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Clinical Outcomes of Drug Coated Balloons versus Drug Eluting Stents in Ostial Left Circumflex Coronary Lesions, Single Center Experience

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ABSTRACT

Background: Therapeutic management for isolated coronary stenosis involving the left anterior descending (LAD) or left circumflex artery (LCx) ostium is challenging. This is attributed to the unpredictable involvement of the distal left main (LM) coronary artery, as reported in a previous intravascular ultrasound (IVUS) study.

Aims and objectives: To compare between stenting ostial left circumflex artery lesions (LCx) vs drug coated balloon as single center experience with impact on Major adverse cardiac events after 6 months.

Subjects and methods: This retrospective study was conducted at Cardiology Department, Zagazig University Hospitals. This study was done on 88 patients who were divided into 2 groups: Drug-coated balloon group: 44 patients and drug-eluting stent group: 44 patients.

Result: Significant differences were found in left ventricular ejection fraction, previous PCI history, coronary dissection after Drug Coated Ballon Angioplasty (DCBA)post-intervention Minimal Lumen diameter(MLD), acute lumen gain, target lesion revascularization and ,Major Adverse Cardiac Events(MACE) Highly significant differences were observed in maximum pre-dilation balloon diameter, Drug coated ballon/ Drug Eluting Stents (DCB/DES)length and number, inflation pressure, follow-up MLD, and late lumen loss.

Conclusion: DCB was connected with lower long-term risks of Target Lesion Revascularization(TLR) and MACEs. It is suggested that use of the DCB strategy alone or usage of the hybrid strategy is safe and effective for the treatment of de novo ostial LCx lesions with a low technical threshold and a high success rate.

Keywords: Stenting ostial left circumflex artery lesions, Drug coated ballon, Single center experience, MACE

INTRODUCTION

Therapeutic management for isolated coronary stenosis involving LAD or left circumflex artery LCx ostium is challenging. This is attributed to the unpredictable involvement of the distal LM coronary artery, as reported in a previous intravascular ultrasound (IVUS) study [1,2].

Various stenting techniques, including ostial and crossover stenting, have been investigated. Because of the preexisting struts at the ostium, the outcomes have not always been ideal. While localized stenting is frequently performed, it can lead to insufficient lesion coverage or the proximal stent border protruding into the neighboring vessel's ostium[3].

Another potential obstacle is plaque movement, which might endanger nearby vessels[4]. Successful stenting of the LM from the MV, sometimes known as the "crossover approach," has been documented. Metal struts covering the side branch (SB) ostium, SB blockage, or severe stenosis due to carina and plaque shift are issues linked with the crossover technique[5].

The best method for ostial LAD or LCx lesion is debatable. Drug coated balloons **(**DCBs) treat in-stent restenosis without permanent struts using antiproliferative drugs [6,7].

DCBs are useful for treating de novo coronary lesions [8,9]. with major benefits in the context of small vessel disease. Using DCBs for bifurcation lesion management has been proposed as a possible therapeutic strategy in previous research [10,11].

the aim of this study was to assess stenting of LCx with drug-coated balloon treatment, based on a single-center experience, and its effect on MACE after six months.

PATIENTS AND METHODS

This retrospective study was done at Cardiology Department, Zagazig University Hospitals. This study was conducted on 88 patients who were divided into 2 groups:

- Drug-coated balloon group: 44 patients
- Drug-eluting stent group: 44 patients

Inclusion criteria: (1) coronary vessel lesions sized 2.5–4.0 mm; and (2) narrowing (diameter stenosis ≥ 50%) within 3 mm from the LAD/LCx takeoff based on the least foreshortened angiographic projection (scilicet, Medina 0, 1, 0 and 0, 0, 1).

Exclusion criteria: (1) angiographically confirmed concomitant distal LM stenosis > 30%; (2) Medina 0, 1, 1 LM bifurcation; (3) nonadherence to the described procedural optimization steps, as revealed by angiographic films and report reviews; (4) myocardial infarction (MI); (5) severe valvular disease or cardiomyopathy; (6) hemodynamic instability or cardiogenic shock; (7) left ventricular ejection fraction (LVEF) ≤ 35% (8) severe renal or hepatic dysfunction.

