

## Original Article

## Early and late clinical outcomes after saphenous vein graft treatment with MGuard™ stents vs. drug-eluting stents

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## ABSTRACT

**Background:** The MGuard™ stent, which has a microscopic polymer mesh coating, is intended to reduce the distal embolization of fragments during percutaneous coronary intervention (PCI) in saphenous vein grafts (SVG). This study evaluated the early and late clinical outcomes of patients undergoing PCI in SVG with MGuard™ stents vs. drug-eluting stents (DES).

**Methods:** Observational, retrospective study conducted at two tertiary centers, involving a cohort of patients with SVG lesions submitted to elective or emergency treatment with MGuard™ stents or DES.

**Results:** A total of 271 patients were included, of whom 220 were treated with DES. The MGuard™ group had a higher proportion of women (25.5% vs. 10.5%;  $p = 0.01$ ), with a mean age of  $65.0 \pm 13.9$  years vs.  $69.0 \pm 9.6$  years ( $p = 0.06$ ). The DES group more frequently used distal protection filter (5.8% vs. 10.0%;  $p = 0.001$ ). Angiographic success was attained in most cases (96.2% vs. 98.0%;  $p = 0.22$ ). The MGuard™ group had lower rates of early major adverse cardiovascular events (MACE) than the DES group (1.9% vs. 13.6%;  $p = 0.01$ ), due solely to the lower incidence of periprocedural infarction. However, the MACE rate at 1 year was higher in the MGuard™ group (14.3% vs. 4.4%;  $p = 0.01$ ) at the expense of a higher rate of target lesion revascularization (7.1% vs. 1.3%;  $p = 0.048$ ).

**Conclusions:** The use of the MGuard™ stent resulted in a reduction of events during hospitalization; however, in the long term the DES were superior in reducing major outcomes, mainly the need for target lesion revascularization.

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## Desfechos clínicos precoces e tardios após tratamento de enxertos de veia safena com stents MGuard™ vs. stents farmacológicos

## RESUMO

**Introdução:** O stent MGuard™, revestido por malha polimérica microscópica, tem a finalidade de reduzir a embolização distal de fragmentos durante a intervenção coronária percutânea (ICP) em enxertos de veia safena (EVS). Avaliamos os desfechos clínicos precoces e tardios de pacientes submetidos à ICP de EVS com stents MGuard™ vs. stents farmacológicos (SF).

**Métodos:** Estudo observacional, retrospectivo, realizado em dois centros terciários, envolvendo uma coorte de pacientes com lesões em EVS, tratados de forma eletiva ou de emergência com stents MGuard™ ou SF.

**Resultados:** Foram incluídos 271 pacientes, sendo 220 tratados com SF. O Grupo MGuard™ apresentou maior proporção de mulheres (25,5% vs. 10,5%;  $p = 0,01$ ), com média de idades de  $65,0 \pm 13,9$  anos vs.  $69,0 \pm 9,6$  anos ( $p = 0,06$ ). O Grupo SF utilizou com maior frequência filtro de proteção distal (5,8% vs. 10,0%;  $p = 0,001$ ). Sucesso angiográfico foi obtido na maioria dos casos (96,2% vs. 98,0%;  $p = 0,22$ ). O Grupo MGuard™ teve menores taxas de eventos cardiovasculares adversos maiores (ECAM) na fase hospitalar que o Grupo SF (1,9% vs. 13,6%;  $p = 0,01$ ) devido exclusivamente à menor incidência de infarto periprocedimento. Entretanto, a taxa de ECAM em 1 ano foi maior no grupo MGuard™ (14,3% vs. 4,4%;  $p = 0,01$ ) à custa de maior taxa de revascularização da lesão alvo (7,1% vs. 1,3%;  $p = 0,048$ ).

## Palavras-chave:

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**Conclusões:** A utilização de stent MGuard™ resultou em redução de eventos na fase hospitalar, porém, no longo prazo, os SF foram superiores em reduzir desfechos maiores, sobretudo a necessidade de revascularização da lesão alvo.

