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Safety And Efficacy Of Drug-Coated Balloon In Large Coronary Artery Disease

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Abstract

Objective: Coronary artery disease is one of the leading causes of death worldwide for which various therapeutic interventions have been proposed. The use of drug-coated balloons (DCBs). DCBs have gained attention as a promising tool for the treatment of large coronary artery disease. This study aims to see the efficacy and clinical outcomes of DCB therapy in large coronary artery disease.

Methods: This prospective observational study involving 60 patients of CAD, was conducted in the Department of Cardiology, Rawalpindi Institute of Cardiology, Rawalpindi. The patients with large coronary artery disease were included and treated with DCB therapy. The effectiveness of DCB as the primary outcome in terms of target lesion revascularization was observed over time. Similarly secondary (adverse outcomes) were also assessed and represented as frequencies and percentages. Analysis was done by SPSS.V.26.

Results: In our study, the mean age was 55.217±9.814 and the mean diameter of the target vessel was 3.1 ± 0.249 mm while that of the lesions was 25.25 ± 8.1 mm. On follow-up, target lesion revascularization was noted in only 8 (13.3 %), similarly, the adverse outcomes like MI in 4 (6.7%), target vessel thrombosis in 5 (8.3%), dyspnea in 8 (13.3%), effort angina in 10 (16.7%), and death was reported in just 2 (3.3%) of the patients.

Conclusion: The use of DCB therapy resulted in a significant reduction in the proportion of patients requiring target lesion revascularization, which was the primary outcome measure. Furthermore, the secondary (adverse) outcomes exhibited a notable decrease in patients who received DCB therapy, thus demonstrating the efficacy of DCB therapy in individuals with large coronary artery disease.

Keywords: Coronary artery disease, Balloon Angioplasty, Myocardial Revascularization, Coronary Thrombosis, Coronary vessels

Introduction

Coronary artery disease (CAD) is one of the leading causes of morbidity and mortality over the globe and is posing a significant healthcare burden.[1] Over the years, coronary artery disease has been treated successfully with PCI using drug-eluting stents. Stenting overcomes the weaknesses of balloon angioplasty alone which include acute recoil, dissection and negative vessel remodeling, but not restenosis because of continued or increased neointimal proliferation with stent. Challenges associated with these problems have led to the development of various intervention techniques, including drug-coated balloons (DCB). DCBs have become popular as a potentially valuable tool in the treatment of large coronary artery disease, using a mechanical, and pharmacological effect. Late lumen loss in large coronary artery disease treated with a DCB was significantly reduced to those treated with standard balloon DCBs that consist of an angioplasty balloon carrying an antiproliferative drug, typically paclitaxel or sirolimus. Released locally in the stenotic artery segment, when inflated, the drug exerts its inhibitory effect in neointimal proliferation.[2] This mechanism is to be used to avoid restenosis, a frequent complication following procedures with percutaneous coronary intervention (PCI) especially in large vessels.

In addition to its antiproliferative properties, DCBs have a mechanical effect in the sense of dilating the narrowed vessel, thereby improving blood flow and myocardial perfusion.

Contributions:
S.H, H.S, A.J, - Conception of study - Experimentation/Study Conduction
S.H, T.A.R, N.P, A.R - Analysis/Interpretation/Discussion
H.S, A.J, A.R - Manuscript Writing
S.H, T.A.R, N.P, - Critical Review

All authors approved the final version to be published & agreed to be accountable for all aspects of the work.

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In several clinical studies, DCBs have demonstrated promising results in large coronary artery disease. DCB therapy has been shown by Nakamura et al. in a randomized controlled trial to be beneficial in patients undergoing angioplasty, demonstrating good outcomes and effectiveness, particularly in large coronary vessels.[3] Also, Felbel et al. in a meta-analysis reported that lower rate of target lesion revascularization in patients treated with DCBs relative to bare metal stents.[4] These findings imply that DCBs may offer improvements in patient outcomes among patients with large coronary artery disease.

