821 Coronary Stenting: Procedural Considerations

Monday, March 30, 1998, 4:00 p.m.-5:30 p.m.
Georgia World Congress Center, Lecture Hall 3

4:00

821-1 Routine High Pressure Post-stent Dilatation did Not Influence Clinical Restenosis in STARS

R. Mehran, J.J. Popma, D.S. Baim, A.J. Lansky, A.S. Abizaid, J.F. Saucedo, K.M. Kent, L.F. Satler, A.D. Pichard, R.E. Kuntz, K. Ho, M.B. Leon. *Washington Hospital Center, Washington DC, USA*

Prior studies have suggested a relationship between high pressure and oversized balloon dilation and excessive late lumen loss after coronary stenting. To determine the clinical consequence of high pressure dilation on late clinical recurrence after optimal stent placement, we reviewed the clinical course of 1650 patients enrolled in the Stent Antithrombotic Regimen Study (STARS). Balloon:artery ratios were determined using quantitative methods (CMS). An injury score (IS) was defined as: *0* (adjunct PTCA pressure ≤ 16 atm & balloon:artery ratio ≤ 1.1), *1* (adjunct PTCA pressure >16 *or* balloon:artery ratio >1.1, and *2* (adjunct PTCA pressure >16 & balloon:artery ratio >1.1)

Mm	≤ 2.76	2.76-3.25	>3.25	p value
Reference, mm	2.5 ± 0.2	3.0 ± 0.1	3.6 ± 0.3	<0.0001
MLD, post	2.2 ± 0.4	2.5 ± 0.4	2.9 ± 0.5	<0.0001
% Stenosis, post	18 ± 14	20 ± 13	21 ± 12	<0.0001
Balloon:artery	1.3 ± 0.2	1.1 ± 0.1	1.1 ± 0.1	<0.0001
PRES, atm	17.4 ± 3.0	17.8 ± 2.0	17.7 ± 3.0	0.219
Target Site Revasc	12%	11%	4%	<0.0001

A multivariable model demonstrated that final MLD and vessel size (OR = 0.431; p < 0.0001) and *not* the injury score (OR = 0.90; p = 0.680) was related to late TSR. *We conclude* from STARS, high pressure post-stent balloon dilatation was not associated with higher clinical restenosis rates.

4:15

821-2 A Comparison of the Long AVE Micro™ Stent II and the Palmaz-Schatz® Stent: A SMART Trial Registry

R. Heuser, R. Kuntz, A. Lansky, K.K.L. Ho, L. Reduto, R. Badger, L.A. Iannone, P. Whitlow, R. Vlietstra. *Columbia Medical Center, Phoenix, AZ; Beth Israel Deaconess Medical Center, Boston, MA, USA*

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. A non-randomized registry of patients with long lesions (mean = 22.6 ± 10.1 mm by QCA) who received the 39 mm AVE MicroStent II was also conducted.

Methods: The data from the 39 mm AVE Micro Stent II implantations (n = 160) were compared to the data for the P/S stent implantations (n = 331) from the randomized trial.

Results: The demographics and 6-month clinical data are:

Demographics	AVE	P/S	p
Single vessel disease	82 (51%)	242 (73%)	<0.001
Double vessel disease	48 (30%)	70 (21%)	0.033
Triple vessel disease	30 (19%)	19 (6%)	<0.001
Prior MI	66 (42%)	103 (31%)	0.025
Prior CABG	23 (14%)	17 (5%)	0.001
CCS III or IV	109 (68%)	230 (69%)	NS
HTN (Rx required)	95 (59%)	190 (58%)	NS
Hyperlipidemia (Rx req.)	69 (43%)	101 (31%)	0.011
Diabetes Mellitus	41 (26%)	57 (17%)	0.03
Lesion length	22.6 ± 10.1	12.1 ± 6.2	
Clinical Results	AVE	P/S	p
Acute procedural success	89.4%	94.7%	NS
TLR	9.2%	8.1%	NS

Conclusion: In spite of a higher risk population in the AVE group, 6-month efficacy of the 39 mm AVE stent and the P/S stent were not significantly different.

