ORIGINAL ARTICLE

Direct Absorb bioresorbable scaffold implantation in acute coronary syndrome

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A b s t r a c t

Background: Direct stent implantation is a preferred technique for primary percutaneous coronary intervention (PCI). For the deployment of a bioresorbable vascular scaffold (BVS), the current guidelines recommend aggressive predilatation. Data about direct BVS implantation in patients with acute coronary syndrome (ACS) are scarce.

Aim: We sought to assess procedural characteristics and immediate outcomes of direct Absorb BVS implantation in ACS patients.

Methods: A total of 91 patients with acute myocardial infarction (MI) requiring urgent coronary revascularisation were enrolled. Among them, 50 patients underwent an attempt of direct Absorb implantation. The control group consisted of 41 patients treated with PCI with BVS deployment after elective predilatation.

Results: In the direct group BVS deployment was successful in 91% of lesions, and in the remaining 9% of lesions direct implantation failed. In the control group scaffolds were successfully deployed after predilatation in 98% of lesions. In one case Absorb implantation failed even after balloon angioplasty. Type C lesions with severe tortuosity and angulation > 90° were associated with failure in direct Absorb deployment. Quantitative coronary analysis showed similar final percentages of diameter stenosis in the study and control groups. Flow analyses did not show significant differences between both methods. During hospitalisation no recurrent MI, scaffold thrombosis, or target lesion revascularisation was reported in either group.

Conclusions: Direct Absorb implantation in ACS patients may be feasible in a suitable lesion anatomy.

Key words: acute coronary syndrome, angioplasty, direct stenting, bioresorbable vascular scaffold

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INTRODUCTION

Absorb is an everolimus-eluting bioresorbable vascular scaffold (BVS; Abbott Vascular, Santa Clara, CA, USA). Current recommendation for BVS implantation is plaque preparation with adequate predilatation [1, 2]. On the other hand, in the setting of large thrombus burden, aggressive predilatation may result in an increased risk of distal embolisation and subsequent flow deterioration [3]. There are scarce data in terms of the feasibility and safety of direct stenting with Absorb BVS [4, 5]. So far, there has been no specific evaluation of this approach in patients presenting with acute coronary syndrome (ACS). The aim of the current study was to assess procedural characteristics and angiographic results of direct BVS deployment in ACS patients.

METHODS

Study population and procedure

The presented single-centre study is an analysis of 91 patients with acute myocardial infarction (MI) treated with primary percutaneous coronary intervention (PCI) with Absorb BVS implantation. A total of 50 patients underwent an attempt of direct Absorb implantation. The control group consisted of 41 patients treated with PCI with Absorb deployment after elective predilatation. Angiographic data were assessed by an

Table 1. Demographic and baseline clinical characteristics

	Direct (50 patients)	Predilatation (41 patients)	p
Age [years]	60 ± 10	60 ± 12	0.8
Male sex	38 (76)	36 (88)	0.2
STEMI	19 (38)	12 (29)	0.5
LVEF [%]	55 (Q1: 45; Q3: 60)	55 (Q1: 47; Q3: 60)	0.5
Previous PCI	2 (4)	4 (10)	0.4
Hypertension	32 (64)	23 (56)	0.5
Hyperlipidaemia	29 (58)	20 (49)	0.4
Diabetes	11 (22)	5 (12)	0.3

Data are presented as number (percentage), mean ± standard deviation, or median (interquartile range). LVEF — left ventricular ejection fraction; PCI — percutaneous coronary intervention; STEMI — ST-segment elevation myocardial infarction

independent core laboratory. The study was approved by the Institutional Board of Ethics. Inclusion criteria comprised acute MI and referral for primary PCI with BVS implantation after a diagnostic coronary angiography. All procedures were carried out by three experienced operators (more than 1000 PCIs in ACS each). The decision whether to perform direct implantation of the Absorb or to precede it with balloon angioplasty was made by the operator after careful examination of the culprit lesion anatomy. The sizes of the chosen scaffolds and balloons for predilatation and postdilatations, inflation pressures, and the use of manual aspiration thrombectomy catheters as well as additional imaging tools such as intravascular ultrasonography (IVUS) or optical coherence tomography (OCT) were also left to the operator's discretion.