Another advantage of DCBs is that they can transport the antiproliferative drug to the target lesion without systemic exposure and the side effects of oral or intravenous administration. Lu et al. described various technological advancements in DCBs that ensure localized drug delivery, improving efficacy while minimizing systemic toxicity.[5] This approach at localized drug delivery also may decrease the risk of stent thrombosis, a serious problem associated with stent-based intervention. Thus, the DCBs are efficacious in large coronary artery disease due to their ability to treat focal stenosis and diffuse disease segments. Unlike stent interventions, DCBs distribute drugs uniformly the entire lesion perimeter, including edges.[6] This feature is especially useful in coronary artery disease of a large size where diffuse disease requires treatment of long-length segments. DCBs are a more comprehensive approach to lesion treatment compared to other DCBs on the market that address only the focal component, resulting in a possibly less need for additional interventions.

However, there are still several challenges in the use of DCBs for large coronary artery disease. The long-term efficacy and safety of the DCBs need to be established through rigorous long-term studies. Although early clinical trials have shown promising results, longer follow-up periods are necessary to assess the durability of the treatment effect and the potential for late adverse events. The objective of this prospective observational study is to see the efficacy and clinical outcomes of DCB therapy in large coronary artery disease.

Materials And Methods

This prospective observational study involving 60 patients of large coronary artery diseases, was conducted in the department of interventional cardiology of Rawalpindi Institute of Cardiology, Rawalpindi. The study was conducted from December 2023 to May 2024. The enrollment of the patients was done using a stratified random sampling technique. All patients who were diagnosed with large coronary artery disease (LCAD), and having aged between 18-80 years were included. LCAD was defined as CAD affecting large-calibre coronary vessels, those with a diameter of ≥2.75 mm, where significant stenosis or occlusion occurs, necessitating intervention. Patients with diffuse coronary artery disease were also included in the study, Similarly, those with a history of active bleeding, recent bleeding in two months, stent restenosis, disease in coronaries < 2.75mm in diameter, and dissection type C or more or more than 30% recoil, after pre-dilatation of the diseased segment, were excluded from our targeted population.

The main outcome of our study was the Target lesion revascularization rate followed by some secondary outcomes like MI, death, target vessel thrombosis, dyspnea and effort angina. The analysis was done by using SPSS.V.26. Qualitative data was presented by frequencies and percentages, similarly, quantitative data was presented by mean and standard deviation. The correlation between categorical variables (type of vessel, gender, number of vessels, indication of procedure, and risk factors) and the primary outcome was done through Fischer exact test, similarly, the correlation between continuous variables (age, vessel diameter and length of lesion) and the primary outcome was done through Whitney-Mann nonparametric test. A P-value of less than 0.05 was considered significant.

Procedure details:

Patients underwent percutaneous coronary intervention (PCI) via radial or femoral artery using a 6–8 Fr guiding catheter. Heparin was administered, maintaining ACT >250 s. Patients received aspirin 300 mg and Clopidogrel 300 mg before PCI. Inclusion criteria required the absence of flow-limiting dissection, dissection type C or more, and <30% recoil after pre-dilation. Pre-dilatation was done with a balloon-to-artery diameter ratio of 0.75:1 or 1:1. Drug-coated balloon (DCB) size did not exceed the pre-dilatation balloon diameter. DCB inflation time was 30-60 s. Post-procedure patients were prescribed aspirin (75mg/day) and Clopidogrel (75 mg/day) for 1 month, followed by lifelong aspirin 75 mg. Follow-up included clinical assessments at 2 weeks, 1 month, 3 months, and 6 months, with optional angiography in case of angina symptoms.

Results

A total of 60 patients were taken under study. Of these, the majority (n=52, 86.7%) were males. The mean age was 55.217±9.814. The majority of patients had no known risk factor (n=24, 40%). The distribution of Risk factors is shown in Figure 1. The mean LVEF was noted to be 40 ± 13.76%. The majority of the patients (n=39, 65%) had STEMI as the indication for intervention followed by NSTEMI (n=12, 20%) and effort angina (n=9, 15%), while the LAD was involved in 25 (41.7%) patients followed by involvement of all three vessels 10 (16.7%), and RCA (13.3%) and LCX (6.7%). The mean diameter of the target vessel was 3.1 ± 0.249 mm while that of the lesions was 25.25 ± 8.1 mm. TLR was noted in only 8 (13.3 %).

