

Miniaturized Self-Expanding Drug-Eluting Stent in Small Coronary Arteries: Late Effectiveness

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Abstract

Background: Small vessels represent a risk factor for restenosis in percutaneous coronary angioplasty (PCA). The Sparrow® self-expanding drug-eluting stent, which has a lower profile than the current systems, has never been tested in this scenario.

Objectives: To evaluate the late effectiveness of the Sparrow® drug-eluting stent, regarding in-stent late lumen loss (LLL).

Methods: Patients with ischemia, symptomatic or documented, were submitted to PCA in vessels with reference diameter < 2.75 mm, divided into two groups regarding Sparrow® stent type: group 1: Sparrow® drug-eluting stent (DES), group 2: Sparrow® bare metal stent (BMS). Clinical follow-up duration was 12 months. Evaluation using quantitative coronary angiography (QCA) was performed immediately and at 8 months. A decrease of over 65% of in-stent LLL with DES was estimated to calculate sample size. IBM® SPSS software, release 19 (Chicago, Illinois, USA) was used for the statistical analysis.

Results: A total of 24 patients were randomized, 12 in each group. The DES and BMS groups were similar in age (63.25 ± 10.01 vs. 64.58 ± 11.54 , $p = 0.765$), male gender (58.3% vs. 33.3%, $p = 0.412$), risk factors and all angiographs aspects. Immediate results were satisfactory in both groups. At 8 months in-stent late lumen loss was significantly lower in DES than in BMS group (DES vs. BMS 0.25 ± 0.16 vs. 0.97 ± 0.76 , $p = 0.008$).

Conclusion: In small-vessel PCA, the Sparrow® DES determined significant reduction in in-stent LLL, when compared to Sparrow® BMS. (Arq Bras Cardiol. 2013;101(5):379-387)

Keywords: Angioplasty, Balloon, Coronary; Drug Eluting Stents; Randomized Controlled Trial; Comparative Study.

Introduction

During percutaneous coronary angioplasty (PCA), small-caliber vessels represent higher complexity with increased rates of target-lesion revascularization (TLR) and more restenosis, when compared with larger-caliber vessels¹⁻⁵, being related to neointimal hyperplasia (NIH), which determines late luminal loss (LLL) after PCA. NIH has the same intensity in vessels of different sizes, with greater impact on small-caliber ones, which respond with greater lumen loss than larger vessels⁶.

With bare-metal stents (BMS), LLL ranges from 0.8 to 1.0 mm. With drug-eluting stents (DES), LLL is always below 0.5 mm being smaller (below 0.3 mm) in those DES with sirolimus, everolimus or biolimus. This greater inhibitory power in NIH has resulted in a significant reduction in

restenosis rates in all groups of patients (P), even in patients with small-caliber vessels. Still, restenosis rates remain higher in smaller-caliber vessels when compared with larger ones⁷⁻⁹.

More distal lesions, tortuosity and calcification, common in small-caliber vessels, hinder stent navigation in conventional dilation systems with balloon-expanding stent (BES).

Stents with thin struts induce lower NIH than the ones with thick struts, even among DES^{10,11}.

In this context, the Sparrow® self-expanding nitinol stent (Cardiomind Inc., Sunnyvale, California) appeared, dedicated to small-caliber vessels. The BMS version of the Sparrow® self-expanding stent (SES) was evaluated by Chamié et al¹², who demonstrated its efficacy and safety. It is mounted on a guide wire system that eliminates the balloon, resulting in 70% lower profile than the conventional balloon-stent system.

This study is the pioneer to evaluate the impact of LLL when using self-expanding Sparrow® DES compared to the BMS version in small-caliber vessels assessed by QCA at eight months, which is the primary objective. Secondary objectives: (1) comparison between the groups regarding vessel, lumen and stent volumes and the percentage of the stent volume obstruction by means of intracoronary ultrasound (IVUS) immediately after implantation and at eight months; (2) description of up to 12 months in

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exchange major adverse cardiac events (MACE - death, myocardial infarction, target vessel revascularization (TVR) and stent thrombosis.

Methods

Study design

The present was a prospective randomized, non-blinded study (the surgeon was unaware of the type of stent used), carried out at the Instituto Dante Pazzanese de Cardiologia, São Paulo (SP), CEP and Conep protocols #3,577 and 14,582 (approved), which evaluated the late effectiveness of the Sparrow® DES when compared to the BMS version by measuring and comparing LLL at eight months through the QCA in patients with lesions in small-caliber vessels (reference diameter ≤ 2.75 mm).

