Mid-term CCTA results for Absorb bioresorbable vascular scaffold in clinical practice. A BVS Expand project

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ABSTRACT

Objectives

To evaluate the mid-term coronary computed tomography angiography (CCTA) outcomes of the Absorb bioresorbable vascular scaffold (BVS) by non-invasive CT imaging in combination with CT perfusion.

Background

BVS were introduced with the aim of overcoming some of late events of metal drug-eluting stent (DES). Data regarding follow-up of BVS by use of CT is limited.

Methods

BVS-EXPAND, a single-centre study includes selected, real-world patients. Complex lesions such as bifurcation and long lesions were not excluded. Eighteen to 24 months after index procedure, consecutive suitable patients underwent CT. Main exclusion criteria were: contrast medium allergy, severe renal insufficiency, Target lesion revascularization (TLR) before CCTA. Additional CT perfusion was performed when a significant non-occlusive stenosis (> 50%) in the target lesion was identified on CCTA. CT-defined BVS success was defined as: stenosis< 50% on CCTA or CT perfusion without perfusion deficits.

Results:

The CCTA cohort consisted of 164 patients. CCTA's were assessable in 160 patients with 215 lesions and within that group, rate of BVS patency was 98.6% of the lesions. CT perfusion was necessary in 9 patients (lesions) with degree of stenosis > 50% and ruled out functionally significant restenosis in five. CT-defined BVS success was achieved in 207 lesions (96.7%); CT-derived failure occurred in 7 lesions (3.3%). Complete quantitative CCTA measures were available in 144 patients with in-scaffold minimal lumen area of 4.2 (± 1.7) mm^2, % area stenosis 10.3 ± 32.1%. Following CCTA three participants required revascularization.

Conclusions

CCTA was able to evaluate most BVS treated patients at mid-term follow-up, where additional perfusion imaging was a valuable addition, needed only in a small group of patients.

Condensed Abstract

This study investigated the CCTA outcomes to describe the mid-term performance of the Absorb BVS in more complex coronary lesions when examined by means of CCTA. Due to the invasiveness, costs of angiography and excellent performance of second-generation drug-eluting stents, routine follow-up after index PCI by invasive coronary angiography has disappeared from the spectrum. CCTA is a non-invasive method to investigate coronary lesions and CT perfusion is a valuable addition. CCTA was able to evaluate most BVS-treated patients at mid-term follow-up.

INTRODUCTION

Currently, percutaneous coronary intervention (PCI) with drug-eluting stents (DES) is the gold standard for the treatment of coronary artery disease (CAD). In comparison with balloon angioplasty alone or PCI using bare metal stents (BMS), PCI with DES drastically decreased the rate of restenosis and revascularization. However on the long-term, DES with their permanent presence of foreign material are not devoid of drawbacks and have a stable average rate of reintervention of 2-4% after the first year. [1, 2] In an attempt to eliminate the potential (late) limitations of DES (neoatherosclerosis, very late stent thrombosis), bioresorbable scaffolds have been developed. The concept consists of a temporary device that restores the blood flow and temporally supports the vessel but that will fully resorb over time. The bioresorbable device most intensely investigated, is the ABSORB bioresorbable vascular scaffold (BVS. Abbott vascular, Santa Clara, CA, USA), which received both CE mark and FDA approval. It is a fully resorbable everolimus-eluting device made of a poly-L-lactide backbone with a poly-D, L-lactide coating. With the exception of two platinum markers at each end of the scaffold, this device is radiolucent and therefore does not interfere with non-invasive computed tomography of the coronary arteries. This is in contrast to metal stents, which cause blooming artefacts with subsequent hampering of luminal assessment. [3] Recently, mid-term outcomes RCTs that compared BVS with Xience, a second-generation everolimus eluting metal DES, showed that the BVS was associated with worse outcomes.[4] [5-7] These results were mainly driven by early scaffold thrombosis (ScT), triggered by the relatively thick struts of the first generation. Development of thin strut BVS is complex and expensive which first requires positive signals from long-term imaging and clinical follow-up.

Coronary computed tomography angiography (CCTA) could be such a technology and greatly improved over the last 20 years with an important increase in spatial and temporal resolution. The enhancement in CT technology enabled a reliable visualisation of the vessel lumen and also detection of significant coronary lesions.

