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Original Article

Internal Medicine Section

Study of Short and Intermediate Term Clinical Outcomes of Patients with Protected and Unprotected LMCA Stenting

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ABSTRACT

Introduction: Significant unprotected Left Main Coronary Artery (LMCA) disease is detected in 5%-7% of cases undergoing Coronary Angiography (CAG). Present guidelines have revealed the significance of anatomical location in left main artery stenosis and syntax scores for determination of Major Adverse Cardiac Events (MACE). Debate still persists over the best treatment regarding outcomes of Coronary Artery Bypass Grafting (CABG) and LMCA stenting for patients with LMCA disease.

Aim: Aim of the study was to evaluate short and intermediate term clinical outcomes of Percutaneous Coronary Intervention (PCI) in LMCA disease in respect to mortality, Cerebrovascular Accidents (CVA), reinfarction, stent restenosis and need for repeat target lesion revascularization.

Materials and Methods: From July 2013 to February 2015, 50 patients underwent LMCA stenting. All patients underwent detailed clinical assessment, detailed 2D echocardiographic assessment. Syntax score was calculated in all patients. Clinical in hospital and outpatient follow up was obtained at one, three, six, nine months and one year.

Results: Mean age was 53.14±9.60 years. On CAG 16 (32%) patients had ostial LMCA lesion, 8 (16%) had mid LMCA lesion, distal LMCA was diseased in 6 (12%). In emergency situation, two bail out LMCA stenting were done for treatment of LMCA dissection. A total of 42 (84%) patients had low syntax score, 6 (12%) had intermediate and 2 (4%) had high syntax score. Only LMCA stenting was done in 22 (44%) patients, LMCA to Left Anterior Descending (LAD) stenting was done in 22 (44%) and LMCA to Left Circumflex (LCX) stenting was done in 6 (12%) patients. Drug-Eluting Stent (DES) was used in 35 (70%) cases while Bare-Metal Stent (BMS) was used in 15 (30%). An 8% mortality and 8% target lesion revascularization rate were observed in our study.

Conclusion: Our study revealed that LMCA stenting is a safe and feasible alternative mode of revascularization in selected patients. Patients most suitable for LMCA stenting in our study were those with isolated ostial/mid LMCA disease, with protected LMCA disease and those who underwent elective stenting procedure.

Keywords: Bail out LMCA stenting, Elective LMCA stenting, LMCA revascularization

INTRODUCTION

In patients undergoing CAG, significant unprotected LMCA disease is detected in 5%-7% of cases [1,2]. Three year mortality rate of patients with medical treatment for Unprotected LMCA (ULMCA) is around 50% [3,4]. CABG showed a significant benefit following the treatment of LMCA stenosis compared with medical treatment [5-8]. Until recently CABG was considered as the gold standard therapy for LMCA disease. However, progresses in percutaneous intervention techniques and stent technology have showed evaluation of the role of PCI for LMCA disease.

Recent guidelines state Class IIa is indication for ostial or midshaft lesions of LMCA. Mid shaft and bifurcation LMCA lesions are to be distinguished as these lesions treated with PCI stenting can have different clinical outcomes [9].

PCI stenting treatment for ostial/midshaft LMCA lesions is associated with favourable clinical and angiographic outcomes [10-15]. Distal LMCA lesion treatment with percutaneous intervention is associated with comparatively higher Target Lesion Revascularization (TLR) rates. But, certain study reported that results in the case of simple bifurcation lesions treated with a one-stent approach are more positive in comparison with complex bifurcation lesions treated with a two-stent approach [16,17]. With one-stent approach results the rate of TLR is relatively reduced (5%) that is same to outcomes found with DES for ostial or mid-ULMCA lesions [10,11,18].

Our study was focused to determine the safety and efficacy of LMCA stenting as an upcoming alternative for CABG.

MATERIALS AND METHODS

From July 2013 to February 2015, 50 patients underwent LMCA stenting in our center. An approval for this study was obtained from the Institutional Ethics Committee (UNMICRC/CARDIO/13/30). They were considered for stenting because of severe LMCA stenosis or severe ostioproximal LAD or LCX lesions. All patients underwent detailed clinical assessment, transthoracic echocardiographic assessment, including 2-dimensional imaging, Doppler studies, and colour flow mapping. Syntax score was calculated in all patients. All subjects gave informed consent, and the risk associated with the procedure was explained. All procedures were done with stand by facility for open and closed heart surgical procedures. All categorical variables have been expressed as frequency (%) using the SPSS program version 20.0.

