

Magnesium bioresorbable scaffold (Magmaris) versus polymer biodegradable ultrathin drug-eluting stent (Ultimaster) in acute coronary syndrome. Mid-term outcomes (2 years)

Adrian Włodarczak¹, Piotr Rola², Szymon Włodarczak¹, Marek Szudrowicz¹, Joanna Jaroszevska-Pozorska¹, Mateusz Barycki², Łukasz Furtan², Michalina Kędzierska³, Adrian Doroszko⁴, Maciej Lesiak⁵

¹Department of Cardiology, The Copper Health Centre (MCZ), Lubin, Poland

²Department of Cardiology, Provincial Specialized Hospital Legnica, Legnica, Poland

³Faculty of Medicine, Wrocław Medical University, Wrocław, Poland

⁴Department of Cardiology, Center for Heart Diseases, 4th Military Hospital, Faculty of Medicine, Wrocław University of Science and Technology, Wrocław, Poland

⁵1st Department of Cardiology, University of Medical Sciences, Poznan, Poland

Adv Interv Cardiol 2024; 20, 1 (75): 67–75
DOI: <https://doi.org/10.5114/aic.2024.136901>

Abstract

Introduction: Acute coronary syndrome (ACS) is a well-known risk factor for adverse clinical outcomes in percutaneous coronary intervention (PCI). Therefore, evaluation of coronary stents in this challenging clinical scenario can provide unique information on device safety and efficacy. Bioresorbable scaffolds (BRS) were designed to overcome long-term complications related to permanent vessel caging with a permanent metallic drug-eluting stent (DES).

Aim: We designed this study to evaluate the mid-term safety and efficiency of the Magmaris BRS in comparison to the leading new-generation ultrathin DES Ultimaster in the ACS population.

Material and methods: We present a retrospective analysis of 2-year follow-up data. The primary outcomes consisted of death from cardiac causes, myocardial infarction, and in-stent thrombosis. The second main study endpoint was defined as target-lesion failure (TLF).

Results: The study population consisted of two cohorts, the first of 193 patients treated with Magmaris implantation and the second of 169 patients treated with Ultimaster implantation. At the 2-year follow-up, there were no significant differences in both study cohorts in terms of primary outcome (5.1% vs. 11%; $p = 0.051$), and TLF (5.6% vs. 8%, $p = 0.41$).

Conclusions: Treatment with a second-generation BRS (Magmaris) versus a novel second-generation DES (Ultimaster) in non-ST-elevation acute coronary syndrome (NSTEMI-ACS) was associated with similar rates of target lesion failure at 2-year follow-up.

Key words: bioresorbable scaffold, Magmaris, magnesium, Ultimaster, acute coronary syndrome, polymer biodegradable, drug-eluting stent, mid-term.

Summary

Bioresorbable scaffolds (BRS) were introduced into clinical practice to overcome the limitations of metallic drug-eluting stent (DES) in terms of permanent vessel encapsulation. Initial enthusiasm for the first-generation BRS Absorb was tempered by safety concerns. In our study, we evaluated the safety and efficacy of the second-generation BRS Magmaris compared to one of the leading second-generation ultra-thin DES (Ultimaster) in the acute coronary syndrome subset at mid-term follow-up. Implantation of the Magmaris was associated with a target lesion failure rate similar to that of the novel DES, suggesting a good safety and efficacy profile for a novel device.

Corresponding author:

Piotr Rola MD, PhD, Department of Cardiology, Provincial Specialized Hospital Legnica, Legnica, Poland, e-mail: piotr.rola@gmail.com

Received: 30.11.2023, **accepted:** 2.03.2024, **online publication:** 22.03.2024.

Introduction

Shortly after its introduction to clinical practice percutaneous coronary intervention (PCI) emerged as the gold-standard therapy for most patients with acute coronary syndromes (ACS) [1]. However, the ACS subset is a well-known risk factor for unfavorable clinical outcomes of PCI. To overcome these shortcomings we can observe continuous research efforts focused on the development of novel coronary stents. Improvements included changes in stent architecture, modification of stents' biopolymer composition, and use of new resorbable polymers or metal alloys as part of the scaffold backbone [2].

The introduction of the first generation of drug-eluting stents (DES) into daily clinical practice marked a turning point in the field of PCI. The first generation of DES overcame the major shortcomings associated with bare-metal stent (BMS) revascularization, namely the reduction of neointimal hyperplasia, leading to a significant reduction in the need for repeat revascularization. The continued evolution of DES technology has resulted in significant reductions in strut thickness. Second-generation DES, also known as ultra-thin strut DES, have increased deliverability and significantly shortened endothelialization time, resulting in a further reduction in device-related adverse events [3]. The Ultimaster coronary stent (Terumo Corporation, Tokyo, Japan) is an ultrathin-strut, cobalt chromium, biodegradable-polymer, sirolimus-eluting stent which showed an excellent overall device safety and efficacy profile in long-term follow-up [4–6].