The clinical reassessment was scheduled for 30 days, six months and 12 months after the procedure. QCA assessment was scheduled immediately before and immediately after the PCA and after eight months. Intravascular ultrasound (IVUS) was also scheduled immediately after stent implantation and after eight months.

Patient selection

Inclusion criteria:

- Age ≥ 18 years.
- Clinical evidence of ischemia (angina or ischemic equivalent) or evidence of ischemia by noninvasive evaluation.
- Target lesion in natural coronary artery with stenosis $\geq 50\%$ and $< 100\%$, analyzed by QCA.
- Target vessel with reference diameter ≥ 2.0 and ≤ 2.75 mm.
- Target lesion with extension ≤ 20 mm.

Exclusion criteria:

- Female gender during pregnancy.
- Left ventricular ejection fraction $< 30\%$ during the prior six months.
- Contraindication to dual antiplatelet use.
- Renal dysfunction (serum creatinine > 2.0 mg/dL).
- Stroke or transient ischemic attack in the previous six months.
- Life expectancy < 12 months.
- Target-lesion located in the left main coronary artery or ostia of the right coronary artery, anterior descending or circumflex arteries. Bifurcation lesion, with thrombus, or in single remaining vessel.
- Target-lesion involving bifurcation.

Analyzed device and implantation technique

The analyzed device was the sirolimus-eluting Sparrow® DES (Cardiomind® Inc., Sunnyvale, California, USA), as compared with the BMS version of the same stent (BMS

Sparrow®). This is a sirolimus-eluting system (6 mg, 60% of the dose of the Cypher® stent) comprising a nitinol SES with a closed-cell design and strut thickness of $67 \mu\text{m}$, mounted on a platform that runs on a guide wire (0.014"), incorporated to a matrix of medical grade PLA/PGLA biodegradable copolymers of the SynBiosys™ biodegradable polymer system. This copolymer matrix adds only 8 microns to strut thickness. The result is a very low profile system, as shown in Figure 1, and up to 70% thinner than any balloon-stent system (Table 1).

A flexible guide wire, with 2-3 cm in length, runs along the stent to allow advancement of the system in the vessel. There are two radiopaque markers that identify the beginning and end of the stent in the guide wire system and allow its precise positioning in the lesion. The compound stent contains nitinol, which has a thermoelastic expansion property (memory metal). Mechanical locks on the stent borders keep it from expanding and attached to the guide wire. A power source (non-sterile external device) is connected to the proximal end of a dilation system sterile adaptable cable, which controls the stent release through an electrolysis mechanism with a 0.5 mA current. Initially, the distal lock is released and then, the proximal one (Figure 2).

The stent system worked with a 0.014" guide wire and the balloon was advanced over this system until the lesion, where predilation was performed. Then, the balloon was retreated to a position, proximal to the proximal stent marker and the stent deployment process was initiated through electrolysis, as previously described. Post-procedural dilation was performed after stent release. To prevent trauma to the stent borders, the balloon was always shorter than the stent. The same guide wire could also be used to perform IVUS.

Study procedures comprised the following sequence: electrocardiogram (ECG) before the procedure and at discharge; cardiac enzymes (CK-MB) and troponin I or T, before and after the procedure, activated clotting time (ACT) after arterial access, at the end of the procedure and before sheath withdrawal; dual antiplatelet therapy with clopidogrel 300 mg and aspirin 100 mg at least 12 hours before the procedure, maintained for at least eight months; use of a 0.6 F sheath and compatible catheter-guides; intravenous heparin (100 U/kg) after sheath placement and intracoronary nitroglycerin (100-200 mg); initial angiography of the vessel in at least two proximal-orthogonal views to allow adequate visualization of the vessel and lesion; evaluation by predilation QCA; ACT with stenting as previously described; sheath withdrawal 3-4 h after the procedure with ACT < 200 s; discharge after 24 h in cases without complications, follow-up visits at 30 days, eight and 12 months; control angiography at eight months; IVUS immediately after stent implantation and after eight months.

The analysis of the QCA and IVUS were performed offline (QCA using the CMS-GFT® software, release 5.1, Medis, Leiden, the Netherlands, and IVUS using the Echoplague® software, Indec Systems, Inc, Mountain View, California, USA).

