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Original article

Clinical follow-up of long nontapered sirolimus-eluting coronary stent in real-world patients with de novo lesions. The Billar registry

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ABSTRACT

Introduction and objectives: Coronary lesions with stent overlapping are associated with higher neointimal proliferation that leads to more restenosis. Furthermore, the tapering of coronary arteries is a major challenge when treating long coronary lesions. This study attempted to assess the safety and clinical level of performance of long nontapered sirolimus-eluting coronary stent systems (> 36 mm) to treat long and diffused de novo coronary lesions in real-world scenarios.
Methods: This was a prospective, non-randomized, multicentre study that included 696 consecutive patients treated with the long nontapered BioMime sirolimus-eluting coronary stent system in long and diffused de novo coronary lesions. The safety endpoint was major adverse cardiovascular events defined as a composite of cardiac death, myocardial infarction, clinically driven target lesion revascularization, stent thrombosis, and major bleeding at the 12-month follow-up.
Results: Of a total of 696 patients, 38.79% were diabetic. The mean age of all the patients was 64.6 ± 14 years, and 80% were males. The indication for revascularization was acute coronary syndrome in 63.1%. A total of 899 lesions were identified out of which 742 were successfully treated with long BioMime stents (37 mm, 40 mm, 44 mm, and 48 mm). The cumulative incidence of major adverse cardiovascular events was 8.1% at the 12-month follow-up including cardiac death (2.09%), myocardial infarction (1.34%), and total stent thrombosis (0.5%).
Conclusions: This study confirms the safety and good performance of long nontapered BioMime coronary stents to treat de novo coronary stenosis. Therefore, it can be considered a safe and effective treatment for long and diffused de novo coronary lesions in the routine clinical practice.

Keywords: Coronary angioplasty. Drug-eluting stent. Nontapered stents.

Seguimiento clínico del *stent* coronario largo no cónico de sirolimus en el mundo real en lesiones de novo. Registro Billar

RESUMEN

Introducción y objetivos: Las lesiones coronarias largas y difusas, cuando se tratan percutáneamente, requieren a menudo superposición de los *stents*, que se asocia a una mayor tasa de reestenosis. Por otro lado, el adelgazamiento progresivo de las arterias dificulta el tratamiento de las lesiones largas. En este estudio se analizan la seguridad y la eficacia clínica de los *stents* liberadores de sirolimus largos no cónicos (> 36 mm) para el tratamiento de lesiones largas *de novo* en un escenario real.

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Métodos: Estudio prospectivo, no aleatorizado, multicéntrico, con 696 pacientes consecutivos con implantación de *stent* BioMime largo no cónico para el tratamiento de lesiones coronarias *de novo* largas y difusas. El criterio de valoración de seguridad fueron los eventos adversos cardiovasculares mayores en el seguimiento, definidos como la combinación de muerte cardiaca, infarto de miocardio, necesidad de nueva revascularización en la misma lesión guiada por la clínica, trombosis del *stent* o hemorragia mayor a los 12 meses.
Resultados: De los 696 pacientes incluidos, el 38,79% eran diabéticos. La edad media fue de 64,6 ± 14 años y el 80% eran varones. La indicación de revascularización fue un síndrome coronario agudo en el 63,1%. Se identificaron 899 lesiones, de las que 742 se trataron con éxito con *stents* BioMime (37-40-44-48 mm). La incidencia acumulada de eventos adversos cardiovasculares mayores fue del 8,1% a los 12 meses, con un 2,09% de muertes de causa cardiaca, un 1,34% de infartos de miocardio y un 0,5% de trombosis del *stent*.
Conclusiones: El presente estudio confirma la seguridad y el buen perfil clínico a 12 meses del *stent* BioMime largo no cónico para el tratamiento de lesiones coronarias *de novo* largas y difusas, por lo que debe considerarse un tratamiento seguro y eficaz para este tipo de lesiones en la práctica clínica habitual.

Palabras clave: Angioplastia coronaria. *Stents* farmacoactivos. *Stents* largos no cónicos.

Abbreviations

CAD: coronary artery disease. **DES**: drug-eluting stent. **MACE:** major adverse cardiovascular events. **PCI:** percutaneous coronary intervention. **SES:** sirolimus-eluting stent. **ST:** stent thrombosis.

