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Comparison of clinical outcomes between very long stents and overlapping stents for the treatment of diffuse coronary disease in real clinical practice☆

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ABSTRACT

Background: The stent length as well as the stent overlap for the percutaneous treatment of diffuse coronary disease have been considered predictors of adverse events. However, there are no comparative data on the use of very long stents or overlapping stents in this scenario.
Objective: To compare the clinical results of very long stents (≥40 mm) or overlapping stents in real clinical practice.
Methods: We included 643 lesions in 628 consecutive patients treated with a single very long stent (≥40 mm) (251 lesions) or ≥2 overlapped stents (392 lesions). We analyzed the procedural characteristics and the presentation of the combined endpoint [cardiovascular death, non-fatal myocardial infarction, need for target lesion revascularization or stent thrombosis] after a follow-up of 20 months.
Results: Total stent length was 54 ± 18 mm and minimum diameter was 2.9 ± 1.2 mm. At the end of follow-up, the rate of adverse events was 8.3% (cardiac death: 4.9%, myocardial infarction: 1.7%, target lesion revascularization: 3.1%, stent thrombosis: 0.7%). There were no significant differences between both groups in the presentation of the combined endpoint. Procedures with overlapping stents had more contrast volume (309 ± 115 vs 273 ± 127 ml; $p = 0.002$), longer duration (47 ± 22 vs 39 ± 18 min; $p < 0.0001$), higher fluoroscopy time (20 ± 13 vs 16 ± 9 min; $p < 0.0001$) and higher number of stents to treat the index lesion (2.2 ± 0.5 vs 1; $p < 0.0001$).
Conclusions: New designs of very long stents allow not only treating increasingly complex lesions, but also simplifying the procedure and decreasing the number of stents with very favorable results similar to those obtained with stent overlap.

1. Introduction

Percutaneous coronary intervention (PCI) in diffuse coronary disease (dCAD) still remains a challenge for interventional cardiologists.

It usually involves very long lesions that, for years, have not been able to be treated with the implantation of a single stent, forcing the overlapping of several stents. In fact, stent overlap has been reported in as many as 30% of patients undergoing PCI [1–3].

Although the restenosis rate after drug-eluting stent (DES) implantation is relatively low, current data indicate that both stent length and stent overlap are associated with major adverse cardiac events (MACE) [4]. However, recent clinical reports have shown the safety and efficacy of overlapping newer-generation DES, compared with overlapping early-generation DES [5].

New stent designs with increasing length are emerging as an interesting tool for the percutaneous treatment of dCAD. In fact, platforms up to 60 mm are available to be used in this scenario reducing stent overlap [6–8]. Thus, it is occasionally difficult to decide whether to use

Abbreviations: AMI, Acute myocardial infarction; dCAD, Diffuse coronary artery disease; MACE, Major adverse cardiovascular events; OS, Overlapping stents; ST, Stent thrombosis; TLR, Target lesion revascularization; VLS, Very long stents.

