Review Article
Research progress and prospects of bioresorbable vacular scaffolds

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Abstract: Percutaneous coronary intervention (PCI) has been established as one of the most efficient strategies for treatment of coronary artery disease. In recent years, bioresorbable vascular scaffolds (BVS) have been used for treatment of patients with coronary artery disease, providing a very promising prospect in the field of cardiology. However, the performance of these scaffolds versus metal stents remains controversial. This article aimed to assess the efficacy and safety of BVS versus metallic stents in patients with coronary artery disease treated by PCI.

Keywords: Bioresorbable vascular scaffolds, metallic drug-eluting stents, metallic stents

PCI has evolved from balloon angioplasty over bare metal stents to the routine use of metallic drug-eluting stents (DES). Coronary artery stents, introduced in the late 1980's, marked an important milestone in the development of PCI by scaffolding the treated arterial segment, thereby eliminating the risk of abrupt vessel closure due to dissections following balloon angioplasty and negative remodelling due to elastic recoil [1]. The current generation of DES is associated with excellent clinical outcomes in terms of restenosis and rates of stent thrombosis (ST), reaching less than 1% [2, 3]. Although DES technology covers the needs of the interventional cardiologists, they cannot be considered an optimal solution, as they permanently trap the coronary in a metallic cage. The presence of a foreign body within the artery wall can cause chronic inflammation and may interfere with endothelial function, resulting in delayed vessel wall healing, which has been associated with a higher risk of ST [4-6]. Permanent DES can also interfere with magnetic resonance imaging and computer tomography coronary angiograms (CTCA). BVS, which temporarily scaffolds the intervened arterial segment followed by complete biodegradation, has been envisioned to overcome the long-term failures of metallic stents, with promising corollaries of restoration of coronary vasomotion, posi-tive vessel remodelling, protective sealing of atherosclerotic plaques, and facilitated access for future bypass anastomoses [7]. These devices feature the unique capability to permit restoration of vascular physiology and integrity, providing a temporary scaffold that is necessary to maintain the patency of the vessel after intervention. They gradually dissolve, liberating the vessel from its cage [8, 9]. Thus, expectedly, bioresorbable scaffolds will potentially overcome the limitations of traditional stents. Such limitations include the risk of late ST, neo-atherosclerosis, and local inflammation caused by the presence of a foreign body [10, 11]. In addition, bioresorbable scaffolds will allow the potential surgical revascularisation of the treated segment, whereas traditional stents often preclude this option. Current ongoing large-scale and randomized clinical trials aim to determine the long-term relative efficacy and safety of bioresorbable scaffolds, compared with current DES. The current study discusses potential additional advantages and limitations that these devices may present in clinical practice. This article focuses on the Absorb BVS (Abbott Vascular, Santa Clara, CA, USA), which has been tested in numerous clinical trials and recently acquired Food and Drug Administration approval.

Absorb BVS

Absorb BVS is made from semi-crystalline poly-L-lactic acid, coated with a layer of a 1:1 mixture of an amorphous matrix of poly-D, L-lactide and eluted with everolimus (8.2 µg/mm). Absorb BVS is manufactured using extrusion and laser machining techniques, featuring 157 µm strut thickness and comprising in-phase zig-zag hoops linked with bridge design. The scaffold degradation was achieved mainly through hydrolysis, followed by macrophage phagocytosis of the resulting degradation products, a process that requires 2-3 years to complete [12].