INTRODUCTION

The most widely used strategy to treat coronary artery disease (CAD) is percutaneous coronary intervention (PCI) with stent implantation, particularly with the current generation of drug-eluting coronary stents (DES), since their distinctive features improve the clinical outcomes of PCI.[1] However, the treatment of long and diffused coronary lesions remains challenging, especially in long lesions in tapered coronary arteries where variations in vessel diameter may require the implantation of > 1 stent per lesion.[2,3]

The use of either multiple stents or a single long stent are the most common treatment strategies for long and diffused lesions in tapered arteries. Both approaches may be associated with clinical failure due to the potential risk of mechanical mismatch of the stent size.[1,4,5] Multiple short overlapping stents with variable diameters are often implanted to adequately match the size of long tapered lesions. Because of potential discrepancies regarding diameters when using long nontapered stents, a proximal optimization technique may be used to reconstruct the vessel natural geometry. However, this solution does not come without problems such as stent fracture due to vessel rigidity, restenosis due to a higher vascular injury, delayed healing, very late stent thrombosis (ST), vessel aneurysm, side branch jailing, higher treatment cost, overuse of antirestenotic drugs, and increased exposure to radiation and contrast media, and death or myocardial infarction.[6,7]

A single long BioMime (Meril Life Sciences Pvt. Ltd., India), an ultrathin biodegradable polymer coated sirolimus-eluting coronary stent (SES) system, is often enough to treat long and diffused lesions. Thus, the local arterial walls can be saved from overexposure to drug/metal avoiding any potential associated adverse events at the follow-up like delayed healing, perioperative myocardial infarction (MI), risk of target lesion revascularization, and very late ST. The aim of this study was to evaluate the safety and level of performance of the long nontapered BioMime SES system (37 mm, 40 mm, 44 mm, 48 mm) in consecutive real-world patients with long and diffused de novo coronary lesions.

METHODS

Study design and population

This was a prospective, non-randomized, multicentre study that included a total of 696 consecutive patients (aged ≥ 18 years) from 14 clinical centers across Spain. All the study investigators are listed in the appendix of this article.

All consecutive patients included had been treated of long and diffuse de novo coronary lesions through the implantation of, at least, 1 long nontapered BioMime system (37 mm, 40 mm, 44 mm, 48 mm). The study was conducted in observance of the privacy policy of each research center including its rules and regulations for the appropriate use of data in patient-oriented research. This study was also conducted in observance of the Declaration of Helsinki, and approved by the ethics committee. Written informed consents were obtained from all the participants before the procedure.

Study device and procedure

The BioMime is a biodegradable polymer coated SES system with different lengths available to treat long and diffused coronary lesions. It uses an ultra-thin strut (65 µm), and a cobalt-chromium platform that has a unique hybrid design of open and closed cells with uniformly thin coating (2 µm) of bioabsorbable polymers, PLLA (poly-L-lactic acid), and PLGA (poly-lactic-co-glycolic acid). The stent elutes sirolimus (1.25 µg/mm^2) between 30 and 40 days after implantation. The currently available long lengths of BioMime are 37 mm, 40 mm, 44 mm, and 48 mm. The device is CE marked.

The PCI was performed according to the standard treatment guidelines and followed by each participant center. Predilatation and postdilatation were left to the operator's discretion though postdilatation was recommended per protocol.

Preoperatively, a 300 mg loading dose of aspirin plus a second anti-platelet agent (clopidogrel, ticagrelor, or prasugrel according to the clinical settings and operator's preference) were administered in all the consecutive patients included.

Postoperatively, all patients were administered a 12-month course of dual antiplatelet therapy plus aspirin (75 mg to 100 mg once a day) indefinitely beyond the first year. A 1.6- and 12-month clinical follow-up was conducted after the index procedure, as required, and based on symptoms.

Endpoints and definitions

The safety endpoints were the occurrence of major adverse cardiovascular events (MACE) at the 1-, 6-, and 12-month follow-up after the index procedure. MACE was defined as a composite of cardiac death, target vessel myocardial infarction, clinically driven target lesion revascularization, ST, and major bleeding.

MI was defined as the development of new pathological Q waves on the electrocardiogram or elevated creatinine kinase (CK) levels ≥ 2 times the upper limit of normal with elevated CK-MB levels in the absence of new pathological Q waves or new ischemic symptoms (eg, chest pain or shortness of breath).[8] Cardiac death was defined as any deaths resulting from AMI, sudden cardiac death, heart failure mortality or stroke. Clinically driven target lesion revascularization was defined as a new PCI performed on the target lesion or coronary artery bypass graft of the lesion in the previously treated segment or within the 5 mm proximal or distal to the stent site or edge of DES inflation. ST was classified based on the definitions established by the Academic Research Consortium.[9] Moderate-to-severe bleeding events were defined according to the GUSTO (Global Use of Strategies to Open Occluded Arteries) criteria. Procedural success was defined as a successful PCI without in-hospital major clinical complications including death, MI, and clinically driven target lesion revascularization. Device success was defined as the deployment of the study stent at the intended target lesion attaining final residual stenosis < 30% of the target lesion estimated both angiographically and through visual estimation.

