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Research Correspondence

Two-year clinical outcomes of resorbable magnesium scaffold versus conventional drug-eluting stents in ST-segment elevation myocardial infarction: A propensity score matching analysis

Scaffolding the coronary vessels and protecting the vulnerable or ruptured plaque without a permanent metallic endoprosthesis is an appealing concept that was materialized with bioresorbable coronary scaffolds (BRS)[1]. Magmaris™ (Biotronik AG, Bülach, Switzerland) is the second generation of drug-eluting, fully-resorbable, magnesium-alloy-based scaffolds demonstrating promising results in stable coronary disease[2]. Data are scarce concerning the outcomes of BRS implantation for ST-segment elevation myocardial infarction (STEMI), but theoretically, they could offer an advantageous alternative mostly because of the preservation of the vessel's mechanical and hydraulic properties after resorption while treating the acute event[3]. The BEST-MAG trial was a propensity-matched study that compared the 1-year clinical outcomes of the Magmaris™ BRS versus contemporary drug-eluting stents (DES) in the setting of STEMI[4]. Thirty patients who fulfilled the eligibility criteria were prospectively enrolled based on a prespecified intracoronary imaging-guided protocol. Primary PCI was performed with magnesium BRS and propensity score matching analysis was applied with the two groups of BIOSTEMI trial (biodegradable polymer DES, n = 648; durable polymer DES, n = 651)[5]. Numerically higher rates of target lesion revascularization (TLR) were observed at one-year follow-up, not reaching statistical significance[4]. We herein report the 2-year results of the study.

Clinical and procedural characteristics of the matched population have been published previously at the 1-year outcomes[4]. Optical coherence tomography (OCT) was performed in all patients at baseline and at 15 months in 17 of the magnesium BRS group. The primary device-oriented composite endpoint (DOCE) of cardiac death, target vessel myocardial re-infarction (attributable to the culprit lesion), and ischemic-driven TLR occurred in 20% in the BRS group vs 10% in both the DES groups ($p = 0.286$) at 2 years. The secondary endpoint of definite/probable device thrombosis occurred in 3.3% of BRS and 6.7% in the biodegradable polymer DES ($p = 0.561$) (**Fig. 1**). In the 15-month follow-up OCT of the magnesium BRS group minimal lumen area decreased from 7.57 ± 1.48 mm^2 to 4.72 ± 2.22 mm^2 ($p < 0.001$). BRS struts were evident in all 17 patients and measurements are presented in **Table 1**.

The 2-year results of the BEST-MAG trial are in line with the 12-month results showing a trend toward more TLRs in the magnesium BRS group that does not reach statistical significance. DOCE seems to appear after 1 year and was mainly driven by an increase in TLR. Joner et al. showed that 94.8% of the magnesium is resorbed in 12 months and only amorphous calcium phosphate remains in the vessel wall of animal models[6]. On the contrary visible struts were present in all followed-up patients of our trial. In the same context, the MAGSTEMI trial was the first to investigate Magmaris™ BRS in STEMI and resulted in higher late-lumen-loss and restenosis rates for the BRS, although not powered for these outcomes[7]. The three-year results consistently demonstrated higher TLR rates for magnesium scaffolds, however, the events were clustered during the first year similar to our findings[8]. These unfavorable outcomes might be mitigated by the introduction of a third-generation thinner-strut

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magnesium BRS. The device demonstrated a favorable safety profile and 38% improved performance compared to its precursor in the 12-month results of the BIOMAG-I trial[9]. Large-scale clinical trials will be needed to evaluate the efficacy and efficiency of this novel magnesium BRS and ascertain if it has a potential role in acute coronary syndromes, specifically in STEMIs. The major limitation of the trial is the small patient sample which results in it being underpowered and, thus, only hypothesis generating.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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DISCLOSURES

None.