Study Subject

LMCA stenting was performed in patients when they met the following criteria:

Inclusion criteria: 1) Patients with LMCA stenosis more than or equal to 50% and clinical symptoms or objective evidence of myocardial ischemia and who denied CABG as revascularization procedure; 2) Patients with significant ostioproximal lesion of LAD or LCX with MEDINA Class of 1:1:1, 1:1:0, 1:0:0, 1:0:1 OR 0:1:1, who were planned to be treated with LMCA to LAD or LMCA to LCX stent placement in view of unfavourable lesion angulation [19,20];

3) Patients with bail out LMCA stenting procedure; 4) Stenting of unprotected LMCA stenosis has been attempted in selected patients when surgery was contraindicated or very high risk as a result of non cardiac comorbidities.

Exclusion criteria: 1) Contraindication to antiplatelets; 2) Associated severe aortic or mitral valve disease that required surgery; 3) Patients in cardiogenic shock, survival of ventricular tachycardia or cardiac arrest, NYHA functional class more than two; 4) Echocardiographically confirmed mechanical complications of myocardial infarction; 5) Recent thromboembolic stroke, acute infection processes.

Clinical follow up: 1) In-hospital adverse clinical events, including death, surgery, local vascular complications were prospectively collected; 2) Clinical outpatient follow up was obtained by monthly telephone interviews. All patients were requested to visit outpatient clinics at one, three, six, nine months and one year and to have follow up check coronary angiogram if symptomatic.

Description of Angioplasty

In all patients, the vessel was accessed via the femoral artery. Size 6/7 French judkins left catheters were used. Before carrying out the procedure, heparin sodium, at a dose of 100 mg/kg, was administered. In all patients, dose of ecosprin 300 mg and clopidogrel 300 mg was given prior to the procedure. In 21 patients, tirofiban bolus, 25 microgram/kg was given with subsequent continuous infusion at 0.15 microgram/kg/min for 18 to 24 hours.

In 42 patients lesions were predilated using a conventional balloon catheter and which was inflated to the pressure necessary to obtain the required degree of distention, in remaining eight patients stent was implanted without predilatation.

Then, the stent was placed across the lesion and, after its position had been confirmed by angiography, stent was deployed at nominal pressure for 10 to 20 seconds. Two orthogonal images were taken to verify the result after stent deployment. Post stent dilatation was carried out using the noncompliant balloon inflated at a high pressure. After angioplasty, all patients were treated with two antiplatelet agents (i.e., acetylsalicylic acid with ticagrelor or clopidogrel). Ecosprin 150 mg once a day was used with clopidogrel 75 mg twice a day regimen and dose of ecosprin was reduced to 75 mg once a day if given along with ticagrelor. Dose of ticagrelor used was 90 mg twice a day and dose of cilastazole was 50 mg twice a day.

RESULTS

Baseline Clinical Characteristics

The baseline characteristics of the study population are presented in the [Table/Fig-1]. Out of 50 patients, 18 who underwent LMCA stenting presented with STEMI, 9 (18%) patients had NSTEMI, 10 (20%) patients presented with unstable angina and 13 (26%) patients gave history of chronic stable angina.

Baseline Angiographic Characteristics

The angiographic details of the patients are shown in the [Table/Fig-2]. On CAG, 16 (32%) patients had ostial LMCA lesion, 8 (16%) patients had mid LMCA lesion, distal LMCA was diseased in 6 (12%). In 20 patients LMCA stenting was done for ostial LAD or LCX lesions and in emergency situation, two bail out LMCA stenting were done for treatment of LMCA dissection which developed while intervening proximal LAD lesions. Out of 50 patient 42 (84%) patients had low syntax score, 6 (12%) patients had intermediate syntax score and 2 (4%) patients had high syntax score. Both the patients with high syntax score had history of coronary revascularization in form of CABG prior to LMCA stenting.