Angiographic assessment

All collected angiograms were sent to an independent Core Laboratory (KCRI, Krakow, Poland) and were examined by an analyst with experience in the evaluation of different bioresorbable platforms. Qualitative and quantitative analyses were performed using CAAS V 2.1.12.2 software (Pie Medical, Maastricht, Netherlands). Standard stent parameters were analysed: minimal lumen diameter, reference vessel diameter (RVD), per cent diameter stenosis (%DS), acute gain, and acute recoil. The following angiographic flow parameters were examined before and after PCI of the infarct-related artery: epicardial antegrade flow using the Thrombolysis In Myocardial Infarction (TIMI) scale and corrected TIMI frame counts (cTFC) using standard landmarks for each artery. The American College of Cardiology/American Heart Association classification was used to define the lesions' anatomy [6].

Statistical analysis

Quantitative variables were presented using mean and standard deviation (for normal distribution of data) or median with interquartile range (for non-normal distribution of data), where applicable. Categorical variables were presented as numbers and percentages. The Mann-Whitney U test (for non-normal

distribution of data) or unpaired (two-sample) Student t test (for normally distributed data) were applied for continuous variables. The χ^2 test was used for categorical (nominal and dichotomous) variables. The level of statistical significance was set at p-value < 0.05. All analyses were performed with SPSS Statistics 24 (IBM, Inc., Armonk, NY, USA).

RESULTS

Clinical data are shown in Table 1. Most of the patients were male, and the most common clinical presentation was non-ST-segment elevation MI (NSTEMI). There were no significant differences in demography and coronary artery disease risk factors between both groups (Table 1). Baseline angiographic analysis showed no significant differences in lesion length, RVD, and %DS between the direct and predilatation groups. However, type C lesions with severe calcifications were more common in the predilatation arm. In the direct group, total occlusion and thrombus in target lesion were more frequent (Table 2). Absorb deployment was successful in 91% of lesions in this group. In the remaining 9% of lesions direct implantation failed. In these cases, the system was gently retrieved and inserted again within a relatively short period of time (max 2 min) after predilatation. In the control group scaffolds were successfully implanted in 98% of lesions. In one patient the delivery of Absorb scaffold was unsuccessful even after balloon preparation. In this case a regular metallic drug-eluting stent (DES) was successfully deployed. Type C lesions with severe tortuosity and angulation > 90° were associated with failure in direct Absorb deployment (Table 3).

During PCI, the use of extra-support coronary wires was more frequent in the predilatation arm. Postdilatation was performed in 94% of lesions from the direct group and in 79% of lesions from the predilatation arm (p = 0.04). Mean postdilatation pressure was 18 atm in both groups. Thrombectomy was performed in 48% of cases in the direct group and 13% of cases in the predilatation arm (p < 0.001). Predilatation with a small-size balloon (1.5 or 2.0 mm) for initial opening of the artery was performed in 17% of cases in the predilatation arm.

Table 2. Baseline angiographic characteristics

	Direct (53 lesions)	Predilatation (48 lesions)	p
Left anterior descending location	20 (38)	23 (48)	0.3
Type C lesion	7 (13)	16 (33)	0.016
Severe tortuosity	5 (9)	6 (12)	0.7
Severe calcifications	0 (0)	5 (10)	0.018
Angulation > 90°	5 (9)	6 (12)	0.7
Lesion length [mm]	13.3 (Q1: 10; Q3: 16)	15.7 (Q1: 11; Q3: 21)	0.3
Minimal lumen diameter [mm]	0.65 (Q1: 0; Q3: 1.03)	0.78 (Q1: 0.13; Q3: 1.16)	0.1
Reference vessel diameter [mm]	2.8 ± 0.5	2.7 ± 0.6	0.3
Diameter stenosis [%]	78 (Q1: 59; Q3: 100)	67 (Q1: 54; Q3: 94)	1.0
Corrected TIMI frame count	100 (Q1: 30; Q3: 100)	30 (Q1: 24; Q3: 100)	0.02
Total occlusion	24 (45)	11 (23)	0.018
Thrombus in target lesion	34 (64)	15 (31)	0.001

Data are presented as percentage (number), mean ± standard deviation, or median (interquartile range). TIMI — Thrombolysis in Myocardial Infarction

Table 3. Lesion characteristics in groups with successful and failed direct Absorb deployment

	Successful (48 lesions)	Failed (5 lesions)	p
Type C lesion	4 (8)	3 (60)	0.013
Severe tortuosity	2 (4)	3 (60)	0.004
Angulation > 90°	2 (4)	3 (60)	0.004
Irregular contour	24 (29)	1 (20)	1.0
Eccentric shape	16 (33)	1 (20)	1.0
Total occlusion	21 (44)	3 (60)	0.6
Thrombus in target lesion	31 (64)	3 (60)	1.0

Data are presented as number (percentage).

