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Metal free percutaneous coronary interventions in all-comers: First experience with a novel sirolimus-coated balloon

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Abstract

Background: *Limus-eluting stents have become the mainstay for percutaneous coronary intervention (PCI). However, even with the latest generation drug-eluting stent, in-stent restenosis and very late stent thrombosis remain a concern. The Selution SLR™ drug-coated balloon (DCB) is a novel sirolimus-coated balloon that provides a controlled release of the antiproliferative drug. Herein we evaluated its performance in a real-world patient cohort with complex coronary artery lesions.*

Methods: *Patients undergoing PCI using the Selution SLR™ DCB were analyzed from the prospective SIROOP registry. We evaluated procedural success and clinical outcomes, including major adverse cardiovascular event (MACE), cardiac death, target vessel myocardial infarction and target lesion revascularization.*

Results: *From September 2020 to April 2021, we enrolled 78 patients (87 lesions) treated using a "DCB only" strategy. The mean age was 66.7 ± 10.4 years and 28 (36%) presented with an acute coronary syndrome. Almost all lesions were type B2/C 86 (99%) and 49 (63%) had moderate to severe calcifications. Procedural success was 100%. After a median follow-up of 11.2 months (interquartile range: 10.0–12.6), MACE occurred in 5 (6.8%) patients. No acute vessel closure was observed.*

Conclusions: *In complex coronary lesions, a "DCB only" strategy using the Selution SLR™ DCB is not just safe and feasible, but also seems to be associated with a low rate of MACE at 1-year follow-up. Our promising results warrant further evaluation in a dedicated comparative trial.* (Cardiol J 2022; 29, 6: 906–916)

Key words: drug-coated balloons, sirolimus, complex coronary lesions, percutaneous coronary interventions, drug-eluting stent

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Introduction

Nowadays, drug-eluting stents (DES) represent the gold standard device used for treatment of the majority of de-novo coronary artery lesions [1]. Despite technical advancements and improved medical therapy, in-stent restenosis (ISR) and very late stent thrombosis (ST) remain a concern, even with the latest generation of DES [2, 3]. Recent reports have indicated an annual stent failure rate up to 2%, especially in complex and long lesions [4–7]. The persistence of metallic platforms, leaving the vessel "caged" after stent implantation, plays an important role in this context [4, 5].

Therefore, drug-coated balloons (DCBs) may have the potential to overcome some of the limitations associated with use of contemporary DES, by releasing an anti-restenotic drug and not leaving a permanent metallic implant behind [8]. With paclitaxel-coated balloons, good outcomes have been reported in ISR, which led to their incorporation as class IA indication in the latest European Society of Cardiology (ESC) guidelines [1, 9–12]. Moreover, several randomized trials have indicated non-inferiority of DCB compared to DES for treatment of de-novo lesions in small sized coronary vessels [13–16].

Albeit there is growing evidence highlighting the utility of DCBs in treatment of coronary artery disease (CAD), data about their performance in large vessels (> 3 mm) and especially complex coronary lesions remains scarce. The Selution SLR™ balloon (MedAlliance SA, Nyon, Switzerland) represents a novel DCB, which carries sirolimus as antiproliferative drug. Sirolimus coated balloons have not been widely studied yet, but some early small studies have suggested promising results in simple coronary lesion [17–19]. In fact, the potential of sirolimus resides, among others, in its stronger suppression of neointimal growth and wider therapeutic window [20].

The aim of the present study was to assess the safety and efficacy of an approach using the novel Selution SLR™ DCB in a real-world CAD population requiring treatment of complex coronary artery lesions, including chronic total occlusions (CTOs) and ISR lesions. Herein, we report 1-year outcome data.

Methods

The analyzed patients were those included in the prospective SIROOP Registry (Prospective Registry Study to Evaluate the Outcomes of Coronary Artery Disease Patients Treated With SIROlimus Or Paclitaxel Eluting Balloon Catheters) (ClinicalTrials.gov identifier: NCT04988685), which was designed to describe the management and outcomes of patients with acute coronary syndrome (ACS) and chronic coronary syndrome (CCS) undergoing percutaneous coronary intervention (PCI) with contemporary DCBs in native coronary and/or ISR lesions. For the current analysis, patients had been treated with the novel Selution SLR™ DCB at the Heart Center of the Luzerner Kantonsspital (Lucerne, Switzerland), which represents a tertiary cardiology facility for the central part of Switzerland.

