Cardiovascular Revascularization Medicine 21 (2020) 1150–1154

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Sustained Safety and Performance of the Second-Generation Sirolimus-Eluting Absorbable Metal Scaffold: Pooled Outcomes of the BIOSOLVE-II and -III Trials at 3 Years

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ARTICLE INFO

Article history:
Received 4 February 2020
Received in revised form 3 April 2020
Accepted 3 April 2020

Keywords:
Stable angina
Bioresorbable scaffolds
Myocardial infarction
Stent thrombosis

ABSTRACT

Background/purpose: To avoid long-term effects associated with permanent implants, bioresorbable vascular scaffolds were developed, as they provide transient vessel support and disappear thereafter. The aim of the BIOSOLVE-II and -III studies was to assess the safety and performance of a magnesium-based sirolimus-eluting scaffold; we report the clinical outcomes at 3 years, 2 years after scaffold resorption.
Methods/materials: BIOSOLVE-II and BIOSOLVE-III are international, prospective multi-center studies, including 184 patients with 189 *de novo* lesions and stable or unstable angina, or documented silent ischemia. Acute myocardial infarction, 3-vessel coronary artery disease, and heavily calcified lesions were excluded. Antiplatelet therapy was recommended for 6 months.
Results: Patients were 65.5 ± 10.8 years old, and lesions were 12.1 ± 4.5 mm long and located in vessels with a diameter of 2.7 ± 0.4 mm. More than half of the lesions (56.5%) were type B2/C lesions. At 2 years, 92.5% (160/173) of patients were symptom-free and 91.5% (151/165) at 3 years; all the other patients had stable angina. At 3 years, target lesion failure occurred in 11 patients (6.3%), consisting of 4 cardiac deaths (2.3%), one target-vessel myocardial infarction (0.6%), and 6 clinically driven target lesion revascularizations (3.4%). There was no definite or probable scaffold thrombosis.
Conclusion: In a low-risk patient population, treatment with a sirolimus-eluting magnesium bioresorbable scaffold can be considered safe, in particular with no definite or probable scaffold thrombosis.
Annotated table of contents: BIOSOLVE-II and -III are prospective, international, multi-center studies including 184 patients with *de novo* lesions. At 3 years, target lesion failure was 6.3%, consisting of 4 cardiac deaths (2.3%), one target-vessel myocardial infarction (0.6%), and 6 clinically driven target lesion revascularizations (3.4%). There was no definite or probable scaffold thrombosis.

1. Introduction

Permanent drug-eluting stents (DES) are associated with long-term adverse events attributed to factors such as persistent inflammation, poor endothelialization, neoatherosclerosis, and stent malapposition. Ten-year outcomes of the SORT-OUT II trial revealed that target lesion revascularization (TLR) and very late stent thrombosis occur in constant

Abbreviations: BRS, bioresorbable scaffold; DAPT, dual antiplatelet therapy; TLF, target lesion failure; TLR, target lesion revascularization.

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https://doi.org/10.1016/j.carrev.2020.04.006
1553-8389/

annual rates [1]. To avoid such long-term events, the aim of bioresorbable scaffolds (BRS) is to provide transient vessel support as long as needed and to disappear thereafter [2].

Initial enthusiasm about BRS was tempered as outcomes from polymer-based BRS were not competitive against contemporary DES; particularly, the elevated scaffold thrombosis rate raised concerns [2–6]. However, in preclinical tests, metallic BRS revealed properties that led to a reduced thrombogenicity compared to the Absorb polymeric BRS (Abbott Vascular, Santa Clara, California) [2]. Furthermore, there are relevant differences between the scaffolds, such as that the Magmaris scaffold has mechanical properties closer to permanent DES, a smaller footprint compared to the Absorb (strut-to-artery ratio of 20% versus 27%), and a different process of degradation [2,7,8].

The aim of the BIOSOLVE-II and -III studies was to assess the performance and safety of the novel magnesium-based Magmaris BRS (called DREAMS 2G during the course of the study) and to obtain the CE mark. Pooled 12-month-outcomes have been previously reported [9]. In this manuscript, we report the outcomes at 3 years, hence, 2 years after the resorption of the scaffold.

