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Outcomes of the two generations of bioresorbable scaffolds (Magmaris vs. Absorb) in acute coronary syndrome in routine clinical practice

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Abstract

Background: *Acute coronary syndrome (ACS) as a clinical manifestation of coronary artery disease (CAD) remains a significant cause of mortality and morbidity, as reported worldwide annually. The second generation of drug-eluting stents (DES) is a gold standard in percutaneous interventions in ACS patients however, permanent caging of the vessel with metallic DES has some drawbacks. Bioresorbable vascular scaffolds (BRS) were designed as a temporal vessel-supporting technology allowing for anatomical and functional restoration. Nevertheless, following the initial encouraging reports, numerous concerns about the safety of BRS occurred.*

Methods: *In this study, a 1-year performance of 193 patients with magnesium BRS — Magmaris (Biotronik, Berlin, Germany) was evaluated in comparison to 160 patients with polymer BRS — Absorb (Abbott-Vascular, Chicago, USA) in the non-ST-segment elevation-ACS setting.*

Results: *The Magmaris, when compared to Absorb showed a significantly lower rate of primary endpoint (death from cardiac causes, myocardial infarction, stent thrombosis) as well as target lesion failure in 30-day and 1 year follow-up. In the Absorb group, a significantly higher rate of stent thrombosis was observed.*

Conclusions: *Data from the present study suggests encouraging safety a profile and more favorable clinical outcomes of magnesium BRS in comparison to the polymer Absorb — BRS.* (Cardiol J 2023; 30, 6: 870–880)

Key words: bioresorbable scaffolds, acute coronary syndrome, magnesium scaffolds, Magmaris, Absorb, percutaneous coronary intervention

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Introduction

Coronary artery disease (CAD) remains a significant cause of mortality and morbidity worldwide [1], despite advances in pharmacotherapy and revascularization techniques. Acute coronary syndrome (ACS) is a leading clinical presentation of CAD as well as being the most common indication for percutaneous coronary interventions (PCI) in everyday clinical practice [2]. The second generation of drug-eluting stents (DES) is a gold standard in PCI procedure. However, permanent caging of the vessel with metallic DES may have some drawbacks. A metallic scaffold — a foreign body implanted inside the vessel wall has an unfavorable impact on the arterial healing process. It induces an inflammatory response by enhancing the macrophage infiltration, endothelial cell migration, and proliferation leading to endothelial dysfunction and increase local thrombogenicity [3]. All these reactions result in an increased rate of unfavorable clinical events as in-stent restenosis, stent thrombosis, or late lumen loss [4]. In the ACS-setting, strictly related to the presence of unstable, vulnerable plaque — all therapeutic efforts should be focused on maintaining short-period vessel patency allowing for a complete artery wall healing. This clinical setup particularly highlights classic DES limitations.

Bioresorbable vascular scaffolds (BRS) were designed as a vessel-supporting technology allowing for anatomical and functional restoration of the vessel without coexisting long-term risk related to the permanent presence of foreign material in the treated vessel. Initial optimism associated with the preliminary studies [5] was restrained by results of the ABSORB II and ABSORB III trials [6, 7] and resulted in ruling out of Absorb scaffold from commercial use. In both trials, the device-oriented composite endpoint was higher in the BVS arm, mostly due to target vessel myocardial infarction and device thrombosis. The mechanisms underlying this unfavorable device outcome are multifactorial and may include changes in polylactide polymer degradation and resorption times, long-term presence and migration of uncovered scaffold struts or neoatherosclerosis. Noteworthy, implantation technique in both studies was suboptimal, not adequate to present recommendations used in this study.

The first generation of BRS has lower radial force, thicker and prone to fracture struts, and has limited expansion volume compared to second-generation DES. Due to these technical imperfections [8] adequate implantation technique has been shown to reduce scaffold failure risk [9]. Despite initial setbacks, the BRS concept is still evolving, and metallic resorbable scaffolds are being developed. Initial data [10, 11] for Magmaris (Biotronik, Berlin, Germany) a novel sirolimus-eluting resorbable coronary magnesium scaffold are encouraging with reasonable efficiency and safety outcomes.