The first Absorb BVS device (revision 1.0) was investigated in humans in the Absorb Cohort A study. In this single-arm, prospective, and open-label study, 30 patients with single de novo coronary artery disease and stable or unstable angina were enrolled [13]. The reported late lumen loss (LLL) was 0.43 ± 0.37 mm at 6 months and 0.48 ± 0.28 mm at 2 years. Vasomotor function was restored at 2 years [14]. The intravascular ultrasound (IVUS) examination at 6 months revealed scaffold shrinkage (from 6.94 ± 1.70 mm^2 to 6.29 ± 1.47 mm^2), which was affected by the plaque composition and was more intense in fibrofatty and lipid-rich lesions [15]. To overcome this drawback, the Absorb BVS was re-designed. The improved Revision 1.1 featured a different design, with its struts having an in-phase hoop and with straight links arrangements to provide an increased radial support to the scaffold. In addition, the polymer in the updated version was processed in such a way that gave the scaffold additional mechanical strength [16]. The efficacy of the Revision 1.1 device was assessed in the multicentre single-arm Absorb Cohort B trial, which recruited 101 patients with single- or two-vessel de novo diseases. All patients received a 3.0 × 18.0 mm BVS. Patients were divided into two groups for follow-up purposes: group 1 was assessed at 6 months and 2 years and group 2 at 1 and 3 years. CTCA was performed in all patients at 18 months. In the first group, at the 6-month follow-up, one target lesion revascularisation (TLR) was observed. LLL was 0.19 ± 0.18 mm. At 2 years, LLL was 0.27 ± 0.20 mm. A similar result was reported for group 2 at 12 months. The scaffold area progressively increased during follow-ups. Although, at 6 months, a significant reduction was observed in the minimal lumen area on IVUS, compared with baseline (6.60 ± 1.22 to 6.37 ± 1.12 mm^2 vs. P < 0.005) [14]. At the 2-year angiographic follow-up, no differences in LLL (0.29 ± 0.16 vs. 0.25 ± 0.22 mm, P = 0.439) were noted between the small (reference vessel diameter, RVD < 2.5 mm) and large vessels (≥ 2.5 mm). At the 2-year clinical follow-up, no differences in ischaemia-driven major adverse cardiac events (MACE) (7.3 vs. 10.2%; P = 0.733) were noted between the two groups, with no observed cases of ST [17].

In addition to the Absorb Cohort B trial, two additional studies were conducted: Absorb Extend and Absorb II. The aim was to investigate clinical outcomes from the 3 study cohorts (Absorb Cohort B, Absorb Extend, and Absorb II), based on assessment of quantitative coronary angiography-maximal lumen diameter (Dmax) [18]. A total of 1,248 patients received Absorb scaffolds in the Absorb Cohort B (Absorb clinical investigation, Cohort B) study (N = 101), Absorb Extend (Absorb extended clinical investigation) study (N = 812), and Absorb II trial (Absorb II randomised controlled trial) (N = 335). Incidence of MACE (a composite of cardiac death, any myocardial infarction (MI) and ischaemia-driven TLR) was analyzed, according to the Dmax subclassification of scaffold oversize group versus scaffold non-oversize group. Preprocedural Dmax was assessed in 1,232 patients (98.7%). In 649 (52.7%) patients, both proximal and distal Dmax values were smaller than the nominal size of the implanted scaffold (scaffold oversize group), whereas in 583 (47.3%) of patients, the proximal and/or distal Dmax were larger than the implanted scaffold (scaffold non-oversize group). Rates of MACE and MI, at 1 year, were significantly higher in the scaffold oversize group than in the scaffold non-oversize group (MACE 6.6% vs. 3.3%; log-rank P < 0.01, all MI: 4.6% vs. 2.4%; log-rank P = 0.04), mainly driven by a higher MI rate within 1 month post-procedure (3.5% vs. 1.9%; P = 0.08). Independent MACE determinants were both smaller in Dmax than the scaffold nominal size (odds ratio [OR]: 2.13, 95% confidence interval [CI]: 1.22 to 3.70; P < 0.01) and the implantation of overlapping scaffolds (OR: 2.10, 95% CI: 1.17 to 3.80; P = 0.01). Of note, in a juvenile porcine model, overlapping Absorb scaffolds showed delayed healing on histology, with optical coherence tomography (OCT)

assessment and slower tissue coverage than nonoverlapping scaffolds. Neo-endothelial coverages of the overlapping segments were 80.1% and 99.5% at 28 and 90 days after implantation, respectively. Accordingly, the coverage in humans may need up to 18 months to be completed [19]. Among patients with MACE, MI occurred in 22.6% of patients treated with overlapping scaffolds. Most were periprocedural MI (19.4%). Thus, overlapping of scaffolds might be a contributing factor of MACE. Scaffold under-expansion due to the deployment of a scaffold in a vessel with a smaller size may be associated with a high postprocedural MI rate, due to several different mechanisms. The oversized scaffold could create vessel dissection or micro-perforation in a small target vessel. Alternatively, the under-expansion of the scaffold may lead to a denser polymer surface pattern and a larger strut footprint to vessel surface area, causing side branch occlusion or microthrombus formation. In this study, the size selection of Absorb scaffolds, with the cutoff value of 0.5 mm Dmax, was shown to be clinically relevant. Current analysis showed that the device vessel mismatch regarding preprocedural angiography features a clinical impact. Therefore, the observed relationship between the device vessel mismatch and clinical outcomes specifically relates to the preprocedural angiographic measurement. Mattesini et al. [20, 21] reported that when OCT is used to guide and optimize Absorb scaffold implantation, post-implantation area stenosis, minimal lumen area, and eccentricity index are similar to those observed after deployment of second-generation metallic DES. The different approach for lesion preparation and routine use of OCT guidance during Absorb scaffold implantation might have contributed to these results. The preprocedural usage of intravascular imaging could further improve clinical outcomes. However, these reports were limited by the lack of a randomized control group, small sample sizes, and short-term follow-ups.

