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Magmaris resorbable magnesium scaffold versus conventional drug-eluting stent in ST-segment elevation myocardial infarction: 1-year results of a propensity score matching comparison

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ABSTRACT

Magmaris® (Biotronik AG, Switzerland) is the first RMS and early experience has shown promising results in stable coronary artery disease. Acute coronary syndromes have been hypothesized as a potential target group for bioresorbable scaffolds, but the efficacy and safety of RMS has not been extensively studied in ST-segment elevation myocardial infarction (STEMI).

BEST-MAG is a prospective multicenter trial designed to evaluate optical coherence tomography (OCT-)guided implantation of resorbable magnesium scaffold (RMS) in STEMI.

Consecutive STEMI patients fulfilling inclusion/exclusion criteria were treated with RMS following a standardized OCT-based implantation technique including systematic pre- and post-dilatation, and baseline plus final OCT imaging. The primary endpoint was a device oriented composite endpoint (DOCE) including cardiac death, target vessel myocardial infarction (TV-MI) and target lesion revascularization (TLR) within 12 months. Clinical outcomes were compared after propensity score matching (PSM) to the results of the randomized controlled BIOSTEMI trial comparing biodegradable polymer sirolimus eluting (BP-SES) and durable polymer everolimus eluting stents (DP-EES) in STEMI.

Between 15th February 2019 and 25th May 2020, 30 patients were included in 5 centers. Procedural success was achieved in all cases based on OCT control with final scaffold expansion of 82 ± 11%. At twelve-months, DOCE rate was 13.3% (n = 4), including 4 cases of TLR (13.3%) and one case of TV-MI (3.3%). No cardiac death occurred, and no scaffold thrombosis (ScT) was observed. Using PSM, DOCE rates in BP-SES and DP-EES groups were 10% and 6% respectively and TLR rates were 3.3% and 0.0%.

In this study, OCT-guided RMS implantation in selected STEMI patients appeared feasible but was associated with numerically higher rates of TLR as compared with conventional drug-eluting stents, although the limited number of patients included in this analysis does not allow drawing statistically significant conclusions.

Abbreviations: ACS, acute coronary syndrome; BP-SES, biodegradable polymer sirolimus-eluting stent; BRS, bioresorbable scaffold; DES, drug-eluting stent; DOCE, device-oriented composite endpoint; DP-EES, durable polymer everolimus-eluting stent; OCT, optical coherence tomography; p-PCI, primary percutaneous coronary intervention; PSM, propensity score matching; RMS, resorbable magnesium scaffold; ScT, scaffold thrombosis; ST, stent thrombosis; STEMI, ST-segment elevation myocardial infarction; TLF, target lesion failure; TLR, target lesion revascularization; TV-MI, target vessel myocardial infarction.

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1. Introduction

Despite undeniable evidence of metallic drug-eluting stent (DES) efficacy for the treatment of coronary artery disease, fully bioresorbable coronary scaffolds (BRS) remain of interest to overcome some limitations of current DES, such as late stent thrombosis (ST) or neoatherosclerotic failure. The resorbable magnesium scaffold (RMS) Magmaris® (Biotronik AG, Bülach, Switzerland) is the first bioresorbable drug-eluting metal scaffold and early experience of RMS has shown promising results in stable coronary artery disease [1–3]. In the setting of acute coronary syndromes (ACS), the use of BRS might be hypothetically advantageous for a number of reasons: 1) It might allow for greater vasomotion restoration in proximal coronary segments where culprit lesions of ST-segment elevation myocardial infarction (STEMI) are frequently located [4]; 2) Vulnerable plaques (ruptured thin-cap fibroatheromas) responsible for STEMIs are usually soft in nature, without extensive calcifications, which might thus provide an ideal substrate for BRS implantation; 3) In patients with acute coronary syndromes, the wider strut of BRS maybe associated with better thrombus entrapment and reduced distal embolization [5]; 4) Vessel sizing in acute coronary syndrome can lead to stent malapposition due to thrombus and vasoconstriction. BRS could potentially avoid complications of such malapposition after scaffold resorption; and 5) STEMI tends to be more common in younger people [6]. Previous generations of polymeric BRS implanted in the setting of ACS showed acceptable results [7,8]. With regards to magnesium-based BRS, findings from animal studies showed hypo-thrombogenic features that might constitute an advantage in ACS due its enhanced thrombogenic state [9]. Furthermore, recent data demonstrated improved vasomotor

