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EDITORIAL COMMENT

Bioresorbable Vascular Scaffold Implantation

To Whom and How?*

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In September 25, 2012, Abbott Vascular (Santa Clara, California) announced the launch of the Absorb, the world's first drug-eluting poly-L-lactide acid-based bioresorbable vascular scaffold (BVS), in Europe and parts of Asia Pacific and Latin America. Several potential advantages related to the transient scaffolding were attributed to this device. The so-called restoration therapy was advocated as the trigger for late lumen enlargement, vascular vasomotor response normalization, or even reduction of further angina pectoris events. These benefits were imputed from the findings of the first-in-man experience by the use of the Absorb BVS (1). Of note, this registry was the only evidence available at the time of the BVS official launch announcement.

Since then, the Absorb scaffold has been implanted in any clinical and anatomical context at the discretion of the interventional cardiologist without any specific implantation protocol. While several landmark trials were recruiting patients, data from single-center registries were reported showing a wide range of outcomes. However, a common finding in most registries was the early scaffold thrombosis rate that appeared to be high above the standard for metallic drug-eluting stents. As a matter of fact, in the GHOST (Gauging coronary Healing with bioresorbable Scaffolding plaTforms in EUrope) multicenter, multinational registry (2) it reached a 2.1% rate at 6 months, which blew all the alarms in the Interventional Cardiology community. The implantation technique was in the eye of the storm and subsequently, expert consensus documents were produced with the aim to standardize BVS use (3). Although results of the first U.S. pivotal trial (4) led to Food and Drug Administration approval of the device (July 2016), concerns about the acute performance of this first-generation BVS remained. Furthermore, first reports on the occurrence of very late thrombotic events (5), new results from independent randomized trials (6), and long-term follow-up of pivotal trials (7,8) pushed the company working together with European regulatory agencies to restrict the use of the device to centers already participating in clinical trials and registries as of May 31, 2017. Ultimately, the inferiority of the first-generation BVS versus current metallic drug-eluting stents has been demonstrated in a recent meta-analysis of 7 trials in which the BVS was associated with increased rates of device-oriented adverse events and device thrombosis cumulatively at 2 years and between 1 and 2 years of follow-up (9).

The BVS implantation technique has arisen as the major contributor for the acute results of the device. The compliance with the so-called pre-dilatation, sizing, and post-dilatation (PSP) criteria has proven to be related to acute outcomes in the GHOST registry (10) as well as in the randomized ABSORB trials. However, whether proper PSP implementation at the day of the procedure may have an impact at long-term follow-up during the vulnerable bioresorption period remains to be prospectively demonstrated.

It is now clear that not all lesions are amenable for current-generation poly-L-lactide acid-based BVS. Heavily calcified vessels, for instance, may induce infraexpansion of the device, acute recoil, and device fracture as a trigger for thrombosis. True bifurcations could also be included in this group as well as small

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vessels that have been recently related to ominous outcomes in the ABSORB III trial (11). Conversely and despite initial concerns (12,13), patients with acute coronary syndromes portend the benefit and the hope of this technology. Patients experiencing a ST-segment elevation myocardial infarction (STEMI) are often young, with single-vessel disease, and with soft plaques located in proximal segments of the coronary tree. Furthermore, results of the only randomized trial in this context obtained reassuring results up to 2 year-follow-up (14).

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Selection of the proper candidate to be treated with Absorb and use of a refined implantation technique is a must for current available technology. In this regard, in this issue of *JACC: Cardiovascular Interventions*, Ielasi et al. (15) present data from the BVS STEMI STRATEGY-IT (A Prospective Evaluation of a Standardized Strategy for the Use of Bioresorbable Vascular Scaffold in ST-segment Elevation Myocardial Infarction) registry, which are most welcome. STEMI lesions require a different approach compared with their chronic stable counterparts. Therefore, the validation in a multicenter registry of a PSP-derived algorithm of treatment for thrombotic stenosis amenable for BVS technology should be congratulated. In fact, this registry has demonstrated a very low acute and subacute adverse event rate by the use of this algorithm. However, several limitations should be highlighted. First, results are poorly generalizable to the entire STEMI population, as only 17% of patients were suitable for Absorb device according to the implanting physician. Second, this registry lacks of long-term follow-up, which precludes any inference on benefits of this implantation technique during the resorption phase of the device. Third, whether this algorithm can also be implemented to other BVS technologies (i.e., metallic-based bioabsorbable scaffold) remains to be prospectively proven.

With regard to future perspectives, next BVS developments and iterations should incorporate a dedicated implantation protocol that should be proven and adapted for all clinical scenarios before being released to the market.

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