Long-Term Outcomes of Absorb Bioresorbable Vascular Scaffold vs. Everolimus-Eluting Metallic Stent
— A Randomized Comparison Through 5 Years in Japan —

Ken Kozuma, MD, PhD; Kengo Tanabe, MD, PhD; Yuji Hamazaki, MD, PhD; Takayuki Okamura, MD, PhD; Jiro Ando, MD; Yuji Ikari, MD, PhD; Yoshihisa Nakagawa, MD, PhD; Hajime Kusano, PhD; Divine Ediebah; Takeshi Kimura, MD, PhD on behalf of the ABSORB Japan Investigators

Background: Bioresorbable vascular scaffolds (BVS) are promising alternatives to metallic drug-eluting stents (DES) in percutaneous coronary interventions. Absorb BVS was comparable to XIENCE (DES) for patient- and device-oriented composite endpoints through 1 year post-procedure. Mid-term results showed increased rates of device-oriented events with Absorb. The objective of this study was to evaluate the long-term safety and effectiveness of Absorb BVS compared with XIENCE metallic DES when implanted in patients in Japan with de novo coronary artery lesions.

Methods and Results: ABSORB Japan randomized 400 patients into either Absorb (n=266) or XIENCE (n=134) treatment arm. Through 5-year follow-up, the composite endpoints of DMR (death, myocardial infarction [MI], and all revascularization), target vessel failure (TVF), major adverse cardiac events (MACE), target lesion failure (TLF), and cardiac death/all MI were evaluated. Individual endpoints included death, MI, coronary revascularization, and scaffold/stent thrombosis. There were no significant differences in the composite or individual endpoint outcomes between the Absorb and XIENCE arms through 5 years or between 3 and 5 years. Numerically lower TVF, MACE, and all MI rates were observed for the Absorb vs. XIENCE arm after 3 years. No scaffold/stent thrombosis was reported beyond 3 years. Post-procedure imaging subgroups showed comparable event rates.

Conclusions: Following resorption of the scaffold, between 3 and 5 years post-procedure, the Absorb BVS performed comparably to XIENCE in all patient- and device-oriented endpoints (ClinicalTrials.gov, #NCT01844284).

Key Words: Bioresorbable scaffolds; Coronary stents; Restenosis; Thrombosis
and were likely related to scaffold sizing and suboptimal implantation technique. Currently, there is a lack of adequate evidence from RCTs to support the safety and performance of BVS vs. metallic stent beyond 3 years, and post-resorption of scaffold.

Herein, we report the 5-year follow-up results from the ABSORB Japan RCT to evaluate the long-term clinical outcomes of Absorb BVS in comparison with CoCr-EES following implantation in patients with ischemic heart disease (IHD).

**Methods**

**Study Design and Population**

ABSORB Japan was a prospective, multicenter, randomized, single-blind, active-controlled study with 400 patients randomized in a 2:1 ratio to treatment with BVS (Abbott Vascular, Santa Clara, CA, USA; n=266) or XIENCE (CoCr-EES, XIENCE PRIME/Xpedition; Abbott Vascular; n=134).

The purpose of the study was to evaluate the safety and effectiveness of the Absorb BVS in the treatment of patients with IHD caused by de novo native coronary artery lesions in comparison with XIENCE, an approved commercial metallic DES for clinical use in Japan.

This study was conducted in compliance with the ethical principles of the Declaration of Helsinki. The Absorb BVS was approved by the Ministry of Health, Labor and Welfare (MHLW) in Japan on November 2, 2016 and was also registered in ClinicalTrials.gov, #NCT01844284. Accordingly, on November 9, 2016, ABSORB Japan was reclassified as a post-marketing clinical trial after marketing approval. The study was then conducted per the standards for post-marketing surveillance and studies as required by the MHLW.
5-Year Results of ABSORB Japan

5-Year Results of ABSORB Japan

of all-cause death, MI, TLR/TVR, and ST. If ST was suspected, an angiographic core laboratory assessed the presence of thrombus. An independent safety oversight committee (The Baim Institute for Clinical Research) was blinded to periodically review the safety data throughout the study.

