■ ORIGINAL ARTICLE

Long-term clinical follow-up of the resorbable magnesium scaffolds in acute coronary syndrome patients

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A B S T R A C T

Background: Research on the resorbable magnesium scaffolds (RMSs) has shown their safety and effectiveness in stable clinical conditions. It seems that this new therapeutic option could be promising for selected acute coronary syndrome (ACS) patients.

Aims: Our analysis aims to analyze the long-term performance of RMSs among ACS patients.

Methods: The study population consisted of consecutive ACS patients treated with the implantation of at least one RMS. The Magmaris ACS Registry was designed as a single-arm observational registry in the 'real-world' treatment practice setting.

Results: The study population consisted of 193 patients, predominantly male (78%), at a mean (SD) age of 64 (9) years and with typical risk factors of ACS. Unstable angina (UA) was the indication for revascularization in 32.1%, non-ST-segment elevation myocardial infarction (NSTEMI) in 65.8% and ST-segment elevation myocardial infarction (STEMI) only in 2.1%. During the mean 24 months of follow-up, ten cases (5.2%) of target lesion failure (TLF) were diagnosed, of which five cases (2.6%) were clinically driven target lesion failure (CD-TLR), four cases (2.1%) were asymptomatic scaffold restenosis and one case (0.5%) was target vessel myocardial infarction (TV-MI). No cardiac deaths and 2 non-cardiac deaths (2.2%, both strokes) were observed. No cases of scaffold thrombosis were observed during the median 24-month follow-up.

Conclusions: The use of the RMSs in selected ACS patients is associated with procedural safety and promises early and long-term clinical efficacy and safety outcomes. Appropriate lesion selection is the key to the long-term success of bioresorbable technology in this patient population.

Key words: acute coronary syndrome, long-term outcome, resorbable magnesium scaffolds

INTRODUCTION

Coronary stents have evolved significantly for the last four decades and have led to improvements in the treatment of patients' with coronary artery disease [1]. Bioresorbable scaffolds (BRSs) were designed to provide all the short-term benefits of permanent stents and, moreover, to relieve potential long-term adverse effect of metallic cage [2].

Although there has been some concern in bioresorbable technology because of increased rates of scaffold thrombosis (ScT), the newer generation of scaffolds have reopened a viable path to the 'leaving-nothing-behind' strategy [3, 4]. Resorbable magnesium scaffolds (RMSs),

with their unique properties, have the potential to be an alternative to metallic drug-eluting stents, especially in the setting of the acute coronary syndrome (ACS) [5].

This analysis is the first to describe the long-term performance of RMSs in patients presenting with ACS.

METHODS

The study population consisted of consecutive ACS patients treated with the implantation of at least one magnesium Magmaris scaffold (BIOTRONIK AG, Bulach, Switzerland) [6]. The patients were treated between 2016 and 2020 in a single high-volume interventional cardiology center with

WHAT'S NEW?

The use of the Magmaris resorbable magnesium scaffolds (RMSs) in selected acute coronary syndrome (ACS) patients is associated with procedural safety, and it promises early and long-term clinical outcomes. Our analysis is the first to describe the long-term performance of RMS in ACS setting. At a median of 24 months follow-up, a target lesion failure (TLF) rate of 5.2% was observed, of which 2.6% were clinically driven target lesion failure (CD-TLR) and 0.5% target vessel myocardial infarction (TV-MI). No cases of scaffold thrombosis were observed during follow-up. Apropriate patient selection is the key to the long-term success of bioresorbable technology.

a large amount of experience with BRSs technology. On admission, all ACS patients were screened according to the previously described inclusion and exclusion criteria (Table 1) [6]. The Magmaris ACS Registry was designed as a prospective single-arm observational study in the setting of 'real-world' treatment practice [6]. The patients were managed as per current standard guidelines. The percutaneous coronary intervention (PCI) strategy, including the selection of medication, stent/scaffolds, and the use of intravascular imaging guidance, was left to the discretion of the operators. Patients received dual antiplatelet therapy (DAPT) for 12 months [7]. Clinical follow-up was obtained by telephone consultation, 30 days after the index procedure and then annually for up to 5 years [6].

