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Original Article

Twelve-month comparative analysis of clinical outcomes using biodegradable polymer–coated everolimus-eluting stents versus durable polymer–coated everolimus-eluting stents in all-comer patients

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ABSTRACT

Aim: The purpose of the present study was to examine whether clinical differences exist between the biodegradable polymer (BDP)–coated Tetrilimus everolimus-eluting stent (EES) and the durable polymer (DP)–coated Xience EES by comparing the major adverse cardiac event (MACE) rate at 12 months in all-comer patients.

Methods: This study was designed as a multicentre, observational, retrospective, investigator-initiated study between January 2016 and October 2016. Two hundred thirteen patients who underwent percutaneous coronary intervention (PCI) with the BDP-EES were compared with 204 patients who underwent PCI with the DP-EES, irrespective of lesion complexity, comorbidities and acute presentation. The primary end point was MACE defined as a composite of cardiac death, myocardial infarction and target lesion revascularization.

Results: Baseline clinical and lesion characteristics of both the groups were similar, although the BDP-EES group had a significantly higher number of patients with diabetes mellitus (39.9% vs. 30.4%; $p = 0.042$) and type C lesion (67.4% vs. 48.1%; $p < 0.001$) than the DP-EES group. The 12-month MACE rate was 4.2% for the BDP-EES group versus 4.9% for the DP-EES group ($p = 0.740$). Mortality was lower in the BDP-EES group than in the DP-EES group (0.9% vs. 2.0%; $p = 0.441$).

Conclusion: The present comparative analysis shows that the BDP-coated Tetrilimus EES was as safe and effective as the DP-coated Xience EES during the 12-month follow-up period despite complex lesion characteristics.

1. Introduction

Drug-eluting stents (DESs) have revolutionised percutaneous coronary intervention (PCI) as the rate of in stent restenosis (ISR) has reduced when compared with bare metal stents.[1] First- and second-generation DESs were very effective initially for few months after the implantation, but as the drug from matrix got washed out, remainders of polymer acted as a platform for occurrence of late or very late (>1 year) stent thrombosis (ST), eventually leading to repeat revascularisation.[2] To overcome such issues, fourth-generation DESs were introduced with biodegradable polymers (BDPs) as drug carrier. Primarily, PCI was only used for simple lesions and single-vessel diseases, but with introduction of newer generation DESs and advancements in procedural techniques, PCI has now been used for complex lesions and multivessel diseases.[3] The credit for such revolution can be given to the use of the BDP in DESs. Unlike durable polymers (DPs), BDPs do not stay in contact with the intima till eternity; instead of that, BDPs erode gradually from the surface of stents and get metabolised by hydrolysis and enzymatic activity and excreted out of the body,[4] thus decreasing the chance of late ST and ISR.

Along with the polymers used, thickness of the strut also plays a pivotal role in development of ISR. Thickness of the strut and biocompatibility are inversely proportional.[5,6] A thinner strut also

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results in decreased mechanical trauma to the vessel. In conjugation with drugs and polymers, a marked change in stent platform has also occurred. Stent platforms which were primitively of stainless steel are now replaced with cobalt–chromium (Co-Cr) and platinum–chromium alloy platforms. While talking about DESs with BDP coating, selection of the stent platform is also important because after the drug release and complete disintegration of the polymer, ultimately it will be the stent platform that will persevere. The Tetrilimus (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) everolimus-eluting stent (EES) is one such fourth-generation DES; it comprises BDP coating, has ultrathin (60-μm) strut thickness and uses the Co-Cr alloy stent platform. The aim of the present study was to examine whether clinical differences exist between the BDP-EES (Tetrilimus) and the DP-EES (Xience; Abbott Vascular, USA) by comparing the major adverse cardiac event (MACE) rate at 12 months in all-comer patients.

