orientation was determined by minimizing the mismatch between vessel outlines in angiograms and the reconstruction projected into that plane. The result was surface-rendered for visualization or planimetry. Vessel curvature, lumen shape, and branch ostia could be easily visualized. Simulated angiograms created by projecting 3D reconstructions to 2D planes compared well with actual angiograms, with up to 71% overlap in lumen area, indicative of the accuracy of the 3D representation. This technique does not depend upon automated pullback and constant-velocity transducer movement, and does not assume the catheter to be straight, torsion-free, or centered in the lumen. This project will be extended to visualize luminal and adventitial surfaces in atherosclerotic arteries, and gated to visualize the vessel during the full cardiac cycle.



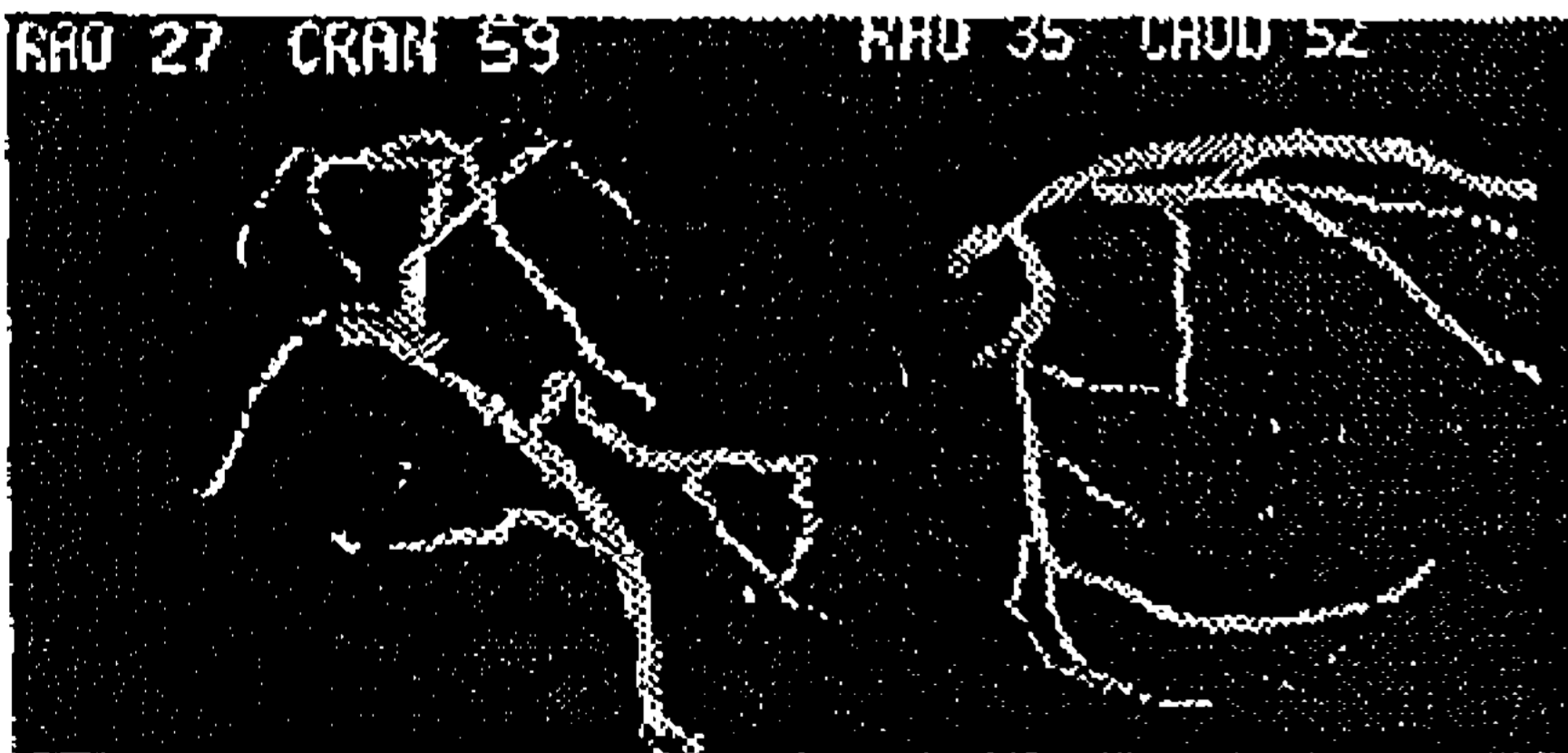
2550

### A 3D Coronary Processing Tool to Optimize Visualization Strategy in the Cardiac Catheterization Laboratory

Shih-Yung J. Chen, Kenneth R. Hoffman, John D. Carroll. University of Chicago, Chicago IL USA, University of Colorado, Denver CO USA

