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Outcomes of drug (paclitaxel) coated balloons in various coronary lesion subsets; A two-year follow-up study.

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Abstract

Background: Drug-coated balloons (DCB) are a promising treatment for coronary artery disease (CAD), but their long-term efficacy in different lesion subsets is unknown. This study assessed the clinical outcomes of paclitaxel-coated balloons over two years, examining various lesion types and patient characteristics.

Methodology: This retrospective cohort study analyzed 102 patients who underwent drug-coated balloon (DCB) treatment for denovo or restenotic lesions. Paclitaxel-eluting balloons were utilized, and the primary objective was to assess the occurrence of major adverse cardiovascular events (MACE), defined as death, myocardial infarction, target lesion revascularization, and target vessel revascularization at different time intervals. Secondary outcomes, including target lesion failure (TLF), target lesion revascularization (TLR), target vessel revascularization (TVR), and target vessel myocardial infarction (TVMI), were also evaluated. Statistical analysis was conducted using SPSS version 22.0.

Results: In this study, the mean age of the participants was 58.49 years, with the majority being male (81.4%). Lesion types included both de novo (49.0%) and in-stent restenosis (ISR) (51.0%). Bifurcation lesions were present in 29.4% of cases, and ostial lesions were observed in 40% of cases. Thrombus was found in 4.9% of cases. The occurrence of MACE was low, with one patient experiencing MACE at 30 days, nine patients between 30 days and 1 year, and six patients between 1 and 2 years. The overall rates of TLF, TLR, TVR, and TVMI were also low. Some patient characteristics, such as diabetes, dyslipidemia, chronic kidney disease (CKD), and dialysis, were associated with a higher risk of MACE. Importantly, no significant differences in outcomes were observed between various lesion subsets and presentations.

Conclusion: DCB proves to be a viable and efficient treatment option for different types of coronary lesions. The occurrence rates of MACE, TLR, TLF, TVR, and cardiac death following the use of DCB are low.

Keywords

Paclitaxel, Drug-Coated Balloon Angioplasty, MACE.

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Introduction

Coronary artery disease (CAD) remains a prominent and consequential health issue worldwide, leading to substantial morbidity and mortality rates[1,2]. In terms of management, percutaneous coronary intervention (PCI) plays a crucial role, serving as a common therapeutic approach for patients with both stable CAD and acute coronary syndromes (ACS)[1]. Advancements in PCI technology have significantly contributed to the field, particularly with the introduction of second and newer-generation devices. These modern stents have revolutionized the landscape of coronary interventions, offering enhanced safety and efficacy compared to their predecessors, such as bare-metal stents (BMS) and first-generation drug-eluting stents (DES). Using second and newer-generation stents in PCI procedures has yielded substantial improvements in patient outcomes[1,2]. These advanced devices have demonstrated superior performance in reducing the incidence of restenosis, minimizing the need for repeat revascularization procedures, and enhancing long-term clinical outcomes. The ongoing evolution of PCI techniques and the adoption of these innovative stents have resulted in more precise and targeted interventions, providing physicians with greater confidence in achieving successful revascularization.

Despite therapeutic advantages, implantation of stents in coronary arteries can have implications in the long term as a result of arterial injury, leading to delayed healing, especially in cases involving DES[3]. Moreover, the presence of stents can cause alterations in the vasomotor tone of both the distal and proximal segments of the stented arteries. These alterations and flow disturbances induced by stenting can contribute to an increased propensity for thrombus formation and inflammation[4]. It is also worth noting that the severity of vessel injury caused by stenting has been linked to elevated levels of neointimal proliferation, which refers to the excessive growth of cells within the inner layer of the artery. This increased cellular growth can eventually lead to neo-atherosclerosis, a condition characterized by the formation of atherosclerotic plaques within the stented segment. These findings highlight the complex interplay between stent implantation, arterial injury, and subsequent biological responses with the potential for ensuing late stent failure. Understanding the mechanisms underlying these phenomena is crucial for improving the safety and efficacy of coronary interventions. Ongoing research aims to identify strategies that mitigate arterial injury, promote favorable healing responses, and minimize the risk of complications such as late stent thrombosis and neo-atherosclerosis[5]. By advancing our knowledge in this field, we can enhance patient outcomes and optimize the long-term success of coronary stent implantation.

