DIFFERENTIAL EFFICACY OF A NEW MG-BASED BIORESORBABLE STENT IN CHRONIC AND ACUTE CORONARY SYNDROMES

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Background

Despite the advances in coronary artery stents' structure and design, a foreign metallic body is left within the vessel imposing physical restraints and altering vessel physiology. The first generation bioresorbable scaffolds made of poly-L-lactic acid were designed to overcome such metal caging but presented a higher thrombosis rate. A second generation bioresorbable stent (MgBVS) made from a magnesium backbone coated by a biodegradable polymer eluting sirolimus was introduced on the market. CE-mark was obtained after the promising results of the BIOSOLVE studies. More recently, the MAGSTEMI randomized controlled trial showed a higher rate of in-device endothelium-independent and -dependent vasomotor response than the SES implant but was associated with a higher late lumen loss, higher rate of target lesion revascularization, without thrombotic safety concerns in this thrombogenic setting.

Objectives

We sought to present long-term clinical outcome of real-life patients treated at our institution with at least one MgBVS for a coronary stenosis.

Methods

In this retrospective observational study, between January 2017 and March 2020, MgBVS were deliberately chosen and implanted for younger patients with de novo lesions after pre-dilatation. Post-dilatation was performed with a non-compliant (NC) balloon. Procedural and clinical data at hospital discharge and 6-month follow-up were collected. MACE was defined as cardiovascular death, target vessel myocardial infarction (TV-MI) and clinically driven target lesion revascularization (CD-TLR). Need for CD-TLR was confirmed by FFR. Assessment of stent patency, vessel size and minimal in-stent lumen area were measured during follow-up with coronary computed tomography angiography (CCTA) scans. Patients were screened for residual ischemia when indicated.

Results

44 MgBVS (mean diameter: 3.2 ± 0.2 mm, length 20.6 ± 4.2 mm) were successfully implanted to treat 43 coronary lesions in 38 patients. IVUS was used in 13% (n=5) and bifurcating lesions treated in 41% (n=18). Calcifications on angiography were found in 16 patients (36%). Post-dilatation with a NC balloon with a mean diameter of 3.4 ± 0.3 mm inflated at 18.4 ± 2.4 atm was performed in 93% of the lesions (n=41).

Patient characteristics	**n=38**	
Age, yrs	55.9 ± 8.1	
Male	30	78.9%
Smoking	21	55.3%
Hypertension	24	63.2%
Diabetes mellitus	15	39.5%
Hyperlipidemia	25	65.8%
Initial presentation		
Acute Coronary Syndrome	24	63.1%
STEMI	9	23.7%
NSTEMI	10	26.3%
Unstable Angina	5	13.2%
Elective PCI	14	36.8%
Lesion location		
LAD	25	56.8%
LCx	6	13.6%
Obtuse Marginal	2	4.5%
RCA	10	22.7%
RI	1	2.3%

Table: *Patients and lesions characteristics*

Overall TLF in 38 patients / 44 lesions	***35 reached 6-mo f-up***	
TLF	4	9%
Cardiac death (tamponade)	1	
TV MI (in-stent thrombosis @ 1 mo.)	1	
CD-TLR (in-stent restenosis @ 1 and 8 mo.)	2	
CABG	0	

On CCTA, one more in-stent restenosis was noted in an initial ACS patient who remained asymptomatic with a negative dobutamine echocardiography, although the minimal lumen area by CCTA was 1.1 mm^2.

Discussion and Conclusion

These 4 MACE occurred in the 24 ACS patients (17%), with 0% for the others, a difference not statistically significant (Fisher exact test, p=0.14) because of the small sample size. In BIOSOLVE II-III studies where ACS patients were excluded, TLF at 1-year was 3.3%. In BIOSOLVE-IV that included only 16% of nonSTEMI, TLF was 4.3%. On the contrary, **our data are more in line with the recently presented MAGSTEMI trial reporting a TLR of 16% among 100% of ACS by design.** Despite careful optimal stent implantation technique, our results call for a word of caution in using MgBVS in ACS, with a need to further improve its design and radial force. Meanwhile, a question still arises: bioabsorbable stents, are we out of the shadows yet?

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Conflict of Interest: None