2. Materials and methods

2.1. Study design and study population

This was a multicentre, observational, retrospective, investigator-initiated and post-marketing clinical follow-up study. Both the devices used in this study are commercially available in India. A total of 417 patients were included from three different centres in India. The participating centres were asked to provide data for consecutive contemporary patients treated with either only the Tetrilimus EES or only the Xience EES from January 2016 to October 2016. The patients were identified retrospectively and divided into two groups; those patients who underwent PCI with only the Tetrilimus (BDP-coated) EES and those with only the Xience (DP-coated) EES were included in this study. The exclusion criteria were as follows: (1) patients who underwent PCI with a non-Tetrilimus EES or non-Xience EES during the same index procedure; (2) patients who received both the Tetrilimus EES and Xience EES during the same index procedure and (3) patients not taking or unable to take dual antiplatelet therapy. As a practice of associated hospitals, a written data release consent form was signed by each patient before discharge, regardless of any study to be conducted in future. The study protocol was approved by the institutional ethics committee and obeyed the principle of good clinical practice and the Declaration of Helsinki.

2.2. Device description

The Tetrilimus EES is a fourth-generation DES. The Tetrilimus EES comprises surgical grade L605 Co–Cr alloy having an ultrathin strut thickness of 60 μm (i.e., Tetrinium coronary stent platform; Sahajanand Medical Technologies Pvt. Ltd., India), everolimus as the active pharmaceutical ingredient and BDP as the drug carrier. The BDP in the Tetrilimus EES slowly and gradually erodes into small molecules, gets metabolised and excreted out from the body via normal metabolic pathways. On the other hand, the Xience EES[7] comprising the Multilink™ Co–Cr backbone with a thin strut having thickness of 81 μm is crimped on a vision balloon. The Xience EES is coated with a DP. Design of both the stent platforms is shown in Fig. 1.

2.3. Data collection and follow-up

The baseline data such as age, gender, medical history, angina status and clinical presentation of all the patients were collected retrospectively from the clinical notes, angiogram reports and procedural angiographic images, inpatient and outpatient notes; along with this, routine laboratory data such as cardiac biomarkers, blood chemistry, glucose levels, lipid levels and 12-lead electrocardiogram were also collected. The patients were followed up either by the existing clinical database or telephonically at 30 days, 6 months and 12 months after the index procedure. The patients who were telephonically followed up were asked a list of set questions to determine the exact status of end point.

2.4. Study end points and definitions

The primary end point of this study was MACEs at 12-month follow-up. The MACE was defined as a composite of cardiac death, myocardial infarction (MI) and target lesion revascularization (TLR). The secondary end points consisted of individual components of the MACE, all-cause mortality, target vessel revascularisation (TVR) and ST. The outcomes of ST were further divided as definite, probable and possible ST as defined by the Academic Research Consortium.[8,9]

Cardiac death was considered in case of any death owing to cardiac cause (MI, low output failure and lethal arrhythmia), unobserved death and death due to unknown reason and all procedure-related deaths including those associated with concomitant treatment. MI was defined as an increase in cardiac troponin values ($>5 \times$ 99th percentile upper reference limit [URL]) in patients who have normal baseline values ($\leq$99th percentile URL) or an increase in cardiac troponin values >20% when the baseline values are elevated and stable or declining. Pathological Q waves are defined as per amplitude, location and depth if appeared in at least two contiguous leads. Restenosis within the stent or in the subsequent 5-mm distal or proximal segment was considered as the need for TLR. Stenosis in any segment of the treated vessel was defined as TVR. Incidence of ST was considered acute if occurred within 24 h, subacute if occurred between 1 and 30 days and late if the incident took place after 30 days. Any symptoms suggestive of an acute coronary syndrome and angiographic or pathological confirmation were termed as definite ST. Any unexplained death in 30 days or target vessel MI without angiographic confirmation of ST was described as probable ST. Unexplained death after 30 days was described as possible ST.

