One-Year Clinical and Computed Tomography Angiographic Outcomes After Bioresorbable Vascular Scaffold Implantation During Primary Percutaneous Coronary Intervention for ST-Segment–Elevation Myocardial Infarction

The PRAGUE-19 Study

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Background—Bioresorbable vascular scaffolds (BVS) represent promising new technology, but data on their long-term outcomes in ST-segment–elevation myocardial infarction (STEMI) setting are missing. The aim was to analyze 1-year clinical and computed tomographic angiographic outcomes after BVS implantation in STEMI.

Methods and Results—PRAGUE-19 is a prospective multicenter single-arm study enrolling consecutive STEMI patients undergoing primary percutaneous coronary intervention (pPCI) with intention-to-implant BVS. A total of 343 STEMI patients were screened during 15 months enrollment period, and 70 patients (mean age 58.6±10.3 and 74% males) fulfilled entry criteria and BVS was successfully implanted in 96% of them. All patients were invited for clinical and computed tomographic angiographic control 1 year after BVS implantation. Restenosis was defined as ≥75% area stenosis within the scaffolded segment. Three events were potentially related to BVS: 1 in-stent restenosis (treated 7 months after pPCI with drug-eluting balloon), 1 stent thrombosis (treated 2 weeks after pPCI by balloon dilatation—this patient stopped all medications after pPCI), and 1 sudden death at home 9 months after pPCI. Four other patients had events definitely unrelated to BVS. Overall, 1-year mortality was 2.9%. Computed tomographic angiography after 1 year was performed in 59 patients. All BVS were widely patent, and binary restenosis rate was 2% (the only restenosis mentioned above). Mean in-scaffold minimal luminal area was 7.8±2.6 mm^2, area stenosis was 20.1±16.3%, minimal luminal diameter was 3.0±0.6 mm, and diameter stenosis was 12.8±11.1%.

Conclusions—BVS implantation in STEMI is feasible and safe and offers excellent 1-year clinical and angiographic outcomes. **(*Circ Cardiovasc Interv*. 2015;8:e002933. DOI: 10.1161/CIRCINTERVENTIONS.115.002933.)**

Key Words: bioresorbable scaffold ■ computed tomography ■ myocardial infarction ■ restenosis ■ stent ■ stent thrombosis

Primary percutaneous coronary intervention (pPCI) is a preferred reperfusion strategy in patients with ST-segment–elevation myocardial infarction (STEMI) whenever it can be performed within <2 hours from the first medical contact.[1] With the development of first-generation drug-eluting stents (DES), the risk of restenosis decreased significantly; however, their benefit was limited by increased late stent thrombosis and reinfarctions.[2–5] Better results have been achieved with the second generation of DES, overcoming most of the first-generation DES limitations.[6,7]

For many years, cardiologists were thinking about a new generation of stents, fulfilling its function in the short-term perspective and then disappearing—restoring coronary vasomotion in the long term without permanent metal cage.[8] The first commercially available resorbable stent was Absorb bioresorbable vascular scaffold (BVS; Abbott Vascular, Santa Clara, CA). Since its first use in humans,[9] promising results have been reported. Favorable preservation of arterial wall physiology in long-term follow-up has been observed. The first BVS trials were done in patients with stable coronary

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WHAT IS KNOWN

- ST-segment–elevation myocardial infarction is a thrombogenic condition with higher risk of stent thrombosis after stent implantation.
- Early clinical outcomes after bioresorbable vascular scaffold implantation in ST-segment–elevation myocardial infarction are promising but the experience is limited.
- Follow up with computed tomographic coronary angiography may be a useful way to follow patients because the stented segment can be easily visualized

WHAT THE STUDY ADDS

- Bioresorbable vascular scaffold implantation in ST-segment–elevation myocardial infarction is feasible and safe with excellent 1-year clinical outcomes and patency rates.
- Computed tomographic coronary angiography is a useful tool for the evaluation of implanted bioresorbable vascular scaffold after ST-segment–elevation myocardial infarction.