The primary endpoint was the rate of target lesion failure (TLF), which is defined as cardiac death, target vessel myocardial failure (TV-MI) or target lesion revascularization (TLR) at 1-year. The secondary endpoints included rates of major adverse cardiac events, which can be defined as the composite of all-cause death, myocardial infarction or target vessel revascularization (TVR), along with target vessel failure (TVF). TLR was defined as any repeated revascularization procedure (percutaneous or surgical) of the original target lesion site, including the scaffold and within 5 mm of the proximal and distal scaffold margins. TVR was defined as any revascularization procedure occurring within the major epicardial vessel in which the scaffold was implanted, or its branches were. TVF was defined as cardiac death, TV-MI or TVR. Definite and probable scaffold thromboses were

defined according to the Academic Research Consortium definitions [8].

All endpoints were evaluated at 30 days, one year and up to 5 years. The local ethics committee approved the study protocol, and the principles of the Declaration of Helsinki were followed. Written informed consent was obtained from each patient.

The device has previously been described [9–12]. The backbone of Magmaris is made of an absorbable magnesium (Mg) alloy. The square-shaped, electro-polished struts are 150 μm × 150 μm in thickness and width, respectively. The surface is coated with 7 μm of the biodegradable PLLA BIOlute polymer and loaded with sirolimus. The process of Mg alloy resorption starts at the backbone's surface and continues inward until only an amorphous footprint of amorphous calcium phosphate is left instead of the struts. About 95% of Mg is resorbed within 12 months. The following scaffold lengths were implanted 15, 20, and 25 mm, with scaffold diameters of 3.0 and 3.5 mm.

Statistical analysis

Continuous variables are expressed as mean (standard deviation) or median (interquartile ranges) for normally or non-normally distributed variables, respectively. The normality of distribution was assessed using the Kolmogorov-Smirnov and Lilliefors tests. Nominal variables were presented as numbers and percentages. Cumulative event rates were estimated using the Kaplan-Meier method. Statistical analysis was performed using SPSS version 20.0 (IBM Corp., Armonk, NY, USA).

RESULTS

The final study population comprised 191 patients due to two cases of unsuccessful RMSs delivery, followed by bailout regular drug-eluting stents (DESs) implantation. The baseline clinical and lesion characteristics of the enrolled patients are shown in Table 2. The patients were predominantly male (78%), at a mean (SD) age of 64 (9) years and with typical ACS risk factors. History of previous myocardial infarction and percutaneous interventions were noticed in 31.1% and 40.4% of the patients, respectively. UA was the indication for PCI in 32.1%, non-ST-segment elevation myocardial infarction (NSTEMI) in 65.8%, and ST-segment elevation myocardial infarction (STEMI) only in 2.1%. A thrombolysis in myocardial infarction (TIMI) flow of 2 or 3 at baseline was observed in all patients. Most le-

Table 1. Inclusion and exclusion criteria for the Polish ACS — Magmaris Registry

Inclusion criteria	Exclusion criteria
Subject is ≥18 years of age	Thrombus in target vessel
Acute coronary syndrome (ACS)	TIMI flow 0 in target vessel
Target lesion stenosis by visual estimation: >50%–<100% and TIMI flow ≥1	Severe calcification in target vessel
Reference vessel diameter between 2.7 and 3.7 mm by visual estimation	Ostial target lesion within 5.0 mm of vessel origin
Target lesion length ≤21 mm by quantitative coronary angiography (QCA) or by visual estimation	Unsuccessful predilatation, here defined as residual stenosis rate more than 20% by visual estimation
Subject is eligible for dual antiplatelet therapy	Planned surgery within 6 months
Subject is willing to sign a patient informed consent form	Known allergies to acetylsalicylic acid, clopidogrel, ticlopidine, heparin or any other anticoagulant/antiplatelet drug required for the procedure