Drug-coated balloons are designed to overcome the limitations of DES. They are semi-compliant balloons that facilitate the local delivery of anti-restenotic drugs[1]. The majority of DCBs currently used in clinical practice elute paclitaxel and have been used in various clinical settings. At present, widespread use of second-generation DES has significantly reduced the incidence of in-stent restenosis (ISR), which was almost unavoidable with BMS[6]. Nevertheless, ISR is reported to occur in 2-10% of DES-treated lesions and is not simple to deal with. Multiple randomized trials of BMS and DES ISR have shown the safety and efficacy of DCBs in in-stent restenotic lesions. A large meta-analysis of 10 randomized trials that compared DCBs with DES showed no difference in hard clinical endpoints; however, a slightly increased risk of target lesion revascularization in DES ISR[7]. Current ESC guidelines have given class I recommendations for using DCBs in in-stent restenotic lesions[8]. DCBs have been investigated in various denovo lesion subsets, i.e., small & large vessels[9,10], bifurcation lesions[11], and ACS lesions[12]. Lastly, DCBs offer a potentially attractive alternative to DES in high-bleeding risk patients[13].

In this all-comers study, we aimed to evaluate the clinical outcomes of paclitaxel-coated balloons (DCBs) in various clinical scenarios and lesion types, focusing on major adverse cardiac events (MACE) over different time intervals, including 30 days, 1 year, and 2 years. By examining these outcomes, we hope to gain valuable insights into the

prolonged effectiveness and safety of the procedure, ultimately contributing to advancing medical knowledge and improving patient care.

Methodology

Study design and population

This retrospective, observational cohort study enrolled patients in whom one or more DCBS were used to treat any denovo or restenotic native or bypass graft lesion between January 2013 and December 2020 at Tabba Heart Institute, Karachi, Pakistan. All patients who underwent treatment with one or more DCBs were included. In contrast, the exclusion criteria for participant selection were the presence of contraindications to DCB treatment, severe comorbidities or medical conditions that may confound the study outcomes, and previous history of complications related to DCB treatment.

Procedure

DCB treatment involved using paclitaxel-eluting balloons (Sequent Please & Sequent Please Neo by B-Braun & Pantera Lux by Biotronik). The procedure was conducted for coronary stenotic lesions, encompassing both in-stent restenotic (ISR) and de novo lesions in both ACS and stable CAD patients. Before DCB treatment, predilation of the lesions was performed using compliant, non-compliant, scoring or cutting balloons. The DCBs were then delivered and inflated for upto 120 seconds, applying a nominal pressure.

The procedural success criterion was the achievement of less than 30% diameter stenosis without encountering dissection or coronary perforation. The duration of dual antiplatelet treatment and the specific type of P2Y12 receptor inhibitors administered were left to the physician's discretion.

Follow-up

Three clinical follow-up assessments were conducted to evaluate the clinical outcomes at specific time intervals, i.e., 30 days, 1 year, and 2 years.

Study End Points

The primary endpoint of the study was to examine the occurrence of major adverse cardiovascular events (MACE) at each of these follow-up points. Furthermore, secondary endpoints, including TLR, TLF, TVR, and TVMI, were specifically evaluated after the initial 30-day period.

During the initial 30-day follow-up, the occurrence of MACE, TLR, TVR, and MI was carefully monitored and documented. Subsequent follow-ups at 1 year and 2 years involved assessing the incidence of MACE to comprehensively understand the extended-term clinical outcomes associated with the procedure. Within the evaluation of MACE, various components, such as death, myocardial infarction, target lesion revascularization (TLR), and target vessel revascularization (TVR), were considered.

Data collection

The data was obtained from online medical records and telephonic consultations. A structured proforma was developed specifically for this study, incorporating all the relevant variables pertaining to baseline characteristics, procedure characteristics, lesion characteristics, and clinical outcomes.

