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SAFETY AND EFFICACY OF SYSTEMATIC LESION PREPARATION WITH A NOVEL GENERATION SCORING BALLOON IN COMPLEX PERCUTANEOUS INTERVENTIONS: RESULTS FROM A PROSPECTIVE REGISTRY

Florin-Leontin LAZAR, Alfonso IELASI, Bernardo CORTESE

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ORIGINAL ARTICLE

Safety and efficacy of systematic lesion preparation with a novel generation scoring balloon in complex percutaneous interventions: results from a prospective registry

Florin-Leontin LAZAR [1], Alfonso IELASI [2], Bernardo CORTESE [1, 3] *

[1]San Carlo Clinic, Paderno Dugnano, Milan, Italy; [2]Istituto Clinico Sant'Ambrogio, Milan, Italy; [3]Fondazione Ricerca e Innovazione Cardiovascolare, Milan, Italy

*Corresponding author: Bernardo Cortese, San Carlo Clinic, Paderno Dugnano, Via Ospedale 21, Milan, Italy.
E-mail: bcortese@gmail.com

ABSTRACT

BACKGROUND: Coronary lesions predilatation with semicompliant (SC) or non-compliant balloons (NC) may be insufficient to obtain an optimal stent expansion, which can lead to in-stent restenosis or thrombosis. Moreover, increasing evidence supporting an optimal lesion preparation is mandatory when drug coated balloons (DCB) are used. To this extent, more "aggressive tools" such as cutting/scoring balloons, atherectomy or lithotripsy may play an important role and improve outcomes.
METHODS: We enrolled 78 consecutive patients from March 2020 to October 2020 with calcific/fibrotic or ostially-located lesions, which were prepared using scoring balloons, in addition to SC/NC balloons and other plaque modification strategies. The final treatment consisted in either stent or DCB usage. The primary endpoint was the rate of clinically-driven target lesion revascularization. Secondary endpoints entailed the procedural success and the individual rates of major adverse cardiac events (MACE) at 12 months.
RESULTS: Most of the patients had left main (LM) or ostial lesions, 65% of them being moderate/severely calcified, with further debulking strategies being required in 15 (19.2%) patients (rotational atherectomy, 3.8% or coronary intravascular lithotripsy, 15.3%). A high-rate of DCB usage was reported. Angiographic and procedural success was obtained in 77 and 76 patients, respectively. We encountered one vessel perforation, which was sealed with a covered stent, without consequence. During follo- up, we observed only 6 MACE, 6 target lesion revascularizations (TLR) and 2 cardiovascular deaths.
CONCLUSIONS: Among patients with high complexity and calcific lesions, an optimal lesion preparation using a dedicated scoring balloon was associated with low clinical events at mid-term follow-up and may be considered to improve immediate procedural success rate.

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KEY WORDS: Cardiology; Heart; Coronary restenosis; Thrombosis.

In the recent years, the number of tools which improve procedural success in percutaneous coronary interventions (PCI) has increased in parallel with the complexity of treated lesions. The main limitations of the widely used drug-eluting stents (DES) are in-stent restenosis (ISR) and stent thrombosis (StT). Stent under-expansion and malapposition, which are often involved in such complications, occur more frequently in calcified or fibrotic lesions or in the absence of an adequate lesion preparation and/or optimization techniques after stent implantation.[1, 2]

In this context, optimal lesion preparation is currently a main focus in complex lesions. While the use of semi-compliant (SC) balloons has become clinical routine for lesion preparation, this strategy alone might imply inadequate stent expansion in heavily calcified lesions, and post dilatation with non-compliant (NC) balloons can only partially improve the outcomes.[3] As a result, many sites started to routinely use non-compliant balloons for common practice when performing lesion predilatation. Even if this strategy appears to be safe, no significant differences were observed regarding improved stent expansion assessed by intracoronary imaging compared to SC balloons.[3]

