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Everolimus-eluting bioresorbable vascular scaffolds for treatment of patients presenting with ST-segment elevation myocardial infarction: BVS STEMI first study

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Aims We evaluated the feasibility and the acute performance of the everolimus-eluting bioresorbable vascular scaffolds (BVS) for the treatment of patients presenting with ST-segment elevation myocardial infarction (STEMI).

Methods and results The present investigation is a prospective, single-arm, single-centre study, reporting data after the BVS implantation in STEMI patients. Quantitative coronary angiography and optical coherence tomography (OCT) data were evaluated. Clinical outcomes are reported at the 30-day follow-up. The intent-to-treat population comprises a total of 49 patients. The procedural success was 97.9%. Pre-procedure TIMI-flow was 0 in 50.0% of the patients; after the BVS implantation, a TIMI-flow III was achieved in 91.7% of patients and the post-procedure percentage diameter stenosis was 14.7 $\pm$ 8.2%. No patients had angiographically visible residual thrombus at the end of the procedure. Optical coherence tomography analysis performed in 31 patients showed that the post-procedure mean lumen area was 8.02 $\pm$ 1.92 mm^2, minimum lumen area 5.95 $\pm$ 1.61 mm^2, mean incomplete scaffold apposition area 0.118 $\pm$ 0.162 mm^2, mean intraluminal defect area 0.013 $\pm$ 0.017 mm^2, and mean percentage malapposed struts per patient 2.80 $\pm$ 3.90%. Scaffolds with >5% malapposed struts were 7. At the 30-day follow-up, target-lesion failure rate was 0%. Non-target-vessel revascularization and target-vessel myocardial infarction (MI) were reported. A non-target-vessel non-Q-wave MI occurred. No cases of cardiac death or scaffold thrombosis were observed.

Conclusion In the present series, the BVS implantation in patients presenting with acute MI appeared feasible, with high rate of final TIMI-flow III and good scaffold apposition. Larger studies are currently needed to confirm these preliminary data.

Keywords Bioresorbable vascular scaffolds • ST-segment elevation myocardial infarction • Optical coherence tomography

Introduction

Primary percutaneous coronary intervention has been demonstrated to be superior to thrombolytic strategy and is currently the treatment of first choice for patients presenting with ST-segment elevation myocardial infarction (STEMI) in experienced centres with limited time delay.[1] First-generation drug-eluting stents (DES) have been shown to reduce the need for repeat revascularization compared with bare-metal stents (BMS),[2–4] and the newer-generation DES with improved biocompatibility of polymers may lower the rate of clinical events also in acute patients.[5,6] However, the implantation of metal devices is not devoid of important limitations, such as permanent caging of the vessel with permanent impairment of coronary vasomotion, side branch jailing, impossibility of late lumen

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enlargement, non-invasive imaging and future surgical revascularization of stented segments.[7] Moreover, in spite of the beneficial effect of neointimal inhibition, the antiproliferative drug elution has been shown to interfere with the vascular healing processes providing the background for delayed strut coverage and persistent or acquired malapposition.[8,9] The above-mentioned limitations can be proposed for both stable and acute patients; however, primary stenting has additional specific characteristics that should be highlighted. Stent placement in acute thrombotic lesions has been reported to be an independent predictor of late stent malapposition after the BMS[10] or DES[11] implantation. Possible explanations for this phenomenon could be the thrombus sequestration behind the struts—which subsequently resolves—and the vasoconstriction during the acute phase. Both these factors may predispose to stent underdeployment, malapposition and finally to stent thrombosis. The everolimus-eluting bioresorbable vascular scaffold (BVS) has been designed to overcome the general limitations of the metallic stents and recently has been shown to provide excellent results for the treatment of stable patients.[12,13] However, so far very limited data are available on the use of this novel device in patients with acute coronary syndromes (ACS).[14,15] Given this background, a pilot study investigating the feasibility and acute performance of the BVS for the treatment of patients presenting with STEMI was initiated.

Methods

Rationale

As of 1 September 2012, the BVS (ABSORB; Abbott Vascular, Santa Clara, CA, USA) has been commercially available in the Netherlands. Based on previous experience and available evidence, reported in ABSORB Cohort A and B Trial[13,16] our institution initiated the use of BVS for the treatment of patients presenting for PCI in everyday clinical practice, with a preference for patients with a good life expectancy as demonstrated by the presence of limited co-morbidities. As these patients might have more complex lesions compared with the ABSORB study patients[16,17] the BVS-EXPAND registry was initiated. The BVS-EXPAND also included patients with ACS (unstable angina or non-STEMI). After the first experience with ACS patients and an interim analysis, a decision was made to extend BVS utilization to the treatment of STEMI.

As an additional measure for assessing the safety of a treatment approach with BVS in STEMI, optical coherence tomography (OCT) imaging was performed, according to clinical judgement, for a more comprehensive evaluation of the acute procedural outcome.

Study design

The present report is an investigator initiated, prospective, single-arm, single-centre study to assess feasibility and performance of the second-generation everolimus-eluting BVS for the treatment of patients presenting with STEMI.

Subjects enrolled were patients of $\geq$18-year-old admitted with STEMI, defined as at least 1 mm ST-segment elevation in two or more standard leads or at least 2 mm in two or more contiguous precordial leads or new left bundle branch block within 12 h after the onset of symptoms. Culprit lesions were located in vessels within the upper limit of 3.8 mm and the lower limit of 2.0 mm by online quantitative coronary angiography (QCA). The absorb BVS was implanted according to the manufacturer's indication on target-vessel diameter ranges and absorb BVS diameters to be used. The absorb BVS with a nominal diameter of 2.5 mm was implanted in vessels $\geq$2.0 and $\leq$3.0 mm by online QCA; the 3.0 mm BVS was implanted in vessels $\geq$2.5 and $\leq$3.3 mm by online QCA; the 3.5 mm BVS was implanted in vessels $\geq$3.0 and $\leq$3.8 mm. Given the manufacturer's indication on maximum scaffold expansion, for each nominal diameter a further expansion of 0.5 mm was allowed. Enrolled subjects were willing to comply with specified follow-up evaluation and to be contacted by telephone. Exclusion criteria comprise pregnancy, known intolerance to contrast medium, uncertain neurological outcome after cardiopulmonary resuscitation, previous percutaneous coronary intervention with the implantation of a metal stent, left main (LM) disease previous coronary artery bypass grafting (CABG), age superior to 75 years, and participation to another investigational drug or device study before reaching the primary endpoints. The enrolment period started on 1 November 2012 and ended on 30 March 2013. Dual antiplatelet therapy after the BVS implantation was planned to have a duration of 12 months. Baseline and post-BVS implantation QCA analysis, OCT analyses at post-BVS implantation, and clinical outcomes at the 30-day follow-up were evaluated.

