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Original Article

Procedural safety and outcome of ultrathin strut stents (<60 μm) in the management of very long coronary artery stenosis (>30 mm) - A retrospective real world study

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Abstract: Background: The ultrathin strut stents (<60 μm) are new in the current stents technology. This technology has assured to have less stent thrombosis, restenosis and better deliverability. Still there is lacking data of using long ultrathin strut stents in very long segment coronary artery disease (>30 mm). Aim: The aim of this retrospective study was to assess the procedural safety and outcome of using ultrathin strut stents in very long segment coronary artery lesion. Methods: In this retrospective analysis, we have enrolled those patients who had an implant of more than 30 mm length of ultrathin strut stents (Evermine 50™ and Tetrilimus stents) in real world patients as per physician discretion. Here, we enrolled 156 patients which included both acute coronary syndrome (ACS) and stable ischemic heart disease (SIHD). The endpoint of this study was to evaluate the immediate procedural success and short to intermediate term follow-up of all-cause mortality and clinically driven target lesion revascularization. Results: Out of these 156 patients (mean age- 61.2 +/- 10.4 years; male: 114), in 12 patients, these long stents couldn't be delivered. In rest 144 patients, 147 ultrathin strut stents were implanted. In about 56% patients were hypertensive and 48% patients were diabetic. About 63% patients had ACS and rest 37% patients had SIHD. The mean duration of follow up was 8.4 +/- 13.9 months. Average stent length and diameter were 39.5 +/- 5.9 mm and 3.03 +/- 0.4 mm, respectively. There was no acute or sub-acute stent thrombosis and no procedural complication. Five patients died during follow-up (all-cause mortality) and rest are all symptoms free. There were no statistical significant differences seen among the stent types. Conclusion: Ultrathin strut stents can be considered for stenting in long segment coronary artery stenosis with reasonably good procedural success rate and have good clinical outcome, but needs further large randomized trial before using in this particular clinical condition. Both the stent designs have similar clinical outcome and procedural success.

Keywords: Angioplasty, coronary artery, stent, ultra-thin strut

Introduction

Long segment coronary artery lesions account for about 20% of all percutaneous coronary interventions (PCI) [1] and it is becoming challenges to the interventional cardiologist to finish with fewer numbers of stents in our developing country to reduce the financial burden to the patient. These types of lesions also have increase restenosis rate [1]. The newer generation biodegradable ultrathin strut drug eluting stents (DES) help in reducing stent thrombosis and restenosis rate by decreasing the strut thickness along with its biodegradable polymer. This newest technique supposed to cause less coronary intimal injury [2]. So far there is no study experimenting the procedural safety and efficacy of this newer generation stents in very long segment coronary artery stenosis (>30 mm). There may not be issues of deliverability while deploying these ultrathin strut stents as decreasing strut thickness though decreases radial strength of a stent but improves trackeability while tracking a long segment stenosis in a coronary artery [3]. We hereby in this study used two ultrathin strut biodegradable polymer

(BDP) coated cobalt-chromium everolimus eluting stents (EES) namely Evermine 50 (Meril Life Sciences Pvt. Ltd., India; strut thickness-50 μm) and Tetrilimus (Sahajanand Medical Technologies Pvt. Ltd., Surat, India; strut thickness-60 μm) in very long segment coronary artery stenosis to assess immediate procedural safety and outcome following stent implantation. This is the first ever trial where we also compare the technical success between these two different ultrathin strut stents.

Methodology

Study design

It was a retrospective observational study conducted in a tertiary care non-governmental teaching institution.

Primary end point

The primary end point of this study was to assess the immediate procedural success and clinical outcome in the post angioplasty period up to 30 days.

Secondary outcome

The secondary outcome was to assess the all-cause mortality during the study period.

Patients

We enrolled all consecutive patients (both acute coronary syndrome and chronic stable angina) who had critical coronary artery stenosis (>70% by conventional angiogram) with a lesion length of 30 mm or more by quantitative coronary angiogram (QCA) and also had angioplasty with ultrathin strut stents (Evermine 50 & Tetrilimus). This retrospective study enrolled all patients who had angioplasty done between December 2017 to November, 2019 with before mentioned stents as per physician discretion. Those patients who didn't give consent to enrol in this study, had angioplasty done with stent length <30 mm and also didn't undergo angioplasty with the above mentioned stents were excluded from this study.

Ethics

The study protocol was approved by the Ethics Committee of the respective authority of our institution. Written informed consent will be obtained from all patients, before inclusion in the study.

