Three-Year Clinical Outcomes of Patients Treated with Everolimus-Eluting Bioresorbable Vascular Scaffolds: Final Results of the ABSORB EXTEND Trial

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Short title: Final results of the ABSORB Extend trial

Conflict of interest: Marianne Stuteville, Divine Ediebah and Krishnankutty Sudhir are full time employees at Abbott Vascular

Total number of words: 3234 (including references and figure legends)

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: [10.1002/ccd.27715](https://doi.org/10.1002/ccd.27715)

ABSTRACT

Background: There is still limited data on the very long term clinical outcomes after ABSORB BRS in daily practice. We sought to evaluate the 3 year-performance of the Absorb BVS for the treatment of low/moderate complexity patients enrolled in the ABSORB EXTEND trial.

Methods: ABSORB EXTEND is a prospective, single-arm, open-label clinical study in which 812 patients were enrolled at 56 sites. This study allowed the treatment of lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.8 mm (as assessed by on-line QCA). In order to determine the independent predictors of MACE, a multivariable logistic regression model was built using a stepwise (forward/backward) procedure.

Results: Average population age was 61 years and 26.5% had diabetes. Most patients had single target lesion (92.4%). Adequate scaffold deployment (PSP) was achieved in 14.2% of the cases. At three years, the composite endpoints of MACE and ischemia-driven target vessel failure were 9.2% and 10.6%, respectively. The cumulative rate of ARC definite/probable thrombosis was 2.2%, with 1.2% of the cases occurring after the 1st year. Independent predictors of MACE were hypertension and the need for “bail out” stent.

Conclusion: At three-year follow-up, the use of ABSORB in low/moderate complex PCI was associated with low and acceptable rates of major adverse clinical events, despite the infrequent use of the recommended contemporary scaffold deployment technique. However, scaffold thrombosis rate was higher than reported with current generation of

metallic DES. The study is registered on clinicaltrials.gov (unique identifier NCT01023789).

Key words: bioresorbable scaffold, everolimus, thrombosis

Introduction

Despite the attractive concept of “vessel uncaging and vascular restoration” that prompted the development of bioresorbable vascular scaffolds (BVS), recent randomized trials and “real-world” registries have raised concern about the safety of the 1st generation of this novel technology, especially due to increased risk of thrombosis within the first weeks of the scaffold implantation¹⁻⁴ and also lately, after the 1st year of follow-up⁵⁻⁸, when mechanical properties of the BVS were expected to have disappeared or markedly attenuated⁹.

While early events seem to be closely related to lesion selection (e.g: treatment of small vessels) and poor deployment technique (e.g.: inadequate vessel sizing, under expansion, etc.), few is known about the real incidence and mechanisms behind the late events (>1 year), since there is a paucity of long term data on these devices.

We sought to evaluate the late (3 years) performance of the Absorb BVS for the treatment of low/moderate complexity patients enrolled in the ABSORB EXTEND trial.

METHODS

Study Population

In the present analysis, we included all patients enrolled in the ABSORB EXTEND trial. The details of this study have been described elsewhere^{10,11}. In brief, this was a prospective, single-arm, open-label clinical trial that enrolled 812 patients at 56 international sites outside of the US. Target arteries should have a reference vessel diameter (RVD) ≥ 2.0 mm and ≤ 3.8 mm, a maximum lesion length of ≤ 28 mm, a diameter stenosis $\geq 50\%$ and $< 100\%$. A maximum of two *de novo* native coronary artery lesions could be treated, each located in a different major epicardial vessel. Major exclusion criteria included a recent MI (< 72 hours before the index procedure) and target lesions located in the left main or within an arterial or saphenous vein graft.

Abbott Vascular (Santa Clara, CA, US) funded the study. The research ethics committee of each participating institution approved the protocol and all enrolled patients provided written informed consent before inclusion. The study is registered on clinicaltrials.gov (unique identifier NCT01023789).

