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INTERVENTIONAL CARDIOLOGY

Operator technique is predictive of BVS-related adverse events

> device thrombosis occurred more frequently with BVS implantation than with EES use

Patients implanted with a bioresorbable vascular scaffold (BVS) have higher rates of target-vessel myocardial infarction and device thrombosis at 3 years than patients treated with everolimus-eluting stents (EESs), according to results from the ABSORB III trial. A comprehensive analysis of the effect of procedural technique on BVS outcomes from the five ABSORB clinical studies indicates that vessel sizing and operator technique are strongly predictive of adverse device-related outcomes during the 3-year follow-up. Whether modulation of operator technique can lead to reduced rates of BVS-related adverse events remains to be determined.

Given their capacity to be completely resorbed after approximately 3 years, BVSs were designed to overcome the occurrence of late adverse events after percutaneous coronary intervention (PCI) related to the permanent metallic caging of coronary arteries by drug-eluting stents (DESs). The poly-L-lactic acid-based everolimus-eluting Absorb BVS (Abbott Vascular, USA) was approved for use in both the United States and Europe after the 1-year outcomes from the large-scale, randomized ABSORB III trial indicated that it was noninferior to EES for the occurrence of target-lesion failure. However, several subsequent small, randomized trials, observational registries, and meta-analyses reported greater 1-year and 2-year rates of device thrombosis and adverse events with BVS use compared with use of contemporary DESs. The ABSORB III investigators now present the outcomes of the prespecified 3-year follow-up analysis.

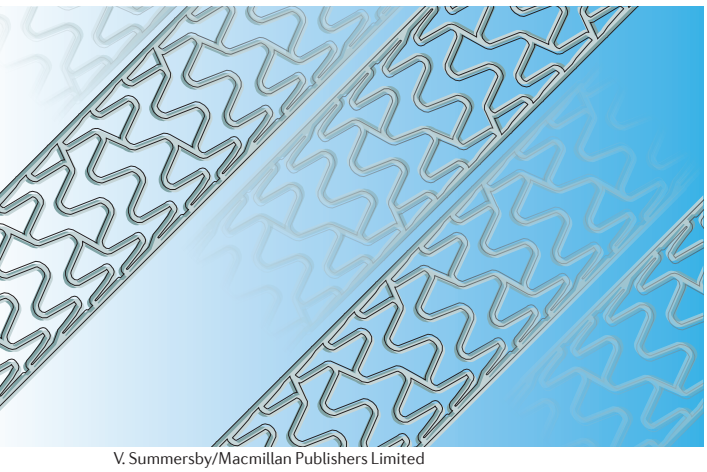
ABSORB III involved 2,008 patients undergoing PCI of one or two *de novo* coronary artery lesions who were randomly assigned in a 2:1 ratio to either the Absorb BVS or the Xience EES (Abbott Vascular). The device-related composite end point of target lesion failure (cardiac death, target-vessel myocardial infarction, or ischaemia-driven target-lesion revascularization) over 3 years was observed more frequently in the BVS group than in the EES group (13.4% versus 10.4%; HR 1.31, 95% CI 0.99–1.73, $P=0.06$). Furthermore, device thrombosis occurred more frequently with BVS implantation than with EES use of between 1 and 3 years, and cumulatively over 3 years.

The increased rates of device thrombosis and target lesion failure associated with BVS use "can be attributed to both design limitations of the first-generation scaffolds, as well as suboptimal implantation technique", according to Gregg Stone, lead investigator of the ABSORB III trial. In a separate study, Stone and colleagues sought to determine the relationship between BVS-related adverse events and operator technique by pooling data from the five ABSORB studies and adjusting for baseline clinical and angiographic characteristics.

Procedural technique was evaluated in 2,973 patients with 3,149 BVS-treated coronary artery lesions. Optimal pre-dilatation, vessel-size selection, and post-dilatation in all BVS-treated lesions were performed in 59.2%, 81.6%, and 12.4% of patients, respectively. Operator selection of properly sized vessels for BVS implantation was an independent predictor of freedom from target lesion failure over 3 years (HR 0.72, $P=0.01$).

"Future studies are now warranted to examine whether the occurrence of events might be indeed reduced by improved technique and to determine whether normalization of vascular structure once the BVS is resorbed can influence its late safety and efficacy profile compared with permanent metallic DESs," comments Salvatore Brugaletta, who was not involved in either study. "I hope industries will enhance device design (for example, use of thinner struts, improved expansion characteristics, and use of new materials) in order to improve their safety."

Karina Huynh



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FURTHER READING Indolfi, C. *et al.* Bioresorbable vascular scaffolds — basic concepts and clinical outcome. *Nat. Rev. Cardiol.* **13**, 719–729 (2016)

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