A study by Collet and colleagues investigated the diagnostic accuracy of CCTA in ABSORB II and reported that accuracy regarding identification of presence and severity of obstructive CAD was similar between CCTA and coronary angiography at three years of follow-up. [8]

The aim of our study was to report mid-term CCTA outcomes to describe the mid-term performance of the Absorb BVS in more complex coronary lesions when examined by means of CCTA.

METHODS

Population

The BVS Expand registry is an investigator-initiated, prospective, single-centre, single-arm study performed in an experienced, tertiary PCI centre. In- and exclusion criteria have been described elsewhere. [9] In brief, patients presenting with NSTEMI, stable or unstable angina (UA), or silent ischemia caused by a *de novo* stenotic lesion in a native coronary artery treated with a BVS were included. Main exclusion criteria were patients with a history of coronary bypass grafting (CABG), presentation with ST-elevation myocardial infarction (STEMI) and patients with expected survival of less than one year. Complex lesions such as bifurcation, calcified (as assessed by angiography), long and thrombotic lesions were not excluded. As per hospital policy patients with a previously implanted metal DES in the intended target vessel were also excluded. Also, although old age was not an exclusion criterion, BVS were in general reserved for younger patients, and left to operator's interpretation of biological age.

For hospital quality control purposes of this new technique within the field of interventional cardiology, CCTA at mid-term follow-up (between 18 months and two years) was offered to all consecutive suitable patients. Exclusion criteria for undergoing a CCTA were contrast medium allergy, severe renal insufficiency, target lesion revascularization (TLR) performed before CCTA, severe calcification and patients who underwent cardiac imaging during the same time point.

Ethics

This is an observational study, performed according to the privacy policy of the Erasmus MC, and to the Erasmus MC regulations for the appropriate use of data in patient-oriented research, which are based on international regulations, including the declaration of Helsinki. Approval of the ethical board of the Erasmus MC was obtained. All patients undergoing clinical follow-up provided written informed consent for the PCI and to be contacted regularly during the follow-up period of the study.

Procedure

PCI was performed according to current clinical practice standards. The radial or femoral routes were the principal routes of vascular access and 6 or 7 French catheters were used depending on the discretion of the operator. Pre-dilatation and post dilation were recommended with a balloon shorter than the planned study device length and with a non-compliant balloon without overexpanding the scaffold beyond its limits of expansion (0.5mm > nominal diameter) respectively. Intravascular imaging with the use of Intravascular Ultrasound (IVUS) or Optical Coherence Tomography (OCT) was used for

pre-procedural sizing and optimization of stent deployment on the discretion of the operator.

Angiographic analysis

Baseline quantitative Coronary Analysis (QCA) was performed by a total of three different independent investigators. Coronary angiograms were analysed with the CAAS 5.10 QCA software (Pie Medical BV, Maastricht, the Netherlands). The QCA measurements provided reference vessel diameter (RVD), percentage diameter stenosis and minimal lumen diameter (MLD).

CCTA

Second and third-generation dual source CT scanners (SOMATOM Definition Flash and SOMATOM Force, Siemens Medical Solutions, Forchheim, Germany) were used. Standard acquisition techniques for coronary techniques were used: Sublingual nitroglycerin was given to all patients. Beta-blockers were optional in patients with a fast heart rate.

A prospective electrocardiographically triggered axial scan mode was used, with an exposure window during diastole and/or systole depending on the heart rate. Tube current and tube voltage were selected semi-automatically on the basis of body size. For CCTA imaging, a contrast bolus of approximately 50 to 60 ml (depending on iodine concentration and expected scan duration) was injected, followed by a saline bolus chaser. Images were reconstructed with a medium smooth kernel (B26, Bv40) and a slice thickness of 0.5-0.7 mm at 5% intervals of the acquired R-R segment. [10]

Scaffold patency was described as a scaffolded tract with a visible lumen and the possibility to evaluate contrast attenuation. First and according to normal practice, the CCTA was evaluated by a radiologist. Lesions were then divided into three groups: no abnormalities identified in target lesion, abnormalities seen but non-significant, significant stenosis (suspected) or total occlusion.