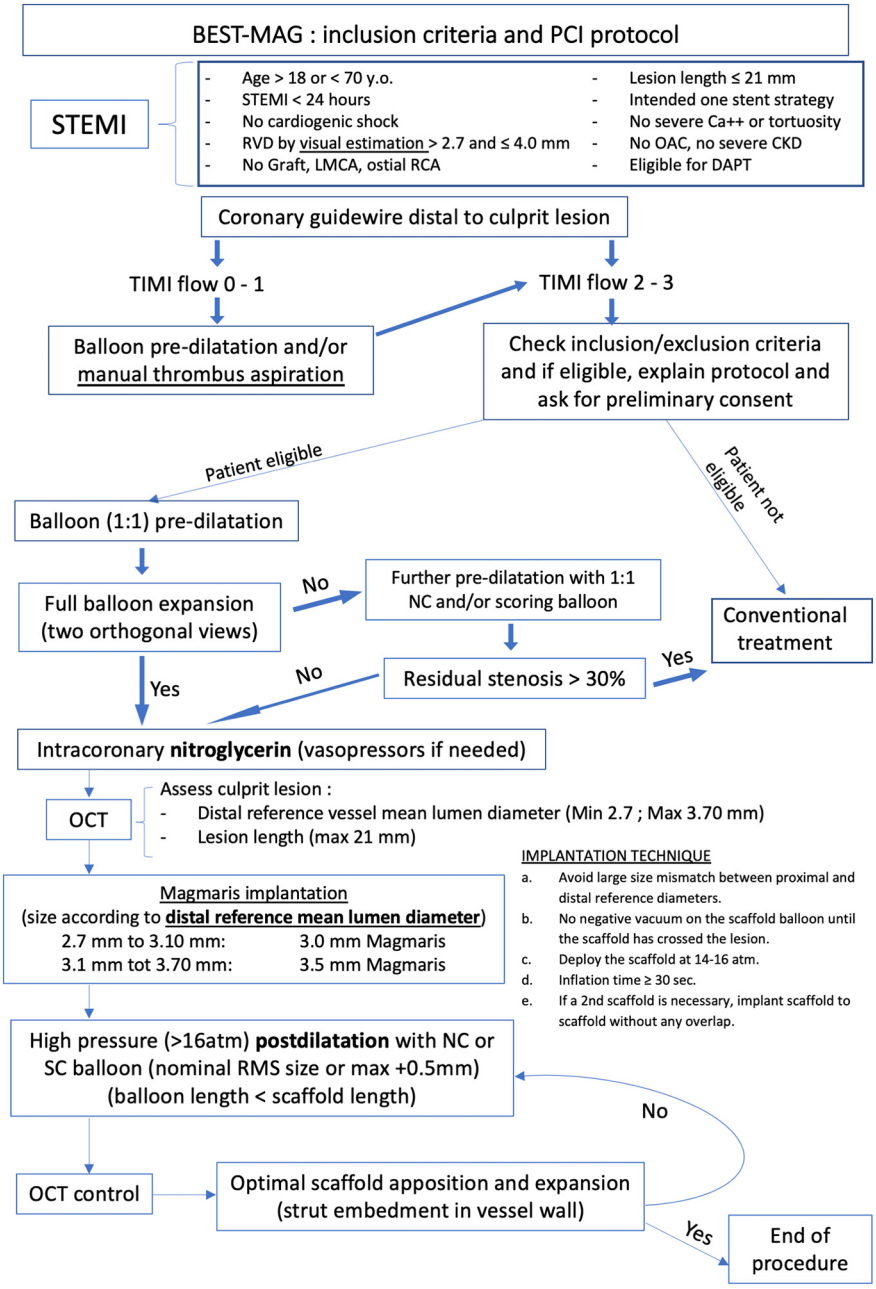

Fig. 1. Inclusion/exclusion criteria and OCT-guided Magmaris® implantation protocol.
CKD indicates chronic kidney disease; DAPT, dual anti-platelet therapy; OAC, oral anti-coagulation; LMCA, left main coronary artery; NC, non-compliant; OCT, optical coherence tomography; STEMI, ST-segment elevation myocardial infarction; RCA, right coronary artery; RVD, reference vessel diameter; RMS, resorbable magnesium scaffold; SC, semi-compliant; TIMI, thrombolysis in myocardial infarction.

endothelial response in coronary segments treated with Magmaris as compared with conventional metallic DES in ST-segment elevation myocardial infarction (STEMI) patients [10].

However, despite these theoretical advantages, the clinical efficacy of Magmaris in ACS and especially in STEMI has not been extensively studied. The limited data available of RMS implantation in STEMI did not include systematic intracoronary imaging, which might have led to inadequate sizing and suboptimal implantation of BRS. To this end, the BEST-MAG study was designed as a multicenter, prospective, single-arm registry of optical coherence tomography (OCT)-guided implantation of Magmaris in the setting of STEMI. Clinical outcomes were compared to those of patients treated with conventional DES from the randomized controlled BIOSTEMI trial [11].

2. Material and methods

BEST-MAG is an investigator-initiated and sponsored multicenter, prospective, non-randomized, observational registry designed to assess feasibility, safety, and clinical results of OCT-guided implantation of Magmaris® in the setting of primary percutaneous coronary intervention (pPCI) for STEMI. Patients presenting with STEMI within 24 h of symptom onset were eligible. Inclusion and exclusion criteria are presented in Fig. 1.

All patients were treated according to a pre-specified standardized implantation technique including systematic adequately sized pre- and post-dilatation, vasodilator administration and OCT imaging to guide BRS implantation (pre- and post-implantation) (Fig. 1) in order to optimize appropriate sizing and final scaffold expansion/apposition.

The study was performed in accordance with the Declaration of Helsinki and with good clinical practice and was approved by the central (Universitair Ziekenhuis Leuven, Belgium) and local ethics committees of all participating centers. All patients provided written informed consent. The study was registered at ClinicalTrials.gov: NCT03955731.

BIOSTEMI was a single-blind, prospective, randomized trial that compared the biodegradable polymer sirolimus eluting stent (BP-SES) Orsiro (Biotronik AG, Bülach, Switzerland) to the durable polymer everolimus eluting stent (DP-EES) Xience (Abbott Vascular, Abbott Park, IL, USA) in patients presenting with STEMI. BIOSTEMI study protocol and results have been previously published [11].