2. Materials and methods

2.1. Study design and population

Study methods have been described in detail previously [8,9]. In brief, BIOSOLVE-II and BIOSOLVE-III are both prospective, international, multi-center clinical studies to assess the safety and performance of the drug-releasing absorbable metal scaffold (DREAMS 2G, commercial name Magmaris).

Main inclusion criteria were stable or unstable angina, or documented silent ischemia and a maximum of 2 single *de novo* lesions in 2 separate coronary arteries ≤21 mm in length. Main exclusion criteria were myocardial infarction within 72 h prior to the index procedure, unprotected left main disease, three-vessel coronary artery disease, heavily calcified lesions, or unsuccessful predilatation.

Follow-up assessments were scheduled at 1, 6, and 12 months, and at 2 and 3 years, and included assessment of the angina status (without mandatory stress test), concomitant medications, and adverse events. Angiographic follow-up was scheduled at 6 months (BIOSOLVE-II) and 12 months (BIOSOLVE-III). In BIOSOLVE-II, the patients were asked for a voluntary 12-month and 3-year angiographic follow-up, whereas no voluntary angiographic follow-up was scheduled for BIOSOLVE-III. If a reintervention was performed, the angiographic assessment prior to the intervention was used for analysis and lesions then precluded from further imaging follow-up. Additional imaging assessments outside the protocol had to be documented and evaluated by the core laboratory. To collect further long-term data, the follow-up of BIOSOLVE-II is planned to be extended to 5 years.

The studies were conducted in accordance with the current guidelines such as Declaration of Helsinki and ISO14155, was approved by the ethics committees and competent authorities, and all patients provided written informed consent. The studies were 100% source document verified, all events were adjudicated by an independent clinical events committee, and images were assessed by an independent core laboratory. (ClinicalTrials.gov NCT01960504 and NCT02716220)

2.2. Device and procedure

DREAMS 2G, commercial name Magmaris (Biotronik AG, Buelach, Switzerland) has been described previously [8,9]. It is a BRS made of magnesium alloy with a 6-crown 2-link design with 150 μm strut thickness and 150 μm strut width and is covered with BIOlute (bioresorbable poly-L-lactic acid that elutes sirolimus). Available scaffold diameters were 2.5, 3.0, and 3.5 mm and lengths of 20 and 25 mm in BIOSOLVE-II, and 3.0 and 3.5 mm with lengths of 15, 20 and 25 mm in BIOSOLVE-III. The device gained the CE mark in June 2016.

Pre-dilatation with a balloon ≤0.5 mm smaller than the reference vessel diameter, but not exceeding the vessel diameter, and a length ≤ lesion length was mandatory. Post-dilatation was performed according to the discretion of the investigator. Dual antiplatelet therapy (DAPT) was recommended for at least 6 months.

2.3. Endpoints

Endpoints at 3 years were (1) target lesion failure (TLF), a composite of cardiac death, target-vessel myocardial infarction [10,11], coronary artery bypass grafting, and clinically driven TLR [12], and (2) scaffold thrombosis [12].

2.4. Statistical analysis

Data are presented on the intention-to-treat population using descriptive statistical methods. Patients in whom an implant was attempted, but the scaffold could not be implanted, were counted for procedure success only, but were exempted from further follow-up. For continuous variables, mean ± standard deviation, for categorical data, absolute and relative frequencies are reported. For clinical outcomes, the follow-up time window of 30 days was considered (up to day 1125) and the denominator was based on patients with either follow-up assessment or a respective clinical event. When appropriate, 95% confidence intervals were calculated. Comparison between the studies were performed using Chi-Square-, Fisher's T-, and Wilcoxon tests. Statistical analyses were performed using SAS 9.4 (SAS Institute Inc. Cary, NC, USA).

