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Update on Clinical Evidence (Part II): A Summary of the Main Post Market Studies

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Bioresorbable vascular scaffolds (BVS, Absorb, Abbott Vascular, Santa Clara, CA) received the CE mark in October 2011, and were approved by the Food and Drug Administration in July 2016. After their introduction in clinical practice a broad amount of post-marketing clinical experience with BVS has been generated so far in Europe and outside the United States. The available BVS registries differ in many aspects, including their being single-center or multicenter, single-arm or controlled, sponsored or investigator-initiated, published or presented at a large-scale international meeting. This article provides an overview of clinical results of the main post-marketing studies of BVS available.

Key words: BVS, registries, clinical outcomes

INTRODUCTION

Randomized trials provide the most genuine comparison between treatments but typically lack of generalizability due to patient selection. Registries are less constrained by exclusion criteria and act as useful complements to randomized trials by providing a snapshot of daily practice in relatively more unselected scenarios.

Bioresorbable vascular scaffolds (BVS, Absorb, Abbott Vascular, Santa Clara, CA) received the CE mark in October 2011, and were approved by the Food and Drug Administration in July 2016 [1]. Thus, not surprisingly, the broadest amount of post-marketing clinical experience with BVS has been generated so far in Europe and outside the United States. The available BVS registries differ in many aspects, including their being single-center or multicenter, single-arm or controlled, sponsored or investigator-initiated, published or presented at a large-scale international meeting. This article is aimed at reviewing the clinical results of the main post-marketing studies of BVS available.

SEARCH STRATEGY

Two independent reviewers (PC and BF) systematically searched MEDLINE/PubMed scientific sessions abstracts, and relevant websites (www.cardiosource.com, www.clinicaltrialresults.org, www.escardio.org, www.tctmd.com, www.pcronline.com, www.theheart.org) for articles published or posted between October 2011 and July 2016, with no restrictions on publication status. Search terms included the keywords and the corresponding MeSH terms for "bioresorbable stent(s)" and "Absorb stent". The reference lists from all eligible studies were scrutinized to identify additional citations. We included studies in human patients that: [1] underwent percutaneous coronary intervention across the broad spectrum of obstructive coronary artery disease; [2] had a nonrandomized design; [3] included patients who received BVS after approval from local regulatory authorities; [4] were available in English language. Studies with inadequate data for abstraction, case reports, studies with <100 patients, studies reporting on selected patients and lesions only (i.e., ST-segment elevation myocardial infarction, acute coronary syndromes, chronic total occlusions, bifurcations) and studies reporting on bioresorbable scaffolds other than BVS were excluded. Where reports with different update status were available, the most inclusive or updated analyses were privileged.

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TABLE I. Characteristics of Single-Center Studies of BVS, Including Selected Baseline Clinical and Angiographic Features of the Study Population

Study	Years Enrollment	N	Setting	FU (months)	ACS (%)	STEMI (%)	DM (%)	ACC/AHA B2/C (%)	Bifurcations (%)	Ostial (%)	CTO (%)	MVD (%)
AMC	2012-2013	135	All-comers	6	40	13	20	67	15	3	8	47
GHOST	2013-2014	319	All-comers	12	50	18	25	51	16.7	3.9	8.4	39
BVS EXPAND	2012-2015	249	Selected	12	43	0	18.5	38.1	21.3	-	4.2	45.6

Data are for most updated reports. ACC, American College of Cardiology; ACS, acute coronary syndrome; AHA, American Heart Association; CTO, chronic total occlusions; DM, diabetes mellitus; FU, follow up; MVD, multivessel disease; STEMI, ST-segment elevation myocardial infarction.

