

Percutaneous Coronary Intervention with Everolimus-Eluting Bioresorbable Vascular Scaffolds in Diffuse Coronary Artery Disease: Current Knowledge and Future Perspectives

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Abstract

The optimal percutaneous treatment of diffuse coronary artery disease (CAD) remains an unsolved issue. Bioresorbable scaffold (BRS) technology has been developed to overcome the disadvantages of metallic drug-eluting stents (DES) due to their permanent struts. Through the resorption process, BRS may provide complete vascular restoration, which appears very attractive in the treatment of diffuse CAD. However, robust evidence on the use of BRS in this setting is lacking and recent data have raised concerns about the safety of this novel technology, especially when BRS are used in complex CAD or without adequate protocol implantation. This review aims at summarizing current evidence and future perspectives on Absorb BRS implantation in complex CAD, such as in distal coronary segments involvement and diffused disease.

Introduction

The optimal percutaneous treatment of diffuse coronary artery disease (CAD) is still an unsolved issue due to the well-known drawbacks of metallic drug-eluting stents (DES) and to the rising incidence of long and complex lesions in an increasingly elderly and comorbid population¹. The concept of bioresorbable scaffold (BRS) technology was introduced more than two decades ago as an alternative to permanent metallic stents to provide, through the resorption process, vessel restoration, preservation of future revascularization options and reduction of late adverse events, such as stent thrombosis (ST), restenosis, and neoatherosclerosis²⁻⁴. First-generation BRS, largely represented by the poly-l-lactic acid (PLLA) ABSORB (Abbott Vascular, Santa Clara, CA, USA) (Absorb BRS), have demonstrated to be non-inferior to second-generation metallic DES in low-to-moderate-complexity scenarios at mid-term follow-up of earlier randomized control trials (RCTs). However, recent meta-analyses and “real-world” registries have raised concerns about the safety of this novel technology, especially when the scaffolds were used in complex clinical and angiographic settings or without the recommended protocol implantation⁵. Therefore, the manufacturer halted the commercialisation of the Absorb GT1 scaffold (Abbott Vascular) with effect from September 2017. This review aims at summarizing current evidence and future perspectives of Absorb BRS implantation in complex CAD, such as in distal coronary segments involvement and diffused disease (Figure 1).

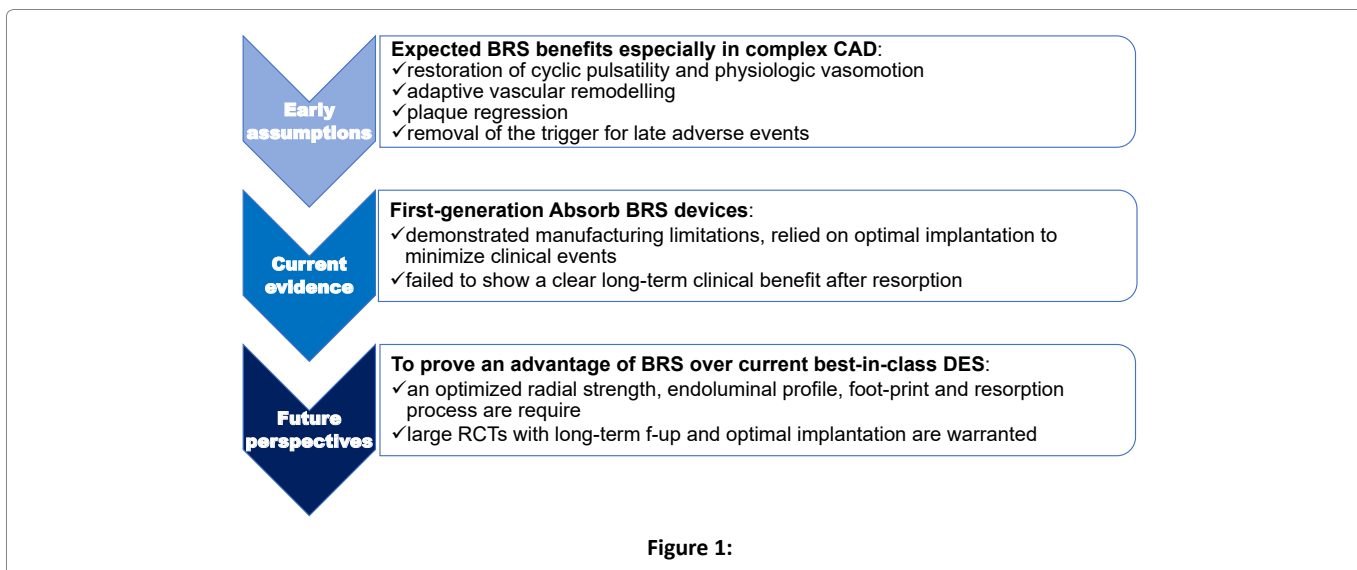


Figure 1:

Evidences from Clinical Trials

Robust evidence related to the outcomes of BRS use in the context of diffuse CAD is still lacking, since only one dedicated RCT versus a metallic II generation DES has been presented in this specific subset (Table I).