In QCA, the following parameters were evaluated: lesion length, reference vessel diameter (RVD), minimal lumen diameter (MLD), percentage of vessel stenosis (PS) calculated

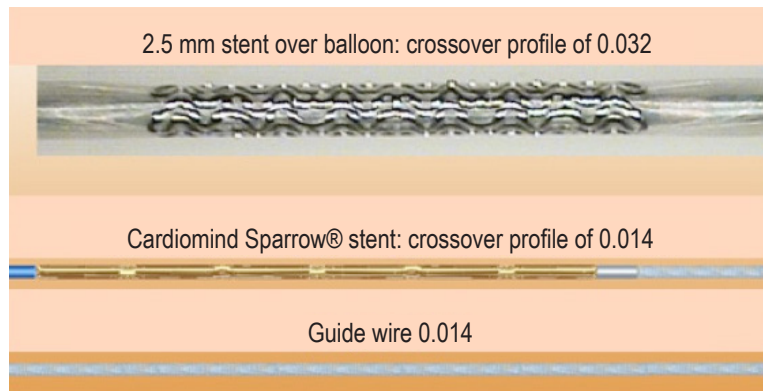


Figure 1 - Evidence of low-profile of the Sparrow® stent deployment system (center) compared to a balloon-expanding stent system (top) and an angioplasty guidewire of 0.014" (bottom).

Table 1 - Sparrow® stent specifications

Stent design and material	Closed-cell design, diamond-shaped , in nickel-titanium (nitinol)
Stent shortening	9-16%
Radiopaque coating	Platinum coating with 3.5 µm
Extension of deployment system in the balloon working segment	170 cm
Total extension of the deployment system	190 cm (extensible to 300 cm)
Deployment system profile	0.014"
Guide tip extension	2-3 cm

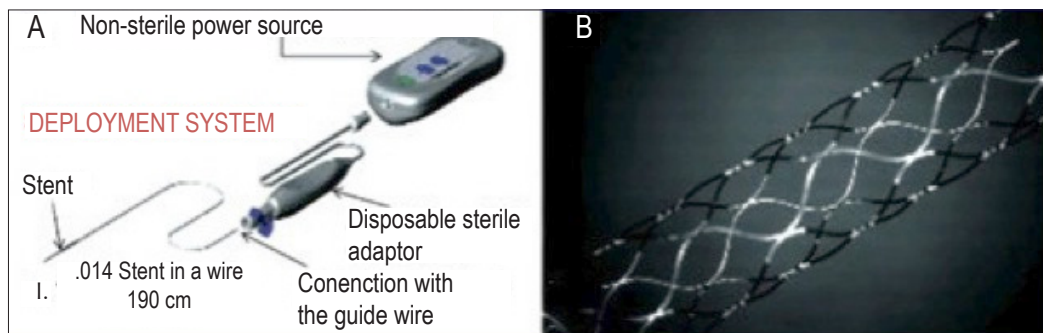


Figure 2 - A: Schematic representation showing all the components of the Sparrow® System. B: Sparrow® Stent in its natural form (expanded).

by the formula $PS = RD - MLD \div RD \times 100$, acute luminal gain (ALG) calculated by $ALG = \text{post-MLD} - \text{pre-DML}$; LLL (difference between the late MLD and MLD immediately after the procedure). These analyses were performed in-stent and in the stent segments 0.5 mm proximal and distal to the stent (analysis of the borders).

The IVUS images corresponded to the recordings of at least

10 mm distal to the stent up to at least 10 mm proximal to the stent, in two acquisitions, the first immediately after the implantation and the second after 8 months. For this purpose an automated stent traction system at a speed of 0.5 mm / sec with a 40 MHz transducer, 2.6-French sheath (Galaxy 2 oullab, Boston Scientific Corporation, Natick, Massachusetts, USA) was used. Were programmed Calculations of areas

and volumes of the vessel, lumen, stent and plaque were programmed, as well as the volume of NIH and the stent volume obstruction percentage, according to the protocol already described in literature. Strut apposition to the vessel wall was also evaluated.

Study definitions

Angiographic success: stent implantation in the target lesion with residual stenosis < 30% and TIMI flow 3. **Procedural success:** angiographic success without major complications (death, myocardial infarction or in-hospital emergency revascularization surgery). **Stent thrombosis:** Academic Research Consortium (ARC) criteria¹³. Major adverse cardiac events (MACE): death (cardiac), nonfatal myocardial infarction (elevation of cardiac enzymes CK-MB or cardiac troponins I and T, up to three times above normal levels until discharge and twice the normal after hospital discharge or appearance of new Q waves in at least two contiguous ECG leads) and TVR. **Binary restenosis:** recurrent target lesion \geq 50% at late control.

