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Immediate and short-term angiographic outcome of drug-coated balloon versus drug-eluting stent in treatment of small-vessel coronary artery disease

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***Abstract*---**Objectives: To compare the immediate and short-term (6 months) angiographic and clinical outcomes in patients with de-novo small vessel disease (SVD) treated with drug-coated balloon (DCB) versus drug-eluting stent (DES) Methods: Sixty patients underwent percutaneous coronary revascularization of SVD (reference vessel diameter <3 mm). They were randomly assigned in a 1:1 ratio to be treated with either: SeQuent® please Neo paclitaxel-eluting DCB (30 patients) or Xience Expedition Evorolimus-eluting DES (30 patients). Angiographic (using Quantitative Coronary Angiogram) and clinical outcomes (MACE) were was assessed immediately and at 6 months follow up. Results: Patients with DES had better immediate angiographic vessel wall expansion and acute lumen gain in comparison to the DCB (1.79 ± 0.21 mm vs 1.64 ± 0.20 mm, p= 0.006). At 6 months follow up, late lumen loss was significantly less in DCB group compared to DES (0.28 ± 0.29 mm vs. 0.42 ± 0.20 mm, p=0.04). However, late minimal lumen diameter (1.81 ± 0.27mm vs. 1.83 ± 0.18 mm, p=0.881), late diameter stenosis (26.3 ± 11.5% vs. 27.7 ± 7.9%, p= 0.584), and net lumen gain (1.35 ± 0.18 mm vs. 1.37 ±

0.15 mm, p= 0.79) were similar between both groups. Immediate and short-term clinical outcomes were comparable, there was no significant difference between both groups in rate of death or recurrent PCI during hospitalization. At 6 months follow up, there was no statistical difference in the rate of MACE, myocardial infarction (3.3% vs. 6.6%, p= 0.6), target lesion revascularization (10.0% vs. 7.1%, p= 1.0) in DCB group compared to DES. Conclusion: In patients with de-novo SVD, using second generation paclitaxel-eluting DCB showed to be safe and non-inferior to DES, with comparable clinical and better short term angiographic outcome.

***Keywords*---**DCB, DES, small-vessel disease, angiographic outcome.

Introduction

Percutaneous coronary intervention (PCI) of small vessel disease (SVD) represents continues challenge for interventional cardiologists. In daily practice, 20– 30% of patients undergoing PCI have significant SVD.[1] In this setting, plain balloon angioplasty and bare metal stent showed early and midterm failure rates up to 50%.[2] Even with second-generation drug-eluting stents (DES) data shows an increased risk of adverse clinical events in small coronary intervention when compared to large vessel stenting.[3]

The rational of drug-coated balloon (DCB) only PCI, leaving no metal scaffold behind, has emerged as an attractive choice for treating in-stent restenosis (ISR) and recently proposed for treating de-novo coronary artery disease.[4,5] The feasibility of the technique in SVD has been tested in several studies, however, the outcomes of this strategy remain controversial and shown mixed results.[6,7,8,9] The aim of this study was to compare the immediate and short-term (6 months) angiographic and clinical outcomes in patients with de-novo SVD treated with DCB versus second generation DES.

Methods

Study population

This was a randomized prospective, single blinded, active-treatment study, between January 2020 and January 2021. The study included 60 patients underwent percutaneous revascularization of de novo coronary lesions in SVD (reference vessel diameter [RVD] <3 mm) assessed with quantitative coronary angiography (OCA). Patients were randomly assigned in a 1:1 ratio to treatment with either SeQuent® please Neo paclitaxel-eluting DCB (B Braun, Berlin, Germany) or second generation Xience Expedition Evorolimus-eluting DES (Abbott, Santa Clara, USA).

Eligible patients were 18 years or older, with a diagnosis of stable or unstable angina. Patients with acute myocardial infarction (MI) within the previous 48 hours, or renal insufficiency (serum creatinine > 1.4 mg/dl) were excluded. Angiographic exclusion criteria included patients with more than 2 vessels disease

requiring treatment, chronic total occlusion or bifurcation lesions (Figure 2).The study protocol was approved by the local ethics committee. A written consent was obtained from enrolled patients.