Plaque rupture and erosion have been shown to be the basis of the pathophysiology of the vast majority of ACS cases. Local transient exacerbation of the inflammatory process is strongly related to both ACS pathways. A novel, less invasive management of this “urgent” instability in coronary circulation has been postulated as a promising therapeutic approach. This would avoid the permanent caging of a vessel with a metallic backbone of a DES, with all the long-term consequences of this fact (transformation of the urgent local inflammatory process into a permanent inflammatory reaction to the foreign body introduced into the vessel wall). Theoretically, BRS technology enables the temporary healing of local hyperinflation associated with ACS and subsequent anatomic and functional restoration of the vessel after the resorption of the scaffold. The main idea of the BRS concept [7, 8] was to provide lumen patency in the early phase, allow vascular healing, and dissolve over time, potentially leading to a reduction of long-term device-related complications. Initial enthusiasm related to the polymer scaffold Absorb (Abbott Vascular, Santa Clara, United States) was restrained after publishing long-term outcomes [6, 9, 10].

Nevertheless, the BRS concept continues to evolve [11], and recently the magnesium bioresorbable scaffold Magmaris (Biotronik, Berlin, Germany) has been introduced to clinical practice [12]. Primary short-term data

are encouraging, particularly in terms of stable CAD [13–15] and partially in the ACS subset [16–20]. Still, future evaluation of this technology is necessary to fully assess the potential gain-risk balance. In particular, clinical data beyond short-term observations (> 1 year) after Magmaris implantation in patients with ACS are still limited.

Aim

In this context, we designed this study to evaluate the long-term safety and efficiency of the Magmaris BRS in comparison to one of the leading new-generation DES, Ultimaster, in the ACS population.

Material and methods

Study design and population

A complete list of study inclusion and exclusion criteria along with a full discussion of all aspects of study design was previously published [19, 21]. Vascular calcification was assessed by angiography as mild (spots), moderate ($\leq 50\%$ of reference lesion diameter) or severe ($> 50\%$ of reference lesion diameter). Briefly, the study population consisted of patients ($n = 362$) with acute coronary syndrome (NSTEMI-ACS) who underwent PCI. Based on implanted devices patients were assigned to one of two arms (193 – Magmaris vs. 169 – Ultimaster). All PCI was performed at the Cardiology Department of the Cooper Health Center in Lubin, Poland, between October 2016 and March 2020. Additionally, all participants included in this retrospective, observational study signed written consent for PCI procedures along with later clinical evaluation. This study was conducted according to the guidelines of the Declaration of Helsinki and was approved by the Medical Lower Silesian Ethics Board (number 20/07/2016, approval 12.07.2016). The study flow chart is presented in Figure 1.

PCI procedures

All PCI procedures were performed by high-volume PCI operators with extensive experience with BRS technology (performing at least 400 PCIs per year and a history of at least 50 BRS implantations before entering the study) at the Cardiology Department of the Cooper Health Center in Lubin between October 2016 and March 2020. Operators were strongly encouraged to meet the “4P” criteria during all the PCI procedures in both study arms. The clinical value of the “4P” implantation technique is well established [22, 23] and is part of contemporary practice for BRS placement [24]. The general features are based on: adequate preparation of the lesion (using a non-compliant (NC) balloon, sized with a 1 : 1 balloon to artery ratio), proper sizing, paying attention to the expansion limits, mandatory post-dilation with a non-compliant (NC) balloon with high pressure (at least 16 atm) sized 1 : 1 balloon/scaffold ratio or higher. The decision regarding support of intravascular ultrasound/optical coherence tomography (IVUS/OCT)

