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Letters

TO THE EDITOR

Bioresorbable Vascular Scaffolds in In-Stent Restenosis

We read with great interest the study of Alfonso et al. (1) assessing the value of bioresorbable vascular scaffold (BVS) for in-stent restenosis (ISR) treatment. The authors prospectively included patients treated with BVS for both bare-metal and drug-eluting stent (DES) ISR. Results were than compared with those obtained from the RIBS V (Restenosis Intra-Stent of Bare Metal Stents: Paclitaxel-Eluting Balloon vs. Everolimus-Eluting Stent) (2) and RIBS IV (Restenosis Intra-Stent of Drug-Eluting Stents: Drug-Eluting Balloon vs Everolimus-Eluting Stent) (3) trials. The results of this study are of interest because they confirm the safety and efficacy of BVS in this complex scenario, as previously suggested (4). Moreover, this is the first study comparing BVS to the current recommended treatment options, DES and drug-eluting balloons (DEB) in ISR setting. The authors found that late angiographic and clinical outcomes were similar to DEB but inferior to everolimus-eluting stents (EES). These results are of important clinical value because treating ISR is still challenging for interventional cardiologists, and the bioresorbable technology is particularly attractive in this setting. However, we think that some considerations have to be done in interpreting these results.

First, attention has been focused recently on the importance of correct BVS implantation to reduce the rate of adverse events with the so-called "PSP" criteria (5,6). The authors reported only a 66% rate of post-dilation, and no data were reported on the use of intracoronary imaging or correct vessel sizing. Indeed, immediately after the procedure, the minimal lumen diameter and the acute gain were similar to DEB, but significantly lower than EES, and remained the same at follow-up. We think that, particularly in a complex scenario such as ISR, a correct implantation technique may provide better short-term results, thus also resulting in better late outcomes. Secondly, in the BVS group, the percentage of patients with diabetes mellitus and recurrent ISR (with more than 1 previous intervention in the target vessel that already failed) were significantly higher compared with the DEB and EES groups. Both are well-established risk factors for ISR treatment failure and might have had an impact on late outcomes. Third, patients included were not treated in the same time period, but were compared with historical cohorts previously included in the RIBS V (2) and IV (3) trials. Moreover, lesion length was particularly low (because of lesion selection criteria), compared with previously reported real-word data on BVS use for ISR treatment (4). However, BVS is particularly attractive and may provide better outcomes compared with DEB, in long or edge-related ISR in which the use of DEB may be easily complicated by dissections or acute recoil. BVS and DEB are complementary devices in the hands of interventionists to avoid further permanent stent implantation. Indeed, BVS should be considered as an alternative option to DEB for those challenging lesions such as diffuse or recurrent-ISR in which multiple stent layers had already been implanted and best current available antirestenosis treatments had already failed.

Recent long-term data on BVS use in de novo lesions showed BVS inferiority compared with DES (7), and the BVS is no more available. However, the "leaving nothing behind" therapy is of great interest, and novel devices are being validated. Probably the next bioresorbable generations with improvements in strut thickness and radial force will provide better outcomes and may represent an important step forward also in this complex setting.

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REPLY: Bioresorbable Vascular Scaffolds in In-Stent Restenosis

We are most grateful to Dr. Moscarella and colleagues for their interest in our study that sought to assess the value of bioresorbable vascular scaffolds (BVS) compared with everolimus-eluting stents (EES) and drug-eluting balloons (DEB) in patients with in-stent restenosis (ISR) (1). Our trial was initiated before the recommendation to use a "pre-dilation-size-post-dilation" strategy for BVS was established. However, from our previous experience in the treatment of ISR, we were fully aware of the importance of lesion preparation and optimization of final results in these patients (2). Indeed, the study protocol emphasized the relevance of lesion preparation, suggesting aggressively tackling any residual stent under-expansion with noncompliant balloons at high-pressure (1). The maximal pressure used in the BVS arm during either pre-dilation (97% of cases) or post-dilation (66% of cases) was 20 ± 4 bar. In addition, a liberal use of intracoronary imaging was recommended, and eventually, 46% of the patients were treated under intracoronary imaging guidance (optical coherence tomography n = 63; intravascular ultrasound n = 2). However, strict criteria for BVS optimization were not pre-defined, and the potential reaction to the imaging findings was left to the operator's discretion. Despite our optimization efforts, the early and late results of BVS on quantitative coronary angiography were poorer than those obtained with EES. Similar results have been reported in previous studies comparing these devices in de novo lesions (3). Interestingly, some studies suggested that accuracy of edge detection by quantitative coronary angiography differs when polymeric BVS are compared with metallic EES, and this technical issue should be also considered when interpreting angiographic findings (4). Furthermore, although there were some imbalances in baseline characteristics among the 3 therapeutic modalities, the differences detected at late follow-up in the main angiographic outcome measures persisted after careful adjustment for potential confounders, as already explained in our report (1). In the RIBS VI (Restenosis Intrastent: Bioresorbable Vascular Scaffolds Treatment) study, we used similar inclusion/exclusion criteria to those used in previous RIBS trials. Accordingly, our findings should not be extrapolated to more adverse anatomic scenarios. Whether the relative efficacy of BVS compared with DEB or EES might be different in patients presenting more complex ISR patterns remains speculative. Finally, we are also deeply interested in elucidating whether additional strategies could help to optimize BVS results in ISR(5). The currently ongoing RIBS VI *Scoring* (Restenosis Intrastent: Bioresorbable Vascular Scaffolds Treatment With Scoring Balloon Pre-Dilatation) study (NCT03069066), also including late angiographic surveillance, will determine whether the early and late results of BVS in patients with ISR may be improved by systematic lesion preparation using scoring balloons before BVS deployment.

We fully agree that BVS represent an attractive therapeutic modality for patients with ISR. Our findings suggest that BVS offer an efficacy similar to DEB, a strategy already supported by robust clinical evidence in this anatomic setting. Moreover, we also concur with the idea that BVS iterations might play a major role in the treatment of ISR. Hopefully, our study will pave the way for future initiatives using the "leave nothing behind" strategy in the treatment of these challenging patients.

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