BVS and DES

Absorb BVS for treatment of complex lesions has been associated with good procedural and early clinical outcomes, in accord with those observed with conventional DES. This finding is concluded from the study by Costopoulos et al. [22]. They examined patients treated with Absorb BVS (n = 92), between May 2012 and August 2013, and those treated with Everolimus-Eluting Stent (EES, Xience PrimeTM, Xience V®, Abbott Vascular, Santa Clara, CA, Promus, Boston Scientific, Natick, MA) (n = 1296), between October 2007 and January 2012, at San Raffaele Scientific Institute and EMO-GVM Cento Cuore Columbus, Milan. Although no significant differences were noted with regards to lesion location and type, pre-dilatation (97.8% vs. 75.8%, P < 0.01), and post-dilatation (99.3% vs. 77.4%, P < 0.01) were more commonly observed in the Absorb BVS group. Intravascular imaging with both IVUS (82.5% vs. 16.8%, P < 0.01) and OCT (21.2% vs. 0%, P < 0.01) was also more common in the Absorb BVS group. Within the Absorb cohort, the scaffold length per lesion was 36.5 ± 19.4 mm, indicating that Absorb BVS was used to treat diffuse diseases in most cases. Systematic double-stenting was performed in 11 (17.8%) cases of the treated bifurcation lesions, of which 8 (12.7%) contained Absorb BVS in both branches. Finally, kissing balloon inflation was performed in 10 (16.1%) cases. Double-stent strategies utilized included T-stenting and mini-crush techniques. No significant differences were observed with regards to periprocedural MI (8.7% vs. 8.7%, P = 1.0), TLR (3.3% vs. 5.4%, P = 0.41), and MACE (3.3% vs. 7.6%, P = 0.19) at 6 months. However, larger studies with long-term follow-ups are required to fully assess the roles of Absorb BVS for treatment of such lesions, examining how the roles compare with that of conventional stents.

BVS in STEMI

A large sample size study by Brugaletta et al. [23] used propensity scores to match each ST-segment elevation MI (STEMI) patients treated by Absorb BVS to comparable STEMI patients treated by everolimus-eluting Xience V stents (EESv) or by bare metal stents (BMS). This study was the first to compare BVS versus EESv versus BMS in STEMI patients, based on propensity score matching. The primary endpoint of this analysis was defined as the combined device-oriented endpoint (DOCE), including cardiac death, target vessel MI, and TLR. At 1 year, no differences were found between Absorb BVS and EESv groups regarding DOCE (HR: 0.94 [95% CI: 0.23 to 4.32], P = 0.994). DOCE also showed no differences between

Absorb BVS and EESv groups at 30 days (HR: 1.31 [95% CI: 0.48 to 3.52], P = 0.593). No differences were found in its individual components either at 30 days or 1 year. At 1 year, the definite/probable device thrombosis rate presented no differences between the groups (HR: 1.10 [95% CI: 0.69 to 17.54], P = 0.948), especially after adjustment for clopidogrel (HR: 2.94 [95% CI: 0.18 to 47.08], P = 0.445) and GP IIb/IIIa inhibitor use (HR: 1.59 [95% CI: 0.10 to 25.43], P = 0.743). Within 30 days after implantation, early definite/probable device thrombosis rates were higher in the Absorb BVS than in the EESv group (2.1% vs. 0.3%, P = 0.059), whereas no differences were found in terms of early definite device thrombosis (1.4% vs. 0.3%, P = 0.341). Considering clinical outcomes between Absorb BVS and BMS, either at 30 days or at 1 year, no differences were found between the two groups. They observed that STEMI patients treated with Absorb BVS featured ST rates that mostly clustered in the early phase.