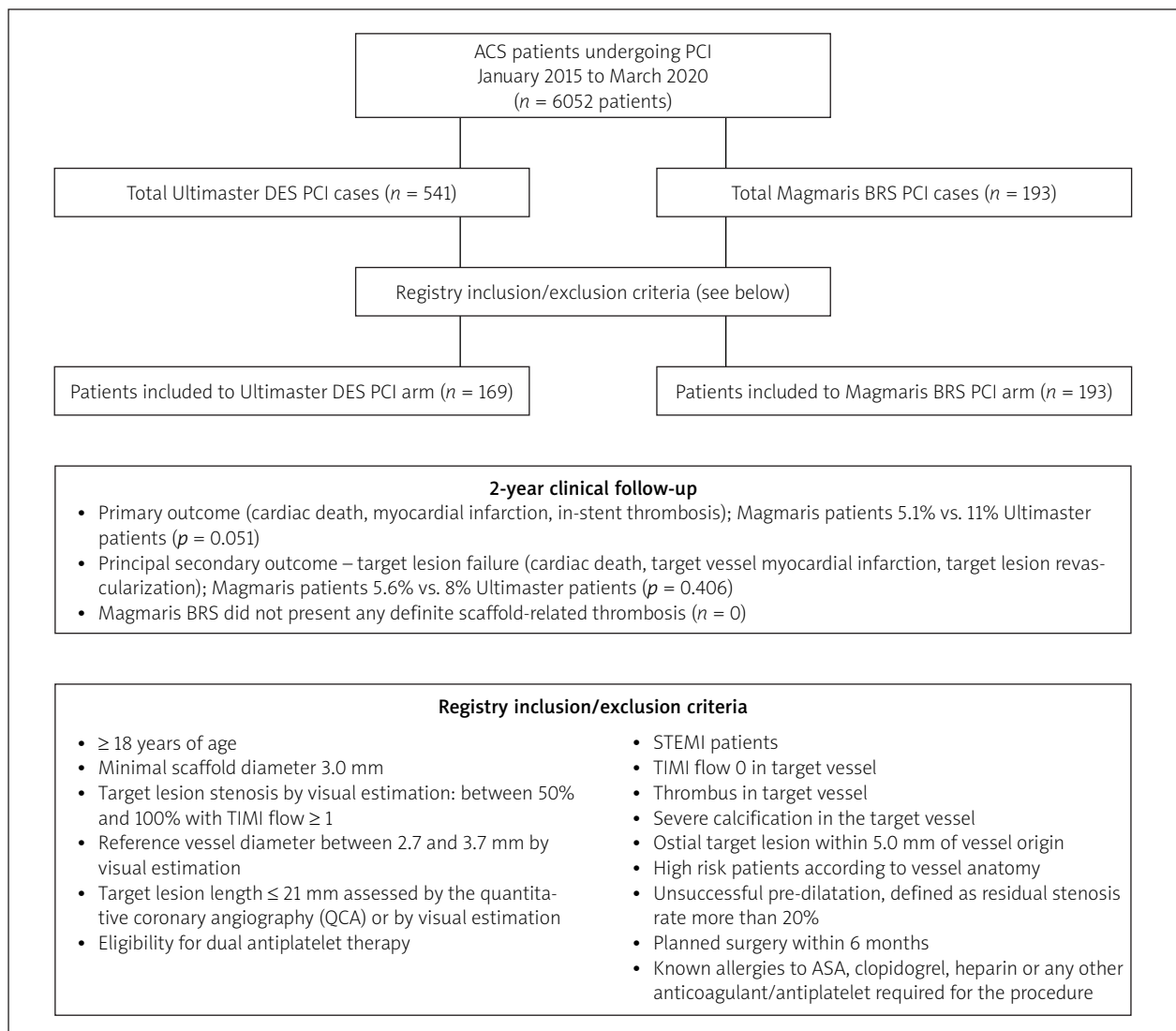


Figure 1. Study flow chart and outcomes

was left to the discretion of the operators. The dual antiplatelet therapy (DAPT) in both study arms was prolonged up to 12 months after implantation in accordance with applicable guidelines ESC/ESH guidelines.

Clinical outcomes

The primary outcomes consisted of death from cardiac causes, myocardial infarction, and in-stent thrombosis. The principal secondary outcomes were device-oriented and defined as target-lesion failure (TLF), target vessel-related myocardial infarction (TV-MI), and target lesion revascularization (TLR). The TLF, TV-MI, TLR, and stent thrombosis were defined in accordance with Academic Research Consortium guidelines [25]. Diagnostic criteria of myocardial infarction met the criteria contained in the Fourth Universal Definition of Myocardial Infarction [26]. Additional clinical variables were collected, including scaffold restenosis, death from any cause, cerebrovascular episodes, and need for any other revas-

cularization procedure. All the clinical data were obtained by trained staff (physicians and/or nurses) during personal visits or telephone contact during the 1-year and 2-year follow-up periods.

Study devices

Magmaris – previously known as DREAMS 2G – is a magnesium bioresorbable metallic scaffold coated (7 μm layer) with a poly-L-lactic acid biodegradable polymer (PLLA) eluting sirolimus (1.4 μg/mm² of the scaffold surface). The approximate time of drug release is calibrated for a 90-day, magnesium backbone resorption time, estimated for at least 1 year, while PLLA resorption lasts for 2 years. The backbone of the Magmaris device is completely radiolucent. Therefore, it has two permanent tantalum radiopaque markers mounted at the distal and proximal stent end. Magmaris is available in only 2 diameters of 3.0 and 3.5 mm and three lengths of 15, 20, and 25 mm.

The Ultimaster is a cobalt–chromium (Co-Cr) coronary stent consisting a thin strut (80 µm) coated on its abluminal side with sirolimus (3.9 µg/mm of stent length), and bioresorbable poly (D,L-lactide-co-caprolactone) copolymer (PDLLA-PCL). Both the drug and polymer are designed for a simultaneous resorption time within 3–4 months. Despite the fact that the Ultimaster DES is available in a wide range of diameter sizes (2.25–4.0 mm) and lengths (from 9 to 38 mm), for the purpose of this study in the Ultimaster cohort we used stents only with two diameters (3.0 and 3.5 mm) and lengths up to 24 mm.

Statistical analysis

Continuous variables were characterized by mean and standard deviation, while categorical variables were characterized by the frequencies. The study cohorts were compared with the nonparametric two-sample Mann-Whitney test for continuous variables and Fisher's exact test for categorical variables. Bonferroni correction was applied to adjust for multiple comparisons. *P*-values ≤ 0.05 were defined as statistically significant. The log-rank test was used to compare the entire survival curve. Additionally, in terms of two major study endpoints we performed non-inferiority analysis. All statistical analyses were performed using the R language by a professional statistician familiar with medical analysis.

Results

The basic clinical characteristics of both study cohorts along with procedural features have already been

already discussed and published previously. Briefly, all mentioned data are presented in Tables I and II.

At 1-year follow-up, no significant differences among primary and secondary endpoints between both study groups were noted. Still, in the Magmaris subpopulation in terms of the primary outcome, we observed a non-statistically significant lower rate of adverse events (1.5% vs. 5% respectively, *p* = 0.07). This difference was more apparent at the 2-year follow-up (5.1% vs. 11% respectively, *p* = 0.051) and was found to be just short of statistical significance. However, when we analyzed the second, device-oriented, composite endpoint of the study – TLF at 2-year follow-up – no significant difference was found (5.6% vs. 8% respectively, *p* = 0.41). In both study cohorts in terms of 2-year follow-up, no episode of stent thrombosis was observed. After 2 years of observation, we did not note any significant differences in terms of scaffold restenosis between the study cohorts (5.1% vs. 4% respectively, *p* = 0.81). Clinical outcomes in both study cohorts were pooled and presented in Table III.