artery disease or mixed stable and unstable angina,[10–15] and one study[12] demonstrated slightly higher than expected stent thrombosis rate. It was only recently that first reports on BVS use in STEMI were published,[16,17] and these were just early outcomes without angiographic control. STEMI patients might potentially benefit from BVS implantation as they are generally younger, with less extensive atherosclerosis and with long life expectancy after successful pPCI. However, STEMI presents the most prothrombotic situation with 4- to 5-fold greater risk of stent thrombosis and with a definite risk of restenosis. Computed tomographic (CT) coronary angiography (CAG) is potentially optimal method for noninvasive assessment of BVS patency: on the contrary to metallic stents, within nonmetallic bioresorbable stents, it can easily evaluate the vessel lumen. Thus, this study aimed to analyze the long-term clinical and CT angiographic outcomes after BVS implantation in the STEMI setting.

Methods

The PRAGUE-19 study is a prospective multicenter open-label single arm study. The design and early results in a pilot group of patients have been published previously.[16] The study is planned to enroll all consecutive STEMI patients during a period of 3 years, that is, till the end of 2015 with follow-up period of another 3 years. This article thus represents interim results focused on 1-year CT angiographic controls.

Study Population

All 343 consecutive STEMI patients referred for pPCI between December 2012 and March 2014 in the 2 study centers were considered for enrollment because the study used BVS implantation as the default strategy for all STEMI patients with below specified exclusion criteria. The only inclusion criteria were STEMI duration <24 hours and signed written informed consent. The exclusion criteria were both clinical (Killip class III-IV, concomitant disease with life expectancy <3 years, indication for oral anticoagulation, contraindication or high likelihood of noncompliance to dual antiplatelet therapy) and angiographic (infarct artery diameter <2.3 mm or >3.7 mm, lesion length >24 mm, extensive infarct artery calcifications or severe tortuosity, STEMI because of stent thrombosis or in-stent restenosis). Seventy patients met these criteria (mean age 58.6±10.3 and 74% males), but in 3 of them, BVS could not be delivered to the culprit lesion, and metallic stent was used instead. Baseline demographic characteristics of the study population are summarized in Table 1. The study protocol prescribes clinical and CT angiographic control after 1 year and clinical, invasive coronary angiographic and optical coherence tomographic control after 2 to 3 years. This report includes consecutive patients enrolled between December 2012 and March 2014 who completed 1-year follow-up.

Ethics

The protocol was approved by the local ethical committee at each center, as well as by the national multicenter ethical committee. The study was conducted according to the Declaration of Helsinki, and written informed consent was obtained from all study patients.

Implantation Procedure

Absorb BVS was described previously.[9–14] According to preclinical studies, the polymer backbone is fully absorbed in 2 to 3 years, and the polymer coating is absorbed faster.[18] All patients received preprocedural aspirin 300 to 500 mg, heparin 100 U/kg IV, and a loading dose of P2Y12 inhibitor (prasugrel or ticagrelor). Bailout use of GP IIb/IIIa inhibitors was left at the operator's discretion. BVS implantation was preceded either by manual thrombus aspiration or by balloon predilatation or both in all patients; balloon postdilatation was not mandatory. Stent sizing was based on visual assessment by an experienced operator (all operators had >10 years' experience with pPCI), and the intention was to slightly oversize the stent (eg, to obtain stent/reference vessel diameter ratio >1), and thus, postdilatation was used only in 37% of patients. Dual antiplatelet therapy (DAPT) with prasugrel or ticagrelor was recommended for 12 months, and patients were allowed to switch to clopidogrel (according to healthcare system, the only fully covered P2Y12 inhibitor) after 1 month should their economic situation require. Optical coherence tomography was used to control the implantation in the initial 21 patients, and after this period, it was used only occasionally.