The primary endpoint of the study was a device oriented composite endpoint (DOCE) that included cardiac death, target vessel myocardial infarction (TV-MI) (attributable to the culprit lesion) and ischemic-driven target lesion revascularization (TLR) within 12 months after the index procedure as defined by the Academic Research Consortium criteria [12].

Secondary endpoints were TLR during follow-up duration, procedural success (defined as the delivery and deployment of RMS at the intended target lesion with a final residual stenosis ≤20% by visual estimation) and definite or probable scaffold thrombosis (ScT) as defined by the Academic Research Consortium criteria [12].

Clinical follow-up was scheduled at 1, 6, 12 and 24 months. Angiographic and OCT follow-up were performed in a pre-specified sub-group

Table 1
Baseline clinical and procedural characteristics in the overall population.

	RMS (n = 30)	BP-SES (n = 648)	DP-EES (n = 651)	*p*-Value*	*p*-Value†
Age, yrs	54.7 ± 10.2	62.2 ± 11.8	63.2 ± 11.8	0.001	<0.001
Male	23 (76.7%)	512 (79.0%)	477 (73.3%)	0.758	0.681
Smoking history	23 (76.7%)	294 (45.4%)	250 (38.4%)	0.003	<0.001
Hypertension	16 (53.3%)	281 (43.4%)	297 (45.6%)	0.295	0.418
Diabetes mellitus	5 (16.7%)	73 (11.3%)	82 (12.6%)	0.369	0.514
Hypercholesterolemia	18 (60.0%)	305 (47.1%)	302 (46.4%)	0.185	0.164
Previous MI	0 (0.0%)	27 (4.2%)	24 (3.7%)	0.989	0.989
Previous PCI	0 (0.0%)	29 (4.5%)	34 (5.2%)	0.988	0.988
Infarct-related artery				0.049	0.031
NA	0 (0.0%)	0 (0.0%)	1 (0.2%)		
LAD	18 (60.0%)	283 (43.7%)	275 (42.2%)		
RCA	11 (36.7%)	263 (40.6%)	262 (40.2%)		
LCx	1 (3.3%)	96 (14.8%)	109 (16.7%)		
SVG	0 (0.0%)	2 (0.3%)	0 (0.0%)		
Left main	0 (0.0%)	4 (0.6%)	4 (0.6%)		
Multivessel disease	10 (33.3%)	49 (7.6%)	50 (7.7%)	<0.001	<0.001
Pre-dilatation	30 (100.0%)	492 (75.9%)	508 (78.0%)	0.975	0.975
Post-dilatation	30 (100.0%)	432 (66.7%)	432 (66.4%)	0.971	0.971
Post-dilatation pressure (mmHg)	18.5 ± 2.4	NA	NA	–	–
Thrombus aspiration	7 (23.3%)	235 (36.3%)	242 (37.2%)	0.002	0.003
Stent/scaffold diameter, mm	3.20 ± 0.25	3.14 ± 0.49	3.14 ± 0.46	0.553	0.498
Stent/scaffold length, mm	22.0 ± 3.4	33.7 ± 18.7	34.9 ± 19.7	0.001	<0.001
TIMI flow grade pre-PCI				0.206	0.459
NA	0 (0.0%)	3 (0.5%)	1 (0.2%)		
0	20 (66.7%)	357 (55.1%)	394 (60.5%)		
1	1 (3.3%)	61 (9.4%)	45 (6.9%)		
2	6 (20.0%)	88 (13.6%)	95 (14.6%)		
3	3 (10.0%)	139 (21.5%)	116 (17.8%)		
TIMI flow grade post-PCI				0.960	0.978
NA	0 (0.0%)	3 (0.5%)	0 (0.0%)		
0	0 (0.0%)	2 (0.3%)	0 (0.0%)		
1	1 (3.3%)	2 (0.3%)	1 (0.2%)		
2	0 (0.0%)	17 (2.6%)	22 (3.4%)		
3	29 (96.7%)	624 (96.3%)	628 (96.5%)		
Chronic kidney disease	1 (3.3%)	76 (11.7%)	78 (12.0%)	0.179	0.170
Radial access	29 (96.7%)	419 (64.7%)	405 (62.2%)	0.007	0.005

Values are mean ± SD or n (%). The *p*-values are from paired *t*-tests for continuous data and chi-squared tests for dichotomous and ordinal data. BP-SES, biodegradable polymer sirolimus-eluting stent; DP-EES, durable polymer everolimus-eluting stent; LAD, left anterior descending artery; LCx, left circumflex artery; MI, myocardial infarction; PCI, percutaneous coronary intervention; RCA, right coronary artery; RMS, Resorbable magnesium scaffold; TIMI, thrombolysis in myocardial infarction.

* Comparison between RMS and BP-SES.

† Comparison between RMS and DP-EES.

(in 2 participating centers) of patients at 15 months but will be evaluated in a separate analysis. In case of uncertainty regarding the report of a clinical event, adjudication was performed by an independent physician (FP).

2.1. Statistical analysis

Descriptive data for continuous variables are presented as mean ± standard deviation, or number (%), as indicated in the tables. Data analyses were performed using SAS version 9.4 (SAS Institute, Cary, North Carolina, United States).

