Review paper

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 H_2O and CO_2. 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

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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 bioresorption 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 at 6-month follow-up [13]. Wiebe *et al.* also evaluated in a single-center fashion the performance of BVS in ST-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 mm^2 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 BVS 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].

Table I. Published registries and trials

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, TVre-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]
Kajiya *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]
Wiebe *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, TVre-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, re-MI, 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	NCT02238054
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. optical 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) – MLA in vessel with vulnerable plaques at 2 years (PROSPECT ABSORB)	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

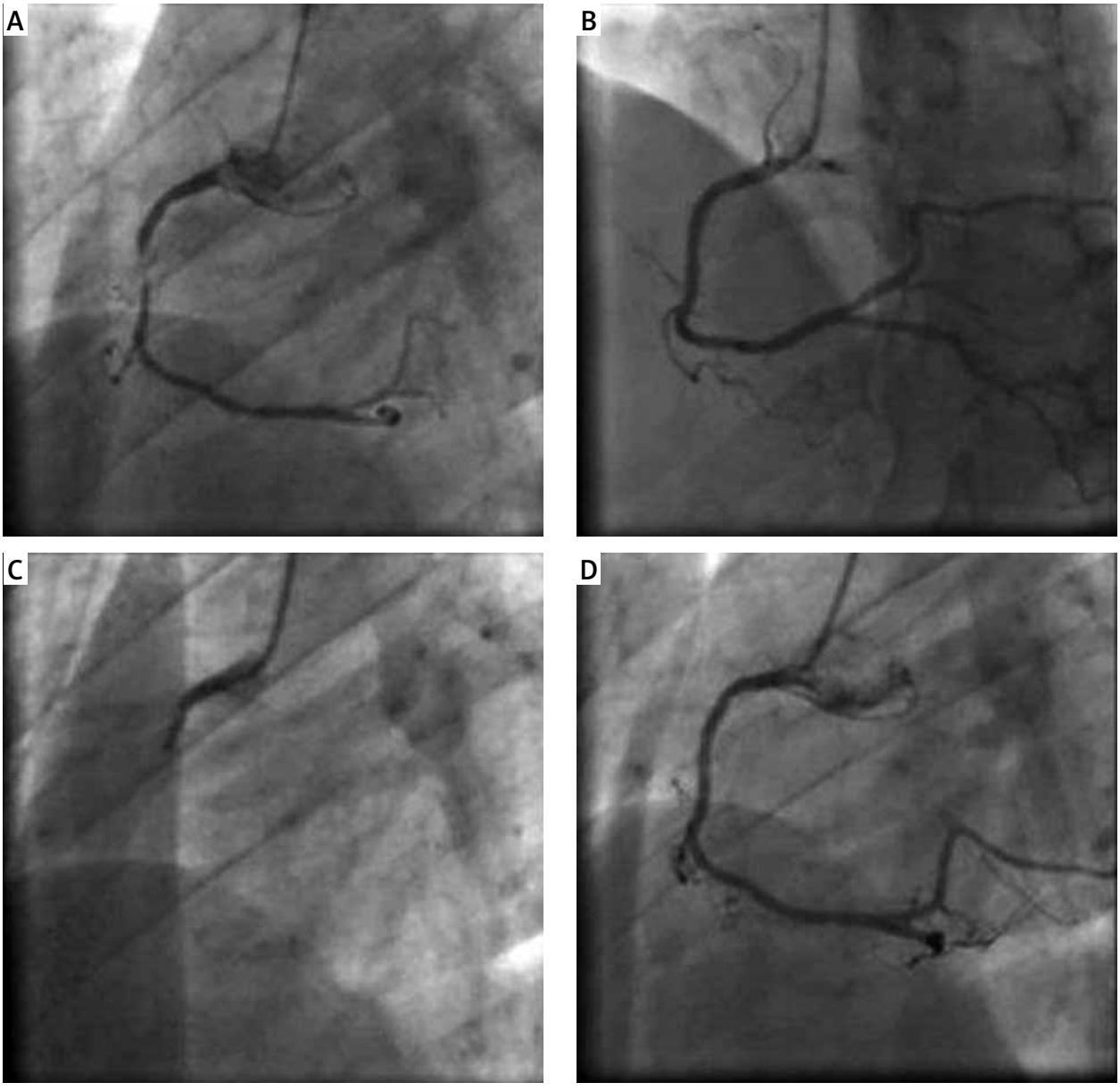

Figure 1. A case of acute scaffold thrombosis. A 46-year-old man was admitted due to an inferior ST-elevation myocardial infarction (STEMI). Coronary angiography showed a ruptured plaque on the right coronary artery (**A**). Thrombectomy was performed and an Absorb bioresorbable vascular scaffold (BVS) 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**)

