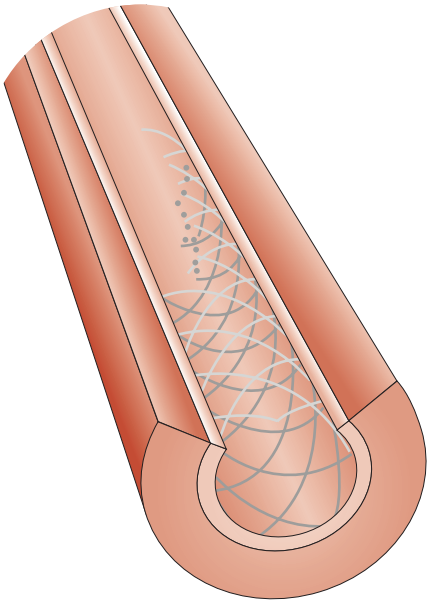
INTERVENTIONAL CARDIOLOGY

# A bright future for biodegradable polymer DESs?



The ISAR-TEST-4 investigators have reported promising results for a novel, biodegradable polymer drug-eluting stent (DES). This randomized controlled trial benefited from a patient population that was representative of routine clinical practice. At 1 year follow-up, the clinical efficacy of the biodegradable stent was found to be noninferior to both the Cypher® (Cordis, Miami Lakes, FL) and Xience® (Abbott Vascular, Abbott Park, IL) DESs, which employ permanent polymers. "The choice of comparator stents is notable" says Dr Robert Byrne from the German Heart Centre, Munich, who was one of the investigators, "as they are the two most effective DESs available on the market."

DESs have been proven to reduce the risk of target vessel restenosis when compared with bare-metal stents, but have also been associated with late stent thrombosis. This outcome is thought to be related to the use of durable polymer coatings, which effectively control drug delivery but can also cause prolonged inflammation of the vessel wall. The use of a polymer that breaks down after the drug has been released could help avoid this problem.

The researchers randomly assigned 2,603 patients with ischemia and ≥50% *de novo* coronary vessel stenosis to receive the biodegradable stent (rapamycin eluting), the Cypher® stent (rapamycin eluting), or the Xience® stent (everolimus eluting) in a 2:1:1 ratio. All participants received antiplatelet medications before, during, and after intervention. There were no significant differences in clinical outcomes (composite of cardiac death, myocardial infarction, or target-lesion revascularization) at 30 days follow-up. At 1 year after intervention, however, the clinical outcome rates were 13.8% and 14.4% in the biodegradable-polymer and permanent-polymer groups, respectively (relative risk 0.96, 95% CI 0.78–1.17, $P$ for noninferiority = 0.005). The incidence of stent thrombosis was the same in each group. In addition, there was no difference in the components of the composite outcome between the different stent types or across prespecified subgroups (patient sex and age, diabetes status, and vessel size).

Prior to publication of the paper by Byrne and colleagues, there were just two randomized controlled trials on the efficacy and safety of biodegradable stents in the literature (the ISAR-TEST-3 and LEADERS trials). Therefore, this analysis from ISAR-TEST-4—the largest randomized trial of DESs published so far—adds considerably to the literature. However, the investigators are quick to point out that the long-term benefits of biodegradable polymer stents remain hypothetical. "We will follow this cohort of patients closely out to 5 years" explains Dr Byrne, "it is to be hoped that, in parallel with data from other investigations in this field, we can provide definitive answers as to whether the promise of biodegradable polymer DESs translates into enhanced long-term patient outcomes."

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**Original article** Byrne, R. A. *et al.* Randomized, non-inferiority trial of three limus agent-eluting stents with different polymer coatings: the Intracoronary Stenting and Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents (ISAR-TEST-4) trial. *Eur. Heart J.* **30**, 2441–2449 (2009).



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