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METHODS

Prior to the intervention, patients who had not previously been prescribed long-term aspirin medication were given 300 mg of aspirin. A loading dose of either 600 mg of clopidogrel or 180 mg of ticagrelor was given. Individuals who had undergone DCB were required to undergo dual antiplatelet therapy DAPT for a duration of one to three months following the surgery. Consistent with the guidelines, patients who had stents implanted at the same time continued to undergo DAPT [12,13].

Exclusion criteria for participation in the trial were a history of heparin, DAPT, limus, or paclitaxel hypersensitivity or contraindication; being a woman of reproductive age; or having a predicted life expectancy of a year or less.

Study Procedures

In the DES group, ostial LAD/LCx lesions was done using any solutions with DES alone according to European Bifurcation Club guidelines [14]. In favorable anatomical conditions, such as a rectangular LAD-LCx angle and clear SB take-off, precise ostial stenting was an alternative to crossover stenting. Otherwise, stent strategies were used to cover both the LM and the diseased vessel, usually the LAD or LCx, via a crossover approach. Proximal optimization technique (POT) was recommended, using a stent with appropriate length (8–9 mm) in the LM to fit the required balloon size. If there were suboptimal results at the SB ostium or future PCI was needed, SB rewiring and kissing balloon inflation were considered, especially in younger patients with significant myocardial mass supplied by the SB[15]. Prior to DCB angioplasty, it was stressed that the lesion had to be well prepared. A balloon-to-vessel ratio of 0.8-1.0 was required for pre-dilation using a plain balloon, non-compliant balloon, scoring balloon (which may include non-slip element (NSE) scoring and cutting balloons), and any combination thereof. No substantial flow-limiting dissection was seen during the DCB-only angioplasty procedure, which was classified as type C according to the National Heart, Lung, and Blood Institute [16] or if at least two perpendicular angiographic images showed a residual stenosis of 30% or less .

A hybrid technique was employed when the amount of remaining stenosis in the proximal 5 mm following lesion preparation was 30% or less. Stent deployment followed DCB angioplasty, with a minimum distance of 3 mm between the stent and the vascular ostium to prevent plaque movement. A paclitaxel and iopromide coating was applied to the DCB (SeQuent TM Please, B. Braun in Europe, brazil, turkey and india which was then sized to the reference vessel using a balloon/vessel ratio of 0.80-1.00. Newer DESs were implanted in cases of extensive dissection or residual stenosis.

Endpoint Definitions

Major adverse cardiovascular events (MACE) including cardiac mortality, target lesion revascularization (TLR), MI and artery thrombosis were recorded as the main outcome of the trial at six months. PCI or CABG with restenosis or thrombosis at the target lesion was characterized as TLR. Subject rates of myocardial infarction, thrombosis in blood vessels, and cardiac mortality were considered secondary outcomes. MI was categorized as either periprocedural (within 48 hours) or spontaneous (beyond 48 hours) based on the presence of troponin levels that were five times the reference limit, ischemic ECG abnormalities, or myocardial damage. The Academic Research Consortium (**2011***)* [24] established the definition of vessel thrombosis. Cardiogenic reasons of death were not known.

Quantitative Coronary Angiography (QCA) Assessment

By applying edge detection techniques, QCA measurements were carried out with a guiding catheter as the calibration reference (QAngio XA version; Medis Medical Imaging, Leiden, the Netherlands). There were three sets of measures taken: before the surgery, immediately after, and after six months. Acute luminal gain (MLD post-intervention minus baseline MLD) and late lumen loss (LLL; MLD post-procedure minus MLD at follow-up) were calculated from the following QCA variables: (1) lesion length; (2) reference vessel diameter (RVD); (3) percent diameter stenosis; (4) minimal lumen diameter (MLD); (5) percent area stenosis.

Ethical Consideration

The Ethics Committees at Zagazig Faculty of Medicine authorized this study. Participants provided written informed consent before to engaging in the experiment. Data were gathered via a standardized computerized case report form. The Helsinki Declaration was followed throughout the study's conduct.