Procedure and angiographic analysis

Before procedure, all patient were preloaded with 300mg of Aspirin and 300mg of clopidogrel then maintained at daily 100 mg and 75mg, respectively. Procedural anticoagulation was achieved with intravenous unfractionated heparin (10000 units) with activated clotting time maintained at 250 to 350 s. After intervention, dual antiplatelet was given for 4 weeks in stable patients treated with DCB, and for 6 to 12 months after DES implantation according to patient's clinical presentation.

Coronary angiograms were analyzed offline by (QCA) using a validated edge detection system (Syngo Artis, version VC21C, Siemens AG, Berlin, Germany). Baseline Minimal lumen diameter (MLD), reference vessel diameter (RVD), and percent diameter stenosis were measured. Post-procedure MLD, diameter stenosis and acute gain (difference between post-procedure MLD and baseline MLD) were measured to assess the immediate angiographic outcome. Late MLD, late lumen loss (LLL) (difference between post-procedure MLD and late MLD), late diameter stenosis and net gain (difference between late MLD and baseline MLD) were measured at 6 months follow up angiography. In the DCB group, the angiography performed in the same baseline projections, for accurate analysis of the treated segment.

In the DCB arm, all lesions were pre-dilated with a standard balloon. Selection of the DCB diameter based on balloon: artery ratio of 1:1 and length 2-5 mm longer than the target lesion. DCB were inflated only once for 30 to 60 seconds (s) at nominal pressure to achieve best lesion expansion and complete apposition of the balloon on the vessel wall. In cases of a suboptimal result, defined as a persistent residual stenosis (≥ 30%) or flow-limiting dissection, bare metal stent (BMS) was permitted. In the DES arm, stent implantation was performed as per standard practice and post-dilation per-operator's discretion.

Outcomes

The primary objective of this study was to show non inferiority of DCB in comparison to second generation DES. Clinical follow-up was performed with visits or telephone contact at 1 and 6 months, all patients were scheduled for coronary angiography at 6 months from initial procedure. Study endpoints included occurrence of major adverse cardiac events (MACE), defined as occurrence of death, myocardial infarction (MI), stroke, stent thrombosis or target lesion revascularization, and angiographic LLL and diameter stenosis using quantitative coronary angiography. Cardiac death was defined as death resulting from cardiovascular causes, and undetermined cause of death is defined as a death not attributable to any other category because of the absence of any relevant source documents.[20] MI was defined by elevated cardiac troponin values with at least one value above the 99th percentile upper reference limit, with

clinical symptoms and relevant ECG changes.[21] TLR was defined as any repeat revascularization within the stented or DEB-treated segment.[10]

Statistical Analysis

Data were analyzed using Statistical Program for Social Science (SPSS) version 25.0 for windows. Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency and percentage. Independent-samples t-test of significance was used when comparing between two means of normally distributed data. Chi-square (X2) test was used to discover if there is a relationship between two categorical variables. Fisher Exact test is a test of significance that is used in the place of chi-square test in 2 by 2 tables due to small sample size. The p. value <0.05 was considered significant.

Results

The baseline clinical and angiographic characteristics were well matched between both groups (Table 1), the majority of patients were female, hypertension and diabetes mellitus were the more prevalent cardiovascular risk factor in both groups with higher frequency of previous PCI in the DES group. Angiographically, right coronary artery (RCA) lesions were significantly treated with DCB (30% vs. 10%, p = 0.053). Procedure characteristics are shown in table 2. For optimal lesion preparation, routine pre-dilation was performed in all lesions in the DCB group and there was no residual stenosis (≥ 30%) or flow-limiting dissection that necessitate bailout BMS implantation.

Angiographic outcome

As shown in table 4, at baseline, there was no difference in lesion length, MLD, and diameter stenosis between both groups. Immediate post procedure analysis showed significant larger acute luminal gain, larger final lumen diameter and less diameter stenosis in DES group compared to balloon group. At 6 months follow up, late lumen loss was significantly less in DCB compared to DES (0.28 ± 0.29 mm vs. 0.42 ± 0.20, p=0.04) (Figure 1), However, late MLD, late diameter stenosis, and net lumen gain were similar between both groups.