CT perfusion

Experienced CT readers (KN or RB) evaluated the CT angiograms, using PCI procedural information on BVS sizes and location but blinded to all other modalities. They set indication for any additional CT myocardial perfusion scans in case of a significant, non-occlusive stenosis on CCTA. This CT myocardial perfusion scan was performed in a separate session.

The dynamic CT myocardial perfusion scan was performed to further determine the functional significance of a morphological significant stenosis detected on CCTA. In a dynamic CT myocardial perfusion scan a series of acquisitions is made during the first pass of a contrast bolus, while the patient is in a hyperaemic state. After 3 min of adenosine infusion (at 140 µg/kg/min) the dynamic CT myocardial perfusion scan was started.

Fifty ml of contrast medium (Ultravist, 370 mgI/ml; Bayer, Berlin, Germany) was injected at 6 ml/s, followed by a saline bolus of 40 ml. A shuttle mode was used to cover the left ventricle acquiring images in alternating cranial and caudal table positions. CT dynamic myocardial perfusion acquisition was started 5 seconds after the start of the contrast medium injection and patients were asked to hold their breath during the entire acquisition (30-35 seconds) [10, 11]. The change in attenuation of the myocardium due to the first pass of the contrast bolus was used to compute myocardial blood flow maps using a hybrid deconvolution model. A functionally significant coronary (re)stenosis would result in a reduction of the myocardial blood flow in the associated myocardial territory [12]. By visual inspection, the myocardial blood flow maps in combination with the CTA potential ischemia causing (re)stenosis of the BVS were identified by an expert CCTA reader (KN).

Quantitative CCTA analysis

In a subgroup of patients, quantitative data of the lesion of interest were analysed off-line by a radiologist on a dedicated workstation using commercially available software Syngo. Via (Siemens, Forchheim, Germany) to perform a quantitative CTA analysis. The optimal imaging phase and the centre lumen line through the treated vessel was automatically selected by the software and manually adjusted when needed. Cross-sections of the vessel were reconstructed, extending approximately 5 mm beyond the device (proximal and distal segments), using the platinum scaffold markers as landmarks. Every BVS was evaluated at three locations: 1. the proximal scaffold segment (defined as the segment extending from the platinum marker to five mm proximal to the marker, was evaluated first by using Syngo.Via to detect the minimal lumen and to determine the lumen areas. An automatic tracer was used and in case of insufficient contrast lumen opacification, it was manually adjusted; 2. the distal scaffold segment (defined as the segment extending from the platinum marker to five mm distal to the marker), was evaluated in the same fashion; 3. the minimal scaffold lumen was assessed by visually selecting the minimal lumen area inside the scaffold (Figure 1). At each location the cross-sectional lumen area surface was measured. If multiple overlapping scaffolds were inserted, they were considered as one lesion; if none were overlapping, they were considered as separate. Reference vessel area was calculated as the average of the proximal and distal lumen reference area segments. The lumen area stenosis was calculated as follows: reference lumen area minus the minimal lumen area as a percentage of reference lumen area. In case of a bifurcation lesion with a large side branch elucidating a significant step down, the reference lumen diameter was based on measures of the distal end only.

Quantitative CTA analysis could not (completely) be performed in case of poor image quality (motion artefacts, insufficient contrast lumen opacification), ostial lesion, too small vessel calibre and total occlusion.

