Bioresorbable vascular scaffold implantation in acute coronary syndromes: clinical evidence, tips and tricks

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Abstract

Percutaneous coronary intervention (PCI) with a drug-eluting stent (DES) is routine treatment for patients with acute coronary syndromes (ACS). However, permanent metallic caging of the vessel has several shortcomings, such as side branch jailing and impossibility of late lumen enlargement. Moreover, DES PCI is affected by vasomotion impairment. In ACS a high thrombus burden and vasospasm lead to a higher risk of acute and late acquired stent malapposition than in stable patients. This increases the risk of acute, late and very late stent thrombosis. In this challenging clinical setting, the implantation of bioresorbable vascular scaffolds (BVS) could represent an appealing therapeutic option. Temporary vessel scaffolding has proved to have several advantages over metallic stent delivery, such as framework reabsorption, late lumen enlargement, side branch patency, and recovery of physiological reactivity to vasoactive stimuli. In the thrombotic environment of ACS, BVS implantation has the benefit of capping the thrombus and the vulnerable plaque. Bioresorbable vascular scaffolds also seems to reduce the incidence of angina during follow-up. Acute coronary syndromes patients may therefore benefit more from temporary polymeric caging than from permanent stent platform implantation. The aim of this review is to update the available knowledge concerning the use of BVS in ACS patients, by analyzing the potential pitfalls in this challenging clinical setting and presenting tricks to overcome these limitations.

Key words: bioresorbable vascular scaffold, acute coronary syndrome, ST-segment elevation myocardial infarction, percutaneous coronary intervention.

Introduction

Percutaneous coronary intervention (PCI) with a metallic stent and in particular with a second generation drug-eluting stent (DES) may be considered as the gold standard treatment for patients presenting with acute coronary syndrome (ACS) [1]. However, permanent delivery of a metallic platform is affected by several drawbacks, such as caging of the vessel, side branches jailing, impairment of vasomotion and impossibility of lumen enlargement [2]. Furthermore, PCI in the context of ACS portends a higher risk of acute and late acquired stent malapposition than in stable patients, due to stent undersizing for vasospasm and thrombus sequestration behind the struts [3, 4]. Bioresorbable vascular scaffolds (BVS) could represent a good therapeutic option to overcome these drawbacks of metallic stents.

The aim of this review is to update the available data concerning the use of BVS in ACS patients, to analyze potential pitfalls in this thrombotic environment, and to provide tips to overcome these limitations.

Bioresorbable vascular scaffolds: a new therapeutic tool for acute coronary syndrome patients

Patients suffering from ACS are often young and therefore have long life expectancy. Ruptured plaques are usually soft with a relatively small plaque burden. Most of the current evidence concerning the use of BVS resides in the experience of the Absorb bioresorbable scaffold (Abbott Vascular, Santa Clara, CA, USA).

The polymeric structure of Absorb consists of a backbone of poly-L-lactide (PLLA) coated with poly-D,L-lactide (PDLLA), which contains and controls the release of the drug everolimus. Chains of PLLA and PDLLA are progressively shortened as ester bonds between lactide units are hydrolyzed. Poly-L-lactide and PDLLA fully degrade to lactic acid that is metabolized via the Krebs cycle to H₂O and CO₂. Small particles are phagocytosed by macrophages [5].

This polymeric structure of the Absorb seems to favor the formation of a thin layer of neointimal tissue over a hypothetical thin-cap fibroatheroma responsible for the
ACS [6, 7]. Moreover, at long-term follow-up the implantation of an Absorb BVS is associated with lumen enlargement, side branch patency, strut reabsorption and recovery of physiological reactivity to vasoactive stimuli [8, 9]. Finally, the complete bioreosorption of polymeric struts may also be associated with a reduction in incidence of angina during follow-up [10]. Acute coronary syndrome patients may therefore benefit more from temporary polymeric caging than from permanent stent implantation [11].