Table 2. Baseline clinical, laboratory and lesions findings

Variables	N = 193 patients
Age, years	64 (9)
Male	150/193 (77.7)
Presentation	
Unstable angina	62/193 (32.1)
NSTEMI	127/193 (65.8)
STEMI	4/193 (2.1)
Hypertension	172/193 (89.1)
Dyslipidemia	156/193 (80.8)
Diabetes mellitus	70/193 (36.3)
Atrial fibrillation	10/193 (5.2)
Tobacco use	93/193 (48.2)
Current tobacco use	44/193 (22.8)
Prior myocardial infarction	60/193 (31.1)
Prior PCI	78/193 (40.4)
Prior CABG	3/193 (1.6)
Ejection fraction	60 (10)
Laboratory	
Troponin T, ng/ml, base	14.9 (10.7–33.5)
Troponin T, ng/ml, max	54.2 (19.0–210.3)
CK-MB, ng/ml, base	2.8 (2.0–5.3)
CK-MB, ng/ml, max	5.8 (2.8–14.6)
Culprit lesion location	N = 194 lesions
Right coronary artery	62/194 (32.0)
Left anterior descending artery	80/194 (41.2)
Left circumflex artery	52/194 (26.8)
Syntax Score	7 (2–9)
A/B1 Lesion Class	144/194 (74)

Values are mean (SD), median (IQR) or n (%).

Abbreviations: CABG, coronary artery bypass grafting; CK-MB, creatine phospho-kinase-muscle/brain; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction

Table 3. Procedural technique and angiographic outcomes

Variables	
Procedures (PCI)	N = 193
Predilatation performed with NC balloon	193/193 (100.0)
OCT-guided PCI	39/193 (20.2)
Implanted scaffolds	N = 204
Mean scaffold length, mm	20.7 (3.3)
Mean scaffold diameter, mm	3.3 (0.3)
Mean deployment pressure, Atm	(0.8)
>1 scaffold for lesion	10/193 (5.2)
Post-dilatation performed with NC balloon	202/204 (99.0)

Values are mean (SD) or n (%).

Abbreviations: NC balloon, non-compliant balloon; OCT, optical coherence tomography; PCI, percutaneous coronary intervention

sions (74%) were classified as type A+B1 according to the AHA/ACC classification.

Scaffold implantation and sizing were done under the Magmaris instructions-for-use (IFU) document using the 4P strategy as the golden rule. Predilatation was mandatory and performed in all lesions with a non-compliant balloon, which was sized according to the vessel's reference diameter (Table 3). In total, 204 scaffolds were implanted. Ten lesions required implantation of two edge-to-edge scaffolds mainly caused by lesion length underestimation. In one patient, multivessel scaffolding was performed during the index procedure. Post-dilatation was mandatory and performed in 100% of the lesions with a non-compliant balloon. Imaging guidance in the form of optical coherence tomography (OCT) was performed in 20% of the patients and was done more extensively in the early stage of the study. The final TIMI 3 flow was achieved in 100% of the patients. During the index procedure, 7 cases of edge dissection were recognized; in 3 cases, additional scaffolds were required, and in 4 cases, additional DESs were implanted.

In 2 cases (1.0%), a transient small side branch (SB) occlusion occurred after the implantation of RMSs, requiring recrossing with the guidewire through the RMSs' strut into the SB and opening the SB with a small balloon in one case. No SB bail-out stenting was needed. On discharge, all patients received DAPT, of whom 117 (61%) were on aspirin plus ticagrelor, and 74 (39%) were on aspirin plus clopidogrel.

To date, a total of 153 patients have reached 1-year follow-up. All patients remained on the prescribed DAPT for 12 months unless the additional revascularization required appropriate DAPT elongation.

