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Bioresorbable Vascular Scaffolds: Should We use Them Again?

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Abstract

Context: An important development in the percutaneous management of coronary artery disease was the creation of the drug-eluting stent (DES). The DES reduces the high incidence of target lesion revascularization associated with balloon angioplasty and bare metal stents by overcoming vessel recoil and restenosis. Despite these advantages, DES carries a persistent risk of stent-related problems due to the permanent implantation of a foreign body and the limitation of arterial vasomotion. Similar to DES, bioresorbable vascular scaffolds (BRS) are intended to distribute drugs and offer mechanical support before completely degrading over the years.
Evidence Acquisition: This study was a review article. The data were acquired from PubMed and Google Scholar. Medical Subject Headings (MeSH) terms were used when available, and only English articles were included in the review.
Results: Recent studies have shown that the BRS is not inferior to modern DES clinically, although some clinical results are worrying, particularly the greater rates of scaffold thrombosis. Early studies showed that BRS was superior to DES; nevertheless, larger-scale applications and longer observations revealed serious problems with their use, such as reduced radial strength and a higher risk of thrombosis, which led to a higher rate of serious adverse cardiac events.
Conclusions: The position of DES was not directly challenged by additional attention to procedural details and research on the second generation of BRS with innovative features. Bioresorbable vascular scaffolds still have an opportunity to demonstrate their supremacy in standout indicators.

Keywords: Bioresorbable Vascular Stents, Drug-eluting Stents, Coronary Heart Disease

1. Context

The term “bioresorbable stents” (BRS), also known as “bioabsorbable” or “biodegradable” stents, describes coronary stents that can completely disintegrate in the body. The key benefit of using a BRS is that it will naturally clear out of the body in a few years, which should lessen any potential long-term side effects that would occur from using a regular metallic stent (1). The Food and Drug Administration (FDA) granted permission for the use of Abbott’s ABSORB (Abbott Vascular, Santa Clara, CA, USA), the first and most thoroughly investigated BRS device, in 2016 (2). Numerous cardiac facilities soon embraced this device. Nevertheless, several investigations since then, notably the ABSORB clinical trials, have demonstrated that ABSORB offered little to no competitive advantage over widely utilized drug-eluting stent (DES) devices (3, 4).

The European Society of Cardiology (ESC) determined that there was insufficient evidence to demonstrate the superiority of BRS stents to DES, and the FDA issued a caution for the use of BRS in 2017. Instead, the ESC suggested that BRS usage by doctors be limited until more information about ABSORB was made public. In September 2017, Abbott pulled ABSORB off the market because patients with BRS implants were experiencing exceptional side effects (5). Considering the aging population and the expectation that individuals will live longer following a percutaneous coronary intervention (PCI) operation, removing foreign objects from the body after treating a blockage still holds appeal.

2. Evidence Acquisition

This study was a review article. The data for relevant literature discussing BRS is acquired from PubMed and Google Scholar. Only English articles were included in the review, Medical Subject Headings (MeSH) terms were

used when available, and keywords if appropriate. The MeSH terms used are "bioresorbable vascular scaffolds", "bioresorbable scaffolds", "bioresorbable stent", and "coronary stent". The abstract of each article was read and included in the study if the study discussed a relevant topic. The reference lists of articles were also searched to identify additional relevant studies.

3. Results

3.1. Advantages of Bioresorbable Vascular Scaffolds

Synthetic biodegradable polymers that make up bioresorbable stents are designed to initially perform similarly to DES before dissolving months after implantation, probably restoring vasomotor function. Bioresorbable vascular scaffolds (BRS) must deliver on all their promises while outperforming DES in terms of performance without compromising too much. Restorative endothelial function with secondary atherosclerotic plaque reduction is another perceptible event (unrealistic with a solid metal stent). After dissolving, it permits the artery to preserve its structural integrity and restore its physiological (systolic and diastolic) characteristics, promoting advantageous remodeling and, as a result, reducing the risk for prolonged inflammation (1).

The benefits of BRS have, therefore, been hypothesized, especially in younger patients or those with acute coronary syndromes, where the metal stain is less likely to heal. Among other characteristics, it was planned to maintain the function of the covered side branches after resorption and avoid the effects of a "full metal coat", particularly in the case of diffuse disease. This would allow for the treatment of restenosis in the stent early on without the need for additional layers of metal stents to fill the space. A surgical revascularization technique is another option provided by BRS. In addition, the patient's desire to avoid having a permanent foreign body is greatly aided by this innovative technique (6). However, current information reveals that most claims about resorption's benefits were exaggerated. The majority of BRS's prospective benefits, including the potential for additional surgical procedures inside the same lesion and the restoration of the physiological function of the endothelium, have not yet been definitively proven.