Bioresorbable vascular scaffolds in acute coronary syndrome: data from registries and clinical trials

Currently available data are mostly limited to observational registries and a few randomized trials (Table I). 1) Single-center registries: Several registries reported a 1-month major adverse cardiovascular event (MACE) rate ranging between 2.6% and 10.7% [12–14]. Additionally, Gori et al. compared outcomes of ACS patients treated with BVS with a control group of patients treated with Xience (Abbott, Abbott Park, IL, USA), showing comparable results at 1- and 6-month follow-up [13]. Wiebe et al. also evaluated in a single-center fashion the performance of BVS in STE-elevation myocardial infarction (STEMI), showing a MACE rate of 8.3% at 137 days [15]. Kochman et al. in an optical coherence tomography study demonstrated a high strut apposition rate (> 95%) immediately after implantation and only one case of subacute scaffold thrombosis [16]. Recently a 1-year optical coherence tomography and angiographic analysis in 133 ACS patients was published [17]. The authors reported 4 deaths (3%) and 4 definite/probable scaffold thromboses (3%). Angiographic follow-up was performed in 75 patients. The binary restenosis rate was 4% (n = 3) and in-segment lumen loss 0.19 ± 0.45 mm. Endothelium-dependent and -independent vasodilation was present in 48% and 49% of the scaffold segment, respectively. Optical coherence tomography analysis, performed in 70 patients, showed a mean lumen area of 6.3 ± 2.3 mm² and a malapposition scaffold rate of 26% (n = 21). 2) Multicenter registries: Several multicenter registries also included patients with ACS. The Polish National Registry (52% of ACS) showed good acute clinical and angiographic outcomes (technical success 100%) [18]. The POLAR-ACS Registry included exclusively patients with ACS, showing a 2% MACE rate at 1-year follow-up [19]. The GHOST-EU (47.4% ACS) and AMC PCI registry (39% ACS) showed a target lesion failure rate at 6 months of 4.4% and 8.5%, respectively [20, 21]. The ASSURE Registry (21.3% unstable angina and 27% STEMI) showed a 5% MACE rate at 1 year [22]. Cumulative incidence of definite/probable scaffold thrombosis was 2.1% in the GHOST-EU registry, 3.0% in the AMC PCI registry, and 0.0% in the ASSURE registry. The Prague 19 and the RAI registries focused exclusively on STEMI [23, 24]. Both registries reported encouraging midterm results. In the Prague 19 registry, BVS patients were compared with an historical control group (treated with a metallic stent), showing similar outcomes. 3) Propensity score matching comparison: The BVS-EXAMINATION Study was designed to compare the 1-year outcome between Absorb BVS and everolimus-eluting metallic stent (EES) and the bare metal stent (BMS) in STEMI. A total of 290 consecutive STEMI patients treated with BVS were matched with 290 STEMI subjects treated with an EES and 290 treated with a BMS. The primary endpoint was a composite device-oriented endpoint. The device thrombosis rate was also analyzed. Incidence of the primary endpoint (cardiac death, target vessel myocardial infarction and target lesion revascularization) was similar between BVS and the other two groups both at 30 days and at 1 year. Definite/probable device thrombosis incidence also did not significantly differ between the three groups (BVS 2.4%, DES 1.4%, BMS 1.7%), though the early scaffold thrombosis rate in BVS subjects was numerically higher [25]. 4) Randomized-controlled trials: To date, EVERBIO II is the only published randomized trial that has enrolled ACS patients treated with BVS (39% of enrolled ACS subjects) [26]. Overall, a total of 240 patients were randomly assigned 1 : 1 : 1 to the BVS, EES (Promus Element; Boston Scientific, Marlborough, Massachusetts) or Biolimus-eluting stent (Biomatrix Flex, Biosensors Europe SA, Morges, Switzerland) group. Nine-month late lumen loss as the primary endpoint did not differ between groups. There were no differences in patient and device-oriented endpoints. No stent thrombosis was reported in the DES group, whereas one possible late scaffold thrombosis was reported in the BVS arm. Based on these data, BVS implantation in ACS seems to be feasible. No definite conclusions may be drawn about scaffold thrombosis, due to discordance between the various studies, which are not powered for this endpoint. The data from ongoing registries and randomized trials will help to completely assess BVS safety and efficacy in ACS (Table II). Among the ongoing randomized trials, the ISAR-ABSORB-MI trial (NCT01942070) with an angiographic outcome at 9 months and the TROFI-II study (NCT01986803) with an optical coherence tomography derived endpoint at 6 months will shed light on the safety and midterm efficacy of these devices as compared to second generation DES.