BVS in ischemic heart disease

Considering the group of ischemic heart disease, Cassese et al. searched Medline, Embase, the Cochrane Central Register of Controlled Trials, scientific session abstracts, and relevant websites for randomized trials investigating BVS versus EES, published or posted between November 30, 2006, and October 12, 2015 [24]. This study was the first meta-analysis of randomized trials investigating the efficacy and safety of Absorb BVS versus EES in patients with ischemic heart disease treated with percutaneous revascularization. Analysis included six trials, comprising data for 3,738 patients with ischemic heart disease, treated with percutaneous revascularization and randomized to receive PCI with either an Absorb BVS (n = 2,337) or an EES (n = 1,401). Median follow-up was 12 months. The primary efficacy outcome was TLR and the primary safety outcome was definite or probable ST. Secondary outcomes were TLF (the composite of cardiac death, target vessel MI, or ischaemia-driven TLR), MI, death, and in-device LLL. Patients treated with Absorb BVS yielded a similar risk of TLR (OR 0.97 [95% CI 0.66-1.43]; P = 0.87), TLF (1.20 [0.90-1.60]; P = 0.21), MI (1.36 [0.98-1.89]; P = 0.06), and death (0.95 [0.45-2.00]; P = 0.89) as those treated with metallic stents. Patients

treated with an Absorb BVS presented a higher risk of definite or probable ST than those treated with a metallic stent (OR 1.99 [95% CI 1.00-3.98]; P = 0.05), with the highest risk between 1 and 30 days after implantation (3.11 [1.24-7.82]; P = 0.02). Lesions treated with Absorb BVS showed greater in-device LLL than those treated with a metallic stent (weighted mean difference of 0.08 [95% CI 0.05-0.12]; P < 0.0001). Compared with EES, Absorb BVS exhibited similar rates of repeat revascularization at 1 year of follow-up, despite inferior mid-term angiographic performance. However, patients treated with Absorb BVS presented an increased risk of subacute ST. Their findings show that BVS manifests a similar risk of repeat revascularization as metallic stents, a higher risk of ST at 1 year of follow-up, and an inferior mid-term angiographic performance. The primary benefits of biodegradable versus metallic stents are expected to emerge several years after the index PCI, when the elution of anti-restenotic drugs is completed and the bioresorbable scaffold is dissolved [25]. Their finding of at least similar efficacy versus the existing best-in-class DES at 12 months is important. The present meta-analysis showed a higher time-dependent risk of definite or probable ST in patients treated with a BVS versus those treated with a metallic stent. A modest increase was observed in the absolute risk of definite or probable ST with a BVS. The rate and timing of definite or probable ST in patients treated with PCI and that received BVS was consistent with those reported in other studies, with most events occurring within 30 days [26]. Whether the higher risk of subacute ST with BVS is attributable to implantation techniques and lesion selection remains to be determined. In this study, although the proportion of patients with post-dilation was higher in the BVS group, results, in terms of in-device minimum lumen diameter, were still inferior to those for metallic stents. Ongoing work aims to optimize the implantation techniques for BVS, aiming to improve clinical outcomes. In this respect, a more liberal use of intravascular imaging to guide scaffold expansion might be important in optimizing acute results, as previously reported [27].

BVS in coronary artery disease or acute coronary syndrome

In the group of coronary artery disease or acute coronary syndrome, Stone et al. performed a

patient-level and pooled meta-analysis of four randomized trials, in which 3,389 patients with stable coronary artery disease or a stabilised acute coronary syndrome were enrolled at 301 academic and medical centres in North America, Europe, and the Asia-Pacific region [28]. The patients were randomly assigned to the Absorb BVS group (n = 2164) or the Xience cobalt-chromium everolimus-eluting stent group (EESc; n = 1225). The summary treatment effects for 1-year relative rates of patient oriented composite endpoints (POCE, including all-cause death, all MI, or all revascularization) showed no significant difference between BVS and EESc (relative risk [RR] 1.09 [0.89-1.34], P = 0.38). Similarly, the 1-year relative rates of DOCE presented no differences between the groups (RR 1.22 [95% CI 0.91-1.64], P = 0.17). Target vessel-related MI increased with BVS, compared with EESc (RR 1.45 [95% CI 1.02-2.07], P = 0.04). Relative rates of all-cause and cardiac mortality, all MI, ischemia-driven TLR, and all revascularization showed no differences between BVS and EESc. Target vessel-related MI was more common with BVS than with EESc, although rates of all MI, cardiac mortality, and all-cause mortality exhibited no differences between the groups. Revascularization measures of efficacy at 1 year were also similar between the two devices. Most importantly, the 1-year rates of POCE of death, MI, or revascularization were similar between BVS and EESc. The 1-year rates of the device-oriented composite endpoint of cardiac death, target vessel-related MI, or ischemia-driven TLR also exhibited no significant differences between BVS and EESc. Patient-related and device-related treatment effects were consistent across most of the clinically relevant subgroups analyzed. Therefore, these findings provide reassurance that overall patient-related and device-related outcomes within the first year are not substantially compromised with the use of BVS. These results are especially noteworthy, as the comparator device in the four trials was an EESc, which is the DES associated with the lowest rate of ST, featuring the greatest freedom from adverse events [29-31]. Additionally, BVS was used, for the first time, by most of the investigators in these studies. Historically interventional device-related outcomes have improved over time with increasing experience. Although overall rates of MI showed no significant increases with BVS, target ves-

