Dr. King, along with the early pioneers of interventional cardiology, displayed courage and conviction in developing the techniques of percutaneous coronary intervention even despite mediocre initial results. Today's generation of interventionalists should adopt a similar mindset to develop their skills with all new techniques. Based on our experience, we would argue that transcaval access is not a "disruptive technology" that "should not be tried at home." It is a potentially valuable skill that can allow for safe, alternative access for those patients with severe aortic stenosis and iliofemoral arterial occlusive disease.

What will you do?

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Bioresorbable Vascular Scaffolds as a Treatment Option for Left Main Lesions

Drug-eluting stents (DES) are valid treatment options for left main (LM) disease (1), but the presence of a permanent metallic foreign body provides the continued risk of late adverse events. Bioresorbable vascular scaffolds (BVS) may be an attractive alternative because of their complete resorption properties. To date, several outcomes have been reported; however, data regarding LM treatment with BVS are lacking (2,3). Therefore, we performed a multicenter retrospective evaluation of the mid-term outcomes of BVS implantation for LM disease.

Data were examined from 60 patients (of a total of 2,765 LM percutaneous coronary interventions [PCI]), from an international registry involving 12 centers, who underwent BVS (Absorb, Abbott Vascular, Santa Clara, California) implantation between June 2012 and December 2015. All patients provided informed consent for the procedure and subsequent data collection and analysis.

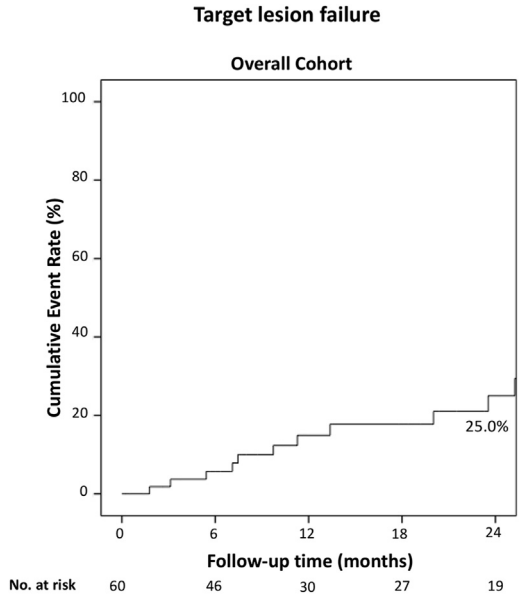
The decision to implant BVS and PCI strategy was dependent on individual operators. PCI with BVS was only performed in patients with reference diameters <4.0 mm and <0.5 mm difference between the proximal and distal reference diameters. PCI was avoided in patients with a concomitant right coronary artery chronic total occlusion or severe calcification of the LM shaft/bifurcation.

The primary endpoint was target lesion failure defined as a composite of cardiac death, target vessel myocardial infarction, and ischemia driven target lesion revascularization (TLR). Cumulative event rates were analyzed using Kaplan-Meier methods.

The mean age of patients was 55.1 ± 8.8 years and 28.3% (n = 17) had diabetes. The mean SYNTAX score of patients was 20.6 ± 9.9. Seventy percent of patients (n = 42) underwent PCI for stable indications, with the remaining 30% (n = 18) for acute coronary syndromes. Most target lesions were LM bifurcations (n = 46; 76.7%), of which 41.3% (n = 19) were true bifurcations. The remaining 14 (23.3%) cases did not involve the LM bifurcation, and received isolated LM shaft stenting. Of the 46 LM bifurcations lesions, a provisional approach was undertaken in 37 cases and elective 2-stenting in 9 cases. The rate of predilatation and post-dilatation was 93.3% (n = 56) and 96.7% (n = 58), respectively. Post-dilatation of the main branch was performed at high pressures (mean, 18.9 ± 4.1 atm). Intravascular imaging was used in most cases (80%; n = 48).

There were no incidences of periprocedural stroke or death. During BVS deployment, 1 patient (provisional LM-left anterior descending strategy) experienced temporary hemodynamic instability. The median follow-up time was 593 days (interquartile range: 230 to 817 days). The primary endpoint of target lesion failure occurred in 14.9% (n = 7) and 25.0% (n = 10) of patients at 1 and 2 years, respectively (**Figure 1**). This was primarily caused by ischemia-driven TLR because the overall TLR rate was 13.4% (n = 6) and 23.6% (n = 9) at 1 and 2 years. The cardiac death rate was 1.8% (n = 1) at 2 years and there were no target vessel myocardial infarction or definite/probable ST segment events at 2 years.

FIGURE 1 Kaplan-Meier Curve of Primary Endpoint of Target Lesion Failure Up to 2 Years Follow-Up



The median time to ischemia-driven TLR was 343 days (interquartile range: 216 to 716 days). Associated findings determined by follow-up intravascular imaging from 9 cases included late recoil (n = 3), intrascaffold tissue growth (n = 4), underexpansion (n = 2), discontinuity (n = 2), and malapposition (n = 1).

Several concerns and restrictions exist regarding BVS deployment for LM disease. They include: 1) restricted BVS expansion capability; 2) lower radial strength when compared with DES; 3) increased delivery profile; 4) prolonged inflation times; and 5) left circumflex side branch jailing (4).