3. Results

Of the 184 patients with 189 lesions enrolled (123 in BIOSOLVE-II and 61 in BIOSOLVE-III), the scaffold could not be implanted in 2 patients in BIOSOLVE-II due to insufficient pre-dilatation; they were subsequently excluded from long-term follow-up (Fig. 1).

In brief, patients were 65.5 ± 10.8 years old, predominantly men (63.6%, $n = 117$), and about one quarter had diabetes mellitus (25.0%, $n = 46$) or a history of prior myocardial infarction (23.4%, $n = 43$). Previous coronary interventions had been performed in 41.3% ($n = 76$) of the patients. Target lesions had a reference vessel diameter of 2.7 ± 0.4 mm, were 12.1 ± 4.5 mm long, had a minimum lumen diameter of 1.2 ± 0.3 mm, and a diameter stenosis of 54.4 ± 11.4%.

Overall, there was no significant difference in baseline parameters between BIOSOLVE-II and -III, except that lesions in BIOSOLVE-III were more frequently bifurcated (21.9% vs 1.6%, $p < 0.0001$), moderate-to-severely angulated (23.4% vs 4.1%, $p = 0.0002$), moderate to heavily calcified (23.4% vs 10.7%, $p = 0.0206$), and complex (Type B2/C lesions) (81.3% vs 43.4%, $p < 0.0001$; 56.5% on average in both trials).

Pre-dilatation was performed in all lesions, with larger balloon diameters used in BIOSOLVE-III (3.0 ± 0.4 mm vs 2.9 ± 0.4 mm, $p = 0.006$). Regarding the implant, in BIOSOLVE-III, device length was shorter (19.5 ± 4.2 mm vs 21.4 ± 2.3 mm, $p = 0.0003$), device diameter was larger (3.3 ± 0.3 mm vs 3.1 ± 0.2 mm, $p < 0.0001$), and inflation time was longer (32 s vs 24 s, $p = 0.0008$). Post-dilatation was performed more frequently in BIOSOLVE-III (83.3% vs 61.2%, $p = 0.002$), but balloon diameters were similar (3.4 ± 0.4 mm vs 3.3 ± 0.4 mm, $p = 0.078$).

The ischemic status improved substantially from baseline to follow-up. While all patients had either stable or unstable angina or documented silent ischemia at baseline, 92.5% of patients (160/173) were without pathological findings at 24 months and 91.5% (151/165) at 36 months (Fig. 2). Patients were on dual antiplatelet therapy in 52.8% (93/176) of cases at 12 months, in 18.5% (32/173) at 2 years, and in 16.4% (27/165) at 3 years.

Clinical follow-up information was available in 98.9% of patients at 2 years and in 95.6% at 3 years. Assessed by an independent clinical

