JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 10, NO. 18, 2017

ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2017.08.009

EDITORIAL COMMENT

No TROFI for Routine Post-Dilatation After BVS Implantation*

Tom Adriaenssens, MD, PhD, Peter R. Sinnaeve, MD, PhD

Once upon a time, skies looked perfectly blue above bioresorbable scaffold (BRS) technology, and the Absorb bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara, California), in particular. Second-generation drug-eluting stents (DES) had to a large extent resolved the vascular healing problems and associated elevated risk of stent thrombosis typical for their first-generation counterparts. Still, the interest of the interventional community was easily captured by the totally new concept of implanting a scaffold that would eventually completely disappear from the coronary vessel wall.

There were more than enough arguments to embrace this new technology, indeed. The development of the device was based on years of extensive material sciences and polymer resorption characteristics research. The first human studies, in a limited number of patients with nonchallenging coronary anatomies, were carefully conducted and revealed promising results. From a clinical point of view, several potential advantages over a permanent metal cage were clear. These included the possibility of later surgical grafting of the vessel, imaging with coronary computed tomography and even the withdrawal of antiplatelet therapy after complete resorption of the polymer device. Furthermore, neoatherosclerosis, lipid degeneration of the neointima, appeared to play a prominent role in the development of very late stent failure in all types of metallic stents, including second-generation DES (1). From this perspective, BRS might very well have been the ultimate answer to these unresolved DES issues.

Born under such a lucky star, few would have predicted the current appreciation of BRS technology and the Absorb BVS in particular. Where did the fairytale go bad?

Although a well-established program of clinical trials was developed, it seems the technology became the victim of its own success. Shortly after its introduction, the device started to be used in large numbers of complex patients and lesion subsets, not at all reflecting the easy lesions in stable patients from the small early trials. The price for this premature inappropriate adoption was paid not much later, with the first reports on elevated risks of BVS thrombosis (2). From that moment on, the focus of the international community was inevitably centered around the problem of scaffold thrombosis. The discussion only seemed to come to an end after recent publication of long-term follow-up data of the ABSORB II trial, the AIDA (Bioresorbable Scaffolds versus Metallic Stents in Routine PCI, The Amsterdam Investigator-Initiated Absorb Strategy All-Comers Trial) trial findings, and a meta-analysis of the larger randomized controlled trials so far, all pointing to an increased risk of scaffold thrombosis (including very late scaffold thrombosis) with BVS (3–5). Taking a step back toward the well-performing second-generation DES seemed a logical conclusion.

In retrospect, it seems too many unsubstantiated assumptions had been made during the adoption of BVS technology.

SEE PAGE 1867

In this issue of *JACC: Cardiovascular Interventions*, Yamaji et al. (6) question the necessity and appropriateness of standard post-dilatation immediately after BVS deployment, another assumption we easily made in our enthusiastic adoption of BVS. In a substudy of

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

From the Department of Cardiovascular Medicine, UZ Leuven, Leuven, Belgium; and the Department of Cardiovascular Sciences, Catholic University Leuven, Leuven, Belgium. Dr. Adriaenssens has served as a consultant and on the Speakers Bureau for Abbott Vascular. Dr. Sinnaeve has served as a consultant and is on the Speakers Bureau for Abbott Vascular.

the ABSORB STEMI TROFI II (Everolimus-eluting bioresorbable stent vs. durable polymer everolimus-eluting metallic stent in patients with ST-segment elevation myocardial infarction: results of the randomized ABSORB ST-segment elevation myocardial infarction-TROFI II trial) trial, the effect of post-dilatation on angiographic and intracoronary imaging parameters at 6 months after device implantation was investigated.

Surprisingly, post-dilatation did not translate into larger lumen area or improved arterial healing characteristics. Even more, in the BRS group, patients undergoing post-dilatation of the device were left with smaller minimal lumen areas at 6 months, as measured with optical coherence tomography (OCT), compared with patients without post-dilatation. With equal post-procedural in-device minimal lumen diameters and device expansion in the group with versus without post-dilatation and a trend toward larger mean neointimal area and mean neointimal thickness in the group with post-dilatation, these results suggest that routine post-dilatation of BVS may not always be necessary, and yet may be potentially harmful at least in terms of restenosis.

The results of this study need to be interpreted with caution. In the TROFI II trial, the decision to perform post-dilatation was left completely at the discretion of the operator, with a recommendation to do so in case of suboptimal angiographic appearance after device implantation. There was no randomization and no specific criteria regarding whether to perform additional post-dilatation. In the end, post-dilatation was performed in just over one-half of patients in the BVS compared with just over a quarter of patients in the everolimus-eluting stent group. As this information was not prospectively captured during the study, it remains unclear whether this was due to a higher incidence of suboptimal angiographic appearance post-deployment of the BVS device, or rather reflecting a common practice of routine post-dilatation of BVS.

In this respect, it is also worth to mention that routine post-dilatation was not a recommendation or even a common practice in the early studies with BVS, but rather introduced and promoted after the first signals of increased risk of BVS thrombosis ensued. In several clinical trials with BVS, post-procedural in-device minimal lumen diameter was significantly smaller after BRS implantation as compared with the control group, suggesting that device expansion is a key target for implantation technique improvement (7,8).

