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Predictors of bioresorbable scaffold failure in STEMI patients at 3 years follow-up☆

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ABSTRACT

Background: Little data are available on the long-term outcomes of bioresorbable scaffold (BRS) in the setting of ST-segment elevation myocardial infarction (STEMI). The aim of this study is to investigate three-years outcomes and predictors of BRS failure in patients presenting with STEMI.

Methods and results: Two prospective, single-arm registries were pooled. Incidence and predictors of clinical outcome were assessed with Kaplan-Meier and Cox regression analyses. From May-2012 to January-2015, 183 STEMI patients (58 ± 13 years, 77% males, 29% diabetics) who received a total of 256 BRS (1.4 ± 0.8 per patient) were included. 248 patients (65 ± 11 years, 74% males, 27% diabetics) treated for stable coronary artery disease (SCAD) served as control. 3-years follow-up was available in 386 (90%) patients. Device-oriented composite endpoint and scaffold thrombosis (ScT) rates were similar in the two groups (STEMI: 11.5% vs SCAD: 12.9%, $P = 0.84$; STEMI: 3.6% vs SCAD: 3.3%, $P = 0.90$). While early ScT was more frequent in SCAD patients, late/very late ScT was a feature of STEMI. While in STEMI patients the incidence of ScT was higher in vessels with RVD > 3.5 mm, a RVD < 2.5 mm was a predictor of events in stable patients. Similarly, BRS undersizing predicted events in STEMI patients, while oversizing was a predictor in stable ones. Finally, the incidence of ScT was reduced in both STEMI and stable patients (from 6.3% to 0% and from 5.80% to 0.9%) when an optimized implantation technique was used.

Conclusions: The incidence of events for three years follow-up was similar in STEMI and SCAD patients, although different timing and features underlie ScT in the two groups.

1. Introduction

The implantation of coronary bioresorbable scaffolds (BRS) was introduced as an attractive therapeutic option for patients with acute coronary syndromes. Despite several potential benefits had been claimed to be associated with the resorption of the scaffold struts in this setting, including the formation of a stable fibrotic cap [1], the restoration of vasomotion, and the removal of a potential source of vascular inflammation [2], a demonstration of their actual clinical significance is still lacking. Further, the advantages of a device are potentially appealing for STEMI patients that are frequently younger and have less extensive coronary artery disease and soft plaques [3,4]. On the other hand, the larger strut thickness compared to current generation metal DES is a potential threat.

A number of studies focused on the performance of the BRS in patients presenting with STEMI with promising short-term results [5–9], while long-term follow-up data are still scanty.

The aim of this study was to investigate three-years outcomes and predictors of BRS failure in patients presenting with STEMI and to compare with patients treated for stable coronary artery disease (SCAD).

2. Methods

2.1. Study design

Two single-arm registries were pooled for the purpose of this investigation. Patients presenting with STEMI (new ST-elevation in at least

Abbreviations: BRS, bioresorbable scaffolds; DES, drug-eluting stents; DoCE, device-oriented composite endpoint; TLR, target-lesion revascularization; TVR, target-vessel revascularization; ScT, scaffold thrombosis; ScR, scaffold restenosis; ARC, academic research consortium; MLD and RVD, minimum lumen and reference vessel diameter; QCA, quantitative coronary angiography; OCT, optical coherence tomography; STEMI, ST-elevation myocardial infarction; SCAD, stable coronary artery disease.

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Table 1
Clinical, lesion and procedural characteristics.

