Absorb GT1 Bioresorbable Vascular Scaffold System — 1-Year Post-Marketing Surveillance in Japan —

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Background: The Japan post-marketing surveillance (PMS) for the Absorb GT1 bioresorbable vascular scaffold (BVS) mandated an intracoronary imaging-guided implantation technique.

Methods and Results: We enrolled 135 patients who were planned to undergo PCI with THE Absorb GT1. Adequate lesion preparation, imaging-guided appropriate sizing, and high-pressure post-dilatation using a noncompliant balloon to minimize final diameter stenosis were recommended. The primary endpoint was the scaffold thrombosis rate at 3 months. All patients successfully received at least 1 Absorb GT1 at the index procedure and completed 1-year follow-up. All 139 lesions were predilatated: cutting/scoring balloon and noncompliant balloon were used in 48 (34.5%) and 58 (41.7%) lesions, respectively. Post-dilatation was performed in 137 (98.5%) lesions with mean high pressure of 18.8 atm. Optical coherence tomography (OCT) was used in 127 of 139 (91.4%) lesions, and revealed 56.7% of lesions had incomplete scaffold apposition (ISA) but only in 1.89% in the per strut analysis. All patients received adenosine diphosphate receptor antagonist at discharge, and 132 (97.8%) patients continued therapy through the year. No definite/probable scaffold thrombosis, cardiac death, myocardial infarction, or ischemia-driven target lesion revascularization was reported up to 1 year follow-up.

Conclusions: Appropriate OCT-guided BVS implantation may prevent incomplete strut apposition, thereby reducing the risk of target lesion failure and scaffold thrombosis.

Key Words: Absorb GT1; Bioresorbable vascular scaffold; Coronary stent; Restenosis; Thrombosis

Fully bioresorbable vascular scaffolds were expected to decrease the incidence of the long-term adverse events of metallic drug-eluting stents caused by the permanent existence of foreign material in the treated vessel.¹ Abbott Vascular (Santa Clara, CA, USA) developed Absorb BVS and obtained Conformité Européenne mark in 2010. Series of head-to-head randomized clinical trials (RCTs) to compare Absorb BVS with the cobalt-chromium everolimus-eluting stent (CoCr-EES) were conducted to further evaluate the efficacy and safety of Absorb BVS.²⁻⁵ The Absorb BVS scaffold is made of poly L-lactic acid and is designed to be fully absorbed within approximately 3

years. After bioresorption, the vessel may recover its physiological function, such as mechanotransduction, cyclic strain, and vasomotion, which theoretically should lower the risk of long-term events. However, higher rates of scaffold thrombosis (ST) were reported in the Absorb RCTs,⁶⁻⁹ and other registries,^{10,11} in both the early and very late phases (when bioresorption is still ongoing), raising questions regarding the safety of the Absorb BVS. Post-hoc analysis suggested that a lack of appropriate scaffold expansion/apposition was the potential cause of ST.^{11,12}

Abbott Vascular recommended an appropriate BVS implantation technique to mitigate the risk of ST, including

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“good lesion preparation”, “quantitative vessel sizing and selection of matched size of BVS”, and “post dilatation with high pressure and noncompliant balloon”.¹³

Absorb GT1 has an identical scaffold to Absorb BVS, but has a new delivery system. Absorb GT1 was approved by the Pharmaceuticals and Medical Devices Agency in Japan on November 2, 2016, with the condition of conducting a well-designed post-marketing surveillance (PMS). All patients who were treated with Absorb GT1 were required to be registered in the PMS, and participating physicians were required to follow the appropriate implantation technique provided by the sponsor. Subsequently, Absorb GT1 was withdrawn from the global market because of low sales volume. However, the clinical significance of appropriate implantation techniques guided by intravascular imaging modalities, especially optical coherence tomography (OCT), need to be shared with the medical community. Herein, we present the 1-year clinical, angiographic, and OCT measurement data from the Absorb GT1 Japan PMS.