In the direct implantation group the procedural and radiation times were significantly shorter and the amount of contrast and radiation dose were significantly lower, compared to patients from the conventional scaffold implantation group (Table 4).

Final flow analysis did not show significant differences between both groups, TIMI 3 flow grade was achieved in 98% of cases in the direct arm and in 94% of cases in the predilatation group. There was no difference in final cTFC between both groups. No-reflow occurred in one case from the predilatation group. Slow-flow occurred in two patients from the direct implantation arm and in two patients from the predilatation arm. Acute gain was significantly higher in the direct group. There were no significant differences in terms of dissection complications, side branch occlusion, and embolisation (Table 5). STEMI patients presented higher baseline %DS, with more frequent total occlusion and thrombus in the target lesion and also higher acute gain and lower %DS after PCI compared to NSTEMI patients (Table 6).

During hospitalisation no recurrent MI, scaffold thrombosis, or target lesion revascularisation was reported in either group.

DISCUSSION

Initially, in the metallic stent era, balloon predilatation was a mandatory procedure before stent deployment. However, aggressive predilatations carry additional risk of plaque disruption, thrombus mobilisation, and distal embolism with subsequent flow deterioration [3]. Despite restoration of epicardial blood flow, tissue reperfusion often remains suboptimal. Over the years, mechanical and pharmacological strategies have been developed to increase myocardial salvage during PCI, including direct stenting, mesh-covered stents, thrombectomy, and glycoprotein IIb/IIIa inhibitors [3]. Several studies showed that direct stent implantation is associated with the reduction of flow disturbances after primary PCI, better ST-segment resolution as well as better survival at 30 days and one year

Table 4. Procedural characteristics of percutaneous coronary intervention with Absorb deployed directly and after predilatation

	Direct (48 lesions)	Predilatation (52 lesions)	p
Radial access	31 (65)	31 (60)	< 0.001
Procedure time [min]	28 ± 11	40 ± 19	0.003
Fluoroscopy time [min]	9.6 ± 5.3	13.9 ± 8	0.006
Contrast dye used [mL]	126 ± 66	163 ± 77	0.006
Radiation dose [Gy]	1.08 ± 0.72	1.33 ± 0.62	0.039
Glycoprotein IIb/IIIa antagonists	19 (39)	14 (27)	0.2
Number of coronary wires	1.23 ± 0.42	1.7 ± 1.0	0.01
Extra-support coronary wires	1 (2)	14 (27)	< 0.001
Additional back-up catheters	23 (48)	26 (50)	1.0
Scaffold length [mm]	18 (Q1: 18; Q3: 23)	23 (Q1: 18; Q3: 28)	0.016
Scaffold diameter [mm]	3.5 (Q1: 3; Q3: 3.5)	3.0 (Q1: 3; Q3: 3,5)	0.1
Scaffold implantation pressure [atm]	14 (Q1:12; Q3: 16)	14 (Q1: 12; Q3: 16)	0.4
Postdilatation balloon diameter [mm]	3.6 (Q1: 3.2; Q3: 4)	3.5 (Q1: 3.2; Q3: 4)	0.3
Postdilatation pressure [atm]	18 (Q1: 16; Q3: 20)	18 (Q1: 16; Q3: 20)	0.3
Thrombectomy	23 (48)	7 (13)	< 0.001

Data are presented as number (percentage), mean ± standard deviation, or median (interquartile range).

