vesicles, can lead to excessive proliferation. Transient systemic inactivation of monocytes and macrophages by iposomal alendronate reduced neointimal formation and restenosis in the stented hypercholesterolemic rabbit model in a manner that can be used independently of stent number, position, or overlap and with possible multiple dosing.

1078-183

The Endothelial Nitric Oxide Synthase (Glu298Asp and -786T>C) Gene Polymorphisms Are Associated With Coronary In-Stent Restenosis

Abigail Ramnath, Mohamed Claygares, Charles Knight, Emma Horos, Kim Pux, Steven Humphries, National Heart and Lung Institute and Royal Brompton Hospital, London, United Kingdom, British Heart Foundation Laboratories for Cardiovascular Genetic Studies, UCL Medical School, London, United Kingdom

Background: Sirolimus, a macrocyclic antibiotic and immunosuppressant, causes late cell cycle arrest. A pilot study using Sirolimus-eluting stents (SES) to treat coronary arterial disease, 30.6% had a prior Ml. The average lesion length was 14.4 mm and the reference diameter (mm) 2.60.

Methods: The primary endpoint of Stent number, positron, or overlap and with possible multiple dosing. The incremental C/E ratio for DES compared with BS was $5542 per repeat revascularization (RepRev) avoided-- similar to the C/E of BS for de novo lesions or brachytherapy-- $1500/pt, total 1-year costs remained higher with DES ($14,245 vs. 513,842, p<0.001). The incremental C/E ratio for RepRev avoided-- similar to the C/E of BS for de novo lesions or brachytherapy-- $1500/pt, total 1-year costs remained higher with DES ($14,245 vs. 513,842, p<0.001).

Conclusions: 1) In a representative population of PCI patients, sirolimus DES improved clinical outcomes but increased overall health care costs by $8000 compared with BS. 2) Nonetheless, considering the quality of life benefits of avoiding restenosis, the C/E of DES compares reasonably with other accepted interventional techniques. 3) Complete 1-year data on the full 1100 pt trial will be available by 2003.

805 Drug-Eluting Stents

Monday, March 31, 2003, 9:15 a.m.-10:30 a.m.
McCormick Place, Room S401

9:15 a.m.

805-1 Two-Year Follow-Up of the RAVEL Study: A Randomized Study With the Sirolimus-Eluting Bx VELOCITY Stent in the Treatment of Patients With De novo Native Coronary Artery Lesions

Marie-Claude Morice, Patrick Seneaux, Costantino Costantini, Egon Swalet, William Wijns, Jean Faiadet, Antonio Colombo, Giulio Guaglioni, Ferenc Molnar, Ernesto Ban Hayashi, Jean Etienne M. Sune, Murat Pehl, on behalf of the RAVEL Trial Investigators, Institut Cardiovasculaire Paris Sud, Massy, France

Background: Coronary stent deployment is a major advance in percutaneous treatment of ischaemic heart disease, but 10-40% of patients still develop angiographic restenosis by 6 months due to neointimal hyperplasia. Patient-specific factors, including genetic factors, can contribute to this process. We have conducted a prospective study to examine the involvement of genetic risk factors (eNOS, ACE, MMP-3, IL-6, and PECAM-1) in restenosis following coronary stent deployment.

Methods: 226 patients who underwent elective coronary artery stenting to de novo lesions in native coronary arteries were studied. 205 (90.7%) patients were restudied by coronary angiogram at 6 months and the stented lesions were assessed with automated quantitative angiography system. Genotype was determined by PCR and restriction enzyme digestion. Results: Restenosis rate, defined as ≥50% diameter stenosis, was 29.3%. The overall genotype frequency distributions were in Hardy-Weinberg equilibrium for all variants. Carriers of the 298Asp allele of the eNOS Glu298Asp polymorphism showed a higher frequency of restenosis with an odds ratio of 1.88 (95% CI: 1.01-3.51, p=0.043) compared to 298Glu homozygotes. Carriers of the -786T allele of the eNOS -786T>C polymorphism also showed a higher frequency of restenosis with odds ratio of 2.06 (95% CI: 1.08-3.94, p=0.028). Other studied genes did not show significant association with coronary in-stent restenosis.