In the face of evidence for the delayed resorption process in Absorb (Abbott-Vascular, Chicago, USA) compare to Magmaris (Biotronik, Berlin, Germany) [12] as well as unfavorable for polymer scaffolds differences concerning expansion, elasticity, time-dependent recoil, radial strength [13] a "real-life" clinical evaluation of the effectiveness and safety of both devices is necessary. This observational study is aimed at evaluating a 1-year performance of magnesium BRS (Magmaris) compared to the polymer BRS (Absorb) in the context of ACS.

Methods

Study population

This investigator-initiated, single-center, double-arm observational study contains pooled data from two BRS — registries that enrolled patients undergoing PCI, with lesions suitable for BRS implantation at our Cardiology Department between April 2012 and March 2020. All subjects involved in this study were over 18 years old, initially diagnosed with unstable angina or non-ST-segment elevation myocardial infarction (NSTEMI) according to guidelines for NSTEMI [14, 15]. Subjects with known allergies to acetylsalicylic acid, clopidogrel, ticagrelor, heparin, or any other anticoagulant/antiplatelet required for the procedure were excluded from the study.

The first group consisted of 193 patients with ACS (without ST-segment elevation myocardial infarction [STEMI]) who received one or more Magmaris (Biotronik, Berlin, Germany) BRS at our Cardiology Department between October 2016 and March 2020 during the initial PCI.

Lesions considered as suitable for Magmaris (Biotronik, Berlin, Germany) were carefully selected in accordance with the inclusion and exclusion criteria in Figure 1 in accordance with the current recommendations and consensus of experts [16].

The second group consisted of 160 carefully selected patients all of whom received at least one Absorb BRS (Abbott-Vascular, Chicago, IL, USA) at our Cardiology Department between April 2012 and August 2017 during the initial PCI.