CT Angiography

Multislice CT (MSCT) scan was performed using a 256-detector-row CT scanner (Brilliance iCT 256; Philips, Best, The Netherlands) or 320-detector-row CT scanner (Aquilion One; Toshiba, Nasu, Japan). Standard acquisition techniques were applied, and oral or intravenous β-blockers were used to control the heart rate. Bolus tracking was used for synchronization of the contrast medium injection with scanning. Prospective ECG triggering was preferred, scanning 70% to 80% of the RR interval for radiation dose reduction. In patients with high or irregular heart rate (at discretion of physician at acquisition), retrospective ECG gating was used. Data sets were stored and transferred to an external workstation (Comprehensive Cardiac Analyses, Brilliance Workspace v. 4.0; Philips Healthcare, Cleveland, OH) for offline analysis. Axial slices, oblique reconstructions, and maximum-intensity projection images were used for evaluation. In addition, semiautomatic MSCT CAG quantitative analysis was performed for

Table 1. Baseline Characteristics of Study Patients (n=70)

Age, y ±SD	58.6±10.3
Females, %	26
Diabetes mellitus, %	9
History of prior myocardial infarction, %	4
History of prior PCI, %	4
Multivessel disease, %	44

PCI indicates percutaneous coronary intervention.

Table 2. Analysis of Reasons Why Patients Did Not Receive BVS (273 Patients Met at Least 1 Exclusion Criterion; They Could Have Multiple Exclusion Criteria)

	N
Clinical reasons	
Killip III-IV class	48
Expected poor compliance to DAPT	24
Comorbidities with presumed limited survival	18
Indication for oral anticoagulation or contraindication for DAPT	9
Stent thrombosis as the cause for this STEMI	7
Angiographic reasons	
Too large (>3.7 mm) or too small (<2.3 mm) diameter of the infarct artery (suitable BVS not manufactured)	95
Extensive vessel calcifications or tortuosity with expected low likelihood of successful BVS deployment	35
Suitable BVS size not momentarily on stock	19
Primary PCI without stent	31

BVS indicates bioresorbable vascular scaffold; DAPT, dual antiplatelet therapy; PCI, percutaneous coronary intervention; and STEMI, ST-segment–elevation myocardial infarction.

BVS restenosis evaluation. Centerline through target vessel lumen was semiautomatically created. Then cross-sectional views of the artery were reconstructed at 0.5 mm steps through the vessel. Vessel lumen in each view was semiautomatically traced. Based on metal markers, the scaffold was identified, and the cross-section with the minimal lumen area and diameter was identified and used for assessment. Reference area and diameter in proximal and distal cross-sections with minimal disease were identified within 5 mm peri-scaffold segment. Reference area and diameter were calculated as an average of the proximal and distal measurements. Finally, the lumen area stenosis was calculated as the reference minus the minimal scaffold area divided by the reference lumen area and expressed as a percentage. Significant stenosis was defined as area stenosis of >75% or diameter stenosis of >50%. The presence of noncalcified, mixed, or calcified plaque was evaluated in each slice within the scaffold segment. All data sets were evaluated by 2 independent readers with at least 5 years experience in cardiac CT evaluation (Drs Petr, Vrana, and Linkova). If any significant disagreement between readers in BVS evaluation was found (inconsistency in reporting of patency or significant restenosis), a third reader was consulted.

Definitions

Device acute success was defined as the delivery and deployment of BVS at the intended target lesion with a final residual stenosis ≤10% by visual estimation. The clinical end points were death, myocardial infarction, and target vessel revascularization. BVS thrombosis was defined according to the Academic Research Consortium definition.[19] CT angiographic BVS restenosis was defined as area lumen stenosis >75% or diameter lumen stenosis >50%.

Statistical Analysis

Continuous variables are presented as mean±standard deviation; categorical variables are presented as frequencies and percentages. Statistical analyses were performed with SPSS software (version 16.0; SPSS Inc, Chicago, IL).