2.5. Adjunctive medication and interventional procedure

All the patients included in this study were given a loading dose of 300 mg of aspirin and 300 mg clopidogrel or 60 mg prasugrel or two tablets of 90 mg ticagrelor each before initiation of the index procedure. During the procedure, anticoagulation was brought about by either heparin or bivalirudin. The intraprocedural glycoprotein IIb/IIIa inhibitor was administered based on the investigator's decision. The procedure was performed as per the standard treatment guideline of every participating centre. All the patients were prescribed aspirin 75–300 mg daily and clopidogrel 75 mg daily or prasugrel 10 mg daily or ticagrelor 90 mg twice daily (dual antiplatelet therapy) for at least 1 month after the index procedure.

2.6. Statistical analysis

Continuous variables are presented as mean ± standard deviation and compared using Student's *t*-test. Categorical variables are presented as frequency and percentage and compared using Fisher's exact test. The Kaplan–Meier curve was used to summarise MACE-free survival. A p-value <0.05 was considered statistically significant. The data were analysed using the Statistical Package for Social Sciences programme (SPSS Inc., Chicago, IL, USA), version 15.0.

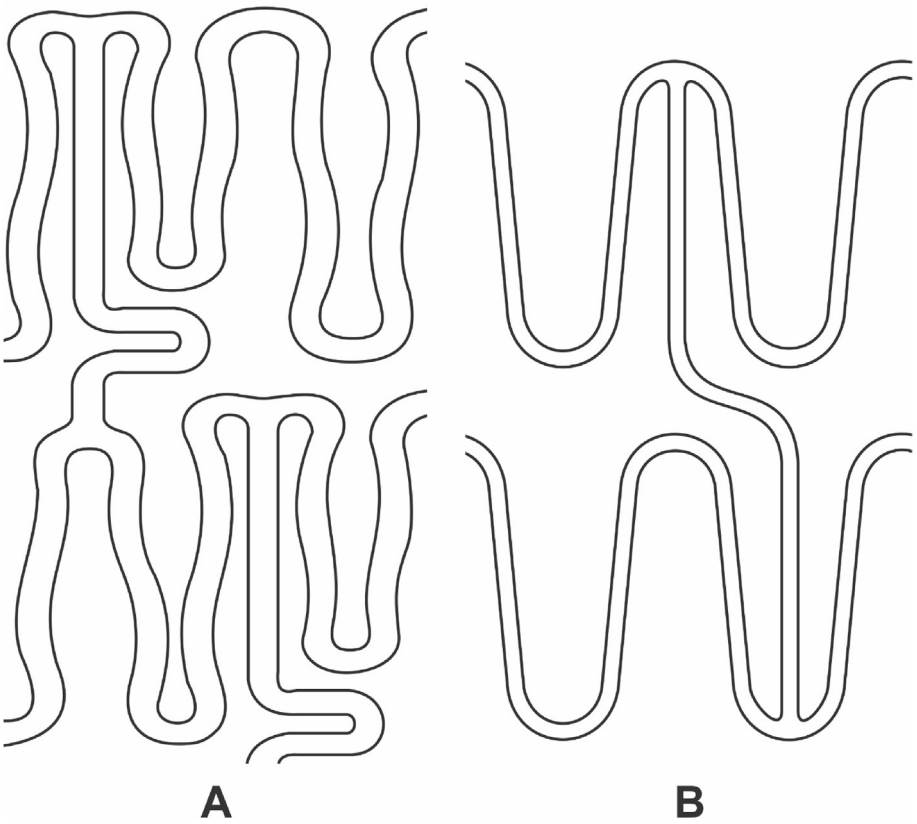

Fig. 1. Stent design: (A) Xience EES and (B) Tetrilimus EES. EES, everolimus-eluting stent.