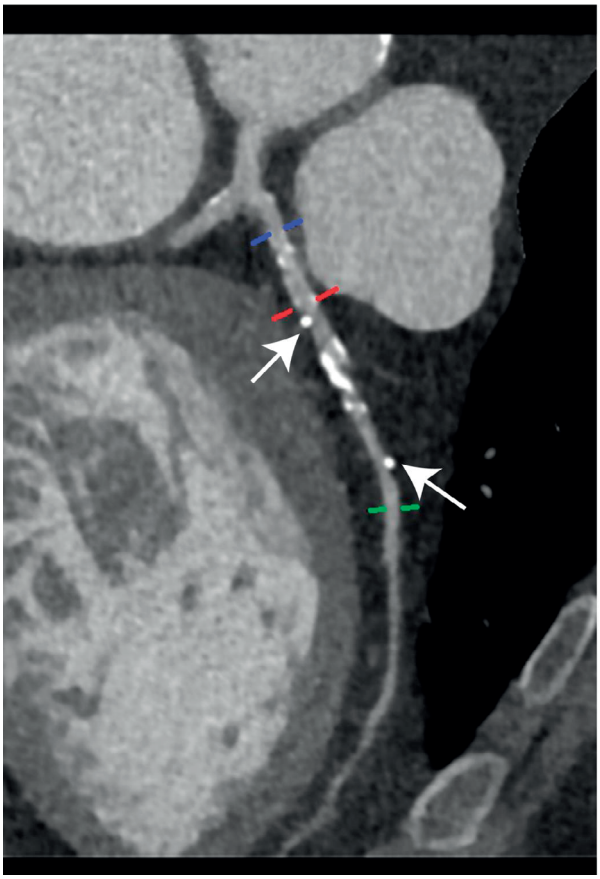

Figure 1 Example QCT measurement
Example of a normal QCT measurement: the blue line shows the proximal reference (5-10 mm distance from proximal scaffold edge), the red line indicates the proximal scaffold border (0.3mm distance from proximal scaffold edge). The green line is the distal reference (5-10 mm distance from distal scaffold edge). The white arrows indicate the two pairs of platinum scaffold markers.

Follow-up

Follow-up information specific for hospitalization and cardiovascular events was obtained through questionnaires or telephone interviews at multiple time points (1 month, 6 months, 1, 2, 3 and in the end: 4 and 5 years). If needed, medical records or discharge letters from other hospitals were requested. Events were adjudicated by an independent clinical events committee (CEC). All information concerning baseline characteristics and follow-up was gathered in a clinical data management system.

Definitions

CCTA feasibility was the percentage of patients with sufficient image quality to assess the target lesion on CCTA. BVS patency was defined as an open vessel at the site of BVS implantation. CT-defined BVS success was described as no stenosis of target lesion, diameter stenosis of < 50% on CCTA or (possible) stenosis of ≥ 50% but with a normal additional myocardial perfusion scan. CT-defined BVS failure was defined as stenosis ≥ 50% on CCTA combined with perfusion deficits during perfusion CT or complete occlusion on CCTA. Definitions of events were as in our previous publication. [9]

Statistical analysis

Categorical variables are reported as counts and percentages, continuous variables as mean ± standard deviation. Quantitative CCTA measures are described as median with interquartile range (IQR). The cumulative incidence of adverse events was estimated according to the Kaplan-Meier method. Patients lost to follow-up were considered at risk until the date of last contact, at which point they were censored. All statistical tests were two-sided and the P value of < 0.05 was considered statistically significant. Statistical analyses were performed using SPSS, version 21 (IL, US).

RESULTS

After applying the exclusion criteria, 195 consecutive patients were invited as suitable for follow-up CCTA, of which 164 accepted the offer. In four patients, poor CCTA quality made any image assessment impossible and thus 160 patients with 215 lesions remained for analysis (Figure 2). In one lesion, patency was assessable but detailed information of degree of stenosis could not be provided.

Figure 3 is an example of a patient with two sequential lesions in the RCA treated with two 28 mm long overlapping BVS with excellent acute outcome. Follow-up CCTA identified an excellent result, even at the location of the overlap.

Baseline characteristics

Table 1 summarizes baseline characteristics of patients, lesions and certain procedural factors of the whole CCTA cohort (n=160). Mean age was 59.9 ±10.0 years, 76.3% were male, 11.9% diabetics and 60.0 % presented with ACS.

The LAD was the coronary artery most frequently treated (53.2%). AHA/ ACC lesion type B2/ C was present in 37.2%, bifurcation in 22.5%, calcification (moderate or severe on angiography) in 39.0%. Pre-dilatation was performed in 89.4%, with a balloon to artery ratio of 1.07. Intravascular imaging using OCT or IVUS was carried out in 58%. Post-dilatation was performed in 51.8% with a maximum post-dilatation balloon inflation

pressure of 15.5 (±3.24) atm. Post-procedural MLD was 2.3 (±0.4) mm, post-procedural % diameter stenosis was 16.5 (±9.3) %.

