

Studies with Drug-Eluting Stents II

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Evaluation of a Tacrolimus-Eluting Coronary Stent Graft for Treatment of Saphenous Vein Graft Lesions: Procedural and 6-Month Follow-up Results of the EVIDENT Trial

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Background: Along with distal embolization, stent restenosis is still a major limitation of percutaneous interventions in treatment of saphenous vein graft lesions. However, drug-eluting stents have recently been shown to be remarkably effective in native coronary arteries, and therefore, might be of benefit in vein graft lesions as well. Tacrolimus is an antiproliferative and anti-inflammatory agent with proven efficacy in other therapeutic areas (transplant medication). The antiproliferative effect is selectively focused on smooth muscle cell activities rather than inhibition of endothelial cell proliferation, which might be favorable in intracoronary applications to avoid recurrent lumen renarrowing. To optimize the treatment of saphenous vein graft lesions, a new tacrolimus-eluting graft stent has been designed, using the polytetrafluoroethylene layer of a coronary stent graft as a drug carrier matrix. The EVIDENT trial has been conducted to evaluate both safety and feasibility of this new stent design.

Methods: The EVIDENT trial is a prospective nonrandomized multicenter trial, investigating safety and feasibility of a 16-mm coronary stent graft loaded with 352 µg FK506 (tacrolimus) in treatment of saphenous vein graft stenoses in a total of 32 patients. The primary endpoint is 30-day safety defined as absence of major adverse cardiac events (MACE). Angiographic and intravascular ultrasound follow-up was scheduled 6 months after the index procedure. Quantitative coronary angiography and qualitative coronary ultrasound analyses have been performed at independent core laboratories.

Results: To date, enrollment has been completed with a technical success rate of 100%. The 30-day MACE rate was 0%, and the 6-month clinical and angiographic follow-up is still ongoing. However, preliminary data based on 16 patients revealed a 6-month MACE rate of 50.0%, including target lesion revascularizations in 7 patients and 2 acute myocardial infarctions (1 myocardial infarction caused by a de novo lesion of the target vessel). The preliminary restenosis rate was 37.5%. Complete procedural, 30-day clinical as well as 6-month clinical, angiographic, and intravascular ultrasound data from the EVIDENT trial will be presented.

Conclusion: The EVIDENT trial demonstrates safety of a new tacrolimus-eluting coronary stent graft in the treatment of saphenous vein graft lesions at 30-day follow-up. However, preliminary 6-month follow-up data suggest that there is no superiority compared with reported outcomes of conventional stent designs. The data set needs to be completed for the final assessment to be made.