TABLE II. Procedural Characteristics and Outcomes of Single-Center Studies of BVS

Study	RVD (mm±SD)	Lesion length (mm)	Overlap (%)	Pre-Dilatation (%)	PD (%)	IVUS/OCT use (%)	TLR	TLF	TVF	ST
AMC	2.34 ± 0.67	-	-	98	55	5/20	6.3	-	8.5	3.0
GHOST	2.9 ± 0.45	21.2 ± 16.8	32.5	96	71	11.6/25.1	4.2	4.9	5.2	1.3
BVS EXPAND	2.42 ± 0.74	22.1 ± 13.9	25.4	89.8	53.3	14.4/24.6	3.8	-	-	1.7

Data are for most updated reports. Outcome data are reported at the longest follow up available. IVUS/OCT, intravascular ultrasound/optical coherence tomography; PD, post-dilatation; RVD, reference vessel diameter; SD, standard deviation; ST, definite/probable scaffold thrombosis; TLF, target lesion failure; TLR, target lesion revascularization; TVF, target vessel failure.

SINGLE CENTER REGISTRIES

Characteristics and outcomes of single center BVS studies that fulfilled the inclusion criteria and had no exclusion criteria are reported in Tables I and II. These registries are relatively small if compared with multicenter registries, but provide interesting data in that they reflect daily practice by inclusion of as many high-risk patients and complex lesions as in typical drug-eluting stent (DES) series (i.e., acute coronary syndromes in 40-50% of patients, diabetes mellitus in 20-25%, bifurcations lesions in 15-20%). A more detailed description of each registry, including insights from cases of scaffold failure where available, is provided below.

Amc

AMC was a prospective registry including 135 patients treated with the BVS at the Academic Medical Center in Amsterdam, The Netherlands, between August 2012 and August 2013 [2]. Angiographic success was 96%. The 6-month rates of cardiac death, myocardial infarction (MI), target vessel failure (TVF) and target lesion revascularization (TLR) were 0.8%, 3.0% and 8.5%, and 6.3% respectively. Definite scaffold thrombosis occurred in 4 patients (3.0%), of which three were subacute and one late. The first case of scaffold thrombosis was attributed to a distal edge dissection. In the second, optical coherence tomography (OCT) showed incomplete expansion of the distal part of a 2.5/18 mm scaffold with a minimal scaffold diameter of 1.90 mm. Finally, in the remaining third and fourth cases the scaffold thrombosis was attributed to dual antiplatelet therapy (DAPT) discontinuation, which occurred seven and five days prior to the clinical event, respectively. These findings underline the importance of optimal implantation techniques and antithrombotic therapy to reduce the risk of scaffold thrombosis. In the AMC registry, post-dilatation was performed in about half of patients (55%).

Ghost

GHOST is an ongoing registry initiated in March 2013, enrolling patients treated with BVS at the Ferrarotto Hospital in Catania, Italy. Clinical results at 1-year of the first eligible 319 patients have been recently published [3]. One-year rates of target-lesion failure (TLF) and TVF were 4.9% and 5.2%, respectively. Cardiac death occurred in 0.9%, target-vessel MI in 1.3%, and TLR in 4.2% at 1 year. Four patients experienced scaffold thrombosis (1.3%), with all cases occurring within 30 days: two acute definite and two subacute, of which one was definite (at 25 days) and one was probable (at 26 days). The first case of acute scaffold thrombosis could probably be explained by residual dissection at the distal edge of a 2.5-mm scaffold and on-treatment high platelet reactivity, as assessed by platelet function testing. The second case of acute thrombosis occurred about one hour after stenting in a patient who had received the clopidogrel loading dose after the procedure, and who still had high platelet reactivity at the time of scaffold thrombosis. The subacute definite scaffold thrombosis could be explained by DAPT discontinuation five days prior to the event. Finally, in the case of subacute probable thrombosis, scaffold underexpansion could be

identified at post-procedural OCT. Once again, these findings are consistent with the likely impact of technical factors and platelet inhibition on scaffold thrombosis, particularly in the periprocedural period. Overall, the results of the GHOST registry were favorable, which is possibly linked with the high rate of post-dilatation (71%) and the good final expansion of the scaffolds at baseline (mean scaffold diameter 3.1 ± 0.4 mm, RVD 2.9 ± 0.45 mm, final MLD 2.70 ± 0.40 mm, acute gain 2.19 ± 0.53 mm). A subanalysis of the GHOST registry focusing on chronic total occlusions (CTO) has been recently reported [4]. A total of 32 patients undergoing BVS implantation in CTO were compared with a historical control group of 54 patients who had undergone CTO stenting with DES. Technical (78.1% vs. 96.3%, $P = 0.012$) and procedural (78.1% and 94.4%, $P = 0.035$) success rates were less likely to be achieved in the BVS compared with the DES group, driven by suboptimal scaffold expansion.