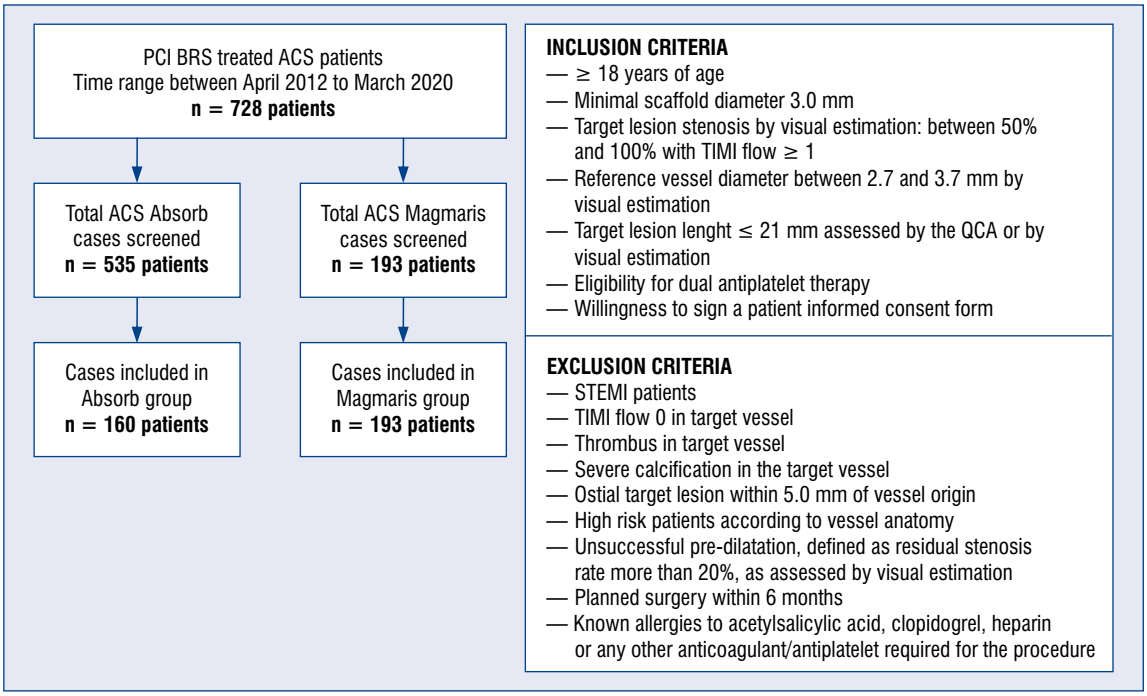

Figure 1. Study population, inclusion and exclusion criteria; ACS — acute coronary syndrome; BRS — bioresorbable scaffolds; PCI — percutaneous coronary intervention; STEMI — ST-segment elevation myocardial infarction; TIMI — Thrombolysis in Myocardial Infraction; QCA — quantitative coronary angiography.

A total of 535 patients were pre-screened and at the first step, populations of patients were selected with ACS (394 patients). At the next stage, patients were excluded with STEMI (72 out of 394). To avoid device-size-related impact on results for further analysis only patients were qualified by having received scaffolds with diameters between 3.0 and 3.5 mm (n = 247). From this group, patients with lesion criteria suitable to those in Figure 1 (n = 217), were selected. Finally, for further analysis only patients (n = 160 with 169 treated lesions) whose stent implantation procedure was followed by "4P strategy" were chosen. This concept was based on aggressive pre-dilatation (mandatory with a non-compliant [NC] balloon sized 1:1 balloon to artery ratio, without significant residual stenosis) and followed by mandatory post-dilatation (high-pressure — not less than 16 atm with NC balloon sized 1:1 balloon/scaffold ratio or up to 0.5 mm longer).

Device and procedures

Magmaris (Biotronik, Berlin, Germany) is a second-generation metallic (magnesium) sirolimus-eluting bioresorbable scaffold with active bioabsorbable coating — BIOlute poly-L-lactic acid (PLLA). Drug release was controlled and extended up to 90 days. An average time of complete scaffold absorption amounting to approximately 1 year. Magmaris (Biotronik, Berlin Germany) used in this study were available in diameters of 3.0 and 3.5 mm and lengths of 15, 20, and 25 mm. The average strut thickness is 150 μm.

The second type of BRS used in this study is the bioresorbable polymer drug-eluting scaffold ABSORB BVS (Abbott-Vascular, Chicago, IL, USA). These devices are composed of PLLA and an everolimus-eluting polymer both of which are bioresorbable in approximately 3 years. The average strut thickness is 150 μm. The device was available in diameters ranging from 2.5 to 3.5 mm with a length from 8 up to 28 mm. However, in this study, only scaffolds with a diameter of 3.0 mm or 3.5 mm and a length 12, 18, 24 mm were included.

All implantations were performed with the 4P strategy which includes: Patient selection (de novo lesions with a vessel diameter and lesion length up to 25 mm), Proper sizing (reference vessel diameter in a range from 2.7 up to 3.7 mm), Pre-dilatation (mandatory with a NC balloon sized 1:1 balloon to artery ratio, without significant residual stenosis), Post-dilatation (mandatory, high-pressure [not less than 16 atm] with NC balloon sized 1:1 balloon/scaffold ratio or up to 0.5 mm longer). The operators were encouraged to use an intravascular imaging

guidance; however, it was not obligatory — the decision was left to their discretion.

The decision to perform PCI was based on current guidelines for ACS management. Use of intravascular imaging guidance was not obligatory — the decision was left to the discretion of the operators. Standard pharmacotherapy was carried out following the current ESC/ESH guidelines for NSTEMI [13, 14], double antiplatelet therapy lasted 12 months.

Endpoints and definitions

The primary outcome was a safety composite of death from cardiac causes, myocardial infarction, or definite or probable stent thrombosis at 30 days and 1-year follow-up. The principal secondary outcome was an effectiveness outcome of target-lesion failure (TLF) defined as cardiac death, target vessel myocardial failure, or target lesion revascularization (TLR). Other secondary outcomes included: scaffold restenosis, death from any reason, other cardiovascular events defined: as cerebrovascular episodes; revascularization procedures as well as myocardial infarct. Myocardial infarction was defined according to the Fourth Universal Definition of Myocardial Infarction [17].

