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One-Year Results Following a Pre-Specified ABSORB Implantation Strategy in ST-Elevation Myocardial Infarction (BVS STEMI STRATEGY-IT Study)☆

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ABSTRACT

Background: data from clinical experiences with Absorb bioresorbable scaffold (BRS) in STEMI raised concerns among clinicians about the device safety because a noteworthy scaffold thrombosis (ScT) rate was reported at early and long-term follow-up. Nevertheless, pre-specified technical suggestions of how to perform an optimal BRS procedure in STEMI were lacking. In this study we sought to assess the 1-year results following a pre-specified BRS implantation strategy in ST-elevation myocardial infarction (STEMI) patients undergoing primary PCI (pPCI).

Methods: This is a prospective, multicenter study on 505 STEMI patients undergoing pPCI with Absorb following a dedicated implantation protocol. The primary end-point (a device oriented composite end-point (DOCE) of cardiac death, target-vessel myocardial infarction (TV-MI) and ischemia-driven target lesion revascularization (ID-TLR) within 30 days) was already reported. We here present DOCE, its singular components and ScT rates (secondary end-points) at 1-year.

Results: According to the study protocol direct Absorb implantation was feasible in 47 (9.3%) patients while post-dilatation was performed in 468 (92.7%) cases. The hierarchical DOCE rate at 1-year was 1.2% (0.4% cardiac death, 0.4% TV-MI and 0.8% ID-TLR) versus 0.6% at 30-day. Two episodes (0.4%) of ScT (one probable subacute and one late definite) were reported. At 1-year, 99.2% patients were on dual antiplatelet therapy (95% with ticagrelor or prasugrel).

Conclusions: A pre-specified Absorb implantation strategy in STEMI patients was associated with persistent low DOCE and ScT rates at 1-year. Longer term follow-up is needed to assess the role of this strategy on preventing very-late events (NCT02601781).

1. Introduction

Bioresorbable vascular scaffolds (BRS) were developed to overcome limitations of "permanent" metallic stents, including delayed arterial

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healing and chronic inflammation [1–2]. Nevertheless, as compared to a cobalt chromium everolimus-eluting stent (Co-Cr EES), Absorb (Abbott Vascular, Santa Clara, CA) BRS has showed an increased risk of device thrombosis [3–5]. Optimal procedural implantation strategies (i.e. mandatory pre-dilatation, vessel sizing and post-dilatation: so called "PSP" approach) were strongly associated with outcomes up to 3 years after Absorb implantation in patients with stable coronary artery disease (CAD) [6]. However, limited data are available on patients with acute coronary syndromes (ACS) and in particular on those suffering from ST-segment elevation myocardial infarction (STEMI).

A prospective evaluation of a pre-specified Absorb implantation strategy (mixing procedural aspects with the strongest dual antiplatelet therapy -DAPT- actually available) in STEMI patients undergoing primary PCI (pPCI) resulted feasible and associated with encouraging clinical results within 30 days after the index procedure [7].

Regardless the decision to stop commercialization of Absorb due to the drop in its use, probably caused by an excessive thrombosis rate reported, further follow-up data are needed to better understand the potential role of a specific "BRS strategy" (patient's selection, implantation technique and DAPT management) to prevent late and very-late device-related events. On these basis, we here report the 1-year results following a pre-specified Absorb implantation protocol in the relatively under-explored but theoretically appealing STEMI setting.

2. Material and methods

The rationale and design of the BVS STEMI STRATEGY-IT was extensively described elsewhere [8]. Briefly, this is an investigator-owned and -directed, prospective, single-arm, multi-center, study intended to obtain data from 500 consecutive STEMI patients eligible to undergo pPCI with Absorb (1.1 or GT1 versions) implantation on the basis of pre-specified inclusion and exclusion criteria [8].

Main inclusion criterion was the presence of STEMI with symptoms onset < 12 h from hospital admission, while main exclusion criteria were common to most Absorb studies including: age > 75 years, and infarct-artery diameter (within planned device deployment segment) < 2.5 mm or >3.7 mm [8].