Definition of endpoints

The immediate procedural success was defined by successful deliverability and placement of the stents with good angiographic lumen diameter (<30% stenosis post stenting) without any death, myocardial infarction (MI), stent thrombosis (ST) or target lesion revascularization during hospital stay. Intravascular imaging was not mandatory during PCI in this study. The clinical outcome up to 30 days was assessed by few safety endpoint like the occurrence of major adverse cardiac events (MACE), composite of cardiac death, myocardial infarction (MI) attributed to the target vessel, and clinically driven target lesion revascularization (CD-TLR) at 1-month follow-up after the index procedure. Cardiac death was defined as any death due to acute MI, stroke or heart failure, death related to procedure, or unknown cause [4]. MI was defined as development of new pathological Q waves on electrocardiogram, or elevation of creatinine kinase (CK) ≥ 2 fold the upper limit of normal with elevated CK-MB in the absence of new pathological Q waves or new ischemic symptoms [4]. CD-TLR was defined as repeat PCI or revascularisation as clinically indicated or coronary artery bypass graft surgery triggered by clinically indicated repeat coronary angiography [5]. Stent thrombosis (ST) was classified according to the definitions of the Academic Research Consortium [5].

Stent design

Evermine 50: The Evermine 50 EES is a fourth-generation DES (Meril Life Sciences Pvt. Ltd., India) which is built on thinnest (50 μm) strut Co-Cr platform. It is coated with BDP: PLGA (poly-lactic-co-glycolic acid) and PLLA (poly-L-lactic acid). Evermine 50 EES uses unique hybrid cell design comprising of an intelligent mix of open cells in the mid segment and closed cells at the edges. The Evermine 50 EES elutes everolimus (1.25 μg/mm^2 of stent area) as an anti-proliferative drug.

Tetrilimus: The Tetrilimus EES is also a fourth-generation DES. The Tetrilimus EES comprises surgical grade L605 CoeCr alloy having a strut thickness of 60 mm (i.e., Tetrinium coronary stent platform; Sahajanand Medical Tech-

Table 1. Demographic and clinical parameter of study subjects

Characteristics	Total no of patients, n=156
Age	61.2 +/- 10.4 years
Male	114 (73%)
BMI	26.2 +/- 3.1
Diabetes	75 (48%)
Hypertension	87 (56%)
Dyslipidemia	80 (51%)
Smoker	59 (36%)
Family history of CAD	33 (21%)
Past history of IHD/PCI/CABG	17 (11%)
ACS (MI/UA/NSTEMI)	98 (63%)
SIHD	58 (37%)
SVD	80 (51%)
DVD	55 (35%)
TVD	21 (14%)
Mean LVEF (%)	40.2 +/- 10.8%

BMI: Body mass index; CAD: coronary artery disease; IHD: ischemic heart disease; PCI: percutaneous coronary intervention; CABG: Coronary artery bypass grafting; ACS: acute coronary syndrome; MI: myocardial infarction; UA: unstable angina; NSTEMI: non ST elevation MI; SIHD: stable ischemic heart disease; SVD: single vessel disease; DVD: double vessel disease; TVD: triple vessel disease: LVEF: left ventricular ejection fraction.

nologies Pvt. Ltd., India), everolimus as the active pharmaceutical ingredient and BDP as the drug carrier.

Concept behind thinner strut platform

The thinnest struts (<75 μm) provide low blood flow perturbance and easy strut nesting to the vessel wall. It also has flexibility and conformability during the process of implantation [6]. The presence of thicker strut shows high protrusion into the lumen which alters blood vessel flow dynamics, creating areas of turbulent flow with altered shear stress. This altered shear stress related to activation of platelets and upregulation of smooth muscle cell proliferation, which may additionally worsen the pathology of an already injured vessel [7, 8]. In contrast, a laminar flow model linked to ultrathin strut stents mimic physiological setting [9]. Hence, more supportive in reducing the formation of in-stent restenosis and maintained the endothelialisation capacity.

Statistical analysis

The demographic and baseline characteristics were summarized using the descriptive statistics. For continuous variable such as age, data were presented as mean ± SD. The categorical variables such as gender, risk factors, cardiac status were presented as frequency and percentages. Percentage was calculated according to the number of patients for whom data were available. Chi-square test was used for comparison between two stent types and *p*-value was considered significant if it was <0.05. All the statistical analysis was performed using software SPSS version 18 (SPSS Inc, Chicago, IL, USA).