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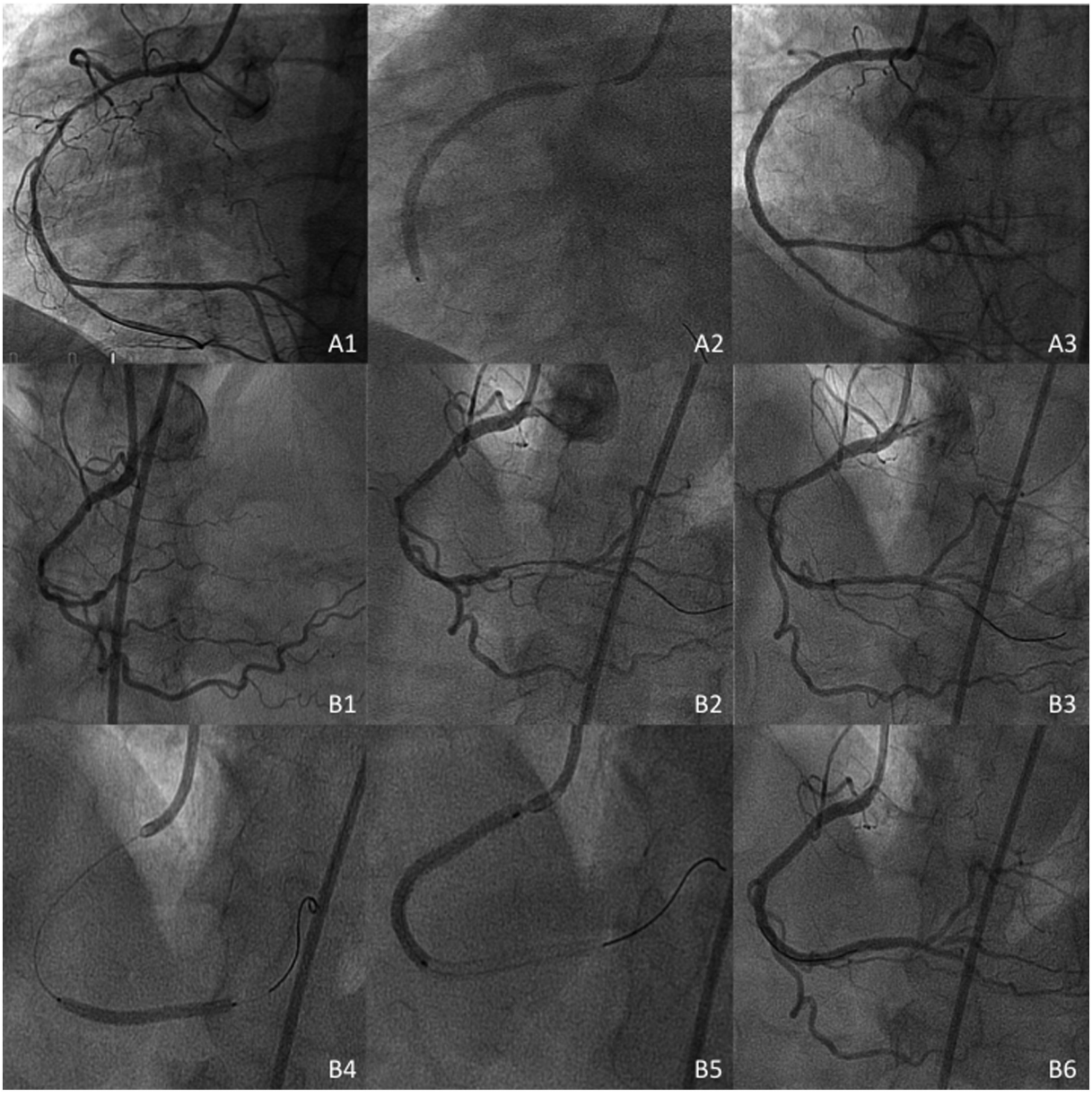

Fig. 1. Angiograms of two patients with diffuse coronary disease of right coronary artery treated with a single very long stent (A) and 2 overlapped stents (B). A1: Angiogram after predilatation; A2: Tapered BioMime™ 60 mm-long (Meril Life Sciences); A3: Final result. B1: Initial angiogram; B2–3: After predilatation; B4: Distal stent implantation (Synergy™ 38 mm, Boston Scientific), B5: proximal overlapped stent (Xience Xpedition™ 48 mm, Abbott Vascular); B6: Final result.

a very long single stent or overlapping 2 or more stents for long lesions (Fig. 1).

There are few comparative data on the use of very long stents (VLS) (≥40 mm) versus overlapping stents (OS) in this scenario. Therefore the aim of the present work was to compare the clinical results of VLS or OS to treat dCAD in real clinical practice.

2. Material and methods

2.1. Patients and study design

This study was single-center, retrospective and observational. We included 2823 consecutive PCIs and analyzed those performed in dCAD in which a single VLS (≥40 mm) or ≥2 OS were implanted. We compared procedural characteristics and clinical outcomes of both groups. When ≥1 VLS were overlapped, they were included in the OS group. Patients were included regardless of their clinical presentation [stable coronary artery disease (SCAD), non-ST elevation myocardial infarction (NSTEMI), or ST elevation myocardial infarction (STEMI)]. We excluded patients admitted for cardiac arrest and lesions with in-stent restenosis/thrombosis or bifurcations treated with a two-stent technique.