Aim of the study was to assess the impact on clinical outcomes of a pre-specified Absorb implantation protocol (previously described) during pPCI [7,8].

Shortly, main steps of the proposed strategy were: 1) administration of the strongest DAPT available (i.e. acetyl salicylic acid i.v. plus ticagrelor 180 mg or prasugrel 60 mg) as soon as possible before pPCI; 2) vessel (and BRS) sizing (by visual estimation and/or on-line QCA or intracoronary imaging left at operator's discretion) after intracoronary vasodilators injection; 3) direct Absorb implantation only in case of residual diameter stenosis (DS) < 30% at the culprit site after TIMI 3 flow restoration (with or without thrombectomy); 4) low threshold for post-dilatation (with a non-compliant -NC- balloon of maximal diameter + 0.5 mm compared to the nominal BRS diameter implanted), mandatory in case of residual DS > 20% at the culprit site.

Absorb diameter was chosen according to the maximal proximal (5–10 mm to the culprit site) reference vessel diameter -RVD- (visually estimated by the operator if on-line QCA was unavailable) in 2 orthogonal angiographic views and correct Absorb diameter sizing was defined when a 3.5 mm BRS was chosen for a RVD between 3.1 and 3.7 mm, 3.0 mm BRS for a RVD between 2.7 and 3.0 mm; and 2.5 mm BRS for a RVD 2.5–2.6 mm).

The study was developed in accordance with the Declaration of Helsinki and was approved by the ethics committees of each of the 22 participating centers. All of these Centers had a prior experience with Absorb implantation (91% > 50 implants while 55% > 100 implants). All patients provided written informed consent prior to study participation.

This trial was recorded in Clinical Trial.gov and identified as *NCT02601781*.

Study end-points were already described [8] and the primary end-point (a device oriented composite end-point –DOCE- of cardiac death, target-vessel myocardial infarction -TV-MI- and ischemia-driven target lesion revascularization -ID-TLR-) within 30 days after the index procedure was reported [7]. In the present manuscript we present the secondary end-points within 1-year follow-up: 1) DOCE; 2) definite/probable ScT; 3) any bleeding defined according to the Bleeding Academic Research Consortium (BARC) definitions; 5) cardiac death, TV-MI, ID-TLR (as singular end-points) [8]. Dual antiplatelet therapy was indicated for at least 12 months after Absorb implantation (with the decision for longer term use left to the discretion of the treating physician according to the specific clinical scenario).

All clinical end-points were adjudicated by an independent Clinical Event adjudication Committee [7,8].

Statistical analysis for DOCE, its singular components and ScT are performed for the overall population. Numerical data are presented as the mean ± standard deviation or median (interquartile ranges). Categorical data are presented as counts and percentages of the total. All data are presented using descriptive statistical methods. All analysis were performed using the SPSS 21.0 software packaging (SPSS, Chicago, IL).

3. Results

A number of 2989 STEMI patients underwent pPCI in 22 centers from September 2015 to early January 2017. Among these patients, 505 (16.9%) were treated with at least 1 Absorb implantation. Mean patient's age was 56.6 ± 9.4 years and 131 (25.9%) patients were younger than 50 years. Most (487, 96.4%) of the patients enrolled resulted clinically stable (Killip Class I-II) at the time of cath-lab arrival. Main lesion and procedural characteristics are described in Table 1.

Manual thrombectomy (not mandatory per protocol) was performed in 227 (45%) patients and an intracoronary vasodilator drug was administered after flow restoration in 351 (69.5%) patients. Absorb GT1 version was used in 411 (81.4%) cases while Absorb 1.1 in the remaining 94 (18.6%). According to the study protocol (DS < 30% at the culprit site after flow restoration), direct Absorb implantation was performed in 47 (9.3%) patients. Pre-dilatation was performed in 458 (90.7%) cases of whom 176 (38.4%) with a 1:1 balloon-to-artery diameter ratio. Absorb post-dilatation was performed in the majority of the

Table 1
Lesion and procedural characteristics.