Definitions

Success rates were defined as follows: device success was the attainment of $<$30% final residual stenosis of the segment of the culprit lesion covered by the BVS, by angiographic visual estimation. Procedure success was defined as device success and no major periprocedural complications (Emergent CABG, coronary perforation requiring pericardial drainage, residual dissection impairing vessel flow—TIMI-flow II or less). Clinical success was defined as procedural success and no in-hospital major adverse cardiac events (MACE). All deaths were considered cardiac unless an undisputed non-cardiac cause was identified. Myocardial infarction (MI) and scaffold thrombosis were defined according to the Academic Research Consortium definition.[18] Target-lesion revascularization (TLR) was defined as clinically driven if at repeat angiography the diameter stenosis was $>$70%, or if a diameter stenosis $>$50% was present in association with (i) presence of recurrent angina pectoris, related to the target vessel; (ii) objective signs of ischaemia at rest (ECG changes) or during exercise test, related to the target vessel; and (iii) abnormal results of any functional diagnostic test.

The device-oriented endpoint target-lesion failure was defined as the composite of cardiac death, target-vessel MI, or ischaemia-driven TLR. Major adverse cardiac events defined as the composite of cardiac death, any re-infarction (Q- or non-Q-wave), emergent bypass surgery (CABG), or clinically driven TLR. Target-vessel failure (TVF) was defined as cardiac death, target-vessel MI, or clinically driven TVR.

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. The BVS received the CE mark for clinical use, indicated for improving coronary lumen diameter in patients with ischaemic heart disease due to *de novo* native coronary artery lesions with no

restriction in terms of clinical presentation. Therefore, the BVS can be currently used routinely in Europe in different settings comprising the acute MI without a specific written informed consent in addition to the standard informed consent to the procedure. Given this background, a waiver from the hospital Ethical Committee was obtained for written informed consent, as according to Dutch law written consent is not required, if patients are not subject to acts other than as part of their regular treatment.

Study device

The second-generation everolimus-eluting BVS is a balloon expandable device consisting of a polymer backbone of poly-L-lactide acid (PLLA) coated with a thin layer of amorphous matrix of poly-D and -L-lactide acid (PDLLA) polymer (strut thickness 157 μm). The PDLLA controls the release of the antiproliferative drug everolimus (100 μg/cm^2), 80% of which is eluted within the first 30 days. Both PLLA and PDLLA are fully bioresorbable. The polymers are degraded via hydrolysis of the ester bonds and the resulting lactate and its oligomers are metabolized by the Krebs cycles. Small particles (<2 μm in diameter) may be also phagocytized and degraded by macrophages.[19] According to preclinical studies, the time for complete bioresorption of the polymer backbone is ~2–3 years.[20] The BVS edges contain two platinum markers for accurate visualization during angiography or other imaging modalities.

Quantitative coronary angiography analysis

Quantitative coronary angiography (QCA) analyses were performed using the Coronary Angiography Analysis System (Pie Medical Imaging, Maastricht, Netherlands).

Analyses were performed at pre-procedure, after thombectomy, after balloon dilatation, and after the BVS implantation with a methodology already reported.[21]

In case of thrombotic total occlusion, pre-procedure QCA analysis was performed as proximally as possible from the occlusion (in case of a side branch distally to the most proximal take off of the side branch). Intracoronary thrombus was angiographically identified and scored in five grades as previously described.[22] Thrombus grade was assessed before procedure and after thombectomy.

The QCA measurements included reference vessel diameter (RVD)—calculated with interpolate method—percentage diameter stenosis, minimal lumen diameter (MLD), and maximal lumen diameter (D_{max}). Acute gain was defined as post-procedural MLD minus pre-procedural MLD (MLD value equal to zero was applied when culprit vessel was occluded pre-procedurally). Complications occurring any time during the procedure, such as dissection, spasm, distal embolization, and no-reflow were reported. As additional information, MI SYNTAX I and MI SYNTAX II scores providing long-term risk stratification for mortality and MACE in patients presenting with STEMI were assessed.[23]

Optical coherence tomography image acquisition and analysis

Optical coherence tomography imaging after the BVS implantation was encouraged in all patients but was not mandatory, subordinated to device availability and left at the operator's discretion.

Therefore, OCT imaging of the culprit lesion after treatment was performed in a subset of the population. The image acquisition was performed with C7XR imaging console and the Dragonfly intravascular imaging catheter (both St. Jude Medical, St. Paul, MN, USA). Image acquisition has been previously described.[24] Briefly, after positioning the OCT catheter distally to the most distal scaffold marker, the catheter is pulled back automatically at 20 mm/s with simultaneous contrast infusion by a power injector (flush rate 3–4 mL/s). In cases where the entire scaffold region was not imaged in one pullback, a second more proximal pullback was performed for complete visualization. Images were stored and analysed offline.

Analysis of the OCT images was performed with the St Jude/Lightlab offline analysis software (St. Jude Medical), using previously described methodology for BVS analysis.[17] Analysis was performed in 1-mm longitudinal intervals within the treated culprit segment, after exclusion of frames with <75% lumen contour visibility. Lumen, scaffold, and incomplete scaffold apposition (ISA) area were calculated in accordance with standard methodology for analysis of bioresorbable scaffolds[17] (*Figure 1A* and *B*), while in sites with overlapping scaffolds, analysis was performed using previously suggested modifications[25] (*Figure 1D*). Specifically, the lumen contour is traced at the lumen border and in the abluminal (outer) side of apposed struts, while in the case of malapposed struts the contour is traced behind the malapposed struts. In cases where the scaffold struts are completely covered by tissue or thrombus, the lumen contour is traced above the prolapsing tissue (*Figure 1C*). The scaffold area is traced following interpolation of points located in the mid-point of the abluminal border of the black core in apposed struts and the mid-point of the abluminal strut frame border in malapposed or side branch-related struts, so that the scaffold area is identical to the lumen area in the absence of ISA and tissue prolapse. Incomplete scaffold apposition area is traced in the case of malapposed struts as the area delineated between the lumen and scaffold contours (*Figure 1B*).