During this period, 2 cases of clinically driven target lesion revascularizations (CD-TLR) (1.3%) and 1 case of TV-MI (0.7%) were observed. Additionally, 14 patients were scheduled for stage procedures of non-culprit vessel after the index PCI, whereby 1 case (0.7%) of asymptomatic scaffold restenosis was diagnosed. Two fatal stroke cases were recognized, with consequent non-cardiac deaths in the second and seventh months after PCI. No scaffold thrombosis was observed.

Two-year clinical outcomes are available in 100 cases. During the second year of follow-up, three cases of CD-TLR (3.0%) were observed (Table 4). Further three cases (3%) of asymptomatic scaffold restenosis were found due to control angiography. Since the index procedure, 70 (36.6%) patients from our study group underwent control angiography scheduled mainly by their family doctor or cardiologist. During the mean 24 months of follow-up, nine cases (4.7%) of in-scaffold restenosis were observed. Scaffold failure occurred mainly because of a partial collapse of the magnesium scaffold or diffused tissue proliferation. The cumulative data are presented in Table 4. To date, no cardiac death or scaffold thrombosis has occurred and no loss to follow-up occurred.

Table 4. Clinical outcome of the study population

	Follow-up			Cumulative
	0–30 day (n = 191)	0–12 month (n = 153)	12–24 month (n = 100)	24 (17–33) month (n = 191)
TLF	0	4 (2.6)	6 (6.0)	10 (5.2)
Cardiac death	0 (0)	0 (0)	0 (0)	0 (0)
TV-MI	0 (0)	1 (0.7)	0 (0)	1 (0.5)
CD-TLR	0 (0)	2 (1.3)	3 (3.0)	5 (2.6)
Asymptomatic-TLR	0 (0)	1 (0.7)	3 (3)	4 (2.1)
Scaffold thrombosis	0 (0)	0 (0)	0 (0)	0 (0)
All death	0 (0)	2 (1.3)	0 (0)	2 (1.0)
All-MI	0 (0)	3 (2.0)	3 (3.0)	6 (3.1)
Any-revascularization	0 (0)	17 (11.1)	13 (13.0)	30 (15.7)
Stroke	0 (0)	3 (2.0)	0 (0)	3 (1.6)

Values are median (IQR) or n (%).

Abbreviations: CD-TLR, clinically driven target lesion revascularization; MI, myocardial infarction; TLF, target lesion failure; TLR, target lesion revascularization; TV-MI, target vessel myocardial infarction

DISCUSSION

The recent experience of RMSs use is still limited, especially regarding long-term follow-up. Initially, Magmaris implantations were limited to patients with a long life expectancy, clinically stable and with short de novo lesions [13–16]. Our Magmaris Registry is one of the first in the ACS (unstable angina/NSTEMI) setting and provides a long-term analysis of magnesium scaffold performance [17].

The crucial part of the project was the proper selection of ACS patients. Relatively young patients with low/mild risk factors and preserved ejection fraction were given preference during screening. Although STEMI patients were not excluded from the Registry, the other exclusion criteria and the difficulty to adhere to the 4P strategy significantly limited the STEMI population in our study group. We believe that appropriately selected patients will achieve the most significant benefit from treatments using this promising technology; the magnesium scaffold is not a therapeutic option for every patient.

In addition to demographic factors, lesion characteristics played the second most important role. Non-calcified, focal, proximal segment lesions were most often selected for Magmaris implantation. However, heavy calcification, challenging tortuosity or angulation, diffuse disease, or thrombus presence in the culprit vessel excluded the patient from our registry. Over time, we obtained good experience with scaffolding longer lesions requiring more than one Magmaris. It seems a desirable option to treat a long soft lesion with RMSs, hence avoiding the full metal jacket design.