Statistical analysis

The analyzes were conducted using the R language [18]. Continuous variables were characterized with their mean and standard deviation, while frequencies were used for categorical variables. The patients were compared between groups with the nonparametric two-sample Mann–Whitney test for continuous variables and the Fisher Exact test for categorical variables. Bonferroni correction was applied to adjust for multiple comparisons.

Multivariate Cox analysis was performed for variables which, obtained statistical significance in the univariate analysis. P-values ≤ 0.05 were accepted as a threshold for statistical significance.

Results

The study was composed of two arms. To the first, 193 patients were recruited after Magmaris BRS implantation, to the second 160 subjects recruited were treated by Absorb implantation. Data regarding baseline clinical characteristics of both groups were pooled in Table 1. In the Magmaris group, compared to Absorb group were observed with a statistically higher prevalence of NSTEMI (84.5% vs. 60.6%, respectively $p < 0.001$). There were no significant differences between both study groups regarding comorbidities. The initial laboratory parameters revealed less advanced lipid disorders and a lower serum creatine level (84.1 ± 22.2 vs. 87.7 ± 17.2, respectively $p = 0.01$) in the Magmaris arm.

Interestingly, in Magmaris arm, in procedural management, we observed a significantly lower prevalence (54.4% vs. 62.6%; respectively $p < 0.001$) of 3.5 mm scaffold size. Additionally this study group had a significantly less aggressive postdilatation (mean pressure [atm] 17.7 ± 0.8 vs. 18.2 ± ± 2.5; respectively $p < 0.001$) along with a lower dose of radiation [mGy] (1056.7 ± 697.8 vs. 1551.0 ± ± 853.3; respectively $p < 0.001$) and contrast volume [mL] (151.5 ± 65.4 vs. 169.1 ± 58.0; respectively $p < 0.001$) used during the PCI procedure. On the other hand in the Absorb arm higher rate of perforation was noticed (4 vs. 0; respectively $p = 0.041$). All data regarding procedural features were collected in Table 2.

In the short term post-discharge period (up to 30 days after the index procedure), primary end point was reported significantly less frequently in the Magmaris group rather than in the Absorb group (0 [0%] vs. 5 [3.1%]; respectively $p = 0.018$). This fact was mainly associated with an increased rate of myocardial infraction in the Absorb arm (0 [0%] vs. 5 [3.1%]; respectively $p = 0.018$) caused by acute stent thrombosis (5 cases). A similar observation was made for a principally secondary outcome — target lesion failure (0 [0%] vs. 5 [3.1%]; respectively $p = 0.018$). This favorable trend in clinical outcome in Magmaris BRS group maintained also in the 1-year follow-up. A significantly lower rate of primary outcome was observed in the Magmaris arm compared to the Absorb arm (3 [1.5%] vs. 13 [8.1%]; respectively $p = 0.003$) with coexisting statistically lowernumber of TLR (3 [1.5%] vs. 9 [5.6%]; respectively $p = 0.042$) caused mainly by target vessel myocardial infarction (2 [1.0%] vs. 9 [5.6%]; respectively $p = 0.026$) and scaffold thrombosis (0 [0%] vs. 6 [3.7%]; respectively $p = 0.008$) including one fatal case. All data regarding clinical outcome were pooled in Table 3. Figure 2 presents the Kaplan-Meyer graph for primary outcome survival free. Additionally, to evaluate potential factors that could have an impact on primary outcomes, the univariable Cox regression analysis was performed (Table 4). Consequently, features that achieved statistical significance ($p < 0.05$) were evaluated in the multivariable Cox regressions model (Table 5).

Discussion

This is the first "real-life" study comparing the 1-year clinical outcomes between two generations

Table 1. Baseline clinical characteristic of both groups.