	$n = 505$ patients
Symptoms-to-balloon (mins), median (IQR)	168.5 (117.5–260)
Medium contrast (ml), median (IQR)	179 (140–220)
Procedural time (mins), median (IQR)	55.0 (40.2–69)
Fluoroscopy time (mins), median	13.5 (9–19)
Manual thrombectomy, n (%)	227 (45.0)
Direct Absorb implantation, n (%)	47 (9.3)
Pre-dilatation balloon diameter sized 1:1 vs. artery diameter/BRS implanted, n (%)	176 (38.4)
Absorb diameter (mm), mean ± SD	3.2 ± 0.3
At least 1 Absorb diameter 2.5 mm implanted, n (%)	51 (10.1)
Absorb length (mm), mean ± SD	22.8 ± 4.8
Intracoronary imaging at least post-BRS implantation, n (%)	52 (10.2)
Post-dilatation, n (%)	468 (92.7)
Post-dilatation despite in-BRS %DS < 20%, n (%)	411 (87.8)
Post-dilatation balloon diameter, mean ± SD	3.42 ± 0.38
Post-dilatation balloon atm, mean ± SD	18.2 ± 6.1
Post-dilatation NC balloon > 1:1*, n (%)	283 (56.0)
Post-dilation using NC balloon > 1:1* with pressure ≥ 16 atm*	207 (41.2)

IQR: interquartile range; atm: atmospheres; SD: standard deviation; BRS: bioresorbable vascular scaffold; DS: diameter stenosis; NC: non-compliant; * performed using a NC balloon with diameter larger than the Absorb nominal diameter up to a maximum of 0.5 mm.

procedures (468, 92.7%) even in case of residual DS in the Absorb-treated segment < 20% (411/468, 87.8%).

According to off-line QCA provided by the central core-lab correct BRS sizing was obtained in 21.5% (95/442 evaluable angiogram) of the cases (visual estimation was the most used tool to assess vessel/BRS diameter). A "culprit vessel only" pPCI with Absorb was adopted for all the cases. The DAPT loading dose (with aspirin i.v.) was administered in 230 (45.5%) patients at the first medical contact while most (481, 95.1%) of the patients received aspirin (100 mg) in addition to ticagrelor (90 mg b.i.d.) or prasugrel (10 mg) at discharge. Among the 137 STEMI patients (27.1% of the total cohort) with multi-vessel CAD, 39 (28.5%) were considered suitable for "step and planned" Absorb implantation (within 60 days after the index procedure) even in the "non-culprit" vessels while the remaining patients (98/137, 71.5%) were treated with current generation DES.

Clinical end-points at different time intervals are shown in Table 2.

At 30 days, follow-up was available for all eligible patients. No definite Absorb thrombosis were reported.

At 1-year, follow-up was available for 96.4% of the eligible patients. Hierarchical DOCE rate was 1.2% (vs. 0.6% at 30-day). ID-TLR rate was 0.8% while TV-MI 0.4% and cardiac death 0.4%. Two episodes (0.4%) of ScT (one fatal probable subacute and one non-fatal definite late in a patient who transiently discontinued DAPT for unknown reasons) were reported. Among patients who experienced an Absorb failure, 4 over 6 were managed by re-PCI with DES-in-BRS implantation and survived the event, while 2 patients died suddenly. Table 3 reports details of patients which experienced Absorb failure at follow-up.

The vast majority of the patients (501, 99.2%) were on DAPT at 1-year after the index procedure. Among these patients a very high proportion (476/501, 95%) was on ticagrelor or prasugrel (in association to aspirin 75/100 mg daily). Main reasons for DAPT discontinuation (3 cases after a down-grade attempt to clopidogrel) within 1-year after the index procedure were recurrent gastro-intestinal bleedings (3 cases) and one intracranial bleeding. Overall hemorrage occurred in 10 (1.9%) patients of whom 5 (1.0%) classified as BARC 3. No fatal bleedings were reported.