Statistical analysis

Since there is no intervention, to study this cohort of patients we thought that the best method was to perform a descriptive analysis for an objective, comprehensive, and informative study of data. A a descriptive statistical analysis of the relevant variables was performed after collecting data. All statistical analyses were performed using the SPSS statistical software platform. Measures of central tendency such as means summarize the level of performance of a group of scores while measures of variability describe the spread of scores among the participants. Both are important to understand the behavior of this cohort. One provides information on the level of performance, and the other tells us how consistent that performance is. Categorical data were expressed as frequency and percentages. No further models were conducted as the idea of this paper was to describe a group of patients, not to compare groups or search for significant inter-group differences.

RESULTS

Baseline demographic and clinical characteristics

The data of 696 consecutive patients (742 BioMime stents implanted, 157 different stents) were collected in the study that mostly included males (80.1%). The baseline demographic and clinical characteristics of patients are shown on table 1. The patients' mean age was 64.6 ± 14 years. Conventional risk factors for CAD in the study population were diabetes mellitus (39%), hypertension (67.2%), dyslipidemia (64.8%), and active smoking (26.44%). The clinical status at admission is shown on table 1. Most patients (63.39%) had acute coronary syndrome.

Table 1. Baseline demographic and clinical characteristics

Patients	N = 696
Patients, demographics	
Age, years	64.6 ± 14
Male	556 (80.1)
Baseline past medical history	
Diabetes mellitus	271 (38.79)
Hypertension	466 (66.80)
Dyslipidemia	452 (64.80)
Active smoker	180 (26.44)
Previous CABG	57 (8.54)
Previous PCI	223 (32.07)
Vascular peripheral disease	69 (10.64)
Previous MI	181 (25.63)
Cardiac status at the index procedure	
Stable angina	254 (36.49)
Unstable angina	29 (4.16)
STEMI	227 (32.61)
NSTEMI	186 (26.72)
Left ventricular ejection fraction < 30%	181 (26)

CABG, coronary artery bypass graft; NSTEMI, non-ST-elevation acute myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.
Data are expressed as no. (%) or mean ± standard deviation.

Lesion and procedural characteristics

Out of a total of 899 lesions identified in 696 consecutive patients, 742 long and diffused de novo type C coronary lesions (1.07 lesions per patient) were successfully treated with long BioMime stents. No other stents were needed to treat the lesion initially handled with a long BioMime device. A total of 157 other lesions were treated with 157 different stents. Therefore, no overlapping was needed in any of the lesions treated with a long BioMime device. A total of 40% of the patients had 1-vessel disease, 37% 2-vessel disease and 23% of the patients had 3-vessel disease. The left anterior descending coronary artery followed by the right coronary artery were the main arteries treated. In 3.8% of the cases BioMime implantation involved the left main coronary artery. The mean length of the implanted BioMime SES system was 43.8 mm along with an average diameter of 3.1 mm. The immediate procedural and device success rates were 99.7% and 100%, respectively. The procedural variables are shown on table 2 and table 3.

Clinical outcomes at follow-up

Clinical follow-up was completed in 96.12% of the patients included at the 12-month follow-up. A total of 3.88% out of 696 patients were lost to follow-up after 12 months.

The cumulative incidence of MACE at the 1-, 6-, and 12-month follow-up was 2.2%, 6.6%, and 8.1%, respectively. The individual

Table 2. Lesion and procedural characteristics

Patients	N = 696
Total no. of lesions treated with the BioMime Morph SES system	742
Total no. of lesions treated with other stents	157
BioMime target lesion location	
Left anterior descending coronary artery	
Proximal LAD	146 (21.40)
Mid LAD	216 (30.80)
Distal LAD	28 (4.50)
Diagonal	11 (1.60)
Right coronary artery	
Proximal RCA	174 (25.10)
Mid RCA	257 (36.80)
Distal RCA	97 (14.10)
Left circumflex artery	
Proximal LCX	56 (8.20)
Mid LCX	90 (12.90)
Distal LCX	28 (4.10)
Left main coronary artery	26 (3.80)
Diseased vessel	1.84 ± 0.78

LAD, left anterior descending coronary artery; LCX, left circumflex artery; RCA, right coronary artery; SES, sirolimus-eluting stent.
Data are expressed as no. (%).

Table 3. BioMime sirolimus-eluting stent system characteristics

Stent lenght (mm)	
37	100
40	189
44	128
48	325
Average stent length (mm)	43.80
Stent diameter (mm)	
2.25	42
2.5	153
2.75	84
3	263
3.5	185
4	13
4.5	2
Maximum pressure	
Predilatation	298 (86)
Postdilatation	376 (54)
Maximum pressure	14.6 ± 3.2
Average stent diamenter used (mm)	3.1

Data are expressed as no. (%).