Procedural Characteristics

[Table/Fig-3] shows the procedural characteristics of the study population. Isolated LMCA stenting was attempted in patients with ostioproximal or mid shaft LMCA lesions while LMCA to LAD stenting or LMCA to LCX was attempted in patients having distal LMCA disease or ostioproximal LAD or LCX bifurcation lesions. For distal LMCA and ostioproximal LAD/LCX disease, single stent approach was used in our study. IV tirofiban was used in 21(42%) patients.

Variable	N=50
Age	
<40 Years	05 (10%)
>=40 Years	45 (90%)
Sex	
Male	43 (86%)
Female	07 (14%)
Cardiac risk factors	
Diabetes	19 (38%)
Hypertension	18 (36%)
Smoking	25 (50%)
LVEF	
≤35 %	15 (30%)
36%-49 %	18 (36%)
≥50%	17 (34%)
Clinical presentation	
STEMI	18(36%)
NSTEMI	09(18%)
UA	10(20%)
CSA	13(26%)

[Table/Fig-1]: Baseline clinical characteristics.
STEMI: ST elevation myocardial infarction, NSTEMI: Non- ST elevation myocardial infarction, UA: unstable angina, CSA: chronic stable angina

Angiographic Characteristics	N=50
Location of Lesion	
Ostio proximal LMCA	16 (32%)
Mid LMCA	08(16%)
Distal LMCA	06 (12%)
Ostio proximal LAD/LCX	20 (40%)
LMCA Stenosis	
≤50%	22(44%)
51%-70%	06(12%)
71%-89%	19(38%)
≥90%	03(6%)
Coronary involvement	
LMCA only	13
LMCA+SVD	06
LMCA+DVD	06
LMCA+TVD	05
Ostio proximal LAD/LCX (SVD) without LMCA	11
Ostio proximal LAD/LCX (DVD) without LMCA	08
Ostio proximal LAD/LCX (TVD) without LMCA	01
Syntax score	
Low (1-22)	42 (84%)
Intermediate (23-32)	06 (12%)
High (≥33)	02 (04%)

[Table/Fig-2]: Baseline angiographic characteristics.
LMCA: Left main coronary artery, LAD: Left anterior descending, LCX: Left circumflex, SVD: single vessel disease, DVD: double vessel disease, TVD: triple vessel disease

Procedural Characteristic	N=50
Elective vs. Urgent	
Elective	48 (96%)
Urgent	02 (4%)
Vessel stented	
LMCA	22 (44%)
LMCA to LAD	22 (44%)
LMCA to LCX	06 (12%)
Type of stents	
DES	35 (70%)
BMS	15 (30%)
Antiplatelet regimen	
Ecosprin+ticagrelor	17 (34%)
Ecosprin+clopidogrel	29 (58%)
Ecosprin+clopidogrel+cilastazole	04 (8%)
IV Tirofiban usage	21 (42%)
Diameter of stent	
<3 mm	01
3 to 3.5 mm	35
3.5 to 4 mm	11
>4 mm	03
Length of stent	
<10 mm	03
10-20 mm	31
20-30 mm	10
>30 mm	06

[Table/Fig-3]: Procedural characteristics.
DES: Drug eluting stent, BMS: Bare metal stent

Decision regarding antiplatelet regimen in the study was taken by treating cardiologist performing the LMCA stenting procedure. There were no laid down criteria for selection of particular antiplatelet regimen in our study. Decision regarding DES vs BMS implantation was taken after thorough discussion with the patients considering tolerance of antiplatelet regimen, noncardiac comorbidities and affordability for stents.

Clinical Outcome on Follow Up

In our study, Major Adverse Cardiac and Cardiovascular Event (MACCE) rate observed was 8 (16%) patients. At one month follow up, two deaths were observed. Out of which, one death occurred in hospital within 24 hours which was probable acute stent thrombosis. Another sudden death within one month of stenting occurred at home. One patient was having unstable angina and on coronary angiogram, he was diagnosed having 90% Intracoronary Stent Restenosis (ISR) in BMS, which was treated successfully with DES implantation. At six months follow up, two sudden deaths at home were observed. The exact cause of death could not be determined as these patients did not undergo postmortem examination. According to the history given by patients relatives, these deaths can be attributed to possible late stent thrombosis. At nine months follow up, one patient underwent TLR in form of CABG for 80% ISR post LMCA to LCX stenting. Two patients developed ISR at follow up duration of one year, which were successfully treated with DES implantation.