Preliminary data

The preliminary safety and efficacy of the Absorb BRS compared to current DES have been established through the short and mid-term follow-up of the trials from the ABSORB clinical development program, including low-to-moderate-complexity scenarios⁶.

Table I. Current evidences from Randomized Control Trials (RCTs) on Absorb BRS use.

Study	Participants		DM (%)		ACS (%)		Mean LL (mm)	Adequate pre dilatation (%)		Adequate post dilatation (%)		Follow-up (months)	TLF (%)		TLR (%)		ST (%)	
	BRS	DES	BRS	DES	BRS	DES		BRS	DES	BRS	DES		BRS	DES	BRS	DES	BRS	DES
ABSORB II (11)	355	166	24	24	23	25	14	100	99	61	59	48	11	6	3	2	3	0
													p=0.04		p=0.5		p=0.03	
ABSORB III (11)	1322	686	32	32	27	25	13	100	100	66	51	36	13	10	7	6	2	1
													p=0.06		p=0.3		p=0.01	
ABSORB JAPAN (11)	266	134	36	36	10	16	13	100	100	82	77	36	6	2	5	2	2	0
													p=0.1		p=0.2		p=0.01	
ABSORB CHINA (11)	238	237	25	23	72	76	14	99	98	63	54	36	3	1	3	1	1	0
													p=0.3		p=0.3		p=0.01	
ABSORB IV*	1299	1308	32	32	24	24	15	100	99	83	45	12	8	6	3	2	1	0
													p=0.2		p=0.08		p=0.1	
COMPARE-ABSORB§	848	822	35	36	52	49	NA	97	79	91	58	12	5	4	3	2	2	1
													p=0.4		p=0.7		p=0.01	
TROFI II (7)	95	96	19	15	100	100	13	56	51	51	26	36	5	3	3	1	2	1
													p=0.4		p=0.1		p=0.1	
EVERBIO (7)	78	80	16	22	34	37	NA	97	86	31	34	24	20	20	17	15	1	0
													p=0.5		p=0.5		p=0.1	
AIDA (7)	924	921	19	17	54	54	19	97	91	74	49	24	10	9	7	5	4	1
													p=0.3		p=0.2		p<0.001	

Values are presented as means or percentages.

BRS: bioresorbable vascular scaffold; DES: drug-eluting stent; DM: diabetes mellitus; ACS: acute coronary syndrome; LL: lesion length; TLF: target lesion failure; TLR: target lesion revascularization; ST: stent thrombosis.

* G.W. Stone at the Transcatheter Cardiovascular Therapeutics meeting, San Diego, September 24, 2018, unpublished

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Longer follow-up in low-to-moderate-complexity scenarios

Nevertheless, the initial optimism was toughened by long-term results of RCTs and several meta-analyses. At first, Absorb BRS failed to encounter its co-primary endpoint of superior vasomotor reactivity and non-inferior late luminal loss compared with the cobalt-chromium everolimus-eluting stent⁷. Afterwards, the device was found to be associated with higher rates of target lesion failure (TLF) compared with metallic DES, driven by an increased risk of target vessel myocardial infarction (TV-MI) and target lesion revascularization and significantly higher rate of device ST^{7,8}.

Features of BRS failure

Several meta-analysis and patient-level pooled analysis on RCTs have identified the following possible explanation for the higher risk of BRS failure compared to metallic DES^{9,10}. First of all, the more aggressive vessel preparation required for BRS implantation, particularly in complex lesions, and the larger footprint of the current scaffolds, might lead to small side branches occlusion, with an increase in periprocedural MI. Secondly, the wider and thicker scaffold struts may also result in non-laminar flow and altered shear stress before the scaffold is covered by neointima, increasing platelets reactivity and thus enhancing the risk for TV-MI and device thrombosis. Struts protrusion and disrupted local-wall shear stress appear also to be important determinants of neointimal growth and neoatherosclerosis. Finally, the disintegration of the polymeric scaffold struts between 1 and 3 years may result in scaffold discontinuities with endoluminal dislocation (intraluminal scaffold dismantling) which may act as substrate for thrombus formation and may be responsible for a substantial proportion of late TV-MI and ST.