Selution SLR™ device

The drug coating of the Selution SLR™ DCB is a formulation consisting of sirolimus as the active pharmaceutical ingredient and four excipients. The specifics of this device are summarized in the **Supplemental Figure 1**. The first excipient is a biodegradable polymer (poly-lactic-co-glycolic acid [PLGA]) that encapsulates the sirolimus into spherical homogenous micro-reservoirs (4 μm in size), which provides a controlled and sustained drug release up to 90 days. The remaining three excipients constitute a phospholipid blend, the proprietary Cell Adherent Technology (CAT™), which contains and protects the micro-reservoirs during delivery, allowing for a maximum drug transfer to the vessel wall during inflation, and with the aim to reduce wash-off of the micro-reservoirs into the bloodstream and help to adhere the drug coating to the surrounding tissues. The drug concentration is 1 μg/mm^2. Available balloon sizes range from 1.5 to 5.0 mm in diameter and 10–40 mm in length [21, 22].

Study population

Consecutive patients from the SIROOP registry, who had been treated with the Selution SLR™ DCB, were analyzed. Since this registry aims to enroll a representative — real-world — CAD population, patients with a CCS as well as ACS were included. Moreover, no angiographic exclusion criteria were applied, which allowed us not only to include the full range of coronary lesions (e.g., long, calcified, thrombotic and chronically occluded lesions), but also bifurcations and ISR lesions.

From every study participant, demographic and procedural data were collected using a dedicated database (REDCap©, Version 10.6.28, established by the Vanderbilt University, Tennessee, USA).

Prospective follow-up information was collected. Clinical follow-up information was obtained from the studied subjects by clinic visits or telephone interviews at 30 days, 6 months and 1 year after the index procedure.

PCI procedure

Device sizing and lesion preparation was performed at the discretion of the involved interventional cardiologists. Noteworthy, internal practice recommendations were established for use of DCB in CAD treatment, which emphasize vigorous lesion preparation using at least scoring/cutting and/or dedicated non-compliant (NC) balloons. This practice is in line with the 3rd DCB consensus paper [9]. To achieve optimal luminal gain, we almost routinely use the highly NC, twin-layer OPN NC® balloon (SIS Medical, Frauenfeld, Switzerland) for lesion preparation and/or post-dilatation following DCB treatment [23]. Moreover, we liberally use optical coherence tomography (OCT) with the Dragonfly® catheter (Abbott Vascular, Santa Clara, CA, USA) for lesion preparation.

Following successful lesion preparation, and in the absence of a major complication(e.g., flow limiting dissections, abrupt vessel closure, perforations), the target lesion/vessel was treated with the Selution SLR™ DCB. Conservative sizing of the DCB was advocated in order to mitigate the risk of dissecting the vessel by overstretching it with the semi-compliant balloon. Each DCB inflation was performed according to device instructions for use, meaning inflating the DCB for at least 45 s was attempted, optimally at least 90–120 s, in order to achieve optimal drug transmission to treated vessel segments. Lesions with suboptimal PCI results after DCB treatment (e.g., flow-limiting dissection, residual stenosis > 30% or a fractional flow reserve value of < 0.80) were treated with a 3rd generation DES.

Regarding the antithrombotic regimen, current antiplatelet guidelines were followed [1, 9, 24]. Patients were pretreated with acetylsalicylic acid (ASA) prior to PCI, if tolerated. At the discretion of the treating physician, the patients were loaded with either clopidogrel, ticagrelor or prasugrel during or after PCI. PCI was performed using heparin (70–100 U/kg body weight, target activated clotting time > 230–250 s during PCI). In patients presenting with CCS, a dual antiplatelet therapy (DAPT) regimen consisting of ASA and clopidogrel was generally prescribed. In complex procedures, including for instance thrombotic or long lesions, the DAPT regimen may have involved ASA and ticagrelor. The duration of the DAPT varied between 1 and 3 months, according to Third Report of the International DCB Consensus Group and patient bleeding and thrombotic risk [9]. In ACS, a DAPT regimen including ASA and ticagrelor or prasugrel for a duration of 12 months [24] was generally aimed for.

In patients, which required oral anticoagulation, the administration of direct oral anticoagulant in combination with ASA maximally for 1 week and clopidogrel for 1 to 12 months was recommended, depending upon the presentation and lesion complexity (CCS vs. ACS) [1].

