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Original Research Article

Clinical and angiographic outcomes of very long drug eluting stents in patients with coronary artery disease undergoing percutaneous coronary intervention: a prospective observational study

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ABSTRACT

Background: To evaluate the procedural feasibility and clinical and angiographic outcomes of very long drug-eluting stents (DES) in patients with diffuse coronary artery disease undergoing percutaneous coronary intervention (PCI).
Methods: This observational study included 111 consecutive adult patients with de novo long coronary lesions treated with DES ≥48 mm between March 2018 and September 2019 at the Department of Cardiology, Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow. Clinical outcomes at 1 and 6 months included major adverse cardiac events (MACE) such as myocardial infarction, angina and congestive heart failure. Angiographic outcomes at 6 months included in-stent restenosis, target lesion revascularization, target vessel revascularization and stent thrombosis.
Results: No significant correlation was observed between clinico-angiographic outcomes and stent length, stent diameter, stent polymer, multi-vessel PCI or diabetic status ($p>0.05$). However, diabetic status significantly affected clinical outcomes at 6 months ($p=0.020$). The incidence of angina was significantly higher at 6 months compared with 1 month. Survival analysis at 1 and 6 months showed no significant difference in patient survival ($p=0.778$).
Conclusions: Very long DES implantation for diffuse coronary lesions appears safe and effective, with low rates of adverse clinical and angiographic events. Stent length, diameter and polymer type did not significantly influence outcomes.

Keywords: Coronary artery disease, Major adverse cardiac events, Percutaneous coronary intervention, Stent thrombosis, Very long drug eluting stents

INTRODUCTION

Coronary artery disease (CAD) has emerged as a critical cause of death in both men and women across urban and rural populations, as well as in developed and developing nations.[1] In India, more than 10.5 million deaths occur annually and among these, CAD accounts for 20.3% and 16.9% of deaths in men and women, respectively.[2] The CUPS study reported that the prevalence of CAD risk in Indians is 11% in non-diabetic patients and 21.4% in diabetic patients.[3] Additionally, around 20% of patients with CAD suffer from long lesion disease.[4] The management of long coronary lesions has become increasingly important in clinical practice due to the rising incidence of long or complex lesions in aging populations with increasing comorbidities.[5] Many patients with complex lesions prefer percutaneous coronary intervention (PCI) over coronary artery bypass grafting (CABG); at the same time, the number and total length of stents placed in patients with multivessel CAD during PCI is gradually increasing.[6] Despite advancements in drug-eluting stents (DES), the problem of in-stent restenosis (ISR) remains a

challenge. The RIBS II trial compared sirolimus-eluting stents with plain old balloon angioplasty (POBA) in patients with bare-metal stent (BMS)-ISR and found that the former significantly reduced restenosis rates (11%) and improved long-term clinical outcomes.[7] Additionally, intravascular ultrasound imaging after sirolimus-DES implantation revealed a marked reduction in neo-intimal proliferation.[7]

Another study with 4 years follow-up demonstrated sustained clinical benefits without any significant increase in major adverse cardiovascular events (MACE).[8] A meta-analysis by Siontis et al confirmed these findings and further showed that repeat stenting with everolimus-DES was superior in reducing myocardial infarction (MI), death, ISR and target lesion revascularization (TLR).[9]

In contrast to the BMS era, stent length and lesion length are considered less important with DES due to significantly reduced ISR rates.[10] However, the effect of lesion length on long-term outcomes in the DES era remains underexplored. Moreover, it is still controversial whether the use of longer stents during PCI improves patient outcomes. Therefore, the objective of this study was to assess the procedural feasibility and the clinical and angiographic efficacy of very long DES (>48 mm) in patients with long coronary lesions.

METHODS

This was a single-center, observational study conducted over 19 months, from March 2018 to September 2019. A total of 111 consecutive patients with de novo long coronary artery lesions attending the Department of Cardiology, Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow, were included. All patients underwent PCI with implantation of new-generation long DES (≥48 mm). The study protocol was approved by the Institutional Ethics Committee and written informed consent was obtained from all patients.