3. Results

3.1. Baseline characteristics

The total study population comprised 417 patients (497 lesions); of whom, 213 patients (258 lesions) received the BDP-EES and 204 patients (239 lesions) received the DP-EES. There was no significant difference in risk factors between the groups except diabetes mellitus; significantly, more number of patients suffered from diabetes mellitus in the BDP-EES group than in the DP-EES group (39.9% vs. 30.4%, $p = 0.042$). There was no significant difference in age, gender quotient, complexity of coronary artery disease and cardiac history of patients between the groups ($p > 0.05$). More number of patients presented with non–ST-segment elevation MI in the BDP-EES group than in the DP-EES group (30.5% vs. 20.6%, $p = 0.020$). Baseline demographic and clinical characteristics are illustrated in Table 1.

3.2. Procedural and lesion characteristics

Significantly, a higher number of patients in the BDP-EES group had type C lesion (as per the American College of Cardiology/American Heart Association scoring) than those in the DP-EES group (67.4% vs. 48.1%, $p < 0.001$), and the number of patients with type A lesion was significantly higher in the DP-EES group ($p = 0.001$). All the other characteristics such as target vessel location and number of stents per patient were relatively similar and did not show any significant difference ($p > 0.1$). Average stent length was also significantly higher in the BDP-EES group than in the DP-EES group (30.7 ± 10.1 vs. 23.7 ± 8.9 mm, $p < 0.001$), but average stent diameter was significantly higher in the DP-EES group (2.9 ± 0.4 vs. 3.0 ± 0.4 mm, $p < 0.001$). Further lesion and procedural characteristics are depicted in Table 2.

3.3. Clinical outcomes

Although significantly more number of patients had risk factors such as diabetes mellitus and severe lesion characteristic in the BDP-EES group, clinical outcomes in both groups were comparable at each follow-up interval. All the patients were followed up for 12-month duration without any dropouts. The details of clinical outcomes at 30 days, 6 months and 12 months are provided in Table 3. The MACE at 12 months was 4.2% and 4.9% ($p = 0.740$) for the BDP-EES group and DP-EES group, respectively. During follow-up, 23 (11.27%) patients from the Xience EES group and 19 (8.92%) patients from the Tetrilimus EES group had undergone coronary angiography because of clinical suspicion of restenosis based on the operator's discretion. The Kaplan–Meier curve for MACE-free survival rate for 12-month duration is shown in Fig. 2.

4. Discussion

Everolimus is a 40-O-hydroxyethyl derivative of sirolimus and was used in both the Tetrilimus EES and Xience EES as an active pharmaceutical ingredient. Some studies have established superiority[10,11] of everolimus, whereas some have reported therapeutic equivalence[12–14] of everolimus when compared with other antiproliferative agents. Both the delivery systems used the Co–Cr alloy stent platform. The differences that existed between the stents were use of polymer combination and stent design. The Tetrilimus EES design comprised long link connectors that enhance overall structural integrity, increase structural support, ensure uniform expansion of stent and provide optimum apposition to the vessel

Table 1
Baseline demographics and clinical characteristics.