Statistical analysis

SPSS version 22.0 was used for the statistical analysis. Continuous variables were expressed as mean and standard deviation, whereas categorical variables were provided as frequencies and percentages. The Chi-square test was used to investigate the association between patient characteristics and clinical outcomes. All p-values were two-sided, with $p<0.05$ denoting statistical significance.

Ethical Considerations

The study protocol for this retrospective study received approval from the Ethics Committee (Ref # THI/IRB/SQ/23-02-2023/105), demonstrating adherence to ethical standards and guidelines, including the principles outlined in the Declaration of Helsinki. Individual informed consent was not

feasible due to the retrospective nature of the study; however, strict measures were implemented to anonymize and remove personal identifiers from the collected medical records, ensuring confidentiality and privacy protection. The study was conducted in compliance with relevant data protection regulations and guidelines. Access to the data was limited to authorized researchers, and robust measures were in place to prevent re-identification or traceability to any individual.

Results

The baseline characteristics of the patients were collected and analyzed, presented in Table 1. The mean age of the participants was 58.49 years, and the majority were male (81.4%). Most patients were non-smokers (89.2%). Pre-existing medical conditions included diabetes mellitus (64.7%), hypertension (80.4%), dyslipidemia (50.0%), and prior myocardial infarction (52.0%).

Table 1: Patient's baseline characteristics (N=102).

Variables		N(%)
Age (years); Mean ± SD		58.49±13.31
Gender	Male	83(81.4)
	Female	19(18.6)
Smoking status	Smoker	11(10.8)
	Non-smoker	91(89.2)
Clinical history	DM	66(64.7)
	Family Hx of premature CAD	3(2.9)
	HTN	82(80.4)
	DL	51(50.0)
	CKD	14(13.7)
	Prior MI	53(52.0)
	Prior PCI	59(57.8)
	Prior CABG	19(18.6)
	Atrial fibrillation	2(2.0)
	Oral Anticoagulation	3(2.9)
	Dialysis	3(2.9)
	LVEF (%); Mean ± SD	46.27±9.74
Clinical presentation	Stable CAD	32(31.4)
	NSTEMI	58(56.9)
	STEMI (Non-culprit)	3(2.94)
	STEMI (culprit)	9(8.65)

Values are mean ± SD or n (%). CABG, coronary artery bypass graft surgery; CAD, coronary artery disease; DCB, drug-coated balloon; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; NSTEMI, Non-ST-Elevation Myocardial Infarction; DM, Diabetes mellitus; HTN, hypertension; DL, Dyslipidemia; Hx, History; CKD, Chronic Kidney Disease.

Table 2 presents the characteristics of procedures and lesions in the study. Lesion types included de novo (49.0%) and in-stent restenosis (ISR) (51.0%). Bifurcation lesions were observed in 29.4% of cases, while 40% had ostial lesions. The mean vessel size was 3.00 mm, and the mean lesion length was 20.02 mm. Thrombus was present in 4.9% of cases. The baseline Thrombolysis in Myocardial Infarction (TIMI) flow grades varied,

with 68.6% having grade 3. Lesion preparation involved different balloon types, with semi-compliant balloons used in 62.7% of cases, non-compliant balloons in 68.7%, and plaque modification balloons in 5% of cases. None of the cases involved atherectomy. The mean DCB diameter was 2.94 mm, and the mean DCB length was 25.07 mm. All patients achieved TIMI flow grade 3 post-DCB treatment. Bailout stenting for distal edge dissections was required in 2.0% of cases.

Table 2: Characteristics of procedures and lesions.

