0.0001). Also, no relationship between FC and culprit stenosis (measured by quantitative angiography) was found ($r = 0.17$, $p = 0.3$). Thallium score was similar in pts with TIMI II (1.3 ± 0.8) and TIMI III flow (1.2 ± 0.8, $p = 0.9$).

Conclusion: Angiographic assessment of myocardial perfusion in the infarct related artery does not correlate with scintigraphic assessment of myocardial viability and, therefore, does not appear to offer an advantage compared to TIMI flow grading.

975 Use of Stents in the Real World

Tuesday, March 26, 1996, 3:00 p.m.–5:00 p.m.
Orange County Convention Center, Hall E
Presentation Hour: 3:00 p.m.–4:00 p.m.

975-69 Initial and Six Months Outcome of Palmaz-Schatz Stent Implantation: STRESS/Benestent Equivalent Vs Non-equivalent Lesions

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To assess efficacy of the Palmaz-Schatz stent (PS) for lesions (les) currently excluded from randomized trials, the immediate and 3–6 months (M) follow up (FU) results were compared between Stress/Benestent (S/B) equivalent les ($n = 152$) and Non-S/B les ($n = 593$): Small vessel (Ref. $D < 3.0$ mm, $n = 236$), Long les (length > 15 mm, $n = 125$), Ostial les ($n = 97$), Total occlusion ($n = 40$), Vein graft ($n = 52$), Restenotic les ($n = 301$), Poor LV ($n = 96$). Before Jul. 1994, 700 patients (pts) (745 le.) underwent PS implantation and 3–6 M FU quantitative angiography was performed in 689 les (93%).

	SAT (%)	D/C/M (%)	Reste. (%)	TLR (%)	MLD (mm) pre	post	FU
S/B Equivalent	1.3	6.6	11	8.6	0.9 ± 0.4	3.0 ± 0.4	2.3 ± 0.6
Non-S/B							
Small	1.5	8.0	30*	19*	0.7 ± 0.4*	2.6 ± 0.4*	1.7 ± 0.7*
Long	1.6	4.8	32*	15	0.6 ± 0.5*	2.8 ± 0.6*	1.9 ± 0.9*
Ostial	2.1	11*	40*	14	0.7 ± 0.5*	2.9 ± 0.5*	1.8 ± 1.0*
Total	0	2.5	40*	7.5	0.0 ± 0.1*	2.7 ± 0.7*	1.6 ± 0.9*
Vein	0	5.8	34*	21*	0.9 ± 0.6	3.2 ± 0.5*	2.1 ± 1.1
Reste.	1	4.0	27*	15*	0.8 ± 0.4*	2.9 ± 0.5*	1.9 ± 0.8*
Poor LV	3.1	14	19	14	0.7 ± 0.5*	3.0 ± 0.5	2.1 ± 0.8

SAT: Subacute thrombosis. D/C/M: Death/CABG/MI at 7 M. Reste: Binary restenosis at 7 M. TLR: Target lesion revascularization at 7 M. *$p < 0.05$ compared with Stress/Benestent Equivalent les.

Conclusion: S/B equivalent les constituted relatively small fraction of les. treated in clinical practices. Immediate results of Non-S/B equivalent les were similar to those of S/B equivalent les. However, FU results of Non-S/B lesion were not comparable to those of S/B les.

975-70 Coronary Perforation: An Unreported Complication After Intracoronary Stent Implantation

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Coronary artery perforation is an uncommon complication after percutaneous intervention, and has not been reported after stent implantation. To determine the incidence of perforation associated with stenting, we reviewed all stent procedures between September, 1993 and May 31, 1995. Among 928 stents deployed in 435 patient there were 10 perforations (2.3%; 6 Palmaz-Schatz, 2 biliary, 4 Gianturco-Roubin). Stent implantation was planned in 3 cases and unplanned in 7 cases (due to severe dissections after another device). Angiographic features associated with perforation included ACC/AHA B2 or C lesion morphology (80%); small vessel diameter (2.6 ± 0.2 mm); oversized stents (Stent/Artery ratio 1.4 ± 0.1); tapering vessel (40%); and need to recross a dissection with a guidewire (20%). Major clinical sequelae included cardiac tamponade (50%), myocardial infarction (40%), emergency surgery (50%), and death (30%). Two cases of tamponade occurred between 5–24 hours after stent deployment in patients without angiographic evidence of perforation.