Angiographic analyzes

All angiograms were analyzed by an independent core laboratory (MedStar Cardiovascular Research Network [MCRN], Washington DC, USA). The lesions were classified according to the American College of Cardiology/American Heart Association (ACC/AHA) lesion classification [25]. Bifurcation lesions were categorized according Medina classification [26]. The reader then scored the calcium based on the three-tier classification system: Minimal or no calcification; calcium covering ≤ 50% of the circumference of the vessel is classified as "Moderate calcification"; calcium covering 50–100% of the circumference of the vessel is classified as "Severe calcification". Dissections were classified according to the National Heart, Lung and Blood Institute (NHLBI) classification system for intimal tears, consisting of type A through type F [27].

Quantitative angiographic analysis (QCA) was performed before and after DCB inflation using CASS Workstation, Version 8.1 (Pie Medical, Maastricht, The Netherlands). Measurements were taken on cine-angiograms recorded after intracoronary nitroglycerine administration. Baseline measurements were taken in the single worst view projection, without foreshortening, nor overlapping and brisk contrast filling. The contrast-filled non-tapered catheter tip was used for calibration or autocalibration in case the former was not successful. The analyst marked the target segment manually and the software automatically outlined the contours of the lumen. As a result, the calculation of the lumen diameters (mean, minimum and maximum) was provided in addition to the interpolated reference vessel diameter and percent diameter stenosis in the treated segment and 5-mm proximal and distal to this.

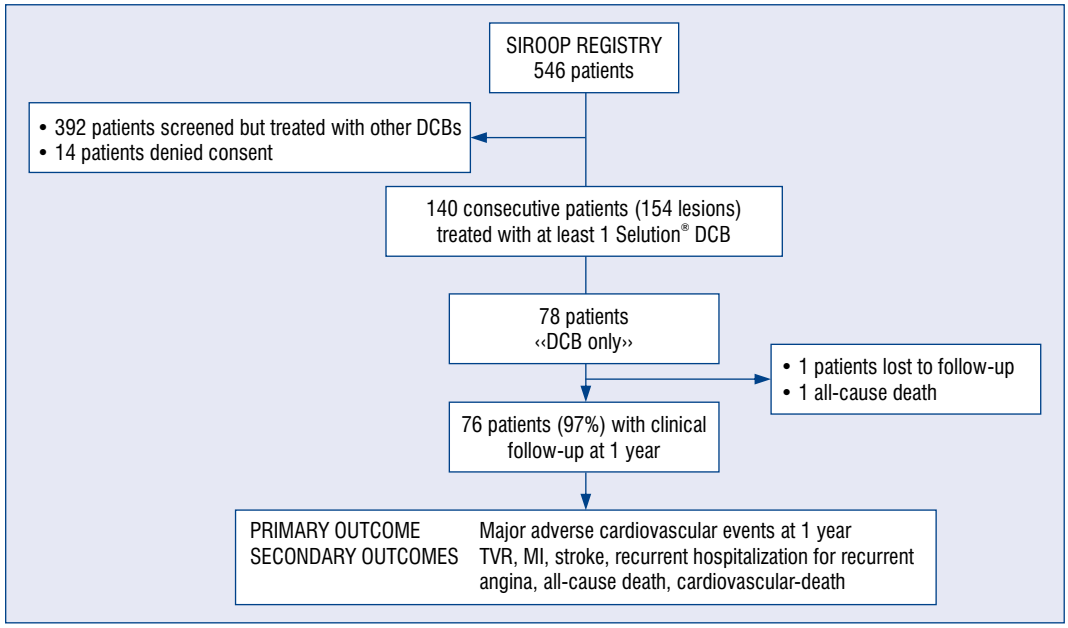

Figure 1. Study flow chart; DCB — drug coated balloon; MI — myocardial infarction; TVR — target vessel revascularization.

Study endpoints

The primary outcome was major adverse cardiovascular event (MACE) defined as composite of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion revascularization (TLR). The secondary endpoints included target vessel revascularization (TVR) and all-cause death according to the criteria of the Academic Research Consortium [28]. Heart failure was defined as an ejection fraction < 40%. Procedural success was defined as < 30% stenosis remaining after PCI with a Thrombolysis in Myocardial Infarction (TIMI) flow grade 3 at the end of the procedure

Statistical method

Categorical variables are displayed as frequencies and percentages, and continuous variables are presented as means (± standard deviations) or medians (interquartile ranges [IQR]), as appropriate. P-values were calculated using paired t-tests and Wilcoxon rank-sum test, where applicable. A two-tailed p-value < 0.05 was considered statistically significant. The analyzes were conducted using STATA version 16 (College Station, Texas, USA).