Inclusion criteria

Patients included were aged >20 years, of either sex, with significant native coronary artery stenosis (>50% by visual estimation) and long lesion length, who underwent PCI with very long stents (>48 mm). Patients presented with silent ischemia, stable angina, unstable angina, ST-elevation myocardial infarction (STEMI) or non-ST-elevation myocardial infarction (NSTEMI).

Exclusion criteria

Patients were excluded if they required elective surgery necessitating interruption of antiplatelet therapy within 6 months, were participating in another investigational study, were dialysis-dependent, had a terminal illness with life expectancy <1 year or were unlikely to complete follow-up.

Study procedure

Baseline clinical characteristics were recorded and all patients underwent detailed history, examination, ECG, 2D echocardiography and biochemical investigations. All interventions were performed using standard techniques. Patients received pre- and post-procedural medications as per guidelines. Glycoprotein IIb/IIIa inhibitors were used at the operator's discretion. All patients received a loading dose of a P2Y12 receptor antagonist (prasugrel, ticagrelor or clopidogrel), followed by dual antiplatelet therapy (DAPT) with aspirin.

Coronary angiography (CAG) and angioplasty (CAP) were performed according to the clinical presentation. Angiographic parameters assessed at baseline and at 6 months included lesion length, stent length, reference vessel diameter, minimal luminal diameter, percent diameter stenosis. Measurements were performed using quantitative coronary angiography (QCA). Lesion length was defined as contiguous coronary narrowing >50%. Lesions were classified using the modified American College of Cardiology/American Heart Association (ACC/AHA) grading system.[11]

Study outcomes

Clinical outcomes included MACE, defined as death, MI, CHF and angina. Angiographic outcomes included target lesion failure (TLF), defined as ISR, TLR, target vessel revascularization (TVR) and stent thrombosis (ST).

Clinical follow-up was performed at 1 and 6 months and angiographic follow-up at 6 months. Primary endpoints were binary ISR at 6 months, MACE at 6 months.

Data analysis

Statistical analysis was performed using SPSS version 23 (IBM Inc., Chicago, IL, USA). Continuous variables were expressed as mean±standard deviation, while categorical variables were expressed as frequencies and percentages. The chi-square test was used for comparison of categorical variables. Spearman rank correlation was used to assess associations between variables. Kaplan–Meier analysis was used to estimate MACE-free survival and the log-rank test was used for comparison. A p value <0.05 was considered statistically significant.

RESULTS

Table 1 summarizes baseline characteristics. The majority of patients were male (74.77%) and aged 40–70 years (88.29%). The most common risk factors were hypertension (43.24%), diabetes (34.23%) and smoking (27.93%).

Dyslipidemia prevalence was relatively low, likely due to statin use. Acute coronary syndrome (ACS) was observed in 66.6% of patients. Reduced LVEF and abnormal ECG

findings were present in 53.15% and 76.58% of patients, respectively. On angiography triple vessel disease (TVD): 56.76%, double vessel disease (DVD): 31.53%, single vessel disease (SVD): 8.11%. Most patients (75.6%) underwent multivessel PCI with very long DES (>48 mm). A total of 118 long stents were used in 111 patients. The most commonly used stent length was 48 mm (68.6%) and sirolimus-eluting stents were used in 92.4% of cases.

Clinical outcomes

There was no statistically significant difference between clinical outcomes at 1 and 6 months in terms of asymptomatic status, CHF, MI or mortality. However, significantly more patients developed angina at 6 months compared to 1 month (p = 0.01).

At 6 months 91.89% were asymptomatic, 1 patient required CABG, 2 deaths were recorded, Kaplan–Meier analysis showed a MACE-free survival rate of 90.1%, with no significant difference between 1- and 6-month follow-up (p=0.778).