A special consideration should be mentioned concerning BVS analysis in MI with the presence of increased tissue prolapse and residual thrombus post-implantation[21,26] (*Figures 1C* and *2*). Tissue prolapse area can be quantified as the difference between the scaffold and the lumen area. For the calculation of prolapse area, in the case that one or more scaffold struts are completely covered by thrombus or tissue, the total black core area of these struts is also measured. Prolapse area is then calculated as [scaffold area + ISA area − lumen area − embedded black core area]. The area of non-attached intraluminal defects (e.g. thrombus) is also measured. Atherothrombotic area is then calculated as the sum of prolapse area and intraluminal defect area and normalized as a percent ratio of the scaffold area (atherothrombotic burden, ATB).[21,26] It should be noted that in the case of bioresorbable scaffolds where measurements of the scaffold area are performed using the abluminal side of the scaffold struts, ATB is overestimated compared with metal platform stents where measurements of the stent area are performed from the adluminal (inner) side of the struts. Additionally, flow area was assessed as [scaffold area + ISA area − atherothrombotic area − total strut area] and the minimal flow area was recorded.

A scaffold strut is defined as incompletely apposed when there is no contact between the abluminal border of the strut and the vessel wall. This does not include struts located in front of side branches or their ostium (polygon of confluence region), which are

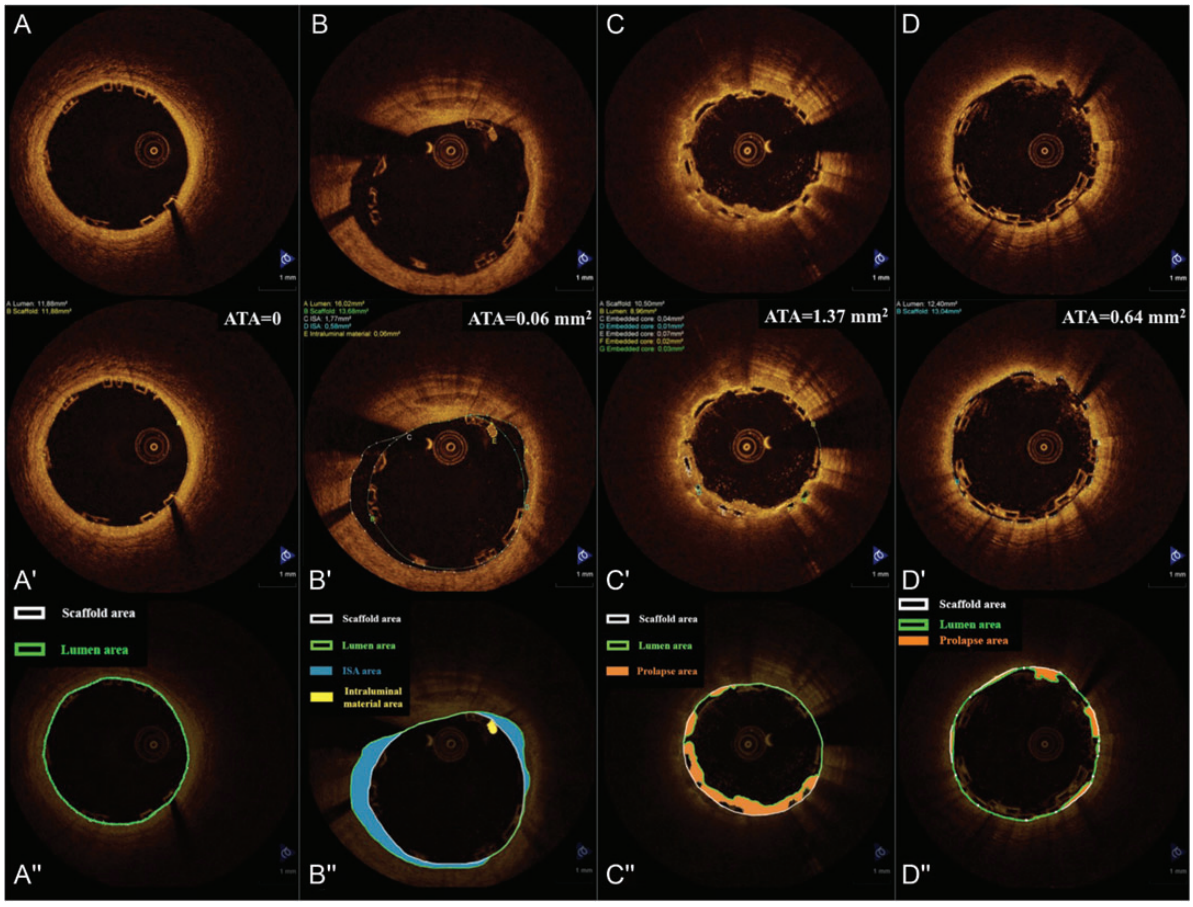

Figure 1 Methodology of optical coherence tomography analysis. (*A*) Good scaffold apposition and absence of incomplete scaffold apposition or tissue prolapse, (*B*) incomplete scaffold apposition, (*C*) sites with high tissue prolapse and struts completely covered by thrombus, and (*D*) overlapping scaffolds. Upper panel shows baseline images, middle panel shows quantitative measurements, and lower panel shows methodology for analysis. ISA, incomplete scaffold apposition; ATA, atherothrombotic area.

defined as side branch-related struts. Intraluminal struts that are part of adjacent clusters of apposed struts in overlapping scaffolds are also not considered malapposed.[25] For illustrative proposes, OCT bi-dimensional images are reported by three-dimensional rendering by dedicated software (Intage Realia, KGT, Kyoto, Japan)[17] (*Figures 2* and *3*).

Statistical analysis

Continuous variables are presented as mean and standard deviation, and categorical variables are reported as count and percentages. Descriptive statistics was provided for all variables. The present study is intended to be a 'first experience investigation' evaluating feasibility and acute performance of the everolimus-eluting BVS for the treatment of patients presenting with STEMI. A patient population of at least 30 patients was planned to be included in the present study. Comparisons among multiple means were performed with analysis of variance (one-way ANOVA). Score (Wilson) confidence intervals were reported for measures of success. Type A intraclass correlation coefficients (ICCs) for absolute agreement were used for assessing intra- and interobserver agreement, while measurement error and 95% limits of agreement were assessed by Bland–Altman analysis. The ICCs were computed with a two-way random effects model (single measures). All statistical tests were performed with SPSS, version 15.0 for windows (IL, USA).

Results

From 1 November 2012 to 30 April 2013, a total of 267 patients presented with acute MI. Twenty-one of those patients were treated percutaneously without any stent implantation (thrombectomy or balloon dilatation alone). Seventy-four had a culprit lesion located in a coronary vessel with a vessel diameter out of the range availability of the BVS (i.e. RVD >4.0 mm). Out of the remaining 172 patients, 125 were meeting the inclusion and none of the exclusion criteria of the present study (47 patients excluded for age, previous PCI or CABG, left main disease). Seventy-six of those patients were treated with metal stents and 49 cases (48 implanted with BVS) were enrolled in the present study (*Figure 4*, *Table 1*). Therefore, the patients implanted with BVS constitute the ~38% of the patients eligible for the present investigation.