Results

Between September 2020 and April 2021, a total of 204 patients were treated with the Selution SLR™ DCB at the Luzerner Kantonsspital. Of these, 78 patients were treated with a "DCB only" strategy, see study flow chart (Fig. 1). Most patients were males, just over a third of patients presented with ACS and around 1/3 of patients had diabetes. The mean prescribed duration of DAPT was 8.6 ± 4.2 months. Further details about baseline characteristics can be found in Table 1.

A total of 87 lesions were successfully treated using a "DCB-only" strategy. The majority of lesions were located in the left anterior descending artery (57%). About half of the lesions had moderate to severe calcifications, 6.9% were ISR and 13% were CTO lesions. In bifurcation lesions, we only treated the main branch using a DCB.

Mean lesion length was 16.7 ± 13.7 mm and minimal lumen diameter was 0.82 ± 0.43 mm. The cumulative curve for minimal lumen diameter pre- and post-PCI is depicted in Figure 2. Lesion preparation was predominately carried out using the OPN NC® balloon (83%) at a mean inflation pressure of 25 ± 8 atm. A total of 35 (45%) lesions were pretreated using a cutting balloon (Wolverine®, Boston Scientific, Minneapolis) in combination with OPN NC®. Mean DCB diameter was 2.7 ± ± 0.7 mm, whereas mean inflation pressure was 8 ± 3 atm. Intravascular imaging with OCT was used in 24% of the cases. At index procedure, there were 4 (6.1%) dissections, 2 type A, 1 type C and 1 type D dissection Notably, all dissections were observed after lesion preparation. Further angiographic and procedural characteristics as well as QCA analysis are reported in Tables 2 and 3, respectively.

Table 1. Baseline characteristics of the study population.

Baseline characteristics	Number of patients (n = 78)
Age [years]	66.7 ± 10.4
Males	68 (89%)
Median follow-up time [months]	11.2 [10;12.6]
Presentation:	
Chronic coronary syndrome	50 (64%)
Acute coronary syndrome:	28 (36%)
NSTEMI	27 (96%)
STEMI	1 (4%)
Cardiovascular risk factors:	
Arterial hypertension	56 (72%)
Diabetes mellitus	18 (23%)
Dyslipidemia	57 (73%)
Current smoking	18 (23%)
Previous MI	30 (38%)
Previous CABG	4 (5%)
Heart failure (EF < 40%)	11 (14%)
Antithrombotics:	
ASA	76 (97%)
Clopidogrel	32 (41%)
Ticagrelor	20 (26%)
Prasugrel	21 (27%)
Oral anticoagulant	11 (14%)

Data are mean (standard deviation), median (interquartile range) or number (percentage), as appropriate; ASA — acetylsalicylic acid; CABG — coronary artery bypass grafting; EF — ejection fraction; MI — myocardial infarction; NSTEMI — non-ST segment elevation myocardial infarction; STEMI — ST-segment elevation myocardial infarction

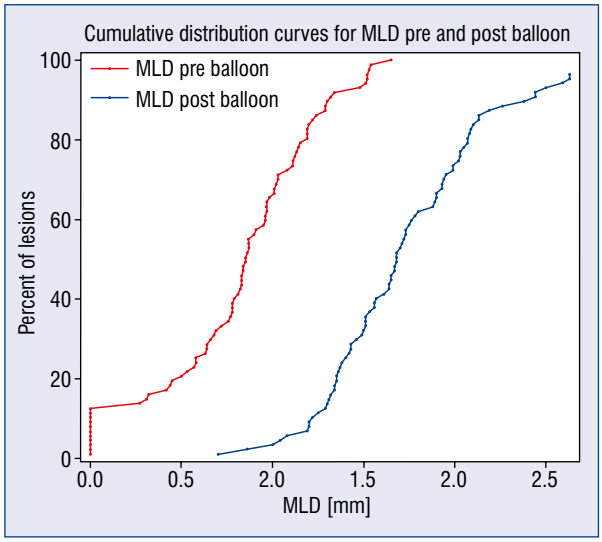

Figure 2. Graph depicting minimal lumen diameter (MLD) pre- (red line) and post-percutaneous coronary intervention (blue line).

Table 2. Lesion characteristics of the study population.

