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Case Report

A STUDY ON THE INFLUENCE OF STENT LENGTH ON ACUTE AND LONG-TERM OUTCOMES IN PATIENTS UNDERGOING ELECTIVE STENTING FOR NATIVE CORONARY ARTERY LESIONS

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A B S T R A C T

Background: Coronary artery disease, which is the main cause of death worldwide, is secondary to the atherosclerotic narrowing of the lumen of the artery. A higher angiographic restenosis rate of 58% has been reported after the intervention of long lesions with balloon angioplasty **Aim of the study:** To evaluate the clinical outcome of long/short stent length (in terms of MACE) at 1 year follow up after Percutaneous coronary intervention. **Materials and Methods:** An observational prospective study detailed history and after thorough clinical examination of 200 patients. **Results:** In our study among Long stent (>25 mm), Over all MACE was 16% vs 4 % in short stent group (<25mm) C, it was found that Mean Peak CPK were significantly elevated in both long stent vs short stent. **Conclusion:** Among the patients who developed MACE, a sub group analysis was done based on stent diameter; which revealed higher incidence of MACE among smaller diameter stents, which is statistically significant.

INTRODUCTION

Coronary artery disease, which is the main cause of death worldwide[1], is secondary to the atherosclerotic narrowing of the lumen of the artery, i.e., stenosis, and reduction in the blood supply to the myocardium. Such arterial stenosis brings a reduction in quantity of oxygen and nutrients supplied for the proper functioning of the entire cardiac muscle[2].

The technique of coronary artery bypass graft surgery, was later replaced by an intervention more effective, less invasive and expensive, i.e., the angioplasty transluminar percutaneous coronary angioplasty (PTCA)[3] .

A stent is a small expandable metallic cage able to support the inside of the artery after its deployment. The stenting procedure occurs simultaneous to the PTCA technique: the stent is deployed in the stenotic coronary artery by the use of a catheter introduced through percutaneous way. The balloon expands the mesh of the stent and deploys it inside the inner coronary artery. Subsequently, the balloon is deflated, while the expanded stent makes contact with the walls of the artery, preventing the collapse of the vessel wall and, therefore, the elastic recoil problem. Once the stent is placed, the cells of the arterial wall grow around the meshes of the device ensuring good placement. Moreover, introduction of drug eluting stent has provides significant reduction in the incidence of restenosis[4,]. However, despite the advances in the interventional cardiology, the treatment of complicated coronary lesions, i.e., diffused lesions, continues to be associated with a lower procedural success rate and an higher complications [5]

While the benefits of stent deployment for shorter lesions has been established; but the value of long stents in longer coronary lesions has not been evaluated to the same extent [6] .
A higher angiographic restenosis rate of 58% has been reported after the intervention of long lesions with balloon angioplasty. Even though, the advent of bare metal stents (BMS) was a breakthrough in Cardiac interventions; it was not completely successful in the treatment of advanced coronary artery disease, involving long lesions. The treatment of resultant diffused in-stent restenosis is again controversial, requiring multiple additional PCI's or coronary artery bypass grafting (CABG)[7]. Thus, owing to the challenges and complications involved it became crucial to develop an optimal strategy for percutaneous intervention of long coronary lesions and other complex subsets.

Aim and Objectives

1. Aimed to evaluate the clinical outcome of long stent length (in terms of MACE) at 1 year follow up after Percutaneous coronary intervention in age group of 50-75 years using long (>25mm) vs short (<25mm).

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2. The study is to identify periprocedural and clinical outcomes of long drug eluting stent implantation.

MATERIALS AND METHODS

This study was conducted at Gandhi Medical College / Hospital, Secunderabad Telangana State from September 2019 to March 2020 with the written informed consent from the patients and after getting approval from ethical committee of Gandhi Medical College. An observational prospective study detailed history and after thorough clinical examination of 200 patients. Routine blood investigations ECG, 2D ECHO CAG were done. These patients were reassessed clinically after 6 months. All data was analyzed at the end of the study and a p value <0.05 will be considered as statistically significant.

Inclusion criteria

All patients with indications for elective percutaneous intervention denovo, i.e., first time by stinting.

Exclusion criteria

- Patients with prior PCI or cardiac surgery.
- Severely compromised ventricular dysfunction (Ejection Fraction [EF]
- < 30%) or cardiogenic shock.
- Age <50 yrs and >75 yrs
- Patients with dye allergies, Hematological disorders, coagulopathies and other chronic diseases.
- Patient with contraindication for long-term dual antiplatelet therapy
- Heavy calcification
- Balloon failed to expand fully.