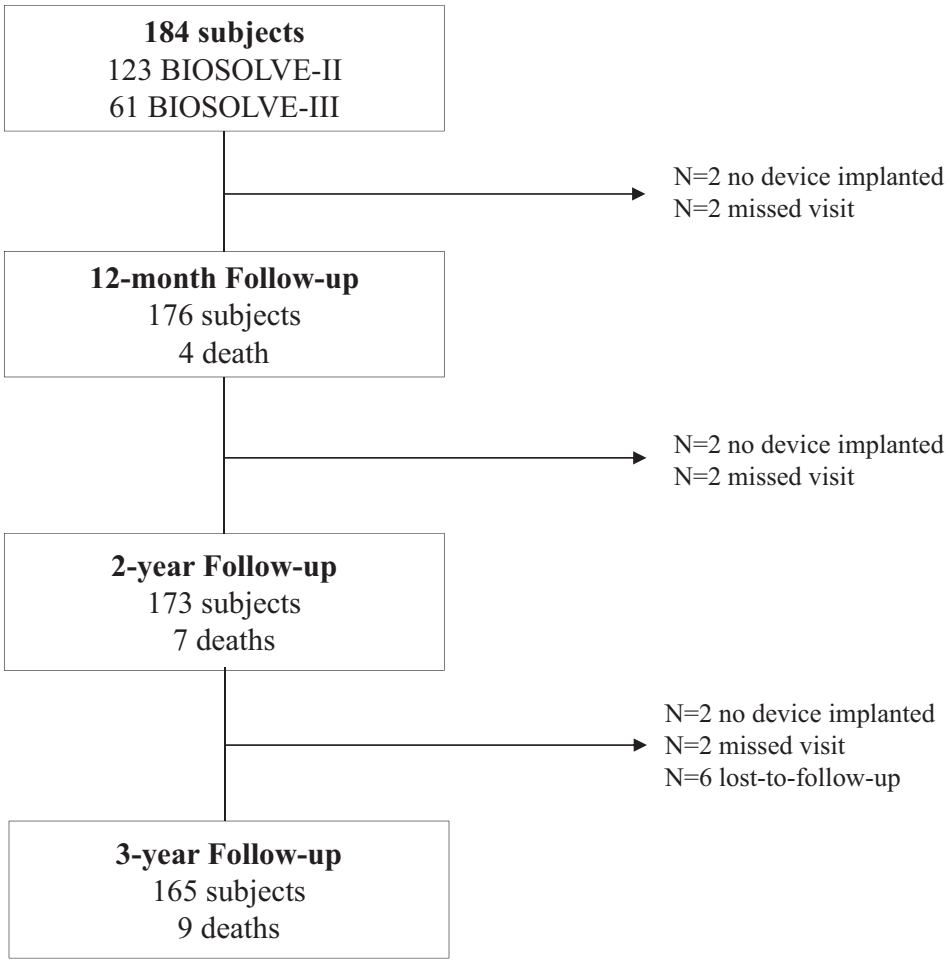

Fig. 1. Study flow-chart. Two patients did not receive an implant and were counted for procedural success only.

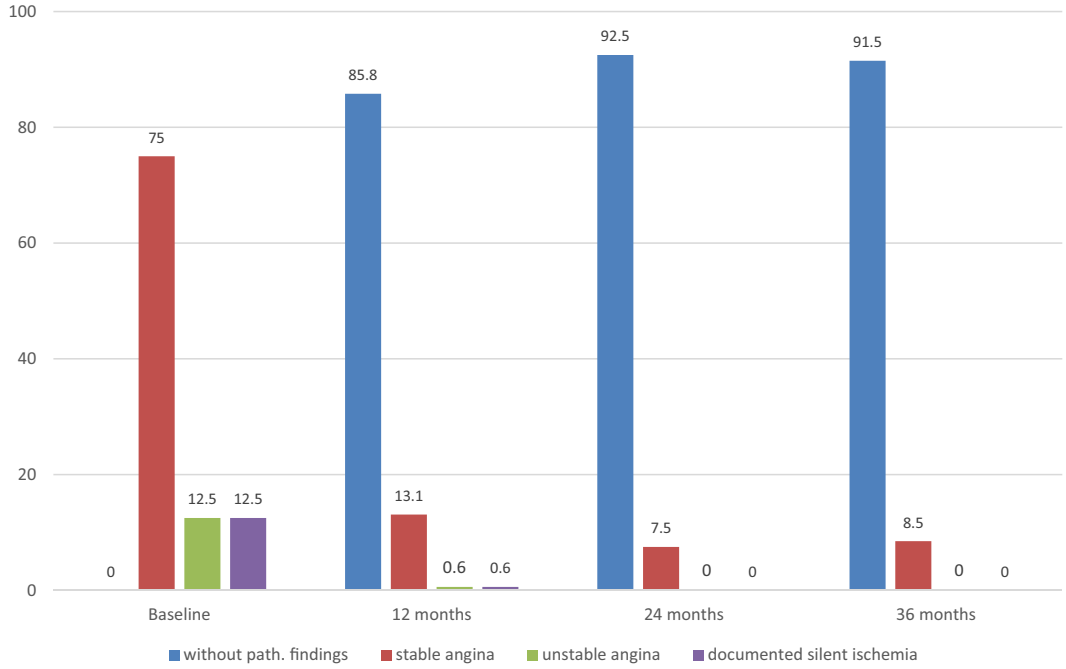

Fig. 2. Angina status at baseline and follow-up [%]. Data were available for 184 patients at baseline, 176 at 12 months, 173 at 24 months, and 165 at 36 months.