Statistical analysis

The data that were collected were then evaluated using software and shown in tables or suitable graphs by computer software. We used the Statistical Package for the Social Sciences (SPSS-20 Inc., Chicago, Illinois, USA for statistical analysis) software for further examination. We deemed results significant in statistics if the p-value was < 0.05. Quantitative variables were presented as the mean $\pm$ standard deviation (SD), whereas qualitative variables were existing as total number and percentage. For the comparison, the student "t" test, Mann Whitney test, and chi-square test (X^2) were employed.

RESULTS

According to table 1, age and gender did not differ across groups, although LVEF did.

Table 1: Demographic dispersion in investigated groups.

	DCB group N=44	DES group N=44	P value
Age Mean ± SD	57.78 ± 10.61	59.89 ± 11.59	0.38
Sex			
Male	32 (72.72%)	34 (77.27%)	0.62
Female	12 (27.27%)	10 (22.72%)	
LVEF Mean ± SD	62±1.25	59±1.02	<0.001*

In table 2, there was a significant difference among groups in prior PCI histories, but not in smoking, hyperlipidemia, diabetes, hypertension, or family history of CAD.

Table 2: Distribution of comorbidities data among studied groups.

	DCB group N=44	DES group N=44	P value
Diabetes mellitus	13 (29.54%)	15 (34.09%)	0.65
Hypertension	22 (50%)	23 (52.27%)	0.83
Smoking	17 (38.63%)	15 (34.09%)	0.66
Hyperlipidemia	12 (27.27%)	14 (31.81%)	0.64
Previous PCI history	11 (25.00%)	4 (9.09%)	0.047*
Previous CABG history	2 (4.54%)	1 (2.27%)	0.55
Family history of CAD	10 (22.72%)	8 (18.18%)	0.60

PCI: percutaneous coronary intervention.
CABG: coronary artery bypass grafting, CAD: coronary artery disease, *: Significant

No significant changes were identified in vascular access, SYNTAX score, or bailout stenting. Statistically significant differences were found in coronary dissection following DCBA, as well as in maximal pre-dilation balloon diameter, DCB and/or DES length, number of DCBs/DESs per lesion, inflation pressure (bar) (Table 3 and figures 1 and 2).

Table 3: Distribution of procedural and angiographic characteristics among studied groups.

	DCB group N=44	DES group N=44	P value
Vascular access			
Trans-radial	2 (4.54%)	1 (2.27%)	0.55
Trans-femoral	42 (95.45%)	43 (97.72%)	
Maximum pre-dilation balloon diameter, mm Mean ± SD	3.07 ± 0.34	2.76 ± 0.6	≤0.004*
SYNTAX score Mean ± SD	26.77 ± 5.42	28.09 ± 5.62	0.27
Length of DCB and/or DES (mm) Mean ± SD	20.71±2.62	17.25±1. 46	≤0.001*
Number of DCBs/DESs used (per lesion) Mean ± SD	1.44 ± 0.50	1.12 ± 0.40	≤0.001*
Inflation pressure (bar) Mean ± SD	8.50 ± 1.49	11.03 ± 2.05	≤0.001*
Coronary dissection after DCBA			
None	27 (61.36%)	14 (31.81%)	0.01*
Type A	11 (25.00%)	8 (18.18%)	
Type B	3 (6.81%)	8 (18.18%)	
Type C	2 (4.54%)	7 (15.90%)	
Type D	1 (2.27%)	5 (11.36%)	
Type E	0 (0.00%)	2 (4.54%)	
Bailout stenting	3 (6.82%)	1 (2.27%)	0.31

*: Significant

The groups had no significant difference in pre-intervention but post-intervention MLD, acute lumen

gain, or follow-up MLD (mm) and late lumen loss was extremely significant (Table 4 and figure 3).

Table 4: Distribution of quantitative coronary analysis among studied groups.

	DCB group N=44	DES group N=44	P value
Pre-intervention MLD (mm) Mean ± SD	1.04 ± 0.56	1.01 ± 0.43	0.72

Cardiovascular mortality and target vessel myocardial infarction were not substantially different across groups, but target lesion revascularization and MACE were (Table 5 and figure 4).