Bvs Expand

The BVS EXPAND registry reported clinical results of 249 patients treated with BVS at the Thoraxcenter in Rotterdam, The Netherlands, from September 2012 to January 2015 [5]. In this registry, patients with patients with a history of coronary bypass grafting, bifurcation lesions requiring kissing balloon post-dilation, and ST-segment elevation MI were excluded by protocol. Angiographic success was achieved in 97.3%. The 12- and 18-month rates of major adverse cardiac events (MACE), defined as the composite of cardiac death, MI and TLR, were 5.5% and 6.8%, respectively. The rates of cardiac mortality, MI, and TLR were 1.3%, 3.8% and 3.8% at 1 year, and 1.8%, 5.2%, and 4.0% at 18 months, respectively. Target-vessel MI at 1 year was observed in 2.8%. The 1-year rate of definite/probable scaffold thrombosis was 1.7% (4 patients), with all cases occurring after 30 day, but within 6 months. In most of these cases, suboptimal implantation in complex lesions (bifurcations, small vessels, CTO, long lesions) was the most likely cause of thrombosis identified, with antiplatelet therapy discontinuation described in one case. Although the results of the BVS EXPAND registry are generally positive, the 1-year rate of device-related events, including scaffold thrombosis was higher compared with that observed in some other registries, most likely due to the more complex population included, with a relevant proportion of patients with small vessels, combined with a possible suboptimal BVS expansion (mean scaffold diameter 3.1 ± 0.4 mm, pre-procedure RVD 2.42 ± 0.74 mm, final MLD 2.30 ± 0.4 mm, acute gain 1.39 ± 0.59 mm). Of note, when applying a <0.70 cutoff value for the ratio of MLD postprocedure/nominal device diameter, the scaffold was underexpanded in a relevant proportion of lesions (26%). Patients with BVS underexpansion tended to have an increased rate of MACE than those with good expansion: 8.0% vs. 3.8% ($P = 0.15$).

MULTICENTER REGISTRIES

Characteristics and outcomes of multicenter BVS studies that fulfilled the inclusion criteria and had no exclusion criteria are reported in Tables III and IV. Most of the registries had no control group, which makes comparisons versus DES unreliable. Comparisons across registries may also sound inappropriate, as the type of patients included and the pattern of BVS implantation techniques varied considerably. Another important consideration regards the differences in the centers experience with BVS implantation, depending on the time of enrollment. A more detailed description of the multicenter registries selected by our search strategy follows below.

Ghost-Eu

The investigator-initiated GHOST-EU (Gauging coronary Healing with bioresorbable Scaffolding plaTforms in EUrope) registry included retrospectively 1,189 patients treated with BVS across 10 centers in Europe between November 2011 and January 2014 [6]. The cumulative incidence of TLF was 4.4% at 6 months. The study reported a 2.1% rate of definite or probable thrombosis at 6 months, with about 70% of thrombotic events concentrated in the first 30 days, suggesting an interplay between the relatively complex case-mix (i.e., BVS were implanted in bifurcation lesions in about one fourth of patients) and procedural factors (i.e., low rate of post-dilatation). However, in a 1-year update of the registry, featuring a propensity score matched analysis of 905 patients from GHOST-EU and 905 patients treated with everolimus eluting stents (EES) (Xience, Abbott Vascular, Santa Clara, CA) in the XIENCE V USA registry, the combined rate of ischemic events was low and nonsignificantly different between treatment groups [7]. In the original report of GHOST-EU, the only independent predictor of TLF was diabetes mellitus [6]. In an expanded cohort of GHOST-EU ($N = 1{,}304$), with one additional recruiting center, ostial lesions also emerged as an independent predictor of 1-year TLF [8]. The results of the bifurcations subset ($N = 289$) have been also recently reported, with Kaplan-Meier estimates of 1-year TLF and scaffold thrombosis of 6.4% and 2.5%, respectively [9].

