Sep 1, 2004

E-SIRIUS: Maintained benefit at two years and no evidence of late catch-up in patients treated with the Cypher stent

ESC news **Munich, Germany -** Two-year clinical results of the European study investigating the Cypher™ sirolimus-eluting stent were presented today at the **European Society of Cardiology Congress 2004** and confirm the benefit seen at one year as well as the clinical benefit the study demonstrated in results reported at eight months.

Lead investigator **Dr Joachim Schofer** (Center for Cardiology and Vascular Interventions, Hamburg, Germany) of the Cordis/Johnson & Johnson-sponsored trial reported that patients treated with the sirolimus-eluting stent continued to have lower rates of target lesion revascularization (TLR) and major adverse cardiac events (MACE) than those treated with a bare-metal stent.

"This translated into curves for survival free of MACE that are still diverging," said Schofer. "There is no indication of a late catch-up phenomenon at present."

Benefit maintained at two years

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The E-SIRIUS study is a multicenter, randomized, double-blind trial conducted at 35 hospitals throughout Europe. The study enrolled 352 patients with de novo native coronary lesions and was designed for patients with a reference vessel diameter of 2.5 to 3.0 mm and a lesion length of 15 to 32 mm. Of the 352 patients enrolled in the study, 175 were randomized to receive the sirolimus-eluting stent and 177 patients were randomized to receive an uncoated metal stent (control group).

Eight-month angiographic results—previously reported by ***heartwire***—showed that 43.6% of all patients who received the conventional bare-metal stent exhibited restenosis. In contrast, only 5.8% of patients treated with the sirolimus-eluting stent experienced restenosis, corresponding to a reduction of 86%. One-year clinical results also reported lower rates of MACE and TLR in the sirolimus-treated patients.

At two years, the reduction in MACE and TLR rates were maintained from 360 days, report investigators. Two-year survival free from MACE was 89.7% in the drug-eluting stent arm and 70.0% in the control arm.

Highlights
Thumbs up, thumbs down

VALUE and MATCH
Drs **Eric Topol** and Rob Califf discuss the VALUE and MATCH trials.

The EP show

Risk stratification for sudden death
With **Drs Eric Prystowsky**, **Arthur Moss**, and **Michael Gold**.

Right ventricular vs biventricular pacing
Can long-term right ventricular pacing actually hurt the heart? With **Drs Prystowsky**, **Wilkoff**, **Saxon**, and **Gold**.

Heart failure

The explosion in HF devices, part

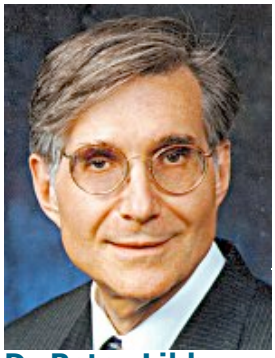
This two-part series explores some of the real-world complexities of device therapy in HF. Experts on both sides of the Atlantic discuss the rewards and frustrations of a highly successful mode of therapy still finding its way.

The explosion in HF devices, part 2
In part 2, experts discuss indication gray areas and other ways in which the clinical trials don't provide much guidance.

Hypertension

The value of VALUE
Results of this trial showed that valsartan and amlodipine were not significantly different in their effects on primary end points. However, differences in secondary end points and blood-pressure lowering are fodder for interpretation.

Features



Dr Peter Libby
A pioneer in the field of vascular biology talks to **heart*wire*** about some of the early decisions he made while investigating the role of inflammation in atherosclerosis.

Standing against the stream: Dr Renu Virmani
Scientist, skeptic, and self-appointed soothsayer of the coronary vasculature: **Dr Renu Virmani** has had

E-SIRIUS: MACE and TLR at 2 years

Clinical outcomes	Sirolimus-eluting stent (n=175)	Bare-metal stent (n=177)	Relative risk reduction (%)	p
Major adverse cardiac events	10.3	29.9	66	0.001
Target lesion revascularization	5.1	26.6	81	0.001

To download table as a slide, click on slide logo below

There was no difference in mortality, MI, emergent CABG, or target lesion CABG between the two groups. There was a significant difference between the two stents in terms of target lesion PCI, with more patients treated with the bare-metal stent requiring revascularization. The superiority of sirolimus to reduce TLR primarily drove the difference in the rate of adverse events between the two groups, said Schofer.

Schofer reported there were two additional deaths in the sirolimus-treated patients in year two, a nonsignificant difference. One patient died of MI after a failed attempt at recanalization of a thrombotic total occlusion of the coronary artery, and the other died from noncardiac-related causes. There was no significant difference in stent- or late-thrombosis rates.

Results in line with other major trials

"The only question remains is when do we say there is no late catch-up? Is it one year? Two years? Five years?"

In a discussion following the presentation of the E-SIRIUS data, **Dr Sigmund Silber** (University of Munich, Germany) said the two-year data provide an opportunity to compare the results with other registries.

With regard to two-year data from **RAVEL** and **SIRIUS**, Silber said the E-SIRIUS data are comparable, "fitting in nicely with these studies," despite the patients in E-SIRIUS having a higher risk of restenosis. The significant difference in MACE rates between the Cypher stent and control are comparable to the other trials, and the 10.3% MACE rate in E-SIRIUS is nearly identical to the two-year rate seen in RAVEL and SIRIUS.

He said he was pleased that no late catch-up has been observed but added, "The only question remains is when do we say there is no late catch-up? Is it one year? Two years? Five years?" Silber said that to address this question, more data are needed with even longer follow-up intervals.

Related links

1. E-SIRIUS published: Restenosis rate of 5.9% in patients treated with sirolimus-eluting stent [*HeartWire* > *News;* Oct 3, 2003]
2. Taxus or Cypher? Cardiologists worldwide air their opinions and concerns [*HeartWire* > *IndustryPulse;* Aug 12, 2003]
3. SIRIUS: The costs of drug-coated stents [*Education* > *Thumbs up, thumbs down;* Nov 25, 2002]
4. Sirolimus-eluting stent gets US regulatory approval at last [*HeartWire* > *News;* Apr 24, 2003]
5. Sirolimus-eluting stent results expanded to longer lesions and smaller vessels, plus longer follow-up duration [*HeartWire* > *News;* Apr 2, 2003]
6. High cost of sirolimus-eluting stent offset over time: SIRIUS cost effectiveness study [*HeartWire* > *News;* Mar 30, 2003]

her share of cordial disagreements over the years. Her colleagues say they listen closely to her every word but don't take all of it to heart.

Poll

Question

Archives

Do you think simvastatin 80 mg should not be given to patients?
(See: *A to Z: Disappointing results for simvastatin 80 mg*)

YES

NO

VOTE

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