Figure 2 presents the Kaplan-Meier graph for the primary outcome and principal secondary outcome-free survival. The log-rank test was used to evaluate the primary outcome survival curve; the *p*-value did not reach statistical significance (*p* = 0.052).

Subsequently, similar analysis for the secondary endpoint was performed, and similarly the *p*-value did not reach statistical significance (*p* = 0.34), thus indicating a lack of significant difference regarding survival between Magmaris and Ultimaster.

Table I. Study patient characteristics

Parameter	Magmaris patients N = 193	Ultimaster patients N = 169	<i>P</i> -value
Age	66.3 ± 8.9	65.2 ± 9.3	0.61
Gender – male (percentage)	150 (77.7%)	128 (75.7%)	0.48
Unstable angina	30 (15.5%)	81 (47.9%)	< 0.001
NSTEMI	163 (84.5%)	88 (52.1%)	< 0.001
Diabetes mellitus type 2	72 (37.3%)	59 (34.9%)	0.79
Oral anti-diabetic treatment	58 (30%)	45 (26.6%)	0.72
Insulin	14 (7.2%)	14 (8.2%)	0.84
Hypertension	171 (88.6%)	158 (93.5%)	0.14
Hyperlipidemia	152 (78.7%)	130 (76.9%)	0.81
Atrial fibrillation	9 (4.6%)	24 (14.2%)	0.002
Previous PCI	78 (40.4%)	61 (36.1%)	0.44
Primary diagnosis of MI	59 (30.5%)	60 (35.5%)	0.50
LV-EF	60.4 ± 10.9%	53.6 ± 3.1%	< 0.001
Total cholesterol [mmol/l]	4.6 ± 1.3	4.95 ± 1.4	0.041
LDL [mmol/l]	2.5 ± 1.2	2.92 ± 1.9	0.025
Triglycerides [mmol/l]	1.8 ± 1.8	1.6 ± 0.8	0.18
Creatinine [µmol/l]	84.1 ± 22.2	82.9 ± 21.9	0.77

LV-EF – left ventricular ejection fraction, NSTEMI – non-ST elevation myocardial infarction, MI – myocardial infarction, PCI – percutaneous coronary intervention, TIA – transient ischemic attack.

Table II. Procedural characteristics

Procedural characteristic	Magmaris patients N = 193	Ultimaster patients N = 169	P-value
Treated vessel: LAD	80 (41.4%)	65 (38.4%)	0.59
Cx	49 (25.3%)	47 (27.8%)	0.63
RCA	61 (31.6%)	56 (33.1%)	0.63
IM	3 (1.6%)	1 (0.6%)	0.82
Predilation balloon:			
Mean diameter [mm]	3.2 ±0.3	3.1 ±0.3	0.092
Mean pressure [atm]	17.7 ±0.8	15.9 ±1.9	< 0.001
Average scaffold number	1.1 ±0.2	1.2 ±0.4	0.48
Average scaffold diameter [mm]	3.28 ±0.27	3.24 ±0.31	0.035
Average scaffold length [mm]	20.8 ±3.3	23.9 ±4.1	0.041
Postdilation balloon:			
Mean diameter [mm]	3.5 ±0.3	3.3 ±0.3	< 0.001
Mean pressure [atm]	17.7 ±0.8	16.7 ±1.0	< 0.001
0.0 mm greater than scaffold	31 (16.6%)	120 (71%)	< 0.001
0.25 mm greater than scaffold	130 (65.2%)	35 (20.7%)	< 0.001
0.5 mm greater than scaffold	32 (18.2%)	14 (8.3%)	< 0.001
Contrast agent volume [ml]	151.5 ±65.4	148.5 ±68.5	0.42
Dose of radiation [mGy]	1056.7 ±697.8	1244.2 ±761.1	0.008
OCT/IVUS guided PCI	41 (21.2%)	28 (16.7%)	0.52
A1/B1 lesion AHA/ACC classification	144 (73.4%)	119 (70.4%)	0.59
Antiplatelet therapy:			
Acetylsalicylic acid	191 (98.9%)	167 (98.8%)	1
Clopidogrel	76 (38.9%)	148 (87.5%)	< 0.001
Ticagrelor	117 (60.6%)	20 (11.9%)	< 0.001

ACC – American College of Cardiology, AHA – American Heart Association ACC, Cx – circumflex artery, IVUS – intravascular ultrasound, IM – intermediate artery, LAD – left anterior descending artery, OCT – optical coherent tomogram, RCA – right coronary artery.

To fully evaluate the difference between the two study cohorts, we performed a non-inferiority analysis of Magmaris stents versus Ultimaster stents in terms of primary and principally secondary endpoints. The odds ratio for the major endpoint in cases with Magmaris vs. Ultimaster was OR = 0.4593873, 95% CI (0.1836107, 1.0865151); nevertheless, the p-value for equal ratios in both groups was non-significant, which did not support rejection of the hypothesis regarding equivalence of these methods. The delta value for non-inferiority analysis was 0.1, and the analysis (using Fisher's test) did not reach statistical significance, thus suggesting that Magmaris was non-inferior to Ultimaster.