Table 4. MACE at the follow-up

	% of patients	MACE
Follow-up		
1 month	682 (97.99)	13 (2.2)
6 to 9 months	675 (97.27)	44 (6.57)
12 months	668 (96.12)	53 (8.1)
MACE		
Bleeding at 1-M		20 (0.29)
Death at 1-M		41 (0.59)
MI at 1-M		41 (0.59)
Bleeding at 12-M		5 (0.75)
Death at 12-M		13 (2.09)
MI at 12-M		9 (1.34)
Total ST at 12-M		3 (0.50)

MACE, major adverse cardiovascular events; M, month; MI, myocardial infarction; ST, stent thrombosis.
Data are expressed as no. (%).

MACE at the follow-up are shown on table 4. The rates of cardiac death were 0.59% and 2.09% after 1 month and 1 year, respectively.

DISCUSSION

In the current study, the long nontapered BioMime SES system proved its safety and level of performance in consecutive real-world patients with long and diffused de novo coronary lesions. Despite the all-comers inclusion criteria defining a high-risk population, and the anatomical need for a long stent, procedural (99.7%) and device (100%) success were achieved and the clinical follow-up was quite favorable.

Studies have shown that the dimensions of coronary arteries taper naturally along with their length. They observed that 23% of the arteries had ≥ 1 mm taper and 19% arteries a 0.5 mm to 0.99 mm taper.[10] Stent sizing is critical for a successful PCI regarding the treatment of long tapered lesions. Stent oversizing (stents that are larger in diameter compared to the healthy artery) may induce pathological stress on the arterial wall, aneurysm formation, late ST, and even late perforations. Stent undersizing, on the other hand, (stents that are smaller in diameter compared to the healthy artery) may lead to ST due to stent malapposition.[11] Consistent with this, tapered stents were developed to potentially minimize clinical failure and maximize clinical benefits in these patients. This fact may be due to the specific design of the BioMime stents.

Ultrathin struts facilitate navegability, flexibility, and conformability of the vessel geometry while maintaining an excellent radial force. In addition, the open cell design throughout the entire body of the stent favors a less stiff device that follows more closely the

tapered contour of the artery resulting in less arterial wall stress. Compliant stents should be considered for tapered artery applications, perhaps even to avoid the need for tapered stents, at least up to 48 mm length, as shown in our data.[12-16]

The use of long coronary stents (≥ 30 mm), but not as long as the lesions treated in this registry, to treat long and diffuse native vessel disease, saphenous vein graft disease, and long coronary dissections is associated with a reasonable procedural success rate and acceptable early and intermediate-term clinical outcomes.[17] The treatment of very long CAD showed similar target lesion faliure at the 2-year follow-up for single DESs compared to overlapped DESs.[18] Our results suggest that both strategies are reasonable therapeutic options for patients with diffuse CAD. However, DES overlap occurs in > 10% of the patients treated with PCI in the routine clinical practice, and has been associated with impaired angiographic and long-term clinical outcomes including death or myocardial infarction.[19] In addition, the development of risk areas for malapposition with a single stent is significantly lower compared to overlapping stents. In cases where stent overlap cannot be avoided, deployment strategies should be optimized or new stent designs considered to reduce the risk of restenosis.[20] A single stent strategy is often more cost-effectiveness, and involves the administration of fewer contrast and fewer balloons. New designs of very long stents allow us not only to treat increasingly complex lesions, but also to simplify the procedure, and reduce the number of stents used with very favorable results, at least, similar to those obtained with overlapping stents.[21] Former studies have confirmed the safety and level of performance of the BioMime Morph, a very long tapered stent (60 mm) that can be considered the treatment of choice for very long and diffused tapered de novo coronary lesions in the routine clinical practice.[22] However, in long lesions treated with single stents of up to 48 mm in length, our results suggest that nontapered stents give very good clinical results.

Limitations

One limitation may be the follow-up period that may not be enough to determine the long-term safety and level of performance of long BioMime SES system in patients with long and diffused de novo coronary lesions.

CONCLUSIONS

This study confirmed the favorable procedural and device success, and the optimal safety outcomes reported at the follow up, of the long nontapered BioMime SES system, up to 48 mm length, in real-world patients with long and diffused de novo coronary lesions.

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AUTHORS' CONTRIBUTIONS

E. Domingo contributed to the study design, database completion, clinical follow-up, data analysis, and manuscript writing. J. Guindo contributed to the study design. R. Calviño Santos, J. Antoni Gomez, X. Carrillo, J. Sánchez, L. Andraka, A. Torres, J. Casanova-Sandoval, R. Ocaranza Sanchez, J. León Jiménez, J.F. Muñoz, R. Trillo Nouche, and M. Fuertes contributed to the database completion, and clinical follow-up. I. Otaegui contributed to the database completion, data analysis, and clinical follow-up. B. García del Balnco contributed to the study design, data analysis, and manuscript writing.

CONFLICTS OF INTEREST

None reported.

APPENDIX 1: STUDY INVESTIGATORS

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