Clinical outcome

As shown in table 5, during the index of hospitalization, there was no significant difference between both groups in term of the rates of death or recurrent PCI, only one patient had stroke in the DES group. All patients were seen at 6 months follow up, there were no statistical difference in the rate of MACE between DCB and DES; MI (3.3% vs. 6.6%, p= 0.6), TLR (10.3% vs. 7.1%, p= 1.0), respectively, moreover there was no cases of death or stent thrombosis occurred in both groups.

Discussion

In this study, we assessed the immediate, short-term angiographic and clinical outcomes of patients with de-novo SVD treated with DCB versus DES. The main

findings can be summarized as the following, there was better immediate angiographic outcomes for patients treated with DES compared to those treated with DCB, this was evident by significant larger acute luminal gain, larger final lumen diameter and less final diameter stenosis in DES group, however, at 6 months follow up, DCB significantly suppressed neointimal hyperplasia as assessed by less late lumen loss with no difference in rates of MACE, MI, and TLR between both groups.

Coronary intervention to SVD still represents a challenge due to the increased risk of adverse clinical outcomes, with higher rates of both restenosis and thrombosis.[11] This could be attributed to the limited ability of small vessels to accommodate the neointimal formation that might eventuate after stent implantation.[12] DCB is a relativily a novel concept in the management of coronary artery disease (CAD), studies using this modality have shown promising results for the treatment of ISR, and currently, DCB is a Class I indication to treat ISR, as per European Society of Cardiology guidelines.[13] In SVD, using DES may not be the optimal choice with its limitations in this setting, DCB could be an attractive treatment option.

Early data came from—(PICCOLETO) trial was not promising, the study was prematurely stopped due to the superiority of the Taxus DES over Dior I DCB in SVD patients, this was attributed to the poor efficacy of the drug used and lack of proper lesion preparation before using DCB.[6] Recently, Tanaka et al, stated that inadequate pre dilation before DCB shown to be an independent predictor of target lesion revascularization (TLR) even after adjusting for reference vessel diameter and lesion length.[14]

On the contrary, in our study, all lesions were pre-dilated adequately using either compliant or non-compliant balloons with no dissection that required bailout stenting. But due to lower dilation pressure in the DCB (10.6 ± 0.9 atm, vs 11.9 ± 1.4 atm) in DSE group, respectively, immediate post procedure angiographic analysis showed significant larger acute luminal gain, larger lumen diameter and less diameter stenosis in DES group compared to balloon group, the same findings were observed in the large randomized RESTORE SVD China study, they assessed the angiographic efficacy of Restore Paclitaxel Eluting Balloon Versus RESOLUTE Zotarolimus-Eluting Stent in treatment of SVD, acute post procedure analysis showed larger final in-segment MLD (1.65 ± 0.26 mm vs.1.98 ± 0.25 mm, $p < 0.001$) and less residual in-segment %DS (19.8 ± 8.8% vs. 12.6 ± 6.4%; $p < 0.001$) in the DES arm.[15]

Megaly et al, in metanalysis of all randomized controlled studies addressed the outcomes of DCB vs. DES in de-novo SVD showed that the use of DCB in SVD PCI is associated with smaller late lumen loss over 6 months.[16] In this study, neointimal hyperplasia was significantly suppressed as evidenced by less LLL in DCB compared to DES (0.28 ± 0.29 mm vs. 0.42 ± 0.20mm, p=0.04) at 6 months angiographic follow up. However, late MLD, late diameter stenosis, and net lumen gain were similar between both groups. Similarly, in BELLO study,[7] they compared the paclitaxel-eluting balloon (PEB) against a first-generation paclitaxel eluting stent (Taxus Liberté), pre-dilatation was performed routinely (96.8%) but with lower pressure which result in less in segment stenosis in DES group and at

6 month follow up the primary angiographic endpoint of non-inferiority regarding angiographic in-stent or in-balloon late loss was met. Both groups showed similar rates of angiographic restenosis, MACE, and repeat revascularization. Furthermore at 2 years follow up there was a tendency towards a lower incidence of MACE in PEB as compared with PES (14.8% vs. 25.3%; p = 0.08).[17]