Table 5. Final angiographic results of percutaneous coronary intervention with Absorb implanted directly and after predilatation

	Direct (48 lesions)	Predilatation (52 lesions)	p
Acute gain [mm]	1.89 ± 0.7	1.59 ± 0.7	0.036
Acute recoil [mm]	0.32 ± 0.23	0.29 ± 0.20	0.8
Diameter stenosis [%]	12.2 ± 6.1	12.7 ± 7.6	0.7
TIMI 3 flow grade	47 (98)	49 (94)	0.5
Corrected TIMI frame count	16 (Q1: 12; Q3: 22)	18 (Q1: 14; Q3: 24)	0.3
Slow-flow	2 (4)	2 (4)	1.0
No-reflow	0 (0)	1 (2)	1.0
Side branch occlusion	1 (2)	1 (2)	1.0
Side branch embolisation	1 (2)	1 (2)	1.0
Distal embolisation	0 (0)	1 (2)	1.0
Dissection	3 (6)	8 (15)	0.2
Bail-out stenting	2 (4)	6 (12)	0.3

Data are presented as number (percentage), mean ± standard deviation, or median (interquartile range). TIMI — Thrombolysis in Myocardial Infarction

Table 6. Differences between ST-segment elevation myocardial infarction (STEMI) and non-ST-segment elevation myocardial infarction (NSTEMI) groups

	STEMI (36 lesions)	NSTEMI (65 lesions)	p
Type C lesions	8 (22)	15 (23)	1.0
Thrombus in target lesion	26 (72)	24 (35)	0.002
Total occlusion	22 (61)	13 (20)	< 0.001
Baseline diameter stenosis [%]	100 (Q1: 72; Q3: 100)	64 (Q1: 54; Q3: 83)	< 0.001
Final diameter stenosis [%]	10 ± 7	13 ± 7	0.036
Final TIMI 3 flow grade	34 (94)	62 (95)	1.0
Acute gain [mm]	2.1 ± 0.6	1.6 ± 0.7	< 0.001
Acute recoil [mm]	0.32 ± 0.20	0.30 ± 023	0.8

Data are presented as number (percentage), mean ± standard deviation, or median (interquartile range). TIMI — Thrombolysis in Myocardial Infarction

[7–10]. Another strategy designed to reduce distal embolisation is the use of a MGuard™ bare metal mesh-covered stent, which traps the potentially embolic material at the level of the culprit lesion. However, the use of mesh-covered stents is limited due to lack of anti-proliferative drugs. They should also be avoided in bifurcation and highly tortuous or calcified lesions [3, 11]. Routine thrombectomy is currently not recommended in primary PCI, but in the presence of large thrombotic burden it may be considered, also with the direct stenting technique [12, 13]. Glycoprotein IIb/IIIa inhibitors are strong antiplatelet agents, which could be used in patients with high risk of ischaemic events (large thrombotic burden) and angiographic complications (distal embolisation, no-reflow phenomenon) [14].

Currently, direct DES implantation is a preferable technique for primary PCI in the ACS setting in suitable coronary anatomy. However, the permanent metallic platform of regular DESs also has some limitations, including impaired vasomotion, reduced potential for vessel remodelling, chronic inflammation processes, and late thrombosis [15]. BVSs were designed to target the limitations of regular DESs with restored vasomotion, arterial remodelling, and late lumen enlargement [16, 17]. Nevertheless, recent data show inferiority of Absorb BVS, compared to regular DES, with higher rates of scaffold thrombosis (probably due to late scaffold discontinuity leading to disruption of laminar flow), possible thrombogenicity of breakdown products, and local inflammation processes occurring after resorption of the scaffold [18]. Data from two studies, ABSORB III and AIDA, showed higher rates of probable/definite scaffold thrombosis in the BVS group compared to the everolimus-eluting stent arm at one and two years of follow-up [19, 20]. Results of the ABSORB II study showed that vasomotor reactivity after three years was not significantly different from the regular DES arm; also, the late lumen loss was greater in the Absorb group [21]. Currently Absorb is not recommended in regular clinical use [18]. A Polish consensus statement on bioresorbable scaffolds also advised against the use of Absorb in routine practice [22]. On the other hand, other scaffolds built of polylactic acid and magnesium have the same strut thickness as the Absorb and are approved for clinical use; therefore, we think that the presented analysis is currently relevant. Nevertheless, a new generation of BVSs with thinner struts and rounder strut cross-section, minimising flow disturbances is being sought. The current Absorb generation presents struts of 152 μm and a crossing profile of 1.4 mm. Due to increased strut thickness, larger crossing profile, and the device's lower penetrating force into the plaque, predilatation was recommended before scaffold deployment. Data about direct BVS implantation technique are scarce. In earlier studies, direct stenting with Absorb was performed, ranging from 9% in a Polish registry to 44% in a randomised TROFI trial [23, 24]. In a Spanish study that included both stable coronary artery disease and ACS patients, direct scaf-