Correlation analysis

A weak and non-significant correlation was observed between clinical/angiographic outcomes and stent length, vessel involvement, stent diameter, polymer type. A moderate and statistically significant correlation was found between diabetes and adverse clinical outcomes at 6 months (p=0.02).

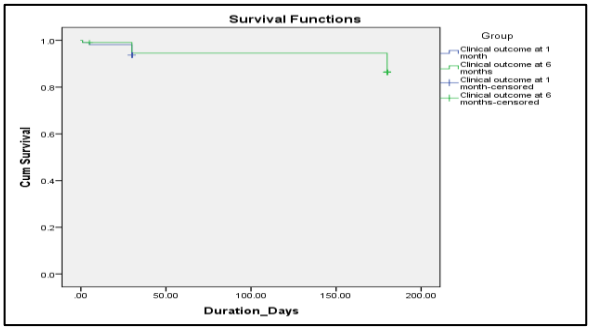

Figure 1: Kaplan–Meier estimates for patient survival.

Table 1: Baseline characteristics of the patients.

Characteristics	N (%)
Age groups (in years) (n=111 (%))	
30–40	6 (5.41)
41–50	25 (22.52)
51–60	37 (33.33)
61–70	36 (32.43)
>70	7 (6.31)
Mean age (mean±SD, years)	56.97±10.04
Gender (n=111 (%))	
Male	83 (74.77)
Female	28 (25.23)
Risk factors (%)	
Hypertension	48 (43.24)
Diabetes mellitus	38 (34.23)
Smoking	31 (27.93)
Dyslipidemia	21(18.9)
Thyroid disorders	9 (8.1)
Alcohol	4 (3.60)
CHF	4 (3.60)
COPD	2 (1.80)
CKD	2 (1.80)
CVA	1 (0.90)
Anemia	1 (0.90)
Clinical presentation (n=111 (%))	
Stable angina	37 (33.33)
Unstable angina	6 (5.41)
STEMI	52 (46.85)
NSTEMI	16 (14.41)
LVEF (%) (n=111 (%))	
>50	52 (46.85)
40–50	36 (32.43)
30–40	16 (14.41)
<30	7 (6.31)
ECG findings (n=111 (%))	
Normal	26 (23.42)

Continued.

Characteristics	N (%)
Abnormal	85 (76.58)
Vessels involved (n=111 (%))	
SVD	9 (8.11)
DVD	35 (31.53)
TVD	63 (56.76)
Left main+DVD	2 (1.80)
Left main+TVD	2 (1.80)
Type of PCI (n=111 (%))	
Single-vessel PCI	27 (24.32)
Multi-vessel PCI	84 (75.68)
Size of long stents (mm) (n=118 (%))	
48	81 (68.6)
50	25 (21.1)
60	12 (10.1)
Type of drug eluting stent (n=118 (%))	
Silrolimus	109 (92.4)
Everolimus	9 (7.6)

Table 2: Various parameters influencing clinical outcome at 1 month and 6 months.

Clinical outcome Parameters	Mortality		MI		Angina		CHF		Asymptomatic		Total		Spearman's rho		*P value	
	1M	6M	1M	6M	1M	6M	1M	6M	1M	6M	1M	6M	1M	6M	1M	6M
Long stents (n=118)																
48 mm	2	2	0	0	1	6	2	2	69	64	74	74	0.042	- 0.007	0.663	0.943
50 mm	0	0	1	0	1	3	0	0	23	22	25	25				
60 mm	0	0	0	0	0	2	0	0	12	10	12	12				
Irrespective of long stents (n=118)																
Number (%)	2 (1.8)	2 (1.8)	1 (0.9)	0 (0.0)	2 (1.8)	11 (9.9)	2 (1.8)	2 (1.8)	104 (93.7)	96 (86.5)	-					
#P value	1.000		0.316		0.010		1.000		0.072							
Single or multi-vessel PCI (n=111)																
Single-vessel PCI	0	0	1	0	1	4	1	1	24	22	27	27	0.109	0.076	0.255	0.430
Multi-vessel PCI	2	2	0	0	1	7	1	1	80	74	84	84				
Diabetic status (n=111)																
Diabetic	2	2	0	0	0	6	1	1	35	29	38	38	-0.051	-0.221	0.598	0.020
Non-diabetic	0	0	1	0	2	5	1	1	69	67	73	73				

Data represented as frequencies, *-Spearman's correlation coefficient, # Chi-square test, p value<0.05 was considered as statistically significant.

