Original Article

Safety of Longer Size Stent in Treating De-Novo Long Coronary Lesion: Outcome at 1.5 Years Follow-Up, A Single Center Experiences

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Abstract:

Background: Percutaneous coronary intervention (PCI) of long lesions by long single stent or overlapping multiple stent might have higher incidences of ISR due to increased metal burden as well as coronary intervention increase cost of hospital stay. Therefore, our primary aim of our study was to evaluate the long-term safety of treating long lesion by a single longer size stent and its follow-up by coronary angiogram and or clinical evaluation at our OPD.

Methods: patient who had gone through PCI from the year 2014 to mid Oct 2017 at our center, had longer lesion and were treated by more than 38mmstent were selected and analyzed. Total 255(Male 213: Female 42) patients were enrolled in this study, underwent elective PCI and follow up CAG at on average 1.5 yrs. Total 267 stents were deployed in 255 patients, in some of the patient had double vessel disease to treat. Mean age for both male: female was(55 :56) yrs. Associated Coronary artery disease (CAD) risk factors were Dyslipidemia, Hypertension, Diabetes Mellitus, Positive FH for CAD and Smoking (all male), CKD, Hypothyroidism.

Results: Among the study group; 192 (75.3 %) were hypertensive; 189(74.1%) were Dyslipidemic, 126(49.4%) patients were Diabetic, positive FH 74(29.4 %), CKD 8 (3.1%), Hypothyroidism 2 (0.8%) and 104(40.8%) were all male smoker. Common stented territory was, LAD 126(49.4%), RCA 115(45.1%), and LCX 24(9.4%).Among the total patient population, Single vessel stented were 236 (92.5%) and DVD 19 (7.5%). Total 267 stents were deployed, among them 48mm were in total 159 (59.6%); among 40 mm were stented in 61(22.8%) and 38 mm in 47(17.6%) vessels. At an average follow-up period of 1.5 years, all stented territory remain patent without any residual stenosis.

Conclusion: We conclude that treating de-novo coronary long lesion by a single longer size stent is safe without any residual stenosis at an average follow-up period of 1.5 yrs. Thus, to reduce chances of recurrent ISR, hospital re-admission and reduce hospital cost as well.

Key Wards: CAG, PTCA, PCI, DES, Long lesion, Stents

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Introduction:

Treating long segment coronary lesion is always a challenge for interventionist to deal with. Percutaneous Coronary Intervention (PCI) by implanting a stent inside a coronary artery, has been shown to decrease the morbidity of acute closure of the vessel.[1] Clinical and angiographic restenosis rates in selected lesions are reduced with coronary stenting as

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compared with angioplasty. [2-3]Multiple or long coronary stents are now being implanted in long lesion or in tandem lesions.

Longer lesion usually need a longer segment to be covered by stents, and thus may require more than one stent. Both greater stented length and higher number of stents may exacerbate the risk of restenosis and mask direct relation lesion length and lumen narrowing after coronary stenting [4-5]Previously, treating long lesion by multiple overlapping stents has shown significant stent restenosis [6-8]

Treatment of long and diffuse coronary lesion have been associated with increased risk of restenosis after PCI. A higher angiographic restenosis of 58% reported after plain balloon angioplasty.[9]Although, the advent of bare metal stents was a breakthrough, was not successful in treating long coronary lesion. Implantation of multiple stents in treating long lesion resulted in diffuse in-stent restenosis. [10] With the advent of drug eluting stents in treating long segment coronary lesion, there has been dramatic reduction of ISR and repeat revascularization as compared to BMS.[11-12]

With the advent of modality of treating coronary stents of different DES, treating of a single long de-novo coronary lesion by using a single stent in our Bangladeshi patient population yet to known clearly. Therefore, we have carried out this non randomized prospective cohort of patient who had PCI with a stent> 38mm in length. Our primary aim of the study was to evaluate the long-term safety of treating long lesion by a single longer size stent and its follow-up by coronary angiogram and or clinical evaluation at our OPD.