Variables		**N(%)**
Lesion type	De Novo	50(49.0)
	ISR	52(51.0)
Bifurcation lesion	Yes	30(29.4)
	No	72(70.6)
Ostial lesion	Yes	40(39.21)
	No	62(60.8)
Vessel size (mm); Mean ± SD		3.00±0.47
Lesion length (mm); Mean ± SD		20.02±10.14
Thrombus present	Yes	5(4.9)
	No	97(95.1)
TIMI Flow (pre-procedure)	Grade 0	10(9.8)
	Grade 1	5(4.9)
	Grade 2	17(16.7)
	Grade 3	70(68.6)
Residual stenosis post-pre-dilation	20%	1(1.0)
	30%	31(30.39)
	40%	62(60.7)
	50%	8(7.8)
Lesion preparation	Semi-compliant balloon	64(62.7)
	Non-compliant-compliant balloon	70(68.6)
	Plaque Modification Balloon	5(4.9)
Device Characteristics	DCB diameter (mm); Mean ± SD	2.94±0.44
	DCB Length (mm); Mean ± SD	25.07±8.14
	Inflation pressure (atm); Mean ± SD	10.57±2.98
Vessel classification	SVD	41(40.2)
	LVD	61(59.8)
Post DCB TIMI Flow	Grade 2	-
	Grade 3	102(100)
Bailout stenting	Yes	2(2.0)
	No	100(98.0)

The clinical outcomes observed in the study are summarized in Table 3. At 30 days, 1 (1.0%) patient experienced a MACE, while the majority, 101 (99.0%) did not. Between 30 days and 1 year, 9 (8.9%) patients had a MACE, and 92 (91.08%) did not. Between 1 and 2 years, 6 (6.52%) patients experienced a MACE, and 86 (93.4%) did not. On the whole, TLF occurred in 5 (4.9%) cases, and 93 (91.2%) did not experience TLF. TLR was required in 5 (4.9%) cases, and 93 (91.2%) did not require TLR. TVR was performed in 6 (5.9%) cases, and 93 (91.2%) did not undergo TVR. Four (3.9%) patients experienced a target vessel myocardial infarction (MI), while 94 (92.2%) did not. Four (3.9%) patients had cardiac death (but no invasive evaluation could be done on those patients),

and 1 (1.0%) had non-cardiac death. Five patients (4.9%) experienced MACE secondary to non-target vessel myocardial infarction, and four of them underwent revascularization of non-target vessels.

Table 3: Clinical Outcomes.

Variables		N(%)
MACE at 30 days (N=102)	Yes	1(0.9)
	No	101(99.0)
MACE at 1 year (N=101)	Yes	9(8.9)
	No	92(91.08)
MACE at 2 years (N=92)	Yes	6(6.52)
	No	86(93.4)
TLF		5(4.9)
TLR		5(4.9)
TVR		6(5.9)
TVMI		4(3.9)
Non-target vessel Revascularization		5(4.9)
Cardiac death		4(3.9)
Non-cardiac death		1(0.9)
All-cause death		5(4.9)
DAPT duration	> 1 year	46(45.1)
	< 1 year	9(8.8)
	1 year	47(46.08)

*Major Adverse Cardiac Events (MACE); Target Lesion Failure (TLF); Target Lesion Revascularization (TLR); Myocardial Infarction (MI); Dual Antiplatelet Therapy (DAPT); Target Vessel Myocardial Infarction (TVMI)

*No details present, including the location of the failure, sudden death, etc.

After a 2-year follow-up of drug-coated balloon angioplasty (DCBA), Table 4 shows the association between MACE outcomes up to 2 years and patient characteristics. Most patients who experienced MACE were diabetic (87.5%), suggesting a significant association between DM and MACE occurrence (p=0.038). Similarly, patients with dyslipidemia were more prevalent in those who experienced MACE (81.3%) compared to their counterparts (44.2%) (p=0.006). There were, 43.8% of patients who experienced MACE had CKD, while in those who hadn't experienced MACE, CKD was present in 8.1% of the patients. This indicates a significant association between CKD and MACE (p<0.01). Moreover, 12.5% of MACE patients were undergoing dialysis, whereas only 1 patient (1.2%) without MACE was on dialysis (p=0.014). Of note, no significant difference in outcomes was noted between various lesion subsets and presentations (ACS vs. stable CAD, Denovo vs. in-stent restenotic lesions, ostial lesions, bifurcation lesions, and small vessel vs. large vessel coronary artery disease).

Table 4: Association between patient characteristics and MACE outcomes within 2 years after DCBA.