Study End Points and Definitions

The primary end point of this study was the three-year composite MACE rate, including cardiac death, non-fatal myocardial infarction (MI), and ischemia-driven target lesion revascularization (TLR). Additionally, we report the long-term rates of target vessel failure (TVF) and scaffold thrombosis.

Device and clinical success have been previously defined, as well as TVF, cardiac death, non-fatal MI and ischemia-driven target vessel failure (ID-TVF). Device thrombosis was categorized as acute (< 1 day), subacute (1-30 days) and late (> 30 days) and was defined according to the ARC guidelines.

“Bail out” scaffold/stent was the use of additional, unplanned device to treat a complication related to the implant of the BVS (e.g edge dissection). This registry allowed the use of either another BVS or a metallic stent as “bail out”, being the decision at operator’s discretion.

Adequate scaffold implantation (PSP) criteria, although not available at the time of the ABSORB Extend Registry enrollment, was defined as below and retrospectively assessed by an independent corelab:

- i. patients with pre-dilatation;
- ii. QCA reference vessel diameter ≥ 2.25 mm ≤ 3.5 mm;
- iii. post-dilatation performed at ≥ 18 atm, with non-compliant balloon diameter $>$ nominal scaffold diameter but $\leq$ nominal scaffold diameter + 0.5mm.

Statistical Analysis

For the descriptive statistics, categorical data are presented as counts and percentages and continuous variables are presented as mean $\pm$ standard deviation (SD).

To determine the independent predictors of MACE, a multivariable logistic regression model was built using a stepwise (forward/backward) procedure, with independent variables entered the model at the 0.20 significance level and removed at the 0.10 level. Variables were eligible for inclusion in the multivariable logistic regression model-building process if the variable was present for 90% of the subjects in the analyses, they had a p-value < 0.2 from the univariable analysis, and if highly correlated with another variable ($r > 0.5$ and $p < 0.05$), had the higher level of significance.

Time-to-event variables are presented as Kaplan-Meier curves. A two-tailed p value < 0.05 was considered statistically significant.

RESULTS

Baseline population and angiographic characteristics

A total of 812 patients were enrolled in the ABSORB EXTEND Single Arm Trial between 11th January 2010 to 2nd October 2013. Mean population age was 61.1 ± 10.7 and

most patients were male (74.3%). Diabetes mellitus was present in 26.5% of the cohort. Acute coronary syndrome (unstable angina / non-ST elevation MI) was the initial clinical presentation in 43.2% of the cases (table 1).

Table 2 displays the most relevant angiographic findings. Most patients had a single lesion treated (92.4%), being the LAD the target vessel in 45.2% of the cases. Overlapping was required in 10.5% of the procedures. Mean reference vessel diameter and lesion length were $2.64 \pm 0.39\text{mm}$ and $12.5 \pm 5.3\text{mm}$, respectively. As per protocol, pre-dilatation was performed in almost all cases in the ABSORB EXTEND patients (99.7%). Post dilation was performed in 68.8% of the cases. Notably, adequate scaffold implantation (PSP) was achieved in only 14.2% of the entire cohort. Need for “bail out” scaffold/stent occurred in 4.2% of the procedures, being 2.2% performed with the implant of an additional BVS.

Clinical events

Table 3 shows the cumulative incidence of clinical adverse events at 30 days, 1 and 3 years. Three-year clinical follow-up was available for all patients. Of note, 40% of all patients were still under DAPT at three years. As noted, the cumulative incidences of hierarchical MACE (9.2%) and TVF (10.6%) were relatively low during the entire follow-up, being mostly driven by peri procedural MI in the first 30 days and by ischemia-driven TLR in the remaining period. The cumulative incidence of definite/probable scaffold thrombosis at 30 days, 1 and 3 years was 0.6%, 1.0% and 2.2%, respectively.

Figure 1 shows the cumulative incidence of MACE (panel A), and TVF (panel B). figure 2 displays the KM curves for cardiac death (panel A), non-fatal MI (panel B), ischemia –driven TLR (panel C) and definite/probable device thrombosis (panel D).