Statistical Analysis

The clinical endpoint rates were evaluated in the intent-to-treat (ITT) population through 1,853 days to include events occurring through the end of the 5-year (+28 days) follow-up window. Binary variables were calculated as counts, percentages, and 95% confidence intervals. Pearson’s chi-squared test or Fisher’s exact test was used when appropriate. Continuous variables were summarized as mean ± standard deviation or as median and interquartile range, wherever appropriate. Kaplan-Meier survival curves were constructed for time-to-event variables and were compared by the log-rank test. Statistical analyses were performed using SAS versions 9.2 and 9.3 (SAS Institute, Inc., Cary, NC, USA).

Role of Funding Source

The sponsor was involved in study design, data collection, data analysis, data interpretation and writing of this report. The corresponding author had full access to the analyzed data in the study and accepts full responsibility for the integrity of the study and the decision to submit for publication.

Results

Patient Disposition

The disposition of 400 randomized patients through the 5-year follow-up of the ITT population is shown in Figure 1.

Table 1. Patient Demographics and Baseline Risk Factors of the ABSORB Japan ITT Population

|                        | ABSORB (n=266) | XIENCE (n=134) |
|------------------------|----------------|----------------|
| Age, a years           | 67.1±9.4 (266) | 67.3±9.6 (134) |
| Male                   | 78.9% (210/266) | 73.9% (99/134) |
| Body mass index, a kg/m²| 24.01±3.03 (260) | 24.27±2.96 (130) |
| Current tobacco use    | 19.9% (53/266) | 21.6% (29/134) |
| Hypertension           | 78.2% (208/266) | 79.9% (107/134) |
| Requiring medication   | 72.2% (192/266) | 73.1% (98/134) |
| Dyslipidemia           | 82.0% (218/266) | 82.1% (110/134) |
| Diabetes mellitus      | 36.1% (96/266) | 35.8% (48/134) |
| Requiring medication   | 31.2% (83/266) | 29.9% (40/134) |
| On insulin             | 9.0% (24/266) | 8.2% (11/134) |
| HbA1c, a %             | 6.23±1.06 (265) | 6.15±0.78 (133) |
| Prior coronary interventions | 36.1% (96/266) | 38.1% (51/134) |
| On target vessel       | 3.4% (9/266) | 5.2% (7/134) |
| Prior MI               | 16.0% (42/262) | 23.9% (32/134) |
| Family history of premature CAD | 6.5% (16/246) | 8.1% (10/124) |
| Current evidence of ischemia | Stable angina | 63.9% (170/266) | 65.7% (88/134) |
|                       | Unstable angina | 9.8% (26/266) | 16.4% (22/134) |
|                       | Silent ischemia  | 26.3% (70/266) | 17.9% (24/134) |

*aMean±SD. CAD, coronary artery disease; HbA1c, hemoglobin A1c; MI, myocardial infarction; N, total number of subjects.
Table 2. Clinical Outcomes in ABSORB Japan Through 5 Years (ITT Population)