events committee, target lesion failure at 36 months was observed in 8 patients in BIOSOLVE-II (6.8%) and 3 patients in BIOSOLVE-III (5.3%), leading to an overall TLF rate of 6.3% [95% CI: 3.2;11.0] (Table 1). Only one case, a TLR, occurred between 2 and 3 years. Overall, 4 cardiac deaths occurred. One at day 2 was probably due to a ventricular arrhythmia caused by a large infarction area after an ST-elevation myocardial infarction that had occurred prior to the index procedure (autopsy confirmed the absence of scaffold thrombosis), two unwitnessed deaths occurred on day 134 and 395, and one nonagenarian died on day 574 of pre-existing chronic heart failure. No probable or definite scaffold thrombosis was reported throughout both studies.

4. Discussion

BRS have been developed to reduce long-term complications associated with a permanent implant. The first device that gained the CE mark was the Absorb polymeric BRS. However, after disappointing mid-term outcomes, such as elevated device thrombosis rates, the company withdrew the device from the market in 2017 [2,4–6].

Yet newer-generation scaffolds may have properties that have the potential to overcome the limitations of the Absorb scaffold, such as the weak mechanical properties, the large strut thickness resulting in less embedding and large protrusion, and the long resorption period [4,5]. The Magmaris scaffold is such a newer-generation BRS. Albeit that its strut thickness is similar to Absorb, Magmaris is less thrombogenic, has a shorter resorption period of only 12 months, and is more fracture resistant as compared to Absorb. So far, in the BIOSOLVE-II and -III studies, no intraluminal masses have been observed by optical coherence tomography or intravascular ultrasound [3,5,9,13,14]. Furthermore, even though both devices have a similar strut thickness, the rounded edges of Magmaris may facilitate embedding into the vessel wall and reduce flow disruption [9,15].

While the 2018 European Society of Cardiology (ESC) guidelines discourage the use of BRS outside clinical trials [6], newer publications recommend that — while being aware of the possible risks — interventionalists should not be discouraged from using new-generation scaffolds in suitable lesions and patients [5]. In fact, the ESC guidelines and the European Association of Percutaneous Cardiovascular Interventions (EAPCI) Task force on bioresorbable scaffolds both acknowledge the promising outcomes of Magmaris, but at the time of publication only limited data were available and the ESC-EAPCI report called for publication of further results [3,6].

Meanwhile, procedural outcomes of >2000 Magmaris implantations are available, as well as 12-month data of 400 patients enrolled in the BIOSOLVE-IV registry [16,17]. Furthermore, our current report provides clinical insights from 184 patients until 2 years after device resorption. The 3-year TLF rate (6.3%, [95% CI: 3.2;11.0]) in patients treated with Magmaris was lower than for the Absorb scaffold (11.7%) and the Xience DES (Abbott Vascular, Santa Clara, California) (8.1%), as previously reported in a pooled meta-analysis [18]. Noteworthy, >90% of patients were symptom-free at 3 years.

Since the introduction of Magmaris to the market, some incidental findings of recoil and compression have been reported [19–21]; however, the 12-month TLR-rate of the first 400 patients enrolled in the BIOSOLVE-IV registry was favourably low, at 4.3% [17]. Notably, in a recent analysis of intravascular ultrasound, virtual histology, and optical coherence tomography images, the edge vascular response after Magmaris implantation did not show significant changes at 12 months except for a fibrous plaque area reduction, which could be translated as a benign process of healing [22].

The absence of definite or probable scaffold thrombosis in BIOSOLVE-II and -III is encouraging, diminishing the concerns about elevated event rates as observed with Absorb. However, meanwhile (in the BIOSOLVE-IV registry) the first scaffold thrombosis for Magmaris has occurred on day 10 after implantation, following cessation of DAPT for planned coronary arterial bypass grafting. Nevertheless, the 12-month stent thrombosis rate in BIOSOLVE-IV was still very low, at 0.3% [17].