Statistical Analysis

The IBM® SPSS Statistics software, release 19 (Chicago, Illinois, USA.) was used for the statistical analyses. Student's *t* test was used to compare means between the groups. For all compared parameters, *p* values < 0.05 were considered significant. Categorical variables were expressed as absolute value or proportion. Continuous variables were expressed as mean and standard deviation. A level of significance of 5% and power of 80% were considered, estimating a LLL decrease with DES of 65% and calculating the minimum sample size of 11 patients for each group.

Results

From January 2009 to April 2010, 24 patients were included, 12 in each group, and prospectively randomized. The clinical characteristics of the patients are shown in Table 2 and disclosed homogeneous groups.

The distribution per artery and per segment was similar between the groups and the lesion was located in the middle and distal segments of the vessel in more than 70% of cases in both groups (Table 3).

There were no significant differences between the DES and BMS groups, in this sequence, regarding the volume of contrast (133.33 ± 23.87 mL versus 120 ± 34.38 mL, *p* = 0.282), procedure time (71 ± 9.2 min versus 62 ± 14.82 min, *p* = 0.350) and maximum pressure postdilatation (15.75 ± 4.67 versus 15.42 ± 3.12 , *p* = 0.839).

PCI was successfully performed in all patients. There were no MACE or complications until discharge.

QCA results of the angiographies performed immediately before and after PCA show that randomization produced similar groups and highlights the homogeneity and immediate outcome success between the groups. Lesion extension was slightly higher in the group with DES, but not significantly (DES: 15.29 ± 5.55 mm versus BMS: 12.91 ± 3.23 mm, *p* = 0.233); stent length (SF 19.92 mm \pm 3.60 versus BMS: 18.00 ± 2.34 mm, *p* = 0.139) and implanted stent diameter (DES 2.58 ± 0.25 mm versus 2.66 ± 0.19 mm, *p* = 0.368) were not different between groups.

Reference vessel diameter immediately before the procedure was similar between the groups (DES = 2.46 ± 0.24 mm versus BMS = 2.42 ± 0.21 mm, *p* = 0.680), demonstrating a small-caliber vessel scenario.

Table 2 - Main clinical characteristics of the 24 patients treated with Sparrow® DES and BMS

Variables	DES (n = 12)	BMS (n = 12)	P
Male gender, n (%)	7 (58.3%)	4 (33.3%)	0.413
Age in years, mean (SD)	63.25 (10.01)	64.58 (11.54)	0.765
Risk factors for CAD, n (%)			
Hypertension	12 (100.0)	10 (83.33)	0.460
Diabetes mellitus	5 (41.66)	3 (25.0)	0.665
Hypercholesterolemia	10 (83.33)	9 (75.0)	1.000
Smoking	8 (66.66)	3 (25.0)	0.101
Coronary antecedents			
CABG surgery	0	0	-
PCI	4 (33.33)	3 (25.0)	1.000
Myocardial infarction	4 (33.33)	2 (16.66)	0.637
Clinical presentation			
Asymptomatic	5 (41.66)	1 (8.33)	0.157
Stable angina	7 (58.33)	11 (91.66)	0.157
Unstable angina	0	0	-

DES: drug-eluting stent; BMS: bare-metal stent; SD: standard deviation; CAD: coronary artery disease; CABG: coronary artery bypass graft; PCI: percutaneous coronary intervention.

Table 3 - Main qualitative angiographic characteristics of the 24 patients treated with DES and BMS Sparrow® stents.

Variables	DES (n = 12)	BMS (n = 12)	P
Treated vessel			
ADA	3 (25.0%)	5 (41.66%)	0.665
Cx	2 (16.66%)	2 (16.66%)	1.000
RCA	2 (16.66%)	1 (8.33%)	1.000
Diagonal branch	3 (25.0%)	4 (33.3%)	1.000
Marginal branch	2 (16.66%)	0	0.460
Vessel segment, n (%)			
Proximal	3 (25%)	2 (16.66%)	1.000
Medial	6 (50%)	6 (50%)	1.000
Distal	3 (25%)	4 (33.3%)	1.000

ADA: anterior descending artery; Cx: circumflex artery; RCA: right coronary artery; DES: drug-eluting stent; BMS: bare-metal stent.