Characteristics	Tetrilimus EES, $n = 213$	Xience family of the EES, $n = 204$	p-value
Demographic characteristics			
Age, (mean ± SD, years)	55.1 ± 11.5	53.0 ± 10.8	0.055
Male, *n* (%)	142 (66.7%)	130 (63.7%)	0.528
Risk factors			
Current smokers, *n* (%)	48 (22.5%)	50 (24.5%)	0.635
Hypertension, *n* (%)	103 (48.4%)	93 (45.6%)	0.571
Hyperlipidaemia, *n* (%)	83 (39.0%)	70 (34.3%)	0.324
Diabetes mellitus, *n* (%)	85 (39.9%)	62 (30.4%)	0.042
Renal insufficiency, *n* (%)	2 (0.9%)	3 (1.5%)	0.679
Left ventricular ejection fraction (%)	46.4 ± 6.5	45.9 ± 7.7	0.473
Complexity of coronary artery disease			
Single-vessel diseases, *n* (%)	86 (40.4%)	76 (37.3%)	0.513
Multivessel diseases, *n* (%)	127 (59.6%)	128 (62.7%)	0.513
Cardiac history			
Prior MI, *n* (%)	8 (3.8%)	7 (3.4%)	0.859
Prior CABG, *n* (%)	3 (1.4%)	9 (4.4%)	0.067
Prior PCI, *n* (%)	15 (7.0%)	24 (11.8%)	0.098
Prior stroke, *n* (%)	0 (0.0%)	2 (1.0%)	0.239
Clinical presentation			
Stable angina, *n* (%)	42 (19.7%)	36 (17.6%)	0.588
Unstable angina, *n* (%)	54 (25.4%)	68 (33.3%)	0.073
STEMI, *n* (%)	52 (24.4%)	58 (28.4%)	0.352
NSTEMI, *n* (%)	65 (30.5%)	42 (20.6%)	0.020
Cardiogenic shock, *n* (%)	3 (1.4%)	4 (2.0%)	0.719

MI, myocardial infarction; SD, standard deviation; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; NSTEMI, non–ST-segment elevation myocardial infarction; EES, everolimus-eluting stent.

Table 2
Lesion and procedural characteristics.

Characteristics	Tetrilimus EES, $n = 213$	Xience family of the EES, $n = 204$	p-value
Number of lesions, *n*	$n = 258$	$n = 239$	–
Target vessel location			
Left anterior descending artery, *n* (%)	117 (45.3%)	114 (47.7%)	0.600
Right coronary artery, *n* (%)	89 (34.5%)	69 (28.9%)	0.178
Left circumflex artery, *n* (%)	50 (19.4%)	52 (21.8%)	0.512
Left main artery, *n* (%)	1 (0.4%)	2 (0.8%)	0.610
Saphenous vein graft, *n* (%)	1 (0.4%)	2 (0.8%)	0.610
Lesion classification (ACC/AHA score)			
Type A, *n* (%)	13 (5.0%)	32 (13.4%)	0.001
Type B1, *n* (%)	33 (12.8%)	43 (18.0%)	0.107
Type B2, *n* (%)	38 (14.7%)	49 (20.5%)	0.091
Type C, *n* (%)	174 (67.4%)	115 (48.1%)	<0.001
Total occlusion, *n* (%)	30 (11.6%)	25 (10.5%)	0.678
Total number of stents, *n*	$n = 275$	$n = 254$	
Number of stents per patient, (mean ± SD, mm)	1.3 ± 0.5	1.3 ± 0.5	0.357
Average stent length, (mean ± SD, mm)	30.7 ± 10.1	23.7 ± 8.9	<0.001
Average stent diameter, (mean ± SD, mm)	2.9 ± 0.4	3.0 ± 0.4	<0.001

EES, everolimus-eluting stent; SD, standard deviation; ACC/AHA, American College of Cardiology/American Heart Association.

wall, while the Xience EES design comprises open cell and nonlinear link for better stent flexibility and vessel conformability. The Tetrilimus EES uses a BDP, and the Xience EES uses a DP. The present study was designed with minimal exclusion criteria to decrease unnecessary patient filtration so that a 'real world' population set-up can be imitated.

In the present study, patients from both the study arms were similar in terms of baseline and clinical characteristics at the time of presentation, excluding the number of diabetic patients. The number of diabetic patients was significantly higher in the BDP-EES group; correspondingly, the studies claim that patients suffering from diabetes are at higher risk of repeat revascularisation and ST and show poor clinical outcomes.[15,16] Moreover, both the study arms had similar target vessel location. However, the patients who underwent BDP-EES implantation had more complex lesions (higher number of type B2/C lesions) and significantly lower number of type A lesions than those in the DP-EES group. These factors play an eminent role in contributing towards the occurrence of clinical events in patients of both the groups, that is, a 4.2% MACE rate in the BDP-EES group and 4.9% in the DP-EES group.