Figure 3 displays a landmark analysis of MACE (panel A) and definite/probable device thrombosis (panel B). As observed, half of the events occurred between 1 and 3

years of follow-up (0.5% between the 1st and 2nd year and 0.6% between the 2nd and 3rd year).

Adequate scaffold implantation (PSP) did not impact the MACE rate after ABSORB implantation in this Extend registry (figure 4). However, of the eight cases of very late scaffold thrombosis, seven occurred among patients who did not fulfilled the PSP criteria. Since the vast majority of the cases did not achieve PSP, this variable was not found as a predictor of negative outcomes in the trial, but the importance of achieving an adequate scaffold implantation should not be minimized by this finding.

Multivariate analysis

The only independent predictors of MACE were hypertension (OR 2.26, 95% CI: 1.18 - 4.32, p=0.01) and use of “bail out” stent (OR 3.32, 95% CI:1.37, 8.05, p= 0.008).

Since cardiac death, TLR and scaffold thrombosis were relatively low frequency events, it was not possible to estimate their independent predictors with reasonable accuracy.

DISCUSSION

The current study shows a relatively low rate of MACE and ischemia-driven TVF among low/moderate patients treated with ABSORB up to 3 years of follow-up. Notably, half of the scaffold thrombosis cases occurred after the 1st year of the index procedure.

Six randomized clinical trials (ABSORB II, ABSORB III, ABSORB China, ABSORB Japan, and EVERBIO II and AIDA)¹²⁻¹⁷ comparing the Absorb BVS with everolimus-eluting metallic stent (EES) have been conducted, including a total of 5,583 patients. The results of each study suggested that, in the midterm clinical follow up (≤ 2 years), there were no differences in the revascularization measures of efficacy (e.g:

ischemia-driven TLR and TVR) between devices, which was confirmed in a patient-level metaanalysis including most of these trials³.

Nevertheless, the same meta-analysis has identified an increase in the risk of target-vessel myocardial infarction with Absorb BVS compared with EES (relative risk, 1.45 [1.02–2.07]; $P=0.04$), mainly because of periprocedural myocardial infarction (relative risk, 1.29 [0.82–2.03]; $P=0.27$) and device thrombosis (relative risk, 2.09 [0.92–4.75]; $P=0.08$) within the first year after the index procedure³.

More recently, 3 years results of the randomized ABSORB China trial did not point to a significant difference in TLF and thrombosis between these devices¹⁸. On the other hand, a larger randomized trial, with more complex population (ABSORB 3) showed a three times higher thrombosis rate with the ABSORB at three years (2.3% vs. 0.7%; $p < 0.01$)¹⁹. More disturbing, a very recent individual-patient-data meta-analysis of three-year outcomes of ABSORB vs Xience from the ABSORB randomized trials showed higher rates of target lesion failure (11.7% versus 8.1%; risk ratio [RR], 1.38; 95% confidence interval [CI], 1.10–1.73; $P=0.006$), driven by greater target vessel myocardial infarction (7.8% versus 4.2%; RR, 1.72; 95% CI, 1.26–2.35; $P=0.0006$) and ischemia-driven target lesion revascularization (6.6% versus 4.4%; RR, 1.44; 95% CI, 1.05–1.98; $P=0.02$), with comparable cardiac mortality (1.1% versus 1.1%; RR, 0.93; 95% CI, 0.47–1.88; $P=0.85$). Device thrombosis rates through 3 years were also higher with BVS (2.4% versus 0.6%; RR, 3.71; 95% CI, 1.70–8.11; $P=0.001$)²⁰. The rate of scaffold thrombosis in this studies was very similar to the reported in the current manuscript at the same follow-up interval.

Plausible mechanisms of the early thrombotic hazard observed with Absorb BVS included rheological alterations caused by the thick struts of the scaffold, as well as technical factors during implantation, including lack of adequate vessel sizing and proper scaffold expansion. Based on these findings, current recommendation for BVS implantation include a recommendation for routine high pressure post dilation and more

liberal use of intravascular imaging modalities (IVUS/OCT) to guide adequate device selection and implantation. Of note, in the present analysis, most of the in-hospital MACE was also driven by peri procedure MI. However, the one-year scaffold thrombosis rate was relatively low (1,0%) and comparable to most 2nd generation metallic DES in studies with similar population and lesion profiles.