Subsequently, the analysis for the secondary endpoint was performed. The odds ratio for Magmaris vs. Ultimaster was OR = 0.4740949, 95% CI (0.1895651, 1.1208551). However, the p-value for equal ratios in both groups was non-significant, which did not support rejection of the null hypothesis regarding equivalence of these methods. The delta value for non-inferiority analysis was 0.1, and the analysis (using Fisher's test) did not reach statistical significance, thus suggesting that Magmaris was non-inferior to Ultimaster.

Discussion

To the best of our knowledge, this is the first study designed to evaluate the mid-term results of the novel magnesium BRS Magmaris compared to the second generation metallic DES Ultimaster in “real life” scenarios in subjects with the ACS subset. The main findings of this study are:

- 1) In our retrospective, non-randomized study cohort Magmaris showed good clinical outcomes in terms of the primary endpoint (death from cardiac causes, myocardial infarction, in-stent thrombosis) and the secondary device-orientated endpoint defined as target-lesion failure (TLF), target vessel-related myocardial infarction (TV-MI), and target lesion revascularization (TLR). Although no significant differences were observed at 2 years, the Magmaris cohort showed a borderline significant primary endpoint reduction (5.1% vs. 11% respectively, $p = 0.051$).
- 2) Magmaris BRS did not present any definite scaffold-related thrombosis after a 24-month observation period.

Data regarding the long-term evaluation of Magmaris BRS are rather sparse and mainly originate from retrospective observational clinical registries [20, 27–29]. Based on

Table III. Clinical outcomes in both study arms

Clinical outcomes	Magmaris patients N = 193	Ultimaster patients N = 169	P-value
1-year clinical follow-up:			
Primary outcome (cardiac death, myocardial infarction, in-stent thrombosis)	3 (1.5%)	9 (5%)	0.07
Principal secondary outcome – target lesion failure (cardiac death, target vessel myocardial infarction, target lesion revascularization)	3 (1.5%)	7 (5.4%)	0.20
Death:			
Any	2 (1%)	0 (0%)	0.50
Cardiac	0 (0%)	0 (0%)	1
Myocardial infarction:			
Any other	3 (1.5%)	4 (2%)	0.71
Target vessel	2 (1.0%)	5 (3%)	0.26
Scaffold:			
Thrombosis	0 (0%)	0 (0%)	1
Restenosis	2 (1%)	2 (1%)	1
Revascularization:			
Target lesion	2 (1%)	3 (2%)	0.67
Target vessel	3 (1.5%)	7 (4%)	0.20
Any other	18 (9.3%)	24 (14%)	0.19
2-year clinical follow-up:			
Primary outcome (cardiac death, myocardial infarction, in-stent thrombosis)	10 (5.1%)	18 (11%)	0.051
Principal secondary outcome – target lesion failure (cardiac death, target vessel myocardial infarction, target lesion revascularization)	11 (5.6%)	14 (8%)	0.41
Death:			
Any	2 (1%)	1 (0.6%)	1
Cardiac	0 (0%)	0 (0%)	1
Myocardial infarction:			
Any other	7 (3.6%)	8 (5%)	0.61
Target vessel	5 (2.6%)	10 (6%)	0.12
Scaffold:			
Thrombosis	0 (0%)	0 (0%)	1
Restenosis	10 (5.1%)	7 (4%)	0.81
Revascularization:			
Target lesion	10 (5.1%)	9 (5%)	0.69
Target vessel	12 (6.1%)	14 (8%)	0.54
Any other	23 (11.7%)	28 (17%)	0.27

this single-arm evaluation despite all of its methodological shortcomings Magmaris showed favorable long-term safety and clinical performance with acceptable target lesion failure rates (5.2% up to 11%), which is comparable to our findings (5.6%) and analogous to novel DES performance [30–32]. Also in our study, we did not note significant differences between the Magmaris and Ultimaster DES in terms of TLF (5.6% vs. 8.0, $p = 0.41$). The lack of mid and long-term data makes the results of our study difficult to compare. However, the obtained results seem to be consistent with the findings previously reported in the short-term evaluation. Hideo-Kajita *et al.* [33] during a 12-month clinical follow-up noted no significant differences in TLF between Magmaris and the biodegradable polymer sirolimus-eluting stent Orsiro (6.0 vs. and 6.4%). Remarkably, the aforementioned meta-analysis suggests

that Orsiro has the best 1-year performance among modern DES [30, 33–35]. Similar favorable outcomes comparing Magmaris to novel DES were also observed by Rola *et al.* [19, 21] and Włodarczak *et al.* [18]. On the other hand, Tousek *et al.* [36] in a small, single-center study ($n = 50$) evaluated in quantitative coronary angiography (QCA) and OCT performance of Magmaris compared to Xience in an ACS setting. Both QCA and OCT revealed a greater extent of late lumen loss in the Magmaris group than in the Xience group after a 12-month follow-up. These unfavorable clinical results were also observed in terms of the STEMI subpopulation. The 1-year evaluation of STEMI patients [37] treated with implantation of Magmaris or Orsiro-DES revealed a significantly higher rate of TLR in the Magmaris group (16.2% vs. 5.3%; respectively $p = 0.03$). Notably, implantation of the second-generation