Due to vessel overlap and foreshortening, multiple projections are necessary to adequately evaluate the coronary tree with arteriography. The traditional trial-and-error method provides views in which overlap and foreshortening are subjectively minimized in two dimension. A method has been developed for reconstructing a 3D coronary tree based on two views acquired from routine angiograms at arbitrary orientation. A computer simulation confirmed the accuracy of 3D vessel centerline reconstruction to within 2% error. Based on any coronary stenosis, a plane of gantry angulations minimizing the segment's foreshortening is calculated yielding multiple computer-generated projection images. With this technique, the 3D structures and relationships of arteries can be clearly identified which are unable to be achieved by other modalities such as intracoronary ultrasound or MRI.

To date 3D reconstruction has been performed in 20 RCA, 16 LCA, and 3 bypass grafts. With 3D coronary reconstruction, it is now possible to virtually determine ideal gantry positions. The assessment of lesion length and diameter narrowing can be optimized for both coronary intervention and studies of progression and regression.



2551

### Assessment of Coronary Artery morphology by Three-Dimensional Echocardiography

Beruhard Koltsch, Susanne Mohr-Kakaly, Thomas Meuzel, Stephan Wager, Beate Kollhaus, Thomas A. Fischer, Uwe Nixdorff, Jargou Meyer. Johannes Gutheberg - Universitat, Mainz Germany

The aim of the study was the quantitative assessment of left main coronary artery (LMCA), left circumflex artery (CX) and left anterior descending coronary artery (LAD) morphology using three-dimensional echocardiography. Results were compared to quantitative angiography. Method: The

three-dimensional data set was acquired using a multiplane transesophageal echocardiography-probe (Vingmed CFM 800 and multiplane probe, 5 MHz) by means of a TomTec 3D workstation. 24 patients were examined (mean age 66 years). Results: In all 24 cases (100%) the accurate determination of the ostium of LMCA was possible (intraluminal diameter of the ostium: 1.1 - 5.8mm, analysis of regression compared to angiography:  $r = 0.86$ ). Visualization of LMCA was possible up to the point of bifurcation in 2 cases (length of LMCA was 2.54mm and 10.8mm, length of determined LAD 8.1mm and 8.7mm, CX 3.2mm and 8.0mm), in 21 cases LMCA was visualized partially (6.1mm to 29.3mm, mean 9.5mm). In one case we found by means of 3D echocardiography that CX and LAD arose separately. Results were confirmed using angiography. CX could be reconstructed in 3 cases (length: 3.2mm - 8.0mm, mean 5.9mm, diameter 1.7 - 3.1mm, correlation to angiography  $r = 0.86$ ). LAD could also be determined in 3 cases (length 8.0 - 8.7mm, mean 8.2mm, diameter 2.6 - 3.0mm, correlation to angiography  $r = 0.56$ ). In one case we found a stenosis (lumen diameter 1.1mm) in the visible part of LMCA by means of 3D echocardiography whereas the angiographic examination showed a stenosis of 60% of this artery. In two cases with a bicuspid aortic valve it was possible to describe the exact origin of LMCA. In 5 cases a three dimensional imaging of the aortic valve and the proximal part of the LMCA was possible to get an impression of the morphology of LMCA. Conclusions: 3D echocardiography provides data about the morphology and the course of the proximal left coronary artery, with close correspondence to results obtained by angiography. It improves the non invasive assessment of proximal coronary artery.