Methods:

Patients who underwent PCI from the year 2014 to May 2018 at our center, had longer lesion and treated by a long stent of more than 38mmstent were selected and analyzed. Patient had baseline pre-PCI coronary angiogram either at our center or elsewhere. Based on QCA images and stented segment, lesions were divided into three group according to the length of the stented segment: Stented segment length 38mm, stented segment length 40mm and stented segment length 48mm. Total 255(Male 213: Female 42) patients were enrolled in this study, underwent elective PCI and follow up CAG at on average 1.5 years. Total 267 stents were deployed in 255 patients, in some of the patient had double vessel disease to treat. Lesions prepared by a low profile balloon, followed by stenting of the lesion. Further, post-dilatation was done by 3.0-3.5mm non-compliant balloon with 16-20ATM for better optimization of stent. Mean age for both male: female was (55 :56) yrs. Associated CAD risk factors were Dyslipidemia, High Blood pressure, Diabetes Mellitus, Positive FH for CAD and Smoking (all male), CKD, Hypothyroidism.

Long lesion: In the present study patient who were treated with stent from 38 mm onward were defined as long lesion. The procedure was considered successful with residual stenosis of <25% was left after stent placement. Death of any cause, myocardial infarction and Target lesion revascularization either by repeat percutaneous coronary intervention (PCI) or Coronary Artery Bypass Grafting (CABG) were considered as major adverse cardiac events. The diagnosis of MI was established in presence of chest pain, ECG changes of Q in 1 or more leads with raised CK-MB or Trop I. The follow-up protocol included phone contact or medical visit at the OPD or coronary angiogram. All patients were given informed consent for intervention and control CAG.

Drug Therapy

All the patients received Aspirin 300 mg and Clopidegrol as a loading dose 300 mg prior to CAG and PCI with or without Ticarel or Prasureland continued for 9-12 months and received atorvastatin along with standard medical management for CAD. During the procedure, an intravenous heparin bolus (100IU/Kg) and GP IIb/IIIa receptor blocker Integrillin were administered as required. The use of GP IIb/IIIa Receptor blocker was recommended as per protocol.

Stents:

Among the stent used; Sirolimus Eluting stent (Biotronik), Everolimus Eluting stent (Boston Scientific and Abbott vascular) and Taxus (Boston Scientific), Resolute Integrity (Medtronic)

Data: Data were presented as mean ± SD with percentage.

Results:

Table 1. shows demographic profile of Studied population. Female were older than male (Male 55: Female 56) yrs. Male are having more cardiovascular risk factors than female, as smokers were all male (Male 2.8: Female 2.5). Female were more obese than male(BMI male 26: Female 28). Table 2. Shows the contrast used and serum creatinine level in studied patient before and after the procedure. Average contrast uses in both sexes are 75ml and s. creatinine level were remaining almost identical in both pre and post procedure. Female has poorly controlled diabetes (Male vs Female:8.9 vs 10.7mmol/L). Table.3. Shows the territory wise the different size stent used in both male and female. Interestingly, it has been shown that in both sexes average vessel diameter in all three territories was less than 3mm in diameter. Figure 1. Shows the percentage distribution of coronary stents according to territory.Figure 2. shows the stented territory, LAD 46%, RCA 45%, LCX 9%. Figure 3. Shows the distribution stents according its length in mm. Figure 4. Shows the of CAD risk factors. 189(74.1%) were Dyslipidemia, 192 (75.3 %) were hypertensive; 126 (49.4%) patients were Diabetic, positive FH 74 (29.4 %), CKD 8 (3.1%), Hypothyroidism 2 (0.8%) and 104 (40.8 %) were all male smoker.Figure 5. shows the stenting of LAD with along 2.75 x 48 mm stent. Figure 6. Shows the stent patency after 1.5 yrs.

