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Bioresorbable Everolimus-Eluting Vascular Scaffold for Long Coronary Lesions

A Subanalysis of the International, Multicenter GHOST-EU Registry

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ABSTRACT

OBJECTIVES The authors sought to investigate 1-year outcomes in patients treated with bioresorbable everolimus-eluting vascular scaffolds (BVS) for "long coronary lesions."

BACKGROUND The present substudy derived from the GHOST-EU registry included 1,722 lesions in 1,468 consecutive patients, enrolled between November 2011 and September 2014 at 11 European centers.

METHODS The lesions were divided into 3 groups according to continuous BVS length: 1) shorter than 30 mm; 2) between 30 and 60 mm; and 3) longer than 60 mm. Primary device-oriented endpoint (target lesion failure [TLF]) was defined as a combination of cardiovascular death, target vessel myocardial infarction, or clinically driven target lesion revascularization.

RESULTS Patients with lesions ≥60 mm had more comorbidities and more complex lesion characteristics, including chronic total occlusions (37%), bifurcation lesions (40.3%), higher Syntax score (16.4 ± 7.8), and higher number of scaffolds implanted per lesion (3.3 ± 0.9 mm). The main target vessel was the left anterior coronary artery in all groups. Median follow-up was 384 (interquartile range: 359 to 459) days. One-year follow-up was completed in 70.3% of patients. TLF at 1 year was significantly higher in group C (group A 4.8%, group B 4.5%, group C 14.3%; overall $p = 0.001$), whereas there were no significant differences between groups A and B. Finally, a numerically higher (but not statistically significant) number of scaffold thromboses were observed in group C when compared with shorter lesions (group A 2.1%, group B 1.1%, group C 3.8%; overall $p = 0.29$).

CONCLUSIONS In a real-world setting, treatment of long coronary lesions with BVS ≥60 mm was associated with a higher TLF rate, driven by myocardial infarction and clinically driven target lesion revascularization.
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ABBREVIATIONS AND ACRONYMS

BMS = bare-metal stent(s)

BVS = bioresorbable vascular scaffolds

CI = confidence interval

DES = drug-eluting stent(s)

HR = hazard ratio

MI = myocardial infarction

PCI = percutaneous coronary intervention

QCA = quantitative coronary angiography

TLF = target lesion failure

TLR = target lesion revascularization

Percutaneous treatment of long coronary artery lesions remains a challenge despite recent technical advances in the field. The optimal management of these lesions is becoming more important due to a rising incidence of long and complex lesions in an increasingly elderly and comorbid population (1).

The advent of drug-eluting stents (DES) has dramatically reduced the rates of restenosis and target lesion revascularization (TLR) and has further improved outcomes compared with bare-metal stents (BMS) (2,3). However, multiple DES implantation (full metal jacket) for diffuse coronary lesions remains associated with high rates of restenosis and stent thrombosis due to several factors including delayed arterial healing, inflammation, and malapposition or incomplete stent apposition) (4,5). Furthermore, the presence of a permanent metallic cage of long coronary segments with DES precludes future surgical revascularization if needed and is associated with a risk of very late stent thrombosis.

