Zotarolimus Noninferior to Everolimus Stent

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One year after implantation, the zotarolimus-eluting coronary stent was found to be noninferior to the everolimus-eluting stent in preventing target-lesion failure.

This "new-generation" stent was tested in a large population with a mix of traits usually excluded from randomized clinical trials of stents, including multivessel intervention, small-vessel disease, long lesions, bifurcations, or trifurcations. "Therefore, we consider that our findings are highly generalizable to patients in everyday clinical practice," said Dr. Patrick W. Serruys of Erasmus University Medical Center, Rotterdam, the Netherlands, and his associates.

In the multicenter open-label study, sponsored by Medtronic CardioVascular, maker of the zotarolimus-eluting stent, patients were randomly assigned to undergo percutaneous coronary intervention (PCI) with placement of either zotarolimus-eluting (1,140 patients with 1,661 lesions) or everolimus-eluting stents (1,152 patients with 1,705 lesions). Patients were followed by telephone or hospital visit at 1, 6, and 12 months, and will be followed annually for 5 years.

The primary end point was target-lesion failure at 1 year, defined as a composite of death from cardiac causes, MI, or target-lesion revascularization. This occurred in 8.2% of patients who received zotarolimus-eluting stents and 8.3% of those who received everolimus-eluting stents, a nonsignificant difference.

The zotarolimus-stent group had significantly reduced rates of death from any cause while they were hospitalized (0.1% vs. 0.8%) and at 30 days (0.2% vs. 0.9%), compared with the everolimus-stent group. However, the 1-year mortality from any cause was 1.6% in the zotarolimus group and 2.8% in the everolimus group, a nonsignificant difference, the investigators said (N. Engl. J. Med. 2010 [10.1056/NEJMoa1004130]).

These results remained consistent across all subgroups of patients. At least one off-label criterion was present in the majority (66.3%) of the patients.

The rate of definite stent thrombosis was significantly higher in the zotarolimus group (1.2%) than the everolimus group (0.3%).

A smaller percentage of patients than expected underwent angiographic assessment of in-stent stenosis. In-stent stenosis was worse in the zotarolimus group but still met the criterion for noninferiority, Dr. Serruys and his colleagues said.

The rates of adverse events were low and compared favorably with those in previous studies, with no significant between-group differences, they added.

"Although our findings are hypothesis generating and require additional investigation, definitive conclusions will be obtained only from longer-term follow-up in large patient populations in studies that have sufficient statistical power to detect differences in rates of stent thrombosis," the researchers said. ■

VITALS

Major Finding: Target-lesion failure at 1 year occurred in 8.2% of zotarolimus-eluting stent patients and 8.3% of everolimus-eluting stent patients; 1-year mortality from any cause was 1.6% (zotarolimus group) vs. 2.8% (everolimus group), nonsignificant differences. Significant differences in in-hospital and 30-day mortality favored the zotarolimus stent. The rate of definite stent thrombosis was significantly higher in the zotarolimus group (1.2%) than the everolimus group (0.3%).

Data Source: Multicenter open-label, randomized study comparing zotarolimus-eluting stents (1,140 patients with 1,661 lesions) with everolimus-eluting stents (1,152 patients with 1,705 lesions).

Disclosures: Dr. Serruys and some associates reported ties to Medtronic Inc., Boston Scientific Corp., and Abbott Labs, maker of the everolimus-eluting stent. The study was sponsored by Medtronic CardioVascular, maker of the zotarolimus-eluting stent.