	Magmaris patients (n = 193)	Absorb patients (n = 160)	P
Age	66.3 ± 8.9	65.8 ± 9.7	0.244
Gander: male (ratio)	150 (77.7%)	117 (73.1%)	0.32
Unstable angina	30 (15.5%)	63 (39.3%)	< 0.001
NSTEMI	163 (84.5%)	97 (60.6%)	< 0.001
Diabetes mellitus type 2	72 (37.3%)	61 (38.1%)	0.912
Oral anty-diabetic treatment	58 (30%)	48 (30%)	1
Insulin	14 (7.2%)	13 (8.1%)	0.841
Hypertension	171 (88.6%)	131 (81.8%)	0.094
Hyperlipidemia	152 (78.7%)	133 (83.1%)	0.343
Atrial fibrillation	9 (4.6%)	5 (3.1%)	0.587
Previous PCI	78 (40.4%)	58 (36.2%)	0.443
Primary diagnosis MI	59 (30.5%)	50 (31.2%)	0.908
Current smoker	57 (29.5%)	52 (32.5%)	0.565
LVEF [%]	60.4 ± 10.9	55.6 ± 13.2	< 0.001
Total cholesterol [mmol/L]	4.6 ± 1.3	5.1 ± 1.3	0.006
LDL [mmol/L]	2.5 ± 1.2	2.9 ± 1.2	0.004
Triglycerides [mmol/L]	1.8 ± 1.8	2.0 ± 1.4	0.232
Creatine [μmol/L]	84.1 ± 22.2	87.7 ± 17.2	0.010
Days of hospitalization	2.7 ± 1.8	3.4 ± 2.7	0.013

LDL — low density lipoprotein; LVEF — left ventricular ejection fraction; MI — myocardial infarction; NSTEMI — non-ST-segment elevation myocardial infarction; PCI — percutaneous coronary intervention

of bioresorbable scaffolds polymeric and magnesium applied in patients in ACS condition. The main findings of this study are: 1) Magmaris, when compared to Absorb showed statistically significantly better clinical outcome for primary endpoint (death from cardiac causes, myocardial infarction, stent thrombosis) as well as TLF in 30-days and 1 year follow up; 2) Absorb group showed a significantly higher rate of stent thrombosis compared to the Magmaris group; 3) Magmaris did not present any definite scaffold thrombosis case after 12 months.

Presumed complete absorption of BRS was supposed to overcome the limitations of metallic scaffolds. Long-term TLF events related to permanent caging of a vessel with metallic struts impaired the vasomotor homeostasis and increased chronic vascular responses. It results in an exacerbation of a local inflammatory response leading to acceleration of neointimal hyperplasia and promotion of platelet activation. An initial short-term observation of Absorb revealed non-inferiority for composite adverse events compere to DES. However, the unfavorable trend toward target lesion revascularization and stent thrombosis was noticed [19]. Long-term observation revealed a higher incidence of scaffold thrombosis and a responsively higher rate of myocardial infarction and TLR [7, 20, 21].

The causes of the increased risk of adverse events related to Absorb are only partly understood. The Absorb was demonstrated to show greater thrombogenicity, delayed endothelialization time, and lower radial force than the second generation of DES, also disturbed spatial structure with struts dismantling into the lumen during the scaffold degradation is postulated as a risk factor [22, 23]. Clinical indications for PCI, vessel size with accompanying anatomical differences in the structure of the atherosclerotic plaque seem to affect the outcome. Soft, lipid-rich lesions related mainly to ACS might expand more easily resulting in a more favorable healing process for BVS scaffold than fibrocalcific lesions in stable CAD [24]. In response to all this data several recommendations regarding patient and lesion selection, adequate lesion preparation, and scaffold deployment technique, were implemented in clinical practice to reduce the risk of thrombotic events [25]. In the current study, thanks to the proper selection of patients and lesions (ACS patients without complex calcified lesion), adequate implantation technique (aggressive predilation and postdilation)

Table 2. Procedural characteristics of both study arms.