Recently, Collet et al. published a metanalysis with the late clinical outcomes (> 2 years) of 1,730 patients treated either with either ABSORB BVS or metallic EES from five randomized clinical trials⁶. Patients treated with the scaffold had a higher risk of definite/probable thrombosis compared with patients treated with metallic DES (OR 2.93, 95% CI 1.37–6.26, P = 0.01). Furthermore, these patients had a trend towards higher risk of TLF (OR 1.48, 95%CI 0.90–2.42, P = 0.09), driven by a higher risk of target vessel myocardial infarction and ischemia-driven target lesion revascularization. No difference was found in the risk of cardiac death. In the ISAR-ABSORB registry, Wiebe et al, showed a 1.3% rate of definite/probable BVS thrombosis between the 1st and 2nd year of follow up²¹. Similarly, in the Extend Registry, ABSORB definite/probable thrombosis rate was of 1.2% after the 1st year of the procedure.

At present, while the causes of acute BVS failure are better understood, the possible mechanism behind late failure of these devices are still not completely understood. Most of the present knowledge is based on retrospective analysis from case reports using intravascular imaging, especially OCT. Among the postulated causes the most frequent observed are: 1) strut malapposition (either persistent or late acquired); 2) late device discontinuity, which is a programmed phenomenon in the bioresorption process of the polymeric device; 3) peri strut low-intensity area on OCT; 4) delayed vessel healing, and; 5) neoatherosclerosis²²⁻²⁵.

Dual antiplatelet therapy (DAPT) has a key importance in the prevention of thrombotic events after BVS. The absence of DAPT is the single most powerful predictor of thrombosis within the 1st year of the procedure. Notably, in Collet's

metanalysis, 92% of the BVS thrombosis after the 1st year occurred among patients who had discontinued DAPT⁶. However, it is not clear whether to prolong these medications would prevent the occurrence of this untoward event. Nevertheless, many services around the world are recommending DAPT for at least two years in patients treated with ABSORB⁸. In our registry, less than half of the entire cohort was on DAPT after the 1st year.

Limitations

This study was limited by the single-arm nature of the design and the inherent lack of a control arm for direct comparison. Also, the lack of systematic invasive evaluation, with use of intravascular imaging (IVUS or OCT), precludes more definite conclusions about the mechanisms related to BVS failure at different timepoints.

Conclusions

At three-year follow-up, the use of ABSORB in non-complex PCI was associated with low and acceptable rates of major adverse clinical events, despite the infrequent use of the recommended contemporary scaffold deployment technique. However, the incidence of scaffold thrombosis was higher than the reported for the current generation of DES.

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Figure Legend

Figure 1. Kaplan-Meir survival curves of MACE (panel A) and target-vessel failure (panel B)

Figure 2. Kaplan-Meir survival curves of cardiac death (panel A), non-fatal myocardial infarction (panel B), ischemia-driven TLR (panel C), and definite/probable scaffold thrombosis (panel D).

Figure 3. Kaplan-Meir landmark survival curves of MACE (panel A) and definite/probable scaffold thrombosis (panel B). As observed, half of the negative events occurred after the first year of follow-up.

Figure 4. Impact of adequate scaffold implantation (PSP) in the late outcomes after ABSORB implantation.

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Date:

2019-01-01

Citation:

Ribamar Costa, J., Abizaid, A., Whitbourn, R., Serruys, P. W., Jepson, N., Steinwender, C., Stuteville, M., Ediebah, D., Sudhir, K. & Bartorelli, A. L. (2019). Three-year clinical outcomes of patients treated with everolimus-eluting bioresorbable vascular scaffolds: Final results of the ABSORB EXTEND trial. CATHETERIZATION AND CARDIOVASCULAR INTERVENTIONS, 93 (1), pp.E1-E7. <https://doi.org/10.1002/ccd.27715>.

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