ABBREVIATIONS

DOCE = device-oriented composite endpoint

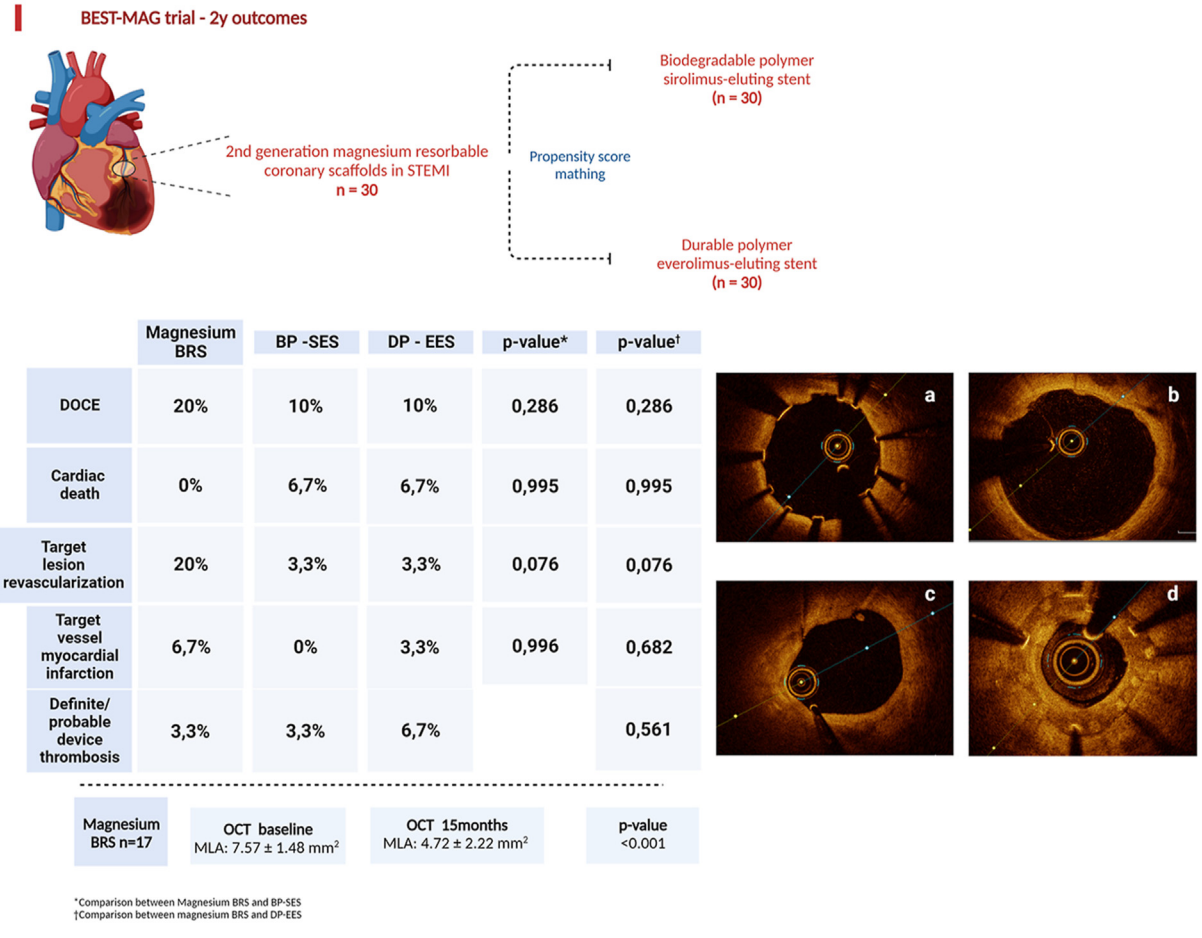
PCI = percutaneous coronary intervention

BRS = bioresorbable coronary scaffold

STEMI = ST-segment myocardial infarction

TLR = target lesion revascularization

FIG. 1 **Graphical display of the BEST-MAG trial 2-year outcomes BRS: bioresorbable coronary scaffold, BP-SES: biodegradable polymer sirolimus-eluting stent, DP-EES: durable polymer everolimus-eluting stenta. a. OCT image after primary angioplasty with magnesium scaffolds. b. OCT image of 15-month follow-up that shows partially resorbed scaffold with some remaining struts and preserved lumen area. c. OCT image of acute coronary syndrome showing strut remnants in the lumen (13 hours) and mixed ruptured plaque (10 hours). d. OCT image showing visible remaining struts of the magnesium scaffold and neointimal hyperplasia resulting in significant lumen loss**



	Magnesium BRS	BP -SES	DP - EES	p-value*	p-value†
DOCE	20%	10%	10%	0,286	0,286
Cardiac death	0%	6,7%	6,7%	0,995	0,995
Target lesion revascularization	20%	3,3%	3,3%	0,076	0,076
Target vessel myocardial infarction	6,7%	0%	3,3%	0,996	0,682
Definite/ probable device thrombosis	3,3%	3,3%	6,7%		0,561

Magnesium BRS n=17	OCT baseline MLA: 7.57 ± 1.48 mm²	OCT 15months MLA: 4.72 ± 2.22 mm²	p-value <0.001

*Comparison between Magnesium BRS and BP-SES
†Comparison between magnesium BRS and DP-EES

TABLE 1 Optical coherence tomography main results in 15-month follow-up in 17 patients treated with resorbable magnesium scaffold

MSA after PCI	MLA in FU	Number of visible struts	Lumen loss	Endpoint
11.39 mm^2	9.2 mm^2	3	19.2%	
9.3 mm^2	6.42 mm^2	4	30.9%	TLR
9.79 mm^2	5.17 mm^2	3	47.2%	
10.33	7.13	4	30.9%	
7.06	4.29	3	39.2%	
6.96	1.65	4	76.3	TLR
5.35	3.76	3	29.7	
7.45	1.01	2	86.4	TLR
8.8	3.51	2	60.1	
6.24	2.75	3	55.9	
9.35	5.97	3	46.1	
8.03	6.68	2	16.8	
6.68	4.24	4	36.5	
7.64	3.14	4	58.9	
6.8	2.91	3	57.2	
7.44	5.48	3	26.3	
6.43	2.25	3	65%	TLR

FU, follow-up; MLA, minimal lumen area; MSA, minimal stent area; PCI, percutaneous coronary intervention; TLR, target lesion revascularization.

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