In conclusion: Coronary perforation is uncommon after stent implantation but may occur in the setting of antecedent severe dissection in small vessels treated with oversized stents. Careful attention to stent size and avoiding high pressure inflations outside the stent may prevent stent-perforation.

975-71 Coronary Stenting in Elderly Patients. Results From the Stent Without Coumadin French Registry

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To evaluate the results of coronary stent placement in elderly patients, a retrospective analysis of the 2901 Pts (mean age: 61.2 ± 10.6 years) included from March 1991 to March 1995 in the Stent Without Coumadin French Registry was performed.

Ticlopidine (250–500 mg/day) was given the day of PTCA for 1 month, aspirin (100–250 mg/day) for > 6 months and low molecular weight heparin (antiXa 0.5–1) for 1 month in phase II (237 Pts), 15 days in phase III (521 Pts), 7 days in phase IV (960 Pts) and not given in phase V (1183 Pts).

The study group include 245 Pts (8.4%) aged $\geq$ 75 years. Nineteen % were female, 49% had unstable, 8% Post M.I ischemia, 2% acute M.I and 41% stable angina. Indication for stenting was respectively: de novo lesion (27%), restenosis (17%), suboptimal result (20%), non occlusive dissection (24%) and occlusive dissection (11%). Stented coronary arteries were LAD: 44%, RCA: 33%, Cx: 16%, L.M: 2% and Bypass: 2%). Palmaz-Schatz stents were used in 79% of cases, AVE stents in 16% and other stents in 5%. One stent was used in 80% of cases and more than 1 in 20%. Balloon used for stenting was 3.32 ± 0.38 mm in diameter with a mean inflation pressure of 12.3 ± 3.0 atm. At 1 month follow-up, vascular complication occurred in 2% of cases (requiring surgery in 1.2%), acute closure in 0.4%, subacute closure in 1.6%, emergency CABG in no case, acute M.I in 1.6%, stroke in 0.4% and death in 3%. The composite end-point of subacute closure, acute M.I., CABG and death occurred in 5% of cases.

In conclusion: coronary stenting without coumadin seems to be a safe approach in elderly patients.

975-72 Coronary Angioplasty Versus Primary Stent Placement for Isolated Proximal Left Anterior Descending Coronary Artery Stenosis

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Proximal left anterior descending coronary artery (LAD) stenosis carries a poor prognosis. Coronary angioplasty (PTCA) has been shown to be a suitable alternative to left internal mammary artery grafting which is considered to be the standard treatment. However, no data are available concerning primary stent (S) placement. To this end we have carried out a prospective study aimed at comparing the efficacy of PTCA or S placement in the treatment of patients (pts) with isolated proximal LAD stenosis. Eligible pts were randomly assigned to PTCA (56 pts; mean age 57 ± 10 yrs) or S (Palmaz-Schatz) placement (60 pts; 57 ± 9 yrs). Pre-intervention clinical and hemodynamic variables did not differ between groups. Follow-up angiograms were obtained in 80% of PTCA-treated pts and in 87% of S-treated pts. Procedure and early and 12-month clinical outcomes were as follows (mean values):

	PTCA	S	
Vessel diameter (mm)	3.1	3.2	NS
Baseline % diameter stenosis	92	91	NS
Final % diameter stenosis	20	3	$p = 0.001$
Procedure success (%)	95	97	NS
In-hospital complication (%)	0	6	NS
12-month restenosis rate (%)	40	19	$p = 0.04$
12-month event-free survival (%)	69	90	$p = 0.02$

Thus, the findings of this study indicate that, in symptomatic pts with proximal LAD stenosis, primary S placement, compared to PTCA, showed: 1) a superior initial angiographic result; 2) a lower 12-month restenosis rate and 3) a more favorable 12-month clinical outcomes.