Variables			MACE (up to 2 years)		p-value
			Yes N(%)	No N(%)	
Baseline Characteristics	Age (Years); Mean ± SD		63.63±12.26	57.53±13.34	0.093
	Gender	Male	12(75.0)	71(82.6)	0.476
		Female	4(25.0)	15(17.4)	
	Smoker	Yes	1(6.3)	10(11.6)	0.524
		No	15(93.8)	76(88.4)	
	DM	Yes	14(87.5)	52(60.5)	0.038*
		No	2(12.5)	34(39.5)	
	HTN	Yes	14(87.5)	68(79.1)	0.435
		No	2(12.5)	18(20.9)	
	DL	Yes	13(81.3)	38(44.2)	0.006*
		No	3(18.8)	48(55.8)	
	Family Hx of premature CAD	Yes	1(6.3)	2(2.3)	0.394
		No	15(93.8)	84(97.7)	
	Prior MI	Yes	11(68.8)	42(48.8)	0.143
		No	5(31.3)	44(51.2)	
	Prior PCI	Yes	11(68.8)	48(55.8)	0.336
		No	5(31.3)	38(44.2)	
	Prior CABG	Yes	4(25.0)	15(17.4)	0.476
		No	12(75.0)	71(82.6)	
	CKD	Yes	7(43.8)	7(8.1)	0.000*
		No	9(56.3)	79(91.9)	
	Dialysis	Yes	2(12.5)	1(1.2)	0.014*
		No	14(87.5)	85(98.8)	
	Atrial Fibrillation	Yes	1(6.3)	1(1.2)	0.178
		No	15(93.8)	85(98.8)	
	Oral Anticoagulation	Yes	1(6.3)	2(2.3)	0.394
		No	15(93.8)	84(97.7)	
	LVEF (%); Mean ± SD		42.50±16.633	46.98±7.794	0.092
	Clinical presentation	Stable CAD	6(37.5)	26(30.2)	0.464
		NSTEMI	10(62.5)	48(55.8)	
		STEMI (Non-culprit)	-	3(3.5)	
		STEMI (culprit)	-	9(10.5)	
Procedural characteristics	Lesion type	De Novo	5(31.3)	45(52.3)	0.122
		ISR	11(68.8)	41(47.7)	
	Multiple lesions treated	Yes	10(62.5)	56(65.1)	0.841
		No	6(37.5)	30(34.9)	
	Ostial lesion	Yes	9(56.3)	31(36.0)	0.129
		No	7(43.8)	55(64.0)	
	Bifurcation lesion	Yes	5(31.3)	25(29.1)	0.860
		No	11(68.8)	61(70.9)	
	Vessel size (mm); Mean ± SD		3.08±0.47	2.98±0.48	0.481

Lesion length (mm); Mean ± SD		23.13±13.32	19.48±9.47	0.199
Thrombus present	Yes	1(6.3)	4(4.7)	0.786
	No	15(93.8)	82(95.3)	
TIMI Flow (pre-procedure)	Grade 0	1(6.3)	9(10.5)	0.368
	Grade 1	1(6.3)	4(4.7)	
	Grade 2	5(31.3)	12(14.0)	
	Grade 3	9(56.3)	61(70.9)	
Residual stenosis post-pre-dilation	20%	-	1(1.2)	0.682
	30%	6(37.5)	25(29.06)	
	40%	10(62.5)	52(60.5)	
	50%	-	8(9.3)	
Semi-compliant balloon	Yes	8(50.0)	56(65.1)	0.251
	No	8(50.0)	30(34.9)	
Non-compliant-compliant balloon	Yes	13(81.3)	57(66.3)	0.236
	No	3(18.8)	29(33.7)	
Plaque Modification Balloon	Yes	1(6.3)	4(4.7)	0.786
	No	15(93.8)	82(95.3)	
Device Characteristics; Mean ± SD	DCB diameter (mm)	2.94±0.38	2.94±0.45	0.979
	DCB Length (mm)	24.00±8.54	25.24±8.12	0.612
	Inflation pressure (atm)	11.14±3.20	10.48±2.95	0.442
Vessel Classification	SVD	6(37.5)	35(40.7)	0.811
	LVD	10(62.5)	51(59.3)	
Post DCB TIMI Flow	Grade 2	-	-	-
	Grade 3	16(100.0)	86(100.0)	
Bailout stenting	Yes	1(6.3)	1(1.2)	0.178
	No	15(93.8)	85(98.8)	

*p<0.05 is considered significant.