Procedural characteristic	Magmaris patients (n = 193)	Absorb patients (n = 160)	P
Treated vessel:			
LAD	80 (41.4%)	88 (52%)	0.036
LCx	49 (25.3%)	24 (14.3%)	0.036
RCA	61 (31.6%)	57 (33.7%)	0.430
IM	3 (1.6%)	0 (0%)	0.339
Predilation balloon:			
Mean diameter [mm]	3.2 ± 0.3	3.1 ± 0.3	0.092
Mean pressure [atm]	17.7 ± 0.8	16.8 ± 1.9	0.067
Average scaffold number	1.1 ± 0.2	1.3 ± 0.5	0.343
Scaffold diameter:			
3.0 [mm]	88 (45.6%)	76 (37.4%)	0.748
3.5 [mm]	116 (54.4%)	127 (62.6%)	< 0.001
Average scaffold length [mm]	20.8 ± 3.3	22.7 ± 4.8	0.002
Postdilation balloon:			
Mean diameter [mm]	3.5 ± 0.3	3.5 ± 0.3	0.067
Mean pressure [atm]	17.7 ± 0.8	18.2 ± 2.5	< 0.001
0.0 mm greater than scaffold	31 (16.6%)	70 (43.8%)	< 0.001
0.25 mm greater than scaffold	130 (65.2%)	64 (40%)	< 0.001
0.5 mm greater than scaffold	32 (18.2%)	26 (16.2%)	1
Syntax score	7.7 ± 4.2	7.9 ± 4.5	0.718
Contrast volume [mL]	151.5 ± 65.4	169.1 ± 58.0	< 0.001
Dose of radiation [mGy]	1056.7 ± 697.8	1551.0 ± 853.3	< 0.001
OCT guided PCI	41 (21.2%)	21 (13.1%)	0.052
Number of edge dissection:	7 (3.6%)	8 (5%)	0.601
Treated with BVS (Magmaris/Absorb)	3 (1.5%)	6 (3.7%)	0.310
Treated with DES	4 (2.0%)	2 (1.2%)	0.693
Perforation of vessel:	0 (0%)	4 (2.5%)	0.041
Treated with covert stent	0 (0%)	3 (1.9%)	0.092
Treated with prolong balloon inflation	0 (0%)	1 (0.6%)	0.453
Side branch occlusion	2 (1%)	1 (0.6%)	1
Antiplatelet drug:			
ASA	193 (100%)	160 (100%)	–
Clopidogrel	76 (36.1%)	122 (76.3%)	< 0.001
Ticagrelol	117 (63.9%)	35 (21.8%)	< 0.001
Prasugrel	0 (0%)	3 (1.9%)	0.092

ASA — acetylsalicylic acid; BRS — bioresorbable vascular scaffold; DES — drug-eluting stent; IM — intermediate artery; LAD — left anterior descending artery; LCx — left circumflex artery; OCT — optical coherence tomography; PCI — percutaneous coronary intervention; RCA — right coronary artery

with accurate sizing (large vessel diameter at least 3 mm), it was possible to select the optimal patient population for BRS technology (Magmaris and Absorb).

The device-orientated results (TLF) obtained by us in the Absorb group under these optimal for BRS conditions seem to be consistent (TLF 5.6% vs. 5%) with the outcome of ABSORB IV randomized trial (study recruitment according to parallel recommendations) [26]. Noteworthy, is that ABSORB IV resulted in non-inferior 30-day and 1-year rates of TLF compared with metallic DES.

Despite adequate compliance with "4P strategy" thrombotic issues were still relatively high

Table 3. Clinical outcomes in both study arms.