Propensity score matching (PSM) was applied to match the STEMI patients treated with RMS in BESTMAG with those treated with BP-SES and DP-EES in BIOSTEMI. PSM was performed using the PSMATCH procedure in SAS version 9.4. First, a logistic regression to score all patients according to study treatment was performed (RMS vs. BP-SES; RMS vs. DP-EES), using clinically relevant clinical and procedural parameters as covariates for the endpoint, including sex, smoking history, diabetes mellitus, hypertension, hypercholesterolemia, infarct-related artery, and presence of multivessel coronary artery disease. As patients treated with RMS received only one scaffold, we decided to restrict the matching to BIOSTEMI patients who were treated with only one stent. Second, we searched and selected the best match case of the BP-SES and DP-EES groups for every RMS patient according to the absolute value of the difference between the propensity score of BP-SES/DP-EES and RMS patients under consideration. Patients in the 2 treatment groups were matched through a full algorithm, i.e., each treated unit was matched with one control unit. The control selected for a particular case was the one closest to the case in terms of distance, whereby the maximum allowed distance for matching was set to 0.30. Analyses were performed on the 2 matched groups (RMS vs. BP-SES and RMS vs. DP-EES), without stratifying by pairs to account for propensity score matching. Time-to-event variables are presented as Kaplan-Meier curves. Hazard ratios (HRs) of all events at 1 year were calculated with Cox proportional hazards models. Events occurring after 365 days were censored.

3. Results

Between 15th February 2019 and 25th May 2020, 30 patients were included from 5 centers in Belgium. Recruitment was stopped prematurely due to slow recruitment partly attributed to the COVID-19 pandemic, reluctance to perform OCT in unstable patients and limited available scaffold sizes. Characteristics of patients included in BIOSTEMI have been previously published [11]. Patients treated with RMS were matched 1:1 to patients from both groups of BIOSTEMI (BP-SES and DP-EES). Baseline demographics and clinical characteristics of the study population and patients from the BIOSTEMI trial before and after PSM are presented in Tables 1 and 2 respectively. Pre-implantation OCT was performed in all patients during the index procedure in the RMS group, and post-implantation OCT was performed in all but one patient (97%); details are summarized in Table 3. Lesion length was 19.31 ± 7.37 mm, proximal and distal vessel reference diameters were 3.37 ± 0.51 mm and 2.18 ± 1.39 mm respectively. Thrombus was present in all cases, hindering image analysis. Final scaffold expansion after post-dilatation was 82 ± 11%. Case examples are illustrated in Figs. 3 and 4.

Patients treated with RMS were significantly younger than those treated with conventional DES, had a higher prevalence of multivessel disease and of smoking history. Thrombus aspiration was less

Table 2
Baseline clinical and procedural characteristics in the propensity-matched population.

	RMS (n = 30)	BP-SES (n = 30)	DP-EES (n = 30)	*p*-Value*	*p*-Value†
Age, yrs	54.7 ± 10.2	59.2 ± 12.0	62.6 ± 9.4	0.108	0.005
Male	23 (76.7%)	22 (73.3%)	21 (70.0%)	0.766	0.560
Smoking history	23 (76.7%)	25 (83.3%)	21 (70.0%)	0.520	0.560
Hypertension	16 (53.3%)	16 (53.3%)	19 (63.3%)	1.000	0.433
Diabetes mellitus	5 (16.7%)	4 (13.3%)	6 (20.0%)	0.718	0.739
Hypercholesterolemia	18 (60.0%)	17 (56.7%)	19 (63.3%)	0.794	0.791
Previous MI	0 (0.0%)	1 (3.3%)	1 (3.3%)	0.996	0.996
Previous PCI	0 (0.0%)	1 (3.3%)	1 (3.3%)	0.996	0.996
Infarct-related artery				0.795	0.722
LAD	18 (60.0%)	19 (63.3%)	19 (63.3%)		
RCA	11 (36.7%)	10 (33.3%)	11 (36.7%)		
LCx	1 (3.3%)	1 (3.3%)	0 (0.0%)		
Multivessel disease	10 (33.3%)	9 (30.0%)	9 (30.0%)	0.781	0.781
Pre-dilatation	30 (100.0%)	22 (73.3%)	25 (83.3%)	0.994	0.994
Post-dilatation	30 (100.0%)	21 (70.0%)	19 (63.3%)	0.993	0.993
Post-dilatation pressure (mmHg)	18.5 ± 2.4	NA	NA	–	–
Thrombus aspiration	7 (23.3%)	18 (60.0%)	21 (70.0%)	0.005	<0.001
Stent/scaffold diameter, mm	3.20 ± 0.25	3.22 ± 0.52	3.24 ± 0.45	0.841	0.668
Stent/scaffold length, mm	22.0 ± 3.4	22.9 ± 6.2	27.6 ± 10.0	0.636	0.003
TIMI flow grade pre-PCI				0.606	0.585
0	20 (66.7%)	19 (63.3%)	23 (76.7%)		
1	1 (3.3%)	0 (0.0%)	0 (0.0%)		
2	6 (20.0%)	5 (16.7%)	2 (6.7%)		
3	3 (10.0%)	6 (20.0%)	5 (16.7%)		
TIMI flow grade post-PCI				0.981	0.981
0	0 (0.0%)	0 (0.0%)	0 (0.0%)		
1	1 (3.3%)	0 (0.0%)	0 (0.0%)		
2	0 (0.0%)	1 (3.3%)	1 (3.3%)		
3	29 (96.7%)	29 (96.7%)	29 (96.7%)		
Chronic kidney disease	1 (3.3%)	3 (10.0%)	3 (10.0%)	0.324	0.324
Radial access	29 (96.7%)	20 (66.7%)	17 (56.7%)	0.014	0.004