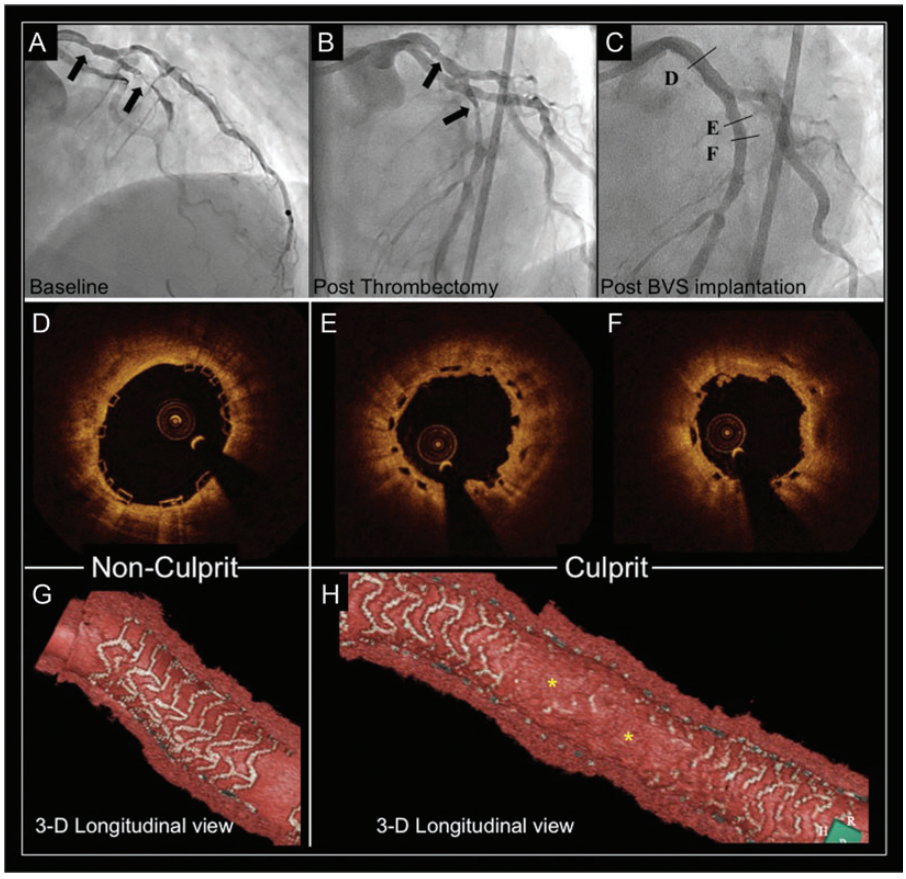

Figure 2 Bioresorbable vascular scaffolds implantation in a culprit and a non-culprit lesion in myocardial infarction. (*A*) Coronary angiography demonstrating a stenotic lesion in proximal LAD (proximal non-culprit lesion) and a total occlusion of the mid-LAD (culprit lesion). (*B*) Angiography following thrombus aspiration. (*C*) Angiography following implantation of a 3.5 × 12 mm bioresorbable vascular scaffolds at the proximal LAD lesion and a 3.0 × 28 mm bioresorbable vascular scaffolds at the mid-LAD lesion. (*D*) Optical coherence tomography image from the proximal non-culprit lesion showing absence of tissue prolapse and thrombus in the 3.5 × 12 mm scaffold. (*E* and *F*) Optical coherence tomography images from the culprit lesion showing complete coverage of the bioresorbable vascular scaffolds by tissue prolapse and presence of small amount of intraluminal defect. (*G*) Three-dimensional optical coherence tomography rendering in the proximal non-culprit lesion with complete scaffold visualization indicating the absence of prolapsing material. (*H*) Conversely, in the three-dimensional rendering of the culprit lesion, the morphology of the bioresorbable vascular scaffolds cannot be fully visualized due to high levels of tissue prolapse (*).

Baseline clinical characteristics of the 172 patients (49 patients included in the intent-to-treat population and 123 patients implanted with metal stents) with vessels size in the range of the BVS availability are reported in *Table 1*. In the intent-to-treat population thirty-eight patients were male (77.6%), mean age was 58.9 ± 10.5 years. Lesions were distributed as follows: left anterior descending 21 (42.9%), right coronary artery 22 (44.9%), and circumflex 6 (12.2%). Baseline clinical data of the enrolled patients were compared with the general population presenting with acute MI and implanted with a metal stent in vessels theoretically suitable for BVS implantation. Minimal differences were observed between the two groups. Namely, age 58.9 ± 10.5 vs. 66.4 ± 12.2, $P < 0.001$ and previous PCI 0% vs. 12.2%, $P = 0.007$. All the other clinical characteristics of the two populations did not show any significant difference.

Mean door-to-balloon time was 31.3 ± 19.5 min. All patients were treated with unfractionated heparin at the dose of 70–100 UI/kg and dual antiplatelet therapy (aspirin plus, prasugrel in 45 patients or clopidogrel in 4 patients). Manual thrombectomy was performed in 38 patients. In 16 cases, direct stenting was performed; a total of 65 scaffolds were implanted (12 patients received overlapping scaffolds—overlap was systematically intended to be minimal). The scaffolds lengths used were 12, 18, and 28 mm, with scaffolds diameters 2.5, 3.0, and 3.5 mm. Mean scaffold length per-lesion was 26.40 ± 13.86 mm, mean scaffold diameter per-lesion was 3.2 ± 34 mm. A highly supportive wire was used in five cases and radial approach was performed in 26 patients (53.0%) (*Table 2*). The procedural success was 97.9% (48/49 patients); in one patient, the delivery of the BVS was unsuccessful (due to the remarkable vessel tortuosity was not