Lesion and periprocedural characteristics	Number of patients/ /lesions (n = 78/n = 87)
Access:	
Radial	70 (90%)
Femoral	8 (10%)
Vessel treated:	
Left anterior descending artery	44 (57%)
Left circumflex artery	23 (29%)
Right coronary artery	20 (26%)
Mean Syntax score	17.1 ± 11.9
Lesion classification ACC/AHA:	
Type B1	1 (1.3%)
Type B2	48 (55%)
Type C	38 (44%)
Aorto-ostial lesion	4 (5.1%)
Bifurcation:	69 (79%)
Medina (1,1,1)	31 (36%)
Medina (1,1,0)	15 (17%)
Medina (0,1,1)	10 (11%)
In-stent restenosis	6 (7.7%)
Chronic total occlusion	11 (14%)
Moderate to severe calcification	49 (63%)
Type of pre-dilatation balloon:	
SC-balloon	9 (12%)
NC-balloon	48 (62%)
Super NC-balloon	65 (83%)
Cutting balloon	35 (45%)
IVL	2 (2.3%)
Rotablation	1 (1.1%)
Lesion preparation:	
Mean diameter of larger pre-dilatation balloon [mm]	2.87 ± 0.6
Mean maximal pre-dilatation pressure [atm]	25 ± 8
Mean DCB diameter [mm]	2.66 ± 0.7
Mean DCB inflation pressure [atm]	8 ± 3
Use of intravascular imaging:	
OCT	19 (24%)
IVUS	1 (1.3%)
Dissections post-DCB:	
Type A	2 (2.3%)
Type B	0 (0%)
Type C	1 (1.1%)
Type D	1 (1.1%)

Data are mean ± standard deviation or number (percentage), as appropriate; ACC/AHA — American College of Cardiology/American Heart Association; DCB — drug coated balloon; DES — drug eluting stents; IVUS — intravascular ultrasound; IVL — intravascular lithotripsy; NC — non-compliant; OCT — optical coherence tomography; SC — semi-compliant balloon

Table 3. Quantitative coronary analysis (QCA).

QCA	Pre-PCI	Post-PCI	P*
Lesion length [mm]	16.7 ± 13.7	–	
Minimal lumen diameter [mm]	0.82 ± 0.43	1.7 ± 0.40	< 0.01
Diameter stenosis [%]	62.7 ± 17.9	16.6 ± 9.8	< 0.01
Reference vessel diameter [mm]	2.10 ± 0.71	2.04 ± 0.42	0.6

Data are mean ± standard deviation or number (percentage), as appropriate; *P values were based on student t-tests or the Mann-Whitney U-tests, as appropriate; PCI — percutaneous coronary intervention

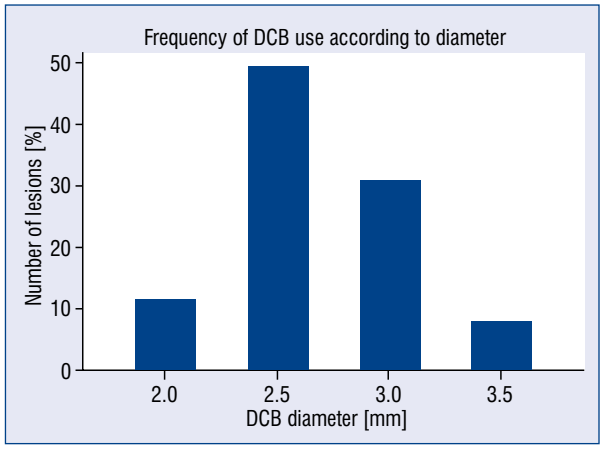

Figure 3. Diagram depicting the frequency of each drug coated balloon (DCB) used according to its diameter.

Furthermore, the percentage of DCB used according to their diameter is depicted in Figure 3. Figure 4 illustrate three representative cases, which were successfully treated using the Selution SLR™ DCB.

After a median follow-up time of 11.2 (IQR 10.0;12.6) months, the primary endpoint MACE occurred in 5 (6.8%) patients, which were all TLR. The leading mechanism of TLR was restenosis most likely attributable to recoil (3 cases, 3.9%), followed by intimal hyperplasia (2 cases, 2.8%). The narratives of the 5 patients presenting with MACE can be found in Table 4. One death secondary to pneumonia was also observed. The details about clinical outcomes are summarized in Table 5.

Discussion

According to available literature, this is the first study investigating outcomes of a real-world CAD population treated with a "DCB only" strategy in complex coronary lesions using the novel Selution SLR™ balloon. In fact, the use of DCBs for treatment of native and moreover complex coronary lesions (including calcified, CTO and ISR lesions) is not widely adopted yet. The present data not only indicates safety of a strategy using sirolimus-coated balloons for CAD treatment, but also highlights a low 1-year MACE rate (< 7%), which is lower than previously reported [6, 29, 30].