Methods

The Absorb GT1 Japan PMS is a prospective, multicenter, PMS of the Absorb GT1 in Japan. The PMS was conducted as per the Good Post Marketing Study/Surveillance Practice of Japan, and was planned to enroll approximately 2,000 patients in 2 phases in up to 200 sites. The plan for Phase 1 (Surveillance Phase) was to recruit 250 patients in approximately 45 surveillance sites, and aimed to confirm the efficacy of physician training. Imaging-guided procedure with intravascular ultrasound (IVUS) or OCT was mandated in this phase. An imaging core laboratory (Cardiocre, Tokyo, Japan) reviewed and analyzed images from the first 150 patients. The plan for Phase 2 was to register the

remaining patients across approximately 200 surveillance sites to confirm the safety of the Absorb GT1, based on the ST rate.

The Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT) provided a consensus letter on December 12, 2016, which requested physicians to: (1) complete the Sponsor’s training session and follow the appropriate implantation technique and patient/lesion selection, (2) follow the Absorb GT1 Instructions For Use, and (3) consider prolonged dual antiplatelet therapy (DAPT) duration depending on each patient’s condition/risk factors.

Inclusion and Exclusion Criteria

Patients were not to be treated if the reference vessel diameter (RVD) was <2.5 mm or >3.75 mm; there was a left main coronary artery lesion, aorta ostial lesion, severe calcification, hinge motion, or ST-elevation myocardial infarction (MI); the patient was undergoing kidney dialysis, was at high bleeding risk, or could not tolerate at least 12 months of DAPT with aspirin and adenosine diphosphate (ADP) receptor antagonists (namely, 3.75 mg/day prasugrel or 75 mg/day clopidogrel). In addition, scaffold overlapping to treat a lesion ≥ 24 mm, or the treatment of a severely tortuous vessel within or proximal to the lesion was not recommended in the early stage of the PMS, until the sponsor agrees based on the interim analysis results.

Registration

Written informed consent was given prior to the index procedure. Patients were registered in the PMS when treatment with the Absorb GT1 was attempted. Lesions for which treatment with the Absorb GT1 was attempted were defined as target lesions. If patients had other significant lesions (such as complex lesions not suitable for the Absorb

Table 1. Baseline Patients' Characteristics

Characteristics	N=135
Demography and risk factors	
Age, years	64.0±10.9 (134)
Male, %	84.4% (114/135)
BMI, kg/m ²	24.40±3.18 (135)
Any diabetes mellitus	39.3% (53/135)
Diabetes treated with insulin	4.4% (6/135)
Lipid disorder requiring medication	62.2% (84/135)
Hypertension requiring medication	68.9% (93/135)
Current smoker	23.7% (32/135)
Family history of coronary artery disease	10.4% (14/135)
Prior coronary intervention	25.9% (35/135)
Prior MI	9.6% (13/135)
Ischemic status	
NSTEMI	0.7% (1/135)
Unknown MI	1.5% (2/135)
Unstable angina	6.7% (9/135)
Stable angina	49.6% (67/135)
Silent ischemia	37.0% (50/135)
Old MI	3.0% (4/135)

Continuous data are shown as mean±SD. Binary variables are shown as % (n/N). BMI, body mass index; MI, myocardial infarction; NSTEMI, non-ST-elevation myocardial infarction.

GT1), they could be treated with other commercially available stents during the index procedure and were defined as “non-target lesions”.

Procedure

OCT imaging was performed using either the Ilumien OCT imaging system (Abbott Vascular, Westford, MA, USA) or optical frequency domain imaging (Lunawave; Terumo Corp., Tokyo, Japan). The recommended technique included “PSP”, defined as adequate lesion preparation (P), appropriate sizing (S), and post-dilatation (P). The objective was to minimize final residual diameter stenosis and incomplete scaffold apposition using a noncompliant balloon at high pressure. Predilatation of the target lesion was mandated. The use of a noncompliant balloon and a cutting/scoring balloon was allowed to achieve optimal predilatation (namely, minimal indentation and asymmetry). Scaffold deployment was performed slowly, by pressurizing the delivery system in 2-atm increments, every 5s, until the scaffold was completely expanded, and the pressure was maintained for 30s. Post-dilatation using a noncompliant balloon (≤0.5mm beyond the nominal scaffold diameter) with high pressure (≥16 atm) was strongly recommended to achieve good scaffold expansion (residual stenosis <10%) and apposition to vessel wall. When the post-procedural assessment was performed using OCT, the target abluminal strut to wall distance was ≤150μm (i.e., equal to strut thickness).