Clinical and Procedural Parameters of Patients Who Developed ISR and Underwent TLR

[Table/Fig-4] presents clinical and procedural parameters of patients who developed ISR and underwent TLR.

Clinical and Procedural Parameters of Sudden Death Patients

Clinical and procedural parameters of patients with sudden cardiac death shown in [Table/Fig-5].

DISCUSSION

This clinical study shows that stenting of LMCA may be safe and effective in carefully selected patients. In the present study the angiographic success rate during angioplasty was 100%, it was also observed in other studies [21,22]. Mortality observed in the study was 4 (8%) patients.

In O'Keefe JH et al., series, they used conventional LMCA balloon angioplasty. Mortality during treatment in patients undergoing elective angioplasty who did or did not have a protected LMCA was 4.3% and 9.1% in the two subgroups, respectively [23]. Mortality at 20 months was 65%. Mortality in this study is quite high as compared to our study (65% vs 8%). Elastic recoil phenomenon occurs frequently with LMCA angioplasty due to abundance of elastic fibers in the arterial walls. The introduction of stents has increased the number of indications for LMCA angioplasty.

In Park S-J et al., series which included 42 patients with similar characteristics, restenosis rate was 22% [22]. Restenosis occurred within two months (mean 1.8±0.3) after LMCA stenting. Only one patient died during coronary artery bypass surgery carried out, because of in-stent restenosis. This study included selected patients with protected LMCA and preserved ventricular function which could be the reason behind favourable results. In our study, total mortality was 8% and restenosis rate was 8%. This high rate occurred because we also included patients with acute myocardial infarction and LV dysfunction in the study. In our study all the patients who died had unprotected LMCA lesions which determines short and long term prognosis.

Name	Patient A	Patient B	Patient C	Patient D
Stent used (DES/BMS)	BMS	DES	BMS	DES
Location of the LMCA lesion	Mid LMCA	Proximal LCX	Distal LMCA with proximal LCX lesion	Mid LMCA
Vessel stented	LMCA	LMCA TO LCX	LMCA to LCX	LMCA
Stent size	LIBERTY 3.5*12	SUPRALIMUS 2.5*33	ZETA 3.5*28	ENDEAVOUR 3.5*18
Antiplatelet regimen	Ecosprin+Clopidogrel +Cilastazole	Ecosprin+ Ticagrelor	Ecosprin+ Clopidogrel	Ecosprin+ Clopidogrel
IV Tirofiban used	Yes	Yes	Yes	No
ISR pattern according to Mehran et al., classification	1 C	1 B	1 C	1 C
Protected/ Unprotected LMCA disease	Protected	Unprotected	Unprotected	Unprotected
Syntax score	24.5	06	29	10
Treatment of ISR	DES implantation	CABG	DES implantation	DES implantation

[Table/Fig-4]: Clinical and procedural parameters of patients who developed ISR and underwent TLR.

Name	Patient W	Patient X	Patient Y	Patient Z
Stent used	DES	DES	BMS	DES
Location of LMCA lesion	Ostial LMCA	Proximal LAD	Proximal LAD with distal LMCA	Proximal LCX with distal LMCA
Stented vessel	Ostial LMCA	LMCA to LAD + LAD	LMCA to LAD	LMCA to LCX
Stent size	Xience prime 3.5*15	XIENCE V 3*28 (LMCA to LAD Stenting, Covering Ostial LMCA and Overlaping With Mid LAD Stent) SONIC 2.5*33 (Mid LAD), XIENCE V 2.5*38 (Distal LAD)	Driver 4*15	Endeavor 3*24
Antiplatelet regimen	Ecosprin+ Clopidogrel	Ecosprin+ Clopidogrel	Ecosprin+ Clopidogrel	Ecosprin+ Clopidogrel
IV Tirofiban used	No	No	Yes	No
Clinical presentation	Anterior Wall STEMI	UA	NSTEMI	UA
Syntax score	11	12	9	19

[Table/Fig-5]: Clinical and procedural parameters of patients with sudden death.

In the ULTIMA multicenter registry [24], which included 17 patients who underwent stent implantation in an unprotected LMCA because of an acute myocardial infarction, in hospital mortality rate was 53% and the 12-month rate of either mortality or the need for surgery was 58%. In our study, only one in hospital mortality was observed and that patient presented with anterior wall STEMI and moderate ventricular dysfunction who underwent angioplasty, died during hospitalization despite successful revascularization.