Recently, the second generation of DCB has shown better efficacy in the RESTORE SVD China study. At 9 months follow up, the DCB was non inferior (29.6 ± 2.0% vs. 24.1 ± 2.0%, p < 0.001) compared to the DES in term of in-segment %DS as a primary angiographic endpoint.[15] In line with our results, PICCOLETO II trial showed that new generation DCB (Elutax SV, Aachen Resonance, Germany), used in de novo SVD lesions in stable or unstable patients was superior than everolimus-eluting stent (EES). In that study, after 180 days, in-lesion LLL was significantly lower in the DCB group (0.04mm vs. 0.17 mm; p = 0.001).[18]

Previous data showed that using DES in SVD double the risk of MACE particularly MI when compared to DEB.[19,3] In this study, both groups showed comparable clinical outcome in term of no MACE, MI, death or stent thrombosis at 6 months, this finding is consistently seen in other studies which compare DCBs and second-generation DES, both modalities were comparable with a similar risk of clinical events at a median follow-up of 12 months; recently, BASKET-SMALL2 showed non inferiority of the paclitaxel DCB SeQuent Please and everolimus-eluting Xience DES, at 1 year clinical follow up showed similar rate of MACE between both groups.[9]

The RESTORE SVD China study confirmed that Paclitaxel-coated balloon was not inferior to new generation DES on cardiac death, MI, and TVR in 1 year follow-up.[15] Moreover, in PICCOLETO II trial,[18] there were no significant differences between DCB and DES in the rates of target lesion failure (TLF), cardiac death, target vessel MI, and TLR at 12 months clinical follow-up, MACE occurred in 7.5% of the DES group and in 5.6% of the DCB group (p = 0.55). In the DES group, there was higher incidence of spontaneous myocardial infarction (4.7% vs. 1.9%; p = 0.23) and vessel thrombosis (1.8% vs. 0%; p = 0.15), in our study, there was no periprocedural MI or stent thrombosis.

Our findings support the strategy of leaving no metal behind in treating de-novo atherosclerotic SVD, we found that second generation paclitaxel-eluting DCB showed noninferiority to DES, with comparable clinical and better short term angiographic outcome at six months follow up.

Limitation

One of the limitations was the small sample size of the study, but we had restricted inclusion criteria and wide range of exclusion criteria. Second, longer angiographic follow up was needed to prove the sustained antiproliferative effect of DCB expressed by less late lumen loss compared to DES, however, we used second generation paclitaxel-eluting DCB in comparison to second generation Evorolimus-eluting DES. We did not use coronary imaging modality which was expected to improve the angiographic and subsequently angiographic and clinical

outcomes, however, QCA is reliable, reproducible angiographic method to assess changes in coronary vessel dimensions and it was the standard method used in similar studies.[20, 22]

Conclusions

The concept of leaving nothing behind during coronary intervention open the door for DCB with its antiproliferative effect as an alternative safe treatment strategy in de novo lesions in SVD. Our data showed that DES have relatively better immediate angiographic outcome. But DCB showed significantly better short term (6 months) angiographic outcome with no difference in MACE, MI, and TLR comparable to DES in patients with SVD.

List of abbreviations

BELLO : Balloon Elution and Late Loss Optimization trial
BMS : Bare-Metal Stent
CABG : Coronary Artery Bypass Graft
DCB : Drug-Coated Balloon
DES : Drug-Eluting Stent
%DS : Percentage of Diameter Stenosis
DM : Diabetes Mellitus
EES : Evorolimus-Eluting Stent
HTN : Hypertension
ISR : Instent-Restenosis
LLL : Late Lumen Loss
MACE : Major Adverse Cardiovascular Events
MI : Myocardial infarction
MLD : Minimal Lumen Diameter
MVD : Multi Vessel Disease
PCI : Percutaneous Coronary Intervention
PES : Paclitaxel-Eluting Stent
PTCA : Percutaneous Trans-luminal Coronary Angioplasty
RVD : Reference Vessel Diameter
SVD : Small Vessel Disease
TLR : Target Lesion Revascularization
TVR : Target Vessel Revascularization
QCA : Quantitative Coronary Angiography

Ethical approval and consent to participate: The study protocol was approved by the local ethics committee of the Cairo University and Ministry of Defense Hospitals. A written consent was obtained from all patients.
Conflict of interest: No conflict of interest associated with this work.

Funding statement: None.