| % (n/N)            | ABSORB (n=266) | XIENCE (n=134) | P value |
|--------------------|----------------|----------------|---------|
|                    | 3–5 years      |                |         |
| Composite endpoints |                |                |         |
| DMR                | 8.7% (21/242)  | 8.9% (11/124)  | 0.95a   |
| TVF                | 3.7% (9/242)   | 4.8% (6/124)   | 0.61a   |
| MACE               | 2.5% (6/242)   | 3.2% (4/124)   | 0.74a   |
| TLF                | 2.5% (6/242)   | 2.4% (3/124)   | 1.00a   |
| Cardiac death/All MI | 1.2% (3/242)  | 3.2% (4/124)   | 0.23a   |
| All-cause death/All MI | 3.3% (8/242)  | 4.0% (5/124)   | 0.77a   |
| Individual endpoints |                |                |         |
| All-cause death    | 3.3% (8/242)   | 1.6% (2/124)   | 0.50a   |
| Cardiac death      | 0.8% (2/242)   | 0.8% (1/124)   | 1.00a   |
| All MI             | 1.2% (3/242)   | 2.4% (3/124)   | 0.41a   |
| TV-MI              | 1.2% (3/242)   | 1.6% (2/124)   | 1.00a   |
| QMI                | 0.8% (2/242)   | 0.0% (0/124)   | 0.55a   |
| NOMI               | 0.8% (2/242)   | 1.6% (2/124)   | 0.61a   |
| All revascularization | 6.2% (15/242) | 6.5% (8/124)   | 0.92a   |
| All TVR            | 4.1% (10/242)  | 4.0% (5/124)   | 0.96a   |
| ID-TVR             | 3.3% (8/242)   | 3.2% (4/124)   | 1.00a   |
| All TLR            | 2.5% (6/242)   | 1.6% (2/124)   | 0.72a   |
| ID-TLR             | 1.7% (4/242)   | 0.8% (1/124)   | 0.67a   |
| Scaffold/stent thrombosis | 0.0% (0/234) | 0.0% (0/122)   | 1.00a   |
| Definite           | 0.0% (0/234)   | 0.0% (0/122)   | 1.00a   |
| Probable           | 0.0% (0/234)   | 0.0% (0/122)   | 1.00a   |
| Cumulative events at 5 years |        |                |         |
| Composite endpoints |                |                |         |
| DMR                | 29.1% (74/254) | 26.8% (34/127) | 0.63a   |
| TVF                | 16.1% (41/254) | 13.4% (17/127) | 0.48a   |
| MACE               | 11.8% (30/254) | 8.7% (11/127)  | 0.35a   |
| TLF                | 11.0% (28/254) | 7.9% (10/127)  | 0.33a   |
| Cardiac death/All MI | 7.9% (20/254) | 6.3% (8/127)   | 0.58a   |
| All-cause death/All MI | 11.8% (30/254) | 7.9% (10/127) | 0.24a   |
| Individual endpoints |                |                |         |
| All-cause death    | 5.9% (15/254)  | 3.1% (4/127)   | 0.24a   |
| Cardiac death      | 1.2% (3/254)   | 0.8% (1/127)   | 1.00a   |
| All MI             | 7.5% (19/254)  | 5.5% (7/127)   | 0.47a   |
| TV-MI              | 6.7% (17/254)  | 4.7% (6/127)   | 0.45a   |
| QMI                | 3.1% (8/254)   | 0.0% (0/127)   | 0.06a   |
| NOMI               | 3.9% (10/254)  | 4.7% (6/127)   | 0.72a   |
| All revascularization | 24.4% (62/254) | 22.8% (29/127) | 0.73a   |
| All TVR            | 15.0% (38/254) | 13.4% (17/127) | 0.68a   |
| ID-TVR             | 13.4% (34/254) | 10.2% (13/127) | 0.38a   |
| All TLR            | 10.2% (26/254) | 8.7% (11/127)  | 0.62a   |
| ID-TLR             | 8.3% (21/254)  | 4.7% (6/127)   | 0.20a   |
| Scaffold/stent thrombosis | 3.8% (9/237) | 1.6% (2/123)   | 0.34a   |
| Definite           | 3.8% (9/237)   | 0.8% (1/123)   | 0.17a   |
| Probable           | 0.0% (0/237)   | 0.8% (1/123)   | 0.34a   |