Procedural aspects: bioresorbable vascular scaffolds limitations and technical tricks

Although preliminary clinical experience with BVS in ACS is promising, some technical limitations should be considered [27].
| Study Title | Study type/design | Number of patients | ACS (%) | Outcomes | Reference number |
|-------------|-------------------|--------------------|---------|----------|-----------------|
| AMC PCI Registry | Prospective, observational registry, open label patients who were enrolled according to operator's discretion | 135 | 39 | TVF (all-cause mortality, MI, TVR) at 6 months = 8.5% | [21] |
| ASSURE registry | Prospective, multi-center registry, that enrolled consecutive patients with lesion length ≥ 28 mm, vessel diameter between 2.0 and 3.3 mm | 183 | UA 21.3% STEMI 27% | MACE (cardiovascular death, MI, ischemia driven TLR) at 1 year = 5% | [22] |
| BVS-EXAMINATION Study | Retrospective, multi-center trial, comparing a cluster of STEMI-BVS consecutive patients with another two of STEMI-Xience/BMS patients (EXAMINATION population) | 290 | 100 | DOCE (cardiac death, TVR-MI, TLR) at 1 year BVS 4.1% vs. DES 4.1% – p = 0.994 BVS 4.1% vs. BMS 5.9% – p = 0.306 | [25] |
| BVS STEMI first study | Non randomized, prospective, single arm study | 49 | 100 | – MACE (cardiac death, any re-MI, emergent CABG, or clinically driven TLR) at 30 days = 2.6% – TVF (cardiac death, target-vessel MI, clinically driven TVR) at 30 days = 0% | [14] |
| EVERBIO II | Randomized, assessor-blinded, single center, all-comers study, comparing BVS with DES Promus Element and Biomatrix Flex (randomization ratio 1 : 1 : 1) | 240 | 39 | Late lumen loss at 9 months BVS 0.28 ±0.39 mm, DES 0.25 ±0.36 mm – p BVS/DES = 0.30 | [26] |
| GHOST-EU registry | Retrospective, multicenter registry, open label patients | 1189 | 47.4 | TLF (cardiac death, TV-MI, clinically driven TLR) at 6 months = 4.4% | [20] |
| Gori et al. | Prospective, consecutive ACS-patients randomized to BVS or Xience depending on operator’s discretion | 150 | 100 | MACE (death, non fatal MI, any PCI) at 30 days BVS 10.7%, DES 15.5% – p > 0.8 | [13] |
| Gori et al. | Clinical, angiographic, functional, and imaging outcomes 12 months after implantation of drug-eluting bioresorbable vascular scaffolds in acute coronary syndromes | 133 | 100 | Clinical outcomes: death 3%; scaffold thrombosis 3% | [17] |
| Kochman et al. | Single arm registry, open label patients with STEMI | 23 | 100 | Clinical adverse events at follow-up: 1 MI at 229 (199–248) days | [16] |
| Kajiy et al. | Registry, single group, STEMI patients who underwent PCI with intent of BVS | 11 | 100 | MACE (cardiac death, MI, TVR) at 1 month = 9.1% | [12] |
| POLAR ACS Study | Prospective, single group registry with consecutive patients presenting ACS | 100 | 100 | MACE (death, MI, clinically driven TLR) at 1 year = 2% | [19] |
| Prague 19 | Prospective registry, consecutive STEMI patients with lesion length < 24 mm, culprit vessel caliber between 2.3 and 3.7 mm | 41 | 100 | MACE (death, MI, TVR) at 6 months = 5% | [23] |
| Polish National Registry | Retrospective, single group, open label patients who had a previous PCI with BVS | 591 | 52 | Technical success (successful BVS delivery) 100%, dissection 2.9%, slow flow 0.5%, no-reflow 0.17%, side branch occlusion 0.33% | [18] |
| RAI registry | Prospective, single arm registry, open label lesions with 2.2 mm ≤ RVD ≤ 3.7 mm, depending on operator’s discretion | 74 | 100 | MACE (cardiac death, MI, TLR, BVS thrombosis) at 6 months = 8.1% | [24] |
| Wibe et al. | Registry, single group, STEMI patients who underwent PCI with intent of BVS | 25 | 100 | MACE (cardiac death, TV-MI, TVR) at 137.0 days (70.0–186.0) = 8.3% | [15] |