fold implantation was attempted in 150 lesions [4]. Successful BVS delivery was achieved in 86% of cases in the direct arm. Longer, C-type lesions and a larger plaque burden were associated with failure in Absorb implantation in that analysis [4]. Another study included a retrospective overview of nine ACS patients treated with direct BVS implantation. Scaffolds were successfully implanted in all patients [5]. In our analysis type C lesions with severe tortuosity and angulation > 90° were associated with failure in direct Absorb deployment.

Outcomes of Absorb implantation vary depending on the centre's and operator's experience, implantation technique, and use of intravascular imaging tools [25]. Standard BVS-specific implantation protocol includes predilatation with a non-compliant balloon up to the size of the RVD, implantation of the Absorb of the same size as the RVD, and high-pressure postdilatation for optimal scaffold apposition, with a non-compliant balloon of the same diameter as the RVD or 0.5 mm larger [26, 27]. On the other hand, overexpansion might lead to strut fracture, so the size of the postdilatation balloon should not exceed the scaffold diameter by more than 0.5 mm. For this reason, precise vessel/scaffold sizing should be performed, preferably with OCT, which also allows accurate assessment of scaffold apposition [22]. Optimal vessel selection is also important, as an RVD of < 2.25 mm has been identified as a predictor of scaffold thrombosis after Absorb implantation [19]. However, due to limited availability and high costs, OCT is generally underused. In our registry, only visual estimations were applied, which is a typical clinical approach in the ACS all-comer populations. In the presented study scaffolds were implanted by highly skilled operators with experience in BVS implantation in both ACS and stable coronary disease patients, with use of IVUS and OCT, and the BVS-specific implantation protocol with high-pressure postdilatation was implemented. The median postdilatation balloon diameter was 3.6 mm in the direct group and 3.5 mm in the predilatation group, whereas baseline reference vessel diameters were 2.8 and 2.7 mm, respectively. Median scaffold diameter was 3.5 mm in the direct group and 3.0 mm in the predilatation arm.

The most important finding of the presented analysis is the feasibility and good immediate angiographic results of direct BVS deployment in patients with acute MI. Our registry shows that the procedure of BVS implantation can be effective in a suitable lesion anatomy. Successful Absorb implantation was achieved in 91% of cases in the direct arm and 98% of cases in the predilatation group.

The presented analysis was a registry, not a randomised study, but it represents real-world data. The registry sample size is relatively small and the results only allow for hypothesis generation and possible planning of larger randomised studies. The methods used in this study were suboptimal. The presented procedural results were based on angiography and quantitative analysis. The use of IVUS or OCT was not

obligatory and the decision whether to use it was left to the operator. The value of an angiographic assessment of a scaffold invisible for fluoroscopy is limited and does not provide information about the scaffold apposition. Finally, frequent use of guiding catheters as an additional back-up could have contributed to the high success rates in BVS deliverability in our analysis.

In conclusion, direct Absorb implantation in patients with acute MI may be effective and feasible in suitable coronary anatomy.

Conflict of interest: *none declared*

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WHAT IS NEW?

In the presented study we show the feasibility and high success rate of direct implantation of the Absorb bioresorbable vascular scaffold in patients with acute coronary syndrome. No significant differences were observed in final flow analyses and angiographic complications between patients treated with direct Absorb deployment and conventional implantation after predilatation. Direct stenting is a preferred technique for primary percutaneous coronary intervention with a regular drug-eluting stent, with several studies showing better immediate and long-term outcomes compared to stent implantation after predilatation. Absorb scaffolds have thicker struts and a larger crossing profile; therefore, for successful scaffold delivery and deployment elective predilatation was initially recommended. So far there has been no specific analysis of direct Absorb implantation technique in patients with acute coronary syndrome.