Table 3: Various parameters influencing angiographic outcomes of long stents at 6 months.

Angiographic outcome parameters	Patent stent	Mild ISR	Moderate ISR	Severe ISR	ISR in other stents	New lesions	Acute stent thrombosis	Sub-acute stent thrombosis	Total	Spearman's rho	P value
Long stents (n= 118)											
48 mm	60	13	2	2	1	1	2	0	81	0.074	0.438
50 mm	16	5	0	1	0	2	0	1	25		
60 mm	8	2	1	0	0	1	0	0	12		
Stent polymer (n=117)											
Biodegradabe	68	16	3	3	0	4	2	1	97	- 0.056	0.552
Biostable	15	4	0	0	1	0	0	0	20		

Continued.

Angiographic outcome parameters	Patent stent	Mild ISR	Moderate ISR	Severe ISR	ISR in other stents	New lesions	Acute stent thrombosis	Sub-acute stent thrombosis	Total	Spearman's rho	P value
Stent diameter (mm) (n=118)											
2.5	33	3	1	1	0	2	1	0	41		
2.75	25	10	1	2	1	0	1	0	40		
3	17	3	0	0	0	2	0	1	23	0.087	0.350
3.5	9	4	1	0	0	0	0	0	14		

Data represented as frequencies; * - Spearman's correlation coefficient; p value<0.05 was considered as statistically significant.

Table 4: Distribution of patients according to the management after 6 months follow-up.

Management	n=111 (%)
Optimal medical	102 (91.89)
Thrombo-suction with management to stent thrombosis	1 (0.9)
DEB to ISR	1 (0.9)
PTCA stent to ISR	1 (0.9)
PTCA stent to new lesion	3 (2.7)
CABG	1 (0.9)
Death	2 (1.8)

DISCUSSION

The success of interventional cardiology lies in reducing disease burden and improving quality of life in patients with CAD.12 Very long and tapered stents have facilitated the treatment of diffuse coronary lesions. For example, the BioMime Morph sirolimus DES has been effectively used in long tapered lesions.[13] The mean age (56.97±10.04 years) reflects earlier onset of CAD in the Indian population compared to Western populations.[14] Male predominance observed in this study is consistent with previous reports.[15] Hypertension, diabetes and smoking were the most common risk factors, consistent with prior studies.[16] Dyslipidemia remains a major contributor to CAD, although its prevalence was lower in this study, possibly due to widespread statin use.[17,18] ACS was the most common presentation, unlike Western populations where stable angina predominates.[19] This suggests more aggressive disease patterns in Indian patients. Multivessel disease was common and multivessel PCI demonstrated favorable outcomes, consistent with previous studies.[20] Diabetes showed a significant association with adverse outcomes at 6 months, although previous studies have reported conflicting findings.[21] Angiographic outcomes showed no significant association between stent length and TLF, consistent with existing literature.[22-24] New-generation DES appear to reduce the impact of lesion length.[25] Biodegradable polymer DES did not significantly differ from durable polymer DES in outcomes but may reduce long-term inflammatory responses.[26-30]

CONCLUSION

Very long drug-eluting stents (>48 mm) are safe and effective for the treatment of diffuse coronary lesions, with high procedural success and favorable short-term outcomes. At 6 months, low rates of MACE and TLF were observed. However, longer-term follow-up is required to establish sustained efficacy, particularly in high-risk populations such as diabetic patients.

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