Furthermore, Danek *et al.* conducted a meta-analysis of 22 studies, comparing other preparation strategies, such as cutting balloons, scoring balloons, rotational and orbital atherectomy, reporting better long-term outcome with such adjuvant tools, as compared to predilatation with SC balloons.[4] Many other studies were conducted to evaluate the safety and efficacy of scoring balloon use in lesion preparation. Moreover, as growing clinical data suggests the benefits of drug coated balloon (DCB) angioplasty in de novo lesions,[5, 6] an optimal lesion preparation is mandatory for obtaining the best results with this strategy as well. The PASSWORD study was conducted to evaluate the systematic lesion preparation with scoring balloons for DCB angioplasty and the authors reported high procedural success and low clinical event rates in de novo lesions when this strategy was adopted.[7]

Materials and methods

Study design and population

This is a 2-center Italian, investigator-driven, prospective registry, aiming to document the immediate performance of a novel scoring balloon technology (Wedge; BrosMed Medical, Dongguan, China) for routine lesion preparation in a complex lesion setting, prior to either DCB or DES use in a consecutive series of patients. A secondary objective of this study is to see the impact on the clinical status at short-term follow-up.

Enrollment started in March 2020 and finished in October 2020 (follow-up ended in November 2020). We evaluated 78 consecutive patients which met the inclusion criteria: 1) clinical indication for PCI (both stable coronary artery disease [CAD] and acute coronary syndromes [ACS]); 2) age >18 year; and 3) native coronary lesion with reference diameters between at least 2.5 mm and at most 4.5 mm and at least one of the following characteristics:

- calcific lesions, assessed by angiography (at least 2 projections) or intravascular imaging (at least 180° of calcium arc);
- fibrotic lesions resistant to dilatation with SC balloon (angiographic assessment);
- ostially-located lesions (left main trunk, left anterior descending artery, circumflex artery, diagonal branch, obtuse marginal branch, right coronary artery).

These inclusion criteria basically defined a high-risk PCI population, as De Marzo *et al.* defined it in a recent review by three main areas (patient's risk factors and comorbidities, complex coronary anatomy and location, multi-vessel disease, left main disease, chronic total occlusion, bifurcation and impaired hemodynamic status).[8]

Patients with known (and untreatable) hypersensitivity or contraindication to aspirin, heparin, clopidogrel, prasugrel, ticagrelor or with visible thrombus at lesion site or recent (<3 months) PCI of the culprit vessel, were excluded.

Study endpoints

The primary endpoint of this study was the rate of clinically-driven TLR, defined as any repeat percutaneous intervention or bypass surgery of the target lesion or vessel performed for symptomatic restenosis or other complication of the target lesion. According to the ESC Revascularization Guidelines, cardiac troponins and electrocardiogram were assessed prior to the intervention and before hospital discharge.[9]

Secondary endpoints entailed the procedural success (defined as technical and angiographic success in the absence of MACE during hospitalization) and the individual rates of MACE (defined as a composite of cardiac death, myocardial infarction and target lesion revascularization) at 12 months.

Interventional procedure

According to the available literature,[10-13] an optimal lesion preparation which permits the use of DCB is defined as a good balloon expansion, less than 30% of residual stenosis, a TIMI flow grade 3 and the absence of flow-limiting dissection. To achieve these goals, the lesion preparation process was left to the operator discretion, in terms of SC or NB use or direct scoring balloon; also, the final therapeutic strategy (either DCB use or DES implantation) was left at the operator discretion. However, in case of DCB use, low-pressure long inflation was performed and if the angiographic result was unsatisfactory (presence of any flow limiting dissection, *i.e.* > type B following NHLBI classification, or residual stenosis >30%), a bailout approach with stent implantation was suggested. Moreover, if the lesion preparation after scoring balloon was considered unsatisfactory, additional plaque modification strategies were allowed, including coronary lithotripsy and rotational atherectomy.

Device characteristics

The Wedge device tested in this study is a new-generation, low profile, semicompliant scoring balloon, with a design consisting in a single nitinol wire enveloped within the balloon fold. Currently, the available balloon diameters range between 1.5-4 mm, and the lengths between 5-30 mm. Figure 1 illustrates the features of the Wedge scoring balloon. Regarding the DES or DCB used for this study, any device was allowed, regardless of the coating drug, diameter or length.