Table-I
Profile of patient

	Male	Female
Number	39	9
Age (yrs)	55.2±10.0	56.4±9.4
BMI(kg/m^2)	25.9 ± 2.3	27.9±3.5
SBP(mmHg)	131±18	133±18
DBP(mmHg)	79.0±9.1	79±12
No Risk Factor	2.8±1.0	2.5±0.8

Data were presented as Mean ± SD

Table-II
Contrast used and S. Creatinine level

	Male	Female
Contrast in ml	76.1±12.4	75.8±10.7
S.Creatinine(pre)	1.25±0.4	1.18±0.34
S. Creatinine (post)	1.24±0.3	1.1±0.21
RBS(mmol/L)	8.9±4.1	10.7±2.8
HbA1C	6.95±4.1	7.4±6.6

Data were presented as Mean ± SD

Table-III
Average size of Stent used with inflation pressure

		Length (mm)			Diameter(mm)			Inflation Pressure (ATM)		
LAD	M	43.5	±	0.3	2.8	±	0.3	16.0	±	1.9
	F	44..0		4.9	2.7		0.3	15.4		1.7
RCA	M	43.7	±	4.7	2.96	±	0.4	15.7	±	1.6
	F	43.7		4.4	2.85		0.3	15.4		1.7
LCX	M	43.4	±	4.5	2.64	±	0.2	15.2	±	1.7
	F	42.0		5.3	2.67		0.1	16.0		1.0

