n = 35 Pts	DS (%)	IAPD (mmHg)
Pre-procedure	72.3 ± 17.2	47.1 ± 24.3
Post-procedure	3.8 ± 13.3	0 ± 4.4
Follow up (27 ± 20 months)		3.2 ± 3.5

DS = Diameter Stenosis, IAPD = Intra-Arm Pressure Difference

Follow up: At a mean follow up of 2 yrs (27 ± 20 months) 32/33 pts (97%) remained asymptomatic. One pt (3%) required repeat balloon angioplasty for restenosis 10 months after the procedure. Two (5.7%) pts died of congestive heart failure at 4 and 28 months respectively.

Conclusion: Stenting of the subclavian and innominate artery can be achieved with high technical success and provides a durable clinical result.

809 Coronary Stenting: Highlighted Abstract Session With Discussion of Current Perspectives

Monday, March 30, 1998, 10:30 a.m.–Noon
Georgia World Congress Center, Lecture Hall 3

10:45

809-2 Coronary Stents Improve Outcome in Acute Myocardial Infarction: Immediate and Long Term Results of the GRAMI Trial

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Background: Stenting as primary therapy in myocardial infarction (AMI) is controversial due to the presence of thrombus.

Methods: 104 patients presenting with AMI <24 hours after onset were randomized to two groups: The Stent group (n = 52) was treated acutely with a GRII stent. The PTCA group (n = 52) received conventional angioplasty. All lesions were suitable for stenting. Baseline demographic, and angiographic characteristics were similar in the two groups. Procedural success was defined as no laboratory death or emergent CABG, TIMI 2 or 3 flow, and residual stenosis ≤30% for PTCA, or <20% for stent. PTCA patients were eligible to cross over to stent for acute closure, type C-F dissections, and residual stenosis >30%. All surviving patients underwent a 7 day angiogram. Long term follow-up was also available.

Hospital Results	Stent (n = 52)	PTCA (n = 52)	p-Value
Procedural success:	98%	94%	NS
Bail out stenting	–	25%	–
Any major adverse event	3.8%	19.2%	0.03
TIMI 3 Flow at 7 days	98%	83.3%	0.028

At one year (range 8–17 months) freedom from major clinical events was higher in the Stent vs. PTCA groups (82.7% and 65.4% respectively, p = 0.002). Target vessel revascularization was 9.6% and 13.4% in Stent and PTCA groups respectively (p = NS).

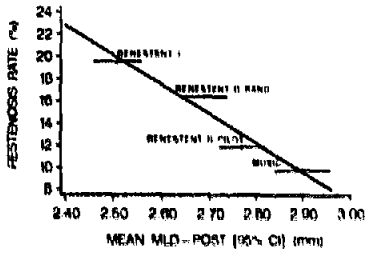
Conclusions: A coronary stent as primary therapy in AMI reduces acute complications and improves TIMI 3 flow. On follow-up freedom from major clinical events is also better.

11:00

809-3 Peri-procedural QCA Following Palmaz-Schatz Stent Implantation Predicts Restenosis Rate at 6 Months: Result of a Meta-analysis of BENESTENT-I, BENESTENT-II Pilot, BENESTENT-II and MUSIC

P.W. Serruys, J. Kootstra, R. Melkert, P. de Jaegere, M. van den Brand, M. Morel. *Thoraxcenter, Cardialysis, Rotterdam, NL, USA*

Between 91 and 97 four trials using the same stent have been coordinated in Cardialysis. QCA has been performed on 804 lesions, using the same methods of analysis (CAAS system). Measurement of MLD, interpolated reference diameter and DS% (pre, post and at f-up) were matched for multiple angiographic views. Over this span of time the restenosis rate (RR) has decreased from 20% (BENESTENT-I) to 10% (MUSIC) while the MLD post-stent has increased from 2.51 mm (BENESTENT-I) to 2.90 mm (MUSIC) in vessels of similar size (3.05 mm) and in pts with comparable demographic baseline characteristics.



From previous multivariate analysis of QCA parameters it appears that LAD, vessel size (VS), MLD_{post}, MLD_{pre} and gain were important variables for prediction of MLD at f-up and RR. These variables were anew statistically tested on a larger population in the meta-analysis resulting in two multivariate models: in the first model all above mentioned variables were tested excluding gain, whereas in the second MLD-post was excluded. For model 1: logit(p) = 1.96 – 1.25 × VS, for model 2: logit(p) = 3.31 – 0.68 × VS –1.17 × MLD_{post}. The Hosmer and Lemeshow test for goodness-of-fit demonstrates the superiority of model 2.

Conclusion: This angiographic meta-analysis confirmed the 'bigger is better' hypothesis in a very homogeneous population treated with the same device and analysed according to consistent methodological approaches in the same angiographic core-lab over a period of 7 years.

11:15

809-4 Neurological Events After Successful Carotid Stenting

M.W. Liu, G.S. Roubin, A. Mathur, S.S. Iyer, L.S. Dean, N.A. Al-Mubarak, J. Vitek, C. Gomez, J. Terry, G. Yates, K. Kretzer, D. Alred. *University of Alabama at Birmingham, Birmingham, Alabama, USA*

Background: Carotid endarterectomy has been shown to reduce neurological events in patients with severe extra-cranial internal carotid stenosis. Carotid stenting has been investigated as a less invasive alternative treatment for carotid stenosis. The long-term neurological events after successful carotid stenting have not yet been reported.

Methods: From Sep. '94 through Jan '97, there were 228 patients with internal carotid stenosis ≥60% that underwent carotid stenting. Percutaneous femoral approach was used. Neurological evaluation was performed by a neurologist before and after the stenting and at 6 month follow-up. Clinical follow-up information was obtained in all patients except one.

Results: Mean age was 68 ± 10 years. There were 161 males, 169 with co-existing severe coronary artery disease. Forty patients underwent bilateral carotid stenting, 27 had a contralateral occlusion and 132 were symptomatic due to the target lesions. Palmaz stents were used in 90 patients and Wallstents in 126. The pre and post stenting diameter stenoses were 77 ± 13% and 3 ± 9%. Five procedures were technical failures and are excluded from the survival analysis. There were 9 procedure related minor strokes and 2 major strokes. Follow-up at 14.3 ± 8.5 months (range 6 to 33 months) showed 4 minor strokes, no major strokes and one neurological death. Cumulative survival free of any stroke or neurological death was 96 ± 1% at hospital discharge, 94 ± 2% at 1 year and 91 ± 3% at 2 years. Cumulative survival free of any major stroke or neurological death was 99 ± 1% at hospital discharge, 99 ± 1% at 1 year and 99 ± 1% at 2 years.

Conclusion: Neurological events after successful carotid stenting appear to be rare in follow-up. This suggests carotid stenting may be an effective treatment strategy in preventing stroke in patients with severe carotid stenosis.

11:30

809-5 Six-Month Clinical and Angiographic Results of the SMART Trial

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Background: The SMART Trial is a prospective, randomized, multicenter, comparative trial of the AVE Micro™ Stent II and the Palmaz-Schatz™ (P/S) stent in de novo and restenotic coronary lesions up to 30 mm in length.

Methods: Patients were enrolled and randomized to receive either the AVE stent (n = 330) or the P/S stent (n = 331).