*Chi-square test. aFisher’s exact test when Cochran’s rule not met. bFisher’s exact test. All P-values are two-tailed and not from prespecified hypothesis testing. Patients only counted once for each type of event in each time period. Revascularization includes TLR, TVR excluding TLR, and non-TVR. Denominators exclude patients who were truly lost to follow-up, defined as patients who were terminated through a given timepoint without any DMR event. Denominators used in the calculations of stent/scaffold thrombosis event rates were based on the analysis population and excluded patients who were lost to follow-up through 5 years without and stent/thrombosis event. DMR, composite endpoint of death, MI and revascularization; ID, ischemia driven; MI, myocardial infarction; NOMI, non-Q-wave MI; QMI, Q-wave MI; TLR, target lesion failure; TV, target vessel; TVR, target vessel revascularization.
5-Year Results of ABSORB Japan

The ITT population included all subjects registered, regardless of whether they received the investigational device or not and included the baseline analysis. There were 12 patients in the Absorb arm, and 7 patients in the XIENCE arm who were lost to follow-up without DMR events, so they were excluded from the 5-year analysis.

Patient Demographics and Baseline Risk Factors
The patients' mean age was approximately 67 years, 88% had stable coronary artery disease, and approximately 36% were diabetic. No significant differences were found in patient demographics or baseline risk factors between the study arms (Table 1). Procedural results are described in Kimura et al.16

Antiplatelet Medication Usage Through 5 Years
Patients were required to take continuous dual antiplatelet therapy (DAPT) of thienopyridine (clopidogrel, ticlopidine, or prasugrel) and aspirin for at least 12 months post-procedure. At the initiation of the study, the majority (>93%) of the patients were taking DAPT. At 3-year follow-up, less than half (Absorb 106/265; XIENCE 50/134) of the patients remained on DAPT. Through 5 years, DAPT was continued in slightly over one-quarter of all patients (Absorb 79/265; XIENCE 36/134). Over 80% of patients were taking aspirin at 3 years (Absorb 237/266; XIENCE 116/134) and 5 years (Absorb 225/266; XIENCE 110/134) post-procedure.

Clinical Outcomes Through 5 Years
Summaries of all composite and component endpoints through 5 years, and between 3 and 5 years are provided in Table 2. No significant differences in event rates were detected between the Absorb and XIENCE arms between 0 and 5 years or 3 and 5 years. The cumulative 5-year rates for DMR, TVF, and TLF were numerically higher in the Absorb arm, but no significant differences were detected.

Figure 2. Kaplan-Meier curves for the estimated cumulative incidence rates of (A) TLF, (B) scaffold/stent thrombosis, and (C) ID-TLR (per ARC definition) through 5 years (per ABSORB III protocol MI definition) with landmark analysis at 3 years. ARC, Academic Research Consortium; HR, hazard ratio; ID-TLR, Ischemia driven-target lesion revascularization; TLF, target lesion failure.
Absorb arm compared with the XIENCE arm, due to a higher number of events through the first 2 years.\(^7\) After 3 years, the event rates were similar between arms, with a slight trend for numerically lower rates of TVF, MACE, all MI in the Absorb arm compared with the XIENCE arm. The Kaplan-Meier estimates for TLF, ST, and ID-TLR are shown in Figure 2A–C. Landmark analysis at 1 year is demonstrated in Figure 3A–C. The majority of differences in clinical events were observed between 1 and 2 years.

### Individual Endpoints

At 5 years, the outcome rates for all-cause death, cardiac death, all MI, TV-MI, all revascularization, all TVR, all TLR, and scaffold/ST were similar in the Absorb and XIENCE arms (Table 2). Individual endpoint results between 3 and 5 years are described next.

Between 3 and 5 years, 8 deaths occurred in the Absorb arm: 6 noncardiac, and 2 cardiac. All deaths in the Absorb arm were deemed not related to the device by the investigator. In the same period, 2 deaths occurred in the XIENCE arm: 1 cardiac and 1 noncardiovascular. The cardiac death was deemed to be possibly related to the device by the investigator.

