Sirolimus Stents at 9 Months Safer in Long Lesions

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WASHINGTON — By angiographic measures, sirolimus-eluting stents outperformed paclitaxel-eluting stents over 9 months in a head-to-head comparison in patients with long coronary lesions, Dr. Seung-Jung Park reported at a symposium sponsored by the Cardiovascular Research Foundation.

"Compared to paclitaxel-eluting stents, sirolimus-eluting stents appear to be more effective in inhibiting neointimal hyperplasia and result in a reduced risk of angiographic restenosis and the need for repeat revascularization in patients with long coronary lesions" in the Percutaneous Treatment of Long Native Coronary Lesions with Drug-Eluting Stents II (LONG-DES II) study, said Dr. Park, who was principal investigator and is chief of interventional cardiology at the Asan Medical Center in Seoul, South Korea.

Despite the favorable results, however, it was noted that longer-term outcomes are needed before making definitive statements regarding the benefits of drug-eluting stents in this lesion subset or which drug-eluting stent is superior. Current guidelines do not extend the use of drug-eluting stents into lesions longer than those seen in the pivotal sirolimus-eluting stent (Cypher) and paclitaxel-eluting stent (Taxus) trials that were used to gain regulatory approval, in which the upper limits were 30 mm in SIRIUS and 28 mm in TAXUS IV.

In a previous, smaller study of patients with long lesions (LONG-DES), the sirolimus-eluting stent was shown to be more effective in reducing angiographic restenosis. The LONG-DES II study sought to compare the efficacy of the two devices in a randomized, controlled fashion. The study included 500 patients with de novo coronary lesions more than 25 mm in length by visual estimation, requiring single or multiple drug-eluting stents, with a planned total stent length of more than 32 mm. Half the patients were treated with sirolimus-eluting stents and the other half with paclitaxel-eluting stents.

Device success neared 100% in both groups. On quantitative coronary angiography, there were no differences in post-procedure acute gain or in diameter residual stenosis. The mean angiographic length of the stented segment was 40.8 mm for sirolimus and 41.1 mm for paclitaxel, a difference that was not statistically significant.

Thirty-day clinical outcomes, including death, myocardial infarction, and target lesion revascularization, also did not differ significantly between groups. One subacute stent thrombosis occurred in the sirolimus-eluting stent arm and none in the paclitaxel arm.

Six-month angiographic follow-up was completed in about 83% of patients and 9-month clinical follow-up was available in all but 6 patients.

The primary end point—the rate of binary angiographic restenosis over 50% at 6 months—was significantly reduced in patients implanted with sirolimus-eluting stents, compared with those receiving paclitaxel-eluting stents. In-segment restenosis was only 3.3% for sirolimus vs. 14.6% for paclitaxel; the in-stent restenosis rates were 2.9% and 11.8%, respectively.

These angiographic differences translated into clinical differences at 9-month follow-up: the incidence of target lesion revascularization was 2.4% for sirolimus, compared with 7.2% for paclitaxel. Target vessel revascularization was undertaken in 3.2% of the sirolimus arm, compared with 7.6% of the paclitaxel arm. Both differences were statistically significant.

In-segment late loss was 0.24 mm for sirolimus, compared with 0.61 mm for paclitaxel. "This is somewhat more late loss than we're used to seeing, even for the sirolimus-eluting stent," commented Dr. Roxana Mehran of New York–Presbyterian Hospital/Columbia University, New York, in a press conference, although she added that it was still reassuring to see the stents perform well even in more complex lesion morphologies. There were two cases of stent thrombosis recorded by 9 months. Both occurred in the sirolimus-eluting stent arm (0.8%) but did not constitute a statistically significant difference, compared with the paclitaxel arm.

The LONG-DES II study was sponsored by Cordis Corp., which markets the Cypher stent. Additional support was provided by the Cardiovascular Research Foundation in South Korea and the Korean Ministry of Health and Welfare. ■