Clinical outcomes	Magmaris patients (n = 193)	Absorb patients (n = 160)	P
30–day FU primary outcome*	0 (0%)	5 (3.1%)	0.018
30–day FU principal secondary outcome: TLF**	0 (0%)	5 (3.1%)	0.018
30–day FU death:			
Any other	0 (0%)	0 (0%)	1
Cardiac	0 (0%)	0 (0%)	1
30–day FU MI:			
Any other	0 (0%)	0 (0%)	1
Target vessel myocardial infract	0 (0%)	5 (3.1%)	0.018
30–day FU scaffold:			
Thrombosis	0 (0%)	5 (3.1%)	0.018
Restenosis	0 (0%)	0 (0%)	1
30–day FU			
Stroke	0 (0%)	0 (0%)	1
TIA	0 (0%)	0 (0%)	1
30–day FU revascularization:			
Target lesion	0 (0%)	5 (0%)	0.018
Target vessel	0 (0%)	5 (0%)	0.018
Any other	0 (0%)	3 (1.88%)	0.095
1-year FU primary outcome*	3 (1.5%)	13 (8.1%)	0.003
1-year FU principal secondary outcome: TLF**	3 (1.5%)	9 (5.6%)	0.042
1-year FU death:			
Any other	2 (2.7%)	2 (2.7%)	1
Cardiac	0 (0%)	1 (0.6%)	0.453
1-year FU MI:			
Any other	3 (1.5%)	4 (2.5%)	0.706
Target vessel	2 (1.0%)	9 (5.6%)	0.026
1-year FU scaffold:			
Thrombosis	0 (0%)	6 (3.7%)	0.008
Restenosis	2 (1.0%)	2 (1.25%)	1
1-year FU:			
Stroke	2 (1%)	4 (0%)	0.416
TIA	1 (0.5%)	0 (0.8%)	1
1-year FU revascularization:			
Target lesion	2 (2.7%)	7 (4.4%)	0.084
Target vessel	3 (2.7%)	8 (5.0%)	0.072
Any other	18 (9.3%)	16 (10.0%)	0.857

*Cardiac death, myocardial infarction, stent thrombosis; **cardiac death, target vessel myocardial infarction, target lesion — revascularisation; ASA — acetylsalicylic acid; FU — follow up; MI — myocardial infarction; PCI — percutaneous coronary intervention; TIA — transient ischemic attack; TLF — target lesion failure

in the Absorb arm. The results of current study confirm this thesis. However, it should be considered that in the present study, no systematic intravascular imaging was performed at the time of the thrombotic event. Therefore, the strict connection to the device can only be presumed. Available data [27, 28] seem to support this point of view. Particularly stent malapposition has been identified as a predictor of scaffold thrombosis [28].

Another factor that could have an impact on the observed stent thrombosis-rate is the antiplatelet therapy. In the Absorb arm more patients received

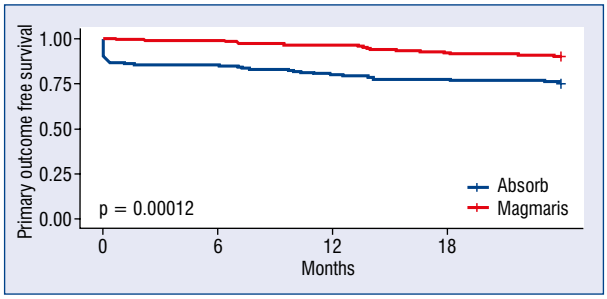

Figure 2. Kaplan-Meyer curves for primary outcome-survival free in both study groups.

clopidogrel instead of ticagrelor. The differences are mainly related to the recommendations focused on dual antiplatelet therapy valid at the time of implantation. Also, the economic availability of ticagrelor at the time of implantation was a key factor. Differences in antiplatelet therapy weren't independent risk factors of primary outcome in the present cohort. Despite the multivariate Cox analysis which did not show statistical significance, the p-value was noticeably low. On the one hand, for the subjects of ACS treated with second-generation DES, data [29, 30] support ticagrelor therapy with simultaneous individualization of DAPT duration. On the other hand, convincing data for BRS is missing. Expert consensus regarding BRS [16, 31] mainly due to augmented risk of scaffold thrombosis support the use of ticagrelor instead for at least 12 months. Nevertheless, the studies [32] conducted so far identify the DAPT discontinuation as a risk factor for thrombosis events, not the type of P2Y12 receptor blocker. Furthermore, recently published data [33] have not shown any benefits from prolonged (between 1 and 3 years) DAPT after BRS implantation.

Results obtained in the Magmaris group are very encouraging. A statistically significant lower rate of device-related adverse events was observed in comparison with the Absorb group. This might

Table 4. Results of the univariable Cox regression analysis for factors affecting primary outcome.