Table 5: Distribution of outcomes among studied groups

	DCB group N=44	DES group N=44	P value
TLR	1 (2.27%)	6 (13.63%)	0.049*
MACE	2 (4.54%)	8 (18.18%)	0.04*
Cardiac death	0 (0.00%)	2 (4.54%)	0.15
TVMI			
Periprocedural	0 (0.00%)	0 (0.00%)	1
Non-periprocedural	0 (0.00%)	1 (2.27%)	0.31

TVMI: target vessel myocardial infarction,*: Significant.

DISCUSSION

This study compared between stenting ostial left circumflex artery lesions (LCX) vs drug coated ballon (DCB) as single center experience with impact on MACE after 6 months.

Our study found no statistically significant difference in age or gender across groups, although the difference in LVEF was significant.

In accordance with the findings that we obtained, **Liang *et al.*** [17] conducted an investigation on the safety and practicability of the DCB policy in cases who had ostial LAD or ostial LCx lesions. They contrasted it with DES-only. The two groups had a statistically significant difference in LVEF but not age or gender.

Furthermore, **Lu *et al.*** [18] evaluated the effectiveness and security of DCB for people with ostial lesions of the left anterior descending or left circumflex arteries. A statistically significant difference in LVEF was identified, but not in age or sex.

The current investigation revealed no statistically significant differences in smoking, hyperlipidemia, diabetes mellitus, hypertension, past CABG history, or family history of CAD; however, a statistically significant difference was seen in the history of previous PCI. Similarly, **Lu *et al.*** [18] found that smoking, diabetes mellitus, hypertension, hyperlipidemia, previous CABG history, and history of CAD were not significantly different between the groups that were studied, but there was a significant difference when it came to previous PCI history.

Also, **Liang *et al.*** [17], reported that there was no significant difference among the 2 studied groups concerning hypertension, hyperlipidemia, smoking, Previous CABG history and Family history of CAD.

The current study reported that there was statistically significant difference regarding coronary dissection after DCBA and there was highly statistically significant difference concerning maximum pre-dilation balloon diameter (mm), length of DCB and/or DES (mm), number of DCBs/DESs used (per lesion) and inflation pressure (bar) between studied groups.

Similarly**, Liang *et al.*** [17], revealed that in terms of maximum pre-dilation balloon diameter (mm), DCB and/or DES length (mm), and inflation pressure (bar), there was a highly statistically significant difference among the groups that were analyzed.

We found that pre-intervention MLD (mm) was not statistically significant, while post-intervention MLD, acute lumen gain, and follow-up MLD and LLL were substantially different.

Liang *et al.* [17] observed no statistically significant difference among groups in pre-intervention MLD (mm), post-intervention MLD, acute lumen gain, and follow-up MLD and LLL.

In addition, **Cortese *et al.*** [19] evaluated the efficacy of an everolimus-eluting stent (EES) and a new DCB in treating patients with newly formed lesions. MLD and % diameter stenosis did not differ appreciably. They found that the DCB group had a substantially reduced (LLL).

The findings of this study demonstrated that although there was a statistically significant difference in MACE and TLR, there was no statistically significant difference in cardiac death and TVMI among the populations that were investigated.

Consistent with **Liang *et al.*** [17], we also found that DCB was more effective than DES in treating ostial LCx or LAD lesions in the three locations that took part in the study. The researchers found that the incidence of TLR and MACEs was reduced in patients managed with the DCB technique after PCI in comparison to those treated with the DES approach. Both the DCB alone and the hybrid strategy were safe and effective for de novo ostial LAD/LCx lesion treatment. The two groups had similar rates of cardiac mortality, TVMI, and vascular thrombosis, suggesting that DCB can replace stenting or be the first-choice therapy for eligible patients.