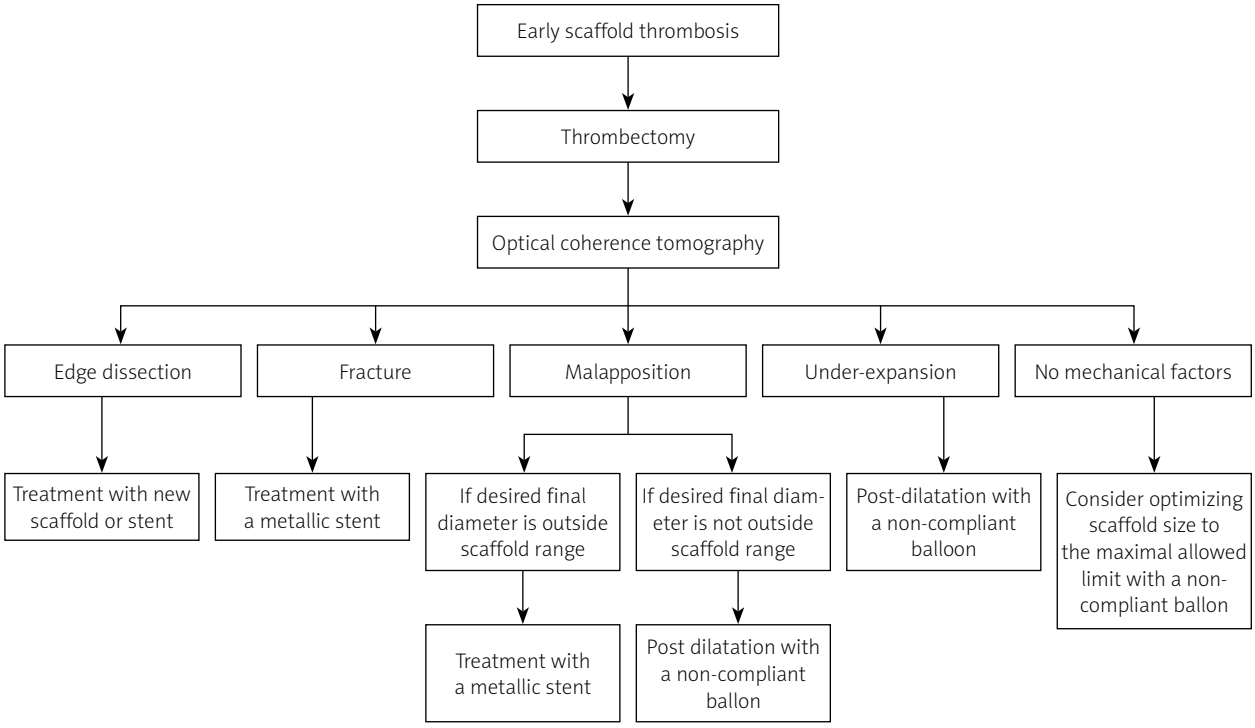

Figure 2. Algorithm for treatment of early scaffold thrombosis. Early scaffold thrombosis can be treated with stent implantation or not. A stent should be implanted in case of scaffold fracture or when the final desired diameter is beyond the BVS scale. Conversely, scaffold post-dilatation can be a good option when the final desired diameter is within the BVS range, when the BVS in under-expanded, or when no mechanical issue can be detected (adapted from reference [27])

to several factors. First, current generation BVS present a rather bulky structure (strut thickness ≈ 150 µm) [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). Vasoconstriction 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

Table III. Bioresorbable scaffolds in clinical development. Data from TCTmd slide presentations, BVS 2014 meeting: http://www.tctmd.com/list.aspx?fid=968379

Scaffold	Strut thickness	Distensibility
Poly-lactic acid platform		
ArterioSorb (Arterius, Bradford, UK)	< 150 µm up to 3.5 mm size	No
DESolve AMI (Elixir Medical Corporation, Sunnyvale, CA, USA)	100 µm	Self-correct to 0.25 mm above nominal diameter
Fortitude (Amaranth Medical, Mountain View, CA, USA)	120 µm	Possible 1 mm over-expansion
MeRes (Meril Lifescience, Vapi, Gujarat, India)	100 µm	No
Mirage Microfiber Scaffold (ManLi Cardiology, Singapore, Republic of Singapore)	125 µm up to 3.0 mm size	No
Tyrosine polycarbonate alloy		
REVA Fantom (Reva Medical Inc., San Diego, CA, USA)	125 µm	One of 3.0 mm caliber can be post-dilated up to 4.87 mm
REVA ReZolve (Reva Medical Inc., San Diego, CA, USA)	122 µm	Not reported
Magnesium structure		
AMS series (Biotronik, Berlin, Germany)	No (165 µm)	Allowed > 2.0 mm post-dilatation
DREAMS series (Biotronik, Berlin, Germany)	120 µm for DREAMS 1.0	Allowed > 2.0 mm post-dilatation
Nitride iron-based framework		
Iron-based Biocorrodible Scaffold (Lifetech Scientific Corporation, Shenzhen, China)	70 µm	Not reported

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-dilatation 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.

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