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EDITORIAL COMMENT

Why Do We Still Tolerate "Suboptimal Deployment"?*

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If you always do what you've always done, you always get what you've always gotten.
—Jessie Potter (1)

The Abbott Absorb bioresorbable scaffold (BRS) (Abbott Vascular, Santa Clara, California) was recently taken off the market (September 2017) after multiple studies documented adverse clinical outcomes in routine clinical practice. In my opinion, lessons learned when we explored optimal balloon angioplasty, then bare-metal stent implantation, and finally drug-eluting stent implantation did not carry over to BRS. To be fair, concerns about the structural integrity of the initial BRS likely contributed to this. The thick struts and very different expansion characteristics compared with contemporary metallic stents resulted in concerns about high pressure inflation or use of oversized balloons. Further, as has been seen with other new devices with perceived benefits, operators were eager to use BRS and may have been overzealous in their vessel selection, resulting in BRS implantation in vessels with diameters below the recommended minimum.

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In this issue of *JACC: Cardiovascular Interventions*, Okada et al. (2) describe the intravascular ultrasound (IVUS) cohort from the ABSORB Japan trial. The ABSORB Japan trial is one of several randomized multicenter trials comparing the Absorb BRS with the Xience cobalt-chromium everolimus-eluting stent (Abbott Vascular). It was 1 of 4 BRS trials commenced in the 2013 timeframe. A total of 400 patients were randomized in a 2:1 (BRS to Xience) ratio. For the IVUS analysis, 150 patients were scheduled, again in a 2:1 ratio. For inclusion in this cohort, a final documentary IVUS imaging run was required. Use of IVUS to guide the procedure was not recommended, nor was it prohibited. Okada et al. (2) provide a rigorous, detailed analysis of both IVUS and quantitative coronary angiography (QCA) analysis after final stent implantation.

To keep these data in perspective, it must be noted that the trial inclusion criteria required lesions <24 mm in length in vessels with a reference lumen diameter between 2.5 mm and 3.75 mm. Additionally, heavily calcified lesions, bifurcations, restenotic lesions, ostial lesions, and left main lesions were excluded. The implantation protocol for BRS has evolved significantly over time (3). The current IVUS study used the following protocol: mandatory predilation and single device per lesion. Sizing of the BRS was suggested at 1:1 based on visual assessment of the reference vessel diameter. Post-dilation was not mandatory, but if performed, should use a noncompliant balloon ≤0.5 mm larger than the nominal BRS diameter.

Core lab QCA analysis was performed. One important finding from this analysis was that the included vessels were relatively small; the mean reference diameter was 2.76 ± 0.45, and 11% of vessels were <2.25 mm. Over 13% of vessels receiving BRS had reference diameters of <2.25 mm. Further, the BRS arm had a significantly smaller final minimal lumen diameter (on average 0.28 mm), due primarily to less acute gain in this arm.

The IVUS analysis showed similar results. The mean reference diameter was 2.98 ± 0.52 mm, with 43% of the BRS arm having vessel diameters <2.75 mm. The MLA was significantly smaller in the BRS

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arm (on average 0.9 mm^2) with more eccentric expansion. The authors analyzed the impact of implantation in small vessels (defined as <2.75 mean reference by IVUS) and the impact of tapered vessels (defined as more than a 20% difference in diameter between the distal and proximal reference diameter). As anticipated, BRS implantation in tapered vessels was associated with less optimal expansion compared with that seen with Xience. When BRS were implanted in small tapered vessels, the effect was most pronounced, with an expansion ratio of only 89% compared with 114% in the Xience arm ($p = 0.02$). Some unexplained differences in implantation technique may have contributed to these findings. In the BRS arm, noncompliant balloons were used more frequently for post dilation, but at a significantly lower pressure (16.3 vs. 19.7 atm; $p = 0.02$). Further, in tapered vessels, the BRS arm used significantly smaller balloons for post-dilation (3.0 vs. 3.5 mm; $p = 0.047$). It appears that the Xience arm upsized by 0.5 mm for post-dilation, whereas the BRS arm did not. Again, this may reflect concern by the operators for scaffold integrity or fear of overexpansion.

In summary, the current study carefully documents that BRS do not behave like Xience during short-term implantation. Expansion is less in all vessel sizes, but significantly so in small vessels and in tapered vessels. Uniformity of expansion is worse regardless of vessel size.