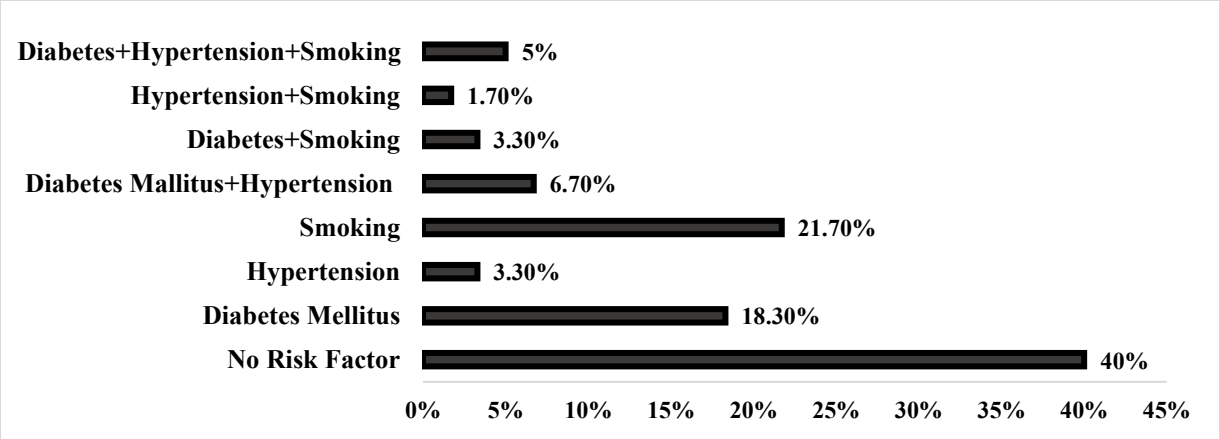

Figure 1: Showing the distribution of data related to the risk factors among patients with large coronary artery disease

On follow-up, the majority of patients did not display any adverse secondary outcomes. Table 1 shows the details of adverse outcomes noted and the effectiveness of DCB in terms of primary and secondary outcomes.

Table 1: Showing the Frequencies and percentages of various outcomes following Drug Coated Ballon therapy

Outcome Variables		Frequency	Percentage
Target lesion Revascularization*	Yes	8	13.3%
	No	52	86.7%
Myocardial Infarction	Yes	4	6.7%
	No	56	93.3%
Target Vessel Thrombosis	Yes	5	8.3%
	No	55	91.7%
Effort Angina	Yes	10	16.7%
	No	50	83.3%
Dyspnea	Yes	8	13.3%
	No	52	86.7%
Death	Yes	2	3.3%
	No	58	96.7%

There was no significant correlation observed between gender, risk factor, indication for intervention, or the number as well as the type of artery involved with the rate of TLR **(Table 2).** There was also no significant relation between the target outcome and the quantitative variables of age, LVEF, the diameter of the target lesion as well as the size of the lesion **(Table 3).**

Table 2: Relationship between qualitative variables and target outcome.

Variable		Frequency		p-value
		Target Vessel Revascularization (n)		
		Yes	No	
Gender	**Male**	5	47	0.065
	Female	3	5	
Risk Factors	**Present**	7	29	0.078
	None	1	23	
Indication	**None**	0	1	0.963
	Effort Angina	1	7	
	NSTEMI	2	10	
	STEMI	5	34	
No. of vessels involved	**One**	5	32	0.930
	Two	2	11	
	Three	1	9	

Table 3: Relationship between quantitative variables and target outcome

	Target Vessel Revascularization (mean)		p-value
Variable	**Yes**	**No**	
Age	52.5 ± 13.00	55.63 ± 9.32	0.405
Diameter of the target vessel	3.03 ± 0.21	3.11 ± 0.25	0.406
LVEF	43.13 ± 8.84	39.49 ± 14.41	0.493
Lesion Length	29.38 ± 7.29	24.62 ± 8.10	0.123

