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STATE-OF-THE-ART REVIEW

Bioresorbable Scaffolds for the Management of Coronary Bifurcation Lesions

Hiroyoshi Kawamoto, MD,[a,b] Neil Ruparelia, MBBS, DPHIL,[a,b,c] Akihito Tanaka, MD,[a,b] Alaide Chieffo, MD,[a] Azeem Latib, MD,[a,b] Antonio Colombo, MD[a,b]

ABSTRACT

The use of bioresorbable scaffolds (BRS) may be associated with benefits including restoration of endothelial function, positive vessel remodeling, and reduced risk for very late (stent) thrombosis compared with metallic stents by virtue of their complete absorption within 3 to 4 years of implantation. When treating bifurcation lesions, these advantages may be even more pronounced. The aim of this review is to summarize current experiences and technical considerations of bifurcation treatment with BRS. Because of the physical properties of current-generation BRS, there are concerns with regard to the efficacy and safety of this novel technology for the treatment of bifurcations, with the potential for increased rates of scaffold thrombosis and side-branch occlusions, and as a consequence, bifurcations have been excluded from the major BRS trials. Nevertheless, BRS have been used for this indication in clinical practice, as evidenced by "real-world" registries. Considering the potential limitations, specific technical considerations and modified bifurcation strategies should be used in an attempt to attenuate problems and achieve optimal procedural and clinical outcomes. (J Am Coll Cardiol Intv 2016;9:989–1000) © 2016 by the American College of Cardiology Foundation.

Technological and procedural advances in recent years have resulted in vastly improved clinical outcomes following percutaneous coronary intervention. In particular, the advent of current-generation drug-eluting stents (DES) reduced the rate of restenosis compared to bare-metal stents (1,2). Although the treatment of complex lesions with metallic DES is now well established (3), coronary bifurcation lesions remain a technical challenge, even with contemporary metallic stents, because of higher rates of increased restenosis (4,5) and stent thrombosis (6), which are likely due to incomplete neointimal coverage and permanent metallic caging of the flow divider and the side branch (SB).

The use of bioresorbable scaffolds (BRS) for the treatment of coronary artery disease is potentially advantageous by virtue of complete bioabsorption of struts, which may result in the recovery of vasomotor function, preserved possibility for positive remodeling, and a potential reduction of very late clinical adverse events because of the absence of a residual permanent foreign body (7). These potential advantages may be even more pronounced in the setting of bifurcation lesions, which are associated with a greater occurrence of adverse events compared with "simple" lesions. However, clinical experience with this novel technology for bifurcation lesions is limited, and there is currently no consensus or recommendation with regard to the optimal technical approach.

Our aim in this review is to summarize current experiences and technical considerations of bifurcation treatment with BRS.

From the [a]Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy; [b]Interventional Cardiology Unit, EMO-GVM Centro Cuore Columbus, Milan, Italy; and the [c]Imperial College, London, United Kingdom. Dr. Latib serves on an advisory board for Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Kawamoto and Ruparelia contributed equally to this work.

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ABBREVIATIONS AND ACRONYMS

BRS = bioresorbable scaffold

DES = drug-eluting stent(s)

IVUS = intravascular ultrasound

KBI = kissing balloon inflation

MB = main branch

OCT = optical coherence tomography

POT = proximal optimization technique

SB = side branch

TAP = T-stenting and small protrusion

SPECIFIC CONSIDERATIONS FOR BRS TREATMENT OF BIFURCATIONS

A number of randomized trials and retrospective studies with metallic stents demonstrated that when possible, a single stent (provisional strategy) is superior to the implantation of stents in both branches of the bifurcation (4,5,8,9). If the bifurcation lesion is not suitable (e.g., because of significant SB disease or the presence of dissection), an elective 2-stent strategy should be adopted with accepted techniques, including mini-crush, DK-crush, T-stenting, and culotte stenting (9). However, these techniques cannot be simply performed with BRS in a similar fashion to DES without taking into account the important differences in physical properties between the 2 platforms. As a consequence, when a BRS is being considered for the treatment of a bifurcation lesion, operators should consider the following: 1) fragility; 2) overexpansion limit; 3) strut thickness and width; and 4) deliverability and crossability.

Specific procedures such as SB ballooning, the proximal optimization technique (POT), or kissing balloon inflation (KBI) used for bifurcation lesions should therefore be modified. Operators should pay careful attention to each step when further optimization of the SB is deemed necessary following BRS implantation to the main branch (MB).

The greater strut thickness (~150 μm) and width of the current BRS (Absorb, Abbott Vascular, Santa Clara, California) compared with DES are important procedural considerations. Strut thickness and malapposition are considered critical factors in modulating thrombogenicity in the setting of metallic stents (10). Therefore, techniques that minimize strut overlapping and protrusion into the vessel cavity should be used to reduce the risk for scaffold thrombosis. Furthermore, the relatively bulky mass of BRS results in a larger device profile compared with the Xience everolimus-eluting stents (Abbott Vascular) (Absorb 1.43 ± 0.02 mm vs. Xience 1.14 ± 0.01 mm; p = 0.04) (11). When a provisional 2-stent strategy (e.g., the T-stenting and small protrusion [TAP] technique) is used, operators should therefore be wary of increased difficulty in delivering a BRS, because of its size and physical properties, leading to fragility. Similar concerns are present regarding other techniques, such as culotte and crush.

CURRENT EXPERIENCE OF BRS USE FOR THE MANAGEMENT OF CORONARY BIFURCATION LESIONS

The pivotal BRS studies to date focused solely on "simple" lesions, excluding bifurcation lesions with SB diameter larger than 2 mm (12,13). The major randomized, prospective, and retrospective BRS studies are summarized in **Table 1**. Currently, there are limited data reporting clinical outcomes following BRS implantation in bifurcation lesions. The prevalence of bifurcation lesions varies greatly among studies and ranges from 15% to 45% (14–21). The only study that investigated clinical outcomes at 1 year following BRS implantation in bifurcation lesions (22) reported rates of major adverse cardiac events and target lesion revascularization to be lower, as expected, in the provisional stenting group (99 lesions) compared with a planned double-stenting group (23 lesions) (major adverse cardiac events: 9.5% vs. 11.2%; p = 0.91; target lesion revascularization: 5.5% vs. 11.2%; p = 0.49; provisional stenting vs. planned double-stenting, respectively). The remaining published data regarding the 2-stent techniques (including provisional double-stenting) with BRS are currently limited to bench tests and case reports (23–26). "Real-world" registries including complex lesions (without exclusion of bifurcations) demonstrated a trend toward higher rates of scaffold thrombosis, especially in the setting of acute coronary syndromes (14,15,27–33).

INDICATION OF BRS FOR BIFURCATION LESIONS

PHYSICAL PROPERTIES OF BRS. On the basis of ex vivo bench testing, Ormiston et al. (11) demonstrated that the 3.0-mm Absorb BRS can be expanded up to 3.8 mm without strut disruption. However, there are no data available supporting these observations in vivo, and current recommendations suggest a maximal overexpansion of 0.5 mm beyond the nominal scaffold size (but this varies among different BRS platforms). We therefore recommend the judicious use of quantitative coronary angiography or baseline intravascular imaging such as intravascular ultrasound (IVUS) or optical coherence tomography (OCT) to determine the suitability of BRS for a bifurcation lesion.

LESION SELECTION. In view of the physical properties and limitations of current-generation BRS, not all bifurcation lesions are amenable to treatment with this technology. Specifically, we do not recommend BRS for the treatment of bifurcations with a >0.5-mm size discrepancy between the proximal and distal MB,