TABLE III. Characteristics of Multicenter Studies of BVS, Including Selected Baseline Clinical and Angiographic Features of the Study Population

Study	Years Enrollment	N.	Setting	FU (months)	ACS (%)	STEMI (%)	DM (%)	ACC/AHA B2/C (%)	Bifurcations (%)	Ostial (%)	CTO (%)	MVD (%)
GHOST-EU	2011-2014	1189	All-comers	6	47.4	16.1	24.8	53.5	26.7	6.1	7.8	40.9
GHOST-EU	2011-2014	905	All-comers	12	42.3	10.7	27.5	54.6	22.0	8.2	7.7	57.9
ASSURE	2012-2013	183	All-comers	12	-	-	26	64.7	3.0	-	4.0	47
ABSORB-EXTEND	2010-2012	512	Selected	12	47	0	26	41	-	-	-	-
MICAT	2012-2014	1305	All-comers	16 (10-21)	50	19	23	38	10.7	5.3	-	-
ABSORB-FIRST	2013-2014	1702	All-comers	12	57.2	-	25.2	47.6	12.6	5.7	9.3	43.4
REPARA	2014-2015	2100	All-comers	6	59	32	24	41.6	18.4	-	-	-
GABI-R	2013-2016	2168	All-comers	1	51.1	32.4	21.5	37.8	3.2	1	6.4	59
IT DISAPPEAR	2014-2016	1002	Selected	1	59.7	22.1	23.7	-	22.3	-	5.7	-
FRANCE ABSORB	2014-2016	2089	All-comers	1	48	17	15.9	43.9	8.0	-	9.0	38

Data are for most updated reports. Abbreviations: ACC, American College of Cardiology; ACS, acute coronary syndrome; AHA, American Heart Association; CTO, chronic total occlusions; DM, diabetes mellitus; FU, follow up; MVD, multivessel disease; STEMI, ST-segment elevation myocardial infarction.

TABLE IV. Procedural Characteristics and Outcomes of Multicenter Studies of BVS

Study	RVD (mm±SD)	Lesion length (mm)	Overlap (%)	Pre-Dilatation (%)	PD (%)	IVUS/OCT use (%)	TLR	TLF	TVF	ST
GHOST-EU	3.0 ± 0.5	19.4 ± 14.4	-	98	49	14.4/13.8	2.5	4.4	4.9	2.1
GHOST-EU	2.97 ± 0.53	20.1 ± 14.9	-	-	51.9	-	4.6	5.8	-	1.8
ASSURE	2.6 ± 0.5	11.6 (9.3-16.5)	10	99	13	-	2.8	2.8	0.5	0
ABSORB-EXTEND	2.62 ± 0.35	11.92 ± 5.27	9	mandatory	-	-	1.8	4.3	4.9	0.8
MICAT	-	-	16	100	50	-	-	-	-	3.0
ABSORB-FIRST	3.07 ± 0.45	18.7 ± 9.3	13.7	91.4	51.5	-	1.5	2.4	-	0.9
REPARA	-	-	16.5	-	45.6	2.5/8.6	1.4	-	-	1.4
GABI-R	2.96 + 0.63	-	-	92	68	5/4	1.5	1.9	2.0	1.3
IT-DISAPPEAR	-	28 ± 13.6	-	98	96.8	20.4	1.0	3.3	-	0.6
FRANCE ABSORB	-	18.4 ± 7.1	-	93	72	–/15.7	0.6	-	-	1.1

Data are for most updated reports. Outcome data are reported at the longest follow up available. IVUS/OCT, intravascular ultrasound/optical coherence tomography; PD, post-dilatation; RVD, reference vessel diameter; SD, standard deviation; ST, definite/probable scaffold thrombosis; TLF, target lesion failure; TLR, target lesion revascularization; TVF, target vessel failure.