Data were presented as Mean ± SD

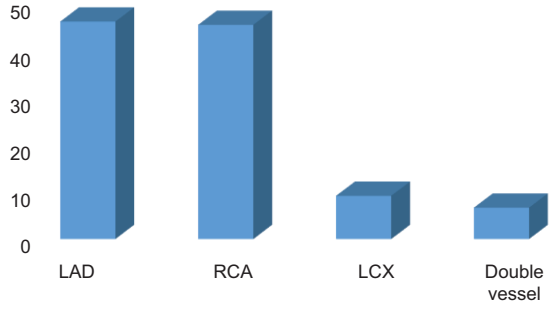

Fig.-1. *Percentage of distribution of Coronary Stent*

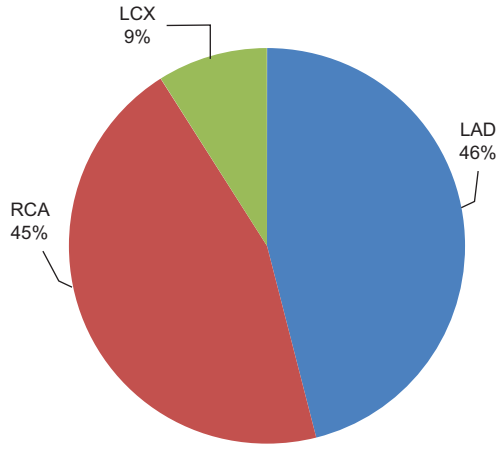

Fig.-2: *Percentage of distribution of Stented territory*

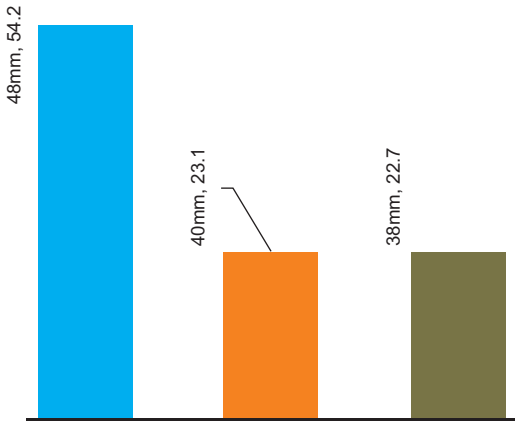

Fig.-3: *Percentage distribution of Stent according to size*

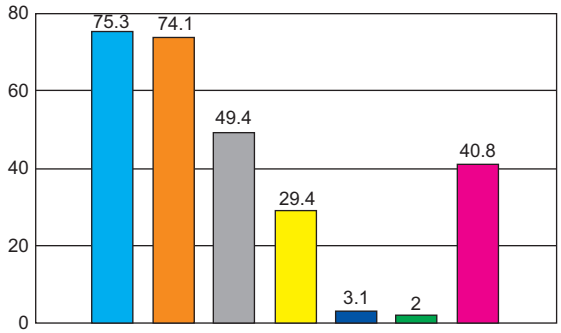

Fig.-4: *Percentage of Distribution of CAD Risk Factors*

Stent positioning *Post PCI*

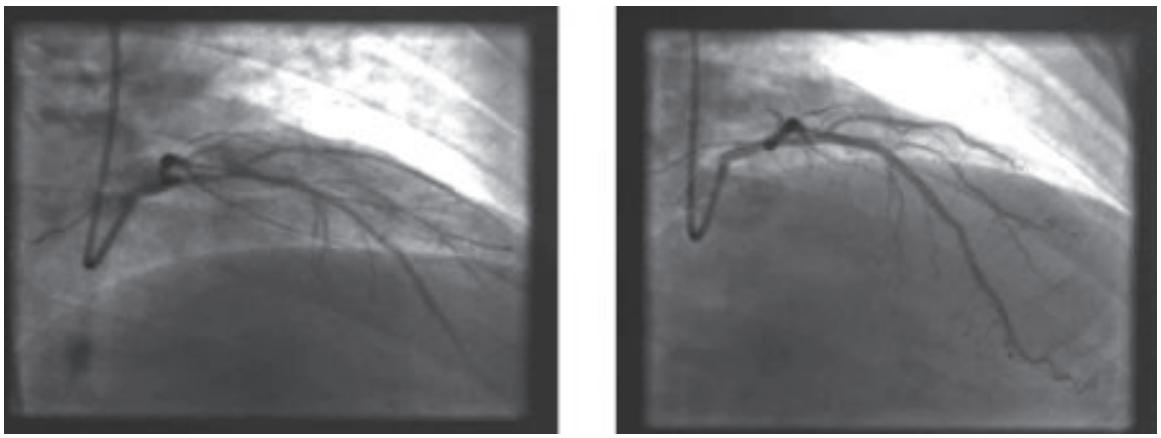

Fig.-5: *Shows PCI of LAD lesion with 2.75 x 48 mm Stent*

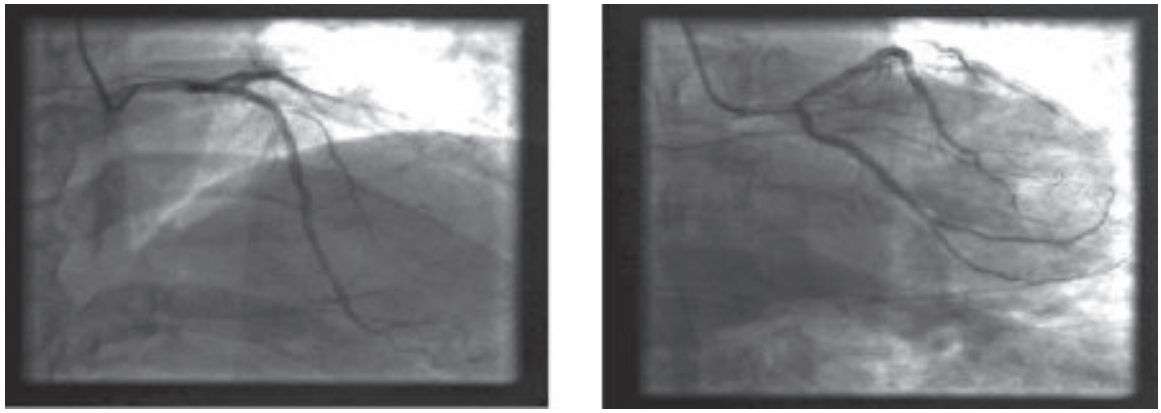

Fig.-6: *Shows Patent LAD and LCX stent after 16 month*

Discussion:

In the era of Percutaneous coronary intervention(PCI) in treating long segment lesion, itself is an important predictor determinant of restenosis. Nonrandomized studies have indicated an increased risk of restenosis after conventional PCI.[13] Multiple or long coronary stents are now being used to treat long lesion or in tandem lesions and shown to have higher restenosis. [6-7]

In this current prospective cohort study, we try to find the stent patency and major adverse cardiac events (MACES) that is stent thrombosis, MI or death after treating long-segment lesion by putting a long stent. In our study, females are more obese than male with poorly controlled diabetes possibly due to lack of exercise or non-compliance to medicine or ignorance. The number of CAD risk factors were more in male than female, possible due to smoking as additive factor in male. This is in favor that suggested, both male and female patients might have different CAD risk factors that trigger the development of coronary artery disease. Interestingly, the average vessel size in all three territories in both male and female were less than 3mm in diameter. In general, we are treating small size vessel in our population where the chances of development of in-stent restenosis is high.[14] Also, the post PCI, Serum Creatinine level didn't change much than the pre PCI Serum Creatinine level, possibly due to controlled uses of ionic contrast uses amount during the entire procedure to keep as much low as possible.[15]