ACS – Acute coronary syndrome, BMS – bare metal stent, BVS – bioresorbable vascular scaffold, CABG – coronary artery bypass graft, DES – drug eluting stent, DOCE – device-oriented composite endpoint, MACE – major adverse cardiovascular event, MI – myocardial infarction, OCT – optical coherence tomography, PCI – percutaneous coronary intervention, RVD – reference vessel diameter, STEMI – ST-elevation myocardial infarction, TIMI – thrombolysis in myocardial infarction, TLF – target lesion failure, TLR – target lesion revascularization, TVF – target vessel failure, TV-MI – target vessel myocardial infarction, TVR – target vessel revascularization, TVr-MI – target vessel re-myocardial infarction, UA – unstable angina.
## Table II. On-going registry and randomized clinical trials — all data from www-clinicaltrials.gov

| Study title | Study type/design | Number of patients | ACS (%) | Outcomes | Status | Clinical trials number |
|-------------|-------------------|--------------------|---------|----------|--------|------------------------|
| ABSORB-ACS  | Prospective registry, open label patients | 300 | 100 | MACE (death, MI, TLR, TVR and scaffold thrombosis) at 30 days and 1 year | Recruiting | NCT02071342 |
| ABSORB BVS | Prospective, multicenter registry, open label patients with *de novo* coronary artery lesions | 1801 | Not provided | Cardiac death, TV-MI, ischemia driven TLR at 1 year | On-going, not recruiting | NCT01759290 |
| ABSORB UK  | Prospective, single arm, post-market registry | 1000 | Not provided | MACE (cardiac death, MI, ischemia driven TLR) at 1 and 3 years | Recruiting | NCT01977534 |
| AIDA       | Prospective, randomized (1 BVS: 1 Xience), single blinded, all-comers, non-inferiority trial | 2690 | Not provided | TVF (cardiac death, MI, TVR) at 2 years | Recruiting | NCT01858077 |
| Bioresorbable Vascular Scaffold in Patients With Myocardial Infarction | Prospective, randomized (BVS vs. Xience), open label trial | 100 | 100 | Procedural (BVS delivery with residual stenosis < 20%, TIMI 2-3 flow without major complications) and clinical (deaths, MACE, TV-R, urgent revascularization, stroke, major bleedings) success for the duration of hospital stay (4-8 days) | Completed, but results pending | NCT02151929 |
| BVS in STEMI | Prospective, randomized (BVS vs Xience), non-blinded, open label trial | 120 | 100 | Coronary Stent Healing Index at 1 year | Recruiting | NCT02067091 |
| BVS-RAI     | Prospective registry, open label patients younger than 75 years old and successful delivery of at least 1 BVS | 2000 | Not provided | Scaffold thrombosis and TLR at 1 year | Recruiting | NCT02298413 |
| CSI-Ulm-BVS | Non-randomized, single group, open label patients with planned delivery of at least 1 BVS | 2000 | Not provided | MACE at 10 years | Recruiting | NCT02162056 |
| FRANCE-ABSORB | Prospective, single arm, open label with French patients in *de novo* coronary lesions | 2000 | Not provided | MACE (death, MI, ischemia driven TLR, CABG) at 1 year | Recruiting | NCT0238054 |
| ISAR-Absorb MI | Prospective, randomized (BVS vs Xience), non-inferiority, open label patients with STEMI and planned stenting in vessels with 2.5 mm ≤ RVD ≤ 3.9 mm | 260 | 100 | Percentage diameter stenosis at coronary angiography at 6-8 months follow-up | Recruiting | NCT01942070 |
| IT-Disappears | Non-randomized, single group, open label patients with multivessel disease, or single lesions > 24 mm | 1000 | Not provided | MACE (cardiac death, non-fatal MI, clinically driven TLR) at 1 year | Recruiting | NCT02004730 |
| PROSPECT II & PROSPECT ABSORB | Multicenter, prospective, randomized (BVS treatment of vulnerable plaques vs. medical therapy) of patients with ACS and plaques prone to rupture and future clinical events | 900 | 100 | Patient level non-culprit lesion related MACE at 2 years (PROSPECT II) | Recruiting | NCT02171065 |
| REPARA Study | Prospective registry, patients with lesion length < 28 mm and 2.0 mm ≤ RVD ≤ 3.8 mm | 1500 | Not provided | MACE (cardiac death, MI, ischemia driven TLR) at 1 year | Recruiting | NCT02256449 |
| TROFI II Study | Prospective, randomized (1 BVS: 1 Xience), single blinded, non-inferiority trial | 190 | 100 | Healing Score evaluated by OCT at six months | Ongoing, follow-up phase | NCT01986803 |