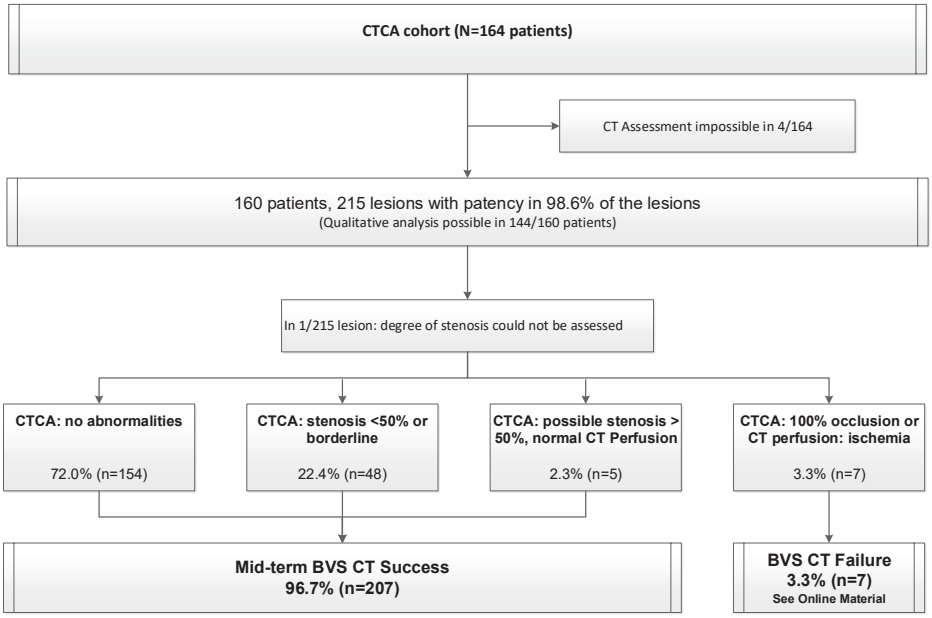

Figure 2 Flowchart of the study

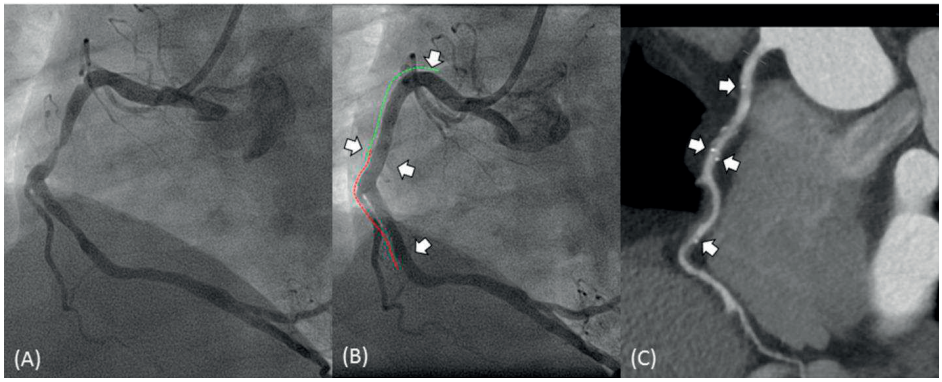

Figure 3 Case description 1

Figure 3 is an example of a successful case. It concerns a 40-year old male, smoking patient with diabetes, dyslipidaemia and a positive family history for CAD. He presented with NSTEMI due to two-vessel disease of the RCA (A) and LAD. The RCA was treated with pre-dilatation, BVS (2x 3.5*28) and post-dilatation (B) The LAD showed a positive FFR (0.75) and one 2.5*18mm BVS was implanted, followed by post-dilatation. He underwent his CCTA 861 days after baseline PCI and all BVS were patent without signs of stenosis (See C for CCTA result of RCA during follow-up).

Table 1. Baseline characteristics

Patient (n=160)	
Age (mean ± SD), years	59.86 (±10.0)
Male gender, %	76.3
Diabetes mellitus, %	11.9
Current smoker, %	33.8
Dyslipidaemia, %	51.9
Hypertension, %	55.0
Family history of CAD, %	46.9
Prior myocardial infarction, %	17.5
Prior PCI, %	10.6
Presentation with ACS, %	60.0
Lesion (n= 215 lesions)	
Treated vessel , %	
LAD	53.2
LCX	22.5
RCA	24.3
AHA/ ACC lesion classification type B2 /C, %	37.2
Calcification	39.0
Bifurcation	22.5
CTO	4.1
Procedure	
Pre-dilatation (%)	89.4
Max pre-dilation balloon diameter (mean ± SD), mm	2.62 (±0.39)
Pre-dilation balloon: artery ratio	1.07 (±0.23)
Post-dilatation (%)	51.8
Maximum post-dilatation inflation pressure (mean ± SD), atm	15.50 (±3.24)
Intravascular imaging (%)	58.1
Pre-procedural RVD (mean ± SD), mm	2.54 (±0.47)
Post-procedural MLD (mean ± SD), mm	2.30 (±0.40)
Post-procedural diameter stenosis, %	16.54 (±9.25)
Lesion length (mean ± SD), mm	23.97 (±13.10)

