1080 Stents: New Devices and Techniques

Wednesday, March 19, 1997, 3:00 p.m.–5:00 p.m.
Anaheim Convention Center, Hall E
Presentation Hour: 3:00 p.m.–4:00 p.m.

1080-13 A Multi-Menter Pilot Study of a Serpentine Balloon-Expandable Stent (beStent™): Acute Angiographic and Clinical Results

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The beStent is a new stainless steel balloon-expandable mesh stent which has a unique serpentine design. Rotation of the unique low-stress junctions upon expansion leads to orthogonal locking of the wires, maximizing radial strength and assuring zero shortening. The stent has delineating gold markers which assure precise positioning. We aim to present the initial acute results in a pilot registry for stent evaluation. 284 stents were used in a total of 217 patients (pts) (age 57.9 ± 3.10; M-178; F-39) in 7 centers, for variable indications. Stents of 15, 25 and 35 mm length were used. The arteries treated were LAD (n = 112, 42%), Circumflex (n = 54, 20.2%), RCA (n = 95, 35.5%) left main (n = 1, 0.4%), and vein graft (n = 5, 1.9%). Lesion types were: A in 42 pts (16.5%); B1 in 53 pts (20.7%); B2 in 81 pts (31.8%); C in 79 pts (31%). 159 pts required 1 stent, 40 pts required 2 stents and 18 pts required 3 or more stents. Anticoagulation protocol included procedural heparin with aspirin with/without ticlopidine. Smooth angiographic results were obtained in all cases with no plaque herniation. Acute angiographic success was obtained in 99% of the pts, and acute clinical success in 97.7% of the pts. Complications were: 2 (0.92%), non-cardiac death; 2 (0.92%), myocardial infarction; 2 (0.92%), stent thrombosis. Therefore, the beStent is useful in treatment of complex lesions of variable length and complexity, providing excellent acute results with a low complication rate, in spite of unfavorable basic clinical and angiographic characteristics.

1080-14 Preliminary Results of the Canadian Cordis Stent Study

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The Cordis coronary stent is made of a single continuous tantalum wire formed into a sinusoidal ribbon that is helically wound to form hoops along the long axis of the device. This new stent design provides good flexibility and radio-opacity.

Between December 1995 and June 1996, 115 pts with de novo (87%) or restenotic coronary lesion (13%) were treated with implantation of 1 (109 pts) or multiple (6 pts) Cordis stents. In this cohort, the mean age was 57.8 ± 9.4 y, 75.7% pts were male and 42.6% presented with unstable angina. Target vessel was the RCA in 30.5%, the LAD in 42.6% and the circumflex artery in 26.9% of cases. Lesion types (ACC/AHA) were distributed as follow: 37.4% type A, 33.9% type B1, 27.0% type B2 and 0.9% type C. After stent delivery, high pressure (≥ 15 atm) intrastent inflation was systematically performed. Postprocedure therapy consisted of aspirin and Ticlopidine. Successful stent delivery was achieved in 111 out of 115 pts (96.5%). In hospital, no death or Q-wave MI were recorded but 2 patients suffered a non-Q wave MI. At 1 month, only one patient needed repeat intervention.

Procedural quantitative coronary angiography available on the first 80 pts revealed a lesion length of 11.36 ± 3.66 mm with an interpolated reference diameter of 3.09 ± 0.44 mm. Preprocedure, minimum lumen diameter (MLD) was established at 0.94 ± 0.39 mm. Postballoon prestent MLD reached 1.88 ± 0.35 mm and final instent MLD was evaluated at 2.48 ± 0.45 mm. Disturbed geometry (uneven struts separation) after final stent expansion was observed in 31.7%. *Conclusion:* The Cordis stent implantation for short de novo or restenotic lesion seems to be feasible and safe. Visually assessed disturbed stent geometry albeit frequent seem to be devoided of acute complication. The acute and 6-month clinical and angiographic follow-up of the entire cohort (115 pts) will be presented.