This is the first time; we have carried out this non randomized single center prospective cohort of patients underwent PCI for their occluded coronaries by a long single stent to treat the de novo long lesion. Previously, Islam et al,[16] demonstrated treating a long segment lesion by multiple overlapping stents; where Sirolimus Eluting Stents (Cypher)

showed reduce ISR than other DES. Since, ISR is one of the important drawback in maintaining the integrity of stent patency and thus patient's clinical improvement. So, we designed to treat long de novo lesion at our center by putting a single stents > 38mm in length. We used three different stent size of 38mm, 40mm and 48 mm. We did not find ISR at 1.5 years after PCI in this patient subset. Even though the average vessel diameter is less than 3mm, which is very common in this Asian population.

It is well known that dramatic advances in treating clogged coronary artery to open and keep its patency, thus to reduce myocardial damage either by PCI,using bare metal stents or different drug eluting stents, leads to reduction CABG.[13]It has been shown thatpercutaneous coronary intervention by stenting over plain PTCA has clear advantages in terms of restenosis, and restenosis driven events for an increasing number of indications.[2-3] In addition, the administration of DAPT for given a given times, has dramatically reduces the development of stent thrombosis or subsequent ISR. [16-18]

Long lesion and long stent are considered as important predictors of restenosis after PCI with Bare metal stent (BMS) or Drug eluting stent (DES).DES have consistently shown to reduce restenosis, need for target lesion revascularization or MACE over the Bare metal stent (BMS). A number of nonrandomized studies have indicated an increased likelihood of restenosis after coronary stent implantation in treating long lesion.[19-20] Longer lesion needs a longer stent to cover the lesion. This increase length may require the placement of >1 stent and may exacerbate the risk of restenosis,mask the direct relationbetween lesion length and lumen narrowing after coronary stenting.

The reason why the implantation of more stents causing more restenosis irrespective of lesion length and stented segment is not known. One possible explanation, is that are difficult to avoid unless intentionally overlapping the stents. Tissue prolapse may occur between stents in same as described for the articulation site of Palamz-schatz stents,[21] has suggested spot stenting seems to be preferable over full jacket for PCI in long lesion. As stented length increases the chances of restenosis and stent thrombosis, since metal, polymer and drug disrupt the intimate morphology and physiology.Adnan kastrati et al has suggested in treating long lesion by a single long stent is favorable over multiple shorts stent.[22]

In our study, female patients are more obese, poorly controlled diabetes, developed CAD in advance age than male patients. Although, in our present study, average stent diameter is less than 3mm in both male and female patients. Therefore, long lesion and small vessel diameter in addition to poorly controlled diabetes, specially in female and smoking in male (as all smoker) might be one of the important determinant in stent patency specially in long lesion.

In this study, we put all drug eluting stent in treating long lesion. Follow up CAG has shown no ISR at 1.5 years after PCI which is very much consistent with described else.[23] Kereiakes et al[24]showed that in the BMS group long lesion has the higher rate of ISR, similarly stent length and lesion length is an independent predictor of ISR in various DES.[19,25]

Conclusion:

Treating long segment coronary lesion, has some drawbacks due to the possibility of development of ISR. Previously, PCI by putting multiple overlapping stent was one of the important modality in treating long coronary lesion. But, the development or risk of possible in-stent restenosis, many has changes to one stent strategy to treat long lesion. With the advent of different DES in different length size and availability of IVUS, the ISR rate has come down. In this perspective non randomized single center cohort, we found treating long de novo coronary lesion by a single long drug eluting stent is safe, without any ISR at 1.5 year follow up in ourpatient population. Thus, to reduce hospital re-admission and reduce hospital cost as well.

Future perspective:

Our future plan is to enroll more patient to do long-term follow-up, to see stent patency and MACE in terms of ISR, MI and death, and hence, if possible to enroll and compare multicenter involvement.

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