This study also supported **Vaquerizo *et al.*'s**[20] retrospective registry of second-generation DCBs for SB ostial lesions (excluding LM bifurcation lesions). The second-generation DCB-Dior II balloon catheter was used to treat 49 cases of de novo Medina 0, 0, 1 lesions and myocardial ischemia with an angiographic success rate of 86% [14% of patients received a bare metal stent for coronary dissection of more than type B or acute recoil]. The MACE rate was 14.3 percent at 12.2 ± 2.2 months, with 0 cardiac deaths, 7 TLRs, and 1 MI. Thrombosis and occlusion were absent. Binary restenosis occurred in 7 patients (22.5%) at 7.2 ± 1.1 months, with a late loss of 0.32 ± 0.73 mm. However, this research omitted ostial LAD/LCx lesions and had a short RVD (2.18 ± 0.34 mm), which may explain the high TLR rate. MACEs and TLR were rarer than RVD, which averaged over 3 mm.

The study performed by **Lu *et al.*** [18] discovered that there was no significant difference among both groups with regard to either the primary or the secondary endpoints (which included MACE, cardiac mortality, TVMI and vascular thrombosis). In terms of the association between treatment approach (DCB-only versus hybrid) and TLR, there was no statistically significant correlation. The researchers came to the conclusion that the safety and efficiency of utilizing DCB alone for ostial LAD and ostial LCx lesions were equal to those of using DCB in conjunction with DES. According to this technique, ostial LAD and LCx disorders are able to be treated in an efficient and technically straightforward manner.

Recent research comparing crossover stenting to one stent placed exactly at the LAD ostium showed that it is feasible and reduces restenosis[21]**.** Thus, based on current knowledge, ostial stenting should be avoided, except if the anatomy is favorable (rectangular angle among the LAD and the LCx, un-diseased LM, and perfect visualization of SB takeoff).

Cortese *et al.* [19] also found no statistically significant difference between MLD and % diameter stenosis. At the 12-month clinical follow-up, 7.5% of the DES group and 5.6 percent of the DCB group experienced severe adverse cardiac events. A greater number of cases of spontaneous myocardial infarction and thrombosis of the blood vessels occurred in the DES group [22].

Erglis *et al.* [22] also evaluated double stent scaffolds for LM bifurcation lesions affecting the LCxostium. In the LCx ostium, DES and a bioresorbable vascular scaffold (BVS) were used to treat the LM extension into the LAD. They looked at how this strategy might play out in the long run. They found that optimizing intravascular ultrasonography following surgery and preparing LCx lesions with a cutting balloon avoided (MACE). Following four years of data gathering, the imaging-guided double stent scaffold technique proved to be technically successful in all patients, with DES placed in the LM and BVS in the LCxostium. The strategy was also quite safe and effective.

CONCLUSION

We found that DCB reduced the risk of TLR and MACEs in the long run. With a low technical threshold and a high success rate, it is proposed that using the DCB technique alone or in combination with the hybrid strategy is safe and successful for treating de novo ostial LCx lesions.

Certainly, the future implementation of randomized controlled trials is of utmost importance for the validation of our research findings.

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REFERENCES

1. **Yun K, Cho J, Lee S *et al.* (3-33):** Optimal technique for ostial left anterior descending coronary artery lesion. J Cardiovasc Interv., 1(4):151–7.
2. **Kayaert P, Coeman M, Gevaert S *et al.* (2021):** Physiology-based revascularization of left main coronary artery disease. J Interv Cardiol., 2021(1):4218769.
3. **Jaffe R, Halon D, Shiran A *et al.* (2015):** Percutaneous treatment of aorto-ostial coronary lesions: current challenges and future directions. Int J Cardiol,. 186:61–6.
4. **Grodecki K, Cadet S, Staruch A *et al.* (2021):** Noncalcified plaque burden quantified from coronary computed tomography angiography improves prediction of side branch occlusion after main vessel stenting in bifurcation lesions: results from the CT-PRECISION registry. Clin Res Cardiol. ,110:114–23.
5. **Erbel R, Aboyans V, Boileau C *et al.* (2014):** ESC guidelines on the diagnosis and treatment of aortic diseases. Kardiol Pol (Polish Hear Journal),72(12):1169–252.
6. **Lu W, Zhu Y, Han Z *et al.* (2017):**Drug-coated balloon in combination with bare metal stent strategy for de novo coronary artery disease: a PRISMA-compliant meta-analysis of randomized clinical trials. Medicine (Baltimore),96(12):e6397.
7. **Wang X, Lu W, Wang X *et al.* (2020)**:Drug-coated balloon angioplasty: predicting outcomes based on different patterns of drug-eluting stent restenosis. Int J Cardiovasc Imaging, 36:171–8.
8. **Lu W, Zhu Y, Han Z *et al.* (2019)**: Short-term outcomes from drug-coated balloon for coronary de novo lesions in large vessels. J Cardiol. ,73(2):151–5.
9. **Jeger R, Farah A, Ohlow M *et al.* (2015):** Long-term efficacy and safety of drug-coated balloons versus drug-eluting stents for small coronary artery disease (BASKET-SMALL 2): 3-year follow-up of a randomised, non-inferiority trial. Lancet ,396(10261):1504–10.
10. **Mínguez J, Asensio J, Vecino L *et al.* (2014):**. A prospective randomised study of the paclitaxel-coated