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## Introduction

The interventional treatment of saphenous vein grafts (SVG) remains a challenge, even in the modern practice of interventional cardiology, due to higher rates of acute complications and late clinical outcomes, compared to intervention in native coronary arteries.<sup>1</sup>

Percutaneous coronary intervention (PCI) in this scenario has unique technical challenges, due to the presence of friable lesion material prone to distal embolization during the procedure, resulting in greater risk of complications, such as the no-reflow phenomenon and periprocedural acute myocardial infarction (AMI).<sup>2,3</sup>

Although drug-eluting stents (DES) have promoted the reduction of restenosis rates in virtually all clinical and angiographic scenarios, furthering the results of PCI, there are still doubts about the effectiveness and late safety of these devices when used to treat lesions in SVG.<sup>4,5</sup>

In this scenario, the use of the MGuard™ stent (InspireMD, Tel-Aviv, Israel), coated with a microscopic ultrathin mesh and aiming to reduce distal embolization of fragments and thus, the rates of acute and late complications post-PCI, has been highlighted.<sup>6-8</sup>

This analysis aimed to evaluate the early and late clinical outcomes of PCI with MGuard™ stenting vs. DES in SVG.

## Methods

### *Study design and target population*

This was an observational retrospective study, carried out at two tertiary centers, involving a cohort of patients with lesions in SVG treated with MGuard™ stent or DES.

The population of this analysis included patients undergoing elective or emergency PCI of SVG, in the routine of the invasive cardiology services of the centers involved, between 2007 and 2012. Patients in the study were selected from the local database; data collection was performed by reviewing medical charts, reports, and angiograms, as well as by telephone contact.

### *Study devices*

The MGuard™ stent is a metallic 316L stainless steel laser-cut platform, with strut thickness of around 80 to 95  $\mu$ m, covered by a double net of microscopic polyethylene terephthalate fibers, which are adhered to the metallic struts. During stent implantation, the net stretches and slides over the expanding stent struts, creating pores  $\leq$  200 microns in diameter. MGuard™ stents are available in diameters ranging from 2.5 to 4.0 mm and extensions of 12 to 39 mm. Details about this stent have been previously published.<sup>3,6-8</sup>

Several drug-eluting stents were used in the DES group, both first and second generation stents, especially the sirolimus, zotarolimus, everolimus, and paclitaxel-eluting stents.

### *Procedure*

In general, interventions were carried out according to the current guidelines.<sup>9</sup> The decision to perform pre- and/or post-dilation was made at the interventionist's discretion, as well as the use of a distal protection filter and glycoprotein IIb/IIIa inhibitors.

The dual antiplatelet pre-treatment procedure consisted of an aspirin (100 to 300 mg) and clopidogrel (300 to 600 mg) loading dose. After the intervention, acetylsalicylic acid 100 mg daily was prescribed indefinitely and clopidogrel 75 mg daily was maintained for 12 months. During the PCI, antithrombin therapy consisted of unfractionated heparin at a dose of 100 IU/kg (or 70 IU/kg, in the case of glycoprotein IIb/IIIa inhibitor use), aiming to achieve activated clotting time > 250 seconds (or between 200 and 250 seconds in the case of glycoprotein IIb/IIIa inhibitor use).

### *Angiographic analysis*

Qualitative and quantitative angiographic analyses were performed offline by an experienced interventionist, following a pre-defined protocol. In general, pre- and post-procedure coronary angiographies were performed after intracoronary nitroglycerin administration (50 to 200  $\mu$ g) in at least two corresponding orthogonal projections, which were stored in the DICOM digital format.

Coronary flow was determined according to the criteria of the Thrombolysis in Myocardial Infarction (TIMI) study.

The quantitative coronary angiography (QCA) analysis was performed using a dedicated computer program with semi-automatic lumen edge detection (QAngio XA, Medis Medical Imaging System, Leiden, The Netherlands).

### *Clinical follow-up and definitions*

The aim of the current analysis was to evaluate the rate of major adverse cardiovascular events (MACE), defined as the occurrence of death, nonfatal myocardial infarction, and target lesion revascularization (TLR), both in the in-hospital and late follow-up (1 year).

Nonfatal AMI was defined as an elevation greater than three-fold in the reference laboratory values of creatine kinase MB isoenzyme (CK-MB) levels. Target lesion revascularization was defined as a new revascularization by PCI or surgical graft in a previously treated segment. Angiographic success was defined as the successful implantation of an MGuard™ stent in the target lesion.