4:30

821-3 The Wallstent in Native Coronary Arteries (WIN) Multicenter Randomized Trial: In Hospital Acute Results

L. Bilodeau, T. Schreiber, J.D. Hilton, S. Rosenblum, S. Mehta, M. McIver, Z. Krajcer, B.H. Wilson, C. Senerchia, L.D. Beck, A. Pedan. *Montreal Heart Institute, Montreal, Canada*

The WIN study is a randomized trial comparing the clinical and angiographic outcome of balloon angioplasty (BA) to Wallstent (ST) implantation, during in-hospital stay and at 6 month follow-up. A total of 464 pts (62 ± 11 yr, 72% male) were randomized to either BA (235) or ST (229). Eighty three percent of pts had unstable angina and 18% presented a restenotic lesion. Target lesion types were 26% B1, 41% B2, and 18% C (15% unclassified); vessels were: 23% LAD, 26% CX, and 48% RCA. In the BA group, 25.7% of pts received a bail out stent according to stringent preset criteria. Procedural success was 99.2% in the ST group and 97.8% in the BA according to the actual protocol. Abrupt and subacute closure were observed in 3 and 2 pts in the ST group compared to 4 and 3 pts in the BA group, respectively (p = NS).

Conclusion: Acutely the Wallstent is as effective as balloon angioplasty. The 6-month clinical follow-up will be presented.

In-Hospital Events

	ST (n = 229) n (%)	BA (n = 235) n (%)	p
30 day death	1 (0.4)	1 (0.4)	0.99
Em CABG	1 (0.4)	2 (0.9)	0.58
Q MI	0 (0.0)	1 (0.4)	0.32
NQ MI	16 (7.0)	12 (5.1)	0.40
CVA	1 (0.4)	0 (0.0)	0.31
CABG	1 (0.4)	2 (0.9)	0.58
Re PTCA	6 (2.6)	2 (0.9)	0.14
Combined	22 (9.6)	13 (5.5)	0.10

4:45

821-4 A Multicenter Randomized Trial Comparing Five Different Types of Slotted-Tube Stents

J. Hausleiter, J. Dirschinger, H. Schühlen, W. Giehrl[1], H. Waller, J. Pache, S. Elezi, A. Wehinger, P. Boekstegers[1], G. Steinbeck[1], A. Schömig. *Deutsches Herzzentrum & Klinikum rechts der Isar, TUM, Germany; [1]Klinikum Großhadern, LMU, Munich, Germany*

Background: The impact of different stent designs on procedural success and major adverse cardiac events (MACE) is not known.

Methods: We conducted a multicenter randomized trial comparing 5 different commercially available slotted-tube stents. Four stent types (Palmaz-Schatz (PS), Johnson & Johnson; NIR, Boston Scientific; Pura A; Devon Medical; ID, Inflow Dynamics) were implanted as bare stents hand-mounted on standard balloon catheters. The Multilink stent (ACS) was used with its stent delivery system (SDS). From May 96 until May 97, 1126 patients were randomized. By August 97, complete 30-days follow-up data are available in 90.5%.

Results: On intention-to-treat basis, overall success rate without MACE at 30-days follow-up was 94.8% with PS, 94.7% with NIR, 96.6% with Pura A, 94.3% with ID and 95.6% with ACS. However, in 14% this was only achieved after deploying stents of other type. 30-day success without MACE, and without deployment of stent types other than randomized, was achieved in 85.9% of PS, 90.3% of NIR, 90.7% of Pura A, 93.3% of ID and 64.2% of ACS. Based on the actually implanted stent type, the occlusion rates were 1.2% for PS, 2.2% for NIR, 1.8% for Pura A, 2.0% for ID, and 1.4% for ACS.

Conclusions: These preliminary data suggest significant differences in procedural success rates, predominantly reflecting differences in trackability. However, MACE and occlusion rates are not significantly different between stent types.

5:00

821-5 Late Quantitative Angiographic Results After NIR Stent Use: Results From the NIRVANA Randomized Trial and Registries

A.J. Lansky, J.J. Popma, R. Mehran, J.F. Saucedo, A.S. Abizaid, C. O'Shaughnessy, J.B. Hermiller, D. Cutlip, R.E. Kuntz, D.S. Baim, M.B. Leon. *Washington Hospital Center, Washington DC, USA*

The NIR Stent is a novel, stainless steel, continuous weave multicellular stent with 7 (2.5–3.5 mm stents) or 9 (3.5–4.0 mm stents) adaptive cells that confer unique flexibility when unexpanded and support and vessel conformability when expanded. The clinical safety and efficacy of the NIR stent in *de novo*

MONDAY ORAL