Results

Analysis of Exclusion Criteria for BVS

Analysis of exclusion criteria for BVS implantation in 273 patients is described in Table 2. Most frequent reason for exclusion was the artery diameter (too small or too large for the available BVS size spectrum). Majority of these patients had too large arteries (>3.7 mm).

Periprocedural and Clinical Data

Periprocedural data (coronary angiographic findings and PCI procedure data) in the acute phase are shown in Table 3. As mentioned earlier, in 3 of 70 (4%) study patients, the BVS could not be delivered to the lesion, and metallic stent was used instead. Clinical outcomes are summarized in Table 4.

CT Coronary Angiography Outcomes

CT-CAG was performed in 59 patients with 65 implanted BVS. Of the remaining 11 patients, BVS implantation failed in 3 (who received bare metal stents), 2 patients died from STEMI complications, 1 patient had renal insufficiency, and 5 patients withdrew consent for the CT angiography (Figure 1). Each CT angiography was reviewed by 2 physicians, and all 59 reports were consistent between both readers in terms of significant restenosis and patency reporting. All 65 BVS were patent, and no significant in-stent restenosis was found (binary restenosis rate at the time of CT angiography is 0%; if one previously treated restenosis is included, the restenosis rate is 2% at 1 year). Quantitative assessment was feasible in 56 patients with 62 BVS (Figures 2 and 3 and Table 5). Mean in-scaffold minimal luminal area was 7.8±2.6 mm^2, area stenosis was 20.1±16.3%, minimal luminal diameter was 3.0±0.6 mm, and diameter stenosis was 12.8±11.1%.

Discussion

This study supports our previously published[16] observations on BVS feasibility and safety by reporting encouraging 1-year outcomes.

Exclusion Criteria

In many centers, BVS are implanted to arteries with 3.7 to 4.0 mm diameter because BVS with nominal size 3.5 mm can

Table 3. Periprocedural Data From Acute Phase Quantitative Coronary Angiography and Primary PCI (n=70)

Left anterior descending (LAD) as infarct-related artery (IRA), %	49
Manual aspiration thrombectomy used, %	36
Balloon predilatation used, %	84
Balloon postdilatation used, %	37
BVS successfully deployed, %	96
Number of implanted BVS per patient, mean±SD	1.14±0.39
BVS nominal diameter, mm, mean±SD	3.32±0.30
BVS minimal luminal diameter, mm, mean±SD	2.54±0.29
BV length, mm, mean±SD	22.62±8.83
TIMI flow 3 before pPCI, %	10
TIMI flow 3 after pPCI, %	96
Percent diameter stenosis before pPCI, %, mean±SD	97.6±3.4
Percent diameter stenosis after pPCI, %, mean±SD	1.9±9.0

BVS indicates bioresorbable vascular scaffold; pPCI, primary percutaneous coronary intervention; and TIMI, thrombolysis in myocardial infarction.

Table 4. In-Hospital and 12 Months Clinical Outcomes per Treatment Analysis (N=67)

Outcome	First Month	Months 2–12
Events definitely related to BVS		
In-stent restenosis (n)	0	1 (successfully treated by DEB)*
Events potentially related to BVS		
Definite stent thrombosis	1† (patient stopped all medications 13 days after pPCI, successfully treated by POBA)	0
Sudden death	0	1 (death at home)
Events definitely not related to BVS		
Death because of STEMI complication	1 (infarction septal rupture, died after emergent surgical repair)	0
Reinfarction in other vessel territory	0	2
Revascularization for recurrent angina, treated by PCI of de novo lesion	0	1

BVS indicates bioresorbable vascular scaffold; CT, computed tomography; DEB, drug eluting balloon; PCI, percutaneous coronary intervention; POBA, plain old balloon angioplasty; and STEMI, ST-segment–elevation myocardial infarction.

*This patient had BVS widely patent at 1 year CT angiographic analysis.

