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STATE-OF-THE-ART REVIEW

The State of the Absorb Bioresorbable Scaffold

Consensus From an Expert Panel

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ABSTRACT

Significant progress has been made in the percutaneous coronary intervention technique from the days of balloon angioplasty to modern-day metallic drug-eluting stents (DES). Although metallic stents solve a temporary problem of acute recoil following balloon angioplasty, they leave behind a permanent problem implicated in very late events (in addition to neoatherosclerosis). BRS were developed as a potential solution to this permanent problem, but the promise of these devices has been tempered by clinical trials showing increased risk of safety outcomes, both early and late. This is not too dissimilar to the challenges seen with first-generation DES in which refinement of deployment technique, prolongation of dual antiplatelet therapy, and technical iteration mitigated excess risk of very late stent thrombosis, making DES the treatment of choice for coronary artery disease. This white paper discusses the factors potentially implicated in the excess risks, including the scaffold consideration and deployment technique, and outlines patient and lesion selection, implantation technique, and dual antiplatelet therapy considerations to potentially mitigate this excess risk with the first-generation thick strut Absorb scaffold (Abbott Vascular, Abbott Park, Illinois). It remains to be seen whether these considerations together with technical iterations will ultimately close the gap between scaffolds and metal stents for short-term events while at the same time preserving options for future revascularization once the scaffold bioresorbs. (J Am Coll Cardiol Intv 2017;10:2349–59)

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ABBREVIATIONS AND ACRONYMS

BRS = bioresorbable scaffold

CoCr-EES = cobalt-chromium everolimus-eluting stent(s)

DAPT = dual antiplatelet therapy

DES = drug-eluting stent(s)

IVUS = intravascular ultrasound

OCT = optical coherence tomography

PCI = percutaneous coronary intervention

PSP = pre-dilatation, vessel sizing, post-dilatation

RCT = randomized controlled trial

RVD = reference vessel diameter

ST = scaffold thrombosis

STEMI = ST-segment elevation myocardial infarction

TLF = target lesion failure

TVMI = target vessel myocardial infarction

The concept of bioresorbable scaffold (BRS) technology was introduced more than 2 decades ago with the goal of avoiding the adverse events related to permanent metallic stents, such as stent thrombosis, restenosis, and neoatherosclerosis.

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By eliminating the stent within a few years after implantation, the aim of the BRS technology was to allow the scaffold to provide mechanical support early on and then disappear, without leaving metal behind. The premise of the BRS was that after complete absorption of the scaffold there would be full restoration of vascular reactivity, a reduction of very late events related to permanent metallic stents and, more importantly, preservation of future revascularization options by either repeat percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery. Over the last decade, the Absorb scaffold (Abbott Vascular, Abbott Park, Illinois) became the leading BRS technology supported by preclinical and clinical data, including thousands of patients who were randomized against the leading drug-eluting stents (DES). Those studies were conducted across 3 continents, and clinical follow-up has continued to accumulate and is actively reported. Although the results from the feasibility studies were encouraging with follow-up for up to 5 years, reports of early, late, and very late scaffold thrombosis (ST) emerged as the technology was approved for marketing. These reports raised concerns among physicians and regulators. The U.S. Food and Drug Administration issued an advisory warning letter about the potential risks and advised that proper patient and lesion selection and optimal deployment techniques could minimize these risks. European and Australian regulators were more aggressive and halted the commercial sales of the Absorb GT1 scaffold (Abbott Vascular) and restricted use to trial centers. Those actions have left physicians and patients confused about how best to move forward with the technology. The purpose of this expert consensus manuscript is to discuss the clinical data, future directions, optimal device implant techniques, and necessary

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