4. Discussion

Main findings of this study on selected STEMI patients undergoing pPCI with Absorb implantation are:

Table 2
Clinical end-points at different intervals of follow-up.

	n = 505 patients
30-day	
Hierarchical DOCE (*Primary end-point*), n (%)	3 (0.6)
Cardiac death, n (%)	2 (0.4)
ID-TLR, n (%)	1 (0.2)
TV-MI, n (%)	1 (0.2)
Definite/probable scaffold thrombosis, n (%)	1 (0.2)
Overall bleedings, n (%)	7 (1.4)
Bleeding BARC 3b, n (%)	2 (0.4)
1-Year	
Hierarchical DOCE, n (%)	6 (1.2)
Cardiac death, n (%)	2 (0.4)
ID-TLR, n (%)	4 (0.8)
Overall TLR, n (%)	5 (1.0)
TV-MI, n (%)	2 (0.4)
Definite/probable scaffold thrombosis, n (%)	2 (0.4)
Overall bleedings, n (%)	10 (1.9)
BARC 3b, n (%)	4 (0.8)
BARC 3c, n (%)	1 (0.2)

DOCE: device oriented composite end-point; PPCI: primary PCI. ID-TLR: ischemia driven TLR; TV-MI: target vessel myocardial infarction. BARC: bleeding academic research consortium.

Table 3
Details of patients which experienced a device-related event at follow-up.

Case	Event	Time after index procedure	Age (Years)	Location	Pre-RVD at offline QCA	IC imaging at index procedure	Absorb		Pre-dilatation	Post-dilatation	Post-dilatation NC balloon diameter	DAPT at the time of event	Event management	Outcome
							Diameter (mm)	Length (mm)						
1	Sudden Cardiac death/Probable ScT	2 days	54	LAD-Diag	2.43	No	3.0	28	Yes	Yes	3.5 3.5	Aspirin and Clopidogrel	–	Death
2	TV-MI/ID-TLR	3 days	48	Distal RCA	3.3	No	3.5	28	Yes	Yes	3.5	Aspirin and Ticagrelor	IVUS-guided PCI with oversized NC balloon only	Alive
3	Cardiac death	26 days	62	LCx-OM	2.52	No	2.5	28	Yes	Yes	2.5	Aspirin and Ticagrelor	–	Death
4	TV-MI/Definite ScT/ID-TLR	2 months	55	Prox RCA	2.96	No	3.5	28	Yes	Yes	4.0	Transiently stopped	Primary PCI with DES in BRS	Alive
5	ID-TLR	5 months	53	Mid LAD	2.41	No	2.5	18	No	No	NP	Aspirin and Prasugrel	Elective PCI with DES in BRS	Alive
6	ID-TLR	10 months	67	Mid LAD	2.1	No	2.5	18	Yes	No	NP	Aspirin and Ticagrelor	Elective PCI with DES in BRS	Alive

RVD: reference vessel diameter; QCA: quantitative coronary angiography; IC: intracoronary; DAPT: dual antiplatelet therapy; ScT: scaffold thrombosis; LAD: left anteriori descending; TV-MI: target-vessel myocardial infarction; ID-TLR: ischemia-driven target lesion revascularization; RCA: right coronary artery; NP: not performed; IVUS: intravascular ultrasound; PCI: percutaneous coronary intervention; NC: non-compliant; LCx: left circumflex; DES: drug-eluting stent; BRS: bioresorbable vascular scaffold.

Table 4
Differences among main studies assessing absorb results in STEMI patients.