Beyond 3 years, there was no difference in all MI events between the Absorb and XIENCE arms. All MI events between 3 and 5 years happened in the target vessel (Table 2).

Numerically, there were more all TVR than all TLR cases, and most of the revascularizations were ischemia driven (ID). No significant difference in the incidence of all TVR, ID-TVR, all TLR, or ID-TLR was observed between the arms.

There were no incidences of definite/probable scaffold/ST in either arm beyond 3 years to 5-year follow-up. There were no unanticipated adverse device effects in this study. Moreover, there were no new safety signals reported between 3 and 5 years.
Figure 4. Kaplan-Meier curves for the imaging cohorts representing estimated cumulative incidence rates of (A) TLF, (B) scaffold/stent thrombosis, and (C) ID-TLR (per ARC definition) through 5 years (per ABSORB III protocol MI definition). IVUS, Intravascular ultrasound; OCT, optical coherence tomography. Other abbreviations as in Figure 2.
Event Rates by Imaging Subgroups

At the beginning of the study, patients were subrandomized into 1 of 3 intravascular imaging subgroups: OCT-1 group underwent optical coherence tomography (OCT) follow-up of the target lesion post-implantation, and at 2 and 3 years; OCT-2 group underwent OCT follow-up at 3 years; and the IVUS group underwent intravascular ultrasound (IVUS) follow-up post-implantation and at 3 years. The OCT-1 and -2 groups had 125 patients each (Absorb, n=83; XIENCE, n=42). The IVUS group comprised 150 patients, with 100 patients receiving the Absorb BVS and 50 patients receiving the XIENCE DES.

Kaplan-Meier estimated cumulative incidence rates through 5 years by imaging subgroup are presented in Figure 4A–C. There were no significant differences in TLF, scaffold/ST, and ID-TLR between the imaging subgroups through 5 years. However, a trend for slightly lower TLF and ID-TLR rates in the IVUS group, and higher scaffold/ST rates in the OCT-2 group was detected as compared with the respective other subgroups.

Discussion

This study demonstrated 5-year clinical outcomes of Absorb BVS as compared with XIENCE stents in a randomized fashion. The rates for all-cause death, cardiac death, all MI, TV-MI, all revascularization, all TVR, all LDL, and scaffold/ST were similar in the Absorb and XIENCE arms at 5 years. No scaffold thrombosis occurred after 3 years in the Absorb BVS arm. There seems to be no signal of an excess of adverse events for BVS over CoCr-EES between 3 and 5 years, although this study was not powered for this clinical endpoint. This study also demonstrated for the first time comparisons of clinical outcomes among no peri-procedural imaging, IVUS-guidance and OCT-guidance groups. A trend for slightly lower TLF and ID-TLR rates in the IVUS group, and higher scaffold/ST rates in the no imaging group was observed.

Although the primary endpoint at 1 year was met and approved in Japan in 2016, the Absorb BVS has already left the market because increases in scaffold thrombosis and TLR were demonstrated up to 3 years in many studies. Recently, 3-year imaging follow-up data of the current study were published.\textsuperscript{49} Longer-term data have been awaited to prove the benefit of the concept “leave nothing behind”. In this study, rates of target vessel MI and TVR in the Absorb group were identical to those in the XIENCE arm between 3 and 5 years. 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 be stabilized pathologically. Metallic stents, either bare metal or drug-eluting, have been proven in pathologic investigations to induce neatherosclerosis at treated segments, which may increase late adverse events.\textsuperscript{20} Long-term follow-up data after 2nd-generation DES showed approximately 2% increase annually in TLF.\textsuperscript{21} Therefore, considerable numbers of adverse events will be anticipated for young patients with long life expectancy, and a completely bioresorbable scaffold may be the solution for this issue. The signal to be equivalent of adverse events in BVS over CoCr-EES seems promising for BVS to return to the field of PCI. However, improvement of the resorption profile and embedding in the vessel wall would be required for bioresorbable scaffolds to be involved in routine clinical practice. In fact, improved new scaffolds with thinner strut and equivalent mechanical integrity have been developed and are ready for clinical trials. Application for the superficial femoral artery is firstly going to be tested in a clinical trial.