Values are mean ± SD or n (%). The *p*-values are from paired *t*-tests for continuous data and chi-squared tests for dichotomous and ordinal data. BP-SES, biodegradable polymer sirolimus-eluting stent; DP-EES, durable polymer everolimus-eluting stent; LAD, left anterior descending artery; LCx, left circumflex artery; MI, myocardial infarction; PCI, percutaneous coronary intervention; RCA, right coronary artery; RMS, Resorbable magnesium scaffold; TIMI, thrombolysis in myocardial infarction.

* Comparison between RMS and BP-SES.

† Comparison between RMS and DP-EES.

Table 3
OCT data during index procedure in RMS group.

Pre-implantation acquisition	30 (100%)
Post-implantation acquisition	29 (97%)
Lesion length (mm)	19.31 ± 7.37
Proximal reference diameter (mm)	3.37 ± 0.51
Distal reference diameter (mm)	2.18 ± 1.39
Minimal lumen area after predilatation (mm^2)	3.91 ± 1.37
Minimum scaffold area (mm^2)	7.57 ± 1.48
Scaffold expansion (%)	82 ± 11

Values are expressed as n (%), mean ± SD.

frequently performed in the RMS group. All considered clinical variables were matched except age in the DP-EES group.

Clinical outcomes at one-year follow-up of RMS, BP-SES and DP-EES patients are presented in Table 4. Fig. 2 represents Kaplan-Meier curves of composite endpoint DOCE and TLR (panels A and B respectively). DOCE in the RMS group was 13.3% versus 10% and 6.7% in the BP-SES and DP-EES groups, respectively (p = NS). Differences in DOCE were driven by higher rates of TLR in the RMS group (13.3%) as compared to 3.3% and 0% in the BP-SES and DP-EES groups respectively (p = NS). There was no definite of probable scaffold thrombosis, although one case of silent scaffold occlusion occurred. The case of silent scaffold occlusion, as defined by the academic research consortium-2 consensus document [13], occurred in a 50-year-old female who presented atypical chest pain 4 months after pPCI without significant electrocardiographic changes nor cardiac biomarkers elevation. Despite reassuring non-invasive testing, an elective angiogram was performed 5 months after the index procedure which revealed occlusion of the treated segment. As revascularization could not be achieved (persistent TIMI 0 flow after balloon angioplasty), intracoronary imaging could not be performed to determine the cause of the occlusion. Dual anti-platelet therapy had not been interrupted. Of note, the final OCT run during the index procedure could not be performed due to patient instability (seizure).

Other cases of TLR included two cases of atypical chest pain with positive noninvasive tests, and one case of NSTEMI with slight troponin rise. All these TLR cases were due to early scaffold recoil.

4. Discussion

The main findings of the BEST-MAG can be summarized as follows: OCT-guided RMS implantation in the setting of p-PCI for selected STEMI patients was associated at 1-year follow-up with numerically higher rates of 1) DOCE rates of 13.3% as compared with matched patients treated with conventional DES of 10.0% and 6.7% with BP-SES and DP-EES respectively, and 2) TLR rates of 13.3% in RMS group versus 3.3% and 0% in BP-SES and DP-EES respectively. However, these differences did not reach statistical significance due to the limited numbers of patients included.

Available data from RMS use in STEMI are scarce. Our results are in line with these previous data. The MAGSTEMI trial is the only published randomized controlled trial prior to our study that compared RMS vs BP-SES in STEMI patients. 150 patients were included (RMS = 74 and BP-SES = 76) and the TLR rates of RMS group were higher (16.2%) as compared with conventional DES group (5.3%), although these numbers might have been inflated by the systematic 12-months angiographic control which does not reflect current clinical practice [10]. Optimal technique implantation as recommended by expert consensus [14] including adequately sized pre- and post-dilatation was systematically applied in our series, as it was in MAGSTEMI and cannot be responsible for the sub-optimal clinical results. Furthermore, systematic OCT guidance was implemented to warrant optimal sizing and implantation to improve clinical outcomes. Unfortunately, such effect was not observed in our series. Indeed, in their study, Sabate et al. did not use systematic imaging and had comparable results [10]. The absence of a clear benefit from systematic use of intracoronary imaging for BRS implantation in STEMI might be explained by the presence of large thrombus burden that makes the interpretation of images challenging. Also, despite the administration of nitrates before vessel measurement during p-PCI,