975-73 Rotational Atherectomy Prior to Stent Implantation

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The safety and efficacy of Palmaz-Schatz stents for the treatment of suboptimal rotational atherectomy (RA) results or as an adjuvant to RA for calcified coronary lesions was assessed in 127 pts. In 50% stents were planned. In 50% stents were placed for suboptimal RA results. The planned and unplanned stent groups were similar in AHA/ACC Lesion Class: B_1 25%, B_2 43%, C_1 32%, mean distal reference diameter (2.75 mm) and mean lesion length (7.453 mm). Vessels treated: LAD 34%, RCA 36%, circumflex 21%, protected left main 7%, unprotected left main 2%. High-pressure (> 16 atm) balloon inflation was performed in all stents. Procedural success (< 50% diameter stenosis without Q-wave MI, bypass surgery or death) was achieved

in 96%. There were 3 Q-wave infarcts (3%) and 1 death (1%). A non-Q-wave infarct was sustained by 6 pts (5%) and 1 pt (1%) required emergency bypass surgery.

The pre and final MLD for both groups was 0.72 and 2.75 mm (diameter stenosis of 75.8 and −11.4%). Patients were discharged on aspirin (ASA) and warfarin 54%, ASA and ticlopidine 42%, or ASA, ticlopidine and low molecular weight heparin 4%. Mean 18-month follow-up on 77% demonstrated: target lesion reintervention 5%, CABG 3%, stent thrombosis 0%, death 5%.

Conclusion: Stent deployment for suboptimal RA results or as an adjunct treatment of calcified coronary lesions provides excellent angiographic results (−11.4% final stenosis) with few major procedural complications.

975-74 Coronary Stent Implantation in Aorto-Ostial Lesions: Immediate and Follow-up Results

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Treatment of aorto-ostial lesions by conventional balloon angioplasty and other new devices (laser, atherectomy devices) is limited by high restenosis rates of up to 60%. This study evaluate immediate and long-term results of stent implantation in aorto-ostial lesions. We treated 35 ostial lesions in 35 patients (mean age 61 ± 13 years, 88% males). The lesion distribution was: 17 ostial RCA, 13 saphenous vein graft aorto-ostial anastomoses and 5 ostial Left Main lesions. Stent indications were: 23 elective (66%), 6 restenosis (17%), 5 suboptimal PTCA result (14%) and 1 dissection (3%). Procedural success was achieved in all attempted procedures. Rotablator was performed prior to stenting in 6 patients. A total of 41 stents were implanted: 21 standard Palmaz-Schatz, 12 short Palmaz-Schatz, 6 biliary Palmaz-Schatz, 1 Wiktor and 1 Gianturco-Roubin stent. Angiographic results are shown in the table:

	Baseline	Post stent	Follow-up
MLD (mm)	0.85 ± 0.62	3.51 ± 0.65	2.48 ± 0.93
%Stenosis	75.2 ± 17.8	−9.2 ± 22.9	26.1 ± 19.3

MLD = minimal lumen diameter

Angiographic follow-up was performed in 29 patients (69% of eligible patients) and restenosis occurred in 5 lesions (23%). *Conclusion:* Stenting of suitable aorto-ostial lesions has favorable immediate and medium-term results and a lower restenosis rate compared to the historical group of patients having treatment by other interventions.

975-75 A Highly Significant 40% Reduction in Ischemic Complications of Percutaneous Coronary Intervention in 1995: Beginning of A New Era?

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1995 was marked in the U.S. interventional community by a dramatic upswing in the number of patients (pts) treated (rx'd) with elective stents, and the first availability of the antiplatelet agent ReoPro. At our center, physicians also were tracked for the first time by pt cost. By mid-year we noted a considerable reduction in ischemic events and this study was formally undertaken to assess differences in pt demographics and outcome for 1995 compared to 1993–94. Pts presenting with acute MI were excluded.

	1993–94 (n = 3732)	1–8/1995 (n = 1260)	p
Age (yrs)	62 ± 11	64 ± 11	< 0.001
Angina at rest (%)	41.7	43.1	0.36
Most complex lesion B2 or C (%)	58.5	51.0	< 0.001
Elective stent (%)	4.8	22.8	< 0.001
ReoPro (%)	0.0	7.0	< 0.001
Cardiac death (%)	0.8	0.6	0.61
Emerg CABG (%)	1.4	0.8	0.06
Q wave MI (%)	1.3	0.5	0.003
Death, Q wave MI, Emerg CABG	3.0	1.7	0.004

Logistic analysis disregarding any particular rx, but correcting for 11 variables [including most complex lesion: odds ratio (OR)/unit (A = 1, B1 = 2, B2 = 3, C = 4) = 2.4, p < 0.001; prior CABG:OR = 0.6, p = 0.005; and shock: OR = 3.1 p = 0.006] found rx in 1995 still to be related to risk of death, MI or CABG (OR = 0.6, p = 0.05). Rx in 1995 became clearly unrelated to outcome (OR = 0.8, p = 0.28) when the variable "stenting in 1995" was added.