Study endpoints were MACE including Target Lesion Revascularization (TLR), Target Vessel Revascularization (TVR), myocardial infarction, stent thrombosis angina inducible ischemia MI in the follow up and Death. Patients who complained of cardiac symptoms were evaluated clinically in the form of Non-invasive testing (Treadmill test [TMT]) unless contraindicated. Follow-up coronary angiography was done for all patients with recurrence of angina or positive non-invasive testing (TMT).

Quantitative angiographic analysis. Five hundred ninety six lesions were available for complete quantitative and qualitative angiographic analysis. Standard morphologic criteria were used for the identification of lesion location, length, eccentricity, calcification and ulceration and lesion minimal lumen diameters and percent diameter stenosis were determined before and after intervention.

Investigations

Routine investigations: Haemoglobin percentage; Total count; Differential count; Erythrocyte sedimentation rate; Urine for protein, sugar and microscopy; Random blood sugar; Blood urea; Serum creatinine; Serum electrolytes;

Specific investigations: Chest Radiograph; ECG; 2D Echocardiography; CPKMB.

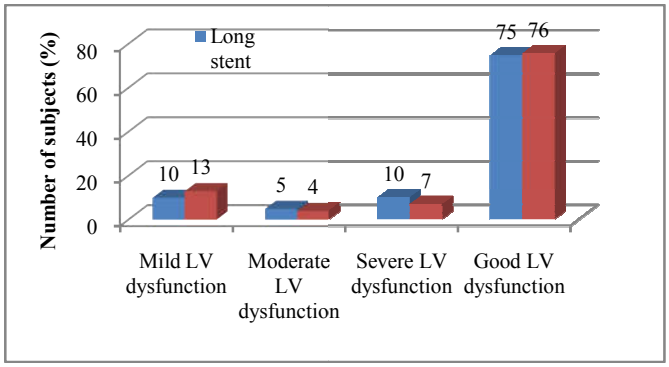
RESULTS

Table 1 Distribution according to sex

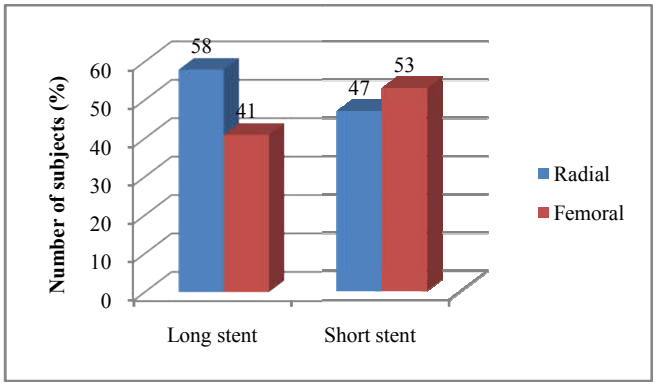
Sex	Long stent		Short stent		P	Inference
	Number	Percent	Number	Percent		
Male	64	64	81	81	0.07	Not Significant
Female	36	36	19	19	0.07	Not Significant

Table 2 Distribution according to risk factors

Variable	Long stent		Short stent		p	Inference
	Number	Percent	Number	Percent		
Hypertension	67	67.0	61	61.0	0.36	Not Significant
Diabetes	40	40.0	43	43.0	0.66	Not Significant
Smokers	25	25.0	23	23	0.74	Not Significant



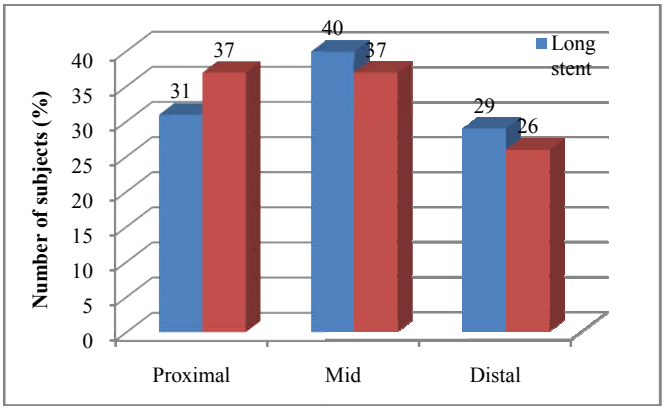
Graph 1 Distribution according to LV dysfunction



Graph 2 Comparison between stents type based on radial and femoral access

Table 3 Comparison based on artery involved

Variable	Long stent		Short stent		p	Inference
	Number	Percent	Number	Percent		
LAD	48	48.0	44	44.0	0.57	Not Significant
LCX	12	12.0	28	28.0	0.02	Significant
RCA	40	40.0	28	28.0	0.07	Not Significant