Bioresorbable scaffolds are expected to recover physiological function after complete resorption. Recovery of vessel vasomotion was not shown at 3 years in the ABSORB II trial.\textsuperscript{22} It is reported that the vasomotor response to nitroglycerin after ABSORB implantation tended to increase between 2 and 5 years.\textsuperscript{23} The timing of the present study may be the proper moment to start demonstrating the benefit of BVS. It is regrettable that a vasomotion test at 5 years was not planned by the protocol. Posthoc investigation for vasomotor response may be endorsed in the future.

In this study, patients were subrandomized into 1 of 3 intravascular imaging subgroups at the time of enrollment. There were no significant differences in TLF, scaffold/ST, and ID-TLR between the imaging subgroups through 5 years due to insufficient numbers of subjects. Operators were not able to use any imaging devices for Absorb BVS implantation when assigned to the OCT-2 group. Although adequate technique (i.e., FSP [preparation, sizing, post-dilatation]) was not recommended during the enrollment period, the imaging arms (IVUS arm and OCT-1 group) tended to show better outcomes than the non-imaging arm. Because the scaffold was not visible by fluoroscopy, confirmation of apposition of struts was not possible with angiography. Incomplete apposition is a major cause of very late scaffold thrombosis.\textsuperscript{24} In this regard, imaging-guided PCI would be helpful to improve BVS outcomes. In Japan, in more than 80% of cases, imaging is performed with IVUS or OCT. Outcomes for the Absorb BVS may be improved when the revised BVS comes onto the market, because appropriate techniques guided by imaging devices have been evolved. In fact, no scaffold thrombosis in 135 patients was reported from a post-marketing study, in which patients underwent BVS implantation with OCT guidance.\textsuperscript{25}

Study Limitations

ABSORB Japan was a modestly-sized trial and not powered for longer-term clinical endpoints. Results from meta-analysis of 4 randomized studies may be better to understand long-term safety.\textsuperscript{26} Scheduled angiographic follow-up (13 months, 2 years, 3 years) may have affected the ID-TLR rate (oculostenotic reflex). ABSORB Japan was initiated in 2013 (i.e., before the adoption of optimal techniques based on peer-to-peer experience). Although post-dilatation was performed in ~80% of cases, the mean pressure applied was relatively low at 15.5 atm.

Conclusions

Neither very late ST nor scaffold thrombosis was observed in either arm of ABSORB Japan and TLF were low and comparable after 3 years, suggesting complete absorption and long-term safety of BVS.

Acknowledgments

We wish to acknowledge all investigators who participated in the ABSORB Japan Trial, and Ananya De of Criterion Edge for writing assistance.

Data Availability

The deidentified participant data will not be shared.
Funding
Abbott Vascular provided funding for this study.

IRB Information
This was an approval study reviewed by Ministry of Health, Labor and Welfare (MHLW) Reference no. Chiken number 12-301.

Disclosures
K.K., K.T., and T.K. were advisory board members of Abbott Vascular Japan. T.K. received research grant from Abbott Vascular Japan. H.K. and D.E. are full-time employees of Abbott Vascular. Others have nothing to disclose. Y.I. and T.K. are members of Circulation Journal Editorial Team.