	P
Age	0.317
Gander — male (ratio)	0.981
Unstable angina	0.484
NSTEMI	0.478
Diabetes mellitus type 2	0.412
Oral anty-diabetic treatment	0.549
Insulin	1
Hypertension	0.268
Hyperlipidemia	0.312
Atrial fibrillation	0.710
Previous PCI	0.465
Primary diagnosis MI	0.123
Current smoker	0.931
LVEF	0.240
Total cholesterol level	0.408
LDL level	0.094
Triglyceride's level	0.029
Creatine level	0.532
Days of hospitalization	0.087
Predilation balloon — mean diameter	0.928
Postdilation balloon — mean diameter	< 0.001
Postdilation balloon — mean pressure	0.001
OCT guided PCI	0.001
Dose of radiation	0.047
Contrast volume	0.212
Syntax score	0.518
Treated vessel LAD	0.604
Treated vessel LCx	0.102
Treated vessel RCA	0.518
Treated vessel IM	0.299
Antiplatelet drug — Clopidogrel	0.498
Antiplatelet drug — Ticagrelol	0.004

IM — intermediate artery; LAD — left anterior descending artery; LCx — left circumflex artery; LDL — low density lipoprotein; LVEF — left ventricular ejection fraction; MI — myocardial infarction; NSTEMI — non-ST-segment elevation myocardial infarction; OCT — optical coherence tomography; PCI — percutaneous coronary intervention; RCA — right coronary artery

Table 5. Multivariate Cox analysis of features affecting the primary outcome.

Variable	HR	95% CI	P
Triglycerides	1.00	1.00-1.01	0.025
Postdilation balloon — mean diameter	1.01	0.89-1.15	0.836
Postdilation balloon — mean pressure	1.03	0.93-1.11	0.369
Dose of radiation	1.00	1.00-1.00	0.194
Antiplatelet drug: Ticagrelol	0.55	0.28-1.09	0.087

CI — confidence interval; HR — hazard ratio

suggest more favorable treatment results than with the use of classic DES. This trend, was remarked upon in a study comparing Magmaris to Orsiro (second generation of DES) [34], was statistically irrelevant. Furthermore, a recently published study suggests favorable safety features and long-term prognosis of patients treated with Magmaris scaffold implanted in terms of ACS [35, 36]. Such a good clinical performance of the magnesium BRS was achieved by overcoming the scaffold thrombosis issues. Previously these favorable outcomes were reported in BIOSOLVE II and III studies [37]. It is probably strictly related to scaffold features, Magmaris provides higher radial strength and less pronounced time-dependent recoil phenomenon. Lower thrombogenicity [38], supported by local hemodynamic properties [39] and increased endothelization [38] compared to polymeric BRS or DES. Novel magnesium backbone improves implantation and periprocedural performance outcomes [40].

It has been proven that using intracoronary imaging for guidance during PCI improves clinical outcomes [41, 42]. However, in the present study prevalence of intravascular ultrasound/optical coherence tomography guided PCI were at a relatively low rate (13.1–21.2%) — improvement in this matter might lead to even better clinical outcomes. It can also be presumed that more efficient reabsorption of Mamgaris compared to Absorb scaffold [43], may emphasize the advantages of the magnesium bioresorbable scaffolds more prominently in long-term observation rather than in short-term. Preliminary research [44] seems to confirm this assumption however, future studies are necessary. Nevertheless, in case of Magmaris scaffold a very late restenosis has been recently described and it should be taken into account when analyzing their favorable effects [45].

Limitations of the study

First, this is a comparison between two non-randomized observational registries. Second, the study compared only short-term outcomes of two generations of BRS without relation to classical DES. Many authors suggest routine use of intravascular imaging to optimize delivery and implantation of BRS. In this study we have observed relatively low-rate image-guided PCI which might affect the outcomes. It has to be taken into account that the present study population was composed of ACS-related patients from "every day" clinical practices, where the use of optical coherence tomography/intravascular ultrasound is generally lower.

Conclusions

Data from the current study suggests more favorable clinical ACS outcomes in the Magmaris group compared to the Absorb group. In the ACS-BRS-Magmaris population no definite scaffold thrombosis occurred after 12 months of follow-up.

Conflict of interest: None declared

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