Follow-up

Clinical outcome data were collected at 1 month, 3 months, and 1, 2, 3, 4, and 5 years after the procedure.

Endpoints

The primary endpoint of the PMS was the ST rate at 3

Table 2. Baseline Lesion Characteristics and Procedural Information

	N=135/L=139
No. of target lesions	
Mean	1.1±0.3 (135)
1	97.0% (131/135)
2	3.0% (4/135)
Target vessel	
LMCA	0.0% (0/139)
LAD	48.2% (67/139)
LCX	22.3% (31/139)
RCA	29.5% (41/139)
Graft	0.0% (0/139)
Lesion type	
De novo	99.3% (138/139)
In-stent restenosis	0.7% (1/139)
Restenosis, other	0.0% (0/139)
Lesion morphology	
ACC/AHA type B2/C	51.8% (72/139)
Severe/moderate calcification	11.5% (16/139)
Severe/moderate tortuosity	10.1% (14/139)
Total occlusion	0.00% (0/139)
Procedural information	
% Predilatation	100.0% (139/139)
- By noncompliant balloon	41.7% (58/139)
- By cutting/scoring balloon	34.5% (48/139)
% Post-dilatation	98.5% (137/139)
Post-dilatation pressure, atm	18.8±3.5 (137)
- By noncompliant balloon	87.59% (120/137)
Lesion success	100.0% (139/139)

Continuous data are shown as mean±SD. Binary variables are shown as % (n/N). LAD, left anterior descending artery; LCX, left circumflex artery; LMCA, left main coronary artery; MLD, minimum luminal diameter; RCA, right coronary artery; RVD, reference vessel diameter.

months, per the Academic Research Consortium definition.¹⁴ The Japanese Pharmaceutical and Medical Device Agency agreed to a full commercial launch of the Absorb GT1 provided the ST rate in 2,000 patients was ≤0.9%. Other clinical endpoints were the same as for the ABSORB Japan RCT (briefly, target lesion failure [TLF]: a composite of cardiac death, MI attributable to the target vessel (TV-MI), or ischemia-driven target lesion revascularization (ID-TLR) at 1 year).³

Endpoint Assessment The angiograms and intravascular (IVUS/OCT) images from the first 150 patients taken pre- and post-procedure were sent to an independent core laboratory (CardiCore, Tokyo, Japan) for analysis. An independent clinical events committee (Baim Clinical Research, Boston, MA, USA) adjudicated all deaths and suspected cases of MI. Periprocedural MI, which was defined as a post-procedural creatine kinase-MB >5-fold of the upper limit of normal, was also included. ST events were adjudicated by a Scaffold Thrombosis Image Review Committee.

Image Analysis

Quantitative coronary angiography (QCA), IVUS, and OCT image analyses were performed at the independent core laboratory. Semi-automated analysis software,

QAngio® XA (Medis Medical Imaging Systems, Leiden, The Netherlands), was used for QCA. The stented segment and the 5-mm periscaffold segments (proximal and distal to the scaffold) were analyzed by an established standard technique. In each segment, minimal lumen diameter (MLD), RVD, and percent diameter stenosis were measured pre- and post-procedure.

Quantitative OCT analysis was performed using QIvus (Medis Medical Imaging Systems). Scaffold segments were analyzed quantitatively every 1 mm. Quantitative cross-sectional analysis of lumen area contours was obtained automatically, and additional manual corrections were performed if necessary. The following parameters were evaluated: lumen area, and abluminal and endoluminal scaffold areas. Volumetric measurements were calculated using Simpson's rule, and the volumetric index was calculated as: volume/stent length. The in-device segment was determined in preprocedural OCT images, and the mean lumen area of the segment was calculated subsequently. Incomplete strut apposition (ISA) was adjudicated when the distance between the lumen and the endoluminal contour was $>157\ \mu\text{m}$ (i.e., scaffold thickness). Qualitative assessment of edge dissection, scaffold disruption, thrombus (post-procedure) and calcification (preprocedure) was performed for all frames.