References
1. Räber L, Magro M, Stefanini GG, Kalesan B, van Domburg RT, Onuma Y, et al. Very late coronary stent thrombosis of a newer-generation everolimus-eluting stent compared with early-generation drug-eluting stents: A prospective cohort study. Circulation 2012; 125: 1110–1121.
2. Nakazawa G, Otsuka F, Nakano M, Vorpahl M, Yazdni SK, Ladich E, et al. The pathology of neothrombosis in human coronary implants bare-metal and drug-eluting stents. J Am Coll Cardiol 2011; 57: 1314–1322.
3. Brugalla S, Gogas BD, Garcia-Garcia HM, Farooq V, Girasis C, Heo JH, et al. Vascular compliance changes of the coronary vessel wall after biodegradable vascular scaffold implantation in the treated and adjacent segments. Circ J 2012; 76: 1616–1623.
4. Lane JP, Perkins LE, Sheehy AJ, Pacheco EJ, Frie MP, Lambert BJ, et al. Lumens gain and restoration of pulsatility after implantation of a biodegradable vascular scaffold in porcine coronary arteries. JACC Cardiovasc Interv 2014; 7: 688–695.
5. Serruys PW, Onuma Y, Garcia-Garcia HM, Muramatsu T, van Geuns RJ, de Bruyne B, et al. Dynamics of vessel wall changes following the implantation of the absorb everolimus-eluting biodegradable vascular scaffold: A multi-imaging modality study at 6, 12, 24 and 36 months. EuroIntervention 2014; 9: 1271–1284.
6. Onuma Y, Serruys PW, Perkins LE, Okamura T, Gonzalo N, Garcia-Garcia HM, et al. Intracoronary optical coherence tomography and histology at 1 month and 2, 3, and 4 years after implantation of everolimus-eluting biodegradable vascular scaffolds in a porcine coronary artery model: An attempt to decipher the human optical coherence tomography images in the absorb everolimus-eluting bioresorbable vascular scaffold. Circulation 2016; 133: 2300–2309.
7. Onuma Y, Dudek D, Thuesen L, Webster M, Nieman K, Garcia-Garcia HM, et al. Five-year clinical and functional multislice computed tomography angiographic results after coronary implantation of the fully resorbable polyeurethane everolimus-eluting scaffold in patients with de novo coronary artery disease: The ABSORB cohort A trial. JACC Cardiovasc Interv 2013; 6: 999–1009.
8. Simsek C, Karanasos A, Magro M, Garcia-Garcia HM, Onuma Y, Regar E, et al. Long-term invasive follow-up of the everolimus-eluting biodegradable vascular scaffold: Five-year results of multiple invasive imaging modalities. EuroIntervention 2016; 11: 996–1003.
9. Stone GW, Gao R, Kimura T, Kereiakes DJ, Ellis SG, Onuma Y, et al. 1-year outcomes with the Absorb biodegradable scaffold in patients with coronary artery disease: A patient-level, pooled meta-analysis. Lancet 2016; 387: 1277–1289.
10. Ali ZA, Serruys PW, Kimura T, Gao R, Ellis SG, Kereiakes DJ, et al. 2-year outcomes with the Absorb biodegradable scaffold for treatment of coronary artery disease: A systematic review and meta-analysis of seven randomised trials with an individual patient data study. Lancet 2017; 390: 760–772.
11. Cassese S, Byrne RA, Jüni P, Wyckeryowska JJ, Puricel S, Ndrepepa G, et al. Mid-term clinical outcomes with everolimus-eluting biodegradable scaffolds versus everolimus-eluting metallic stents for percutaneous coronary interventions: A meta-analysis of randomised trials. EuroIntervention 2018; 13: 1565–1573.
12. Ali ZA, Gao R, Kimura T, Onuma Y, Kereiakes DJ, Ellis SG, et al. Three-year outcomes with the absorb biodegradable scaffold: Individual-patient-data meta-analysis from the ABSORB randomized trials. Circulation 2018; 137: 464–479.