balloon catheter in bifurcated coronary lesions (BABILON trial): 24-month clinical and angiographic results. EuroIntervention,10(1):50–7.

11. **Worthley S, Hendriks R, Worthley M *et al.* (2015)**:Paclitaxel-eluting balloon and everolimus-eluting stent for provisional stenting of coronary bifurcations: 12-month results of the multicenter BIOLUX-I study. Cardiovasc Revascularization Med.,16(7):413–7.
12. **Valgimigli M, Bueno H, Byrne R *et al.* (2018):** ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS: the Task Force for dual antiplatelet therapy in coronary artery disease of the European Society of Cardiology (ESC) and of the European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J ., 39: 213−260.
13. **Neumann F, Sousa-Uva M, Ahlsson A *et al.* (2019):** 2018 ESC/ EACTS guidelines on myocardial revascularization. Eur Heart J ., 40: 87−165
14. **Burzotta F, Lassen J, Banning A *et al.* (2018):** Percutaneous coronary intervention in left main coronary artery disease: the 13th consensus document from the European Bifurcation Club. EuroIntervention ., 14: 112−120
15. **Lu W, Pan L, Han Z *et al.* (2022):** Stentless at ostium: a novel approach for treating ostial left anterior descending or left circumflex coronary artery lesions with drug-coated balloons. Am J Transl Res.,14: 6256−6267.
16. **Huber MS, Mooney JF, Madison J *et al.* (1991)**: Use of a morphologic classification to predict clinical outcome after dissection from coronary angioplasty.Am J Cardiol ., 68: 467− 471
17. **Liang P, Wen-Jie L, Zhan-Ying H *et al.* (2023)**:Drug-coated balloons for the treatment of ostial left anterior descending or ostial left circumflex artery lesions: a patient-level propensity score-matched analysis. J Geriatr Cardiol JGC. ,20(10):716.
18. **Lu W, Pan L, Han Z *et al.* (2022)**: Stentless at ostium: a novel approach for treating ostial left anterior descending or left circumflex coronary artery lesions with drug-coated balloons. Am J Transl Res. ,14(9):6256.
19. **Cortese B, Di Palma G, Guimaraes M *et al.* (2020):** Drug-coated balloon versus drug-eluting stent for small coronary vessel disease: PICCOLETO II randomized clinical trial. Cardiovasc Interv. ,13(24):2840–9.
20. **Vaquerizo B, Fernández-Nofreiras E *et al.* (2016):**Second-generation drug-eluting balloon for ostial side branch lesions (001-bifurcations): mid-term clinical and angiographic results. J Interv Cardiol. ,29(3):285–92.
21. **Rigatelli G, Zuin M, Baracca E *et al.* (2019)**: Long-term clinical outcomes of isolated ostial left anterior descending disease treatment: ostial stenting versus left main cross-over stenting. Cardiovasc Revascularization Med. ,20(12):1058–62.
22. **Erglis A, Narbute I, Sondore D *et al.* (2022):** Four-Year Outcomes of Left Main Percutaneous Coronary Intervention with a Bioresorbable Scaffold in the Circumflex Ostium. J Interv Cardiol. ,2022(1):7934868.
23. **The Academic Research Consortium (*2011):*** Autopsy validation study of the academic research consortium stent thrombosis definition. JACC Cardiovasc Interv., 4(5):554-9.