Bioresorbable vascular scaffolds (BVS) boast the unique ability to satisfy the temporary need for mechanical support during initial arterial healing following percutaneous coronary revascularization, obviating the long-term disadvantages of permanent metallic prostheses.

Based on the results of the ABSORB trial cohort A (n = 30) (1) and cohort B (n = 101) (2), the Absorb BVS (Abbott Vascular, Santa Clara, California) was the first such device to obtain CE mark approval and become available for clinical use in Europe. Registry data have demonstrated sustained efficacy of the BVS during 5-year follow-up (3–5), based on multimodality imaging, as well as the presence of unique findings such as restoration of nitrate-induced vasomotion (6) and vessel enlargement (positive remodeling) in the treated segment after 2 to 5 years of scaffold deployment (3).

Notably, more than 60,000 patients have been treated worldwide with Absorb in the past 3 years, despite the absence of a single randomized trial comparing these devices with contemporary metallic drug-eluting stents (DES). Recently, the results of 2 randomized trials comparing the Absorb BVS with metallic DES were released.

In ABSORB II, Serruys et al. (7) compared the BVS with the everolimus-eluting cobalt-chromium Xience stent. This study had a 2:1 single-masked design and coprimary endpoints of nitrate-induced vasomotion (a novel endpoint) and changes in minimum lumen diameter (in-stent late loss) at 3 years (a traditional endpoint). However, the Lancet publication only contained the results for secondary endpoints, such as acute (peri-procedural) performance, and the composite clinical endpoints of death, myocardial infarction, coronary revascularization, and angina status at 6 and 12 months. Despite superior acute performance of the metallic stent over the polymeric scaffold (i.e., higher in-stent acute gain and less residual stenosis), both devices showed excellent midterm clinical performance, with low and comparable rates of clinical adverse events. Although these preliminary results might reassure enthusiasts of this novel technology, including us, it is important to note that the trial was not powered to specifically address any of the secondary endpoints; therefore, the results should be interpreted cautiously.

In this issue of the Journal, Puricel et al. (8) presented the acute and 9-month angiographic results of the single-center, randomized (1:1:1) EVERBIO II (Comparison of Everolimus- and Biolimus-Eluting Stents With Everolimus-Eluting Bioresorbable Vascular Scaffold Stents II) trial (NCT01711931), comparing the Absorb BVS and 2 of the most-used contemporary DES, the everolimus-eluting platinum-chromium stent (EES) and Biolimus-eluting stainless steel stent (BES) (8). Interestingly, the trial was designed to show superiority of the metallic DES at the midterm invasive follow-up.

The investigators should be congratulated on carrying out the first “real-world” randomized comparison of the best-in-class metallic DES and the first market-approved BVS. For a 1-year period, they enrolled 240 consecutive patients, including those with acute coronary syndrome (39%), chronic
total occlusions (1.5%), and lesions involving vein grafts (4%).

Despite marked differences in composition, thickness, crossing profile, and radial strength, the Absorb BVS was associated with reasonable acute performance, with comparable in-stent acute gain (1.97 ± 0.66 mm vs. 2.13 ± 0.5 mm; p = 0.31) and residual stenosis (9.0 ± 5.3% vs. 7.7 ± 5.2%; p = 0.08), although acute recoil, as expected, was higher with the BVS (9.3 ± 6.5% vs. 6.7 ± 4.8%; p < 0.01). Contrary to the researchers’ a priori hypothesis, at the 9-month angiographic evaluation, the Absorb BVS was associated with a low and equivalent in-stent late luminal loss versus DES (0.30 ± 0.39 mm vs. 0.23 ± 0.36 mm; p = 0.19). However, the in-segment analysis showed a discrete but significantly higher lumen loss at the edges of the BVS (0.31 ± 0.45 mm vs. 0.18 ± 0.47; p = 0.04), which did not translate into a higher rate of binary in-segment restenosis (12% with Absorb vs. 14% with the combined metallic DES; p = 0.83).

Encouragingly, there was only a single case of BVS thrombosis.

Although the EVERBIO II data are reassuring, a few points require scrutiny. First, despite being the first randomized angiographic comparison between metallic DES and BVS, the sample size remains modest. Furthermore, it is unclear why the investigators included 2 groups of metallic DES as comparators because their primary endpoint was based on 9-month angiographic parameters and there is no evidence of differences in EES and BES at this time point.

Second, although the enrolled population reflects the daily practice and patient composition of Sweden’s Fribourg University Hospital, it may not represent patients in routine clinical practice elsewhere. Although patient characteristics, including vessel size and lesion length, are comparable with published “all-comer” patient populations, the mean number of stents/scaffold per patient (1.2) is rather low, suggesting that only 1 lesion may have been treated in most patients (9,10). Also, the investigators did not report the percentage of treated bifurcation, ostial, and calcified lesions or procedure and device success rates. Differences in lesion complexity might confound angiographic and clinical outcomes and are therefore important to fully understand this novel device’s performance and limitations.

Third, to explain the slight increase in late lumen in-segment loss, the researchers mentioned a possible “transient constrictive effect found at scaffold edges,” as previously described by Gogas et al. (11) in a retrospective evaluation of the ABSORB cohort B population. Other explanations might also be related to “geographic miss,” especially at the time of post-dilation because the operators relied only upon the proximal and distal markers to identify scaffold boundaries. Core laboratory difficulties in accurately ascertaining the in-scaffold and in-segment regions, especially in calcified vessels treated with non-radiopaque BVS, as well as “play of chance,” alternatively explain the in-segment differences observed.

Finally, as Puricel et al. (8) highlighted, metallic stents and the current BVS devices are deployed differently. With BVS, careful vessel sizing, “aggressive” pre-dilation, and particular attention to the balloon used for post-dilation help minimize risk of scaffold damage (12). This may account for the differences in pre-dilation rates and deployment pressure observed in the EVERBIO II trial. Overall, the rates of post-dilation were very low (31% with EES, 30% with BES, and 34% with BVS) and smaller than usually reported in clinical registries, even with BVS (13-15). Whether this reflected the researchers’ daily practice or their particular concern with scaffold rupture, we believe that post-dilation is an essential “step” in either stent or scaffold implantation and should be more often performed.

Although considered a children’s book, The Little Prince by Antoine de Saint-Exupéry is also an adult philosophical fable, with several observations about life and human nature, such as “One sees clearly only with the heart. What is essential is invisible to the eyes.” The results of the present study are reassuring that the radiolucent BVS technology may be a step in the right direction to fulfill this premise.

REFERENCES

KEY WORDS ABSORB, bioresorbable vascular scaffold, drug-eluting stent(s), randomized trial