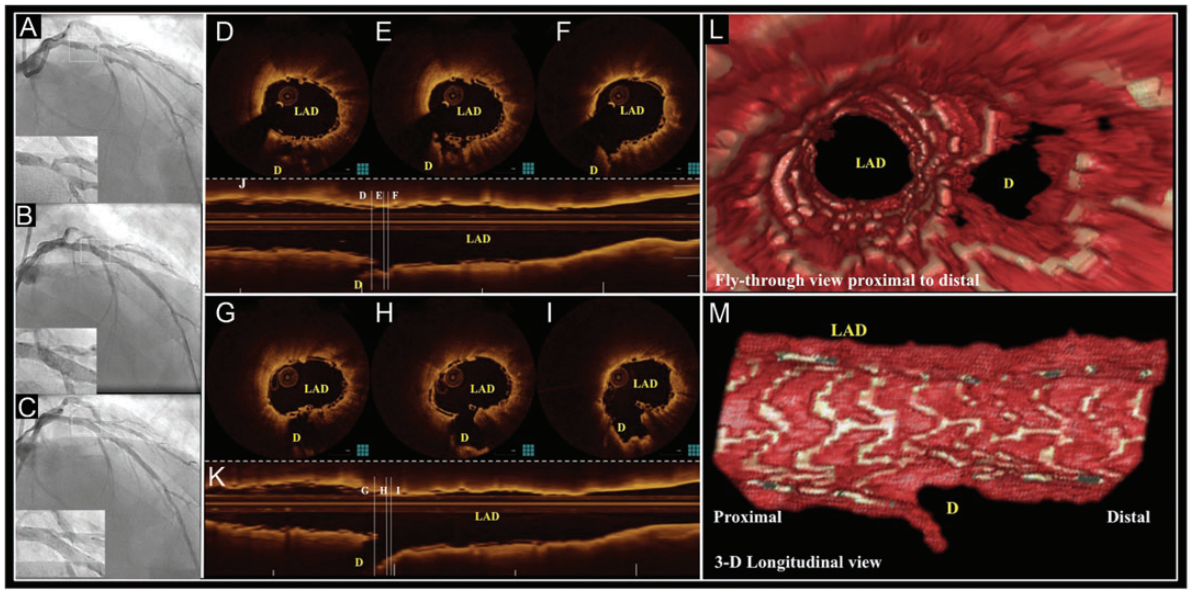

Figure 3 Bioresorbable vascular scaffold implantation in a thrombotic bifurcation lesion treated with provisional approach. (*A*) Coronary angiography pre-intervention. (*B*) Angiography following bioresorbable vascular scaffold implantation in the LAD, showing pinching of the ostium of the diagonal (D). (*C*) Final angiographic result following side branch dilation with 2.0 × 15 mm balloon. (*D–F* and *J*) Optical coherence tomography cross-sectional images and l-mode after bioresorbable vascular scaffolds implantation showing the compromise of the side branch after implantation and presence of thrombus at the side branch ostium. (*G–I* and *K*) Optical coherence tomography cross-sectional images and l-mode after side branch dilation, showing the opening of the carina of the side branch. (*L* and *M*) Three-dimensional reconstructions confirm the opening of the side branch ostium.

possible to advance the BVS at the site of the lesion) and a metallic DES was implanted. Clinical success was 97.9% (48/49 patients).

Quantitative coronary angiography analysis

The QCA is reported only in patients implanted with BVS. In 50.0% of those patients, pre-procedure TIMI-flow was 0 and the RVD was 2.94 ± 0.77 mm. In the non-totally occluded vessels, the RVD was 2.62 ± 0.63 mm, with an MLD of 0.75 ± 0.44 mm and a mean diameter stenosis of 70.8 ± 12.5%. After thrombectomy and balloon dilatation, TIMI-flow grade 0 was present in 2.5 and 0.0% of patients, respectively, and TIMI-flow III in 52.5 and 59.3% of the cases, respectively. After the scaffold implantation, there were no cases of TIMI-flow 0, and a TIMI-flow III was achieved in 91.7% of patients, the mean post-procedure in-scaffold % diameter stenosis was 14.7 ± 8.2%, in-scaffold MLD was 2.44 ± 0.49 mm (*Table 3*). No angiographically visible residual thrombus was observed at post-procedure.

Optical coherence tomography findings

Optical coherence tomography analysis was performed in a subgroup of 31 patients implanted with BVS. Mean lumen area was 8.02 ± 1.92 mm^2, minimum lumen area 5.95 ± 1.61 mm^2, and minimum flow area 5.62 ± 1.66 mm^2. Incomplete scaffold apposition (ISA) was observed in 20 patients with a mean ISA area of 0.118 ± 0.162 mm^2 and a mean percentage of malapposed struts per patients equal to 2.80 ± 3.90%. The mean prolapse area was 0.60 ± 0.26 mm^2, and the mean intraluminal defect area was 0.013 ± 0.017 mm^2. Scaffolds with >5% malapposed struts were 7 (*Table 4*). The OCT analysis stratified by scaffold size (5 BVS 2.5 mm, 13 BVS 3.0 mm, 24 BVS 3.5 mm) showed different lumen, scaffold, and flow areas, but similar amounts of incomplete stent apposition, plaque prolapse, and intraluminal mass areas (*Table 5*). In three cases, the observation of scaffold malapposition by OCT, guided an additional post-dilatation and in one patient the visualization of considerable intraluminal thrombus as assessed by OCT led to a repeated thrombus aspiration.

Intra-observer variability was excellent. Intraclass correlation coefficients were 0.999 for lumen area and 0.999 for scaffold area, and the corresponding measurement errors and limits of agreement were 0.01 mm^2 (−0.12 to 0.15 mm^2) for lumen area and −0.01 mm^2 (−0.20 to 0.17 mm^2) for scaffold area. Similarly, inter-observer intraclass correlation coefficients were 0.997 for lumen area and 0.987 for scaffold area, and the corresponding measurement errors and limits of agreement were −0.01 mm^2 (−0.30 to 0.28 mm^2) for lumen area and −0.22 mm^2 (−0.68 to 0.24 mm^2) for scaffold area.

Clinical outcomes

At the 30-day follow-up, the rate of the device-oriented endpoint, target-lesion failure, was 0%. None of the patients experienced target-vessel re-infarction, emergent bypass surgery, or clinically driven TLR. No cases of cardiac death or scaffold thrombosis were reported. The MACE rate was 2.6% as one patient, after discharge developed a non-Q-wave MI related to a non-target-vessel lesion and underwent a non-target-vessel revascularization within the