sel-related MI occurred more frequently with BVS than with EESc, due, in part, to nonsignificant increases in periprocedural MI and device thrombosis with BVS. Although not significant, a 0.6% absolute increase in definite device thrombosis contributed to the 1.0% absolute difference in non-periprocedural target vessel-related MI with BVS, compared with EESc, with the remainder being attributed to the target vessel-related MI not related to device thrombosis. Device and procedure success rates were also lower, to a certain extent, with BVS than with EESc. Greater strut thickness and post-PCI in-device diameter stenosis with BVS than with EESc might have contributed to these target vessel MI-related events. Improved procedural techniques with BVS (more aggressive plaque modification before BVS implantation, routine high-pressure noncompliant balloon post-dilatation to ensure adequate scaffold expansion, and more frequent use of intravascular imaging to optimise lesion coverage and scaffold dimensions) might further reduce thrombosis rates. However, neither cardiac nor all-cause mortality increased with BVS and all measures of clinical effectiveness at 1 year were similar with BVS and EESc, indicative of the similar in-segment luminal dimensions achieved [32]. Combined with the overall similar rates of POCE and DOCE, these findings support the safety and effectiveness of BVS use at 1 year for treatment of patients with stable coronary artery disease and stabilized acute coronary syndromes.

Ali et al. conducted a systematic review and meta-analysis to evaluate 2-year outcomes of BVS, compared with EES, in 5,583 patients, included in seven randomized trials. There was individual patient data available from the four industry-sponsored trials, with 3,389 patients [33, 34]. According to aggregate-level and individual patient data meta-analyses, BVS proved to be inferior to EES for DOCE, a composite of cardiac mortality, target vessel MI, or ischemia-driven TLR. Although no differences were noted in mortality, BVS was associated with a 52% increase in the risk of MI and a 40% increase in ischemia-driven TLR (both increases were significant). The relative risk of ST was more than three times higher throughout the entire follow-up period in BVS than in EES (2.3% [73 out of 3187] vs. 0.7% [16 out of 2281]; Relative risk [RR] 3.35 [95% CI 1.96-5.72], P < 0.0001), with

a concerning 10 times higher relative risk of very late ST between 1 and 2 years (0.8% [24 out of 3005] in the BVS group vs. 0.1% [2 out of 2104] in the EES group; RR 9.67 [2.04-45.82], P = 0.0042). Analysis revealed that the primary safety endpoint of device thrombosis at 2 years occurred more commonly with BVS than with EES, contributing to increased rates of DOCE with BVS. Between 1 and 2 years after device implantation, more events, especially target vessel-related MI and device thrombosis, accrued in patients treated with BVS than in those treated with EES. Significant interactions were present between the device type and several baseline variables for 2-year DOCE. According to multivariable analysis, pre-procedure quantitative coronary angiography RVD of less than 2.25 mm (among other factors) was an independent predictor of adverse outcomes after BVS. This study showed higher 2-year relative risks of DOCE and POCE with BVS than with EES, principally due to an increased risk of ST and target vessel-related MI events over time. Significant differences in 2-year DOCE, between BVS and EES, were no longer observed after exclusion of events related to device thrombosis, emphasizing the importance of preventing such events in improving the safety profile of BVS before complete bio-resorption.