CABG, coronary artery bypass graft surgery; CAD, coronary artery disease; DCB, drug-coated balloon; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; NSTEMI, Non-ST-Elevation Myocardial Infarction; DM, Diabetes mellitus; HTN, hypertension; DL, Dyslipidemia; Hx, History; CKD, Chronic Kidney Disease.

Discussion

In this observational study, the clinical outcomes of drug (paclitaxel) coated balloons were observed. After 30 days, only 1 (1.0%) of the patients had a MACE, while 9 patients (8.9%) experienced MACE between 30 days and 1 year. Between 1 and 2 years, 6 patients (6.52%) experienced MACE. The safety and effectiveness of DCB treatment in actual clinical settings have been demonstrated by a thorough registry research comprising more than 2000 patients across 75 sites in 8 countries[14]. For the treatment of BMS and DES restenosis, randomized trials have demonstrated that Angioplasty with PCB is better than uncoated balloon angioplasty[15-17]. According to the reported rates of MACEs during a 9-month follow-up, the study's data showed that DCB treatment produces positive results[16]. During a 5-year follow-up, the clinical event rate was significantly lower in patients treated with the DCB, with 59.3% of patients with uncoated balloons experiencing MACE vs. 27.8% in those treated with DCB (p=0.009)[18].

In addition to the major adverse cardiovascular events, TLF (4.9%), TLR (4.9%), TVR (5.9%), TVMI (3.9%), and cardiac death occurred in 3.9% of the

patients in the present study. Our findings' low rates are consistent with those seen in other published registries[14,17,19], indicating a similar degree of efficacy and safety. This low event rate is due to meticulous lesion preparation and DCB application in accordance with established technique[20]. Scheller et al. reported significantly low TLR among patients with. Drug-coated balloons (9.3%) vs uncoated balloons 38.9% (p=0.004)18. Sella et al. reported a combination of low TLR (6.7%) and bailout stenting (13.7%) rates after a DCB-PCI-only approach[20]. Lee et al., in a Large-Scale Multicenter Korean Registry Study, the primary outcome, TLF, occurred in 6.7% of patients; cardiac death was observed in 1.6% of patients, TVMI in 1.5%, and TLR in 5.1% of patients[21].

During 2 years follow-up period, this study examined the impact of baseline characteristics and procedural factors on the occurrence of MACEs in patients who underwent DCBA. The findings revealed that dyslipidemia could be a significant predictor of adverse cardiac events, as a higher percentage of patients with dyslipidemia experienced MACE compared to those without this condition. Furthermore, the study demonstrated a significant association between CKD, the need for dialysis, and the occurrence of MACE. This indicates that both CKD and the requirement for dialysis are important risk factors for unfavorable cardiac outcomes after DCBA. Additionally, most patients who experienced MACE were diabetic (87.5%), suggesting a significant association between DM and MACE occurrence (p=0.038). Existing literature supports the notion that diabetic patients exhibit a higher frequency of cardiovascular mortality, MACE, and TLR than non-diabetic individuals. This highlights the increased risk faced by diabetic patients in relation to adverse cardiac events[26].