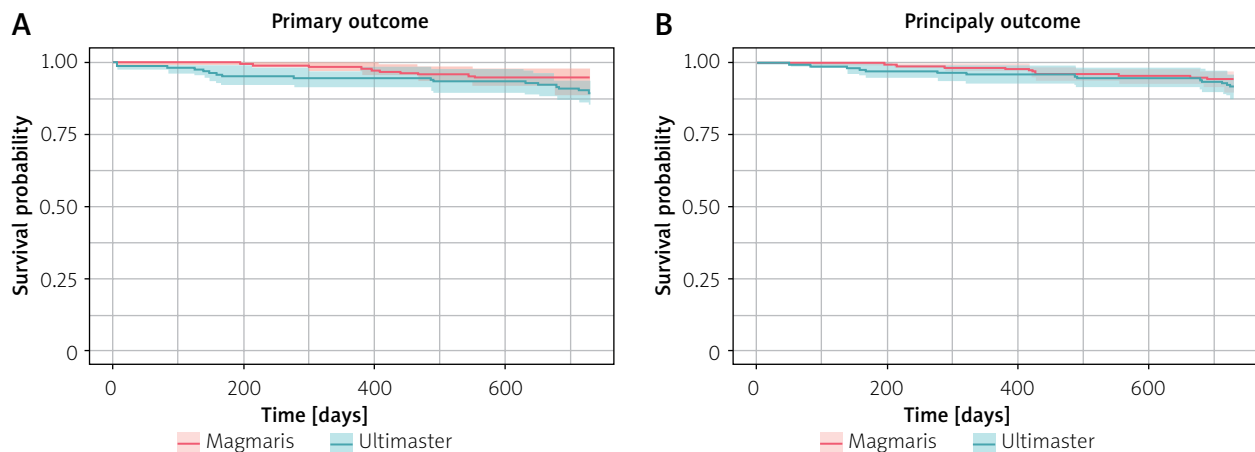


Figure 2. Kaplan-Meier event-free survival curves for the main study endpoints

BRS (Magmaris) was associated with a significantly lower number of TLFs compared to the first-generation BRS (Absorb) (1.5% vs. 5.6%; $p = 0.048$) [18, 38].

The risk of stent thrombosis and repeat target lesion revascularization after PCI is higher in patients with ACS at enrollment [39, 40]. Although initial safety and efficacy trials of first-generation BRS and second-generation metallic BRS (Magmaris) focused primarily on patients with stable coronary artery disease [7, 8, 29, 33], several factors could theoretically benefit the ACS population. ACS patients are often young, with a long life expectancy and a lower incidence of previous coronary intervention with DES use, which could potentially promote vessel healing after BRS implantation. In addition, culprit unstable ACS lesions are generally composed of soft, easily expandable plaque, which appears to be conducive to the “4P” implantation strategy so critical to optimal BRS deployment [22–24]. Moreover, the higher strut thickness of the BRS compared to metallic DES may be beneficial in the process of thrombus entrapment under the struts after scaffold implantation, and it may be reflected in the reduction of the distal flow impairment [41–43]. On the other hand, the ACS subset per se increases stent thrombosis rates [44]. This, combined with the previously described trend toward higher scaffold thrombosis rates with first-generation BRS [9, 45, 46], may negate any theoretical benefit of BRS. However, this was not confirmed in a pooled meta-analysis [47]; nevertheless, the increased rate of device-related endpoints led to restrained commercial use of the first-generation BRS. On the other hand, short-term data on the use of Magmaris in the ACS subpopulation are encouraging [16–21]. However, recently published long-term data [48] suggest that the subgroup of NSTEMI patients had a significantly higher rate of TLF after implantation of the Magmaris BRS compared to non-NSTEMI patients (9.3% vs. 6.2%, $p = 0.025$). Yet, the results of our study did not confirm this observation, as the TLF rate of 5.6% was similar to the non-ACS cohort (6.2%) [46].

This study has several limitations. The study has a retrospective non-randomized observational character. The study population is relatively small compared to leading DES studies, but still, in terms of “real-life” BRS studies is noticeably high. Finally, despite the study population consisting of NSTEMI-ACS patients, we observed a relatively low number of intravascular guidance PCI procedures.

Conclusions

In our study population (NSTEMI-ACS) implantation of a second-generation BRS (Magmaris) in comparison to therapy with a novel ultrathin second-generation DES (Ultimaster) was associated with a similar rate target lesion failure in terms of 2-year follow-up. Furthermore, none of the thrombotic safety concerns occurred in either study cohort.

Conflict of interest

The authors declare no conflict of interest.

References

- Jia S, Liu Y, Yuan J. Evidence in guidelines for treatment of coronary artery disease. *Adv Exp Med Biol* 2020; 1177: 37-73.
- Scafa Udriște A, Niculescu AG, Grumezescu AM, Bădilă E. Cardiovascular stents: a review of past, current, and emerging devices. *Materials* 2021; 14: 2498.
- Leone A, Simonetti F, Avvedimento M, et al. Ultrathin struts drug-eluting stents: a state-of-the-art review. *J Pers Med* 2022; 12: 1378.
- Gherbesi E, Danzi GB. The Ultimaster coronary stent system: 5-year worldwide experience. *Future Cardiol* 2020; 16: 251-61.
- Tadano Y, Kotani JI, Kashima Y, et al. Predictors of clinical outcomes after coronary implantation of bioresorbable polymer sirolimus-eluting Ultimaster stents in all-comers: a report of 1,727 cases. *Catheter Cardiovasc Interv* 2019; 94: 91-7.
- Liu Y, Xiao D, Wu Y, et al. Bioresorbable scaffolds vs. drug-eluting stents for patients with myocardial infarction: a systematic review and meta-analysis of randomized clinical trials. *Front Cardiovasc Med* 2022; 9: 974957.