Statistical Analysis

Success rate was calculated among the intent-to-treat (ITT) population. Other analyses were performed in the Full Analysis Set (FAS), defined as patients who received at least 1 Absorb GT1 device. Data were summarized using descriptive statistics. Continuous variables are summarized as mean $\pm$ standard deviation and categorical variables as percentages by categories. All analyses were performed using SAS for Windows, version 9.3 or higher (SAS Institute, Cary, NC, US).

Results

A total of 135 patients were enrolled from December 13, 2016 to December 17, 2017 (Figure). All 135 patients registered in the PMS successfully received at least 1 Absorb GT1 during the index procedure. Therefore, both the ITT population and FAS analyses were based on 135 patients. All patients completed their 3-month and 1-year follow-up.

Key baseline demographic variables, risk factors, and lesion characteristics are shown in Table 1. Mean patient age was 64.0 years. Baseline characteristics showed that 26% of patients had a prior coronary intervention, and 87% had stable coronary artery disease. Target lesion characteristics

are shown in Table 2. In total, 139 lesions were treated. Most patients had treatment of only 1 study target lesion. Only 1 lesion had in-stent restenosis. Type B2/C lesions per ACC/AHA classification were limited to 52%. Only 12% of lesions were classified as severe/moderate calcification. Mean RVD was 2.73 mm, mean % diameter stenosis was 63%, and mean lesion length was 13.8 mm; these values were similar to those reported in previous Absorb BVS pivotal investigations.³ Predilatation was mandatory and

Table 3. QCA Measurements and OCT Analysis Data

Preprocedural QCA measurements		L=139
Lesion length, mm		13.84 $\pm$ 4.74 (139)
RVD, mm		2.73 $\pm$ 0.41 (139)
MLD, mm		1.00 $\pm$ 0.30 (139)
%DS		63.1 $\pm$ 9.5 (139)
Post-procedural QCA measurements		L=139
RVD, mm		2.81 $\pm$ 0.39
In-segment MLD, mm		2.30 $\pm$ 0.38
In-device MLD, mm		2.49 $\pm$ 0.36
In-segment %DS, mm		18.4 $\pm$ 6.3
In-device %DS, mm		12.9 $\pm$ 5.6
In-segment acute gain, mm		1.29 $\pm$ 0.44
In-device acute gain, mm		1.48 $\pm$ 0.44
Preprocedural OCT measurement (core lab assessment)		L=127
Proximal MLA, mm ²		8.04 $\pm$ 2.51 (110)
In-device MLA, mm ²		5.09 $\pm$ 1.49 (122)
Distal MLA, mm ²		6.29 $\pm$ 2.30 (115)
Minimal lumen area, segment, mm ²		1.94 $\pm$ 0.94 (122)
Post-procedural OCT measurement (core lab assessment)		
Proximal MLA, mm ²		8.21 $\pm$ 2.47 (121)
In-device MLA, mm ²		8.18 $\pm$ 1.85 (127)
Distal MLA, mm ²		6.54 $\pm$ 2.21 (123)
In-device minimal lumen area, mm ²		6.86 $\pm$ 1.77 (127)
Acute disruption, %		1.59% (2/126)
% Lesions with ISA (N)		56.7% (72/127)
% Struts with ISA (N)		1.89 $\pm$ 3.63 (127)
Maximal distance of malapposed strut, mm		0.33 $\pm$ 0.12 (72)

Continuous data are shown as mean $\pm$ SD. Binary variables are shown as % (n/N). %DS, percent diameter stenosis; ISA, incomplete scaffold apposition; MLA, mean lumen area; MLD, minimal lumen distance; OCT, optical coherence tomography; QCA, quantitative coronary angiography; RVD, reference vessel diameter.