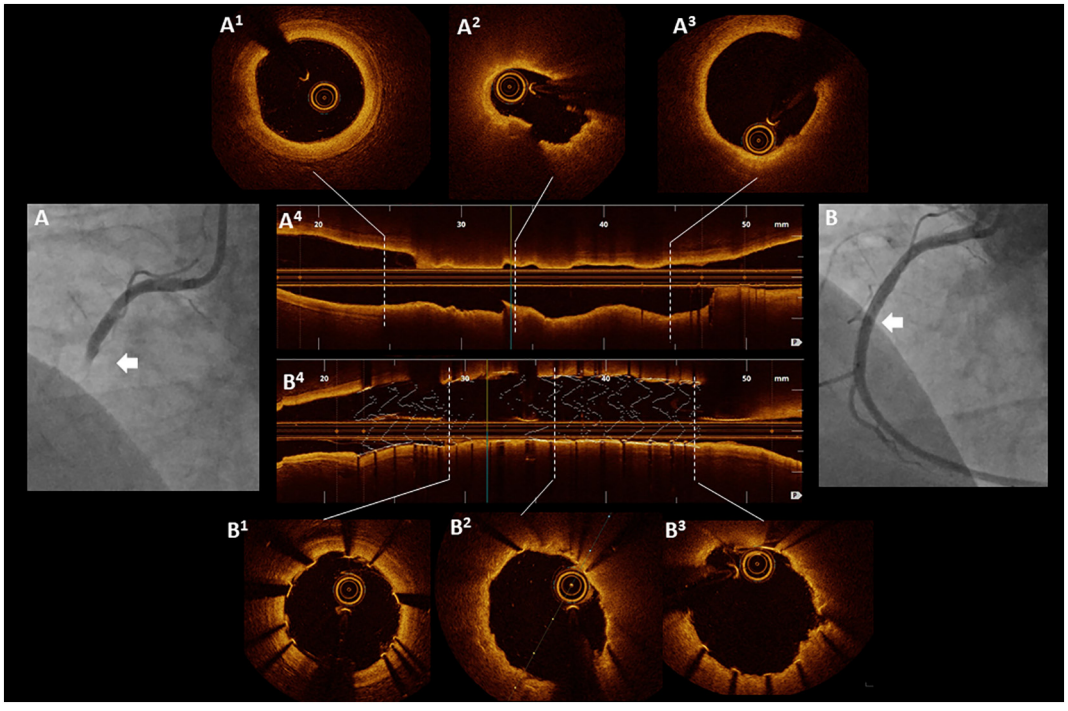

Fig. 3. Case example of 63-year-old male with an inferior STEMI.
Baseline angiography with thrombotic occlusion of the right coronary artery (panel A, white arrow) and optical coherence tomography imaging after pre-dilatation with a 2.5 mm non-compliant balloon (panels A1–A4). Angiography post implantation of a 3.5 × 25 mm Magmaris and post-dilatation with a 3.5 non-compliant balloon (panel B) with optical coherence tomography imaging (panels B1–B4).

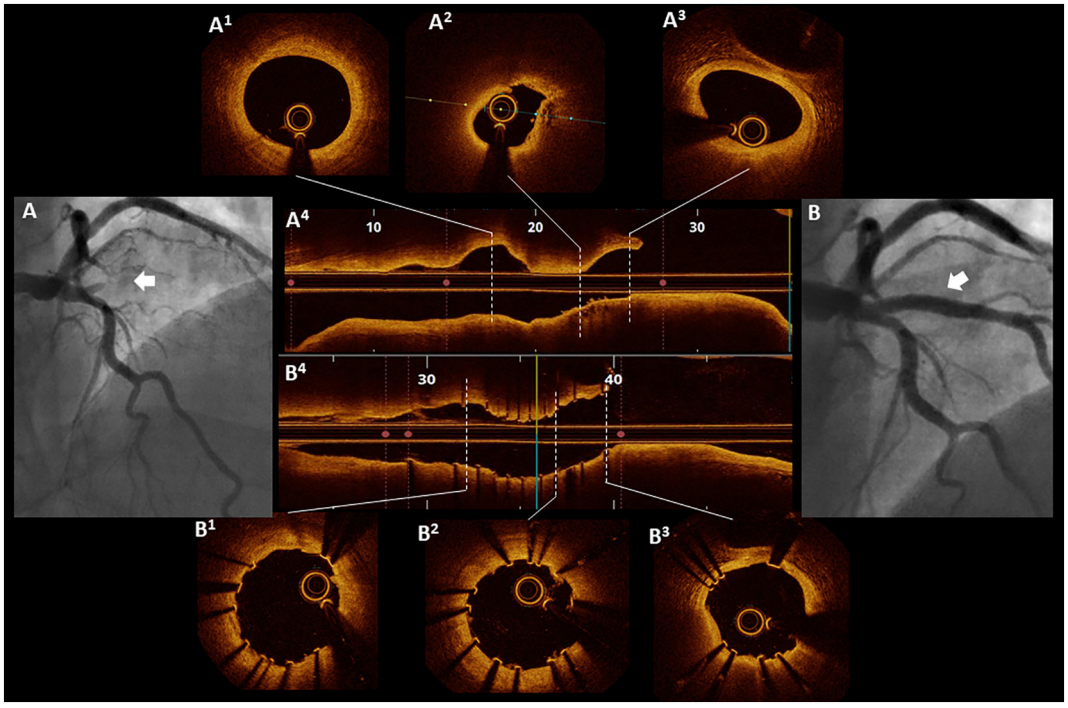

Fig. 4. Case example of 44-year-old male with an anterolateral STEMI.
Baseline angiography with thrombotic occlusion of large 1st diagonal branch (panel A, white arrow), and optical coherence tomography imaging after pre-dilatation with a 2.5 mm non-compliant balloon (panels A1–A4). Angiography post implantation of a 3.0 × 15 mm Magmaris and post-dilatation with a 3.0 non-compliant balloon (panel B) with optical coherence tomography imaging (panels B1–B4).

some vasoconstriction might have persisted, leading to underestimation of the vessel dimensions, and hence, to scaffold/vessel mismatch. This also could partly explain the less-than optimal expansion of the BRS in our study as shown by the final OCT run: mean scaffold expansion was 82% in our series despite systematic pre-dilatation and high-pressure post-dilation (Table 3).