The severity of the lesions included in the study is well demonstrated in the pre-procedural results of MLD (DES = 0.75 ± 0.20 mm versus BMS = 0.73 ± 0.17 mm, $p = 0.750$) and PS (SF = $69.36 \pm 6.37 = 69.67\%$ versus BMS + 5.46% , $p = 0.905$).

The immediate results after the procedure measured by MLD (DES = 2.46 ± 0.22 mm versus BMS = 2.39 ± 0.13 mm, $p = 0.350$) and PS (DES = $4.59 \pm 3.52\%$ versus BMS = $4.94 \pm 4.41\%$, $p = 0.869$) confirm successful angiographic procedure in both groups, with similar benefits, which is reflected in satisfactory absolute gain in both groups (DES = 1.71 ± 0.28 mm versus BMS = 1.66 ± 0.12 mm, $p = 0.614$), a result of the difference between the pre-procedural and post-procedural MLD.

At eight months, the parameters analyzed by QCA, as demonstrated in Table 4, showed significant differences between the groups regarding the ability to maintain the results recorded in the evaluation immediately after the procedure, i.e., MLD and PS. These results are reflected in the comparison of LLL between groups, the primary objective of this study, which was significantly lower in the group with DES (DES vs BMS = 0.25 ± 0.16 vs $= 0.97 \pm 0.76$ mm, $p = 0.008$).

Figure 3 shows study patients' individual response regarding PS, with the DES group showing more homogeneous and maintenance of the response pattern.

The analysis of the 5 mm proximal and distal to the stent immediately after stent implantation and at eight months, as shown in Table 5, disclosed no significant differences between the groups regarding MLD and PS, resulting in LLL with no significant difference. Although the analysis of the proximal and distal segments to the stent did not show significant differences between the groups, there was a trend of higher LLL in the BMS group compared with DES group, most markedly in the proximal segment.

Technical difficulties in the progression of IVUS catheter to an adequate point beyond the stent (including 5 mm distal to it, to include the entire segment of interest) restricted data collection provided by this type of evaluation

predicted in the study, precluding the provision of full information, differently from what occurred with the QCA.

Nevertheless, it was observed that the self-expanding stent showed an increase in volume over time from 14.8% in the DES group and 2.5% in the BMS group. There was no strut malapposition in this group of patients.

Up to 12 months of evolution, there was no patient loss to follow-up. All patients used dual antiplatelet therapy throughout the study, as required by the protocol. There were no reports of death, nonfatal myocardial infarction or need for myocardial revascularization.

Although four patients had binary restenosis in the BMS group, the clinical translation of this finding resulted in new PTCA in three patients, only. Specifically, the patient that had occlusive restenosis, was maintained in clinical treatment due to the good evolution.

Clinical event compatible with in-stent thrombosis was not observed in either group during follow-up.

Discussion

New research in this area is of relevance because the small-caliber vessels represent 40-50% of cases of PCA, and this subgroup, although it has been strongly benefited from the advent of DES, still carries a higher risk of restenosis and TVR, when compared with larger-caliber vessel results^{7,14,15}. This study represents the first clinical experience with drug-eluting SES in small-caliber vessels.

The primary objective of reducing in-stent LLL in this study was achieved with Sparrow® DES and the absolute value found of 0.25 ± 0.16 mm shows that the performance of this platform was equivalent to the best results with drug-eluting stents.

The patients in our study are also part of a larger cohort, the multicenter CARE II study¹⁶, which included a larger number of patients and of which initial results, presented at the 2010 Transcatheter Cardiovascular Therapeutics Congress showed data similar to those found here.

Table 4 - In-stent quantitative coronary angiography variables at eight months

Variables	DES (n = 12)	BMS (n = 12)	p	CI (95%)
IRD (mm), 8 months				
mean (SD)	2,44 (0,19)	2,24 (0,42)	0,153	(-0,08; 0,47)
MLD (mm), 8 months				
mean (SD)	2,19 (0,19)	1,42 (0,81)	0,008	(0,14; 0,19)
PS (%), 8 months				
mean (SD)	10,70 (3,95)	39,89(30,89)	0,007	(-0,24; -1,29)
LLL (mm)				
mean (SD)	0,25 (0,16)	0,97 (0,76)	0,008	(-1,19; -0,22)

