A n innovative approach to the comparison of different percutaneous coronary intervention devices is to deploy them in different arteries within the same individual, thereby removing the confounding influence of patient-related factors on outcomes (Figure).  

Preferably, the influence of lesion-related factors would be minimized by randomly allocating individual lesions to one or other treatment.

See Article by Cassese et al

In this issue of Circulation: Cardiovascular Interventions, Cassese et al\(^5\) report an intraindividual comparison of the performance of everolimus-eluting bioresorbable vascular scaffolds (BVS) versus durable metallic everolimus-eluting stents (DES) in the same individual but in different arteries. The 90 patients undergoing percutaneous coronary intervention to 239 lesions were assigned, at operator discretion, to receive a BVS (n=112) or DES (n=127). The primary end point of in-device late lumen loss at 6 months of angiographic follow-up was greater in lesions treated with a BVS (0.30±0.59 mm) than with a DES (0.22±0.48 mm, P=0.035). However, after adjustment for baseline angiographic differences, device type no longer significantly influenced late lumen loss.\(^5\)

This is not a randomized trial. Although the contribution of patient-related factors that may influence outcome between groups was controlled for in the study design, there were important baseline lesion-related differences. As would be expected, BVS were deployed in easier lesions; they were less likely to be used in left main or bifurcation lesions, or in those with important calcification. However, BVS were disadvantaged by being deployed in smaller vessels and in lesions with a smaller minimal luminal diameter. Although adjustment was made for these differences, there is always doubt whether statistical methods can adjust for all potential confounders.

The authors conclude that in patients receiving multilevel percutaneous coronary intervention, a revascularization strategy with BVS displays acceptable antirestenotic efficacy compared with DES. The results are hypothesis generating but are in line with published randomized trials using the same devices.\(^5\)  

Five years after the first clinical Absorb coronary implantation,\(^10\) Conformité Européenne (CE mark) approval was granted in 2011. Subsequently, the device became commercially available in many parts of world outside of the United States and Japan.

With >3 million durable stents being implanted worldwide each year,\(^11\) why is the number of Absorb coronary implants in the 5 years since 2011\(^12\) only 150,000? Part of the reason may be that assessment of outcomes after percutaneous coronary intervention with stent deployment has traditionally focussed on 2 main problems, stent thrombosis and restenosis, and in the first 6 to 12 months post procedure. This may be too soon for the manifestation of potential advantages of a resorbable scaffold, which may be beyond 3 years when the device has resorbed.

BVS are more difficult to implant. The 150-µm strut thickness and larger crossing profile (1.4 mm) mean that they less easily track down calcified and tortuous vessels. They then must be optimally expanded to achieve optimal wall apposition. If the operator misjudges vessel size and implants a scaffold that is too small, the scaffolds are less forgiving than DES with post-dilatation. Delivery problems can be reduced by careful lesion vessel selection and preparation. Through a 6F guide catheter, Absorb delivery can be facilitated by a buddy guidewire. Our bench testing shows that preloading a 2.5- or 3.0-mm (but not a 3.5 mm) Absorb scaffold into a 6F Guideliner (Vascular Solutions Inc, Minneapolis, MN) can aid delivery. A 7.5F sheathless Eaucath (Asahi Intecc, Aichi, Japan) can accommodate a 7F Guideliner to enhance delivery of a 3.5-mm Absorb, and allow delivery of all scaffold sizes via a radial approach.

Absorb strut fracture can be avoided by obeying postdilatation rules.\(^13,14\) In particular, if a postdilating balloon is not oversized, fracture will not occur no matter what the inflation pressure.\(^13,14\)

Once implanted, an increased rate of scaffold/stent thrombosis has been reported with the Absorb scaffold compared with the everolimus-eluting metallic stent during the next 12 months.\(^15\) Although it is likely that this can be mitigated by an optimized implantation strategy,\(^16\) some of the increased risk likely relates to the greater scaffold strut thickness adversely altering coronary flow and shear forces.\(^17\)

However, patients are often out-of-sight and out-of-mind by the time that the potential benefits of scaffolds might manifest some years post implantation.\(^18\) There is physician uncertainty around the clinical importance of potential advantages of, for instance, restoration of coronary vasemotion.

The report by Cassese et al\(^5\) is timely because in July this year, the US Food and Drug Administration approved the
Absorb GL1 polymeric fully resorbable everolimus-eluting scaffold system. US clinical sites will have the advantage of learning from the European and Asia-Pacific real-world experience with BVS. Time will tell whether this translates to their sustained clinical uptake.

Disclosures

J.A. Ormiston is an advisory board member for Boston Scientific Corporation and has received minor honoraria. The other author reports no conflicts.

References


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Of Stents and Scaffolds: Trial Data and the Real World
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