Table 4. Antiplatelet Therapy

	Post-procedure (N=135)	3 months (N=135)	1 year (N=135)
DAPT	96.3% (130/135)	94.8% (128/135)	93.3% (126/135)
Aspirin	96.3% (130/135)	96.3% (130/135)	94.8% (128/135)
ADP receptor antagonist	100.0% (135/135)	98.5% (133/135)	97.8% (132/135)
- Prasugrel	78.5% (106/135)	76.3% (103/135)	72.6% (98/135)
- Clopidogrel	17.8% (24/135)	18.5% (25/135)	21.5% (29/135)
- Ticagrelor	0.7% (1/135)	0.7% (1/135)	0.7% (1/135)
- Ticlopidine	3.7% (5/135)	3.0% (4/135)	3.0% (4/135)

Binary variables are shown as % (n/N). ADP, adenosine diphosphate; DAPT, dual antiplatelet therapy.

Table 5. ST per Academic Research Consortium Definition

Item	GT1 PMS (N=135)
Acute/subacute ST (0–30 days)	
Definite/Probable	0.0% (0/135)
Overall ST (0–90 days)	
Definite/probable	0.0% (0/135)
Late ST (31–365 days)	
Definite/probable	0.0% (0/135)
Cumulative ST (0–365 days)	
Definite/probable	0.0% (0/135)

Binary variables are shown as % (n/N). ST, scaffold thrombosis.

done in all lesions. Noncompliant balloon or cutting/scoring balloon was used in 41.7% and 34.5% of lesions, respectively. Post-dilatation was done in 98.5% of target lesions and the mean post-dilatation pressure was 18.8 atm. All patients successfully received an Absorb GT1.

Post-procedural QCA and OCT results are shown in **Table 3**. OCT was used for post-procedural intravascular assessment in 127 of 139 (91.4%) target lesions (Illumien OCT imaging system was used in 123 [96.9%] lesions). Angiographic acute gain was 1.29 mm in-segment and 1.48 mm in-device. Minimal lumen area by OCT improved from 1.94 mm² preprocedure to 6.86 mm² post-procedure. Percentages of strut and lesions with ISA were 1.89% and 56.7%, respectively. Calcification was identified in 45 (36.9%) lesions. There was no significant difference in the frequency of predilatation using cutting/scoring balloon between the groups of calcified and noncalcified lesions (31.9% vs. 40.0%, $P=0.368$). On the other hand, the balloon/QCA-RVD ratio tended to be greater in the group with calcified lesions (1.12 ± 0.13 vs. 1.07 ± 0.17 , $P=0.087$). There was no significant difference in the percentage of lesions with ISA (64.6% vs. 50%, $P=0.1385$) nor of the percentage of struts with ISA (2.55 ± 4.73 vs. 1.56 ± 2.83 , $P=0.200$) between the groups of calcified and noncalcified lesions.

All patients received ADP receptor antagonist at hospital discharge, and 97.8% patients continued therapy through 1 year. Approximately three-quarters of the patients received prasugrel as the ADP receptor antagonist (**Table 4**).

No definite/probable ST was reported at 1-year follow-up (**Table 5**). In addition, no cardiac deaths, MIs, or ID-TLR were reported up to 1 year. TLR was performed immediately after the index procedure in 1 patient during the same hospital stay; it was a non-ischemia-driven TLR event (**Table 6**). In that patient, an additional stent was implanted at the proximal edge of the implanted Absorb GT1 to achieve complete strut apposition based on post-procedural image review after the patient had left the cathlab. Core laboratory assessment revealed 10% ISA but the maximum distance was $<400\mu\text{m}$ ($330\mu\text{m}$) in this patient. The 2 patients with post-procedural strut disruption did not show any 1-year clinical events.

Discussion

The main findings from the Absorb GT1 PMS study were: (1) lesion success rate was 100%, (2) struts with ISA were rare, (3) pre- and post-dilatations were performed more proactively, and (4) no cases of ST (primary endpoint), death, or MI occurred.