Some observational data indeed suggest that the risk of device thrombosis may decrease with mandatory pre- and post-dilatation (9). However, no prospective imaging or clinical trial has evaluated the effect of routine post-dilatation so far.

It would be naive to believe that all late adverse events with BVS can be prevented by an optimized implantation technique including routine post-dilatation. Inherent problems with the current device design (e.g., the strut thickness of 150 μm), leading to increased thrombogenicity, will remain pending further improvements to the platform. In contrast to earlier beliefs and expectations, the BVS also does not seem to be immune for the development of neoatherosclerosis, with an inherently associated risk of very late device failure.

In retrospect, it remains striking, however, that the interventional community so easily follows recommendations (in this case routine post-dilatation of BVS) without strong evidence of its necessity or beneficial effects. Apart from a retrospective analysis of the ABSORB EXTEND registry (10), showing no effects on clinical or angiographic results, no solid data on the topic have been published so far. Few data are available with respect to the acute effects of high-pressure balloon post-dilatation on the structural integrity of the scaffold. Fabris et al. (11) report reassuring data based on OCT images. However, we should remain vigilant, as it appears that small yet perhaps structurally important injuries to the scaffold are not easily picked up with OCT but only with more detailed imaging modalities that are currently not available for in vivo human use (12).

Further research, hopefully conducted with new iterations of the device (with smaller struts and a less thrombogenic profile) will need to confirm the increase in neointimal area associated with post-dilatation observed in this study and if so, whether this is of clinical significance (considering as well the tendency to late lumen enlargement after BVS implantation) and outweighing potential beneficial effects of post-dilatation such as improved device expansion.

In this regard, the study by Yamaji et al. (6) should not read as an epilogue to the BVS story, but rather as the prologue of a new chapter in BRS, where industry, investigators and operators can make a new start toward the adoption of BRS technology to a broader range of patients, hopefully remembering the hard lessons recently learnt.

ADDRESS FOR CORRESPONDENCE: Dr. Tom Adriaenssens, Department of Cardiovascular Medicine, University Hospitals Leuven, Belgium and Department of Cardiovascular Sciences, Catholic University Leuven, Belgium, Herestraat 49, 3000 Leuven, Belgium. E-mail: tom.adriaenssens@uzleuven.be.

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 10, NO. 18, 2017
SEPTEMBER 25, 2017:1878–80

REFERENCES

1. Adriaenssens T, Joner M, Byrne R, et al. Optical coherence tomography findings in patients with coronary stent thrombosis. A report of the PREvention of late Stent Thrombosis by an Interdisciplinary Global European effort (PRESTIGE) consortium. Circulation 2017 Jul 18 [E-pub ahead of print].

2. Capodanno D, Gori T, Nef H, et al. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry. EuroIntervention 2015;10:1144–53.

3. Serruys PW, Chevalier B, Sotomi Y, et al. Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II): a 3 year, randomised, controlled, single-blind, multicentre clinical trial. Lancet 2016;388:2479–91.

4. Wykrzykowska JJ, Kraak RP, Hofma SH, et al. Bioresorbable scaffolds versus metallic stents in routine PCI. N Engl J Med 2017;376:2319–28.

5. Ali ZA, Serruys PW, Kimura T, et al. 2-year outcomes with the Absorb bioresorbable scaffold for treatment of coronary artery disease: a systematic review and meta-analysis of seven randomised trials with an individual patient data substudy. Lancet 2017 Jul 18 [E-pub ahead of print].

6. Yamaji K, Brugaletta S, Sabaté M, et al. Effect of post-dilatation following primary PCI with everolimus-eluting bioresorbable scaffold versus everolimus-eluting metallic stent implantation: an angiographic and optical coherence tomography TROFI II substudy. J Am Coll Cardiol Intv 2017;10:1867–77.

7. Gao R, Yang Y, Han Y, et al. Bioresorbable vascular scaffolds versus metallic stents in patients with coronary artery disease: ABSORB China trial. J Am Coll Cardiol 2015;66:2298–309.

8. Ellis SG, Kereiakes DJ, Metzger DC, et al. Everolimus-eluting bioresorbable scaffolds for coronary artery disease. N Engl J Med 2015;373:1905–15.

9. Puricel S, Cuculi F, Weissner M, et al. Bioresorbable coronary scaffold thrombosis: multicenter comprehensive analysis of clinical presentation, mechanisms, and predictors. J Am Coll Cardiol 2016;67:921–31.

10. De Ribamar Costa J Jr., Abizaid A, Bartorelli AL, et al. Impact of post-dilation on the acute and one-year clinical outcomes of a large cohort of patients treated solely with the Absorb bioresorbable vascular scaffold. EuroIntervention 2015;11:141–8.

11. Fabris E, Caiazzo G, Kilic ID, et al. Is high pressure postdilation safe in bioresorbable vascular scaffolds? Optical coherence tomography observations after noncompliant balloons inflated at more than 24 atmospheres. Catheter Cardiovasc Interv 2016;87:839–46.

12. Bennett J, Vanhaverbeke M, Vanden Driessche N, et al. Absorb bioresorbable vascular scaffold in complex coronary bifurcation interventions: insights from an in vivo multimodality imaging study. Circ Cardiovasc Interv 2016;9:e003849.

KEY WORDS BVS, BVS failure, BVS thrombosis, BRS, post-dilatation, optical coherence tomography