CAD: coronary artery disease, CTO: chronic total occlusion, MLD: minimum lumen diameter, PCI: percutaneous coronary intervention, RVD: reference vessel diameter. Values are mean (±SD) or median (interquartile range)

CCTA

Median duration from index procedure until CCTA was 714 (IQR: 639 – 754) days. See Table 2 for median dose length product (DLP) and effective dose.

When assessed by CCTA, in 98.6 % of the 215 lesions BVS patency was achieved. In one lesion, degree of stenosis could not be assessed.

Table 2. CCTA (perfusion) acquisition

CCTA (n= 160)	
CTDIvol (mGy)	19.52 (13.36 – 35.17)
DLP (mGy-cm)	288.15 (186.15 – 473.55)
Radiation effective dose (mSv)	4.09 (2.63 – 6.73)
CT perfusion (n = 9)	
CTDIvol (mGy)	37.24 (25.00 – 45.06)
DLP (mGy-cm)	338.10 (238.93 – 441.83)
Radiation effective dose (mSv)	5.51 (3.70 – 6.44)
Tube voltage (KV)	70 (70 – 70)

CCTA: Computed tomography coronary angiography, CTDI: CT dose index, DLP: dose length product. Values expressed as median (interquartile range)

In 154/ 214 lesions (72%) no target lesion abnormalities were seen on CCTA. In 53 lesions (24.7%) some non-significant changes, representing minor neo-intima hyperplasia, were seen. In 12 lesions (5.6%, 12 patients) an anatomical significant stenosis of the target lesion was reported. Three of them showed total occlusion.

CT Perfusion

In four patients, BVS failure was identified by additional CT perfusion. Figure 4 demonstrates an example of a patient with two BVS (2.5*28mm) in the LAD for spontaneous coronary artery dissection. CCTA showed ISR at level of the second scaffold and the additional CT perfusion revealed a small area of ischemia. Therefore, CT-defined BVS success was 96.7% of the lesions (Figure 2).

Two patients were subsequently treated by PCI. The other patients were initially treated conservatively, of whom one was treated through PCI during follow-up (> two years post-CCTA). However, during this re-intervention, only a non-target vessel was treated. FFR of the target-vessel was negative and the BVS was patent. In patients who did not have anatomically or functionally significant stenosis, no events occurred during follow-up.

Quantitative CCTA

Complete quantitative analysis was available in a subgroup of 144/160 patients with 194 lesions (Table 3). Quantitative analysis of the lesion was not possible in case of the presence of total occlusion (n= 3 patients), vessel calibre of too small diameter (n=3), too much calcification (n=3), insufficient amount of contrast (n=4) or motion artefacts (n=8).

In-scaffold minimal lumen area was 4.2 ± 1.7 mm^2. In-scaffold percentage area stenosis was 10.3 ± 32.1. In-segment area stenosis was 30.6 ± 25.2 %. Lesions that showed significant abnormalities on CCTA had smaller but non-significant reference areas: 4.3 vs 5.8 mm^2, p=0.69. Out of the seven patients with CT-defined BVS failure, five had MLD <

2.4 mm at baseline. Patients with a suboptimal result post-PCI (MLD <2.4 mm), showed smaller MLA during follow-up CT: 3.9 vs 4.7 mm^2 (p=0.03).