There are an ample number of studies available for the DP-coated EES.[14,17–19] The MACE rates at 12 months were 5.1% according to the SPIRIT V study,[17] one of the benchmark studies for the Xience V EES. The results are comparable with those of the present study, where 12-month MACE rates were 4.9% in the DP-EES group and 4.2% in the BDP-EES group. Another single-arm study,[20] which was carried out on 1000 Indian patients and showed safety and efficacy of the Xience V EES, depicted 2.9% of all-cause death, MI and revascularisation at 12-month duration; these reported event rates were lower than those of the present study. The higher MACE rates in the present study may be because more number of patients in the DP-EES group had severe lesion type B2/C (68.6% vs. 46.8%). This depicts that not only stent characteristics but also the lesion characteristics pose influence towards the clinical

Table 3
Clinical outcomes in 12 months.

Clinical outcomes	Tetrilimus EES, $n = 213$	Xience family of the EES, $n = 204$	p-value
30 days			
Death, *n* (%)	1 (0.5%)	2 (1.0%)	0.616
Cardiac death, *n* (%)	1 (0.5%)	1 (0.5%)	1.000
Noncardiac death, *n* (%)	0 (0.0%)	1 (0.5%)	0.489
MI, *n* (%)	1 (0.5%)	0 (0.0%)	1.000
TLR, *n* (%)	0 (0.0%)	0 (0.0%)	–
TVR, *n* (%)	0 (0.0%)	1 (0.5%)	0.489
Stent thrombosis,[a] *n* (%)	2 (0.9%)	1 (0.5%)	1.000
Definite, *n* (%)	2 (0.9%)	0 (0.0%)	0.499
Probable, *n* (%)	0 (0.0%)	1 (0.5%)	0.489
Possible, *n* (%)	0 (0.0%)	0 (0.0%)	–
MACE, *n* (%)	2 (0.9%)	1 (0.5%)	1.000
6 months			
Death, *n* (%)	2 (0.9%)	4 (2.0%)	0.441
Cardiac death, *n* (%)	1 (0.5%)	2 (1.0%)	0.616
Noncardiac death, *n* (%)	1 (0.5%)	2 (1.0%)	0.616
MI, *n* (%)	1 (0.5%)	0 (0.0%)	1.000
TLR, *n* (%)	4 (1.9%)	3 (1.5%)	1.000
TVR, *n* (%)	0 (0.0%)	2 (1.0%)	0.239
Stent thrombosis,[a] *n* (%)	2 (0.9%)	1 (0.5%)	1.000
Definite, *n* (%)	2 (0.9%)	0 (0.0%)	0.499
Probable, *n* (%)	0 (0.0%)	1 (0.5%)	0.489
Possible, *n* (%)	0 (0.0%)	0 (0.0%)	–
MACE, *n* (%)	6 (2.8%)	5 (2.5%)	0.816
12 months			
Death, *n* (%)	2 (0.9%)	4 (2.0%)	0.441
Cardiac death, *n* (%)	1 (0.5%)	2 (1.0%)	0.616
Noncardiac death, *n* (%)	1 (0.5%)	2 (1.0%)	0.616
MI, *n* (%)	3 (1.4%)	4 (2.0%)	0.719
TLR, *n* (%)	5 (2.3%)	4 (2.0%)	1.000
TVR, *n* (%)	1 (0.5%)	2 (1.0%)	0.616
Stent thrombosis,[a] *n* (%)	2 (0.9%)	1 (0.5%)	1.000
Definite, *n* (%)	2 (0.9%)	0 (0.0%)	0.499
Probable, *n* (%)	0 (0.0%)	1 (0.5%)	0.489
Possible, *n* (%)	0 (0.0%)	0 (0.0%)	–
MACE, *n* (%)	9 (4.2%)	10 (4.9%)	0.740