IRD: interpolated reference diameter; MLD: minimum luminal diameter; PS: percentage of stenosis; LLL: late luminal loss; SD: standard deviation; DES: drug-eluting stent; BMS: bare-metal stent

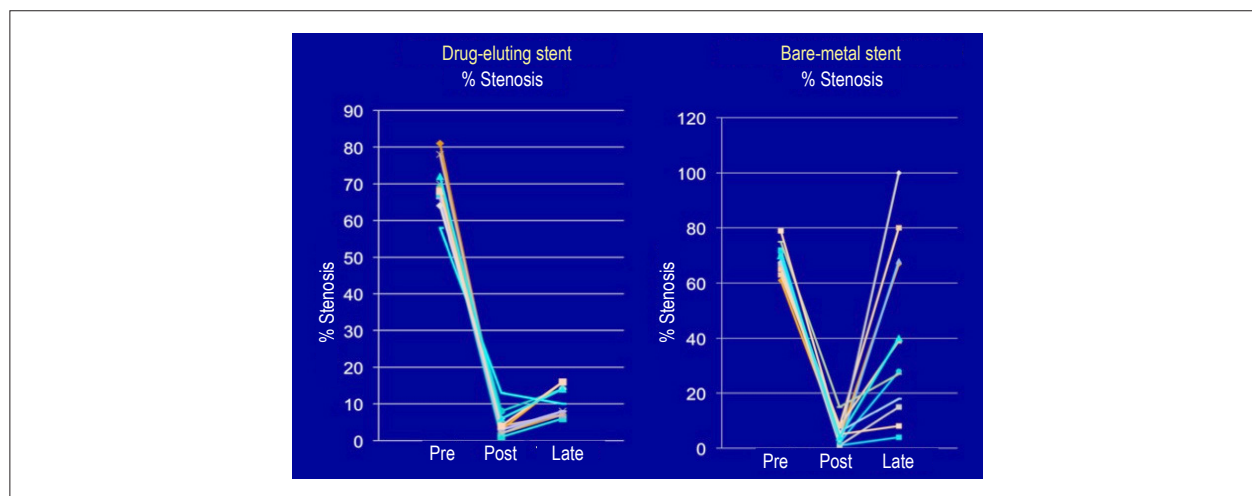


Figure 3 - Demonstration of individual variation in the percentage of stenosis before and after the procedure and at eight months of evolution in the two treatment groups (Sparrow® DES versus Sparrow® BMS), showing greater dispersion and loss of result in the BMS group at the late follow-up.

The CARE II study¹⁶, with inclusion criteria similar to those in our study, including the patients in this cohort, involved 137 patients in three groups, comparing Sparrow® DES (group 1) with Sparrow® BMS (group 2) and the Driver®/Microdriver® bare-metal balloon expandable stent (group 3). The primary objective was the assessment of LLL at eight months by IVUS. At eight months a significantly lower LLL was observed in the DES group, similar to what was found by QCA in our study (0.29 + 0.45 mm). In the group with Sparrow® DES, the binary restenosis was 6.7% and the incidence of MACE at eight months was 6.25%, confirming the results of our study in a larger population.

There was no binary restenosis at the borders in the group of patients with DES, differently from the previously described Sirius study report. This may be related to Sparrow® stent system implantation technique, which minimizes the chances of barotrauma to the stent borders. In the group with DES, two cases (16%) of binary restenosis

were recorded, both involving the proximal border, but they were not isolated cases, reflecting a proliferative restenosis process and, therefore, associated with undesired proliferation of in-stent NIH.

Safety problems with DES, shown by late and very late in-stent thrombosis (low, but greater than that observed with the BMS), were probably related to chronic inflammatory stimulation determined by the durable polymers, which hinder the re-endothelialization process¹⁷⁻²⁰. In the present study, in-stent thrombosis did not occur during a 12-month follow-up. The use of bioabsorbable polymers in the Sparrow® stent may have contributed to this fact.

Even in the age of DES, there have been studies showing that the smaller the strut thickness, the lower the LLL¹¹. In this context, the Sparrow® stent has an additional advantage, as it has thinner struts than all other available stent models.