Table 3. Quantitative CCTA Assessment

	Total
In-scaffold, mm^2	
Minimal lumen area (mean ± SD)	4.2 ± 1.7
Median reference area (mean ± SD)	5.0 ± 2.1
Area stenosis, % (mean ± SD)	10.3 ± 32.1
In-segment, mm^2	
Area stenosis, % (mean ± SD)	30.6 ± 25.2

Values described as mean ± standard deviation (SD) or median (interquartile range [IQR])

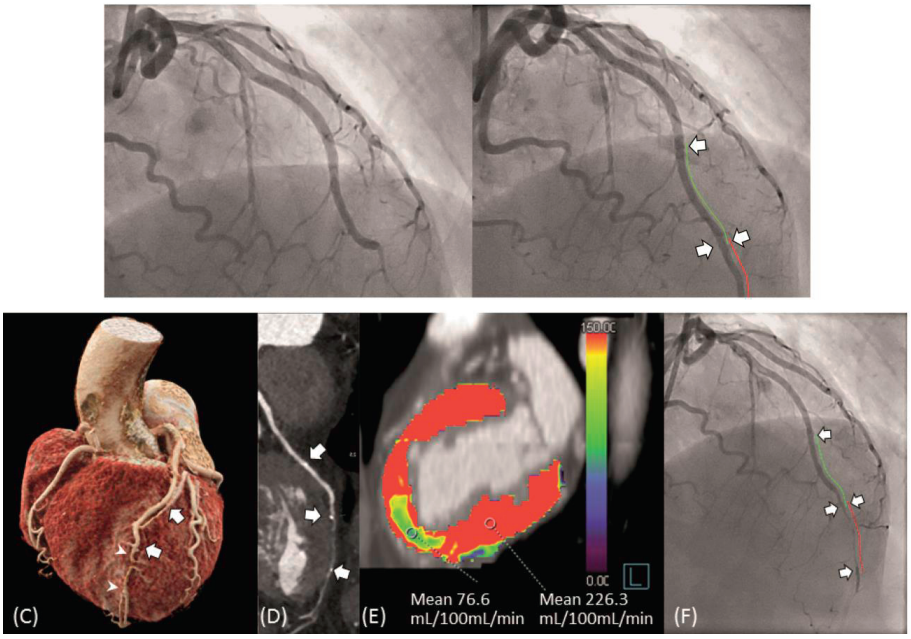

Figure 4 Case description 2
A 53-year old female patient presented with an anterior STEMI based on an intramural haematoma. (A) For TIMI I flow, initial balloon angioplasty did not result in stable TIMI III flow due to acute recoil for which two overlapping 2.5 x 28 mm BVS scaffolds were implanted (B). Follow-up CTCA (C and D for 3D image) showed a well patent proximal scaffold with minimal contrast in the distal scaffold suggestive for scaffold failure. CT-perfusion (E) demonstrated localised ischemia in the territory of the distal LAD. Subsequent angiography (F) confirmed target lesion failure, mainly due to late recoil and minimal neo-intima on IVUS which was successfully treated with balloon angioplasty only. Subsequent follow-up for one year was without recurrent events.

Clinical outcomes

Clinical outcomes (reported as Kaplan-Meier estimates) are described in Table 4. Median duration of follow-up after baseline PCI was 1456.50 (IQR: 1098.25 – 1472.50) days and follow-up of at least three years post-PCI was available in 85.6%. We focussed on events that took place after CCTA and up to three years after baseline PCI. Those event rates were as follows: rate of death was 0.7% (one patient, non-cardiac cause); rate of MI was 0% and TLR rate was 3.5%. There were no cases of scaffold thrombosis. In three patients, TLR occurred after CCTA

Table 4. Clinical outcomes, described as Kaplan-Meier estimates (n =160 patients)

	Post-CCTA
Death, % (n)	0.7 (1)
Cardiac death, % (n)	0.0 (0)
Myocardial infarction, % (n)	0.0 (0)
Target lesion revascularization % (n)	3.5 (3)
Target vessel revascularization, % (n)	3.5 (3)
Non-target vessel revascularization, % (n)	2.8 (4)
Definite/ probable scaffold thrombosis, % (n)	0.0 (0)

DISCUSSION

In this sub-cohort of the BVS Expand registry, we have reported on the mid-term CCTA and clinical outcomes of a sub-cohort of patients treated with the ABSORB BVS for a variety of lesion complexity. The main findings were as follows: 1) CCTA was a successful tool to establish non-invasively CT-derived BVS success at mid-term follow-up in almost all patients including more complex lesions. 2). Additional CT perfusion imaging provides important functional information in moderate or severe restenotic lesions. 3) Non-clinical CT-derived BVS failure is a rare event. 4) Patients with CT-derived BVS success at mid-term were free from thrombosis or TLR during follow-up after CT imaging.