### *Statistical analysis*

Continuous variables are shown as mean  $\pm$  standard deviation and compared using Student's *t*-test. Categorical variables are reported as absolute numbers and percentages and compared using the Chi-squared test or Fisher's exact test, as appropriate, with  $p < 0.05$  being considered statistically significant. Analyses were performed using the Statistical Package for Social Sciences (SPSS) program, version 16.0 (SPSS Inc., Chicago, USA).

## Results

A total of 271 patients were analyzed, with 220 in the DES Group. The mean age of patients was  $65.0 \pm 13.9$  years in the MGuard™ group and  $69.0 \pm 9.6$  years in the DES group ( $p = 0.06$ ). The MGuard™ group had a higher proportion of female patients (25.5% vs. 10.5%;  $p = 0.01$ ), previous myocardial infarction (58.8% vs. 35.9%;  $p = 0.003$ ) and renal impairment (25.9% vs. 12.5%;  $p = 0.001$ ), and a lower proportion of hypertensive patients (66.6% vs. 88.6%;  $p = 0.001$ ). The time since coronary artery bypass graft was shorter in the MGuard™ group ( $10.0 \pm 3.8$  years vs.  $12.0 \pm 5.9$  years;  $p < 0.001$ ). The clinical characteristics of patients are shown in Table 1.

Angiographic and procedural characteristics are shown in Table 2. Most of the treated lesions were located in the body or distal anastomosis of the graft, particularly in the MGuard™ group. Minimal luminal diameter, lesion length, and diameter stenosis were similar between groups. The DES group used distal protection filter more often when compared to the MGuard™ group (5.8% vs. 10.0%;  $p = 0.001$ ), but the use of glycoprotein IIb/IIIa inhibitors showed no difference between groups (2.0% vs. 2.7%;  $p > 0.99$ ). Angiographic success was attained in most cases in both groups (96.2% vs. 98%;  $p = 0.22$ ).

The MGuard™ group had better in-hospital clinical outcomes (MACE: 2.0% vs. 13.6%;  $p = 0.01$ ; *odds ratio* – OR: 7.89; 95% confidence interval – 95% CI: 1.05-59.3) due exclusively to a lower incidence of periprocedural myocardial infarction (2.0% vs. 13.6%;

$p = 0.014$ ), and showed no difference regarding mortality rates and TLR (Table 3).

However, contrary to the initial in-hospital outcomes, the MACE rate at 1 year of follow-up was statistically higher in the MGuard™ group (14.3% vs. 4.4%,  $p = 0.01$ ; OR: 0.24; 95 CI: 0.07-0.76). At the analysis of these late clinical outcomes, there was no difference in the incidence of death (2.4% vs. 2.6%;  $p = 0.94$ ) and AMI (4.8% vs. 0.6%;  $p = 0.09$ ), but there was a higher TLR rate in the MGuard™ group (7.1% vs. 1.3%;  $p = 0.048$ ).

## Discussion

The main finding of the present study is the fact that the MGuard™ stent has demonstrated its effectiveness in the immediate phase of PCI, with a reduction in periprocedural AMI. On the other hand, as it is not an antiproliferative drug-eluting device, its efficacy in the medium term was reduced when compared to DES, which are now considered the gold standard for restenosis prevention after PCI.

The performance of the MGuard™ device has been tested in several studies. Grube et al. published a prospective study of 41 patients evaluating the MGuard™ stent, and PCI in saphenous vein grafts represented 56% of the procedures. In that study, no patient received glycoprotein IIb/IIIa inhibitors or distal embolic protection device. The angiographic and procedure success rates were 100% and 95%,