TABLE I.—*Baseline characteristics.*

Parameters	Values
Number of patients	78
Age (median)	69
Sex (M), N. (%)	55 (70)
History of smoking, N. (%)	51 (66)
Diabetes, N. (%)	34 (44)
Hypertension, N. (%)	65 (83)
Dyslipidemia, N. (%)	41 (53)
Family history of CAD, N. (%)	18 (23)
Dialysis, N. (%)	0 (0)
Prior MI, N. (%)	15 (19)
Prior PCI, N. (%)	39 (50)
Peripheral vascular disease, N. (%)	10 (13)
LV EF, %, (SD)	52 (18)
Stable CAD, (%)	67%
Unstable angina, (%)	8%
NSTEMI, (%)	10%
STEMI, (%)	15%

CAD: Coronary artery disease; MI: myocardial infarction; PCI: percutaneous coronary intervention; LVEF: left ventricular ejection fraction; NSTEMI: non-ST segment elevation myocardial infarction; STEMI: ST segment elevation myocardial infarction; SD: standard deviation.

Results

A total number of 78 patients (55% men) were treated consecutively and included in the registry, according to the established strategy. The majority of patients (67%) were elective cases with a high-risk profile, as most of them were smokers and many patients had diabetes, hypertension, prior myocardial infarction (MI) or PCI. The main baseline characteristics can be found in Table I.

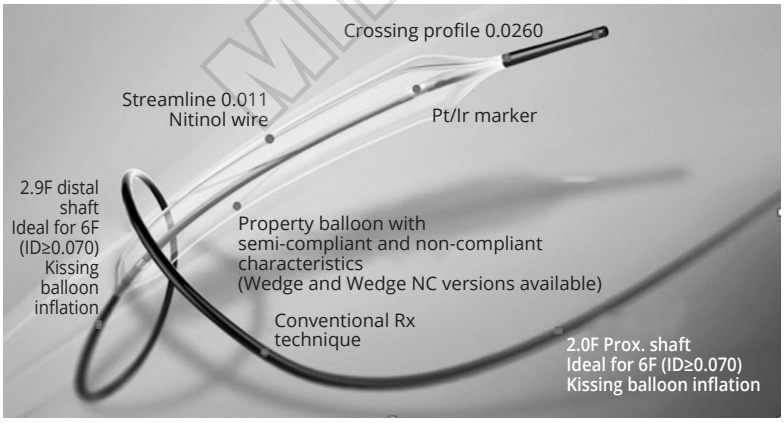

Figure 1.—Wedge scoring balloon. Pt/Ir: Platinum/iridium.

TABLE II.—*Procedural characteristics.*

Periprocedural MI, N. (%)	16 (20)
Fluoroscopy time, min	23
Vessel treated, LM, %	29
Vessel treated, LAD, %	38
Vessel treated, CX, %	8
Vessel treated, RCA, %	25
Segment treated, proximal, %	64
Segment treated, mid, %	30
Ostial lesion, %	30
Segment treated, distal, %	6
% Diameter stenosis	83
RVD, mm	3.4
Lesion length, mm	28
MLD, mm	0.66
Calcium, severe, %	27
Calcium, moderate, %	38
Calcium, light, absent, %	35
Predilatation before scoring balloon, %	98
Type of balloon, SC, %	30
Type of balloon, NC, %	70
Length of predilatation balloon, mm	14.2
Diameter of predilatation balloon, mm	2.7
Length of Wedge balloon, mm	14.5
Diameter of Wedge balloon, mm	2.9
Final % diameter stenosis after predilatation (before Wedge)	58
Final % diameter stenosis after Wedge	29
Wedge atmospheres, mmHg	12
Final treatment DES, N. (%)	56 (72)
Final treatment DCB, N. (%)	22 (27)
Final treatment POBA, N. (%)	1 (1)
Final treatment length, mm	32
Final treatment diameter, mm	3.4
Postdilatation (0.1), %	54
Final MLD, mm	3.3
Final % diameter stenosis	4
Atherectomy, N. (%)	3 (3.8%)
Shockwave, N. (%)	12 (15.3%)
Final TIMI flow 3, N. (%)	77 (99)
Angiographic success, N. (%)	77 (99)
Procedural complications, n	1
Antithrombotic treatment at discharge	
ASA treatment discharge, %	73
Clopidogrel treatment, %	62
Prasugrel/ticagrelor treatment, %	38