Table 1
Clinical outcomes.

	24 months[a]	36 months[a]
TLF	10 (5.5)	11 (6.3)
Death	7 (3.9)	9 (5.2)
Cardiac death[a]	*4 (2.2)*	*4 (2.3)*
Target-vessel MI	1 (0.6)	1 (0.6)
CD-TLR	5 (2.7)	6 (3.4)
CD-TVR	8 (4.3)	9 (5.2)
CABG	0	0
Scaffold thrombosis definite or probable	0	0

Data are presented as n and frequencies (%). CABG-coronary artery bypass graft, CD-TLR-clinically driven target lesion revascularization, CD-TVR-clinically-driven target vessel revascularization, MI-myocardial infarction, TLF-target lesion failure.

[a] Reflecting a period up to 760 days at 2 years and 1125 days at 3 years.

5. Limitations

Both trials had a nearly identical design and, hence, bear the same limitations that have been reported in detail previously [8,9,23]. Aside from the common limitations of non-randomized studies, the lack of mandatory angiographic follow-up is the main limitation, resulting in only 48 patients with 3-year angiographic follow-up in BIOSOLVE-II [23] and none in BIOSOLVE-III. A strength of these trials is that 100% source document verification was performed and that all events have been adjudicated by an independent clinical events committee.

6. Conclusion

In the two trials, there was only one case of target-vessel myocardial infarction and no cases of definite or probable scaffold thrombosis. Furthermore, TLF and TLR were within the ranges of contemporary permanent DES. With the caveat that the utmost care has to be applied during patient implantations, and DAPT needs to be meticulously adhered to, this metal bioresorbable scaffold can be considered a safe device in simple lesions.

CRediT authorship contribution statement

Michael Haude: Conceptualization, Methodology, Investigation, Writing - original draft, Writing - review & editing, Supervision. **Hüseyin Ince:** Investigation, Writing - review & editing. **Stephan Kische:** Investigation, Writing - review & editing. **Ralph Toelg:** Investigation, Writing - review & editing. **Nicolas M. Van Mieghem:** Investigation, Writing - review & editing. **Stefan Verheye:** Investigation, Writing - review & editing. **Clemens von Birgelen:** Investigation, Writing - review & editing. **Evald Høj Christiansen:** Investigation, Writing - review & editing. **Emanuele Barbato:** Investigation, Writing - review & editing. **Hector M. Garcia-Garcia:** Investigation, Writing - review & editing. **Ron Waksman:** Investigation, Writing - review & editing.

Declaration of competing interest

MH reports study grants and personal fees from Biotronik, Abbott Vascular, Cardiac Dimensions, and Philips. HI reports speaker fees from Abbott, Boston Scientific, Astra Zeneca, Daiichi Sankyo, Novartis, Bristol Meyers (BMS), Pfizer. AA reports grants from Biotronik. RT reports personal fees from Biotronik and Abbott Vascular. PAL reports grants from Biotronik. NvM reports personal fees from Abbott Vascular and Pulsecath and grants from Medtronic, Pulsecath, Boston Scientific, and

Edwards LifeSciences. SV reports personal fees from Biotronik, Elixir and Neovasc. CvB reports institutional research grants from Abbott Vascular, Biotronik, Boston Scientific, and Medtronic. HGG and RW report that MedStar was the core laboratory of the study, and RW reports grant and personal fees from Abbott Vascular, AstraZeneca, Biosensors, Biotronik, Boston Scientific, Chiesi, personal fees from Amgen, Corindus, Lifetech Medical, Medtronic, Philips Volcano and Pi-Cardia LTD, being an investor in MedAlliance, and grants from Edwards Lifesciences. All other authors have no conflicts of interest to declare.

Acknowledgements

We thank Beatrix Doerr for her expert medical writing assistance, reimbursed by Biotronik AG.

Funding: This study was funded by Biotronik AG, Buelach, Switzerland.

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