**Table 1**  
Basal clinical characteristics.

Characteristics	MGuard™ (n = 51)	DES (n = 220)	p-value
Age, years	65.0 ± 13.9	69.0 ± 9.6	0.06
Female gender, n (%)	13 (25.5)	23 (10.5)	0.01
Diabetes mellitus, n (%)	17 (33.3)	79 (35.9)	0.87
Dyslipidemia, n (%)	39 (76.5)	160 (72.7)	0.72
Arterial hypertension, n (%)	34 (66.6)	195 (88.6)	0.001
Smoking, n (%)	14 (27.4)	50 (22.7)	0.46
Renal impairment, n (%)	27 (25.9)	28 (12.5)	0.001
Previous AMI, n (%)	30 (58.8)	79 (35.9)	0.004
Previous PCI, n (%)	10 (19.6)	65 (29.6)	0.15
Clinical presentation, n (%)			0.06
Stable angina	28 (54.9)	106 (48.2)	
ACS without ST elevation	19 (37.3)	109 (49.4)	
ACS with ST elevation	4 (7.8)	5 (2.3)	
Time of CABG, years	10.0 ± 3.8	12.0 ± 5.9	< 0.001

DES: drug-eluting stent; AMI: acute myocardial infarction; PCI: percutaneous coronary intervention; ACS: acute coronary syndrome; CABG: coronary artery bypass grafting.

**Table 2**  
Angiographic and procedural characteristics.

Characteristics	MGuard™ (n = 51 patients, 53 lesions)	DES (n = 220 patients, 249 lesions)	p-value
Lesion site, n (%)			0.04
Ostium	4 (7.5)	43 (17.3)	
Body or distal anastomosis	49 (92.5)	206 (82.7)	
Reference diameter, mm	3.16 ± 0.70	3.3 ± 0.72	0.57
Length, mm	16.9 ± 13.9	18.3 ± 9.2	0.32
MLD, mm	1.02 ± 0.56	0.97 ± 0.49	0.41
Diameter stenosis pre, %	69.4 ± 17.7	68.2 ± 9.7	0.19
Pre-dilation, n (%)	13 (25.4)	68 (27.3)	0.44
Post-dilation, n (%)	23 (45.0)	107 (43.0)	0.64
Stent length, mm	22.3 ± 8.0	20.6 ± 6.8	0.86
Stent/lesion ratio	1.1 ± 0.3	1.1 ± 0.4	0.64
PMax of deployment, atm	15.2 ± 3.6	14.6 ± 3.2	0.09
Diameter stenosis post, %	3.0 ± 0.5	3.8 ± 3.4	0.006
GPI IIb/IIIa, n (%)	1 (2.0)	6 (2.4)	> 0.99
Distal protection filter, n (%)	3 (5.8)	22 (10.0)	0.001
Final TIMI III flow, %	50 (94.3)	227 (91.2)	0.45
Angiographic success, %	51 (96.2)	244 (98.0)	0.22

DES: drug-eluting stents; MLD: minimal luminal diameter; PMax: maximum pressure; GPI IIb/IIIa: glycoprotein IIb/IIIa inhibitors; TIMI: Thrombolysis in Myocardial Infarction.

**Table 3**  
In-hospital and late clinical outcomes.

Outcomes	MGuard™ (n = 51)	DES (n = 220)	p-value
In-hospital phase			
MACE, n (%)	1 (1.9)	30 (13.6)	0.01
Death, n (%)	0	0	NA
AMI, n (%)	1 (1.9)	30 (13.6)	0.01
TLR, n (%)	0	0	NA
Outcomes up to 12 months (non-cumulative)			
MACE, n (%)	7 (14.3)	9 (4.4)	0.01
Death, n (%)	1 (2.4)	5 (2.6)	0.94
AMI, n (%)	2 (4.8)	1 (0.6)	0.09
TLR, n (%)	4 (7.1)	3 (1.3)	0.048

DES: drug-eluting stent; MACE: major adverse cardiovascular events; AMI: acute myocardial infarction; TLR: target-lesion revascularization; NA: not applicable.

respectively. After 6 months of follow-up, 19.5% of patients were submitted to target vessel revascularization. At the later follow-up of these patients (12 months to 27 months), only one additional target vessel revascularization was observed.<sup>10</sup>

Costa Jr. et al., in an angiographic study protocol at 6 months after MGuard™ stent implantation in 30 patients, found a mean age of patients of 63 years, with 38% of diabetics. None of the patients used distal embolic protection devices. The late luminal loss was  $1.0 \pm 0.4$  mm and the percentage of in-stent volume obstruction was  $28.5 \pm 15.6\%$ .<sup>11</sup>

Guimarães et al. tested the MGuard™ device in a retrospective analysis of 65 patients, of whom 68% of the interventions were in SVG. The angiographic success rate was 91.8% and, in the late follow-up ( $2.6 \pm 1.4$  years), the TLR rate was 12.3%.<sup>7</sup>

The findings of these studies are similar to the present one, in which angiographic success was attained in 98% of procedures and the rate of repeat revascularization 12 months after the MGuard™ device implant was 7.1%.