Some limitations may be overcome by careful case selection and optimal implantation strategies. More specifically, the operator must ensure that LM diameter must not exceed 4.0 mm with <0.5 mm difference between the proximal and distal reference diameters. Optimal implantation strategies include pre- and post-dilatation to high pressures, and intravascular imaging guidance. Regarding prolonged inflation times, temporary hemodynamic instability occurred in only 1 case without any other periprocedural complications. Finally, side branch strut dilatation is of concern when a large left circumflex artery is the side branch, because of the risk of side branch strut fracture and main branch scaffold distortion with ballooning. Mini-kissing balloon inflations or sequential inflations may minimize risk.

In conclusion, the use of BVS in highly selected patients with LM disease was technically possible; however, the TLR rate was high when compared with trials involving DES. By contrast, there were no definite/probable ST segment or target vessel myocardial infarction events at midterm follow-up. Notably, the number of patients and events in our cohort was small with no control group, so firm conclusions cannot be made. Therefore, the use of BVS in LM disease should remain exploratory and DES remains the preferred platform.

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Bioresorbable Vascular Scaffolds and Very Late Scaffold Thrombosis

Searching an Explanation and a Solution

The recently presented 3-year outcomes of the ABSORB II trial reporting 6 very late scaffold thrombosis (ScT) cases (1) provided a concerning signal regarding current generation bioresorbable vascular scaffolds (BVS).

Prior reports suggested suboptimal implantation including underexpansion and malapposition being the main predisposing factors for ScT, especially up to 1 year, stressing the importance of dedicated implantation techniques. The basic concept of optimal implantation is to obtain "adequate expansion with full apposition." We believed that most ScT events could be prevented if an optimal result is confirmed by intravascular imaging at the end of the procedure. Even with respect to very late ScT, we assumed that full strut apposition would allow sufficient neointimal coverage to prevent intraluminal scaffold dismantling in the later stages of the resorption process.

Several months before the ABSORB II report, 2-year outcomes of the ABSORB Japan trial reported 4 very late ScT cases (2). However, very late ScT did not occur in the subgroup where post-implantation optical coherence tomography was performed, and suboptimal implantation was suspected as the culprit in the ScT cases. Therefore, we believed that it highlighted the importance of post-procedural confirmation with intravascular imaging. By contrast, the 6 very late ScT cases in the ABSORB II trial generate a sense of confusion. Post-procedural intravascular ultrasound was performed in all 6 cases, demonstrating what appears to be adequate strut apposition and scaffold expansion. These findings raise concern regarding whether very late ScT can occur even after obtaining an optimal final result, and whether an unknown scenario might exist during the resorption process.

To our knowledge, the real-world BVS Milan-cohort is unique in that it involves predominantly complex lesions in which a dedicated optimal implantation strategy was consistently used from the first BVS case (3). Following the report of the 3-year ABSORB II data, we urgently updated clinical follow-up, and reviewed the details of all ScT cases including not only definite/probable but also possible ScT cases.

We examined all consecutive lesions treated with Absorb BVS (Abbott Vascular, Santa Clara, California) at 2 high-volume centers in Milan, Italy, between May 2012 and August 2016 (518 lesions with 340 patients). The latest clinical follow-up was performed in November to December 2016 by either clinical visits or telephone interview (clinical follow-up rate, 98.5%). The principles of our BVS implantation strategy have been previously described (3).

Of 518 lesions, most (76%) were type B2 or C as per American College of Cardiology/American Heart Association classification, 46% were bifurcations, the total scaffold length per patient was 54 ± 34 mm, and 45% of patients received at least 1 BVS of 2.5 mm. Pre- (97%) and post-dilation (99.8%) were performed in almost all cases (mean post-dilation pressure was 21 ± 4 atm and the balloon/scaffold ratio was 1.03 ± 0.09). Intravascular imaging was performed in most cases (86%). During the follow-up period (median: 706 days; interquartile range: 355 to 1,088 days), definite or probable ScT was observed in 4 patients (1.2%; 1 acute [Day 0], 1 subacute [Day 3], and 2 late [Day 63 and Day 143]). In contrast, very late definite/probable ScT was not observed. Possible ScT was detected in 5 cases (3 sudden death, 2 unknown death). The details of the cases are shown in Online Table 1. Any cessation of dual antiplatelet therapy was observed in 27.6% of patients until the latest follow-up.

In this update: 1) the occurrence ratio of definite/probable ScT seems acceptable considering the complex lesion subset, and very late ScT was not observed; 2) all definite/probable ScT cases involved a reasonable trigger; and 3) regarding the 5 possible ScT cases detected, we maintain a suspended judgment, although a cause other than ScT seems feasible in all of them.

The problem arising now is that it seems that very late ScT events may have also occurred in cases with acceptable post-procedural results. Despite full strut apposition and an apparent acceptable final result, the lack of consistent high pressure post-dilation in the ABSORB II might have resulted in insufficient embedment into the vessel wall, incomplete endothelialization, and possibly very late events; however, this is merely hypothesis generating.