Graph 3 Comparison between stents type based on segment involved

Table 4 Comparison Pre procedural characteristics between stents type

Variable	Long stent		Short stent		p	Inference
	Number	Percent	Number	Percent		
Calcification	9	9.0	6	6.0	0.42	Not Significant
Bifurcation	10	10.0	9	9.0	0.8	Not Significant
Total occlusion	24	24.0	14	14.0	0.07	Not Significant

Table 5: Comparison of type of culprit vessel between stents type

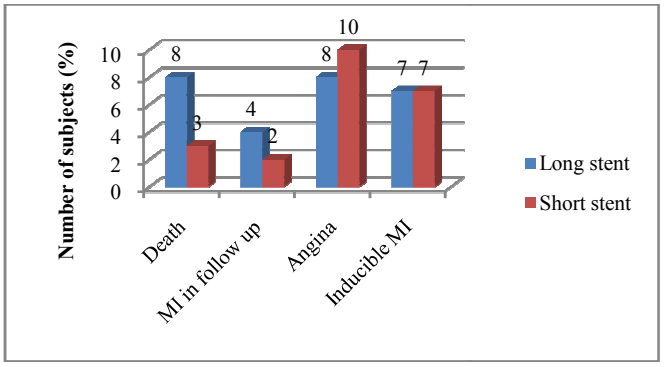
Variable	Long stent		Short stent		p	Inference
	Number	Percent	Number	Percent		
A	9	9.0	2	2.0	0.06	Not Significant
B1	11	11.0	9	9.0	0.63	Not Significant
B2	58	58.0	77	77.0	0.06	Not Significant
C	22	22.0	12	12.0	0.05	Not Significant

Table 6 Comparison based on requirement of pre dilatation /direct stenting between stents type.

Variable	Long stent		Short stent		P	Inference
	Number	Percent	Number	Percent		
Pre dilatation	79	79.0	58	58.0	0.061	Not Significant
Direct	18	18.0	27	27.0	0.12	Not Significant

Table 7 Comparison immediate post procedural complications

Variable	Long stent		Short stent		p	Inference
	Number	Percent	Number	Percent		
Elevated cardiac enzymes	12	12.0	15	15.0	0.53	Not Significant
Periprocedural MI	8	8.0	2	2.0	0.051	Not Significant
Periprocedural death	4	4.0	1	1.0	0.17	Not Significant



Graph 4 Comparison of post procedural complications between stents type

Table 8 Comparison of MACE between stents type

Variable	Long stent		Short stent		p	Inference
	Number	Percent	Number	Percent		
Follow up CAG	4	4.0	3	3.0	0.7	Not Significant
Stent thrombosis	4	4.0	1	1.0	0.17	Not Significant
Follow up PTCA	4	4.0	6	6.0	0.51	Not Significant
TVR	2	2.0	1	1.0	0.56	Not Significant
TLR	2	2.0	5	5.0	0.24	Not Significant
Overall MACE	16	16.0	14	14.0	0.62	Not Significant

Table 9 Comparison between stent types

Variable	Long stent		Short stent		p	Inference
	Number	Percent	Number	Percent		
Incidence of stroke	3	3.0	1	1.0	0.08	Not Significant
Arrhythmia	1	1.0	0	0.0	0.6	Not Significant
Non fatal cardiac arrest	2	2.0	1	1.0	0.9	Not Significant
Congestive heart failure	1	1.0	1	1.0	1.0	Not Significant

DISCUSSION

Long stenting is frequently associated with prolonged intracoronary manipulation and overlapping stent placement, which may lead to injury to the vessel wall integrity[8]

Procedural Success

According to literature, the group led by Antonio Colombo, in which 185 patients (266 lesions) with stenosis >20mm were treated[9]; even though these authors did not detail their in-hospital results, they observed that failure in stent deployment occurred in 9% of the patients.

In our study none had failure in stent deployment

MACE

According to literature, Suh *et al*[10] concluded that Length of the stented segment was independently associated with the incidence of stent thrombosis and death or myocardial infarction after DES implantation.

The value of stent length >31.5mm is a threshold for the prediction of stent thrombosis. In our present study more than 25mm DES for treatment of long stent lesion had overall high MACE compared to less than 25mm. The presence of diabetes has been associated with worse outcomes after percutaneous coronary intervention with BMS and DES [11,12].