Regarding the performance of the DES when compared to conventional stents, the RRISC (Reduction of Restenosis in Saphenous Vein Grafts with Cypher Sirolimus-Eluting Stent) randomized trial selected 75 patients (96 lesions in saphenous vein grafts) to receive the Cypher™ DES or bare-metal stents. In this analysis, the use of DES was associated with 37% reduction in the risk of binary restenosis (11.3% vs. 30.6%;  $p < 0.024$ ), with similar rates of death and AMI in the short-term follow-up.<sup>12</sup>

Regarding the present analysis, in-hospital AMI rates were favorable for MGuard™ when compared to the DES group (2.0% vs. 13.6%;  $p = 0.01$ ), a finding that may be explained by the fact that the device is coated with an ultrathin microscopic net, which may have been able to reduce distal embolization and the resulting complications. As for the rate of AMI in the long-term follow-up (4.8% vs. 0.6%;  $p = 0.09$ ), the lack of statistical significance may have resulted from the number of patients included in the study.

Esteves et al. published a comparative, nonrandomized study of PCI in saphenous vein grafts with 38 patients (16 in the MGuard™ group and 22 in the group with conventional stenting with distal embolic protection filter), demonstrating similar MACE rates between the groups.<sup>6</sup>

Assali et al. published the results of the comparison between 68 patients treated with DES and 43 patients who received bare-metal stents for lesions in SVG. At the 2-year follow-up, the use of bare-metal stents was associated with a marked reduction in event-free survival (58.1% in the bare-metal stent group vs. 79.4% in the DES group;  $p = 0.02$ ), essentially due to a decrease in the TLR rate (14.7% vs. 32.6%;  $p = 0.03$ ).<sup>13</sup>

In another randomized study, Brilakis et al. compared Taxus™ DES with bare-metal stents in PCI of SVG (39 patients in the bare-metal stent group and 41 patients in the DES group). In the fol-

low-up (mean of 1.5 years), the use of DES was associated with significant reduction in MACE rate (28% vs. 5%; relative risk – RR = 0.38; 95% CI: 0.15 to 0.74;  $p < 0.003$ ), as well as a reduction in TLR (46% vs. 22%; RR = 0.65; 95% CI: 0.42–0.96;  $p < 0.03$ ), with no difference in infarction and mortality rates.<sup>14</sup>

Two recent meta-analyses including more than 5,000 patients found better outcomes with use of DES compared to the use of bare-metal stents, mainly at the expense of lower rates of TLR.<sup>15,16</sup>

The present study is in line with those described above, with higher MACE rates at 12 months in the MGuard™ group (non-drug-eluting device) compared to the DES group, at the expense mainly of a higher incidence of TLR (7.1% vs. 1.3%;  $p = 0.048$ ). Considering the higher event rates in the treatment of venous grafts compared to intervention in native coronary arteries, and the mean age of patients ( $\geq 65$  years in both groups), it is observed that the rates of MACE and, mainly, of TLR in the present study can be considered acceptable.

#### Study limitations

This is a retrospective, nonrandomized study, whose main limitations are the small number of patients and a heterogeneous population. A multicenter, randomized trial with a longer follow-up is necessary to evaluate the efficacy of the MGuard™ device in the long term compared to DES.

#### Conclusions

The use of the dedicated MGuard™ stent resulted in a reduction of clinical events during hospitalization. However, in the long term, drug-eluting stents were superior in reducing major adverse outcomes, especially regarding the need for target lesion revascularization.

The results suggest that the next generation of MGuard™ stents, with the use of anti-proliferative drugs, may combine the best of both devices.

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None declared.

#### Conflicts of interest

The authors declare no conflicts of interest.

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