RMS has been hypothesized as a good candidate for ACS treatment due to unique low thrombogenicity characteristics as demonstrated in an ex-vivo shunt model [15]. From this point of view, RMS did not raise any thrombotic safety concern.

TLR events in our study were driven by ACS presenting as unstable angina, which suggests the absence of thrombus formation and embolization. Mechanism of scaffold failure was mainly due to early recoil, possibly due to insufficient scaffolding time and loss of radial strength of the device. Current generation of Magmaris® has a resorption time of approximately 12 months, and a scaffolding time (radial support) of 3 months. In comparison, Absorb® BRS (Abbott Vascular, Santa Clara, CA, USA) had a minimal resorption time of 24–32 months, and a scaffolding time of 6 months [16]. Such characteristics might be related to early scaffold recoil/collapse and new iterations of the current RMS with longer scaffolding time, thinner struts and higher radial force may help to resolve the above limitations.

Sub-optimal implantation technique of BRS is associated with higher event rates [17], and such technique might be harder to strictly adhere to in the clinical setting of STEMI due to the presence of thrombus, vasoconstriction, and potential hemodynamic instability. However, strict adherence to current implantation recommendations was applied, attested by the pre- and post-dilatation rates. Systematic OCT imaging was expected to improve clinical results through optimal implantation; however, OCT in the setting of STEMI is not always feasible, due to patient instability and emergent situation, and interpretation of the images is hindered by the presence of thrombus. Furthermore, despite nitrates administration, residual vasoconstriction might persist. Although we did not compare OCT-guided with conventional angiographic-only implantation, OCT does not appear to help improve results of RMS implantation in STEMI. Pre-dilatation balloons might have been undersized due to vasoconstriction frequently associated with STEMI. However, STEMI is frequently associated with plaque ruptures that are

Table 4
Clinical outcomes at 1 year.

	RMS (n = 30)	BP-SES (n = 30)	DP-EES (n = 30)	OR (95% CI)*	*p*-Value*	OR (95% CI)†	*p*-Value†
DOCE	4 (13.3%)	3 (10.0%)	2 (6.7%)	1.39 (0.28–6.80)	0.689	2.15 (0.36–12.76)	0.398
Cardiac death	0 (0.0%)	2 (6.7%)	2 (6.7%)	NA	0.995	NA	0.995
Target vessel myocardial re-infarction	1 (3.3%)	0 (0.0%)	0 (0.0%)	NA	0.998	NA	0.998
Target lesion revascularization	4 (13.3%)	1 (3.3%)	0 (0.0%)	4.46 (0.47–42.51)	0.194	NA	0.996
Definite/probable device thrombosis	0 (0.0%)	1 (3.3%)	1 (3.3%)	NA	0.996	NA	0.996
Definite device thrombosis	0 (0.0%)	0 (0.0%)	1 (3.3%)	NA	1.000	NA	0.998
Probable device thrombosis	0 (0.0%)	1 (3.3%)	0 (0.0%)	NA	0.998	NA	1.000

CI, confidence interval; OR, odds ratio. The p-values are from paired t-tests for continuous data and chi-squared tests for dichotomous and ordinal data. BP-SES, biodegradable polymer sirolimus-eluting stent; DOCE, device-oriented composite endpoint; DP-EES, durable polymer everolimus-eluting stent; NA, not applicable; RMS, resorbable magnesium scaffold.
* Comparison between RMS and BP-SES.
† Comparison between RMS and DP-EES.

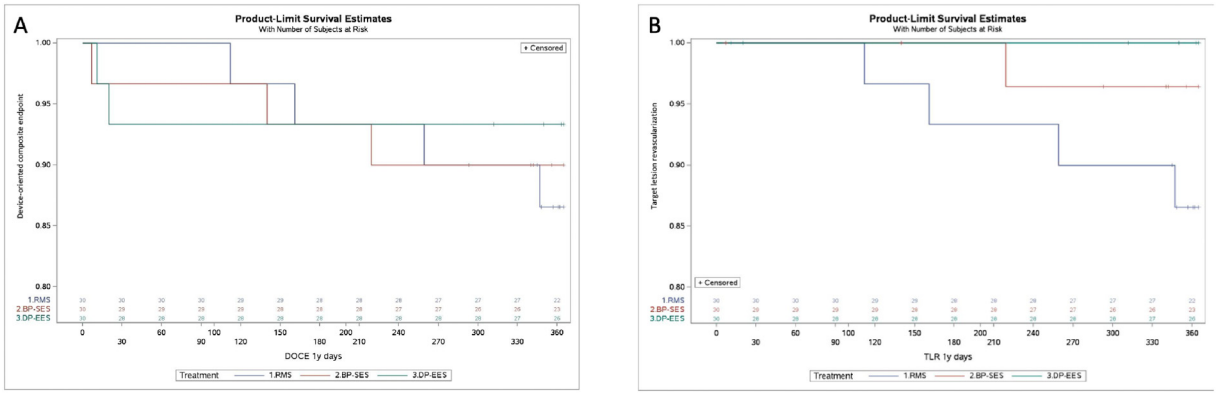

Fig. 2. Time-to-event curves for device-oriented composite endpoint (DOCE) (A) and target lesion revascularization (TLR) (B). BP-SES indicates biodegradable polymer sirolimus-eluting stent; DP-EES, durable polymer everolimus eluting stent; RMS, resorbable magnesium scaffold.

usually easily expanded, as opposed to stable coronary artery lesions, making predilatation theoretically less critical than adequately sized post-dilatation [18,19].