	All patients ($n = 431$)	SCAD patients ($n = 248$)	STEMI patients ($n = 183$)	*P*-value
Age (years)	62 ± 12	65 ± 11	58 ± 13	<**0.0001**
Male	324 (75.2%)	183 (73.8%)	141 (77%)	0.50
Hypertension	307 (71.2%)	198 (79.8%)	109 (59.6%)	<**0.0001**
Diabetes	96 (22.3%)	67 (27%)	29 (15.8%)	**0.006**
Smoking	184 (42.7%)	75 (30.2%)	109 (59.6%)	<**0.0001**
Family history	97 (22.5%)	61 (24.6%)	36 (19.7%)	0.24
Hyperlipidemia	184 (42.7%)	124 (50.0%)	60 (32.8%)	<**0.0001**
Prior CABG	6 (1.4%)	5 (2.0%)	1 (0.5%)	0.25
Prior PCI	139 (32.3%)	129 (52.0%)	10 (5.5%)	<**0.0001**
Prior stroke/TIA	10 (2.3%)	7 (2.8%)	3 (1.6%)	0.53
GFR, (ml/min)	83 ± 51	79 ± 21	89 ± 24	<**0.0001**
LVEF (%)	51 ± 8	50 ± 9	51 ± 9	0.22
Lesion characteristics				
LM treated with BRS	0 (0%)	0 (0%)	0 (0%)	1
LAD treated with BRS	193 (44.9%)	109 (44.1%)	84 (45.9%)	0.77
LCX treated with BRS	105 (24.4%)	80 (32.3%)	25 (13.7%)	**0.0001**
RCA treated with BRS	133 (30.9%)	59 (23.8%)	74 (40.4%)	**0.0003**
Ostial lesion	32 (7.4%)	22 (8.9%)	10 (5.5%)	0.20
CTO	10 (2.3%)	10 (4.0%)	0 (0%)	**0.006**
Bifurcation	58 (13.5%)	40 (16.2%)	18 (9.8%)	0.06
Procedural characteristics				
Number of vessels treated with BRS	1.15 ± 0.4	1.2 ± 0.4	1.1 ± 0.4	0.82
BRS per patient	1.4 ± 0.8	1.4 ± 0.8	1.4 ± 0.8	0.60
Predilatation	429 (99.8%)	246 (99.6%)	183 (100%)	1
Diameter predilatation ballon (mm)	2.76 ± 0.37	2.72 ± 0.33	2.84 ± 0.42	**0.0017**
Minimum stent diameter (mm)	2.9 ± 0.38	2.86 ± 0.36	3.03 ± 0.38	<**0.0001**
Total implanted stent length per patient (mm)	35.7 ± 47.8	42.3 ± 60.9	26.8 ± 15.9	**0.0009**
Optimal implantation technique	197 (45.8%)	110 (44.5%)	87 (47.5%)	0.56
Postdilatation	200 (46.4%)	116 (46.8%)	84 (45.9%)	0.92
Diameter postdil balloon	3.18 ± 0.41	3.15 ± 0.39	3.27 ± 0.43	**0.0043**
Pressure postdil balloon	14.8 ± 3.1	14.5 ± 3.1	15.3 ± 3.1	0.08
Overlap	58 (13.5%)	37 (14.9%)	21 (11.5%)	0.32

CABG: coronary artery by-pass; PCI: percutaneous coronary intervention; eGFR: glomerular filtration rate (CMDKI); TIA: transient ischemic attack; B2 or C: lesion type (AHA classification) B2 or C; STEMI: ST-elevation myocardial infarction; LVEF: left ventricular ejection fraction: SCAD: stable coronary artery disease; CTO: chronic total occlusion; BRS: bioresorbable vascular scaffold. The bold values indicate significance at p<0.05.

two consecutive leads with typical symptoms, left bundle branch block or evidence of acute thrombotic occlusion of an epicardial artery with typical symptoms and unclear ECG) or stable coronary artery disease (SCAD, including stable angina and silent ischemia) caused by a de novo stenotic lesion treated with a BRS were included in the registries.

Table 2
Clinical outcome and predictors.

	SCAD patients (*n*?=?248)	STEMI patients (*n*?=?183)	*P*-value
All-cause death, % (*n*)	4.8 (12)	7.1 (13)	0.20
Device-oriented composite endpoint, % (*n*)	12.9 (32)	11.5 (21)	0.84
Target lesion revascularization, % (*n*)	11.7 (29)	5.5 (10)	**0.04**
Target vessel revascularization, % (*n*)	15.0 (37)	10.4 (19)	0.23
Scaffold thrombosis, % (*n*)	3.6 (9)	3.3 (6)	0.90
Scaffold restenosis, % (*n*)	7.7 (19)	2.7 (5)	**0.04**
STEMI-ScT	*P*-value	HR	95% CI
Post-RVD	**0.0001**	16.43	4.24 to 63.62
Ostial lesion	0.07	4.87	0.87 to 27.15
SCAD-ScT	*P*-value	HR	95% CI
Post-RVD	**0.005**	0.07	0.01 to 0.45
Overlap	**0.003**	7.29	1.96 to 27.16
STEMI-DoCE	*P*-value	HR	95% CI
eGFR	**0.018**	0.98	0.96 to 0.99
Residual stenosis	**0.049**	1.04	1.00 to 1.08
SCAD-DoCE	*P*-value	HR	95% CI
B2/C lesions	**0.003**	3.10	1.49 to 6.45
Overlap	**0.002**	3.11	1.50 to 6.48

eGFR: glomerular filtration rate (CMDKI); B2 or C: lesion type (AHA classification) B2 or C; STEMI: ST-elevation myocardial infarction; RVD: reference vessel diameter (mm); SCAD: stable coronary artery disease. The bold values indicate significance at p<0.05.