Results

*Demographic and clinical characteristics (**Table 1**)*

About 156 patients were enrolled during this study period. The mean age of our study subjects was 61.2 +/- 10.4 years and out of them 114 patients was male and rest was female. Out of these 156 patients, 75 (48%) patients are diabetic, 87 (56%) patients are hypertensive and 80 (51%) patients are dyslipidemic. About thirty-six percent patient had history of smoking and another twenty-one percent patient had family history of coronary artery disease (CAD). Eleven percent patients had previous history of ischemic heart disease (IHD), PCI or coronary artery bypass grafting (CABG). About 63% patients diagnosed as acute coronary syndrome (ACS) and rest 37% patients had stable IHD (SIHD). In about fifty-one percent, coronary angiogram revealed single vessel CAD and another forty nine patients had multivessel CAD.

*Lesion and procedural characteristics (**Table 2**)*

Among 156 patients, 144 patients and 147 lesions was successfully stented with very long (>30 mm) ultrathin stents. In 12 patients, these long stents couldn't be delivered successfully so smaller stent length was delivered. The failure was due to excessive tortuosity of the vessel prevented delivery of stent in 7 cases and unusual eccentric calcium spurs prevented tracking in other 5 cases. Average stent length and diameter were 39.5 +/- 5.9 mm and 3.03 +/- 0.4 mm, respectively. The most common target vessel in this study was left anterior descending (LAD) artery (43%) followed by right coronary artery (RCA) in (42%) cases. About ten percent of our study patients had chronic total

Table 2. Lesion and procedural characteristics

Characteristics	Patients (n=156)
Total number patient treated	144
Number of ultrathin strut very long (>30 mm) stents used	147 (1.02 per person)
Average lesion length by QCA	32.6 +/- 2.4 mm
Average stent length	39.5 +/- 5.9 mm
Average stent diameter	3.03 +/- 0.4 mm
Lesion location	
LAD	62 (43%)
LCX/OM/RAMUS	21 (15%)
RCA	60 (42%)
SVG graft	01
Chronic total occlusion	15 (10%)
Bifurcation	7 (5%)
Predilation	137 (95%)
Post dilation	132 (92%)
TIMI III flow post procedure	139 (97%)
Use of buddy wire or mother & child technique for stent deployment	55 (38%)
Antiplatelets used	
Aspirin	144 (100%)
Clopidogrel	103 (72%)
Ticagrelor	41 (28%)

QCA: quantitative coronary angiogram; LAD: left anterior descending; LCX: left circumflex; OM: obtuse marginal; RCA: right coronary artery; SVG: saphenous venous graft.

Table 3. Clinical outcome during follow-up

Characteristics	Patients (n=144)
All cause death	5 (3%)
Cardiac	2 (1.4%)
Non cardiac	3 (1.6%)
MI	0
CD-TLR	0
ST	0
MACE	0

MI: myocardial infarction; CD-TLR: clinically driven target lesion revascularization; ST: stent thrombosis; MACE: major adverse cardiac events.

occlusion (CTO) and five percent patient had undergone bifurcation stenting. Predilation and postdilation was performed in good number of cases, 95% and 92% respectively. Among these 144 cases, where successful device deployment was performed, buddy wire technique used in 31 cases and another 24 cases mother and child technique was used for successful deliverability of the very long stent. All patients were planned to put on dual antiplatelet therapy for at least 12 months.

*Clinical outcome during follow-up (**Table 3**)*

There was no acute or sub-acute stent thrombosis and no procedural complication seen during hospital stay or with 30 days after the index procedure. The mean duration of follow up was 8.4 +/- 13.9 months. Five patients died during follow-up (all-cause mortality) and rest are all symptoms free during follow-up. Among these 5 cases, two patients died due to acute decompensated heart failure after 3 months of coronary intervention and both of them had baseline severe left ventricular systolic dysfunction. The remaining 3 patients, 2 patients died due to lung infection and another patient died due to chronic kidney disease.

*Comparison between two different stent types in our study (**Table 4**)*

Among 156 patients enrolled in this study, 65 patients were in Evermine50 arm and 91 patients were in Tetrilimus stent arm. Six patients in Evermine50 arm and 9 patients in Tetrilimus arm had failed implantation and finally 60 Evermine50 and 87 Tetrilimus stents