2.2. Procedure and stent implantation

All the interventional strategies were according to the recommendations of the clinical practice guidelines [9]. The implantation of a single VLS or ≥2 OS was left to the operator. The stents used for overlapping were new generation DES or BMS (limited to non-diabetic patients, vessels ≥3 mm in diameter and non-bifurcated or aorto-ostial lesions). The VLS used in this period were: the 48 mm length Xience Xpedition cobalt chromium everolimus-eluting stent (Abbott Vascular), the

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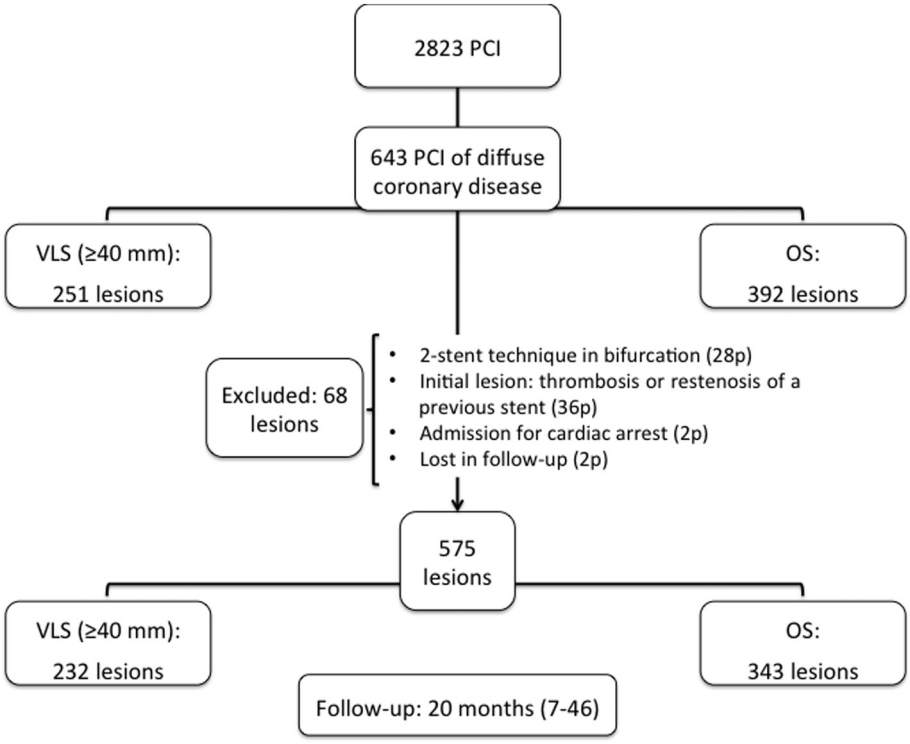

Fig. 2. Flowchart of the study. OS: overlapping stents; PCI: percutaneous coronary intervention; VLS: very long stent.

40 mm length Orsiro cobalt chromium sirolimus-eluting stent (Biotronik), the 48 mm length Synergy platinum chromium everolimus-eluting stent (Boston Scientific), and the 50 and 60 mm length BioMime Morph cobalt chromium sirolimus-eluting tapered stent (Meril Life Sciences). The only very long BMS was the 40 mm length Prokinetic Energy cobalt chromium stent (Biotronik).

2.3. Follow-up and clinical definitions

After PCI, serial electrocardiograms and cardiac biomarkers determinations were performed. Clinical assessment was performed at 1, 6, and 12 months after the procedure and at the end of follow-up. Angiographic follow-up was only performed in those patients with new symptoms, ischemia or deterioration of ventricular function in non-invasive tests.

Angiographic success was defined as a post-PCI diameter stenosis <20% with TIMI-3 flow and without any procedural complication. Major cardiovascular adverse event (MACE) rate [cardiovascular death, myocardial infarction (MI), stent thrombosis (ST) or need for treated lesion revascularization (TLR)] at the end of follow-up was established as the primary endpoint. As secondary endpoints, we analyzed the individual events of the composite endpoint. All deaths were considered cardiac unless another specific cause was documented. MI was defined according to the current recommendations [10] and only those related to the treated lesion, whether periprocedural or during follow-up, were considered. TLR or ST was defined according to the Academic Research Consortium criteria [11].

2.4. Statistic analysis

Quantitative variables that follow a normal distribution were expressed as mean ± standard deviation and those which not as median (range). Qualitative variables were expressed as percentages. For comparisons between quantitative variables *t*-test or Wilcoxon test

Table 1
Baseline characteristics.