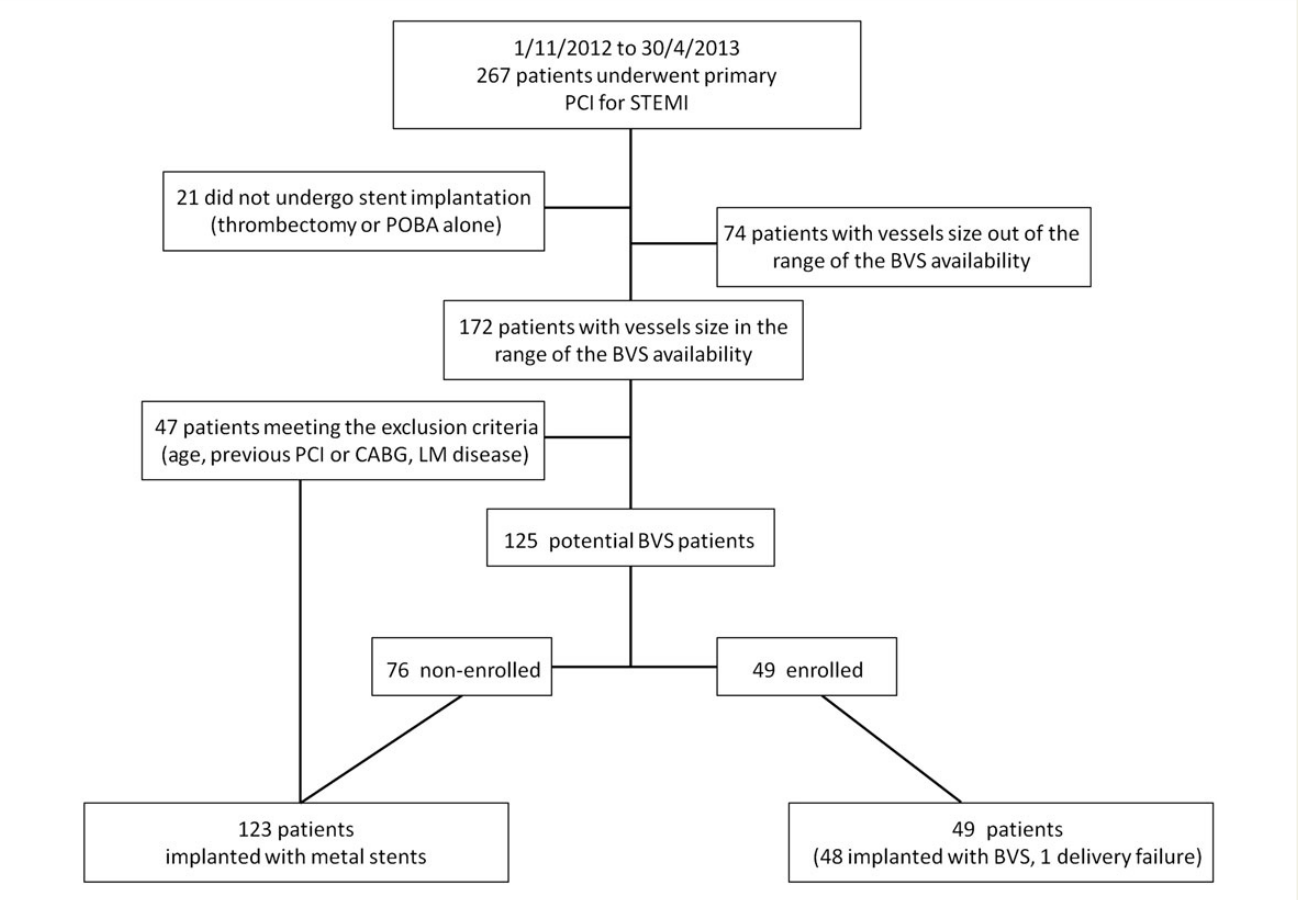

Figure 4 Flow-chart of the study. From 1 November 2012 to 30 April 2013, a total of 267 patients presented with acute myocardial infarction. Twenty-one of those patients were treated percutaneously but without any stent implantation (thrombectomy or balloon dilatation alone). Seventy-four had a culprit lesion located in a coronary vessel with a vessel diameter out of the range availability of the bioresorbable vascular scaffolds (i.e. reference vessel diameter >4.0 mm). Out of the remaining 172 patients, 125 were meeting the inclusion and none of the exclusion criteria of the present study (47 patients excluded for age, previous PCI or CABG, left main disease). Seventy-six of those patients were treated with metal stents and 49 cases (48 implanted with BVS) were included in the present study.

30 days post-procedure. This was the only event reported in the studied population (*Table 6*).

Discussion

The everolimus-eluting BVS has been tested so far only in elective patients with stable, unstable angina, or silent ischaemia;[16,17,27–29] showing promising results up to 4-year follow-up[30] for the first-generation and up to 2 years for the second-generation BVS.[12,13,31] The present study represents an early investigation reporting clinical and angiographic data on the use of the second-generation BVS for the treatment of patients presenting with STEMI and evaluating acute results with high-resolution intracoronary imaging (OCT).

A high device, procedural, and clinical success rates were observed with all the scaffolds achieving a residual stenosis <30% and no in-hospital MACE. Such data are supportive of feasibility and good acute performance of the BVS for the treatment of patients with acute MI.

Angiographic data

The everolimus-eluting BVS was implanted in patients presenting with ST-segment elevation and a thrombus burden 4 or 5 in 63.0% of the cases. A theoretical concern related to the implantation of the BVS in such thrombotic lesions is the fact that scaffold positioning and placement may need a more aggressive lesion preparation (pre-dilatation) compared with standard metal devices, due to its slightly higher profile. We hypothesized that this strategy might be prone to an increase in distal embolization following balloon inflations, favouring no-reflow and reducing the rate of final TIMI-flow III.

However, the analysis of the post-procedural angiographies revealed a TIMI-flow III in 91.7% of the cases; such results are in line with recently reported large trials evaluating the performance of metallic stents in patients presenting with acute MI.[5,6] Less thrombus embolization may result from a different pattern of thrombus dislodgment and compression to the arterial wall after deployment of a device with a larger strut width (157 μm) compared with currently available metallic stents. The percentage of vessel wall area

Table 1 Baseline clinical characteristics intent-to-treat population and patients treated with metallic stent in the enrolment period

Clinical characteristics	BVS (N = 49)	Metal stents (N = 123)	P-value
Age (year)	58.9 ± 10.5	66.4 ± 12.2	<0.001
Male, *n* (%)	38 (77.6)	93 (75.6)	0.845
Hypertension, *n* (%)	19 (38.8)	53/105 (50.5)	0.225
Hypercholesterolemia, *n* (%)	11 (22.4)	30/100 (30.0)	0.435
Diabetes, *n* (%)	4 (8.2)	14/116 (12.1)	0.590
Smoke, *n* (%)	27 (69.2)	46/116 (39.7)	0.120
Family history of CAD, *n* (%)	12 (24.5)	31/95 (32.6)	0.343
Peripheral vascular disease, *n* (%)	1 (2.0)	8 (6.5)	0.449
Kidney disease, *n* (%)	1 (2.0)	7 (5.7)	0.442
Prior MI, *n* (%)	1 (2.0)	14 (11.4)	0.070
Prior PCI, *n* (%)	0 (0.0)	15 (12.2)	0.007
Prior CABG, *n* (%)	0 (0.0)	3 (2.4)	0.559
COPD, *n* (%)	2 (4.1)	5 (4.1)	1.000
Culprit vessel			0.624
LM, *n* (%)	0 (0)	2 (1.6)	
LAD, *n* (%)	21 (42.9)	52 (42.3)	
RCA, *n* (%)	22 (44.9)	46 (37.4)	
LCX, *n* (%)	6 (12.2)	21 (17.1)	
SVG, *n* (%)	0 (0)	2 (1.6)	

Patients with vessels diameters not feasible for BVS implantation (i.e. reference vessel diameter ≥4.0 mm) were excluded.
Data are expressed as mean ± SD or number and proportion, *n* (%).
CAD, coronary artery disease; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; LM, left main; LAD, left anterior descending; RCA, right coronary artery; LCX, circumflex; SVG, saphenous vein graft.