A standard PCI includes the implantation of at least one metallic stent. However, even the latest generation DES have a permanent risk of target lesion failure due restenosis or stent thrombosis ranging between 0.8% and 1% per year in simple lesions, and much higher in complex lesions, reaching up to 15% 3 years after stent implantation [6]. Several factors related to adverse long-term outcomes after stent implantation, particulary ISR and ST, have been attributed to the presence of a metallic stent, whose scaffolding properties are often only needed for a short period of time [31]. The implantation of bioresorbable scaffolds, particularly the Absorb™, was supposed to eliminate many of the limitations associated with DES, but unfortunately, those expectations have not been met. Albeit the early results were rather promising, the Absorb™ has been withdrawn from the market, since it showed to be inferior to contemporary DES for treatment of CAD [32–34]. In this context, DCBs represent an attractive alternative for a "leaving nothing behind" strategy.

It is common sense that adequate lesion preparation is key when using DCB in CAD. Especially in complex lesions, it is often challenging to achieve sufficient acute luminal gain without creating flow-limiting dissections, requiring the implantation of a stent. In order to achieve optimal luminal gain, we generally aim for adequate lesion preparation, if necessary, even combining cutting balloons (Wolverine®) and super non-compliant OPN NC® balloons. This approach led to only few flow-limiting dissections and moreover to excellent acute luminal gain, as highlighted in Table 2.

The Selution SLR™ DCB utilizes micro-reservoirs, which encapsulate the sirolimus drug.

