ANGIOPLASTY – STENTS AND ATHERECTOMY, LASERS AND OTHER DEVICES

901-19 Long-Term Follow-Up of "Stent-like" (< 30% Diameter Stenosis Post) Angioplasty: A Case for Provisional Stenting

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Since it is unclear whether the improved 1 yr clinical and 6 mth angiographic outcome after stent implantation is the result of its scaffolding properties or the late effect of a larger initial dilatation of the stenosis, we evaluated the outcome following 'Stent-like' PTCA (n = 90) and compared it to the complete Stent group (n = 259) and the patients with a QCA diameter stenosis post-stenting (DS) ≤ 30% (n = 213). The study population comprised 516 pts with stable angina randomised to either elective Palmaz-Schatz stent implantation or balloon angioplasty (PTCA) in Benestent-1. 'Stent-like' PTCA was defined as PTCA pts with DS ≤ 30%. 35% of pts in the PTCA group had a DS ≤ 30% compared to 87% in the Stent. The results were as follows: event, dead/mi/cabg/ptca; success, pts with assigned therapy and no inhospital events; restenosis, ≥ 50% diameter stenosis follow-up (fup)

	"Stent-like" PTCA (n = 90)	Total Stent population (n = 259)	Stent DS ≤ 30% (n = 213)
Success	78 (87%)	225 (87%)	199 (93%)
Mld at fup (mm)	1.84 ± 0.52	1.82 ± 0.64	1.84 ± 0.61
Restenosis	14 (16%)	51 (22%)	36 (18%)
Event free	69 (77%)	199 (77%)	169 (79%)

In conclusion: Our data suggest that 'Stent-like' PTCA result in a clinical and angiographic long-term outcome equivalent to stenting, therefore a strategy of provisional stenting should be prospectively tested on a population treated with balloon angioplasty with on-line QCA DS ≤ 30% post procedure.

901-20 A Randomized, Clinical Trial of Radiation Therapy to Reduce Restenosis Following Coronary Stenting—Early Results

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The *SCRIPPS* (Scripps Coronary Radiation to Inhibit Proliferation Post-Stenting) trial is a double-blind, randomized trial that couples coronary stent implantation with ionizing radiation to treat both the recoil and proliferative components of restenosis. To date, following stent placement, 30 patients with restenotic lesions have been randomized to receive either transcatheter iridium-192 or placebo, non-radioactive seeds. Target vessels included native coronaries (13 lesions) and vein grafts (17 lesions). The mean lesion length was 10.2 ± 6.3 mm and mean reference vessel diameter was 3.0 ± 0.7 mm. Dosimetry was calculated using intravascular ultrasound (IVUS) measurements of the radiation source to internal elastic membrane (IEM) distance. Iridium ribbons were advanced into the stented region through a non-centered, 4 Fr catheter. Mean iridium-192 specific activity was 97.6 ± 29.2 mCi and mean dwell time was 36 ± 7.0 min. Mean shortest distance between radiation source and IEM was 1.02 ± 0.16 mm resulting in a mean maximum target dose of 2651 ± 349 cGy. The mean longest distance between the radiation source and the IEM was 3.3 ± 0.47 mm resulting in a mean minimum radiation dose of 732 ± 83 cGy.

All pts are scheduled for 6-month angio and IVUS exam. Pts with subsequent restenosis are decoded and, if in placebo arm, crossed over to radiation therapy. With a mean follow-up of 2.8 months, 2 pts (both in placebo group) required reintervention for recurrent restenosis. No other adverse events have occurred.

Radiation therapy coupled with stenting can be performed without early adverse events. Long-term results will be presented.

901-21 Final Results of Phases II, III, IV and V of Medtronic Wiktor Stent Implantation Without Coumadin

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From December 1993 to september 1995, in 5 French institutions, 422 patients were prospectively treated after Wiktor stent implantation with Ticlopidine (250 mg/day), Aspirin (100 mg/day) for 1 month and LMWH for 4 weeks in phase II (79 patients), 2 weeks in phase III (96 patients), 1 week in phase IV (65 patients) and there was no LMWH in phase V (182 patients).

Indications for stenting were:

	Phase II	Phase III	Phase IV	Phase V
Suboptimal result	56%	46%	40%	46%
First intention	14%	26%	30%	38%
Restenosis	18%	16%	20%	13%
Bail out	12%	12%	10%	3%

Most patients (92%) received 1 stent, 6% received 2 and 2% received 3.

Results:

	Phase II	Phase III	Phase IV	Phase V
Procedural success	97%	97%	95%	97.5%
Stent occlusion	1.36%	1%	1.5%	1%
Death	1.36%	0%	0%	0%
Emergency CABG	1.36%	1%	0%	0%
Vx complications	1.36%	1%	1.5%	0%

Conclusion: these data suggest that with a good implantation technique, post Wiktor stenting treatment with Ticlopidine and Aspirin seems to reduce in Hospital major complications, additional treatment with LMWH does not seem beneficial.

CARDIAC PACING

901-22 Electromagnetic Filters Impede Adverse Interference of Pacemakers by Digital Cellular Telephones

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Recent reports suggest that digital cellular telephones may adversely interfere with pacemaker function. The purpose of this study was to determine if electromagnetic filters in pacemakers impede interference from digital cellular telephones.

Sixty-five patients with permanent pacemakers from four different manufacturers were studied (175 tests). Digital cellular telephones were placed in close proximity (1–5 cm) to the pulse generator during continuous electrocardiographic monitoring. Adverse interference observed included pacemaker inhibition, p-tracking of electromagnetic noise, asynchronous activation, and inappropriate safety pacing. Pacemakers from only one manufacturer had electromagnetic filter and these pacemakers were not susceptible to interference (0% – 0/28). Units from the other three manufacturers without electromagnetic filters were susceptible to interference (16.9% – 11/65; 41% – 23/56; and 46% – 12/26). Pacemakers from the manufacturer which were resistant to interference were further tested in vitro. Standard units with electromagnetic filters were compared with the same units which had the filtration device removed. Two pacemakers studied in vitro with electromagnetic filters were completely resistant to interference when exposed to digital telephones (0% interference) while two unfiltered devices were susceptible to interference to the same digital telephones (100% interference).

Conclusion: Electromagnetic filters in pacemakers can provide protection from interference from digital cellular telephones.

901-23 Decreased Acute Current Drain With Steroid Eluting High Impedance Pacing Leads: Results From a Multicenter Clinical Trial

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Increasing pacemaker pulse generator longevity by reducing pacing current drain is a desired goal of advances in lead technology. The sensing and pacing performance of a new small tip steroid eluting electrode (1.2 mm^2 surface area, high impedance lead, HI) Medtronic Capsure Z leads atrial J 5534 and ventricular 5034 was compared to that of a standard steroid eluting lead (5.8 mm^2 surface area, control lead, C) Medtronic CapSure SP leads atrial J 5524 and ventricular 5024. A total of 305 patients received pairs of the control lead (C, 5524/5024) and 190 patients received pairs of the high impedance lead (HI, 5534/5034) and were studied with respect to pacing capture thresholds (CT) measured at 2.5 Volts in ms, lead impedance (ohms) and sensing threshold (S, mV). Clinical characteristics of the patient population were similar. These leads are compared at 3 months following implantation below:

SUNDAY POSTER