View metadata, citation and similar papers at core.ac.uk

brought to you by CORE

provided by Elsevier - Publisher Connector

1044-56 Paclitaxel-Eluting Stent in Complicated Lesions or Patient Subsets: A Subanalysis From the TAXUS II Study

Leo Finci, Sigmund Silber, Eberhard Grube, Jorge Belardi, John Ormiston, Bradley Strauss, Giuglio Guagliumi, Mary Russell, Antonio Colombo, Antonio Colombo, EMO, Centro Cuore Columbus, Milano, Italy, Internistische Klinik Dr. Müller, Munich, Germany

Background. Several studies demonstrated superiority of drug-eluting stents compared to bare metal stents in relative simple lesions and patients.**Aim**. The aim of the study was to analyze the results of paclitaxel eluting stents in patients with complicated lesions or in diabetics and to compare with bear metal stent patients having similar characteristics. Patients were selected from the randomized TAXUS II study.
Methods. The TAXUS II study was a randomized, prospective study in 536 patients evaluating immediate and 12 months results in patients implanted with slow and moderate release paclitaxel stent with versus bare metal stent. From the baseline population, the subgroups of patients with complicated lesion were selected as follows (Taxus vs Controls): diabetics (32 vs 40 patients), female (68 vs 59 pts) small vessel of <2.75mm (130 vs 145), lesion length of >10 mm (130 vs 140), multiple stents (14 vs 19), or use of GP IIb/IIIa inhibitors (41 vs 47 pts). Results were expressed as a target lesion revascularization (TLR) rate at a follow-up time of 12 months.
Results. Table shows the TLR rate.

	Paclitaxel stent	Bear Metal stent	P value
Diabetics	3.1%	20%	0.037
Female	0	20.3%	0.0001
Small vessels (<2.75mm)	4.6%	16.9%	0.0016
Long lesions (>10mm)	4.6%	16.4%	0.0026
Multiple stents	0	15.8%	0.002
GP IIb/IIIa inhibitors	2.4%	10.6%	0.020
Overall	3.5%	14.1%	0.001

Overall there was a 75% improvement for paclitaxel group compared to the bear metal stent group. **Conclusions.** The paclitaxel stent has proven its superiority over bear metal stent in terms of TLR at one year even in patients with complicated lesions, such as small vessel, long lesions or diabetics.

1044-57 Initial Experience With Sirolimus-Eluting Stents in Left Main no Option Patients: Data From the SECURE Trial

Steven J. Yakubov, Paul S. Teirstein, Jeffrey W. Moses, Martin B. Leon, Theodore A. Bass, Marco A. Costa, Andrew J. Carter, Tim A. Fischell, Riverside Methodist Hospital, Columbus, OH

Background: Left main (LM) coronary angioplasty is a controversial area with little data to support the routine use of stents in this setting. Initial data from 20 LM patients treated with a sirolimus-eluting stent (SES) under a compassionate use protocol (SECURE) are reported here.
Methods: A total of 252 "no option" patients were enrolled at 5 centers with clinical follow-up at 1, 6 and 12 months, and QCA and IVUS at 8 months in patients with previous brachytherapy. Results: Available data from LM patients are summarized below. Presence of diabetes and prior CABG were significantly greater in LM patients (diabetes: 60% vs 36%, p=0.04; prior CABG: 95% vs 74%, p=0.05). All LM cases were for single vessel disease. Procedural success was 92%. No additional adverse events have been reported with a mean follow-up of 144 days (range 28-367 days). Angiographic follow-up and additional clinical follow-up will be presented.

Demographics (N = 20)	
Mean age	65.1
Male (%)	80
CCS Class III/IV (%)	55
Smoking Hx (%)	60
Diabetes (%)	60
Prior MI (%)	45
Prior CABG (%)	95
Prior Brachytherapy (%)	58
Number of lesions/pt	1
Number of stents/pt	1.2
RVD (mm)	2.35
Lesion Length (mm)	24.9
Stented Length (mm)	24.0
Post in-stent MLD (mm)	2.49

Conclusion: Left main stenting in this high risk subgroup appears to be safe using sirolimus-eluting stents.