Conclusions: Complications of percutaneous intervention appear to be reduced in 1995, possibly due to a decrease in lesion complexity, more elective stenting and other factors.

975-76 Elective Coronary Stenting Versus Balloon Angioplasty in Smaller Native Coronary Arteries: Results From STRESS

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Palmaz-Schatz stents have been designed and FDA-approved for large coronary arteries with diameters ≥ 3.0 mm. The goal of this STRESS Trial substudy was to compare the efficacy of elective stent implantation and angioplasty (PTCA) for new lesions in smaller native coronary arteries. Of 407 patients enrolled in this prospective randomized trial, 214 (53%) patients were determined by core laboratory quantitative analysis to have reference vessel diameters < 3.0 mm. 111 patients were assigned to PTCA (mean diameter 2.65 ± 0.24 mm) and 103 patients were assigned to stenting (mean diameter 2.71 ± 0.21 mm). Endpoints were analyzed by intention-to-treat. Baseline clinical and lesion characteristics were comparable for the two groups. Abrupt closure (in or out of lab) occurred in 3(2.7%) patients in the PTCA group and 4(3.9%) patients in the stent group (p = ns). Minimal lumen diameters in mm were as follows:

Group	Baseline	Post Procedure	6 month F/U	Net Gain
PTCA	0.68 ± 0.21	1.78 ± 0.36	1.30 ± 0.52	0.63 ± 0.53
Stent	0.72 ± 0.25	2.29 ± 0.38	1.56 ± 0.56	0.84 ± 0.59
p	ns	<0.0001	0.001	0.013

Thus, stenting conferred a larger initial lumen which persisted after 6 months. Restenosis (≥ 50% diameter stenosis at follow-up) occurred in 44/84(52%) patients assigned to PTCA and in 33/93(35%) patients assigned to stenting (p = 0.024). There were no significant differences in clinical events between the two groups. Target lesion revascularization was performed in 25(23%) PTCA patients and 16(16%) stent patients (p = ns). In conclusion, the results of this STRESS Trial substudy suggest that elective stent placement provides superior angiographic outcome and less restenosis than PTCA in vessels slightly smaller than 3 mm.

976 Restenosis: Proliferation and Migration

Tuesday, March 26, 1996, 3:00 p.m.–5:00 p.m.
Orange County Convention Center, Hall E
Presentation Hour: 4:00 p.m.–5:00 p.m.

976-45 High Plasma Angiotensin-Converting Enzyme Levels, and Insertion/Deletion Genotype Are Associated With Restenosis After Coronary Stenting

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Angiotensin-converting enzyme (ACE) I/D genotype does not appear to be consistently associated with restenosis after balloon coronary angioplasty. The ACE genotype determines plasma levels of the enzyme. Via Angiotensin II, ACE can promote smooth muscle cell proliferation. This is reported to be the most important component of restenosis after coronary stenting (CS), but not after balloon dilatation. We investigated the relationship between ACE plasma levels, I/D ACE genotype, and long-term restenosis after CS.

Sixty-three consecutive patients (p) were treated with a first, elective, single-vessel CS. Basal plasma ACE levels were measured with a quantitative kinetic determination using FAPGG substrate (mean normal values 30 + – 10 U/L), and a complete laboratory screening was obtained in all p. Amplification by polymerase chain reaction was used in the determination of ACE gene polymorphism. No p received ACE-inhibitor therapy throughout the study. Restenosis was defined as the presence of > 50% stenosis of the treated lesion, as measured with a Philips DCI Quantitative Coronary Angiography system at 6-month angiographic follow-up. Plasma ACE levels and I/D polymorphism in p with and without restenosis were as follows (percentages in brackets):

	No.	ACE(U/L)	D/D	I/D	I/I
Restenosis	13	47.3 ± 17#	11 (85)*	2 (15)	0
No Restenosis	50	20.5 ± 11#	15 (30)*	25 (50)	10 (20)

#p < 0.0001; *p < 0.001