	BVS STEMI STRATEGY-IT [7]	BVS EXAMINATION [20]	BVS STEMI First [21]	Prague-19 [27]	TROFI II [18]	RAI STEMI [28]
Patients, n	505	290 (BVS arm)	151 (BVS arm)	114	95 (BVS arm)	317
Primary PCI, %	100	NA	NA	100	100	73.2
Thrombus aspiration, %	45	75	76.7	NA	81	6.3
Pre-dilatation, %	90.7	81	54.1	NA	56	92.7
Post-dilatation, %	92.7	36	39.7	NA	50	95
DAPT including prasugrel and ticagrelor, %	95.1	66.7	NA	NA	63.1	77
Intravascular imaging at baseline, %	10.2	NA	NA	5.2	NP	11
30-day definite/probable ScT, %	0.2	2.1	2.8	2.6	0	NA
30-day DOCE, %	0.6	3.1	NA	NA	0	NA
1-year definite/probable ScT, %	0.4	2.4	2.8**	2.6	1.1	2.5
1-year DOCE, %	1.2	4.1	8.1***	NA	2.1	4.1

DAPT: dual antiplatelet therapy. ScT: scaffold thrombosis. NA: not available. DOCE: device oriented composite end-point. NP: not performed at the index procedure; **: only definite ScT; ***: assessed as a composite of cardiac death, any re-MI, or clinically driven TLR.

1) the persistence of a low DOCE rate between 30-day (0.6%) and 1-year (1.2%) follow up, compared to historical STEMI cohorts treated by Absorb without a specific implantation strategy; (Table 4)
2) the fact that patients' selection, procedural strategy and adherence to the strongest DAPT available may have influenced the encouraging 1-year results.

New generations DES represent the current benchmark in PCI and are indicated in all patients and lesion subsets [9] including STEMI [10]. Although those sophisticated platforms mix thin struts with biocompatible or biodegradable polymers, they all have potential shortcomings related to the permanent caging of the coronary wall [2]. In this context, BRS were developed with the aim to reduce the risk of late DES-related events. Absorb was the first BRS introduced on the market and up to date the most evaluated in clinical practice. After initial enthusiasm based on early small investigations on selected patients [1,11], randomized trials [12–14] and meta-analyses [5,15] have shown higher rates of TV-MI and ScT with Absorb compared to a Co-Cr EES, during the healing and active bioresorption phases. This led to reduced BRS use and the recent (September 2017) decision by the manufacturer to halt production. Sub-optimal Absorb implantation techniques as well as device characteristics related to the degradation process at follow-up have been hypothesized as probable causes for the disappointing results [16,17].

ACS at admission and STEMI in particular, were exclusion criteria for most of the randomized Absorb trials making the "acute" setting an under-explored subset for BRS technologies [8]. The only randomized study comparing Absorb vs. a Co-Cr EES in STEMI showed comparable results between the two devices in terms of arterial healing at 6 months [18]. Furthermore, not only the acute gain and the post-procedural minimal lumen diameter were identical in both treatment arms but also the lipidic change of neointima at follow-up was less prominent with BRS compared to DES, supporting the concept that soft, acute lesions could be a "sweet spot" (compared to stable lesions) for the BRS [18,19].

Next to the only Absorb randomized study (not powered for clinical end-point) in STEMI, two propensity matched-analyses vs. Co-Cr EES in the same setting, demonstrated a higher ScT rate at different time intervals [20,21]. However these studies were performed during an "early Absorb phase" where a cautious implantation approach was suggested to avoid BRS fracture [22] and any specific Absorb implantation protocol was suggested during pPCI.

The BVS STEMI STRATEGY-IT study represents the first prospective evaluation of a predefined Absorb implantation strategy during pPCI. The study was designed (before the so called "PSP- approach") to provide a simple chart to drive Absorb implantation in STEMI according to the residual %DS following vessel recanalization (pre-dilatation or direct stenting) and BRS implantation (post-dilatation or not). The possibilities to perform a direct Absorb implantation (in case of %DS <30 at the culprit site after vessel recanalization) as well as a pre-dilatation using also an "undersized" balloon, distinguish since the beginning our strategy from the various PSP criteria (where pre-dilatation with a nominal balloon diameter at least 1:1 ratio with RVD is mandatory). Even our post-dilatation (theoretically avoidable in case of <20% residual DS after Absorb implantation) suggestion partially deviate from the PSP strategies where BRS post-expansion using a larger (maximum +0.5 mm) diameter NC balloon than the nominal Absorb implanted is mandatory. However, PSP criteria were mainly validated in stable patients/lesions and it is actually unknown if they could fit even for STEMI patients with softer lesions. Optimal PSP strategies may be indeed difficult to be achieved during pPCI, because pre- and/or post-dilatation are usually not recommended in the acute setting to avoid thrombus/plaque dislodgement and embolization [23]. Moreover, the adrenergic-mediated vasoconstriction, typical of the acute phase of CAD, may interfere with an adequate vessel sizing [24] that could be suboptimal by visual estimation or QCA [25].