These favorable characteristics of the deployment system of the self-expanding Sparrow® stent – thin struts,

Table 5 - Quantitative coronary angiography in the 5 mm proximal and distal to the stent immediately after implantation and at eight months

Variables	DES (n = 12)	BMS (n = 12)	p	CI (95%)
Immediate MLD (mm)				
Proximal, mean (SD)	2.49 (0.18)	2.43 (0.20)	0.491	(-0.11; 0.23)
Distal, mean (SD)	2.51 (0.18)	2.45 (0.20)	0.474	(-0.11; 0.23)
PS (%), immediate				
Proximal, mean (SD)	3.62 (2.77)	3.58 (2.07)	0.971	(-2.11; 2.19)
Distal, mean (SD)	2.91 (2.92)	2.88 (1.99)	0.980	(-2.16; 2.21)
MLD (mm), 8 months				
Proximal, mean (SD)	2.21 (0.26)	1.74 (0.79)	0.075	(-0.05; 0.98)
Distal, mean (SD)	2.31 (0.28)	1.90 (0.74)	0.104	(-0.094; 0.89)
PS (%), 8 months				
Proximal, mean (SD)	9.41 (7.40)	23.28 (30.72)	0.144	(-33.19; 5.46)
Distal, mean (SD)	4.19 (1.50)	16.32 (27.12)	0.154	(-29.37; 5.12)
LLL (mm)				
Proximal, mean (SD)	0.28 (0.19)	0.69 (0.67)	0.064	(-0.84; 0.028)
Distal, mean (SD)	0.17 (0.17)	0.54 (0.65)	0.080	(-0.80; 0.52)

MLD: minimum luminal diameter; PS: percentage of stenosis; LLL: late luminal loss; SD: standard deviation; DES: drug-eluting stent; BMS: bare-metal stent.

bioabsorbable polymer, antiproliferative drug from the *limo* family, additional expansion property over time and deployment technique that minimizes trauma to the borders – may be at the root of its good performance as demonstrated in our study and ratified by the results of the CARE II study¹⁶.

The evaluation by IVUS in this study, as in the CARE II¹⁶ showed a trend to stent expansion over time, more markedly in the group with drug-eluting stents, a finding that motivates further research.

The limitations of this study included the small numbers of patients, which was related to logistical issues regarding the endoprosthesis availability, the randomization, which was not blinded, and the impossibility of IVUS evaluation, an important tool for the assessment of the mechanistic performance of stents.

The subsequent analysis by QCA and IVUS were performed without knowledge of the type of stent used, which lessens the non-blinded randomization problem.

Broad inclusion criteria, without restrictions regarding tortuosity and calcification, in addition to vessel diameter, may be related to the low rate of IVUS performance in this study.

The present study paves the way for further research with larger sample sizes and even comparison with other DES systems, so that the clinical impact of this new device can be assessed by demonstrating, in a pioneering way, the performance of the self-expanding Sparrow® stent in small-caliber vessels, validating its efficacy through the objective parameter of LLL outcome and its safety by the absence of stent thrombosis at 12 months.

Conclusions

The results of this study allow us to conclude:

1. In patients submitted to percutaneous transluminal coronary angioplasty in natural coronary arteries with reference diameter ≤ 2.75 mm, the use of self-expanding DES Sparrow® compared with the bare metal version of the same stent, resulted in significant reduction of late lumen loss (within eight months after the index procedure).

2. Angiographic measurements regarding the immediate outcome after the procedure (percentage of stenosis, minimal lumen diameter and acute luminal gain) were satisfactory in both groups with no significant differences between them.

3. Angiographic measurements regarding the impact of treatment with Sparrow® DES in segments that are 5 mm proximal and distal to the stent showed outcome maintenance at eight months when compared to immediate outcomes (minimal luminal diameter and percent stenosis), thus demonstrating the absence of angiographic adverse effects at the stent borders in this group of patients.

Author contributions

Conception and design of the research: de Oliveira FRA, Mattos LAP, Abizaid A, Staico R, Botelho R, Sousa JE, Sousa A; Acquisition of data: de Oliveira FRA, Abizaid A, Abizaid AS, Costa JR, Costa R, Staico R, Botelho R, Sousa JE, Sousa A; Analysis and interpretation of the data: de Oliveira FRA, Mattos LAP, Sousa JE, Sousa A; Statistical analysis: de Oliveira FRA, Sousa JE; Obtaining funding: de Oliveira FRA; Writing of the manuscript: de Oliveira FRA,

Mattos LAP, Costa JR; Critical revision of the manuscript for intellectual content: Mattos LAP, Abizaid A, Sousa JE, Sousa A; Clinical monitoring of patients: Abizaid AS.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

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