Discussion

Very late restenosis and thrombosis are ongoing concerns after DES implantation. Contemporary DES has substantially improved event-free survival, compared with earlier-generation devices, for patients undergoing PCI. This has resulted in especially low rates of adverse events within the first year after implantation. However, the permanent rigid frame, common to all metallic stents, straightens and fixes the external dimension of the vessel, eliminates beneficial flow-related and pressure-related vascular effects, and serves as a nidus for persistent inflammation, neo-atherosclerosis, and strut fractures [5, 35]. The presence of a permanent metal structure in the coronary vasculature has been associated with a 2%-3% annual risk of stent-associated events, potentially lasting throughout the lifetime of the patient [2, 36]. In contrast, a fully bioresorbable scaffold offers the potential to mitigate long-term stent failure by restoring normal vascular adaptive response and reducing the sequelae from late

stent fractures and neo-atherosclerosis. BVS is more conformable than DES, restoring cyclic pulsatility by 6 months and vasomotor responses by 12 months [14, 37]. Through the removal of the mechanical constraints of a metallic frame, BVS results in increased luminal dimensions over a 5-year period, given the adaptive remodelling of the external elastic membrane, strut resorption, and plaque regression changes. These become impossible after implantation of a metallic DES [38, 39]. The formation of a protective 150-200 μm thick neointima after scaffold absorption might normalize endothelial shear stress and stabilize the lesion site [40, 41]. Complete device bio-resorption and replacement with a contractile neo-media could, thereby, improve long-term outcomes, compared with DES. Removal of the nidus for late adverse events could be especially important for young patients with coronary artery disease undergoing PCI, as well as in those presenting with acute coronary syndromes due to the thrombosis of a lipid-rich plaque, in which DES heals poorly [42]. Other potential benefits of BVS include the avoidance of a so-called full metal jacket in diffuse disease (facilitating later bypass graft surgery if necessary), late un-jailing of covered side branches (potentially reducing ischemia and restoring access for future intervention), and compatibility with non-invasive computer tomography angiographic imaging (through avoidance of the blooming artefact of metallic stents).

In recent years, considerable improvements have been made in the field of bioresorbable stents, with encouraging results emerging from their use in clinical practice [43, 44]. Further developments in this area are expected, as more companies enter the bioresorbable field. To date, the use of bioresorbable scaffolds has been limited to clinical trials and simple lesions in 'real-world' patients. As further evidence emerges regarding their use, interventional cardiologists will increasingly use these devices for treatment of more complex lesions. These devices will hopefully improve the already excellent results obtained with PCI, especially with regards to in-stent restenosis, ST, and clinical outcomes in high-risk patients, such as those with diabetes. Further development in BVS technology should aim to address strut thickness without compromising radial strength, thus improving device deliverability and ena-

bling the easier treatment of more complex lesions. For optimization of PCI with BVS, several crucial points must be implemented. Lesions suitable for BVS should be selected carefully. The appropriate device size should be selected according to the mentioned techniques. The lesion should be prepared with pre-dilatation and the scaffold implantation procedure should be performed rigorously and patiently. Target segment should be assessed with intracoronary imaging techniques before implantation and the scaffolded segment should be evaluated for mal-apposition and disruption after implantation. For optimization of PCI with BVS, in the next few years, OCT systems with faster pullback speeds may be used. For axial deployment optimization to reduce mal-apposition and under-expansion rates, both OCT and IVUS should be performed frequently to prevent hazardous results. On the other hand, associated with scaffold geometry, scaffolds with thinner struts will be useful in obtaining better optimization results at post-implantation in terms of less flow disruption within the scaffolded segment and related less risk of thrombus or neointimal hyperplasia formation. BVS with thinner streamlined struts will be useful for local hemodynamics within the scaffolded segments. Hybrid intravascular imaging, with the combination of OCT and IVUS, may render the potential for detection of high-risk lesions and identification of high-risk patients that can benefit from aggressive treatment of coronary atherosclerosis to obtain optimal PCI results.

Conclusion

Bioresorbable scaffolds are a relatively new technology, introduced to address the limitations of traditional metallic stents. This novel technology not only provides transient scaffolding and restores flow in the diseased segment but also restores vascular integrity and function [45, 46]. More than 19 years has passed since the first implantation in humans. Although several BVS are available, these devices still feature limited application. Several unmet clinical needs favouring BVS technology remain unresolved. These include treatment for diffuse disease, particularly among patients with premature atherosclerosis in young individuals, challenging restenotic lesions, and restoration of vascular physiology. Within 30 days after implantation, early definite/probable device thrombosis rates were higher with Absorb BVS than with metallic stents. Compared with metallic stents, BVS was associated with lower efficacy and higher thrombotic complications at a median time of follow-up of 2 years. This paradox is due to the totally different design and behavior of BVS, thus requiring further extensive studies. Whether the goal of BVS becoming the 'workhorse' intracoronary device of the future will be realized remains to be answered from ongoing and upcoming clinical studies. Studies, with extended follow-ups in a larger number of patients, are necessary to fully assess expected long-term advantages of Absorb BVS.

Acknowledgements

Disclosure of conflict of interest

None.

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