In our study among Long stent (>25 mm),Over all MACE was 16 % vs 4 % in short stent group(<25mm)

Our present study showed no statistically significant association of MACE parameters including death, stent thrombosis, TVR, TLR and myocardial infarction in patients with varied stent length (p>0.050) though rate of overall MACE was significantly not different in patients with stent length more than 25 mm compared to less than 25 mm (p=0.62).

In our study among Long stent (>25 mm), 4 % had Follow up CAG, 4 % had stent thrombosis, 4 % had Follow up PTCA, 2 % had TVR, 2 % had TLR. Over all MACE is 16 %

Among Short stent (<25 mm), 3 % had Follow up CAG, 1 % had stent thrombosis, 6 % had Follow up PTCA, 1 % had TVR, 5 % had TLR. Over all MACE is 4 %

Comparing follow up outcomes in terms of MACE among both groups showed no significant statistical difference between them suggesting the characteristic is not influenced with stent length.

Restenosis

Kornowski *et al*[13], evaluating 117 patients treated with 3 or more stents (48% with lesions >20mm), as compared with 1,673 patients in whom one or 2 stents were implanted, reported similar indices of procedural success (97%), of Q wave infarction (0.9%), and of emergency surgery (3 stents = 1.7% versus 1 or 2 stents = 1.1%; p=NS). Only the incidence of non- Q wave infarctions was significantly higher in the group with long stents>20mm (23% versus 13%; p=0.005).
The incidence of restenosis was 48%, with 75% of the lesions restudied, and also a higher index than that of the present study though angiographic follow up is not done in our study, but overall complications is much low[14].

The clinical and angiographic outcomes of long lesion angioplasty are not as good as focal lesions.The implantation of stents may improve the outcome of these procedure. The superiority of coronary stent deployment to simple balloon angioplasty (BA) is well documented. Previously higher cost and higher rate of stent thrombosis and restenosis with multiple stents were major drawbacks of long lesion stenting[15]. Schofer *et al*[16] compared the binary restenosis rate and clinical major adverse cardiac events (MACE) of SES versus BMS in lesions longer than 15 mm length with a reference vessel diameter of about 2.5-3 mm and found a significantly lower restenosis rate (5·9 vs 42.3%, p=0·0001) and fewer MACE at 9 months follow up (8·0 vs 22.6%, p=0·0002), due mainly to a lower need for target lesion revascularisations (4·0 vs 20·9%, p<0·0001).

But all the patients in our study underwent drug eluting stent, so no comparison done with the bare metal stents.

Comparision with Other Stents

Kim *et al*[17] in the Long-DES Registry Study showed that SES was associated with a lower angiographic restenosis rate than PES in patients with lesions >24 mm in length, this was a non randomized study, however in another randomized study they showed similar results and stated on the superiority of SES over PES regarding the restenosis rate and need for revascularization.

Our study is a non randomized study and comparison is not made for outcomes between different drug eluting stents. We used only one stent type: Yukon Choice.

Outcomes Based on Lesion Length and Stented Length

The use of adjunctive devices such as Rotablator [18] and excimer laser, although initially facilitating acute success, did not lead to improvement in late outcome. In this study we sought to evaluate the influence of stent length on late clinical outcome. The overall event-free survival rate at the 6 month follow-up is comparable with the data from the Wellstent native study (75·2%), but somewhat lower than published results of trials using balloon expandable stents, such as BENESTENT and STRESS.

Previous large retrospective studies in single centres have described disappointing results with elective stenting of long lesions and lesion length has been identified as an independent risk factor for in-stent restenosis and adverse cardiac events.
After 34% of lesions had required 'bail-out' stenting, because of unacceptable or occlusive dissection or diameter stenosis >50%, despite repeat inflations, the remaining patients were randomly assigned to additional stenting or acceptance of the result. Interim analysis revealed inferior clinical results at 6 months in the additional stenting group, whereas the power calculation for the study had been based on an assumption of a 30% reduction in major adversecardiac events by stenting[19]. Accordingly, the study was terminated with the conclusion that a strategy of 'provisional stenting' was appropriate for percutaneous revascularization of long lesions.

Since all of these studies have employed a variety of stent types, it seems that the adverse outcomes are independent of the stent design, although the Wallstent has historically tended to be linked with poorer outcomes, without objective evidence to prove this. Escaned *et al* [20], The strategy of provisional stenting for lesions < 20mm in length has been shown to be inferior to primary stenting. "Spot" stenting is time consuming, has greater equipment costs, and has not been evaluated with a controlled trial. The current study found that covering normal or mildly diseased segments of long lesion by stent had negligible influence on overall lesion restenosis or need for repeat revascularisation.