Table 6. Clinical Results

1 month (30 days)*	
DMR	0.7% (1/135)
TVF	0.0% (0/135)
MACE	0.0% (0/135)
TLF	0.0% (0/135)
Cardiac death/all MI	0.0% (0/135)
TLR	0.7% (1/135)
- ID-TLR	0.0% (0/135)
TVR	0.7% (1/135)
- ID- TVR	0.0% (0/135)
All revascularization	0.7% (1/135)
3 months (90 days)*	
DMR	0.7% (1/135)
TVF	0.0% (0/135)
MACE	0.0% (0/135)
TLF	0.0% (0/135)
Cardiac death/all MI	0.0% (0/135)
TLR	0.7% (1/135)
- ID-TLR	0.0% (0/135)
TVR	0.7% (1/135)
- ID- TVR	0.0% (0/135)
All revascularization	0.7% (1/135)
1 year (365 days)*	
DMR	2.2% (3/135)
TVF	0.0% (0/135)
MACE	0.0% (0/135)
TLF	0.0% (0/135)
Cardiac death/all MI	0.0% (0/135)
TLR	0.7% (1/135)
- ID-TLR	0.0% (0/135)
TVR	0.7% (1/135)
- ID- TVR	0.0% (0/135)
All revascularization	2.2% (3/135)

Binary variables are shown as % (n/N). DMR=all deaths, all MI, all revascularization. ID, ischemia-driven; MACE, major adverse cardiac events; MI, myocardial infarction; TLF, target lesion failure; TLR, target lesion revascularization; TVF, target vessel failure; TVR, target vessel revascularization.

To the best of our knowledge, this is the first study to report no 1-year ST events among all other multicenter Absorb BVS studies that have enrolled more than 100 patients and used OCT guidance. We speculate that this favorable result was because: (1) adequate predilatation was performed, which is supported by the fact that a cutting/scoring balloon (34.5%) or a noncompliant (41.7%) balloon was used frequently; (2) appropriate sizing was determined by intracoronary imaging guidance; and (3) sufficient post-dilatation was performed in 99% of target lesions with a high mean pressure of 18.8 atm. Compared with the present Absorb GT1 PMS study, the ABSORB Japan RCT³ had the following PCI-procedural concerns that may have contributed to ST events: (1) adequate predilatation was still underappreciated, because the cutting/scoring balloon was used only in 19.5% of lesions; (2) IVUS/OCT was used in only approximately 70% of the patients per the protocol; and (3) post-dilatation was performed in only 82% of target lesions, using a lower mean pressure of 15.5 atm. As a result, the OCT data

showed a considerably lower proportion of struts with ISA (1.89% vs. 4.83%) and lesions with ISA (56.7% vs. 82.2%) in the Absorb GT1 PMS study. Based on previous investigations suggesting that a suboptimal implantation technique may lead to increased event risk, especially ST, a European expert consensus has proposed a BVS-specific implantation protocol,¹⁵ emphasizing the importance of PSP. The value of PSP-based procedures in BVS implantation was shown in a previous investigation,¹³ although intravascular imaging evaluation of ISA was not performed. In comparison with the ABSORB Japan RCT, the present PMS data showed a lower incidence of ISA as observed by OCT. Indeed, the risk of ST was shown to be dramatically diminished by using high-pressure dilatation under IVUS guidance in the early days of the bare metal stents era.¹⁶

In this Absorb GT1 PMS study, 97.8% of patients received an ADP receptor antagonist. We speculate that strict continuation of DAPT contributed to reducing ST after Absorb GT1 implantation.

We suspect that intracoronary imaging guidance, procedural improvements, and strict DAPT continuation reduced the risk of ST in patients following Absorb GT1 implantation. The encouraging 1-year outcomes of the present study raise hope for the development of a next-generation BVS that can overcome the innate drawbacks of metallic stents.

Study Limitations

Limitations included the possibility of type 2 error because of the limited sample size and the paucity of the data in relation to complex lesions.

Conclusions

Appropriate OCT-guided balloon dilatation and BVS sizing may prevent ISA, thereby reducing the risk of TLF and ST.

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