Xience Bests Taxus in Target-Lesion Failure

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Everolimus-eluting coronary stents produced a 38% relative reduction in the 1-year rate of target-lesion failure and a 45% relative reduction in target-lesion revascularization, compared with paclitaxel-eluting stents, according to randomized study.

In what the researchers described as the only clinical trial to date that was large enough to establish the superiority of one drug-eluting stent over another, the primary end point of target-lesion failure 1 year after percutaneous coronary intervention was 4.2% with everolimus-eluting stents, compared with 6.8% with paclitaxel-eluting stents, a significant difference.

The everolimus-eluting stent (Xience V, Abbott Vascular) also was superior with respect to the secondary end point of ischemia-driven target-lesion revascularization at 1 year, with a 2.5% rate of this outcome, compared with a significantly higher 4.6% rate for the paclitaxel-eluting stent (Taxus Express, Boston Scientific), said Dr. Gregg W. Stone of Columbia University, New York, and his associates in the Abbott-sponsored SPIRIT IV study.

Target-lesion failure at 1 year was 4.2% with the everolimus-eluting stent, compared with 6.8% with the paclitaxel-eluting stent. Rates of all-cause and cardiac death did not differ.

However, the rates of cardiac death and of death from all causes were not significantly different between the two stents. This may be due in part to the low mortality in both groups after just 1 year. Longer follow-up "will determine whether these differences are durable or increase over time," the investigators said.

In addition, the everolimus-eluting stent did not show superiority in patients with diabetes—a major subgroup that accounts for a significant portion of stent procedures, they noted.

Dr. Stone and his colleagues compared the two devices in 3,687 patients, including 1,185 with diabetes, who underwent PCI at 66 U.S. medical centers in 2006-2008. These study subjects had up to three untreated coronary artery lesions that were as long as 28 mm, in vessels with a diameter of 2.5-3.75 mm.

The subjects were randomly assigned to receive everolimus-eluting stents (2,458 patients) or paclitaxel-eluting stents (1,229 patients) and were followed for 1 year.

The everolimus-eluting stent was superior regarding target-lesion failure and ischemia-driven target lesion revascularization; it was noninferior to the paclitaxel-eluting stent in the secondary end point of cardiac death or target-vessel myocardial infarction.

The everolimus-eluting stent also was superior in the secondary end point of preventing stent thrombosis, with a 1-year rate of 0.85%, compared with a 1.10% rate for the paclitaxel-eluting stent group. This represents a relative reduction of 75%, Dr. Stone and his associates wrote (N. Engl. J. Med. 2010; 362:1663-74).

These findings were consistent across 11 subgroups of patients, regardless of patient symptoms or smoking, hypertension, or cholesterol status; the number of lesions treated; which coronary vessels were involved; and the dimensions of the lesions or the vessels.

The sole exception was the large subgroup of diabetic patients, in whom there were no significant differences in outcomes between the two stents. A discrepancy in outcomes has been reported previously for diabetic patients receiving stents, and "suggests that the mechanisms of restenosis or the response to antiproliferative agents may vary in patients with insulin resistance or deficiency," the researchers noted.

The SPIRIT IV trial was sponsored by Abbott Vascular. Dr. Stone reported ties to Abbott, Boston Scientific, Osprey Medical, InfraReDx, Reva Medical, Merck, CoreValve, St. Jude Medical, Edwards, and numerous other pharmaceutical and device companies. ■