†This patient refused to come for CT angiographic control after 1 year, but is alive and well.

be expanded ≤4.0 mm. However, we do not consider such approach in the best interest of the patient because our routine strategy in pPCI for STEMI (where frequently a mild diffuse coronary spasm is present) is to oversize. It is well known that the most frequent cause of restenosis or stent thrombosis is stent undersizing. In other words, we never use 3.5 mm stent size into a 3.7 to 4.0 mm artery, and rather we use 4.0 mm stent for such artery. This size unfortunately is not yet available for BVS. The second most frequent cause for exclusion was Killip III-IV class. Because the goal of this study is to observe long-term outcomes and bioresorption of the BVS takes 2 to 3 years, a significant proportion of Killip III-IV class patients would have rather low chance to live long enough to benefit from stent resorption.

Clinical Outcomes

Two patients died: one after surgical repair of postinfarction ventricular septal rupture, and second died suddenly at home 9 months after the BVS implantation. Definite stent thrombosis (confirmed by CAG and treated by re-PCI) was observed in 1 patient who spontaneously stopped all medications 13 days after BVS implantation. Clinical outcomes are in agreement with other reports on BVS implantation in STEMI.[17,20–23] Brugaletta et al[20] concluded that cumulative incidence of device-oriented end point did not differ between BVS and DES group either at 30 days (3.1% versus 2.4%) or at 1 year (4.1% versus 4.1%) comparing 290 consecutive STEMI patients in each arm.

Stent Thrombosis and DAPT

Incidence of BVS thrombosis among different studies varies. Dudek et al reported one definite stent thrombosis in a cohort of 98 ACS patients evidently associated with discontinuation of DAPT immediately after index PCI.[23] Diletti et al[17] and Kajiya et al[21] did not report any stent thrombosis in 11 and 49 STEMI patients in 30-day follow-up. On the other hand, in a recent larger BVS study, including STEMI patients, an increased rate of stent thrombosis in BVS group comparing to those with DES implantation in early (30-day) follow-up (2.1% versus 0.3%; P=0.059) has been reported. Interestingly, at 1-year follow-up, the difference in frequency of stent thrombosis was not so evident (2.4% versus 1.4%; P=0.948) because of low incidence of events in the BVS arm beyond 30-day follow-up.[20] A large systematic analysis of BVS thrombotic events from Gauging Coronary Healing With Bioresorbable Scaffolding Platforms in Europe (GHOST-EU) registry included 1189 patients who underwent PCI with Absorb BVS implantation. Twenty-three stent thrombosis at 6-month follow-up (cumulative incidence of 2.1%) were observed. Majority (70%) of events occurred in 30-day follow-up, and median time of occurrence after PCI was 5 days.[12] It is hypothesized

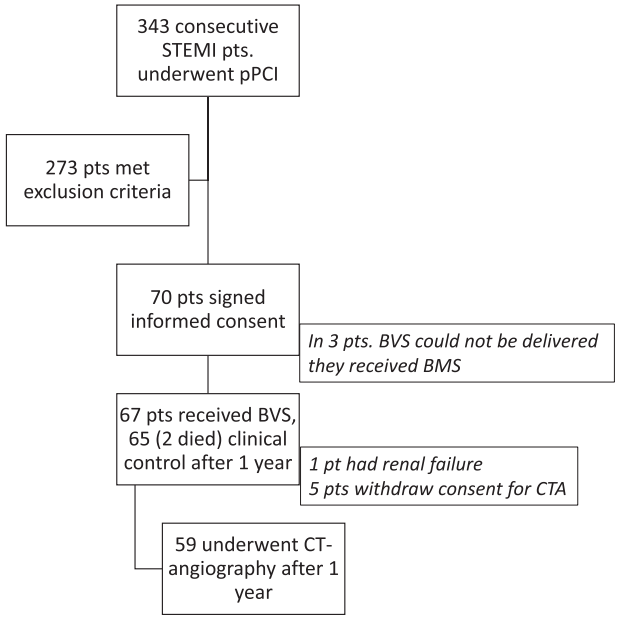

Figure 1. Scheme of patient enrollment and follow-up. BMS indicates bare metal stents; BVS, bioresorbable vascular scaffold; CT, computed tomography; CTA, computed tomographic angiography; pPCI, primary percutaneous coronary intervention; pts, patients; and STEMI, ST-segment–elevation myocardial infarction.