Conclusions: In patients with coronary artery disease, the possession of the 298Asp and -786T variants of the eNOS gene is a risk factor for coronary in-stent restenosis, demonstrating the importance of the nitric oxide system in restenosis.

805-2 Cost-Effectiveness of Sirolimus Drug-Eluting Stents for the Treatment of Complex Coronary Stenoses: Results From the Randomized SIRIUS Trial

David J. Cohen, Amnet Bakshi, Chauko Shu, Louise Gilchrist, Ronna H. Besozin, Richard P. Caputo, Charles O'Shaugnessy, Martin B. Leon, Jeff Moss, Richard E. Kuntz, on behalf of the SIRIUS Investigators, Beth Israel Deaconess Medical Center, Boston, MA, Harvard Clinical Research Center, Boston, MA

Background: Previous studies have demonstrated that sirolimus drug-eluting stents (DES) dramatically reduce angiographic and clinical restenosis compared with conventional stenting. However, the cost-effectiveness (C/E) of DES in routine clinical practice is unknown. Methods: We prospectively measured medical resource utilization and cost for 1100 PCI patients randomized to either sirolimus DES or bare stents (BS) as part of the SIRIUS trial. Costs were assessed from the U.S. societal perspective, and each DES was assumed to cost $3000/stent. Results: Resource utilization and 1-year cost data for the first 400 randomized patients are displayed below (see Table). Although DES reduced the rate of target vessel revascularization by 62% and follow-up costs by $1500/pt, total 1-year costs remained higher with DES (Δ $14,245 vs. $13,842, p<0.001).

The incremental C/E ratio for DES compared with BS was $5542 per repeat revascularization (RepRev) avoided-- similar to the C/E of BS for de novo lesions or brachytherapy-- $1500/pt, total 1-year costs remained higher with DES ($14,245 vs. 513,842, p<0.001).

Conclusions: 1) In a representative population of PCI patients, sirolimus DES improved clinical outcomes but increased overall health care costs by $8000 compared with BS. 2) Nonetheless, considering the quality of life benefits of avoiding restenosis, the C/E of DES compares reasonably with other accepted interventional techniques. 3) Complete 1-year data on the full 1100 pt trial will be available by 2003.

805-3 One-Year Follow-Up of the SIRIUS Study: A Randomized Study With the Sirolimus-Eluting Bx VELOCITY in the Treatment of Patients With De novo Native Coronary Artery Lesions

David P. Holmes, Jr., Martin B. Leon, Jeffrey W. Moses, Jay McAllister, Mel Clark, Igor Palacios, Mark Bates, John Lopez, Alan G. Young, Richard E. Kuntz, on behalf of the SIRIUS Trial Investigators, Mayo Clinic, Rochester, MN

Background: The Sirolimus-eluting stent (SES) dramatically reduce angiographic and clinical restenosis compared with conventional stenting. However, the cost-effectiveness (C/E) of DES in routine clinical practice is unknown. Methods: We prospectively measured medical resource utilization and cost for 1100 PCI patients randomized to either sirolimus DES or bare stents (BS) as part of the SIRIUS trial. Costs were assessed from the U.S. societal perspective, and each DES was assumed to cost $3000/stent. Results: Resource utilization and 1-year cost data for the first 400 randomized patients are displayed below (see Table). Although DES reduced the rate of target vessel revascularization by 62% and follow-up costs by $1500/pt, total 1-year costs remained higher with DES (Δ $14,245 vs. $13,842, p<0.001).

The incremental C/E ratio for DES compared with BS was $5542 per repeat revascularization (RepRev) avoided-- similar to the C/E of BS for de novo lesions or brachytherapy-- $1500/pt, total 1-year costs remained higher with DES ($14,245 vs. 513,842, p<0.001).

Conclusions: 1) In a representative population of PCI patients, sirolimus DES improved clinical outcomes but increased overall health care costs by $8000 compared with BS. 2) Nonetheless, considering the quality of life benefits of avoiding restenosis, the C/E of DES compares reasonably with other accepted interventional techniques. 3) Complete 1-year data on the full 1100 pt trial will be available by 2003.

* Adjusted to account for the availability of stent lengths up to 33 mm in clinical practice

9:45 a.m.

805-4 Drug-Eluting Stents

Monday, March 31, 2003, 9:15 a.m.-10:30 a.m.
McCormick Place, Room S401

9:15 a.m.