Discussion

This study has shown that target lesion revascularization (TLR) by DCB was relatively low, occurring in only 13.3% of patients, demonstrating its efficacy in reducing the need for repeat revascularization. This suggests that DCB therapy is a promising alternative to conventional interventions, particularly in large coronary artery disease. One of the most significant findings in studies comparing DCBs with DES is the reduced rate of TLR with the use of DCBs. According to a study by Gitto et al, the use of DCB was significantly (*P*=0.003) associated with reduced rates of TLR when they were followed for 2 years, similarly the propensity score matching analysis was also favouring the use of DCB.[7] A similar study by Yamada et al was also showed a reduced rate of TLR or failure at 6.3% in patients who underwent DCB therapy, however; in our study, the rate was 13.3% but less than the conventional therapy.[8]

The underlying mechanism for the reduced TLR rate with DCBs involves the delivery of drugs like paclitaxel, which inhibit neointimal hyperplasia—a key process in restenosis[3]. The balloon inflation delivers the drug uniformly across the lesion, ensuring that the vessel wall receives an adequate therapeutic dose without the mechanical trauma associated with stent implantation. This method proves especially beneficial in larger coronary arteries, where the sheer size and blood flow dynamics can pose additional challenges for stent-based therapies. The rate of MI on DCBs compares well with DES. This is consistent with Zhang et al's study, which also demonstrated the efficacy of reduced rates of MI (RR 0.16 [0.03 to 0.90]; P=0.04) as well as major adverse cardiac events of DCB therapy.[9] Without a permanent metal scaffold, there is less risk of stent thrombosis, a known cause of late-stage MIs. Finally, the absence of need for DAPT for DCBs minimizes the risk of bleeding, which in turn helps to achieve better overall outcomes and reduced MI rate.[10]

It is well known that any coronary intervention includes mortality rates, all-cause and cardiac-specific, as indicators of its long-term success. DCBs studies appear to not raise mortality and even may have a minor reduction effect. The lower incidence of adverse events such as stent thrombosis and restenosis,[3] that produce the ischemic problems attributed to DES may be the source of this. Additionally, the reduced dependency on prolonged DAPT decreases the risk of bleeding-related deaths, which is particularly advantageous in elderly populations or those with contraindications to prolonged antiplatelet therapy. Target vessel thrombosis (TVT) is a severe complication often associated with stent placement. The use of DCBs significantly mitigates this risk as they do not leave a permanent foreign body within the vessel which is in line with our study findings where the use of DCB was associated with significantly reduced TVT. This absence eliminates the nidus for thrombus formation that stents inherently provide. Consequently, the incidence of TVT is lower with DCBs, leading to better long-term vessel patency and fewer emergency revascularization procedures. According to a study by Felbel et al, the use of DCB was associated with a decreased risk of vessel thrombosis, however; the comparison between DCB and DES placement was not statistically significant 0.01 (0.00–0.02) in DCB vs. 0.01 (0.00–0.01) in DES.[4]

Dyspnea, often a symptom of heart failure or significant myocardial ischemia, has also been shown to decrease following DCB interventions. The reduction in restenosis and subsequent ischemic events contributes to improved cardiac function and symptomatic relief. Patients treated with DCBs report fewer angina-related symptoms and improved exercise tolerance, enhancing their quality of life. The safety profile of DCBs is highly favourable compared to DES.[11,12] The elimination of a permanent scaffold reduces the risk of chronic vessel injury and inflammation, which are precursors to adverse events such as stent thrombosis and restenosis. Furthermore, the shorter duration of DAPT required with DCBs minimizes the risk of bleeding complications, a significant concern in patients with high bleeding risk [10]. Future studies with longer follow-up periods and larger patient cohorts will be crucial to fully establish the long-term benefits and potential limitations of DCBs in diverse clinical settings.

Conclusions

The use of DCB therapy resulted in a significant reduction in the proportion of patients requiring target lesion revascularization, which was the primary outcome measure. Furthermore, the secondary (adverse) outcomes exhibited a notable decrease in patients who received DCB therapy, thus demonstrating the efficacy of DCB therapy in individuals with large coronary artery disease.

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