Table 4. Comparison between two different stent types

Variables	Evermine arm (n=65)	Tetrilimus arm (n=91)	*P* value
Demographic & clinical parameter			
a.→Mean age (years)	63.1 +/- 5.6 years	65.4 +/- 5.5 years	0.203
b.→Sex (M:F)	49:16	65:26	0.828
c.→Diabetes	35 (54%)	40 (44%)	0.472
d.→Hypertension	38 (58%)	49 (54%)	0.761
e.→Dyslipidemia	33 (51%)	47 (52%)	0.937
f.→ACS	40 (61%)	58 (64%)	0.893
g.→SIHD	25 (38%)	33 (36%)	0.849
h.→Mean LVEF (%)	44.6 +/- 6.3	45.3 +/- 5.8	0.239
i.→Multivessel disease	31 (48%)	45 (49%)	0.898
Lesion & procedural characteristics			
a.→Average lesion length	34 +/- 1.1 mm	33 +/- 2.5 mm	0.269
b.→Average stent length	42.6 +/- 3.4 mm	44.2 +/- 4.8 mm	0.282
c.→Average stent diameter	3.0 +/- 0.25	3.0 +/- 0.5	0.684
d.→Lesion location (LAD/LCX/RCA)	25/8/27	37/13/33	0.855
e.→CTO/Bifurcation	06/03	09/04	0.881
f.→Pre/post dilation	57/54	80/78	0.991
g.→TIMI III flow post procedure	58	81	0.914
h.→Use of buddy wire/mother child technique	23 (35%)	32 (35%)	0.889
i.→Failure of deployment	06 (9%)	09 (10%)	0.881
j.→Use of IC imaging	12 (18%)	22 (24%)	0.621
k.→DAPT	100%	100%	0.908
Clinical outcome			
a.→All cause death	2	3	0.699
b.→Cardiac death	1	1	0.628
c.→MI/ST/MACE/TLR	0	0	

ACS: acute coronary syndrome; SIHD: stable ischemic heart disease; LVEF: left ventricular ejection fraction; LAD: left anterior descending; LCX: left circumflex; RCA: right coronary artery; CTO: chronic total occlusion; IC: intracoronary; DAPT: dual antiplatelet therapy; MI: myocardial infarction; CD-TLR: clinically driven target lesion revascularization; ST: stent thrombosis; MACE: major adverse cardiac events.

were implanted in 144 patients (total 147 stents). There were no statistically significant differences seen in any of the cilinical or procedural variables included in this study.

Discussion

This retrospective study was designed to assess the procedural safety and technical success of ultra thin strut (<60 μm) stents in real world all comer patients with very long segment coronary artery lesion (30 mm or more) as there is no data available in this type of CAD. Ultrathin strut design was supposed to increase deliverability, reduce arterial injury and hence facilitate faster endothelialisation and has associated with reduce thrombogenicity [10]. In our study, among 156 cases, in 12 (8%) cases this long stent couldn't be delivered. Recently published two meta-analysis confirmed the safety and efficacy of biodegradable polymer coated ultrathin strut stents have favourable outcome in compare with second generation durable polymer coated DES [11-13]. Though recent meta analysis comparing safety and efficacy of bio degradable polymer coated vs durable polymer coated DESs has shown to have similar outcomes at a short term (1 year) [14, 15]. Another trial on CTO also has found the safety and efficacy of polymer free ultrathin strut stents in this clinical situation [16]. Only few trials so far have been done on this new generation ultrathin strut stents which showed comparable safety and efficacy of using these two stents in real world population [17-19]. Intervention in long segment coronary artery

lesions are prone to have increased TLR and repeated intervention as lesion length is a predictor of in stent restenosis [20, 21]. There is lack of data in using these new generations stents in this particular clinical situation. Our study was an all comer real world study and about fifty percent patient has multivessel disease. In nine-two percent cases, we have successful PCI done with these two new generation ultra thin strut >30 mm stents. In about thirty-eight percent cases buddy wire or mother-child technique required for stent deliverability. There was only 5 deaths (2 cardiac) happened during follow-up and no death, MI, TLR or ST happened during first month after revascularization.

As there was no previous study comparing these ultrathin struts BDP coated stents so we were unable to compare with the previous study. We found both the ultrathin struts have similar clinical and procedural outcome while deploying in this particular clinical situation of very long segment coronary artery stenosis.

The present study has severe limitations. Though it was evaluated retrospectively and there were no control subjects. It has intermediate term follow-up and sample size was small. Intravascular imaging was not mandatory for PCI in all patients due to financial constrain. There was no routine angiographic follow-up done in the study subjects. Keeping in mind about these limitations, it could be an eye opener in using these ultrathin struts stents in this clinical scenario but the finding from the present study should be interpreted with caution. We need large long term randomized head to head trial to assess the safety and efficacy of the ultrathin struts long stents.

Conclusion

Low incidence of all cause death rate and absence of MACE, MI, ST at early 30-day follow-up indicates that long ultrathin struts BDP coated DES may have encouraging safety and efficacy in unselected real-world patients with long segment high risk complex CAD. These stents can be considered for stenting in long segment coronary artery stenosis with reasonably good procedural success rate and have good clinical outcome as it may reduce cost of the procedure in our developing nation, but we needs further large randomized trial before routinely using in this particular clinical condition. Both the stents type here used in this study is found to have similar clinical outcome and procedural success rate.

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Disclosure of conflict of interest

None.

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