3.2. Generations of Bioresorbable Vascular Scaffolds

The ABSORB and DESolve (Elixir Medical Corporation, Sunnyvale, CA, USA) poly-L-lactic acid (PLLA) and magnesium-based DREAMS G1 (Biotronik, Berlin, Germany) scaffolds served as the foundation for the first generation of BRS. The ABSORB stent features a PLLA backbone with struts that are approximately 150 μm thick. It also contains a bioresorbable poly-D, L-lactic (PDLLA) coating that is 7 μm thick and secretes everolimus with pharmacokinetics that are similar to those of the Xience (Abbott Laboratories, Abbott Park, IL, USA) DES. Due to the decreased tensile strength, reduced stiffness, and the possibility of deformation, it became necessary to increase the strut thickness to create the proper mechanical framework for these stents. Studies have revealed that because ABSORB stents can stretch up to 0.7 mm beyond the nominal diameter, precise lesions, wise patient selection, and suitable implantation procedures are necessary to prevent strut breakage or aberrant decomposition. Because ABSORB stents are radiolucent, they could not be visible under fluoroscopy. For radiographic recognition, two platinum markers were added to the stent's ends at both ends for this reason. Due to their small size, identification needs fluoroscopic imaging of the highest caliber (2, 7, 8).

Similar to DESolve, which is made of a PLLA-based scaffold and features two platinum-iridium markers to facilitate radiographic imaging, it is provided with a similar strut thickness (150 μm in the first generation).

The second generation, DESolve Cx plus, includes struts that are 120 μm thick, 14 to 28 mm in length, and 2.5 to 4.0 mm in diameter. The continually growing array of scaffolds with improved qualities and innovative characteristics are included in the second generation of BRS (9). The tyrosine analog-based arterial remodeling technology (ART) (Terumo, Tokyo, Japan), DESolve Cx plus, the magnesium-based Magmaris (Biotronik, Berlin, Germany), and the PLLA-based Fantom (REVA Medical, Inc., San Diego, CA, USA) were all introduced to clinical practice. They were created as a result of an effort to construct a structure using thinner struts. The struts' diameter is limited to 100 μm, as opposed to 150 μm in the prior generation. A decreased risk of scaffold thrombosis (ScT) occurrence and a shorter need for dual antiplatelet treatment (DAPT) are thought to be connected with reduced thickness because it is thought to result in fewer blood flow disruptions. The newest generations are constructed from polymers, such as PLLA and desaminotyrosine polycarbonate derivatives or magnesium metal. These materials achieve mechanical qualities similar to regular DES while providing higher protection against fractures during post-implantation dilatation (10).

3.3. Mechanisms of Bioresorbable Vascular Scaffolds Failure

Bioresorbable scaffold failure is caused by numerous factors. Bioresorbable scaffolds deployment in small

vessels (reference vessel diameters of less than 2.25 mm) and strut fracture due to disruption of the plastic scaffold, malapposition, or prolapse of struts into the lumen during the dissolving process are some of the possible causes of BRS failure. The term "intraluminal scaffold dismantling" refers to this occurrence, which might be the root of extremely late ScT (11). These results emphasize the requirement for a rigorous operator technique, which includes intravascular imaging-based exact assessment of vessel dimensions, aggressive vessel preparation (predilation), and post-dilation to enhance the apposition of BRS. In this regard, 60% of patients in the ABSORB III trial underwent post-dilation following BRS deployment (12).

With intracoronary imaging, Sotomi et al. assessed potential mechanical reasons for ScT in published case reports, which included 43 cases of ScT (17 cases of acute or subacute thrombosis and 26 cases of late or very late thrombosis). Malapposition (23.5%) was the most common reason for thrombosis in the acute and subacute phases, followed by exposed struts (17.6%), under-deployed struts (11.8%), acute scaffold disintegration (5.9%), overlapping stents (5.9%), and acute scaffold recoil (5.9%). Malapposition continued to be the most frequent mechanism of thrombosis in the late or very late phases, accounting for 34.6% of cases, followed by late scaffold discontinuity (30.8%), peri-strut low-intensity areas (19.2%), uncovered or under-deployed struts (15.4%), incomplete lesion coverage or scaffold recoil (11.5%), restenosis (7.7%), neoatherosclerosis (3.8%), and bifurcation (3.8%) (13).

The BRS can prevent neointimal hyperplasia and strut discontinuity, which can lead to strut prolapse into the lumen and potentially lead to restenosis or stent thrombosis before the BRS is completely absorbed into the artery wall. This "intraluminal scaffold dismantling" mechanism has been postulated to explain the higher rates of very late bioresorbable scaffold thrombosis and increased rates of myocardial infarct. Furthermore, it has been demonstrated that the BRS performs worse in vessels that are smaller and similarly when the scaffold size is greater than the reference vessel diameter (14).

The evidence suggests that these meticulous lesion selection and deployment methodology methods can enhance results. One mechanism for extremely late stent thrombosis, for instance, seems to be the resorption of originally malapposed scaffold struts, which results in thrombosis from mechanical disruption. For BRS implantation, lesion complexity is a crucial factor. Heavy calcification, significant angulation or tortuosity, left main or ostial lesions, bifurcation lesions, thrombotic lesions, and chronically occluded lesions were just a few of the exclusion criteria in the ABSORB randomized trials. Although there are registry data and reports from real-world practices on these more difficult lesions from countries other than the USA, these were often submitted by operators with extensive device experience and excellent technique (15).