TABLE 1 Patient Characteristics

	BVS Length			
	<30 mm (n = 1,111)	30-60 mm (n = 276)	≥60 mm (n = 81)	p Value
Age, yrs	62.2 ± 11.1	62.1 ± 10.1	59.3 ± 27.2	0.12
Male	876 (78.8)	224 (81.2)	73 (90.1)	0.04
Current smoker	350 (31.5)	72 (26.1)	24 (29.6)	0.21
DM	267 (24.0)	85 (30.8)	28 (34.6)	0.01
Insulin-dependent DM	95 (8.7)	29 (10.8)	9 (11.3)	0.47
Hypertension	810 (72.9)	194 (70.3)	62 (76.5)	0.49
Dyslipidemia	573 (51.6)	149 (54.0)	49 (60.5)	0.26
Family history of CAD	329 (29.6)	94 (34.1)	32 (39.5)	0.08
Previous PCI	353 (31.8)	107 (38.8)	35 (43.2)	0.02
Previous CABG	51 (4.6)	15 (5.4)	4 (4.9)	0.84
Previous TIA/stroke	39 (3.5)	10 (3.6)	3 (3.7)	0.99
eGFR, ml/min/1.73 m^2	85.5 ± 27.2	87.1 ± 27.1	92.1 ± 26.3	0.03
Stable angina/silent ischemia	528 (47.5)	180 (65.2)	63 (77.8)	<0.001
Acute coronary syndrome	583 (52.5)	96 (34.8)	18 (22.2)	<0.001
Unstable angina	148 (13.3)	36 (13.0)	6 (7.4)	0.31
NSTEMI	223 (20.1)	26 (9.4)	10 (12.3)	<0.001
STEMI	212 (19.1)	34 (12.3)	2 (2.5)	<0.001
LVEF, %	54.0 ± 9.6	54.2 ± 8.1	52.8 ± 10.9	0.96
Multivessel disease	396 (35.6)	133 (48.2)	40 (49.4)	<0.001
Prasugrel use	246 (22.5)	57 (22.5)	20 (25.6)	0.82
Ticagrelor use	3 (0.3)	3 (1.2)	1 (1.3)	0.09

Values are mean ± SD or n (%).

BVS = bioresorbable vascular scaffolds; CABG = coronary artery bypass graft; CAD = coronary artery disease; PCI = percutaneous coronary intervention; DM = diabetes mellitus; eGFR = estimated glomerular filtration rate; LVEF = left ventricular ejection fraction; NSTEMI = non-ST-segment elevation myocardial infarction; STEMI = ST-segment elevation myocardial infarction; TIA = transient ischemic attack.

Bioresorbable vascular scaffold (BVS) treatment of long coronary lesions is particularly attractive due to its complete resorption within 3 to 4 years, allowing for the possibility of positive vessel remodeling and restoration of vasomotor and endothelial function. Furthermore, this approach does not preclude future surgical or percutaneous revascularization, allows for follow-up with noninvasive imaging, and possibly reduces the risk of very late stent thrombosis. Several pivotal studies have demonstrated the safety and efficacy of this novel technology; however, there are limited data on outcomes following BVS implantation in this patient group.

The aim of this study was therefore to analyze 1-year outcomes following BVS implantation in long coronary artery lesions.

METHODS

STUDY DESIGN AND PATIENT POPULATION. The GHOST-EU (Gauging coronary Healing with bioresorbable Scaffolding plaTforms in EUrope) registry is an investigator-initiated, retrospective, multicenter registry conducted in 11 European centers in Italy, Germany, Poland, Spain, and the United Kingdom; specific details about this registry are described in a previous publication, reporting 30-day and 6-month outcomes (6). This study was an "all-comer" registry including consecutive patients who were treated with at least 1 Absorb BVS (Abbott Vascular, Santa Clara, California) for the treatment of coronary artery lesions. The present substudy included a total of 1,722 lesions in 1,468 patients, enrolled between November 2011 and September 2014. All lesions were divided into 3 groups according to continuous BVS length: 1) <30 mm; 2) 30 to 60 mm; and 3) ≥60 mm.

PROCEDURES AND FOLLOW-UP. All interventions were performed according to current best practice. The decision to perform post-dilation and intracoronary imaging, the choice of antithrombotic/antiplatelet therapy, and the choice of metallic DES or BMS implantation, when required, was not prespecified and was left to the operators' discretion. A loading dose of aspirin 250 to 500 mg was administered before percutaneous coronary intervention (PCI), unless patients were already on chronic aspirin therapy, followed by 75 to 100 mg oral daily lifelong. A loading dose of clopidogrel (300 to 600 mg), prasugrel (60 mg), or ticagrelor (180 mg) was administered before or immediately after PCI, unless patients