Role of procedural technique in moderate-to-high-complexity scenarios

As previously suggested by several observational registries, the pooled analysis of Stone at al. from the ABSORB program's studies assessed the role of procedural technique on BRS outcomes to overcome the structural limitations of the current generation of device¹¹. As a matter of fact, BRS implantation in properly sized vessels and optimal post-dilation were independent predictors of freedom from TLF through short and long-term follow-up. Moreover, implantation of scaffolds in very small vessels were strongly associated with ST up to 3 years of follow-up and an aggressive pre-dilation was associated with reduced thrombosis rate beyond 1 year. The manufacturer emphasized that the discouraging outcomes of earlier BRS

RCTs were affected by imperfect implantation technique in addition to limitations of the current device generation. In fact, optimal pre-dilation, vessel size selection and post-dilation were performed in only 59.2%, 81.6%, and 12.4% of patients, respectively. The 1-year results from the latter ABSORB 4 trial, indeed, showed a superimposable ST and TLF rates (respectively of 0.7% in BRS arm vs. 0.3% in DES arm, $p=0.16$ and of 7.6% vs. 6.3%, $p=0.19$) in the context of better vessel selection (only 4% of patients had vessels <2.25 mm by QCA) and implantation technique (post-dilation was undertaken in 84% of ABSORB BRS cases) than in prior ABSORB trials (G.W. Stone at the Transcatheter Cardiovascular Therapeutics meeting, San Diego, September 24, 2018, unpublished). Conversely, the mid-term results of the Compare Absorb Trial in a high-risk patient and/or complex lesion population not investigated in previous RCTs, as acute coronary syndromes, bifurcations, long lesions and chronic total occlusions, highlighted again the structural limitations of the current scaffold generation showing a significantly higher rate of ST in the BRS group (2% vs 0.6%, $p=0.01$) (P.C. Smits at the Transcatheter Cardiovascular Therapeutics meeting, San Diego, September 24, 2018, unpublished). Longer-term follow-up is required to understand the true safety and efficacy profile of BRS during (0-3 years) and beyond (3-10 years) its complete bioresorption. The beneficial effects of PSP protocol on ensuring scaffold-wall apposition may principally impact very late results (>1 year).

Evidences from Observational Registries

The percutaneous treatment of complex coronary artery disease with BRS might greatly benefit from successful vessel healing over long coronary segments that may require more frequently repeat percutaneous or surgical revascularizations¹². However, the structural limitations of the current scaffold generation, like the strut thickness, the larger profile and the reduced deliverability, have limited an extensive application of this technology in complex coronary lesions. Therefore, available outcome data are mainly deriving from registries (Table II).

Preliminary data in complex scenarios

The favourable initial reports on the clinical outcomes of the Absorb prompted on its use in more complex clinical and coronary anatomy conditions. Indeed, the first "real-world" prospective registries of Absorb showed acceptable outcomes, but reported a disturbing, unpredicted high ST rate possibly related to an inadequate implantation technique¹³.

PSP concept

Further studies have speculated that adverse events after BRS implantation may be more frequent with either scaffold under or oversizing as well as with implantation in

Table II. Current evidences from observational registries on Absorb BRS use in diffuse CAD.

Study/First author	Study design	Participants	Settings	DM (%)	ACS (%)	Mean LL, mm	Adequate pre and postdilatation (%)	Follow-up (Months)	TLF (%)	TLR (%)	ST (%)
Tarantini et al. (26)	prospective	337	Small Vessels	26	53	24	98	12	4	3	2
Masiero et al. (25)	prospective	143	Full-plastic jacket	35	68	>56	98	22	6	3	1
Geraci et al. (17)	prospective	81*	Long lesions	28	18	>60	80	12	14	10	4
Biscaglia et al. (21)	prospective	162	Long lesions	28	54	44	96	12	9	7	2
Mojoli et al. (23)	prospective	377	Long lesions	24	60	48	98	12	6	3	1
Testa et al. (22)	prospective	1002	Long lesions/ multivessel CAD	26	60	40	97	12	10	5	1
Fam et al. (20)	prospective	105	CTO	35	24	34	90	6	4	2	1
Yaginuma et al (19)	prospective	69	CTO	13	0	26	NA	12	10	10	0
Mitomo et al (24)	retrospective	65	CTO	40	0	21	95	38	0	0	0

BRS: bioresorbable vascular scaffold; CAD: coronary artery disease; DM: diabetes mellitus; ACS: acute coronary syndrome; LL: lesion length; TLF: target lesion failure; TLR: target lesion revascularization; ST: stent thrombosis.

small vessels and suboptimal angiographic results^{14,15}. This has led to the concept of “PSP” to optimize BRS outcomes: aggressive pre-dilatation to improve vessel compliance and facilitating full scaffold expansion; appropriate vessel sizing, in particular avoiding of very small vessels in which BRS has excessive surface area coverage and polymer volume occupancy; routine, aggressive post-dilatation with slightly oversized noncompliant balloons at high pressure to ensure maximize scaffold dimensions, reduce shear stress, and avoid acute malapposition¹⁶.