The favourable overall lesion outcomes obtained in our study with relatively normal segments as well as severely diseased segments of long lesion covered by long stent were attained with close matching of overall lesion length and stent length. An IVUS study has shown that increasing the stent to lesion ratio while optimising full lesion coverage actually decreased target lesion repeat revascularisation rates [21].

Outcomes in our study compare favourably with previously published, larger and mostly retrospective series of balloon expandable stent deployment for long lesions. Lesion length in our trial is proportionate with stented length in both the groups. Not with standing these adverse features, our adverse clinical outcomes were relatively low.

Overlapping of stents has been associated with increased neointimal hyperplasia and overlap has been associated with higher restenosis in some but not all clinical studies. Minimising the overlapping of stents in the current study (mean 1 stent per long lesion) may contribute to the relatively low restenosis rates and favourable outcomes. As this feature in the study was clearly a selection bias.

Periprocedural/Post Procedural Complications

Kornowski *et al*[22] from USA conducted a study to assess the clinical outcomes after the use of long coronary stents. They evaluated procedural success, major in-hospital complications, target lesion revascularization and long-term (one year) clinical outcomes in 1,226 consecutive patients (1,259 native coronary lesions) who underwent a single vessel intervention using a single long (≥25 mm, 116 patients) or short (<20 mm, 1,110 patients) tubular-slotted stent. However, major in-hospital complications tended to occur more frequently in patients treated with longer stents (3.4% vs. 1.0%, p 5 0.04). The rate of periprocedural non-Q-wave myocardial infarction (MI) (creatine kinase-MB ≥ times normal) was notably higher after long stent implantation (23% vs. 11%, p 5 0.001). Target lesion revascularization at one year was 14.5% vs. 13.8% (p 5 0.69), and target vessel revascularization rate was 19.6% vs 17.3% (p 5 0.41) in the long versus short stent group, respectively. There was no difference in one year mortality (2.5% vs. 3.5%, p 5 0.49) or Q-wave MI (2.7% vs. 1.2%, p 5 0.48), and the overall cardiac event-free survival was similar for the two groups (81%). So they came out with conclusion that use of single coronary long (≥20 mm) versus short (<20 mm) stents is associated with: increased major procedural complications.

Our results were similar in terms of raised CPK levels (statistically significant) in long stent group. But comparing immediate post procedural complications among both groups showed no significant statistical difference between them suggesting the characteristic is not influenced with stent length.

Yasir Adnan *et al*[23] conducted prospective study; Clinical outcomes (Myocardial infarction [MI], unstable angina[UA], and positive ETT) at three months stratified by 3 tertiles of stent length and diameter each, were measured in patients who

underwent PCI with DES for coronary artery lesions. There were slightly higher rates of MI, U.A and positive ETT in the longest stent length tertile (>28mm) compared with the shortest stent length tertile (<22mm) at three months, but statistically not significant.

Our study results were also similar as the clinical outcomes were not statistically significant.

Comparing Mace Based on Stent Diameter

Agarwaal *et al*[24] in a study found the incidence of stent thrombosis to be significantly higher in patients who received Gianturco-Roubin stents, 2.5 mm diameter vs >/= 3 mm diameter (13 % vs 2 %,p <0.0002). Similar results were found by George *et al*[25], where 25 % stent thrombosis in those implanted with 2 mm Gianturco- Roubin stent vs 0 % in those who had 4 mm stent.

In our study among those who had MACE, a sub group analysis was done based on stent diameter, Two groups were divided among those who had MACE: a) Stent diameter >/= 3 mm, b) Stent diameter < 3 mm. It was concluded in our study that the incidence of MACE was higher in small diameter group which goes in favour with the earlier studies.

New alternative therapies like stent coating with anti proliferative compounds, such as rapamycin or catheter-based brachy therapy can reduce restenosis after stenting of long lesions into the range of 'short' lesions, and they were not addressed.

CONCLUSION

- The use of DES longer than 25mm in CAD had a overall comparable MACE rate with DES shorter than 25mm length.
- Longer stents were shown to be associated with increased clinical events mainly TLR, TVR, periprocedural MI, periprocedural death, exertional angina, MI in follow up, inducible ischemia, stent thrombosis, and death due to any cause though none of them attained statistical significance.
- Post procedural complications among both groups showed no significant statistical difference but comparing Peak CPK in both the groups, it was found that Mean Peak CPK were significantly elevated in both long stent vs short stent
- Among the patients who developed MACE, a sub group analysis was done based on stent diameter; which revealed higher incidence of MACE among smaller diameter stents, which is statistically significant.

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