Early results of RMSs implantation are strongly correlated with the technical aspects of the procedure [6]. Adherence to proper implantation techniques, precisely the 4P strategy (proper patient and lesion selection, proper scaffold sizing, predilatation for lesion preparation and post-dilatation) reduces the risk of mistakes which have been observed during implantations of first-generation BRSs [15, 16]. Additionally, the previous experience of Absorb scaffolds raised a safety concern because of the increased ScT rates compared with metallic stents [18]. In a preclinical study, the Magmaris scaffold had significantly less platelet deposition and thrombus formation along with less inflammatory cell deposition than the Absorb or the Orsiro stent (BIOTRONIK) or even a 316L stainless steel stent with the same geometry and design [19, 20]. A 2-year analysis of the pooled population of the BIOSOLVE-II and BIOSOLVE-III trials confirmed no probable or definite ScT [14]. The results of the BIOSOLVE-II and international registry BIOSOLVE-IV — or even the high-risk population of the MAGSTEMI trial — have released the metallic magnesium scaffold from the ScT 'class effect' [14–16, 21, 22]. Our study has confirmed that the use of a magnesium scaffold, even in the ACS setting, does not raise any concerns about increased ScT.

Estimation of the RMSs' resorption period is an essential factor for setting DAPT duration. During the resorption phase, scaffold discontinuity and polymer breakdown are observed, and it may increase the risk of thrombus formation. Therefore, 12 months of DAPT is recommended for all ACS Magmaris patients. The duration of DAPT needs to be balanced against the increased risk of bleeding events. Unfortunately, in our study, two cases of fatal stroke occurred during the 12 months of DAPT.

On the other hand, the shorter period of bioresorption could lead to an early loss of mechanical support, resulting in scaffold's 'late recoil' and restenosis [23]. In the 6- and 12-month angiographic follow-up of the BIOSOLVE-II trial, the late loss in-scaffold were 0.37 (0.25) mm and 0.39 (0.27) mm, respectively [24, 25]. At one year of the subgroup analysis of the first 400 patients of the BIOSOLVE-IV, the CD-TLF rate was 4.3%, which is comparable to the results of the FANTOM II trial, where major adverse cardiac events occurred in 4.2% and target lesion failure in 4.2% of the 240 patients at 12 months [26]. However, in our population, the CD-TLR barely reached 1.3% and cumulative TLF 2.6% at 1-year follow-up. The 2-year TLF rate was 5.9% in a pooled population of the BIOSOLVE-II and BIOSOLVE-III trials [14]. Despite this, both of the above trials enrolled stable pa-

tients with simple lesions. In our ACS Magmaris population, the 2-year cumulative TLF reached 5.2%. Although caution should be applied in interpreting the results across studies because of the small number of cases, these findings support the evidence for favorable long-term results of using Magmaris in the ACS setting. The latest presented pooled analysis of BIOSOLVE-II and BIOSOLVE-III demonstrated similar rates of TLF (6.4%) and clinically driven revascularization (3.7%) at the 36-month follow-up when compared with second-generation DES [27].

In the present study, the Magmaris RMSs demonstrated excellent safety results through a 12- to 24-month clinical follow-up. The data is very encouraging for magnesium scaffolds as a therapeutic option for patients presenting with UA or non-ST-segment elevation ACS. Although Magmaris ACS procedures appear safe and feasible, larger randomized studies with longer follow-ups are needed, especially in the ACS setting.

Study limitations

A low number of study patients, the setting restricted mainly to NSTEMI or UA patients and an observational, single-arm design are the relevant limitations of our study. No control group was available to compare the use of the scaffold with DES. Admittedly there was also a selection bias as operators were prompted to choose less complex lesions for Magmaris implantation.

CONCLUSIONS

The use of the Magmaris RMS in selected ACS patients is associated with procedural safety and promises early and long-term clinical and safety outcomes. Appropriate patient selection is the key to the long-term success of bioresorbable technology. Further evaluation in larger prospective randomized controlled trials is needed before scaffold technology can be rolled out to everyday use in interventional cardiology.

Article information

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