3.4. Future Directions: Should We Use It?

The biodegradable scaffold Absorb BRS® is not the only one being developed. The prototype device that was released to the market had several problems that could be fixed, as is always the case with new technologies. It is thought that the increased rate of adverse events might be related to the thickness of the Absorb BRS® strut. The strut thickness of the novel scaffolds in development, such as the DEsolve®, the MeRes100® (Meril Life Sciences Pvt. Ltd., Vapi, India), or the Biolute® (Envision Scientific Pvt. Ltd., Surat, India), is 100, 100, or 108 μm, respectively (16, 17).

If this development is successful, it will enable the achievement of the required radial strength while concurrently reducing the crossing profile. Thinner struts might also lessen the disruption of coronary blood flow and the protrusion of struts into the vascular lumen when they overlap, which can reduce the thrombogenicity of such devices. The Mirage BRS® (Manli Cardiology, Singapore), a microfibre scaffold with streamlined strut geometry and round struts, exhibits a comparable advancement in technical design. It is designed to limit blood flow separation, ensure high shear stress, and minimize platelet activation (18).

Choosing the optimal resorption window while keeping in mind that the rate of radial strength loss cannot be too fast is another crucial consideration. The higher risk of vessel/plaque rebound might be explained by the shortened resorption phase, which might also minimize the risk of stent thrombosis. This is where the DEsolve scaffold has shown promising outcomes. It takes 1 year and 2 years, respectively, for it to biodegrade and absorb (16).

Based on a study by Baron et al., BRS (ABSORB) is associated with higher initial cost when compared to DES (Xience) ($15,035 ± 2,992 vs. $14,903 ± 3,449; P = 0.37); however, there was no difference in total 1-year healthcare cost between the two groups ($17,848 ± 6,110 vs. $17,498 ± 7,411; P = 0.29) (19). Another study conducted by Wykrzykowska et al. showed that the 2-year cumulative thrombosis rates were 3.5% for BRS and 0.9% for DES (hazard ratio: 3.87; 95% confidence interval [CI]: 1.78 - 8.42; $P < 0.001$) (20) This finding means that healthcare costs and complication risks for BRS patients might increase after the first year. Several tactics have been researched to fight BRS's inferiority, including improving implantation and extending the duration of DAPT (21). The best method

for implanting a BRS involves "PSP" (pre-dilatation, sizing, and post-dilatation) to prevent stent thrombosis and an inappropriate scaffold size. In an observational study, this method has been shown to reduce the rates of ScT in BRS to be comparable to DES (22). Further intravascular imaging has also been advocated to lower ScT rates; however, this comes with the dangers and drawbacks that come with routine invasive operations. Another suggestion to prevent stent thrombosis is to extend DAPT for patients with BRS implants to 3 years (until finishing bioresorption) (23).

Previous studies for DES have shown that the prolongation of DAPT was associated with a lower rate of stent thrombosis than aspirin only and was not harmful. In the ABSORB II trial, none of the patients who continued DAPT until the end of the study developed late or very late ScT (7). This is likely related to the thicker struts in older-generation BRS, as thicker struts generate more injuries during implantation and high endothelial shear stress. Some centers suggest using prasugrel or ticagrelor in the first 30 days after implantation, only switching to clopidogrel once 30 days have passed. The former P2Y12 inhibitors are more potent and achieve more potent platelet inhibition, which is especially useful early as thrombosis rates are high. Moreover, it is recommended to use DAPT for at least 12 months for BRS patients. If patients are predicted to be unable to tolerate at least 12 months of DAPT, the implantation of other types of stents should be considered (24). Currently, a randomized clinical trial is ongoing with the aim of determining optimal DAPT duration after BRS (21). It is thought that current-generation BRS designs with circular struts of lower diameter and faster resorption times are superior to second-generation BRS and might be able to provide better results (25).

4. Conclusions

The BRS is a brand-new class of medical equipment with the potential to enhance the management of coronary artery disease. The third generation BRS is the newest one, which has many advantages and gives better results than the previous generation; also, it is superior to the regular DES, so it is more recommended. The alleged long-term advantages also need to be demonstrated. Early experiments and clinical practices indicate that adverse outcomes are associated with implantation in smaller vessels, insufficient vascular preparation, and a lack of post-dilation. It makes sense that the long-term advantage of a fully resorbed stent would become clear if the safety worries can be allayed by judicious lesion sizing and selection in addition to improved insertion technique.

Footnotes

Authors' Contribution: SL conceived and designed the evaluation and drafted the manuscript; participated in designing the evaluation, performed parts of the statistical analysis, and helped draft the manuscript; re-evaluated the clinical data, revised the manuscript, performed the statistical analysis, and revised the manuscript; collected the clinical data, interpreted them, and revised the manuscript; and re-analyzed the clinical and statistical data and revised the manuscript.

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