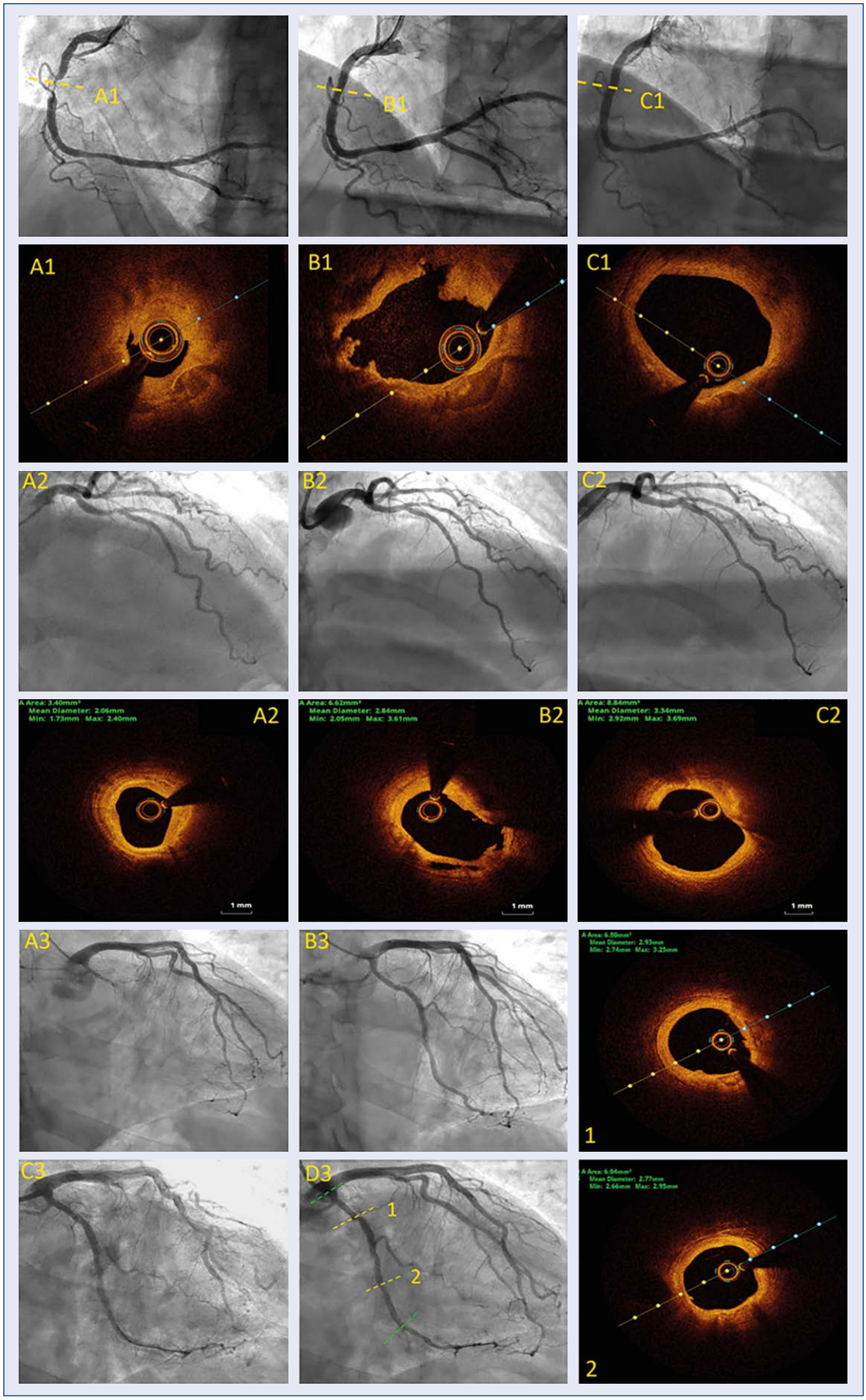
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Figure 4. Three representative cases of patients undergoing drug coated balloon-percutaneous coronary intervention (DCB-PCI) in different clinical settings, depicting angiographic and optical coherence tomography (OCT) findings at index procedure and follow-up undergoing; **A1–C1.** Patient with non-ST segment elevation myocardial infarction undergoing PCI of a subtotal stenosis of the mid right coronary artery (99% stenosis, arrow): **A1.** Initial angiogram and OCT of the culprit segment showing a heavy calcified and thrombus rich lesion; **B1.** Final angiogram and OCT after PCI with 4.0 OPN® NC (24 atm) and 1 × 4.0 × 30 mm Selution™-DCB (120 s, 10 atm) showing good acute luminal gain and no-flow limiting dissection; **C1.** Angiogram and OCT after 2 months follow-up showing both angiographic and OCT acute luminal gain and positive vessel remodeling; **A2–C2.** Patient with chronic coronary syndrome undergoing DCB-PCI of a bifurcation lesion of the proximal left anterior descending artery (LAD); **A2.** Angiogram at index procedure showing a bifurcation lesion Medina (1,0,0) of the proximal LAD. In the corresponding OCT, a mixed lipid/fibrous plaque is identified; **B2.** Angiogram and OCT findings after treatment of the main branch only, using 3.25 × 10 mm Wolverine® (20 atm), 3.5 × 15 mm (26 atm) OPN® NC and finally 1 × 3.0 × 20 mm Selution™-DCB (120 s, 6 atm) depicting an acute luminal gain with minimal luminal area (MLA) 6 mm^2 and a non-flow limiting dissection; **C2.** Angiogram and OCT at 3 months follow-up showing complete vessel healing with further luminal gain (MLA 8.8 mm^2); **A3–D3.** Patient with a chronic total occlusion (CTO) of the left circumflex artery (LCX) treated with DCB-PCI; **A3.** Angiogram showing a CTO of the LCX before PCI; **B3.** Angiogram after DCB-PCI depicting successful antegrade recanalization of the artery and treatment with 2.0 × 10 mm Wolverine® (18 atm), 2.5 × 10 mm OPN® NC (18 atm) and 1 × 2.5 × 40 mm Selution™-DCB (120 s, 6 atm) and 1 × 3.0 × 30 mm (120 s, 6 atm); **C3.** Angiogram at 6-month follow-up showing nice results with good luminal gain; **D3.** Angiogram and corresponding OCT runs (**1, 2**) at 18-month follow-up depicting persistent late luminal gain (**1, 2**).

Those micro-reservoirs are supposed to provide a sustained drug release up to 90-days [22]. Thus, the "cuts" and "cracks" created in the intima and media layers by the combined use of cutting and NC balloon represents an excellent entry port for penetration of the antiproliferative agent sirolimus.

The BASKET-SMALL II was a large trial indicating the non-inferiority of DCBs compared to DES up to 3-years follow-up [16, 35]. However, this trial was very selective and only included small vessels (< 3 mm) and rather simple coronary lesions. In contrast, the present cohort comprised a large portion of highly calcified lesions (63%), bifurcations (79%) and even CTOs (14%). Despite its complexity, this cohort showed similar MACE rate at 1-year as the pivotal BASKET-SMALL II Trial (6.8% vs. 7.5%, respectively) [16]. Likewise, the PICCOLETTO-II trial, which included mostly simple lesions and vessels with even smaller diameters than the BASKET--SMALL II trial (diameters ranged between 2.0 and 2.75 mm), reported a MACE rate of 5.6% at 1 year, which was slightly lower than observed in the present study cohort [15].