	Overall sample n = 575 lesions (565 patients)	Single very long stent n = 232 lesions (224 patients)	Overlapping stents n = 343 lesions (341 patients)	*p*
Age (years)	66.9 ± 11.8	65.6 ± 12	67.8 ± 12	0.037
Male	436 (77.2%)	183 (81.7%)	253 (74.2%)	0.03
BMI	28.7 ± 4.9	28.6 ± 4.8	28.8 ± 4.9	0.7
Smoker	208 (37.1%)	90 (40.1%)	118 (34.6%)	0.2
Diabetes mellitus	227 (40.5%)	86 (38.4%)	141 (41.3%)	0.4
Dyslipidaemia	279 (49.9%)	103 (46%)	176 (51.6%)	0.13
Hypertension	390 (69.5%)	150 (66.9%)	240 (70.4%)	0.28
Clinical presentation				
SCAD	231 (40.9%)	83 (37%)	148 (43.4%)	0.27
NSTEMI	213 (37.7%)	92 (38%)	121 (35.5%)	
STEMI	121 (21.5%)	48 (21.4%)	72 (21.1%)	
LVEF	49 ± 13%	49.2 ± 14	48.9 ± 12	0.7

BMI: body mass index. LVEF: left ventricle ejection fraction. NSTEMI: non ST-elevation myocardial infarction. SB: side branch. SCAD: stable coronary artery disease. STEMI: ST-elevation myocardial infarction.

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Table 2
Angiographic and procedural characteristics.

	Overall sample n = 575 lesions (565 patients)	Single very long stent n = 232 lesions (224 patients)	Overlapping stents n = 343 lesions (341 patients)	p
Treated vessel				
LM	10 (1.7%)	2 (0.9%)	8 (2.3%)	0.49
LAD	236 (41.2%)	99 (42.7%)	137 (39.9%)	
LCx	87 (15.1%)	27 (11.6%)	60 (17.5%)	
RCA	237 (41.3%)	102 (43.9%)	135 (39.4%)	
Other	5 (0.8%)	2 (0.9%)	3 (0.9%)	
Syntax score	21 ± 13	18.1 ± 12	22 ± 13	0.015
Bifurcation	154 (26.8%)	48 (20.7%)	106 (30.9%)	<0.0001
CTO	94 (16.3%)	27 (11.6%)	67 (19.5%)	0.21
Number of stents[a]	1.7 ± 0.7	1	2.2 ± 0.5	<0.0001
Total stent length (mm)	54 ± 18	45.6 ± 4.7	59.6 ± 21.8	<0.0001
Maximum stent diameter (mm)	3.17 ± 0.47	3.1 ± 0.4	3.2 ± 0.5	0.01
Minimum stent diameter (mm)	2.9 ± 0.5	3.1 ± 0.4	2.7 ± 0.5	<0.0001
Stent type				
BMS	75 (13%)	26 (12.1%)	49 (14.9%)	0.003
DES	398 (69.2%)	179 (77.1%)	219 (63.8%)	
BMS + DES	102 (17.7%)	27 (11.2%)	75 (21.6%)	
Any BMS	156 (27.1%)	38 (16.4%)	118 (34.4%)	<0.0001
Predilatation	460 (80%)	180 (77.6%)	280 (81.6%)	0.5
Postdilatation	209 (36.3%)	85 (36.6%)	124 (36.1%)	0.2
Duration of procedure (min)	44 ± 21	38.8 ± 19	47 ± 22	<0.0001
FT (min)	19.1 ± 12.3	16.2 ± 8.8	20.4 ± 13.4	<0.0001
Contrast volume (ml)	297 ± 120	273 ± 127	309 ± 115	0.002
Angiographic success	568 (98.8%)	228 (98.3%)	340 (99.1)	0.45

BMS: bare metal stent; Cx: circumflex artery; CTO: chronic total occlusion; DES: drug eluting stent; FT: fluoroscopy time; LAD: left anterior descending; LM: left main; RCA: right coronary artery.
[a] Number of stents to treat index lesion.

was used. Qualitative variables were compared using the Chi^2 or McNemar tests. A statistical significance level of 0.05 was considered and the 95% confidence interval of the target analysis variables was calculated. For the multivariate analysis, logistic regression was used and all the significant variables in the univariate analysis were included. All statistical analyzes were performed using SPSS (version 20.0, SPSS Inc.).

3. Results

Of the 2823 PCIs performed in the study period, 643 lesions in 628 consecutive patients were treated with implantation of a VLS or OS.

Sixty-eight lesions were excluded before the analysis because they met at least one of the exclusion criteria. The remaining 575 lesions (565 patients) were analyzed (Fig. 2).