1080-15 QCA Comparison of J&JIS, Cook Flexstent, AVE Micro Stent and ACS Multilink Stents

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To compare mechanical properties of stents currently available in the USA, we performed QCA assessment of minimal luminal diameter (MLD), lesion length, and percent diameter stenosis (%D) pre and post procedure. Recoil was defined as difference between balloon diameter (BD) and MLD post, divided by BD. Palmaz-Schatz (P-S) consecutive stents (n = 88) were compared with Gianturco-Roubin (G-R) (n = 25), AVE Micro Stents (n = 51) and ACS Multilink (ML) stents (n = 6). There was no difference in lesion morphology, reference diameters, baseline % D or Balloon/Artery ratios. Baseline MLD was smallest in AVE compared to P-S group. Stented segments were longest in G-R and M-L groups. Residual % D was higher in G-R group, while MLD was highest in AVE and P-S groups.

	MLD	Length	% D post	MLDpost	Recoil, %
P-S	1.3 ± 0.5	12.2 ± 4.5	7.8 ± 20.7	2.8 ± 0.6	24.6 ± 13.0
G-R	1.1 ± 0.7	20.7 ± 5.8*	19.9 ± 23.8	2.3 ± 0.6*	26.9 ± 14.9
AVE	1.0 ± 0.4#	11.0 ± 0.2!	−4.8 ± 21.8!	2.8 ± 0.6!	25.9 ± 15.0
ML	1.2 ± 0.4	16.8 ± 5.6&	5.9 ± 5.9	2.7 ± 0.3	19.1 ± 5.1^

*P-S vs. G-R $p < 0.05$; # P-S vs. AVE $p < 0.05$; !G-R vs. AVE $p < 0.05$; &AVE vs. ML $p < 0.05$.

Deployment pressure was highest for P-S stents and lowest for AVE and G-R (15.8 ± 2.1 vs. 9.9 ± 3.2 and 10.6 ± 4.1 ATM respectively, $p < 0.01$). Incidence of post stent dissections was higher for P-S and G-R groups (25 and 36%) and lowest for AVE (5.9%, $p < 0.01$). Although amount of recoil was similar in P-S, AVE and G-R groups, the pressure required to properly deploy stents was different. In longer lesions the use of G-R stents resulted in higher % D and smaller MLD, suggesting necessity for preliminary debulking or the use of different stents.

1080-16 A New Delivery System for the Palmaz-Schatz Stent

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The high profile and compliance of conventional stent delivery systems requires large guiding catheters, aggressive predilatation and stent expansion at high-pressure after delivery. Hand-crimping of the stent on non-compliant PTCA balloons is increasingly used but this technique is hampered by the risk of stent loss.

This study reports the first clinical application of a new non-compliant balloon catheter designed for stent delivery. The characteristics of the balloon material (modified PET) are such that the Palmaz-Schatz stents become deeply embedded and firmly attached to the balloon after hand-crimping. Thirty-seven J&J stents (3 × 8 mm, 22 × 14 mm, 2 × 20 mm and 8 × 30 mm) were implanted in 29 lesions (LAD: 45%, LCX: 24%, RCA: 31%) of 23 patients. Stent implantation was immediately successful in 31/35 stents (95%). In the two cases of complete failure of stent deployment, the stent could not negotiate very tortuous proximal vessels. Two other cases required further predilatation or the use of a more rigid guide wire. In both cases, the stent could be successfully withdrawn into the guiding catheter. At a mean inflation pressure of 16 ± 3 Atm (range 8–20) no balloon ruptures were observed. Accurate positioning of the stent was facilitated by the 2 markers at the balloon ends and by the optimal visualization after contrast injection, even with 6 Fr guiding catheters (3 cases).

In conclusion, this new delivery system maintains all the advantages of hand-crimped stents on non-compliant balloons minimizing the risk of stent loss.

1080-17 Arterial Sealing Device After Coronary Stenting: Sewing or Anchoring?

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Percutaneous arterial suturing (PAS) (Techstar™), using 2 brands of 3/0 suture and Percutaneous arterial anchoring (PAA) (Angioseal™), with intravascular anchor and collagen delivery, are new techniques to close femoral puncture ≤ 8 F. In order to assess these two methods after coronary stenting, we compared 2 consecutive series of pts treated at the end of the procedure. Pts received a ticlopidine/aspirin drug regimen and were raised at 4 hrs. Baseline clinical data were similar in both groups. All pts had early and late clinical follow-up; vascular ultrasonography was systematically done