MI, myocardial infarction; TLR, target lesion revascularisation; TVR, target vessel revascularisation; MACE, major adverse cardiac event; EES, everolimus-eluting stent.
[a] According to the Academic Research Consortium (ARC) criteria.

outcomes of patients after stent implantation. A study, EVOLVE China,[21] carried out on the Chinese population, used the BDP-EES in 205 patients and reported higher MACE rates at 12 months than those of the present study (5.5% vs. 4.2%). Both the BDP-EES differed in strut thickness (74–81 μm vs. 60 μm) and the stent platform (platinum–chromium vs. Co–Cr). A meta-analysis[22] compared newer generation ultrathin strut BDP-coated DESs against 2nd-generation thicker strut DP-coated DESs and showed that ultrathin strut BDP-coated DESs were able to reduce 1-year risk of target lesion failure compared with the other. This denotes that strut thickness plays a crucial role and should be taken into consideration while stent selection.

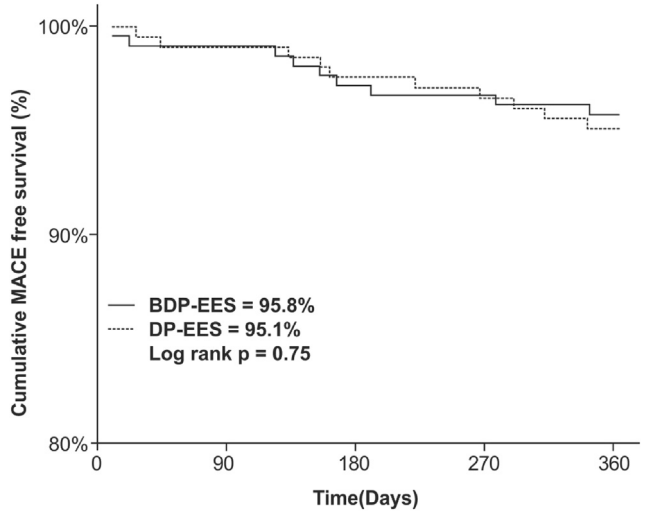

Fig. 2. Kaplan–Meier curve for 12-month MACE-free survival rate. MACE, major adverse cardiac event; BDP, biodegradable polymer; EES, everolimus-eluting stent; DP, durable polymer.

Mori et al[23] conducted a study comparing development of neoatherosclerosis between the DP-coated Co–Cr EES and bare metal Co–Cr stent and established that the DP-coated Co–Cr EES had favourable outcome in terms of intimal suppression, healing and inflammation but had worse outcomes in development of neoatherosclerosis when compared with bare metal stents; bare metal Co–Cr alloy stents were better at sustaining the development of neoatherosclerosis. These findings also provided a theoretical possibility that use of BDP-coated Co–Cr EESs may provide superior effects than the DP-coated and bare metal Co–Cr EES, and further focus on the BDP was recommended. Recent literature comparing safety and efficacy of BDP-coated vs DP-coated DESs has also quoted that both the delivery systems have similar outcomes at a short term (≤1 year).[24,25] The major finding from the present study is that there were no significant clinical differences between the devices, and the BDP-EES is noninferior and competent to the DP-EES.

4.1. Study limitation

The present study was limited by its retrospective, single-blind nature. Lesion characteristics reported here were evaluated by the investigators at the time of the procedure or from angiographic reports. No data were available on in-segment late loss as no follow-up angiography was carried out. Although an adequate number of patients were there in both the study groups, a study incorporating a higher number of participants is needed for events occurring at less frequency.

5. Conclusion

Despite significantly more number of diabetic patients and complex lesion characteristics in the Tetrilimus EES group, the BDP-coated Tetrilimus EES performed at par and emerged as efficient as the DP-coated Xience EES during the 12-month follow-up. Clinical outcomes of both the devices were commensurate at each pre-determined time points.

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Conflict of interest

The authors declare no conflict of interest.

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