2552

### Side Effects of Ionic Versus Nonionic Contrast Media in Cardiology (CIC-Study): A Multicenter Trial on 2690 Patients

Gerhard Hellge, Bernd Vogel, Ulrich Tebbe, Heinrich Kreuzer. Medical Faculty, Goettingen Germany

In behalf of the German Society of Cardiology and Cardiovasc. Res. a study was performed comparing the side effects of ionic (I) and nonionic (NI) contrast materials (CM) in elective cardiology. Methods: The randomized double-blind study enrolled 2690 patients from 8 centers, 1350 received a monomeric ICM (Diatrizoate, Urografin<sup>R</sup>, Schering), 1340 a monomeric NICM (Iopromid, Ultravist<sup>R</sup>, Schering). We documented anamnestic data like atopia, allergy, cardiac status and medication as well as data on CM effects on hemodynamics, rhythm, creatinine and the incidence of adverse reactions, complications and need of therapeutic interventions. The evaluation included logistic regression and calculation of odds ratios for risk factors (SAS<sup>R</sup>). Results: Basic data of the groups were not different, both received 121 ml CM. Major results are given in the table. Odds ratios indicate risk/protective factors for allergic reactions, dyspnoe, angina and bradycardia. Conclusions: Mild and moderate adverse effects were reduced significantly by use of NICM whereas severe reactions requiring major therapeutic interventions and thromboembolic complications occurred very rarely after both CM without significant differences.

Major data (% incidence)	ICM	NICM	signif.
Arrhythmias, total	27.9	4.7	$p < 0.001$
AV-Bloc, Asystole	5.1	0	$p < 0.001$
VT, Fibrillation	0.30	0.22	ns
Adverse reactions, total	14.4	4.5	$p < 0.001$
severe	0.67	0.45	ns
Thrombotic events (TIA,MI)	0.37	0.37	ns

2553

### Are Quantitative Angiographic Results After Coronary Intervention Affected by the Specific Analysis Algorithm?

Alexandra J Lansky, Teraza Y Conway, Yan Zhang, Cynthia Senerchia, Nicole B Burwell, Shigenori Ito, Anthony B Pierre, Lahaina R Hall. Washington Hospital Center, Washington DC USA, Beth Israel Hospital, Boston MA USA, Harvard Medical Center, Boston MA USA

Binary angiographic restenosis rates after balloon angioplasty have varied substantially in new device restenosis trials (CAVEAT: 57%; Benestent: 33%), possibly due to differences in the angiographic algorithms (QCA) used in these studies. To assess the correlation between two QCA algorithms (Artrek; CMS-non GFT), we performed blinded, identical frame QCA in 629 patients before, after, and late following coronary intervention. Pearson correlation (P-Corr) is reported (see Table). Between system differences in pre-MLD were highest in irregular lesions (0.16 mm versus 0.12 mm in smooth lesions;  $p = 0.033$ ). Acute gain (Artrek: 1.54 mm; CMS: 1.53 mm) and late loss (Artrek: 0.80 mm; CMS: 0.85 mm) were similar. No differences in restenosis rates (>50% follow-up stenosis) were identified (Artrek, 39% vs. CMS, 38%). We conclude that between-system QCA differences 1) are highest for pre-MLD, relating, in part, to lesion contour, but 2) do not appear to influence final angiographic results or late restenosis rates using these two systems.

N=629	Artrek CMS	P-Corr	Mean	Difference ± SD
Reference, mm	3.07 ± 0.40	3.22 ± 0.45	0.92†	0.15 ± 0.18†
MLD Pre, mm	0.92 ± 0.32	1.05 ± 0.35	0.81†	0.13 ± 0.21†
Final, mm	2.46 ± 0.51	2.58 ± 0.55	0.92†	0.11 ± 0.22†
Follow-up, mm	1.67 ± 0.70	1.75 ± 0.72	0.96†	0.08 ± 0.19†
% Stenosis Pre	69.9 ± 9.8	67.3 ± 10.0	0.78†	2.7 ± 6.6†
Final	20.7 ± 14.0	21.4 ± 14.7	0.90†	0.7 ± 6.5†
Follow-up	44.4 ± 22.0	44.0 ± 21.4	0.95†	0.5 ± 6.3†

† $p < 0.001$ 

2554

### IMA- AND VEIN GRAFT PATENCY CONTROL BY ECHOCARDIOGRAPHY VERSUS THERMAL CORONARY ANGIOGRAPHY AS COMPARED DURING CORONARY BYPASS SURGERY.

James Likungu, Winfried Rütz, Paul G Kirchoff. Department of Cardiovascular Surgery, Bonn Germany

The values of thermal coronary angiography (TCA) and echocardiography (E) for intraoperative assessment of coronary calcification, graft patency and flow in vein- and internal mammary artery