Assure

The ASSURE registry enrolled 183 consecutive patients treated with BVS between April 2012 and March 2013 at six German centers [10]. At one year, there were one (0.5%) death due to gastrointestinal bleeding under DAPT and three (1.6%) MIs, not related to the target vessel. Over one year, TLR occurred in 5 patients (2.8%), of whom two had long lesions (38.4 mm and 24.0 mm) in small vessels (RVD 1.7 mm and 2.3 mm), treated with overlapping 3.0-mm scaffolds. A third patient had an in-scaffold restenosis of a vein graft in a BVS malapposition, confirmed by intravascular ultrasound at seven months. In the fourth patient, TLR was performed due to an incomplete proximal BVS expansion noted by OCT at eight months. The fifth patient with a left main/left anterior descending lesion needed coronary artery by-pass surgery because of a total occlusion of the proximal left anterior descending at 11 months. Overall, the 1-year rate of BVS-related events was 2.8%. No cases of scaffold thrombosis were observed. The results of the ASSURE registry were very favorable compared to other registries, most likely due to the combination of the less complex population enrolled and the optimal BVS expansion (pre-dilatation balloon diameter/RVD ratio 1.1, pre-procedure RVD 2.6 ± 0.5 mm, final MLD 2.5 ± 0.4 mm, acute gain 1.54 ± 0.51 mm).

Absorb Extend

ABSORB EXTEND is a prospective single-arm registry that enrolled 812 patients at 56 international sites (NCT01023789). The registry admitted only patients with up to two moderately complex lesions ≤28 mm in length, located in different epicardial vessels. A published interim 1-year analysis of the first 512 patients enrolled reported cumulative TLF and definite or probable scaffold thrombosis rates of 4.3% and 0.8%, respectively.[11] One-year data from the full cohort were consistent, with 5.0% TLF and 1.0% thrombosis (Abizaid A, presented at EuroPCR 2015). Interestingly, in

ABSORB EXTEND, systematic postdilatation did not emerge as a significant treatment modifier [12]. Differently, in an expanded cohort that mostly included patients from ABSORB EXTEND, implantation of an oversized BVS in a relatively small vessel appeared to be associated with a higher 1-year rate of combined ischemic events, driven by more frequent early MI [13]. In a propensity score matched analysis of BVS and EES, including all patients from ABSORB EXTEND, BVS were associated with comparable rates of TLF and numerically albeit nonsignificantly higher rates of scaffold thrombosis (1.0% vs. 0.3%) compared with EES (Abizaid A, presented at EuroPCR 2015). In a propensity score matched study including 551 patients from ABSORB cohort B ($n = 101$) trial and ABSORB EXTEND ($n = 450$), there was no significant difference in 1-year TLF between BVS and EES among diabetic ($n = 136$) and non-diabetic patients ($n = 415$) [14]. An earlier propensity score matched report including 435 patients from ABSORB EXTEND suggested BVS to be associated with a higher incidence of post-procedural side branch occlusion compared with EES [15].

Micat

The MICAT registry encompassed a total of 1305 patients from 2 German and 2 Swiss centers, with a focus on scaffold thrombosis [16]. The incidence of probable and definite scaffold thrombosis was 1.8% at 30 days and 3.0% at 12 months. In a multivariable analysis, ostial lesions and impaired left ventricular ejection fraction were independently associated with scaffold thrombosis. Lower post-procedural MLD and RVD were also associated with scaffold thrombosis, whose risk appeared to rapidly increase for post-procedural MLD <2.4 mm (for the 2.5- to 3.0-mm BVS) and 2.8 mm (for the 3.5-mm BVS). Interestingly, the authors performed a time-dependent analysis based on the introduction and implementation of a BVS-specific implantation strategy across participating sites. At 12 months, the scaffold thrombosis rates fell from 3.3% to 1.0% after the implementation of the BVS-specific protocol, an effect that remained significant after adjustment for potential confounders.

