The evidence indicates that not all DES are equal

As with all new technologies the early research is focused on demonstrating efficacy and safety. Stent research is no different, and just like other DES the results from early ENDEAVOR clinical trials were used to position this stent as ‘the safest DES’.

New data presented at TCT 2008 have suggested there is an increased safety risk with the Endeavor zotarolimus-eluting stent when compared with the Cypher sirolimus-eluting stent in patients with coronary artery disease.

Nine-month results from SORT-OUT III: A Prospective Randomized Comparison of Zotarolimus-Eluting and Sirolimus-Eluting Stents in Patients with Coronary Artery Disease showed increased rates of MI, stent thrombosis, and target lesion revascularisation (TLR) with the Endeavor stent.

SORT-OUT III was designed to reflect clinical practice, and investigators used patient-driven clinical events collected in three Danish registries. More than 2300 patients were included in the study and randomised to treatment with the zotarolimus-eluting stent or sirolimus-eluting stent.

All patients were treated with dual antiplatelet therapy for at least 12 months. Most lesions treated were B- and C-type lesions or off-label indications, and roughly half of all patients underwent PCI for the treatment of stable angina. On average 1.5 lesions were treated per patient with 1.7 stents, with a mean length of approximately 20 mm in both groups.

At nine months, there were statistically significant increased risks of “ARC definite” stent thrombosis and Myocardial Infarction (MI) (Figure 1), as well as higher rates of STET and clinically significant restenosis (Figure 2) in the Endeavor group. There was no difference in all cause mortality and cardiac mortality between two groups although there were trends toward increased risk in the Endeavor group.

Registry Data supports findings from SORT-OUT III

In another comparison of the CYPHER stent with the ENDEAVOR stent, an analysis of registry data showed higher mortality rates at two years, as well as more stent thromboses, higher TLR rates, and in-segment restenosis in patients treated with the ENDEAVOR stent.

The use of drug-eluting stents (DES) has grown considerably in volume and in scope since the introduction of the CYPHER® sirolimus-eluting stent (Cordis) in 2002. DES are now employed widely in high-risk patients and complex lesions. These indications are very different from the simple de novo lesions and low risk patients enrolled in early clinical studies including those trials comparing Endeavor™ Zotarolimus-eluting stents (Medtronic) and XienceV™, Everolimus-eluting stents (Abbott).

When considering treatment options for such patients, the interventional cardiologist should therefore seek robust clinical evidence to support their choice of DES. This is especially important when considering the durability of the long-term benefits of DES, and more importantly what the long-term safety of DES is.
Here are the two-year findings from the Western Denmark registry, a large database that collects detailed patient and procedure data on coronary interventions from three high-volume interventional centres in western Denmark. Between 2005 and 2007, more than 6000 patients were treated with either the CYPHER or ENDEAVOR stent. Follow-up beyond two years showed the zotarolimus-eluting stent to be associated with an increased risk of all-cause mortality and a trend toward increased cardiac mortality compared with the sirolimus-eluting stent (Figure 3). There were also higher rates of stent thrombosis, TLR, and in-segment restenosis with the Endeavor stent.

The SORT-OUT III investigators plan to follow patients out to two years, the period during which patients stop dual antiplatelet therapy, in order to reassess in a randomised fashion a worrisome finding from the Western Denmark Heart Registry.

The results from both SORT-OUT III and Western Denmark Registry contrast with two-year follow-up data from the ENDEAVOR III trial, as well as nine-month and two-year data from the ENDEAVOR IV trial.

Follow-up data from ENDEAVOR IV, a randomized trial comparing the zotarolimus eluting stent Endeavor and the paclitaxel eluting stent Taxus™ in patients with coronary artery disease, showed more late lumen loss with the zotarolimus-eluting stent at one year, but the difference in TLR at 2 years reached statistical significance only in the angiographic follow-up group. In addition, there were reduced rates of all MIs in the Endeavor group and a trend for reduced rate of very late stent thrombosis.

**Important Information:** Prior to use, refer to the “Instructions for use” supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions. As part of the Cordis policy of continuous product development we reserve the right to change product specifications without prior notification. The CYPHER SELECT™ PLUS Sirolimus-eluting Stent is not for sale in the USA. Not intended for distribution in the USA. Sirolimus-eluting Stent made by Cordis pursuant to a license from Wyeth Pharmaceuticals. The third-party trademarks are the trademarks of their respective owners.

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