In this study, we observed no significant effect of the clinical presentation (Stable CAD, NSTEMI, and STEMI) on the DCB outcomes in terms of MACE within 2 years. In particular, no MACE was reported in STEMI patients, whether DCBs were used in culprit or non-culprit vessels. DCBs can be of particular interest in STEMI patients as they may allow restoration of normal coronary physiology and avoid stent-related complications such as stent thrombosis and acute and late stent malapposition, which is more prevalent in the STEMI population. Besides, as patients with STEMI are relatively younger, avoiding permanent metal implants in these patients can keep future percutaneous or surgical revascularization options viable. Previously, Ho et al. have investigated DCBs in 89 STEMI patients. At 30 days follow-up, no cases of abrupt closure, TVR, or TVMI were observed[24]. In the PAPPA study, which included 1-year follow-up of DCBA in STEMI patients, 5 % MACEs were reported[25]. Favorable results were also reported in the Relevation randomized trial, which assessed fractional flow reserve (FFR) at 9 months post DCBA in STEMI patients[26]. Subsequent 2 years of clinical outcomes of the revelation study demonstrated sustained efficacy and safety of DCBA in STEMI patients[27]. Our study findings also favor DCBA in STEMI settings; however, long-term follow-up and large-scale randomized trials will further validate the safety of DCBs in this scenario.

Similar findings are noted in NSTEMI patients, which comprised 56.9% of the study population. Previously, the PEPCAD NSTEMI trial has demonstrated the superiority of DCBs over stents in terms of TLF, while no significant differences were observed in the rates of death, MI, and TLR[12]. Nevertheless, larger randomized trials are needed to further investigate the use of DCBs in NSTEMI patients[12].

Regarding lesion characteristics, there was no significant difference in MACE between denovo versus ISR lesions. However, numerically more favorable trend was noted in denovo lesions. All 3 patients among the study population (2.9%) who underwent DCBA in vein graft lesions (all 3 were instant restenostic lesions, and of them, 2 had NSTEMI and one had stable CAD) did not suffer MACE. Among bifurcation lesions, 5 out of 30 suffered MACE, which was statistically insignificant. In sub-analysis, out of 7 left main bifurcations, 2 suffered MACE. No significant difference in MACE was noted between ostial or nonostial lesions. Among patients with small vessel disease, five patients experienced MACE during the follow-up

period, while among patients with large vessel disease, 8 experienced MACE. The difference in MACE incidence between the two groups was not statistically significant (p=0.864). Emerging research has provided compelling evidence supporting the effectiveness of DCB interventions in various lesion subsets. Specifically, studies have demonstrated the efficacy of DCB in small-vessel disease, acute myocardial infarction (MI), and bifurcation lesions. In the context of small-vessel disease, DCB interventions have shown promising results[28]. Another study conducted on the efficacy and safety of drug-coated balloons (DCB) has reported consistent outcomes regardless of the size of the blood vessels involved. However, it did reveal a notable advantage of DCB over paclitaxel-eluting stents in terms of target vessel revascularization (TVR), non-fatal myocardial infarction, and major adverse cardiovascular events (MACE), particularly in cases involving very small coronary arteries[29].

Finally, DCB provides an opportunity to shorten DAPT duration, especially in patients with high bleeding risk. In the present study, an overwhelming majority (> 90%) took DAPT for one year or more. Hence, regarding the safety of short-term DAPT with DCBs, no definitive conclusions can be drawn. Trials have since suggested DAPT durations ranging from 1 to 12 months. However, no RCTs have specifically determined the optimal DAPT duration following DCBA[30]. The European Society of Cardiology suggests a conservative approach: 6 months of DAPT for stable CAD patients treated with DCB and considering shorter durations for high-risk bleeding cases. For ACS patients with stents, 12 months of DAPT is recommended, with consideration for discontinuation after 6 months in high-risk bleeding situations[31].

Despite giving significant information, the study has several drawbacks. It was done retrospectively, which may have introduced inherent biases and confounding factors. Furthermore, the sample size was limited, which may restrict the findings' generalizability. Furthermore, the study only looked at the relationship between baseline characteristics, procedural parameters, and clinical outcomes, not other potential confounding variables. Future studies with larger sample numbers and prospective designs are needed to confirm and build on these findings.

Conclusion

It is concluded that DCB treatment is effective and feasible for various types of coronary lesions, encompassing both denovo and in-stent restenotic lesions, both in stable and acute settings. The inference is based on several factors; collectively, the low occurrence rates of MACE, TLR, TLF, TVR, and cardiac death observed following the use of DCB support the conclusion. These findings highlight the potential benefits of DCB in improving patient outcomes and reducing the need for additional interventions.

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