Considering the target lesion failures in the current cohort, 5 (6.8%) patients had a MACE after a median time of 187 (IQR: 140; 198) days and presented mainly with stable angina. Restenosis most likely attributable to recoil was present in 3 (3.9%) patients and intimal hyperplasia was responsible for the other 2 (2.8%) cases. While the final angiographic result at the end of the index procedure was very good in patients with intimal hyperplasia, lesion recoil was already obvious at the end of the procedure and further aggravated in the following months (**Suppl. Fig. 2**). Nonetheless, one needs to take into account that none of the studied patients required urgent revascularization. This is reassuring and indicates that in the absence of a freshly implanted DES, the treated coronary lesions may be more "forgiving" and the risk for acute vessel closure may be negligible, as long as there is good flow after DCB treatment. Although angiographic follow-up was obtained in only in a small sub-set of patients, those cases demonstrated early luminal gain and comparative OCT-imaging (at index and follow-up) showed good vascular healing, as described in a recent case report [36].

The application of DCBs in such complex lesions is relatively new and many more lessons about adequate optimal lesion preparation, plaque morphology, choice of DCB and combination with DES, remain to be learned. Furthermore, it is of paramount importance that patient safety is not compromised when applying new therapeutic approaches. This study demonstrates that the Selution® DCB is safe and effective when applied in a complex lesions with dedicated lesion preparation.

Limitations of the study

There are several limitations which apply to the present study. First, this is an observational single-center study, which may limit its generalizability and does not allow drawing firm inferences. Second, a relatively small cohort of patients was

Table 4. Narratives of the patients with a major adverse cardiovascular events (MACE).

MACE number	Time to MACE [days]	MACE presentation	Presumed cause of MACE	Indication for index PCI	Targeted vessels	Type of lesion	Target vessel	DCB diameter [mm]	DCB length [mm]	P2Y12 inhibitor
1	122	UA	Restenosis*	UA	1	No BL	Mid LAD	3.5	20	Prasugrel
2	159	Stable CAD	Restenosis*	Stable CAD	1	No BL	Mid LAD	2.5	30	Clopidogrel
3	187	Control angiography	Intimal hyperplasia	Stable CAD	1	BL (1,1,1)	Proximal LCX	2.5	30	Prasugrel
4	191	Stable CAD	Restenosis*	Stable CAD	1	BL (1,0,0)	Proximal LAD	2.5	30	Clopidogrel
5	205	Control angiography	Intimal hyperplasia	Stable CAD	1	BL (1,0,0)	Ostial LAD	3.5	20	Clopidogrel

*Most likely attributable to recoil BL — bifurcation lesion; CAD — coronary artery disease; CV-death — cardiovascular death; DCB — drug-coated balloon; NSTEMI — non-ST-segment elevation myocardial infarction; LAD — left anterior descending coronary artery; LCX — left circumflex coronary artery; PCI — percutaneous coronary intervention; RCA — right coronary artery; UA — unstable angina

Table 5. Clinical outcomes.

Clinical outcomes	6 months	1 year
Patients at follow-up	78 (100%)	76 (97%)
Primary endpoint:		
MACE	3 (3.8%)	5 (6.8%)
TLR	3 (3.8%)	5 (6.8%)
TV-MI	0 (0%)	0 (0%)
Cardiac death	0 (0%)	0 (0%)
Secondary endpoints:		
TVR	0 (0%)	1 (1.4%)
All-cause death	0 (0%)	1 (1.4%)
CABG	0 (0%)	0 (0%)
Re-hospitalisation for HF	2 (2.6%)	3 (4.0%)

Data are presented as number (percentage) and represent cumulative event rate; CABG — coronary artery bypass grafting; MACE — major adverse cardiac events; HF — heart failure < 40%; TLR — target lesion revascularization; TV-MI — target vessel myocardial infarction; TVR — target vessel revascularization

included. Third, angiographic follow-up was not routinely performed. In hindsight, this might have been helpful for better understanding vascular healing characteristics after DCB-PCI. Finally, there was no control group.

Conclusions

The present study provides important insights into the safety and feasibility of an approach using the novel sirolimus-coated Selution SLR™ balloon only for treatment of complex coronary lesions. By studying a real-world CAD cohort treated with this DCB, not only a very high rate of procedural success is highlighted (e.g., no acute vessel closure), but moreover a low rate of MACE at 1 year follow-up (< 7%). This promising signal warrants further investigation in a dedicated randomized trial comparing the Selution SLR™ balloon with contemporary DES.

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