Author`s contributions*:*

Ahmed Said designed the study and collected data. **Ahmed Sabry** was the main

interventionist. **Amr El-Faramawy** and **Daila El-Ramisy** managed data designing, interpretation and reviewing. **Mohamed Abdel-Ghany** was the study supervisor.

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Tables and Figures

Table 1. Baseline clinical and angiographic characteristics

	DCB (n=30)	DES (n=30)	P-value
Age (years)	58.2 ± 8.0*	59.3 ± 8.3	0.591
Risk factors			
Female gender	21 (70%)	19 (63.3%)	0.584
Smoking	6 (20%)	11 (36.7%)	0.152
Hypertension	20 (66.7%)	22 (73.3%)	0.573
Diabetes Mellitus	21 (70%)	20 (66.7%)	0.781
Family History	6 (20%)	5 (16.7%)	0.739
Dyslipidemia	15 (51.7%)	17 (56.7%)	0.703
Previous MI	5 (16.7%)	6 (20%)	0.739
Previous PCI	7 (23.3%)	10 (33.3%)	0.390
Previous CABG	2 (6.7%)	1 (3.3%)	1.000
Multivessel disease	5 (16.7%)	6 (20%)	0.739
Treated vessel			
LAD	6 (20%)	4 (13.3%)	0.488
LCX	1 (3.3%)	3 (10%)	0.612
RCA	9 (30%)	3 (10%)	0.053
Diagonal	6 (20%)	7 (23.3%)	0.754
OM	4 (13.3%)	8 (26.7%)	0.197
PDA/PL	4 (13.3%)	5 (16.7%)	1.000
Target lesion			
Reference vessel diameter (mm)	2.46 ± 0.12	2.47 ± 0.11	0.741
Lesion length (mm)	15.3 ± 3.2	17.1 ± 4.2	0.069
Baseline MLD (mm)	0.45 ± 0.13	0.45 ± 0.14	0.923
Baseline diameter stenosis (%	81.7 ± 5.1	81.9 ± 5.6	0.904

* Data are presented as mean ± SD or n (%).
MI= Myocardial infarction, PCI= Percutaneous Coronary Intervention, CABG= Coronary Artery Bypass Graft

Table 2. Baseline procedure characteristics

	DCB (n=30)	DES (n=30)	P-value
Balloon pre-dilatation	30 (100%)*	6 (20%)	<0.001
DCB			
Diameter (mm)	2.48 ± 0.13		-
length (mm)	17.3 ± 3.1		
Inflation pressure (atm)	10.6 ± 0.9		
Inflation time (sec)	51.7 ± 7.2		
Dissection+ BMS	0 (0%)		
DES			
Diameter (mm)		2.50 ± 0.11	-
length (mm)		18.5 ± 4.3	
Inflation pressure (atm)		11.9 ± 1.4	
Post-dilatation, n (%)		8 (26.7%)	

* Data are presented as mean ± SD or n (%).
DCB= drug coated balloon, DES= drug eluting stent, BMS= bare metal stent, atm= atmospheric pressure, sec= seconds

Table 3 Immediate and short term (6 months) angiographic outcome

	DCB (n=30)	DES (n=30)	P-value
Immediate post procedure			
Final lumen diameter (mm)	2.09 ± 0.16*	2.24 ± 0.15	0.001
Final diameter stenosis (%)	15.3 ± 6.8	9.5 ± 4.6	<0.001
Acute gain (mm)	1.64 ± 0.20	1.79 ± 0.21	0.006
Six months follow up			
Late MLD (mm)	1.81 ± 0.27	1.83 ± 0.18	0.881
Late diameter stenosis (%)	26.3 ± 11.5	27.7 ± 7.9	0.584
Late lumen loss (mm)	0.28 ± 0.29	0.42 ± 0.20	0.040
Net gain (mm)	1.35 ± 0.18	1.37 ± 0.15	0.792

* Data are presented as mean ± SD or n (%).
MLD= minimal lumen diameter

Table 4. Six months clinical outcome.

