Cardiovascular Revascularization Medicine 20 (2019) 4

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Bioresorbable Scaffolds and Bifurcations

This does not sound like a logical combination. After the initial excitement about bioresorbable scaffolds (BRS), it is now clear that first-generation BRS (Absorb BVS, Abbott Vascular, Santa Clara, CA) have a clearly increased stent thrombosis risk for relatively non-complex lesions, as included in the ABSORB series of studies around the world [1]. Using these devices in bifurcation lesions with already-increased stent thrombosis risk is even more challenging [2], especially if a two-stent technique is necessary [3]. Yet, as the authors of the paper by Rampat et al. in this issue of *Cardiovascular Revascularization Medicine* point out, bifurcation lesions are at an increased risk for recurrent events, even with current-generation drug-eluting metallic stents (DES) [4]. The use of current permanent implants in coronary arteries needs to be seen in a larger perspective. Current median age of patients at first percutaneous coronary intervention (PCI) is 63 years; 87.1% of these survive 5 years, and over 80% of patients younger than 60 survive 10 years [5]. The recent data of the ISAR-TEST 4 randomized trial showed an overall 10-year survival rate of 70.2% [6]. Yet target lesion revascularization (TLR) with modern DES is still over 20% in this last cohort. For other implants like ocular lenses and orthopedic joint replacements, the treatment goals are much higher and in the range of 95% at 10 years. After improving our 1-year post-PCI results, first by the use of bare metal stents (BMS) and later with DES reaching a 1-year TLR rate of <10%, we have to set our next goals in improving our 10-year results at the same level as other implants. The current >20% late TLR rate is simply not acceptable in this wider perspective.

Late device failure, frequently resulting in TLR, is a complex process and a combination of progressive classical atherosclerotic disease in a caged vessel with no possibilities for positive remodeling, altered local flow dynamics, absence of natural vasomotion and accelerated by inflammatory processes related to the drug, coatings and the permanent metallic implants themselves. Late TLR is especially frequent in patients with diabetes, for long lesions, with small vessels, and for bifurcation lesions. Therefore, the goal to develop and use new techniques for these increasingly common types of lesions is still sound. The purpose of the authors of the current paper, to determine the best implantation strategies for BRS currently limited in overexpansion capabilities, is sensible. The observation that distal sizing resulted in more malapposition in the proximal end of the scaffold on optical coherence tomography (OCT) vs. the use of proximal sizing increases our knowledge of optimal bifurcation treatment. With current DES, proximal optimization using larger-diameter post-dilatation balloons up to the carina to avoid this malapposition is recommended [7]. Yet because of the material characteristics of the first-generation BRS, the correction capability is restricted to +0.5 mm. As demonstrated by the authors of the current manuscript, for the first generation BRS, this is insufficient in bifurcations with side branches >2 mm when smaller devices aiming at correct size for the distal vessel are used resulting in >5% malapposition, of which more than half are >300 microns, which usually will remain malapposed beyond 6-month follow-up. On the other hand, proximal sizing is not the solution with a potential increased risk of distal edge dissections.

With this information in mind, next-generation BRS should, besides thinner struts, also have larger expansion capabilities.

New bioresorbable scaffolds based on different materials are evaluated and commercially available in several countries. Current magnesium-based BRS are at a lower risk of strut fracture (DREAMS 2G, Magmaris, Biotronik AG, Buelach, Switzerland), have higher overexpansion capabilities and could be evaluated in bifurcation lesions [8]. Next-generation poly-L-lactic acid-based scaffolds have significantly thinner struts (DESolve Cx Plus, (Elixir Medical), MeRes100 (Meril Life Sciences), Firesorb (MicroPort, Shanghai, China)), which should reduce the current high early scaffold thrombosis rate. Thinner struts and larger expansion capabilities will again attract the use of these devices in bifurcation lesions where current DES outcomes are less favorable. Current development and first commercial uptake will be strongest in the up and coming markets of India and China, where the volume of PCIs is growing by double digits every year, procedures are self-paid, venture capital is largely available, and government support for development of innovative technology is intense. From these countries, improved devices will revitalize the BRS concept, and interventional cardiologists should investigate the optimal implantation technique and evaluate the long-term outcomes in complex lesions, where current technology still has limitations.

References

[1] Ali ZA, Gao R, Kimura T, Onuma Y, Kereiakes DJ, Ellis SG, et al. Three-Year Outcomes With the Absorb Bioresorbable Scaffold: Individual-Patient-Data Meta-Analysis From the ABSORB Randomized Trials. Circulation 2018;137(5):464–79.
[2] Felix CM, van den Berg VJ, Hoeks SE, Fam JM, Lenzen M, Boersma E, et al. Mid-term outcomes of the Absorb BVS versus second-generation DES: A systematic review and meta-analysis. PLoS One 2018;13(5):e0197119.
[3] Naganuma T, Colombo A, Lesiak M, Capodanno D, Gori T, Nef H, et al. Bioresorbable vascular scaffold use for coronary bifurcation lesions: A substudy from GHOST EU registry. Catheter Cardiovasc Interv 2017;89(1):47–56.
[4] Rampat R, Mayo T, Hildick-Smith D, Cockburn J. A Randomized Trial Comparing Two Stent Sizing Strategies in Coronary Bifurcation Treatment With Bioresorbable Vascular Scaffolds - The Absorb Bifurcation Coronary (ABC) Trial. Cardiovasc Revasc Med 2019;20:43–9.
[5] van Boven N, van Domburg RT, Kardys I, Umans VA, Akkerhuis KM, Lenzen MJ, et al. Development and validation of a risk model for long-term mortality after percutaneous coronary intervention: The IDEA-BIO Study. Catheter Cardiovasc Interv 2018;91(4):686–95.
[6] Kufner S, Joner M, Thannheimer A, Hoppmann P, Mayer K, Cassese S, et al. Ten-Year Clinical Outcomes From a Trial of Three Limus-Eluting Stents With Different Polymer Coatings in Patients With Coronary Artery Disease. Circulation 2018;139:325–33.
[7] Hildick-Smith D, Lassen JF, Albiero R, Lefevre T, Darremont O, Pan M, et al. Consensus from the 5th European Bifurcation Club meeting. EuroIntervention 2010;6(1):34–8.
[8] Haude M, Ince H, Abizaid A, Toelg R, Lemos PA, von Birgelen C, et al. Sustained safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de novo coronary lesions: 12-month clinical results and angiographic findings of the BIOSOLVE-II first-in-man trial. Eur Heart J 2016;37(35):2701–9.

Robert-Jan van Geuns
Department of Cardiology, Radboudumc, Nijmegen, The Netherlands

https://doi.org/10.1016/j.carrev.2018.12.014
1553-8389/