The 30-day results obtained in a selected (in terms of age, symptoms onset to hospital presentation, hemodynamic conditions and coronary anatomy features) population underwent pPCI showed a high procedural success rate and a relatively low 30-day hierarchical DOCE (0.6%) and ScT (0.2%) rates [7].

The goodness of the early clinical findings is now confirmed at 1-year follow-up. Indeed, hierarchical DOCE and ScT rates were 1.2% and 0.4%. These outcomes result sensibly lower compared to those coming from other studies on this topic where DOCE and ScT rates ranged from 4.1% to 8.1% and 2.4% to 2.8% within 12 months follow-up (Table 4) [20−21].

In particular, one definite late ScT (0.2%) occurred between 30 days and 1-year (in a patient who transiently discontinued DAPT) while 2 ID-TLR (0.4%) were reported during the same time interval. These results appear of interest because they toughen the concept that specific Absorb implantation rules are required to mitigate the occurrence of early and mid-term events in different scenarios such as stable CAD [6] and STEMI.

Patient's selection, in association with a high post-dilatation rate (even if "only" 60.4% using an "oversized" NC balloon compared to the nominal diameter of the BRS implanted) plus the most efficacious DAPT regimen administered may have influenced the low event rates despite a very low intravascular imaging guide and an apparent sub-optimal vessel/BRS sizing according to off-line QCA (this aspect may raise questions about the best tool to evaluate vessel and BRS size during pPCI).

Based on our 1-year clinical data obtained using different criteria compared to conventional PSP, we could speculate that a different strategy might be acceptable to achieve favorable clinical results following BRS implantation in STEMI. Next to specific plaque modification or Absorb optimization during pre- and post-dilatation, the DAPT regimen represents another fundamental step of the Absorb-treated patients management. In our study, a very high proportion of patients (95.1%

of total) received at discharge the more potent (compared to clopidogrel) prasugrel (10 mg daily) and ticagrelor (90 mg bid) and then maintained (95%) the prescribed DAPT up to 1-year. The higher platelet inhibition (compared to clopidogrel) supported by these modern drugs [26] could have played an important role to reduce the risk of Absorb thrombosis related to the thicker polymeric struts compared to those of current metallic DES. In this context, patient's selection for BRS implantation should be originally oriented to subjects with a low bleeding risk (i.e. young patients without comorbidities such as chronic renal or liver failure or diseases requiring oral anticoagulation) who may theoretically have a good compliance to DAPT for at least 1-year up to maximum 3 years after BRS implantation.

Whether the proposed strategy of combining an optimal DAPT regimen and a tailored Absorb implantation might impact the long-term (>1-year) outcomes of STEMI patients remains to be investigated.

Main limitations of this study are the observational nature and the lack of a direct comparison with a current generation DES allow us to consider these data as largely hypothesis generating. Furthermore, the STEMI cohort enrolled preclude the generalization of the outcomes reported in an all-comers STEMI population. Because the incidence of adverse events was limited within 1-year follow-up, we could not assess the predictors of clinical events, particularly DOCE (6 cases) and ScT (2 cases). Furthermore, the 1-year results obtained following a dedicated Absorb implantation strategy do not apply to other BRS (i.e. metallic or polymeric with thinner struts) actually available on the market.

In conclusion this study represents the first prospective evaluation demonstrating that a tailored, pre-specified Absorb implantation strategy in selected STEMI patients undergoing pPCI is associated with a lower 1-year DOCE and ScT rates compared to historical Absorb STEMI cohorts. The potential impact of the proposed strategy on very late outcomes needs to be assessed.

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