Table 2 Procedural data intent-to-treat population

Procedural data	N = 49
Medications	
Aspirin, *n* (%)	49 (100)
Prasugrel, *n* (%)	45 (91.8)
Clopidogrel, *n* (%)	4 (8.2)
Glycoprotein IIb/IIIa antagonists, *n* (%)	17 (34.7)
Unfractionated heparin, *n* (%)	49 (100)
Mean door-to-balloon time (min)	31.3 ± 19.5
Manual thrombectomy, *n* (%)	38 (77.5)
Direct stenting, *n* (%)	16 (32.7)
Pre-dilatation, *n* (%)	33 (67.3)
Mean pre-dilatation balloon diameter per-lesion (mm)	2.6 ± 0.67
Post-dilatation, *n* (%)	10 (20.4)
Mean post-dilatation balloon diameter per-lesion (mm)	3.5 ± 0.47
Overlapping, *n* (%)	12 (24.5)
Overlap scaffolds diameters 3.5 mm–3.5 mm, *n* (%)	5 (10.2)
Overlap scaffolds diameters 3.5 mm – 3 mm *n* (%)	5 (10.2)
Overlap scaffolds diameters 3.5 mm–2.5 mm, *n* (%)	1 (2.0)
Overlap scaffolds diameters, 3 mm–2.5 mm, *n* (%)	1 (2.0)
Total number of scaffolds, *n*.	65
Mean scaffolds per-lesion, *n*.	1.35 ± 0.60
Mean scaffold length per-lesion (mm)	26.40 ± 13.86
Mean scaffold diameter per-lesion (mm)	3.2 ± 34
Supportive wire, *n*. (%)	5 (10.2)
Radial approach, *n*. (%)	26 (53.0)

Data are expressed as mean ± SD or number and proportion, *n* (%).

covered by the BVS polymer (scaffold/vessel ratio) has been previously evaluated to be 26%,[32] a value considerably higher compared with what observed for conventional metallic DES (i.e. EES provides a percentage stent/vessel ratio equal to 12%).[32] This characteristic of the BVS might be associated to an increased capacity of capturing debris and thrombotic material behind the struts before embolization to distal microcirculation. This so-called snow racket concept (entrapment of thrombotic material between the stent and the vessel) is currently the basis for the design of novel devices and clinical studies.[33]

Optical coherence tomography findings

Given its high resolution, OCT allows the assessment of *in vivo* strut apposition and presence of thrombus.[24,34–36]

The present analysis was performed at 1 mm intervals in the OCT pullback. Although, the possibility for a more strict assessment of OCT analysis in thrombotic lesion may be considered,[21] this methodology is the current standard applied in our institution for clinical studies, and the most commonly used in the literature.

Previous reports defined a stent malapposed if at least 5% of struts were observed to be malapposed;[37,38] in the present investigation, only seven scaffolds (22.6%) investigated with OCT showed a strut malapposition of >5%, with an overall mean struts malapposition equal to 2.8 ± 3.90%. A recently reported study using a similar methodology to investigate malapposition after metallic balloon expandable stent implantation in STEMI patients showed a total of 37.1% malapposed stents (stents with >5% malapposition) with a mean percentage of strut malapposition equal to 5.99 ± 7.28%.[38] In addition, the mean ISA area was 0.118 ± 0.162 mm^2, a value in line with data reported for metallic stent implantation in patients presenting with STEMI.[21,38] Similarly, the amount of intraluminal defect after scaffold implantation was minimal and comparable with what is observed in metallic stents.[21] Notably, these results were consistent among different scaffold sizes.

Clinical outcomes

In the present series, none of patients treated with BVS experienced a clinical event related to the treated vessel at the 30-day follow-up. These observations support the feasibility of BVS implantation in patients presenting with acute STEMI.

Table 3 Angiographic analysis in patients implanted with bioresorbable vascular scaffolds

Angiographic data	N = 48
Pre-procedure	
TIMI-flow, % (*n*)	
0	50.0% (23/46)
1	15.2% (7/46)
2	21.7% (10/46)
3	13.0% (6/46)
Thrombus burden, % (*n*)	
0	0.0% (0/46)
1	6.5% (3/46)
2	17.4% (8/46)
3	13.0% (6/46)
4	13.0% (6/46)
5	50.0% (23/46)
Total occlusion (*N* = 23)	
RVD (mm)	2.94 ± 0.77
Non-total occlusion (*N* = 23)	
RVD (mm)	2.62 ± 0.63
MLD (mm)	0.75 ± 0.44
Diameter stenosis (%)	70.8 ± 12.5
After thrombectomy	
TIMI-flow, % (*n*)	
0	2.5% (1/40)
1	7.5% (3/40)
2	37.5% (15/40)
3	52.5% (21/40)
Thrombus burden, % (*n*)	
0	0.0% (0/40)
1	30.0% (12/40)
2	35.0% (14/40)
3	22.5% (9/40)
4	10.0% (4/40)
5	2.5% (1/40)
After pre-dilatation	
TIMI-flow, % (*n*)	
0	0.0% (0/27)
1	7.4% (2/27)
2	33.3% (9/27)
3	59.3% (16/27)
Before BVS implantation	
RVD (mm)	2.63 ± 0.53
MLD (mm)	1.21 ± 0.46
Diameter stenosis (%)	53.2 ± 16.1
D_{max} (mm)	3.01 ± 0.52
Post-procedure	
TIMI-flow, % (*n*)	
0	0.0% (0/48)
1	0.0% (0/48)
2	8.3% (4/48)
3	91.7% (44/48)
In-scaffold	
RVD (mm)	2.86 ± 0.52
MLD (mm)	2.44 ± 0.49
Diameter stenosis (%)	14.7 ± 8.2
In-segment	
RVD (mm)	2.74 ± 0.59
MLD (mm)	2.20 ± 0.53
Diameter stenosis (%)	21.8 ± 12.0
MI syntax score I[a]	10.0 (7.0–15.0)
MI syntax score II[a]	7.0 (4.25–10.0)
Dominant right coronary artery, % (*n*)	93.8% (45/48)
Scaffold-to-artery ratio	1.19 ± 0.24
Complications occurring any time during the procedure, % (*n*)	
Dissection	6.3% (3/48)
Spasm	4.2% (2/48)
Distal embolism	14.6% (7/48)
No-reflow	2.1% (1/48)

Data are expressed as mean ± SD or proportion (%).
[a]MI syntax scores I and II are expressed as median (interquartile range).