The PRAGUE-22 study recently evaluated late lumen loss in ACS patients (STEMI, NSTEMI and unstable angina) treated with magnesium-based BRS versus conventional DES [20]. Fifty patients were randomized to be treated with Magmaris (n = 25) or Xience (n = 25). Late luminal loss diameter was more important in the BRS group than in the DES group (0.59 ± 0.37 vs. 0.22 ± 0.20 mm; $p = 0.01$). Similar findings were observed in a study assessing vascular outcomes in a subset of patients from the MAGSTEMI trial [21]. Such phenomenon is mainly explained by early recoil of the BRS due to insufficient radial strength and resorption time.

TLR rates of RMS in STEMI observed in this study, as in others [10], may appear higher than those observed with previous generations of BRS in STEMI. However, no direct comparison between RMS and polymeric BRS will ever be performed, as Absorb® BRS was withdrawn from the market in 2017 due to elevated rates of late events such as ScT. First generation polymeric BRS had been tested and compared with conventional DES, with acceptable results. Tamburino et al. had performed a PSM analysis comparing STEMI patients treated with Absorb BRS and DP-EES (Xience, Abbott Vascular) from the GHOST-EU and XIENCE V USA registries [22]. At one-year follow-up, DOCE were respectively 5.8 vs 7.6% and TLR rates were 4.6 vs 3.5%. Similarly, Brugaletta et al. compared results from STEMI patients treated with Absorb BRS and patients treated with DES or bare metal stent (BMS) from the EXAMINATION trial [23]. After PSM analysis, DOCE at one-year follow-up were 4.1% vs 4.1% vs 5.9% in BRS, DES and BMS groups respectively. TLR rates were 1.7% vs 1.4% vs 3.4% respectively. Magmaris® RMS does not appear to have long-term safety concerns, as 5-years follow-up data in stable de novo lesions from the BIOSOLVE-II trial showed low TLR rates (5.6%), with most events occurring during the first 2 years post PCI [3]. Therefore, there is a hope that future iterations of RMS might reduce the elevated rate of mid-term TLR in STEMI patients.

This study presents several limitations: the small number of patients and events render this study underpowered for statistical comparisons. Selection bias due to the necessity of performing systematic OCT, excluding unstable patients, and due to the limited scaffold size, excluding patients with small or large culprit vessels. The comparator groups from the BIOSTEMI trial were added post-hoc and consequently random assignment to the treatment groups was not possible. Furthermore, despite the PSM, residual confounding factors cannot be ruled out.

5. Conclusions

OCT-guided RMS implantation in selected STEMI patients appears feasible but is associated with higher rates of TLR as compared with conventional DES, although the limited number of patients included in this analysis does not allow drawing statistically significant conclusions. Therefore, as recommended in current guidelines and expert recommendations, RMS should not be used routinely in STEMI outside of clinical trials [4,24]. Future iterations of the device might help to overcome these limitations through higher radial force, lower strut thickness, greater scaffold size portfolio and longer scaffolding durations.

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CRediT authorship contribution statement

Quentin de Hemptinne: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Funding acquisition, Resources. **Panagiotis Xaplanteris:** Conceptualization, Methodology, Formal analysis, Investigation, Writing – review & editing, Supervision. **Antoine Guédès:** Investigation, Writing – review & editing, Resources. **Fabian Demeure:** Investigation, Writing – review & editing, Resources. **Bert Vandeloo:** Investigation, Writing – review & editing, Resources. **Christophe Dugauquier:** Investigation, Writing – review & editing, Resources. **Fabien Picard:** Validation, Supervision, Writing – review & editing. **David W. Warne:** Formal analysis, Visualization, Data curation, Software. **Thomas Pilgrim:** Resources, Investigation, Data curation, Writing – review & editing. **Juan F. Iglesias:** Resources, Investigation, Data curation, Writing – review & editing, Supervision. **Johan Bennett:** Conceptualization, Methodology, Formal analysis, Investigation, Writing – review & editing, Supervision, Resources, Project administration, Visualization.

Declaration of competing interest

Quentin de Hemptinne reports a relationship with Biotronik AG that includes: consulting or advisory and speaking and lecture fees. Fabien Picard reports a relationship with Biotronik AG that includes: consulting or advisory and speaking and lecture fees. Thomas Pilgrim reports a relationship with Biotronik AG that includes: funding grants and speaking and lecture fees. Juan Iglesias reports a relationship with Biotronik AG that includes: consulting or advisory, funding grants, and speaking and lecture fees. Johan Bennett reports a relationship with Biotronik AG that includes: consulting or advisory, funding grants, and speaking and lecture fees.

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