Table 5. CT Coronary Angiography Data 1 Year After BVS Implantation (65 BVS in 59 Patients for Semiquantitative Analysis and 62 BVS in 56 Patients for Quantitative Analysis)

Radiation dose, mSv, mean±SD	7.6±5.0
Contrast dose, mL, mean±SD	60±5
Number of patent BVS, n (%)	65 (100%)
Binary restenosis rate, %	0
Reference vessel diameter proximal to BVS, mm, mean±SD	3.6±0.5
Reference vessel diameter distal to BVS, mm, mean±SD	3.3±0.5
BVS minimal luminal diameter, mm, mean±SD	3.13±0.46
Diameter stenosis within BVS, %, mean±SD	12.8±11.1
Reference vessel area proximal to BVS, mm^2, mean±SD	10.6±3.0
Reference vessel area distal to BVS, mm^2, mean±SD	8.7±2.7
BVS minimal luminal area, mm^2, mean±SD	7.8±2.6
Area stenosis within BVS, %, mean±SD	20.1±16.3

BVS indicates bioresorbable vascular scaffold; and CT, computed tomography.

that because of unique structure of scaffold supplying the function of DES and dissolving within <3 years, the restoration of physiological vessel wall functions could eliminate risk of late stent thrombosis and achieve superiority of BVS to DES.[24] DAPT duration after BVS implantation remains uncertain. Most authors recommend 12-month DAPT with a strict minimum of 6 months.[12,17,20–23] The early abrupt cessation of DAPT by the patient was clearly the major contributing factor for stent thrombosis in 1 case reported.

Restenosis

Low restenosis rate is encouraging facing the fact that this study enrolled consecutive STEMI patients with relatively smaller arteries (the most frequent exclusion criterion was too large artery). On the other hand, the prevalence of diabetes mellitus in this cohort was remarkably low and potentially might influence outcomes. The exclusion criteria (especially the maximal lesion length) were selected to allow single-stent strategy for most patients—such strategy is less likely in diffusely diseased diabetic arteries. The unique BVS composition makes it CT friendly; radiolucent material allows lumen visualization of the same quality as in other segments. In contrast, interpretation of metallic stent restenosis, especially when the stent diameter does not exceed 3 mm, is limited because of blooming artifacts.[25] Previously reported trials have shown that CT evaluation of BVS is feasible and could not be limited only to assessment of treated vessel patency but can be extended for more precise analysis of in-scaffold lumen area and exact quantification of percentage of restenosis. Up to date, only few reports involving MSCT evaluation of patients after BVS implantation have been published. Onuma et al[14] investigated 18 patients treated for stable coronary artery disease with BVS at 18 months and 5 years. They showed mean area stenosis of 31.6% in 18 months and 33.3% at 5 years. No significant restenosis was reported. Verheye et al[15] reported on 12 patients a 15.9% stenosis at 12-month follow-up. Our report showed that MSCT for BVS is feasible because all devices were interpretable even in cases with small BVS diameter (2.5 mm) and as well in subjects who had relatively higher heart rate, which is challenging for CT scan interpretation.