ACS — Acute coronary syndrome, BVS — Bioresorbable vascular scaffold, CABG — coronary artery bypass graft, MACE — major adverse cardiovascular event, MI — myocardial infarction, MLA — minimal lumen area, OCT — optical coherence tomography, RVD — reference vessel diameter, STEMI — ST-elevation myocardial infarction, TIMI — thrombolysis in myocardial infarction, TLR — target lesion revascularization, TVF — target vessel failure, TV-MI — target vessel myocardial infarction, TVR — target vessel revascularization.
Due to low polymer radial strength, optimal lesion preparation is mandatory; when inflated balloons are not well expanded, lesion preparation should be improved with short high-pressure balloons [27, 28]. However, pre-dilation prolongs the procedural time and fluoroscopy time and increases the volume of contrast administered. This is an important issue especially in hemodynamically unstable patients (for example “last remaining vessel patients”), in whom the need for pre-, post-dilatation and prolonged scaffold inflation can be an important limitation. In any case, direct scaffolding is feasible (32.7% in the BVS STEMI first study), but there are no data on outcome [12–26].

Post-dilatation is also an important step, and it has to be performed with a non-compliant balloon in a balloon-artery ratio of 1 : 1, the size of the implanted BVS not exceeding 0.5 mm [29].

Scaffold thrombosis appeared to be the most important limitation of polymeric scaffolds in the early phase after implantation [20, 25, 30] (Figure 1). It can be linked

**Figure 1.** A case of acute scaffold thrombosis. A 46-year-old man was admitted due to an inferior ST-elevation myocardial infarction (STEMI). Coronary angiography showed a ruptured plaque on the right coronary artery (A). Thrombectomy was performed and an Absorb bioresorbable vascular scaffold (BVS) 3.0/18 mm was successfully implanted (B). Two hours later, the patient presented with an acute scaffold thrombosis (C). After thrombectomy and Abciximab administration, post-dilatation with a non-compliant balloon 3.25/12 mm was performed, with good final angiographic results (D)
to several factors. First, current generation BVS present a rather bulky structure (strut thickness $\approx 150 \mu\text{m}$) [31]. Acute and chronic inflammatory reaction following BVS implantation could also play a role [32]. The presence of a high thrombus burden in the context of STEMI and post-procedure enhanced platelet reactivity could facilitate the thrombosis [33]. Some procedure-related factors, such as acute incomplete apposition or inappropriate vessel sizing, could also be taken into account [33, 34] (Figure 2). Vasocostriction of coronary arteries and the presence of thrombus are common features in the context of ACS. These features should be taken into consideration to correctly select the scaffold size [27]. In this scenario, several thrombectomy crossings and the use of intracoronary nitrates may be helpful. Although routine use of thrombectomy did not demonstrate any clinical benefit [1, 35], when BVS implantation in ACS is planned, the use of a manual aspiration catheter may provide an additional value beyond thrombus removal and BVS sizing, for example in prediction of lesion crossability by BVS [27].

The use of intracoronary imaging is encouraged especially during the initial implants. Intravascular ultrasound imaging may facilitate correct balloon and scaffold sizing as well as evaluation of BVS expansion. Optical coherence tomography may obtain more accurate images of BVS integrity, apposition and presence of residual thrombus or edge dissections [27].

The antiplatelet regimen is another critical issue of BVS in ACS. Although no specific recommendations are given in the guidelines [1], it is advisable to optimize the antithrombotic regimen in the acute phase (i.e. use of IIb/IIIa inhibitors) and to use the most potent oral agents available (prasugrel or ticagrelor). Regarding the duration of double antiplatelet therapy (DAPT) the evidence is still lacking, as the latest trials testing shortening of DAPT do not apply to BVS [36, 37]. Twelve months is recommended for ACS patients, according to current guidelines [1]. However, in the case of complex procedures, with multiple overlapping scaffolds, for example, it may be recommended to prolong DAPT [38].