1044-58 Drug-Eluting Stent Utilization and Outcomes From the Strategic Evaluation of New Transvascular Therapies (STENT) Group: A Large Prospective Multicenter "Real-World" Registry of Percutaneous Coronary Intervention

Charles A. Simonton, Bruce Brodie, Barry Cheek, Gregory San, Fred Krainin, Patricia Walker, Sherry Laurent, Carolinas Heart Institute, Charlotte, NC

Background:Drug-eluting stents (DES) and other new coronary devices receive US approval based on randomized trials in selected pts. Subsequent device utilization and clinical outcomes in the broader range of patients treated with these devices is learned slowly from single-center registries or smaller randomized trials. The **STENT** Group was developed to provide a large, prospective registry to quickly evaluate the "real world"outcomes of new devices.
Methods: Six regional centers representing a broad range of practice were selected. Data coordinators were assigned for prospective in-hospital and longterm clinical data collection in pts undergoing PCI. Data fields include baseline clinical profiles, lesion characteristics, procedural devices and medications, in-hospital outcomes and complications, and longterm follow-up at 3 and 9 months to retrieve major adverse cardiac events (MACE). Informed consent is obtained in all pts. All data is submitted by each center into a secure web-based central database.
Preliminary Results: As of this submission, a total of 1057 pts have been consented into the registry since approval of DES in May 2003. Stent utilization is shown below.
Conclusions: The STENT Group represents a unique multicenter network of centers committed to the rapid "real world" evaluation of new coronary devices. An annual volume of 8000 consented PCI cases is projected, and acute and late outcomes on completed patients with DES will be reported at the time of presentation.

Total PCI	1057
PCI with DES (%)	638 (60)
PCI with Bare Metal Stent (BMS) (%)	344 (33)
Total Stent PCI(%)	921 (87)
DES + BMS Same Procedure	61 (6)
Total #DES per case	1.28

1044-59 The REAL Registry of Drug-Eluting Stents: An Italian Survey in Emilia Romagna Region

Aleardo Maresta, The REAL Registry Investigators, S. Maria delle Croci Hospital, Ravenna, Italy, Health Care Emilia Romagna Agency, Bologna, Italy

As drug eluting stents (DES) are at the beginning of their diffusion process, it is relevant to assess in which clinical indications they are actually used, and whether the extremely encouraging results of Randomized Clinical Trials (RCTs) hold true in routine clinical practice.
In July 2002 a register of PCI procedures with DES was launched in Emilia Romagna a 4-million residents italian region, aimed at monitoring the impact of this new technology in clinical practice. Information on the clinical characteristics of patients receiving DES is routinely collected from 11 centers performing PCI.
As for May 2003, DES were implanted in 1142 lesions and 1027 pts (16.5% of global PCI). Patients' clinical characteristics were similar to those enrolled in the RAVEL and SIRIUS study, except for AMI in 7.2%, subacute MI in 7.4%, low (<35%) left ventricular ejection fraction in 9%. Treated lesions were: 69% type B2-C, 15.5% ostial location, 9% occlusion, 19% bifurcation, 2.2% left main, 1.7% venous graft, 1.4% last vessel, 6% vessel providing significant collaterals, 5.5% in-stent restenosis. The mean lesion length was 18+-8 mm and 26% of lesions were longer than 20 mm. The mean reference diameter was 2.79+-0.29 mm. The number of DES implanted was 1.16/pt and 5% of lesions was treated with two or more DES. Angiographic success was 98.5% with 1.85% of in-hospital Major Adverse Cardiac Events (MACE). MACE at 8+-2 months follow-up, now available for 140 out of 145 pts treated with DES from July to December 2002 in 4 centers, are as follows: death 2%, target lesion revascularization 3.1%, PCI on other lesions 5%.
These data provide some information on the actual patterns of use of DES in routine clinical practice. Although the angiographic characteristics partly diverge from those of RCTs, acute and preliminary follow-up results are encouraging, reflecting those of pts enrolled in the few randomized studies available. Complete follow-up will be available on March 2004.

1044-60 Treatment of Multivessel Coronary Artery Disease With Sirolimus-Eluting Stent Implantation: Immediate and Mid-Term Results

Dejan Orlic, Goran Stankovic, Erminio Bonizzoni, Flavio Airoldi, Alaide Chieffo, Nicola Corvaja, Giuseppe Sangiorgi, Massimo Ferraro, Carlo Briguori, Matteo Montorfano, Mauro Carlino, Antonio Colombo, EMO, Centro Cuore Columbus, Milano, Italy, San Raffaele Hospital, Milano, Italy

BACKGROUND
This study aimed to evaluate clinical outcome following multivessel stenting with sirolimus-eluting stent (SES) in unselected lesions.Safety and effectiveness of multivessel SES implantation is currently unknown.
METHODS
Multivessel SES implantation was evaluated in 155 consecutive patients treated on 511 lesions. Major adverse cardiac events were analyzed (MACE: death, myocardial infarction (MI) and repeat revascularization) at 30 days and at 6 months in all eligible patients
RESULTS
573 SES were implanted in 3.3±1.3 lesions per patient with angiographic success of 99.4%. SES were implanted on 2 vessels in 128 patients (400 lesions) and on 3 vessels