Longer follow-up in complex scenarios

Accordingly, subsequent larger observational registries in complex anatomies subsets have confirmed as follows: first, treatment of diffuse CAD with BRS was associated with a non-negligible rate of procedural failure, probably due to the specific features of current Absorb BRS (e.g. the strut thickness, expansion and sizing limits) which might hamper its use especially in severely calcified lesions and small vessels^{17,18}. Secondly, the analysis of mid-term outcomes after percutaneous treatment with BRS of complex lesions PCI not reveal a significant increase of device-oriented composite end-point compared to low-to-moderate-complexity scenarios, despite high rates of TV-MI and TVR^{19,20}. The higher rates of MI mainly driven by peri-procedural events may be explained by the larger extension of CAD and once again by the structural characteristics of the device, with consequent higher risk of small branch occlusion and distal embolization²¹⁻²³. Finally, these studies reported a lower rate of ST especially when a carefully lesion selection and predefined implantation technique were performed²⁴⁻²⁶. As a matter of fact, Regazzoli et al. demonstrated a very low incidence of TLF and ST at 4-year follow-up adopting a dedicated implantation strategy of BRS in a real-world cohort of patients with a high prevalence of complex lesions (69.4% of type B2 or C lesions; 10.3% of severe calcific lesions; 26.1% of bifurcations)²⁷. This led to a

pre and post-dilatation rate >99%, as compared to a rate of 40-72% in earlier scaffold registries. Another novel aspect was the liberal adoption of intracoronary imaging and a high rate of prolonged dual antiplatelet therapy (DAPT).

Role of DAPT

As a matter of fact, all patients who experienced late or very late ST in the former RCTs were not on DAPT, while no ST occurred in patients who never interrupted DAPT up to 3 years²⁸. To blunt the rates of ST noted with BRS, closely related to the high-risk profile of the current device, procedural technique and late dismantling, the most recent international guidelines mandated a minimum DAPT duration of 12 months. Moreover, as suggested by available evidence on very-late follow-up, it might be reasonable prolonging DAPT beyond 12 months in patients when multiple devices are implanted or in the presence of overlapping points where 2 layers of struts further increase the tendency to thrombus formation for the mechanisms described previously^{28,29}.

Future perspectives

In summary, meticulous lesion preparation for appropriate expansion of BRS, postdilatation with an appropriately sized noncompliant balloons to maximize the chance of adequate apposition, careful lesion evaluation with intra-vascular imaging during all steps of the procedure and maintenance of long-term DAPT in case of suboptimal procedural results were the main PCI principles that may have contributed to the achievement of better outcomes in these later registries^{30,31}. These analyses support the potential feasibility of BRS implantation in complex scenarios with adequate lesion selection and meticulous procedural steps in order to maximize scaffold dimensions, embed struts into plaque, avoid acute malapposition, and reduce shear stress which may thus have favorable effects on clinical outcomes during the

scaffolds healing and resorption phases, even as late as 3 years³². Moreover, this data implies that further efforts to improve scaffold design and optimize BRS implantation are required and justify further research including direct comparison with standard metal drug-eluting stents and analysis of angiographic, intravascular imaging and clinical results at long-term follow-up³³. Nevertheless, the presence of diffuse CAD involving complex lesions not appropriate for pure scaffolding PCI (e.g. long lesions with reference vessel diameters too large or small or involving an ostial or severely calcified segment) does not necessarily mean that the concept of “leaving left behind” should be set aside. Accordingly, a hybrid coronary revascularization with an off-pump beating-heart revascularization procedure followed by a staged PCI suitable for BRS optimal implantation or a metal free hybrid strategy of BRS for larger size vessels and DEB for smaller sized vessels could be considered^{34,35}.

Conclusions

Restoration of cyclic pulsatility and physiologic vasomotion, adaptive vascular remodelling, plaque regression, and removal of the trigger for late adverse events were expected BRS benefits over current generation metallic DES especially in complex CAD. However, first-generation Absorb BRS devices demonstrated significant manufacturing limitations, relied on optimal implantation to minimize clinical events and failed to show a clear long-term clinical benefit after resorption. A new generation of BRS with an optimized radial strength, a sleeker endoluminal profile, a smaller foot-print, and a resorption process not interacting with vessel wall are key requisites to improve outcomes. Moreover, well conducted large RCTs with long-term follow-up and optimal implantation practices are warranted to determine whether the differences with metallic stent may be lessened by structural improvements, procedural precautions and adequate DAPT and to prove a tangible advantage of BRS over current best-in-class DES (i.e., angina reduction, vasomotion, TLF). To fulfil their promises and be successfully adopted in everyday clinical practice, BRS must meet these standards of evidence.

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