LM: Left main; LAD: left anterior descendent; CX: circumflex; RCA: right coronary artery; RVD: reference vessel diameter; MLD: minimal lumen diameter; SC: semi-compliant; NC: non-compliant; DES: drug eluting stent; DCB: drug coated balloon; POBA: plain old balloon angioplasty.

Lesions and procedural characteristics

Lesion complexity was high: many patients had LM disease treated (29%) or ostial location (32%). Target vessels were large (average diameter was 3.4 mm), with long lesions (28 mm). Moreover, lesion calcification, which is one of the main reasons for scoring balloon adoption, was moderate or severe in most of the patients (65%). What is more, almost all patients (98%) undergoing lesion preparation before the Wedge scoring balloon was used, in 70% of the cases with a NC balloon. Wedge balloon used had an average diameter of 2.9 mm and was 15 mm long. Even so, 15 patients required further debulking strategies (3.8% rotational atherectomy and 15.3% coronary lithotripsy). In 27% of patients, the final treatment consisted in the use of DCB, whilst in the rest received DES implantation. Angiographic success was achieved in all patients except one, which had a TIMI 2 final flow. There was one peri-procedural complication, consisting in a vessel perforation (distal, calcific RCA) after Wedge use, which was immediately sealed with a covered stent, without any consequences for the patient. The main procedural characteristics are summarized in Table II.

Procedural success was obtained in all patients except for 2: the first had a Q-wave myocardial infarction caused by stent thrombosis after 2 days, treated with urgent revascularization without other complications. The second one had a TLR (residual stenosis at the distal DES edge) caused by recurrent unstable angina 2 days after the intervention. No other in-hospital complications occurred.

The average follow-up was 326 (±82) days. During this period, we observed 6 MACE (8%), 6 TLR and 2 cardiovascular deaths, with the main follow-up findings being summarized in Table III.

TABLE III.—*In-hospital outcomes and follow-up.*

In-hospital outcome		Follow-up	
Procedural success, N. (%)	76 (98)	Follow-up length, days (SD)	326 (82)
In-hospital MACE N. (%)	2 (2.5)	MACE, N. (%)	6 (8)
In-hospital MI N. (%)	2 (2.5)	MI N. (%)	3 (4)
In-hospital TLR N. (%)	1 (1)	TLR N. (%)	6 (8)
In-hospital cardiac death N. (%)	0	Cardiac death N. (%)	2 (2.7)
In-hospital total death N. (%)	0	Total death N. (%)	2 (2.7)
In-hospital vessel thrombosis N. (%)	1 (1)		

ASA: Acetylsalicylic acid; MACE: major adverse cardiovascular events; MI: myocardial infarction; TLR: target lesion revascularization; SD: standard deviation.

Discussion

Optimal lesion preparation is one of the most important contributors to a good stent expansion, angiographic success and lower rates of long-term complications.[4, 14-16] Scoring balloons have been developed for this purpose and predilatation with a scoring balloon have been demonstrated to enhance stent expansion, thus minimalizing the difference between predicted and achieved stent dimensions.[14] One of the mechanisms for this benefit of scoring balloons is the induction of a higher degree of intimal disruption,[16] which might also enhance the drug absorption, distribution and transfer to the target cells.[17] This mechanism of action was demonstrated by Tzafriri *et al.* in an *ex-vivo* study and the authors found not only an improved acute lumen gain after scoring balloon use, but also a higher procedural success rate for DCB use after lesion preparation by this device.[17]

Our registry shows good clinical performance of the studied scoring balloon, in terms of device deliverability, safety and efficacy at mid-term follow-up, in a population which has several milieus of lesion complexity. Interesting, despite lesion preparation before scoring balloon use was performed in all patients, the use of Wedge warranted a further improvement in % diameter stenosis from 58% to 29%, meaning that this device was able to improve further the dilatation properties of SC and NC balloons used for the first approach, with a net increase of 29% diameter stenosis.