### Future bioresorbable vascular scaffolds developments in acute coronary syndrome

Current CE-approved BVS are the Absorb (Abbott Vascular, Santa Clara, CA, USA) and the DESolve (Elixir Medical Corporation, Sunnyvale, CA, USA) [39]. Both are made of poly-lactic acid and have strut thickness of 150 µm.

The DESolve [40, 41] has a larger range of expansion than the BVS, with the peculiarity of “self-correction” acute recoil. In the first-in-man study it showed good efficacy and safety in 16 enrolled subjects (stable angina
patients 68.8%, unstable angina subjects 0.0%). No device-related MACE at one year were reported. No data on ACS are currently available. Among on-going trials with the DESolve, only the DESolve X-Pand Global Post Market Registry (NCT02453035) [42] is recruiting patients with acute myocardial infarction. This is a prospective, single-arm, multi-center, observational registry, aiming to assess clinical outcome with Elixir BVS in the “real world”. The primary outcome is the MACE (cardiac death, target vessel myocardial infarction and target lesion revascularization) rate at 1-year clinical follow-up. Scaffold thrombosis is also assessed.

New BVS platforms are currently under development, aiming to reduce strut thickness and improve scaffold distensibility (Table III). Drug kinetics, materials and bioresorption rate will also differ. Therefore, accurate knowledge of the new devices and future trials to test the safety and efficacy of second generation BVS are warranted.

**Conclusions**

Clinical experience of BVS implantation in ACS is currently limited. Available data suggest good acute and midterm performance. Lesion preparation, adequate vessel sizing (including with the use of intravascular imaging techniques), attention to BVS expansion limits, post-dilation and importance of optimized DAPT are mainstays of BVS PCI [27, 43].

The early scaffold thrombosis rate appears to be higher than expected in a few registries. In this regard, large-scale randomized trials with long-term follow-up will determine the potential and limitations of the current generation BVS in this context.

Finally, the new generation BVS may overcome most of the current technical pitfalls and may therefore improve clinical outcomes.

**Conflict of interest**

The authors declare no conflict of interest.

**References**

1. Authors/Task Force members, Windecker S, Kolh P, Alfonso F, et al. 2014 ESC/EACTS Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J 2014; 35: 2541-619.

2. Serruys PW, Garcia-Garcia HM, Onuma Y. From metallic cages to transient bioresorbable scaffolds: change in paradigm of coronary revascularization in the upcoming decade? Eur Heart J 2012; 33: 16-25b.
3. Hong MK, Mintz GS, Lee CW, et al. Incidence, mechanism, predictors, and long-term prognosis of late stent malapposition after bare-metal stent implantation. Circulation 2004; 109: 881-6.

4. Hong MK, Mintz GS, Lee CW, et al. Late stent malapposition after drug-eluting stent implantation: an intravascular ultrasound analysis with long-term follow-up. Circulation 2006; 113: 414-9.

5. Ormiston JA, Serruys PW, Regar E, et al. A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial. Lancet 2008; 371: 899-907.

6. Scalone G, Brugaletta S, Gómez-Monterrozas Q, et al. Bioresorbable scaffolds: focus on vascular response and long-term safety. Panminerva Med 2015; 57: 1-13.

7. Brugaletta S, Radu MO, García-García HM, et al. Circumferential evaluation of the neointima by optical coherence tomography after ABSORB bioresorbable vascular scaffold implantation: can the scaffold cap the plaque? Atherosclerosis 2012; 22: 106-12.

8. Karanasos A, Simsek C, Gnanadesigan M, et al. OCT assessment of the long-term vascular healing response 5 years after everolimus-eluting bioresorbable vascular scaffold. J Am Coll Cardiol 2014; 64: 2343-56.

9. Brugaletta S, Heo JH, García-García HM, et al. Endothelial-dependent vasomotion in a coronary segment treated by ABSORB everolimus-eluting bioresorbable vascular scaffold is related to plaque composition at the time of biodesorption of the polymer: indirect finding of vascular reparative therapy? Eur Heart J 2012; 33: 1325-33.

10. Serruys PW, Chevallier B, Dudek D, et al. A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent for ischaemic heart disease caused by de-novo native coronary artery lesions (ABSORB II): an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial. Circ 2015; 385: 43-54.