Our study demonstrated that even in patients with more complex anatomy, CCTA could be routinely used to follow-up the patients after BRS implantation. Patency was 98.6% and the rate of adverse events after CT, was low. When compared to the ABSORB Cohort A and B studies in which CCTA was also performed [13, 14], the percentage of calcification, longer lesion length and AHA/ ACC lesion classification type B2/C illustrates the higher complexity of our patient population. Polymeric BRS technology, through its radiolucency and complete resorption, could be very suitable for non-invasive follow-up. Evaluation of newly introduced technologies in medicine after initial approval is essential. Patients in routine practice differ importantly from patients studied in approval studies where success rates reported in first-in-man studies and RCT including highly

selected patients, are generally higher. Most post-approval investigator-initiated studies rely only on clinical follow-up specific protocols and, in the best case, independent event adjudication by experienced investigators. Invasive coronary angiography has been the objective standard to establish metallic stent patency and presence of in-stent restenosis. Due to the invasiveness, costs of angiography and excellent performance of second-generation DES, routine follow-up after index PCI by invasive coronary angiography (ICA) has disappeared from the spectrum. CCTA is a non-invasive image modality with a high sensitivity and relatively low specificity, particularly for identification of hemodynamically significant CAD. Evaluation of BVS using CCTA was described in several publications and appeared to have a high diagnostic accuracy. [8, 13, 15] [16] Our study lacked validation with angiography; however, a recent study concluded that the accuracy of the Absorb BVS to detect in-scaffold luminal obstruction, when angiography and IVUS were used as references, was high. [17]

Investigation of efficacy after local introduction of new technology with the best feasible techniques should be routine for every hospital. [18]

In our cohort, in only four patients image quality was not sufficient to assess scaffold patency, let alone severity of stenosis or even quantitative CT measures. Rate of patency and also mid-term CT-defined BVS success were high. Our study showed that when a CT perfusion was performed, perfusion deficits were seen in approximately 50% of the cases. The advantage of CT perfusion is the possibility to perform it on-site and in the same session as CCTA. CT perfusion improves the performance of CCTA in the identification of functionally significant CAD and also improves specificity. [10, 19]

In order to discriminate between lesions that are hemodynamically significant and those who are not and with the aim of diminishing unnecessary referrals for ICA, physiological assessment of the target lesion is of importance. One of the possibilities is by using quantitative vessel analysis [20] or MR perfusion[21] and CT-derived fractional flow reserve (FFR_{CT}).[10, 19] Quantitative CTA analysis improved specificity from 41% - 76% for percentage area stenosis [22] and accuracy from 49% - 71% for percentage diameter stenosis. [20]

FFR_{CT} has been advocated as additional technology to improve specificity of CCTA, revealing good diagnostic accuracy. [23] Several studies have investigated FFR_{CT}. [19, 24-27] Currently, the HeartFlow FFR_{CT} is the only the FDA-approved CCTA derived FFR platform, which can be used off-site only and at significant costs. As so, we selected CT perfusion for our research.

Post-CCTA adverse events up to three years after baseline PCI occurred in only three patients. In all of the other patients, no adverse events of the target lesion were reported after CCTA was performed and therefore this appeared as a rare event. In comparison to other mid-term clinical results [28], outcomes at three years are good with a low rate of death and no cases of ScT.

Findings of our study show that CCTA is feasible in patients treated with Absorb BVS, which can be useful information also for other bioresorbable devices, as the current generation BVS has been taken out of the market.

CONCLUSION

CCTA was able to evaluate most BVS-treated patients at mid-term follow-up. Rates of patency and CT-defined BVS success were high. Additional perfusion imaging was a valuable addition, needed only in a small group of patients. Clinical outcomes at three years were promising without cases of scaffold thrombosis and no TLR post-CT when CCTA results were good.

LIMITATIONS

The size of our CCTA cohort was relatively limited. There might have been selection bias at the moment patients were included in the CCTA cohort. Quantitative assessment was not possible in all of the patients. Variations in image quality occurred due to calcification and platinum markers causing blooming, motion artefacts. Lastly, there was no validation with angiography or intravascular imaging.

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Part III

Implications of failed cases for future applications