Postdilatation

Postdilatation was used in 26 (37%) patients, but 2 different strategies between 2 participating centers were used. In one center, postdilatation after BVS implantation was performed routinely (17/18 patients). In the second center, stent oversizing

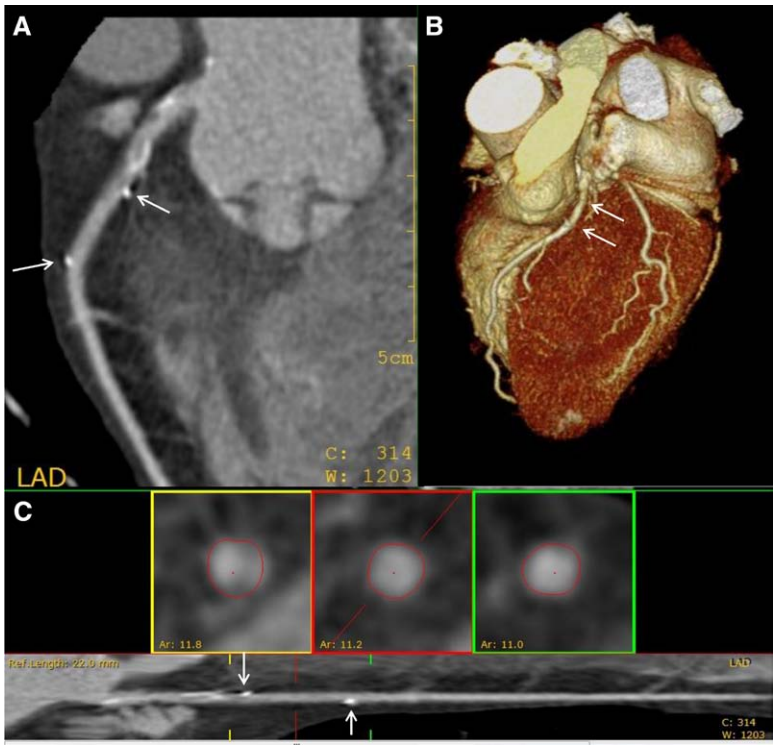

Figure 2. Computed tomographic (CT) angiography of 78-year-old woman treated by bioresorbable vascular scaffold (BVS; 3.5/18 mm) for anterior ST-segment–elevation myocardial infarction (STEMI). At curved multiplannar reconstruction (MPR; **A**), 3D volume rendering (**B**), and straight MPR reconstructions (**C**), proximal and distal markers are clearly identified in left anterior descending (LAD; white arrows). For quantitative assessment (**C**), proximal and distal reference cross-sections (yellow and green box) were identified for reference area measurement. In-scaffold segment was analyzed using 0.5 mm slice thickness to find a cross-sectional view with minimal lumen area. Area stenosis was 1.7%.