7. Rola P, Włodarczak S, Doroszko A, et al. The bioresorbable magnesium scaffold (Magmaris)-State of the art: from basic concept to clinical application. *Catheter Cardiovasc Interv* 2022; 100: 1051-8.
8. Toong DWY, Toh HW, Ng JCK, et al. Bioresorbable polymeric scaffold in cardiovascular applications. *Int J Mol Sci* 2020; 21: 3444.
9. Serruys PW, Chevalier B, Sotomi Y, et al. Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II): a 3 year, randomised, controlled, single-blind, multicentre clinical trial. *Lancet* 2016; 388: 2479-91.
10. Smits PC, Chang CC, Chevalier B, et al. Bioresorbable vascular scaffold versus metallic drug-eluting stent in patients at high risk of restenosis: the COMPARE-ABSORB randomised clinical trial. *EuroIntervention* 2020; 16: 645-53.
11. Kawashima H, Ono M, Kogame N, et al. Drug-eluting bioresorbable scaffolds in cardiovascular disease, peripheral artery and gastrointestinal fields: a clinical update. *Expert Opin Drug Deliv* 2020; 17: 931-45.
12. Peng X, Qu W, Jia Y, et al. Bioresorbable scaffolds: contemporary status and future directions. *Front Cardiovasc Med* 2020; 7: 589571.
13. Haude M, Toelg R, Lemos PA, et al. Sustained safety and performance of a second-generation sirolimus-eluting absorbable metal scaffold: long-term data of the BIOSOLVE-II First-in-Man Trial at 5 Years. *Cardiovasc Revasc Med* 2022; 38: 106-10.
14. Bennett J, De Hemptinne Q, McCutcheon K. Magmaris resorbable magnesium scaffold for the treatment of coronary heart disease: overview of its safety and efficacy. *Expert Rev Med Devices* 2019; 16: 757-69.
15. Al Nooryani A, Aboushokka W, AlBaba B, et al. Long-term performance of the magmaris drug-eluting bioresorbable metallic scaffold in all-comers patients' population. *J Clin Med* 2022; 11: 3726.
16. Rola P, Włodarczak A, Łanocha M, et al. Outcomes of the two generations of bioresorbable scaffolds (Magmaris vs. Absorb) in acute coronary syndrome in routine clinical practice. *Cardiol J* 2022; 30: 870-80.
17. Włodarczak A, Łanocha M, Szudrowicz M, et al. The 1-year safety and efficacy outcomes of Magmaris, novel magnesium bioresorbable vascular scaffolds in diabetes mellitus patients with acute coronary syndrome. *J Clin Med* 2021; 10: 3166.
18. Włodarczak A, Rola P, Szudrowicz M, et al. Sex differences in the clinical features and outcomes of patients with acute coronary syndrome treated with two generations (Absorb and Magmaris) of bioresorbable vascular scaffolds. *J Clin Med* 2021; 10: 3768.
19. Rola P, Włodarczak A, Barycki M, et al. Biodegradable polymer DES (Ultimaster) vs. magnesium bioresorbable scaffold (BRS Magmaris) in diabetic population with NSTEMI-ACS: a one-year clinical outcome of two sirolimus-eluting stents. *J Diabetes Res* 2021; 2021: 8636050.
20. Włodarczak A, Łanocha M, Lesiak M, et al. Long-term clinical follow-up of the resorbable magnesium scaffolds in acute coronary syndrome patients. *Kardiologia Pol* 2021; 79: 827-32.
21. Rola P, Włodarczak A, Włodarczak S, et al. Magnesium bioresorbable scaffold (BRS) Magmaris vs biodegradable polymer DES Ultimaster in NSTEMI-ACS population-12-month clinical outcome. *J Interv Cardiol* 2022; 2022: 5223317.
22. Dimitriadis Z, Polimeni A, Anadol R, et al. Procedural predictors for bioresorbable vascular scaffold thrombosis: analysis of the individual components of the "PSP" technique. *J Clin Med* 2019; 8: 93.
23. Ortega-Paz L, Brugaletta S, Sabaté M. Impact of PSP technique on clinical outcomes following bioresorbable scaffolds implantation. *J Clin Med* 2018; 7: 27.
24. Fajadet J, Haude M, Joner M, et al. Magmaris preliminary recommendation upon commercial launch: a consensus from the expert panel on 14 April 2016. *EuroIntervention* 2016; 12: 828-33.
25. Garcia-Garcia HM, McFadden EP, Farb A, et al. Academic Research Consortium. Standardized end point definitions for coronary intervention trials: the Academic Research Consortium-2 Consensus Document. *Circulation* 2018; 137: 2635-50.
26. Thygesen K, Alpert JS, Jaffe AS, et al. Executive Group on behalf of the Joint European Society of Cardiology (ESC) American College of Cardiology (ACC) American Heart Association (AHA) et al. Fourth universal definition of myocardial infarction (2018). *J Am Coll Cardiol* 2018; 72: 2231-64.
27. Al Nooryani A, Aboushokka W, AlBaba B, et al. Long-term performance of the magmaris drug-eluting bioresorbable metallic scaffold in all-comers patients' population. *J Clin Med* 2022; 11: 3726.
28. Galli S, Troiano S, Pallosi A et al. Sustained safety and efficacy of magnesium reabsorbable scaffold: 2-year follow-up analysis from first Magmaris Multicenter Italian Registry. *Cardiovasc Revasc Med* 2022; 41: 69-75.
29. Haude M, Toelg R, Lemos PA, et al. Sustained safety and performance of a second-generation sirolimus-eluting absorbable metal scaffold: long-term data of the BIOSOLVE-II First-in-Man Trial at 5 Years. *Cardiovasc Revasc Med* 2022; 38: 106-10.
30. Taglieri N, Bruno AG, Ghetti G, et al. Target lesion failure with current drug-eluting stents: evidence from a comprehensive network meta-analysis. *JACC Cardiovasc Interv* 2020; 13: 2868-78.
31. Koni E, Wanha W, Ratajczak J, et al. Five-year comparative efficacy of everolimus-eluting vs. resolute zotarolimus-eluting stents in patients with acute coronary syndrome undergoing percutaneous coronary intervention. *J Clin Med* 2021; 19: 1278.
32. Ma WR, Chandrasekharan KH, Nai CS et al. Clinical outcomes of percutaneous coronary intervention for de novo lesions in small coronary arteries: a systematic review and network meta-analysis. *Front Cardiovasc Med* 2022; 9: 1017833.
33. Hideo-Kajita A, Garcia-Garcia HM, Kolm P, et al. BIOFLOW-II, BIOSOLVE-II and BIOSOLVE-III investigators. Comparison of clinical outcomes between Magmaris and Orsiro drug eluting stent at 12 months: pooled patient level analysis from BIOSOLVE II-III and BIOFLOW II trials. *Int J Cardiol* 2020; 300: 60-5.
34. Iannaccone M, Barbero U, De Benedictis M, et al. Comparison of bioresorbable vs durable polymer drug-eluting stents in unprotected left main (from the RAIN-CARDIOGROUP VII Study). *BMC Cardiovasc Disord* 2020; 20: 225.
35. Ono M, Hara H, Tomaniak M, et al. The ultra-thin strut sirolimus-eluting coronary stent: SUPRAFLEX. *Future Cardiol* 2021; 17: 227-37.
36. Toušek P, Lazarák T, Varvařovský I, et al. Comparison of a bioresorbable, magnesium-based sirolimus-eluting stent with a permanent, everolimus-eluting metallic stent for treating patients with acute coronary syndrome: the PRAGUE-22 Study. *Cardiovasc Drugs Ther* 2022; 36: 1129-36.
37. Sabaté M, Alfonso F, Cequier A, et al. Magnesium-based resorbable scaffold versus permanent metallic sirolimus-eluting stent in patients with st-segment elevation myocardial infarction: the MAGSTEMI randomized clinical trial. *Circulation* 2019; 140: 1904-16.

