One-Year Clinical Results With the Slow-Release, Polymer-Based, Paclitaxel-Eluting TAXUS Stent in Patients With Diabetes Mellitus

The one-year clinical results of a polymer-based paclitaxel-eluting stent in preventing restenosis in patients with coronary artery disease were recently reported by Stone and colleagues. In the diabetic cohort, target lesion revascularization (TLR) was reduced by approximately 66%. The authors suggest that this technology should be the standard of care for stent implantation in the majority of de novo atherosclerotic lesions as studied in their clinical trial. With regard to patients with type 2 diabetes mellitus, we feel this conclusion is premature. Extrapolation of these results to this patient population cannot be made on the basis of the design of this trial.

First, this type of post hoc subset analysis carries a high risk that the differences observed may be due to chance alone (type I error), and therefore, the authors should be cautious in making conclusions about the diabetic cohort. Confirmatory prospective randomized trials powered to determine differences in angiographic restenosis and TLR are needed in patients with type 2 diabetes undergoing coronary stent placement.

Second, TLR was mostly clinically rather than angiographically driven because the majority of patients (57%) in this trial did not receive angiographic follow-up. This is an important fact for two reasons: (1) TLR rates are often higher in trials with angiographic rather than clinical follow-up, and (2) clinical follow-up is notoriously unreliable in diabetic patients because these patients are known to have significantly greater incidence of silent ischemia than their nondiabetic counterparts. In fact, TLR rates in this trial were approximately 50% higher in patients receiving angiographic rather than clinical follow-up and probably could be expected to be much higher within the diabetic subset. Moreover, comparison of TLR rates with other trials in which a greater percentage of patients received angiographic follow-up may not be possible. The use of this stent in diabetic patients undergoing coronary stent placement cannot be considered standard of care until larger trials confirm its safety and efficacy in this patient population.

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Response
We appreciate the comments of Drs Finn and Gold about the outcomes of patients with diabetes in the TAXUS-IV trial. However, the currently available data strongly support the safety and efficacy of the TAXUS stent in this high-risk cohort, which was a prespecified subgroup in TAXUS-IV for which randomization was stratified. First, angiographic restenosis was markedly reduced by 81% in diabetic patients with the TAXUS-SR (slow-release) stent compared with the bare metal stent (from 34.5% to 6.4%, P<0.0001)—if anything, greater than the 65% reduction present with TAXUS in nondiabetic patients (24.4% versus 8.5%, P<0.0001). Second, the oculostenotic reflex does not explain the observed clinical benefit present in patients with diabetes in this trial; among the 129 randomized patients with diabetes in TAXUS-IV not in the angiographic follow-up cohort, the 1-year rates of target lesion revascularization (TLR) were 8.1% with the TAXUS stent compared with 22.3% with the control stent, a 66% reduction (P=0.045). Finally, the polymer-based paclitaxel-eluting stent was also strikingly effective in diabetic patients with focal lesions randomized in the TAXUS-II trial (12-month TLR reduced from 20.3% with the control stent to 3.1% with the TAXUS-SR or -MR [moderate-release] stent, an 85% reduction, P=0.037) and in diabetic patients with long lesions in the TAXUS-VI trial (9-month TLR 22.0% with the bare metal stent versus 2.6% with the TAXUS-MR stent, an 88% reduction, P=0.008). In all of these trials, the outcomes with the TAXUS stent were equally robust in insulin-treated patients as in those managed with oral medication. Safety concerns have not surfaced with the TAXUS stent in diabetic patients; stent thrombosis, aneurysm formation, and late stent malapposition have been infrequently observed and with similar frequency in the control and treatment groups.

Thus, the data from 458 diabetic patients randomized in 3 prospective, double-blind trials demonstrate a striking improvement in event-free survival with the polymer-based, paclitaxel-eluting stent. Favorable effects have also been reported with the sirolimus-eluting stent in patients with diabetes, justifying the stance that drug-eluting stents should now be considered the standard of care for diabetic patients with appropriate lesions.

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