11. Scalone G, Brugaletta S, Gómez-Monterrozas Q, et al. ST-segment elevation myocardial infarction – ideal scenario for bioresorbable vascular scaffold implantation? Circ J 2015; 79: 263-70.

12. Kajtya T, Liang M, Sharmar RK, et al. Everolimus-eluting bioresorbable vascular scaffold (BVS) implantation in patients with ST-segment elevation myocardial infarction (STEMI). EuroIntervention 2013; 9: 501-4.

13. Gori T, Schulz E, Hink U, et al. Early outcome after implantation of absorbable drug-eluting scaffolds in patients with acute coronary syndromes. EuroIntervention 2014; 10: 1036-41.

14. Diletti R, Karanasos A, Muramatsu T, et al. Everolimus-eluting bioresorbable vascular scaffolds for treatment of patients presenting with ST-segment elevation myocardial infarction: BVS STEMI first study. Eur Heart J 2014; 35: 777-86.

15. Wiebe J, Möllmann H, Most A, et al. Short-term outcome of patients with ST-segment elevation myocardial infarction (STEMI) treated with an everolimus-eluting bioresorbable vascular scaffold. Clin Res Cardiol 2013; 103: 141-8.

16. Kochman J, Tomanik M, Pietrasik A, et al. Bioresorbable everolimus-eluting vascular scaffold in patients with ST-segment elevation myocardial infarction: optical coherence tomography evaluation and clinical outcomes. Cardiol J 2014. doi: 10.5603/CJ.a2014.0090. [Epub ahead of print]

17. Gori T, Schulz E, Hink U, et al. Clinical, angiographic, functional, and imaging outcomes 12 months after implantation of drug-eluting bioresorbable vascular scaffolds in acute coronary syndromes. JACC Cardiovasc Interv 2015; 8: 770-7.

18. Rzeszutko Ł, Siudał Z, Włodarczak A, et al. Use of bioresorbable vascular scaffolds in patients with stable angina and acute coronary syndromes. Polish National Registry. Kardiol Pol 2014; 72: 1394-9.

19. Dudek D, Rzeszutko Ł, Zasada W, et al. Bioresorbable vascular scaffolds in patients with acute coronary syndromes: the POLAR ACS study. Pol Arch Med Wewn 2014; 124: 679-77.

20. Capodanno D, Gori T, Net H, et al. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffold: routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry. Eurointervention 2014. pii: 20140707-06. doi: 10.4244/EIJY14M07_11 [Epub ahead of print].

21. Kraak RP, Hassell ME, Grundeken MJ, et al. Initial experience and clinical evaluation of the absorb bioresorbable vascular scaffold (BVS) in real-world practice: the AMC Single Centre Real World PCI Registry. Eurointervention 2014. pii: 20140316-04. doi: 10.4244/EIJY14M08_08. [Epub ahead of print].

22. Wöhrlie J, Naber C, Schmitz T, et al. Beyond the early stages: insights from the ASSURE registry on bioresorbable vascular scaffolds. Eurointervention 2014. pii: 20140906-04. doi: 10.4244/EIJY14M12_10. [Epub ahead of print].

23. Kočka V, Malý M, Toušek R, et al. Bioresorbable vascular scaffolds in acute ST-segment elevation myocardial infarction: a prospective multicentre study ‘Prague 19’. Eur Heart J 2014; 35: 787-94.

24. Ielasi A, Cortese B, Varricchio A, et al. Immediate and midterm outcomes following primary PCI with bioresorbable vascular scaffold implantation in patients with ST-segment myocardial infarction: insights from the multicentre “Registro ABSORB Italiano” (RAI registry). Eurointervention 2014. pii: 20140629-04. doi: 10.4244/EIJY14M11_11. [Epub ahead of print].

25. Brugaletta S, Gori T, Low AF, et al. Absorb bioresorbable vascular scaffold versus everolimus-eluting metallic stent in ST-segment elevation myocardial infarction: 1-year results of a propensity score matching comparison: the BVS-EXAMINATION Study (Bioresorbable Vascular Scaffold-A Clinical Evaluation of Everolimus Eluting Coronary Stents in the Treatment of Patients With ST-segment Elevation Myocardial Infarction). JACC Cardiovasc Interv 2015; 8: 189-97.