The primary endpoint of the study, clinically-driven TLR, occurred totally in 8 patients at 1 year, in a highly ischemic risk patient population, with multivessel disease, small coronary vessels or long lesions. There were no significant differences between the two final treatment arms (DES or DCB) in terms of TLR and MACE.

These results are in accordance with the literature, as the implementation of a scoring balloon prior to stenting led to low TLR and target vessel revascularization rates, with larger lumen gain and improved outcomes when compared to conventional balloon predilatation, even in complex settings such as left main interventions.[18] The main results are summarized in Figure 2, alongside the study design and procedural characteristics.

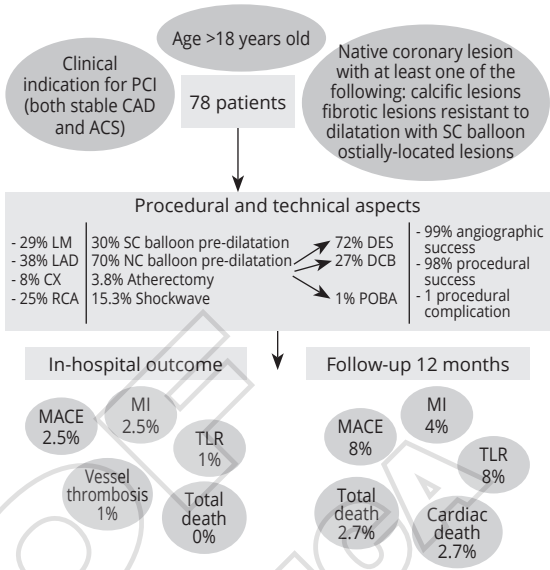

Figure 2.—Central illustration: procedural and technical aspects in the use of Wedge Scoring Balloon.
PCI: Percutaneous coronary intervention; CAD: coronary artery disease; ACS: acute coronary syndrome; SC: semi-compliant; NC: non-compliant; LM: left main; LAD: left anterior descendent; CX: circumflex; RCA: right coronary artery; DES: drug eluting stent; DCB: drug coated balloon; POBA: plain old balloon angioplasty; MACE: major adverse cardiovascular events; MI: myocardial infarction; TLR: target lesion revascularization.

We believe that the improved immediate technical performances of the Wedge device (high trackability and deliverability), with reference to previous generation scoring balloons, may result in a wider adoption of this therapy, also taking into consideration the increase in lesion complexity of current-era interventional cardiology.

DCB subgroup

DCB treatment was used in 27% of the patients. This strategy was adopted not only for small vessel disease, but also in more complex lesions such as multivessel disease, calcific or ostial lesions and large vessels, as there is growing evidence supporting their use in such complex settings.[19-23] Interesting, the similar clinical results in terms of MACE and TLR *vs*. DES treatment, came along with a non-inferiority in terms of acute lumen gain, differently from other observations in previous DCB studies, where stenting

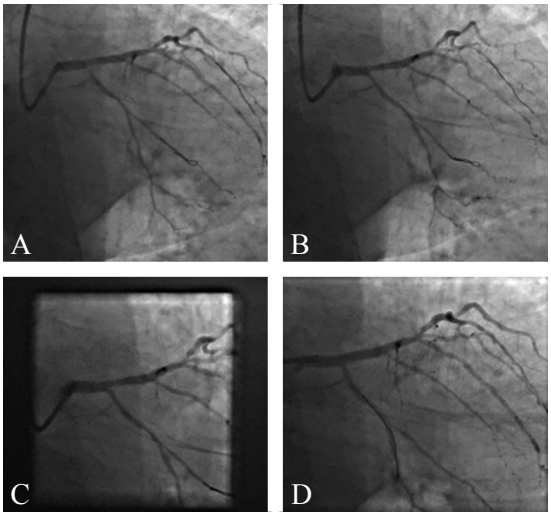

Figure 3.—DCB treatment of a critical ostial CX stenosis and in-stent restenosis of ostial LAD. A) Basal angiography showing sub-occlusive, calcific stenosis of the ostium of the circumflex artery and moderate in-stent restenosis of the ostial LAD; B) angiographic result after predilatation with increasing diameter balloons (2.0 mm SC, 2.5 mm SC, 2.75 mm NC); C) angiographic result after predilatation with Wedge SC Scoring balloon (2.5 mm), showing net improvement of diameter stenosis; and D) final angiographic result, after 3.0 mm DCB treatment of ostial CX and 4.0 mm DCB treatment of LM-ostial LAD.