Absorb First

ABSORB FIRST is a sponsored, prospective, 1,801-subject international registry designed to evaluate BVS in all-comers patients from 87 sites (NCT01759290). An interim report of 1702 patients at 1 year preliminarily disclosed device and technical success in virtually all cases, with very low TLF (2.4%), and definite or probable scaffold thrombosis in 0.9% of cases (Seth A, presented at TCT 2015). In ABSORB FIRST, diabetes mellitus and overlap use emerged as independent predictors of TLF, while acute coronary syndromes, ostial lesions, and overlap use were independently associated with scaffold thrombosis. A ≤ 1 ratio between device size and RVD was associated with a 1-year lower risk of scaffold thrombosis (Seth A, presented at TCT 2015).

OTHER MULTICENTER REGISTRIES WITH CLINICAL OUTCOMES REPORTED AT <12 MONTHS

Repara

REPARA is a prospective, multicenter registry that enrolled 2,448 patients at 60 Spanish and Portoguese sites. Originally intended as a 1,500-patient registry, the sample size has been extended due to the high inclusion rate. Preliminary 6-month results in 2,100 patients have been presented, with MI in 2.1%, TLR in 1.4% and device thrombosis in 1.4% (Hernandez F, presented at EuroPCR 2016). The primary 1-year endpoint is pending.

Gabi-R

GABI-R is an ongoing multicenter registry enrolling BVS patients at 93 sites in Germany and Austria.[17] Thirty-day outcomes of 2,168 patients have been reported (Hamm C, presented at EuroPCR 2016). The investigators reported MI in 1.6%, TLF in 1.9%, TLR in 1.5 and definite scaffold thrombosis in 1.3%. Long-term data collection of patients included in GABI-R is ongoing.

It Disappears

IT-DISAPPERS is a prospective Italian multicenter registry of 1002 patients from 38 centers promoted by the Italian Society of Interventional Cardiology that included only patients with long lesions (≥ 24 mm) or multivessel disease. As part of the study, an implantation protocol has been published to recommend harmonized practices across participating sites [18]. This resulted in very high rates of predilatation and post-dilatation (98% and 96.8%) (Petronio AS, presented at EuroPCR 2016). Thirty-day follow up showed TLF in only 3.3% and scaffold thrombosis in 0.6% despite the high risk features of patients included.

France Absorb

FRANCE-ABSORB aims to include all BVS procedures in France with a 5-year follow up, as required by the French Health Authority. In the last update of the

registry (Koning R and Le Breton H, presented at EuroPCR 2016), 87 French centers have included 2089 patients with only 0.6% TLR and 1.1% definite thrombosis at 30 days. The low rate of periprocedural events in this registry possibly reflect the high rate of compliance with the implantation rules imparted by the manufacturer, with predilatation in 93% and postdilatation in 72% of patients.

CONCLUSIONS

Data on BVS use in the real world are inevitably heterogeneous and typically limited by the lack of comparators. However, registries have the merit of capturing more complex patients and lesions than those of randomized clinical trials. In addition, some registries included a large amount of patients, which enabled meaningful analyses of independent predictors of adverse clinical events. In the registries described in this review, low rates of ischemic events, including scaffold thrombosis, were noted in studies that implemented best practices of scaffold implantation, reflecting the instructions of the manufacturer (i.e., predilatation, optimal sizing, post-dilatation). Registries reporting high rates of events were generally those earlier in time or those with the highest rates of BVS use for complex lesions or clinical scenarios. Finally, there is a wealth of large national and international multicenter registry of BVS in the pipeline, whose primary results are pending. These studies and their subanalyses will contribute significantly to our understanding of the strengths and limitations of BVS as a workhorse device.

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