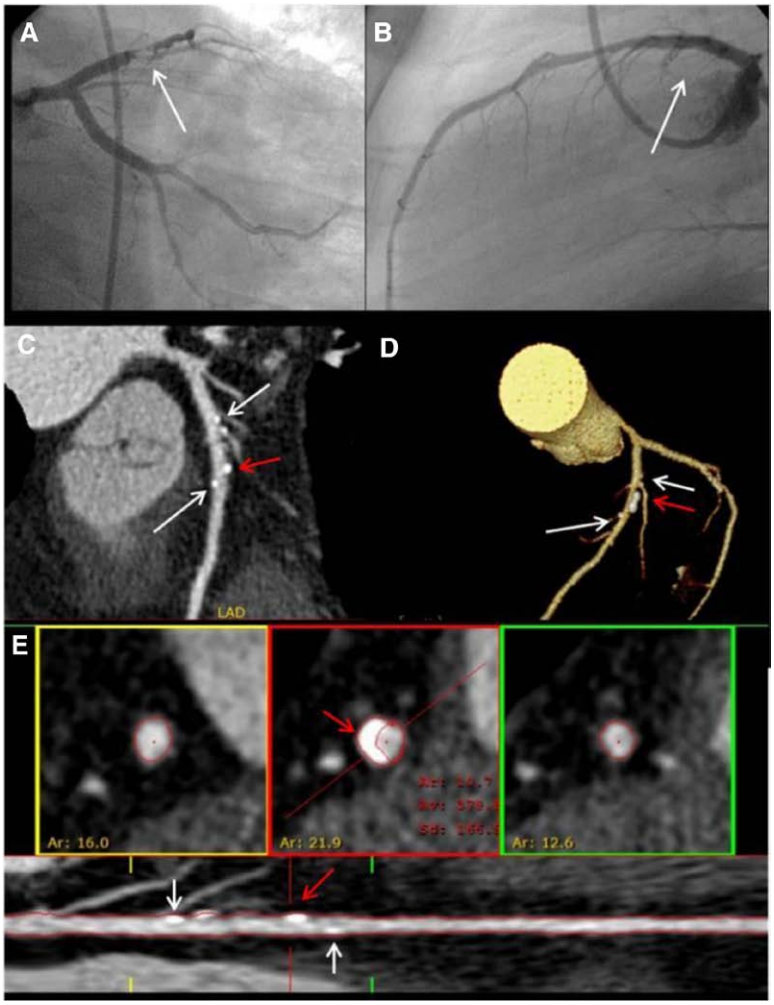

Figure 3. Fifty-two-year-old man referred for anterior ST-segment–elevation myocardial infarction (STEMI). **A**, 95% left anterior descending (LAD) stenosis with thrombi and thrombolysis in myocardial infarction (TIMI) 2 flow was predilated, and (**B**) bioresorbable vascular scaffold (BVS) 3.5/18 mm was implanted. At curved multiplannar reconstruction (MPR; **C**) and 3D volume rendering (**D**) reconstructions of LAD, proximal and distal markers of BVS are clearly identified (white arrows). Dense eccentric calcified plaque at distal part of scaffold (red arrow). Quantitative multislice CT (MSCT) analysis (**E**): yellow and green boxes show proximal reference lumen areas that were traced and measured. After analysis of scaffold area slice by slice of 0.5 mm thickness, cross-section of minimal lumen area was identified (red box) and vessel wall and lumen were traced (red color lines). Lumen area stenosis was 25.2% (reference lumen area was 14.3 mm^2 minimal in-scaffold lumen area 10.7 mm^2). Notice positive vessel wall remodeling because of large calcified plaque behind scaffold at cross-sectional seen in red box.

was preferred, and eventual postdilatation was left at discretion of operator and was performed only in 9/52 patients (in 7 based on optical coherence tomography finding and in 2 based on CAG alone). Despite different strategies used with relatively low postdilatation rate, excellent clinical and morphological outcome was observed. The same strategy was implemented by Diletti et al with postdilatation rate of 20.4%.[17] Gori et al postdilated 14% cases.[22] Both reports showed excellent clinical outcome after BVS implantation in ACS patients. It appears that this strategy seems to be at least equal to routine postdilatation in case of precise BVS diameter sizing (BVS/vessel ration >1) and postprocedural scaffold apposition control.

CT Coronary Angiography

Numerous reports have documented high diagnostic accuracy of current-generation MSCT.[25–28] However, because of the blooming effect of the metal parts of bare metal stents or DES, their evaluation with the use of MSCT angiography is limited, particularly if the size of the stent is ≤3 mm.[25] In contrast to metallic stents, the patency and precise quantification of percentage restenosis of BVS can be assessed using MSCT angiography because of their favorable structure and composition.[14,25] The comparison of acute phase quantitative coronary angiography with 1-year CT-CAG is methodologically difficult because of the inherent differences between these 2 methods. However, the increase in minimal luminal diameter within implanted BVS from the acute phase quantitative coronary angiography (2.54 mm) to 1-year CT-CAG (3.13 mm) is of interest and may suggest vessel remodeling. This will be further elucidated in future by invasive CAG and optical coherence tomography controls after 3 years as prescribed by this study protocol.

Thus, BVS implantation in STEMI is feasible and safe and offers excellent 1-year clinical and angiographic outcomes.

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Disclosures

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