3.1. Baseline characteristics

The baseline characteristics of the patients are shown in Table 1. 77.2% were male and mean age was 66.9 ± 11.8 years. 40.5% were diabetics. Clinical presentation was stable ischemic heart disease in 40.9% of cases, 37.7% NSTEMI and 21.5% STEMI.

3.2. Procedural characteristics

The treated vessel was the left main coronary artery in 1.7% of cases, left anterior descending artery in 41.2%, left circumflex artery in 15.1% and right coronary artery: 41.3%. Treated lesions affected a coronary bifurcation in 26.8% cases and mean Syntax score was 21 ± 13.

The culprit lesions were treated with bare metal stents (BMS) in 13% of cases, with DES in 69.2% and in 17.7% of cases with a combination of both. The number of stents was 2.4 ± 1.1, total stent length was 54 ± 18 mm and the minimum diameter was 2.9 ± 0.5 mm.

The procedures with OS used more contrast volume (309 ± 115 vs 273 ± 127 ml, $p = 0.002$), had a longer duration (47 ± 22 vs 39 ± 18 min, $p < 0.0001$) and a higher fluoroscopy time (20 ± 13 vs 16 ± 9 min, $p < 0.0001$). In addition, in the VLS group, fewer stents were used (1 vs 2.2 ± 0.5, $p < 0.0001$). The angiographic success was 98.8%. The rest of procedural characteristics are shown in Table 2.

3.3. Adverse events during follow-up

After a median follow-up of 20 months (7–46) the rate of adverse events was 8.3% (cardiac death: 4.9%, AMI: 1.7%, TLR: 3.1%, ST: 0.7%) (Table 3). There were no significant differences between both groups in

Table 3
Major adverse cardiovascular events.

	Single very long stent n = 232 lesions (224 patients)	Overlapping stents n = 343 lesions (341 patients)	p
Cardiac death	3 (3.9%)	10 (5.6%)	0.39
MI related to the treated lesion	2 (1.3%)	6 (2.2%)	0.46
TLR	2 (0.9%)	5 (4.7%)	0.011
ST	0 (0.4%)	4 (0.9%)	0.49
MACE	6 (6.2%)	16 (9.7%)	0.15

MACE: major adverse cardiovascular events; MI: myocardial infarction; ST: stent thrombosis; TLR: target lesion revascularization.

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the presentation of the combined endpoint (OS: 9.7% vs VLS: 6.2%, $p = 0.15$), cardiac death (OS: 5.6% vs VLS: 3.9%; $p = 0.39$), AMI (OS: 2.2% vs VLS: 1.3%, $p = 0.46$) or ST (OS: 0.9% vs VLS: 0.4%; $p = 0.49$), although differences were found in the TLR rate (OS: 4.7% vs VLS: 0.9%, $p = 0.01$).

After adjusting the variables unequally distributed between both groups through multivariate analysis, no significant differences were found between groups in the rate of any adverse event. The only independent predictors of MACE rate at the end of follow-up were the age: OR 1.07 [95% CI (1.01–1.14); $p = 0.018$] and the minimum stent diameter: OR 5.03 [95% CI (1.3–21.9); $p = 0.017$].

4. Discussion

The main findings of this study were that the use of VLS to treat dCAD showed very favorable clinical outcomes, similar to those obtained with OS after a median follow-up of 20 months. In addition, procedures with OS were longer, and required more contrast volume and fluoroscopy time. As expected, in the VLS group, fewer stents were used.

DCAD is more and more frequently observed in hemodynamic laboratories due to the aging of the population and the high prevalence of cardiovascular risk factors. In the present study, of all the angioplasties performed in the study period, up to 22.8% had dCAD. PCI in this setting remains a challenge for the interventional cardiologist that has traditionally forced to overlap stents to cover the entire diseased segment [1–3]. With the development of new-generation DES, the outcomes of stent overlapping have improved; however, it is still associated with major adverse cardiac events (MACE) [4] probably due to several reasons:

- Stent overlap has been associated with increased neointimal proliferation and lumen loss due to delayed healing and increased inflammation [4,12].
- It may result in wide variations in mural drug concentration with areas of depletion and excessive concentration [13].
- Overlapped portions, make the vessel rigid due to the excess of metal, are more prone to stent fracture, and cause higher vascular injury that lead to more restenosis [6].
- The overlap geometry has been described to cause unfavorable flow conditions that may worsen clinical outcomes [14].
- An increase in side branch jailing due to the presence of a double layer of stent struts increases the probability of new revascularizations during follow-up [1,4].