was associated with improved immediate performance.[23] Figure 3 and Figure 4 describe the implementation of Wedge prior to DCB use in de novo lesions, where an optimal preparation is mandatory. Unfortunately, studies directly comparing different lesion preparation strategies before DCB use are lacking.

Limitations of the study

This study was not designed to compare a scoring balloon with conventional NC and SC balloons for lesion preparation, therefore, even if the safety and efficacy of this approach has been observed, we cannot conclude that this therapy should become routine for lesion preparation. What is more, the hypothesis that a lesion preparation with scoring balloon prior to DCB use could improve drug tissue uptake will need to be assessed in further, dedicated research. Other limitations of the current report are the absence of core lab analysis for lesion assessment and the fact that only clinical follow-up was available.

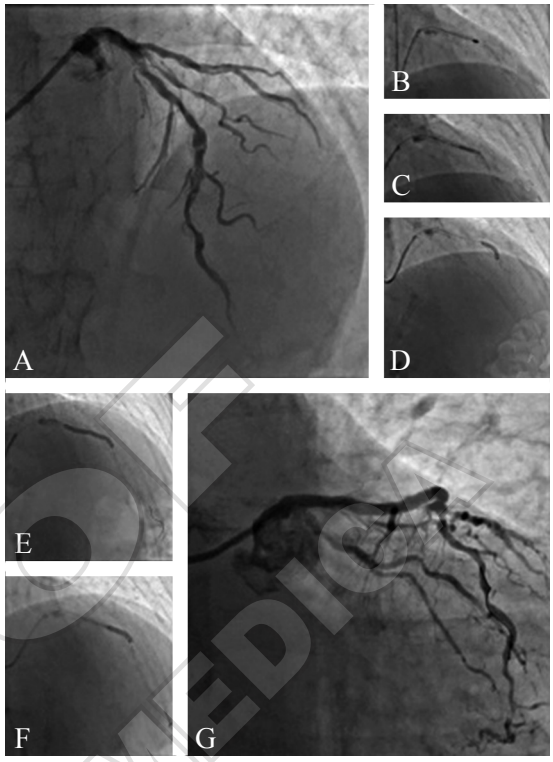

Figure 4.—Optimal lesion preparation of a severely calcified lesion of proximal and mid LAD using several plaque modification techniques. A) Basal angiography showing critical calcific stenosis of the proximal and mid LAD; B) rotational atherectomy (1.75 mm burr); C) shockwave therapy of the mid LAD stenosis (8 applications); D) Wedge scoring balloon for optimal lesion preparation of the mid LAD stenosis; E) long DES implantation (3.5 mm); F) post-dilatation of the stent using a NC balloon (4.0 mm); and G) final angiographic result showing good stent expansion after optimal lesion preparation and optimization techniques.

Conclusions

Among patients with high complexity and calcific lesions, an optimal lesion preparation using a dedicated scoring balloon was associated with low clinical events at mid-term follow-up and may be considered to improve immediate procedural success rate.

Key points

• An optimal lesion preparation is mandatory in order to reduce the risk of stent underexpansion and malapposition, which are often involved in in-stent restenosis and thrombosis.

- The use of cutting balloons, scoring balloons, coronary lithotripsy and atherectomy as plaque modification strategies have been reported to improve the outcomes in complex percutaneous angioplasties, as compared to standard predilatation using semi-compliant balloons.
- The results of the current study suggest that among patients with high complexity lesion, the routine use of a scoring balloon could represent a safe and effective strategy to improve immediate procedural success rate, and possibly reduce long term adverse events.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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