26. Puricel S, Arroyo D, Corpataux N, et al. Comparison of everolimus- and biolimus-eluting coronary stents with everolimus-eluting bioresorbable vascular scaffolds. J Am Coll Cardiol 2015; 65: 791-801.

27. Tamburino C, Latib A, van Geuns RJ, et al. Contemporary practice and technical aspects in coronary intervention with bioresorbable scaffolds: a European perspective. Eurointervention 2015; 11: 45-52.

28. Brown AJ, McCormick LM, Braganza DM, et al. Expansion and malapposition characteristics after bioresorbable vascular scaffold implantation. Catheter Cardiovasc Interv 2014; 84: 37-45.

29. Mattesini A, Secco GG, D’Ara G, et al. ABSORB biodegradable stents versus second-generation metal stents: a comparison study of 100 complex lesions treated under OCT guidance. JACC Cardiovasc Interv 2014; 7: 741-50.

30. Fernández-Rodríguez D, Brugaletta S, Otsuki S, et al. Acute absorb and procedural secondary outcomes from a randomised controlled trial. JACC Cardiovasc Interv 2014; 7: 741-50.

31. Kolandaivelu K, Swaminathan R, Gibson WJ, et al. Stent thrombogenicity early in high-risk interventional settings is driven by...
stent design and deployment and protected by polymer-drug coatings. Circulation 2011; 123: 1400-9.

32. Otsuka F, Pacheco E, Perkins LE, et al. Long-term safety of an everolimus-eluting bioresorbable vascular scaffold and the cobalt-chromium XIENCE V stent in a porcine coronary artery model. Circ Cardiovasc Interv 2014; 7: 330-42.

33. Kirtane AJ, Stone GW. How to minimize stent thrombosis. Circulation 2011; 124: 1283-7.

34. Brown AJ, McCormick LM, Braganza DM, et al. Expansion and malapposition characteristics after bioresorbable vascular scaffold implantation. Catheter Cardiovasc Interv 2014; 84: 37-45.

35. Jolly SS, Cairns JA, Yusuf S, et al.; TOTAL Investigators. Randomized trial of primary PCI with or without routine manual thrombectomy. N Engl J Med 2015 Mar 16 [Epub ahead of print].

36. Valgimigli M, Campo G, Monti M, et al.; Prolonging Dual Anti-platelet Treatment After Grading Stent-Induced Intimal Hyperplasia Study (PRODIGY) Investigators. Short- versus long-term duration of dual-antiplatelet therapy after coronary stenting: a randomized multicenter trial. Circulation 2012; 125: 2015-26.

37. Valgimigli M, Patialiakas A, Thury A, et al.; ZEUS Investigators. Zotarolimus-eluting versus bare-metal stents in uncertain drug-eluting stent candidates. J Am Coll Cardiol 2015; 65: 805-15.

38. Ishibashi Y, Onuma Y, Muramatsu T, et al.; ABSORB EXTEND Investigators. Lessons learned from acute and late scaffold failures in the ABSORB EXTEND trial. EuroIntervention 2014; 10: 449-57.

39. Wiebe J, Nef HM, Hamm CW. Current status of bioresorbable scaffolds in the treatment of coronary artery disease. J Am Coll Cardiol 2014; 64: 2541-51.

40. Verheye S,Ormiston JA, Stewart J, et al. A next-generation bioresorbable coronary scaffold system: from bench to first clinical evaluation: 6- and 12-month clinical and multimodality imaging results. JACC Cardiovasc Interv 2014; 7: 89-99.

41. Ormiston JA, Webber B, Ubod B, et al. An independent bench comparison of two bioresorbable drug-eluting coronary scaffolds (Absorb and DESolve) with a durable metallic drug-eluting stent (ML8/Xpedition). EuroIntervention 2015 Feb 16. pii: 20141214-03. doi: 10.4244/EIJY15M02_03 [Epub ahead of print].

42. DESolve® X-Pand Global Post Market Registry Data from ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/study/NCT02453035?term=elixir+coronary&rank=6

43. Everaert B, Felix C, Koolen J, et al. Appropriate use of bioresorbable vascular scaffolds in percutaneous coronary interventions: a recommendation from experienced users: a position statement on the use of bioresorbable vascular scaffolds in the Netherlands. Neth Heart J 2015; 23: 161-5.