In addition, it has been shown to be time-consuming and associated with a significant increase in material expenditure [4]. Finally, multiple stenting procedures increase exposure to radiation, and contrast volume. Therefore, VLS could theoretically simplify the procedure and improve the results. However, there have been few studies that directly compare VLS with OS in long lesions, and the results of implantation of short stents in short lesions are of limited applicability to long stents of long complex lesions.

It is noteworthy the preference for OS in apparently more complex lesions such as bifurcations or LM lesions. Probably the greatest experience with shorter stents and their better deliverability favored their use in these scenarios. This fact could also influence the longer duration of procedures in which OS was performed.

The clinical results of the present work were favorable, with an adverse events rate similar and even lower than those of recent studies [15]. Bouras et al. analyzed 328 very long lesions (≥35 mm), with a control cohort of 500 lesions >24 to <35 mm to which a XIENCE V stent was implanted. Mean lesion length was 47.1 ± 13.7 mm in the very long lesion group and 28.1 ± 2.4 mm in the control group. There was no significant difference in the rates of target lesion failure between the very long lesion and control groups (8.9 vs 10%, $p = 0.63$), MACE (9.2 vs 10%, $p = 0.74$) or stent thrombosis (1.6 vs 1.5%, $p = 0.92$) at 1 year [15].

In the present study, a reduction of the TLR rate was observed in the VLS group in the univariate analysis. However, after the multivariate analysis adjustment, in which we included the unequally distributed variables between groups and those that had a significant association with TLR rate in the univariate analysis (age, gender, use of BMS, total stent length, minimum stent diameter, bifurcation, Syntax score and OS), no significant differences were observed regarding TLR rate.

In one of the few studies that compare a long single stent or OS for long lesions, Mori et al. evaluated the angiographic and 1-year clinical outcomes between both groups obtaining results similar than ours. They analyzed 112 lesions with long (30 to 38 mm) lesions treated with everolimus-eluting stent, using one long stent (49 lesions) or 2 OS (63 lesions). The rates of freedom from major adverse cardiac events (92.9% vs 93.1%, $p = 0.91$) and target lesion revascularization (94.5% vs 95.1%, $p = 0.79$) during 1-year follow-up were similar between the 2 groups. There was no stent thrombosis [16]. The overlap status was not significantly associated with the late loss. The mechanisms that could explain these results, as ours, may be the higher biocompatibility of newer platforms which reduces hypersensitivity reactions, the lower strut thickness, which results in better endothelialization, and the lower dose of the antiproliferative drug, which yields less vascular toxicity at the overlapping site compared to previous generations of DES [12,17–21].

As shown in this paper, there is a percentage of cases in which the lesions are so long (>60 mm) that overlapping cannot be avoided, but even in these cases, the use of VLS can maintain certain advantages by reducing the number of overlapping stents, simplify the procedure and reduce costs.

To summarize, VLS could be superior to OS in terms of medical expenses, safety (less radiation exposure and contrast administration) and angiographic results (avoiding overlapping segments) although they could be inferior in terms of stent delivery in vessels with severe calcification or tortuosity.

4.1. Limitations

It is a retrospective single-center registry with all the limitations that are supposed to these studies. Although an adjustment for the variables that were distributed differently in both groups was made through multivariate analysis, since there is no randomization, it cannot be ruled out that other not studied factors may have influenced the result. A high percentage of BMS was used, since at the beginning of the study, there was pressure for the health expenditure that involved using DES in all the lesions. In any case, the use of BMS was limited to favorable scenarios. The use of BMS was higher in the OS group and this could influence the differences in TLR rate. However, the use of BMS was not an independent factor associated with any adverse event. Thus, the authors believe that this factor does not modify the study results and reflects real clinical practice. Study design makes it difficult to draw definitive conclusions and randomized studies are needed to confirm these results.

5. Conclusions

Clinical outcomes with the new designs of very long stents in the percutaneous treatment of diffuse coronary disease are very favorable and similar to those obtained with the stent overlap after a median follow-up of 20 months. The use of very long stents can reduce the number of stents per patient, and may be a factor associated with a lower duration of procedures, fluoroscopy time and contrast volume.

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