Biodegradable DES Shown As Effective, Safe as Cypher

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WASHINGTON — A biodegradable, polymer-based, rapamycin-eluting stent developed by a group in Germany is at least as effective as the Cypher stent, Dr. Julinda Mehilli reported at a conference on transcatheter cardiovascular therapeutics, sponsored by the Cardiovascular Research Foundation.

Although the use of polymers in drug-eluting stents (DES) may provide better release kinetics of the drug, their permanent presence in the vessel is believed to have a negative impact on the long-term outcome. Polymer-free and biodegradable polymer-based DES are two potential approaches to eliminate the presence of permanent polymers, said Dr. Mehilli, of the Technical University, Munich.

In this study, called ISAR-TEST 3, the investigators compared both the polymer-free (PF) rapamycin-eluting stent and a rapamycin-eluting stent that uses a mixture of biodegradable polymer (BP) and natural resin with the permanent polymer rapamycin-eluting stent Cypher in a randomized trial involving 605 patients with coronary artery disease: 202 were randomized to BP DES, 202 to Cypher, and 201 to PF DES. About a third of all three groups had unstable angina and a history of myocardial infarction, with no significant differences in baseline angiographic characteristics. A majority of the patients (79%-83%) had multivessel disease, and about three-fourths had complex lesions.

The primary end point, in-stent late lumen loss at 1 year, was 0.17 mm for BP DES, 0.23 mm for Cypher, and 0.47 mm for PF DES. Compared with the Cypher, the results demonstrated noninferiority for the BP DES but not for the PF DES, Dr. Mehilli reported.

Rates of angiographic restenosis were 9.0% for the BP DES, 10.8% for the Cypher, and 16.9% for PF DES. Clinical restenosis (target lesion revascularization) rates were 5.9%, 7.9%, and 12.9%, respectively, all nonsignificant differences, compared with Cypher. Death or myocardial infarction occurred in 2.5% with BP DES, 3.5% with Cypher, and 4.0% with PF DES, while death rates were identical (2.5%) in each of the groups.

Definite/probable/possible stent thrombosis (Academic Research Consortium definition) occurred in 1.0% of the BP DES group, 2.0% with Cypher, and 1.5% of the PF DES recipients, also not significantly different. The three types of DES did not differ in terms of their safety profile at 1 year, Dr. Mehilli reported.

In a critical appraisal of ISAR-TEST 3, Dr. Jeffrey J. Popma called it "an important study" because "Reduction in intimal hyperplasia will not simply be enough as we move forward with our [DES] programs. We're looking for new stents that have rapid endothelialization, less inflammation, and a reduction in the requirement for antiplatelet therapy, and these two agents may do that."

The bioresorbable polymer might result in less very late stent thrombosis, while the microporous surface would possibly produce more rapid endothelialization, noted Dr. Popma, director of invasive cardiovascular services at Caritas Christi Health Care System, St. Elizabeth Research Center, Harvard Medical School, Boston.

However, he questioned whether "in-stent" late loss was the right primary study end point. While it is the best measure for the degree of intimal hyperplasia within the stent, it has no implications for endothelialization and healing. In-segment follow-up percent diameter stenosis would be a better predictor of clinical events, he said. ■

Drug-Eluting Stent Thrombosis Rate Suggests Acceleration Over Time

VIENNA — The incidence of stent thrombosis following placement of drug-eluting coronary stents suggested a possibly rising, curvilinear incidence during 3 years of follow-up of more than 5,000 patients.

In addition, almost half of the stent thromboses that occurred a year or more after stent placement happened while patients were still on dual antiplatelet therapy, said Dr. Gregory J. Mishkel said while presenting a poster at the annual congress of the European Society of Cardiology.

The finding "calls into question the necessity of clopidogrel continuation beyond the current prescribed recommendations" of 1 year, said Dr. Mishkel, co-director of the coronary catheterization laboratory at the Prairie Heart Institute at St. John's Hospital in Springfield, Ill., and his associates in their poster.

The review included 5,342 patients at Prairie Heart who received their first DES during May 2003–December 2006. Follow-up data on stent thrombosis was available for 5,173 (97%) of the patients; the average duration of follow-up was 1.8 years.

During follow-up, 50 patients had a definite stent thrombosis, 13 had a probable event, and 54 had a possible stent thrombosis. Among the 50 definite thromboses, 34 (68%) occurred a year or more after placement; and of those, 15 (44%) occurred while the patients were still on dual antiplatelet therapy.

After the first 30 days, the rate of definite or probable stent thrombosis during the next 11 months was 0.2%. During the second 12 months the thrombosis rate increased by 0.6%, to a cumulative rate of 0.8%. During the last 12 months, the rate increased by another 0.7%, to a cumulative rate of 1.5%, said Anna L. Moore, a database coordinator who collaborated on the study.

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