	DCB (n=30)	DES (n=30)	P-value
In-hospital outcomes			
Recurrent PCI	0 (0%)	0 (0%)	-
Death	0 (0%)	0 (0%)	-
Stroke	0 (0%)	1 (3.3%)	1.000
6-months outcomes			
MI	1 (3.3%)	2 (6.6%)	0.611
Stent thrombosis	0 (0%)	0 (0%)	–
Death	0 (0%)	0 (0%)	-
TLR	3 (10.0%)	2 (7.1%)	1.000

Data are presented as number (%).

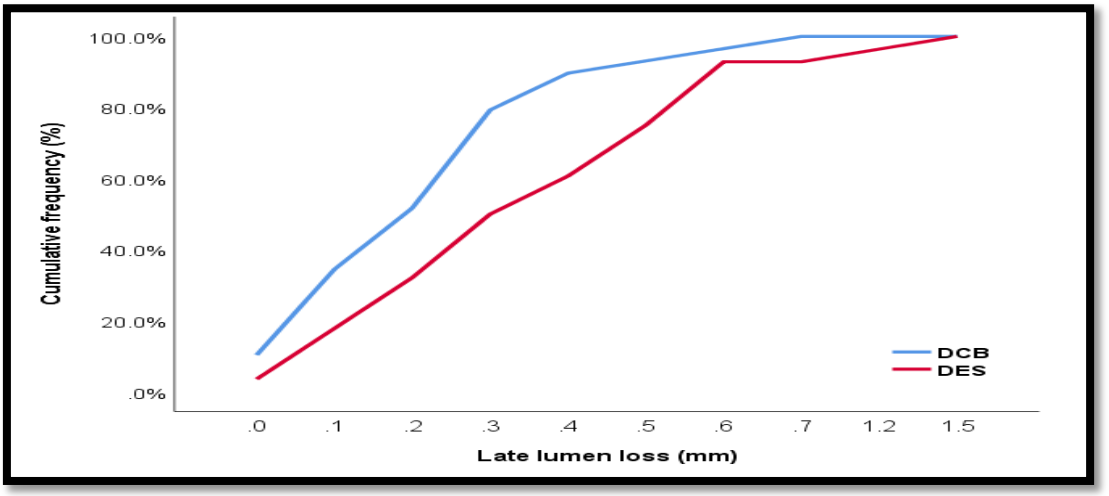

Figure 1. The cumulative percentage of late lumen loss in DES and DCB groups.

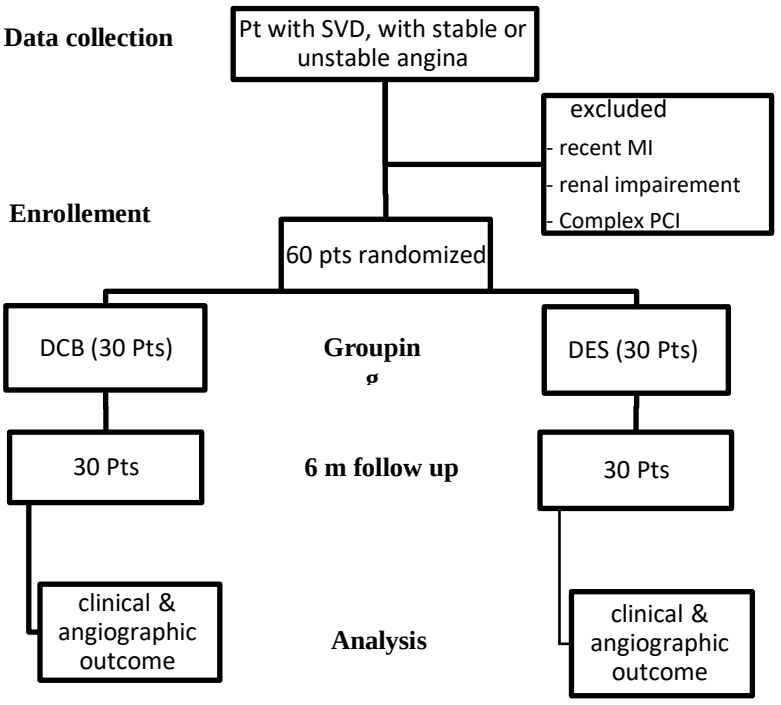

Figure 2. Flow chart for patient selection. SVD= small vessel disease, MI= myocardial infarction, DCB= drug coated balloon, DES= drug eluting stent, Pts= patients.