38. Iwańczyk S, Araszkiwicz A, Grygier M, et al. Very long-term follow-up of patients with coronary bifurcation lesions treated with bioresorbable scaffolds. *Kardiol Pol* 2022; 80: 302-6.
39. Zhao X, Liu C, Zhou P, et al. Thrombosis and major bleeding risk after primary PCI among patients with multivessel coronary artery disease. *Front Cardiovasc Med* 2022; 8: 729432.
40. Kukreja N, Onuma Y, Garcia-Garcia HM, et al. Interventional cardiologists of the thoraxcenter (2000 to 2005). The risk of stent thrombosis in patients with acute coronary syndromes treated with bare-metal and drug-eluting stents. *JACC Cardiovasc Interv* 2009; 2: 534-41.
41. Diletti R, van der Sijde J, Karanasos A, et al. Differential thrombotic prolapse burden in either bioresorbable vascular scaffolds or metallic stents implanted during acute myocardial infarction: the snowshoe effect: insights from the maximal footprint analysis. *Int J Cardiol* 2016; 220: 802-8.
42. Kędziora A, Konstany-Kalandyk J, Litwinowicz R, et al. Hybrid techniques for myocardial regeneration: state of the art and future perspectives. *Adv Interv Cardiol* 2022; 18: 360-5.
43. Zasada W, Dziewierz A, Partyka L et al. Dissections after bioresorbable vascular scaffold implantation in the POLAR ACS Registry. *Adv Interv Cardiol* 2022; 18: 131-6.
44. Nso N, Nassar M, Zirkiyeva M, et al. Factors impacting stent thrombosis in patients with percutaneous coronary intervention and coronary stenting: a systematic review and meta-analysis. *Cureus* 2022; 14: e23973.
45. Schnorbus B, Wiebe J, Capodanno D, et al. Twelve-month outcomes after bioresorbable vascular scaffold implantation in patients with acute coronary syndromes. Data from the European Multicenter GHOST-EU Extended Registry. *EuroIntervention* 2017; 13: e1104-11.
46. Wykrzykowska JJ, Kraak RP, Hofma SH, et al. AIDA Investigators. Bioresorbable scaffolds versus metallic stents in routine PCI. *N Engl J Med* 2017; 376: 2319-28.
47. Sotomi Y, Miyazaki Y, Collet C, et al. Does acute coronary syndrome impact on the incidence of thrombosis after the implantation of an Absorb bioresorbable vascular scaffold? *EuroIntervention* 2017; 12: 2025-7.
48. Włodarczak A, Montorsi P, Torzewski J, et al. One- and two-year clinical outcomes of treatment with resorbable magnesium scaffolds for coronary artery disease: the prospective, international, multicentre BIOSOLVE-IV registry. *EuroIntervention* 2023; 19: 232-9.