The present study did not include routine angiographic follow up. TLR rate was 8% (i.e., in 4 of 50 patients). Repeat PCI in form of TLR was done in three patients. In contrast to reports of other series [21], one patient was referred for surgery in the present study. The benefit of check coronary angiogram has not been established in this context. DES implantation could help reduce revascularization rates and cardiac events during follow up.

Other previous studies of stenting of LMCA stenosis by Ellis SG et al., Tamura T et al., and Karam C et al., (albeit in small numbers of patients) showed acceptable angiographic restenosis rates and clinical events during follow up [24-26]. In the current study, the angiographic restenosis rate (8%) was lower to that of the previous studies (22%).

Compared with restenosis rates after balloon angioplasty or laser angioplasty, low restenosis rates after stenting of LMCA stenosis may be attributed to larger post-stent lumen dimensions, to the effect of stents in resisting pathologic arterial remodeling and acute recoil and also in 70% of patients, DES were used.

The results of the SYNTAX (Synergy between PCI with TAXUS drug-eluting stent and cardiac surgery) trial [27] reported at the European Society of Cardiology Congress 2008 in Munich, Germany, showed that DES placement was inferior to CABG surgery as a treatment option for patients with multivessel and left main coronary disease. The SYNTAX study randomized 1800 patients with three-vessel and left main disease to PCI with DES versus CABG. The study found that at the one year follow up major adverse outcome including cardiovascular or cerebrovascular events (death, heart attack, stroke, or repeat revascularization) was seen in 17.8% of the total sample size. In our study at one year follow up, major adverse cardiovascular and cerebrovascular event rate was 16%.

Erglis A et al., randomized 103 ULMCA patients to either BMS or PES [28]. Lesions were pre dilated with cutting balloons, and results were optimized with intravascular ultrasound. The restenosis rate was significantly reduced in the PES and no hospital mortality was found.

The ISAR-LEFT-MAIN randomized trial [29] focused on this debatable subject and provides compelling evidence in support of the significance of DES in ULMCA patients.

Study constitutes the large dedicated randomized trial performed in uLMCA (607 patients). A total of 30 day mortality was only 1.3%. The combined primary end point (death, myocardial infarction, target vessel revascularization) was similar in both groups (13.6% PES vs. 15.8% SES). In this study, also intravascular ultrasound was not used.

The Left Main Coronary Artery Stenting (LE MANS) registry presented that during the 30 day period, MACCE found in 12 patients and death occurred in four patients [30]. There were 17 (12.1%) angiographically confirmed cases of restenosis found after 12 months.

In our study, MACCE at 30 days was 6% and angiographically confirmed cases of restenosis were 8% at one year follow up.

Twelve month clinical and angiographic outcome after stenting of unprotected left main coronary artery stenosis with paclitaxel-eluting stents-results of the multicentre FRIEND registry [31] showed cardiac death occurred in 3 (2%) patients at a median follow up of 472±75 days and MACCE in 16 (10.6%) patients. In our study, MACCE rate was 16%. In FRIEND registry, study population was treated only with DES, while our study was not restricted to patients treated with DES.

LIMITATION

Present study was non randomized study which is the main limitation. Intracoronary imaging like Intravascular Ultrasound (IVUS) and Opticle Coherence Tomography (OCT) were not used in the present study. Our study did not include check CAG as a routine follow up protocol in every patients. In addition, small sample size could have contributed to our inability to identify poor prognostic indicators like advanced age, presence of comorbidities like diabetes mellitus, low ejection fraction, acute myocardial infarction, extensive coronary artery disease or bail out stenting.

CONCLUSION

Even though CABG was the preferred mode of revascularization in the past, our study revealed that LMCA stenting is a safe and feasible alternative mode of revascularization in selected patients. Patients most suitable for unprotected LMCA stenting may be those with isolated ostial or proximal LMCA disease. Relatively low incidence of major cardiac event was noted in individuals who underwent elective LMCA stenting for protected LMCA disease. Acute STEMI and unprotected LMCA disease are principle risk factors as well as poor prognostic indicators in patients undergoing urgent LMCA stenting. LMCA stenting is an upcoming alternative option for patients with suitable lesion morphology and high surgical risk.

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