Table 4 Optical coherence tomography findings post-implantation in patients implanted with bioresorbable vascular scaffolds

OCT variables	N = 31
Analysed length (mm)	28.16 ± 13.29
Analysed struts, *n*	245 ± 135
Minimum lumen area (mm^2)	5.95 ± 1.61
Mean lumen area (mm^2)	8.02 ± 1.92
Lumen volume (mm^3)	225.78 ± 113.63
Minimum scaffold area (mm^2)	6.69 ± 1.94
Mean scaffold area (mm^2)	8.54 ± 1.97
Scaffold volume (mm^3)	240.07 ± 118.48
Minimum flow area (mm^2)	5.62 ± 1.66
ISA area (mm^2) (*N* = 20)	0.118 ± 0.162
Mean prolapse area (mm^2)	0.60 ± 0.26
Mean intraluminal defect area (mm^2)	0.013 ± 0.017
Maximum intraluminal defect area (mm^2)	0.094 ± 0.077
Mean atherothrombotic area (mm^2)	0.61 ± 0.27
Mean atherothrombotic burden (%)	7.29 ± 3.12
Malapposed struts per patient (%)	2.80 ± 3.90
Scaffolds with at least 1 malapposed strut, *n* (%)	20 (64.5)
Scaffolds with >5% malapposed struts, *n* (%)	7 (22.6)

ISA, incomplete scaffold apposition.
Data are expressed as mean ± SD or number and proportion, *n* (%).

Table 5 Optical coherence tomography findings post-implantation stratified by scaffold size in patients implanted with bioresorbable vascular scaffolds

OCT variables				
Scaffold size	**2.5 mm (*N* = 5)**	**3.0 mm (*N* = 13)**	**3.5 mm (*N* = 24)**	***P***
Analysed length (mm)	18.80 ± 1.30	22.23 ± 6.46	21.33 ± 7.38	0.628
Minimum lumen area (mm^2)	4.08 ± 0.24	5.60 ± 0.93	7.18 ± 1.58	0.001
Mean lumen area (mm^2)	5.42 ± 0.75	7.18 ± 1.03	9.25 ± 1.72	0.001
Minimum scaffold area (mm^2)	4.53 ± 0.51	6.13 ± 1.02	8.06 ± 1.82	0.001
Mean scaffold area (mm^2)	5.62 ± 0.28	7.66 ± 0.88	9.82 ± 1.70	0.001
Minimum flow area (mm^2)	3.84 ± 0.28	5.17 ± 0.86	6.77 ± 1.60	0.001
ISA area (mm^2) (*N* = 25)	0.190 ± 0.318 (*N* = 3)	0.063 ± 0.072 (*N* = 10)	0.133 ± 0.177 (*N* = 12)	0.429
Mean prolapse area (mm^2)	0.40 ± 0.19	0.54 ± 0.27	0.62 ± 0.29	0.246
Mean intraluminal defect area (mm^2)	0.007 ± 0.008	0.016 ± 0.021	0.012 ± 0.018	0.628
Maximum intraluminal defect area (mm^2)	0.072 ± 0.081	0.102 ± 0.086	0.068 ± 0.065	0.096
Mean atherothrombotic area (mm^2)	0.40 ± 0.19	0.56 ± 0.27	0.64 ± 0.30	0.237
Mean atherothrombotic burden (%)	6.00 ± 4.66	7.42 ± 3.79	6.20 ± 3.39	0.594

ISA, incomplete scaffold apposition.
Data are expressed as mean ± SD or number and proportion, *n* (%).

Table 6 Clinical outcomes at the 30-day follow-up intent-to-treat population

Clinical events	*N* = 49	95% CI
Target-lesion failure	(0/49) 0%	(0–7.41)
TVF	(0/49) 0%	(0–7.41)
Cardiac death	(0/49) 0%	(0–7.41)
Target-vessel MI	(0/49) 0%	(0–7.41)
Q-wave MI	(0/49) 0%	(0–7.41)
Non Q-wave MI	(0/49) 0%	(0–7.41)
Clinically driven target-vessel revascularization	(0/49) 0%	(0–7.41)
Any MI	(1/49) 2.6%	(0–10.69)
Q-wave MI	(0/49) 0%	(0–7.41)
Non Q-wave MI	(1/49) 2.6%	(0–10.69)
Major adverse cardiac events	(1/49) 2.6%	(0–10.69)
Non-target-vessel revascularization	(1/49) 2.6%	(0–10.69)
Definite or probable scaffold thrombosis	(0/49) 0%	(0–7.41)

Data are expressed number and proportion, *n* (%). 95% CI, 95% confidence interval.

Data showed in the present report with optimal acute performance in terms of final TIMI-flow and scaffold apposition may suggest that everolimus-eluting BVS could be considered for the treatment of patients presenting with STEMI, however, due to the limited number of patients and events, caution should be made in reaching firm conclusions. Further larger studies are needed to fully evaluate the performance of the present device in STEMI patients.

Limitations

The present study represents a feasibility study with a limited number of patients. The small sample size does not allow reaching conclusions in terms of clinical outcomes. The lack of a head-to-head comparison with the current standard of care is a major limitation of the present study. A longer follow-up is needed to fully evaluate the performance of this novel device in patients presenting with acute MI. During the enrolment period, the implantation of either metallic stent or BVS in STEMI patients was left to the operator's discretion; this methodology may be prone to selection bias. Therefore, these data should not stimulate at the current state of knowledge the use of BVS in patients presenting with acute MI. Larger randomized studies are needed to confirm these preliminary observations.

Conclusion

In the present investigation, the implantation of the everolimus-eluting BVS was observed to be feasible in patients presenting with STEMI with optimal acute performance. These data are preliminary and need further confirmation in randomized controlled trials to define the true role of BVS for the treatment of patients presenting with acute myocardial infarction.

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