Much has been learned since this study was initiated. A strategy of pre-dilation, proper sizing, and post-dilation (PSP) was developed (4). Using such a strategy, and employing very high pressure post-dilation, BRS have been successfully implanted, even in calcified lesions (5). Post hoc analysis of the multiple ABSORB clinical trials to assess whether the employed implantation technique would meet the PSP standard has been undertaken (6). In this analysis, optimal implantation technique was defined as follows. Proper vessel sizing was pre-specified to be present when the reference vessel diameter of the target lesion was >2.25 mm and <3.75 mm, as determined by QCA, consistent with visual reference vessel assessment of 2.5 to 4.0 mm. Optimal target lesion pre-dilation was pre-specified as pre-dilation with a nominal balloon diameter to reference diameter ratio of >1:1. Optimal post-dilation was pre-specified as post-dilation with a noncompliant balloon at >18 atm and larger than the nominal scaffold diameter, but not by >0.5 mm larger. For a technique to be considered optimal in a patient with multiple target lesions, it had to be applied in all lesions. In this analysis of 3,096 ABSORB trial lesions, only 5% had optimal implantation technique! As was seen in the current study (the ABSORB Japan trial), the pooled analysis found that implantation in small vessels (<2.25 mm) was the strongest predictor of poor outcome, especially for stent thrombosis. Optimal post-dilation had significant long-term benefits in reducing target lesion failure.

The take-home message from the current IVUS analysis of the ABSORB Japan trial is to reaffirm that visual angiographic guidance of device implantation will often lead to suboptimal results. In the balloon angioplasty days, we learned that IVUS-guided sizing resulted in improved short-term outcomes (7). In the bare-metal stent days, we again saw that IVUS guidance improved clinical outcome compared with angiographic guidance (8). More recently, the same findings have been observed for drug-eluting metallic stents, including in randomized trials of complex lesions (9,10). Recent data suggest that IVUS guidance can improve BRS implantation as well (5). This leads to the question of why we continue to implant new devices without using intravascular guidance and expect to get different results? I suggest it is time for insurance providers and hospital credentialing boards to require the use of intravascular imaging guidance for the majority of coronary interventions. The data support that such a strategy will improve the outcomes for all of our patients; no one should object to that!

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REFERENCES

1. Ahern T. Search For Quality Called Key To Life. The Milwaukee Sentinel October 24, 1981;5:5.

2. Okada K, Honda Y, Kitahara H, et al. Bioresorbable scaffold for treatment of coronary artery lesions: intravascular ultrasound results from the ABSORB Japan trial. J Am Coll Cardiol Intv 2018;11:648–61.

3. Bangalore S, Bezerra HG, Rizik DG, et al. The state of the Absorb bioresorbable scaffold: consensus from an expert panel. J Am Coll Cardiol Intv 2017;10:2349–59.

4. Ortega-Paz L, Capodanno D, Gori T, et al. Predilation, sizing and post-dilation scoring in patients undergoing everolimus-eluting bioresorbable scaffold implantation for prediction of cardiac adverse events: development and internal validation of the PSP score. EuroIntervention 2017;12:2110–7.

5. Kawamoto H, Ruparelia N, Latib A, et al. Expansion in calcific lesions and overall clinical outcomes following bioresorbable scaffold

implantation optimized with intravascular ultrasound. Catheter Cardiovasc Interv 2017;89:789–97.

6. Stone GW, Abizaid A, Onuma Y, et al. Effect of technique on outcomes following bioresorbable vascular scaffold implantation: analysis from the ABSORB trials. J Am Coll Cardiol 2017;70:2863–74.

7. Stone GW, Hodgson JM, St Goar FG, et al., Clinical Outcomes With Ultrasound Trial (CLOUT) Investigators. Improved procedural results of coronary angioplasty with intravascular ultrasound-guided balloon sizing: the CLOUT pilot trial. Circulation 1997;95:2044–52.

8. Parise H, Maehara A, Stone GW, Leon MB, Mintz GS. Meta-analysis of randomized studies comparing intravascular ultrasound versus angiographic guidance of percutaneous coronary intervention in pre-drug-eluting stent era. Am J Cardiol 2011;107:374–82.

9. Elgendy IY, Mahmoud AN, Elgendy AY, Bavry AA. Outcomes with intravascular ultrasound-guided stent implantation: a meta-analysis of randomized trials in the era of drug-eluting stents. Circ Cardiovasc Interv 2016;9:e003700.

10. Ahn JM, Kang SJ, Yoon SH, et al. Meta-analysis of outcomes after intravascular ultrasound-guided versus angiography-guided drug-eluting stent implantation in 26,503 patients enrolled in three randomized trials and 14 observational studies. Am J Cardiol 2014;113:1338–47.

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