13. Felix CM, van den Berg VJ, Hoeks SE, Fam JM, Lenzen M, Boerma E, et al. Mid-term outcomes of the Absorb BVS versus second-generation DES: A systematic review and meta-analysis. PLoS One 2013; 10: e0197119.
14. Ellis SG, Gori T, Serruys PW, Neff H, Steffenino G, Brugaletta S, et al. Clinical, angiographic, and procedural correlates of very late absorb scaffold thrombosis: Multistudy registry results. JACC Cardiovasc Interv 2011; 4: 638–644.
15. Chevalier B, Cequier A, Dudek D, Haude M, Carrie D, Sabaté M, et al. Four-year follow-up of the randomised comparison between an everolimus-eluting bioresorbable scaffold and an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II Trial). EuroIntervention 2018; 13: 1561–1564.
16. Kimura T, Kozuma K, Tanabe K, Nakamura S, Yamane M, Muramatsu T, et al. ABSORB Japan. A randomized trial evaluating everolimus-eluting Absorb biodegradable scaffolds versus everolimus-eluting metallic stents in patients with coronary artery disease: ABSORB Japan. Eur Heart J 2015; 36: 3332–3342.
17. Cutlip DE, Windecker S, Mehran R, Boam A, Cohen DJ, van Es GA, et al. Academic Research Consortium. Clinical end points in coronary stent trials: A case for standardized definitions. Circulation 2007; 115: 2344–2351.
18. Onuma Y, Sotomi Y, Shiomi H, Ozaki Y, Namiki A, Yasuda S, et al. Two-year clinical, angiographic, and serial optical coherence tomographic follow-up after implantation of an everolimus-eluting bioresorbable scaffold and an everolimus-eluting metallic stent: Insights from the randomised ABSORB Japan trial. EuroIntervention 2016; 12: 1090–1101.
19. Onuma Y, Honda Y, Asano T, Shiomi H, Kozuma K, Ozaki Y, et al. Randomized comparison between everolimus-eluting biodegradable scaffold and metallic stent: Multimodality imaging through 3 years. JACC Cardiovasc Interv 2020; 13: 116–127.
20. Otsuka F, Vorpahl M, Nakano M, Foorst J, Newell JB, Sakakura K, et al. Pathology of second-generation everolimus-eluting stents versus first-generation sirolimus- and paclitaxel-eluting stents in humans. Circulation 2014; 129: 211–223.
21. Gada H, Kirtane AJ, Newman W, Sanz M, Hermiller JB, Mahaffey KW, et al. 5-year results of a randomized comparison of XIENCE V everolimus-eluting and TAXUS paclitaxel-eluting stents: Final results from the SPIRIT III trial. JACC Cardiovasc Interv 2013; 6: 1263–1273.
22. Serruys PW, Chevalier B, Sotomi Y, Cequier A, Carrie D, Pieck JJ, et al. Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II): A 3 year, randomised, controlled, single-blind, multicentre clinical trial. Lancet 2016; 388: 2479–2491.
23. Dudek D, Rzeszutko L, Onuma Y, Sotomi Y, Depukat R, Veldhof S, et al. Vasomotor response to nitroglycerin over 5 years follow-up after everolimus-eluting bioresorbable scaffold implantation. JACC Cardiovasc Interv 2017; 10: 786–795.
24. Karanasos A, Van Mieghem N, van Ditzhuijzen N, Felix C, Daemen J, Autter A, et al. Angiographic and optical coherence tomography insights into bioresorbable scaffold thrombosis: Single-center experience. Circ Cardiovasc Interv, doi:10.1161/CIRCINTERVENTIONS.114.002369.
25. Suzuki N, Kozuma K, Nakamura S, Amaebi K, Saioto S, Shibata Y, et al. Absorb GT1 bioresorbable vascular scaffold system: 1-year post-marketing surveillance in Japan. Circ J 2019; 83: 2460–2465.
26. Stone GW, Kimura T, Gao R, Kereiakes DJ, Ellis SG, Onuma Y, et al. Time-varying outcomes with the absorb biodegradable vascular scaffold during 5-year follow-up: A systematic meta-analysis and individual patient data pooled study. JAMA Cardiol, doi:10.1001/jamacardio.2019.4101.