

The Outcome of LM PCI: A Single Center Experience of First 50 Cases without In-site IVUS Facility

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Abstract:

Introduction: Left main disease (LMD) is related to significant morbidity and mortality. This study was done to evaluate the clinical major adverse cardiovascular event (MACE), including unstable angina, myocardial infarction, heart failure, target vessel revascularization, stroke and death in patients undergoing left main stenting without availability of in-site intravascular imaging (IVUS).

Methods & Materials: It was a prospective observational study done in National Institute of Cardiovascular Diseases & Hospital (NICVD) from March 2014 to June 2019. Our study included 50 patients who underwent Percutaneous Coronary Intervention for left main disease without use of IVUS. All the patients were followed up for 1 year & 2 years, one patient was lost to follow-up. Outcomes included in MACE were death, myocardial infarction, unstable angina, heart failure, stroke and target vessel revascularization (TVR).

Results: Fifty patients (mean age 58.4 ± 4.1 years, 44 male, 06 female) were treated with a mean SYNTAX score of 24.8 ± 2.6 . Thirty two (64%) patients had stable angina, 17 (34%) had unstable angina/non ST-elevation myocardial infarction, and 1 (02%) had ST-elevation Myocardial infarction. Among the risk factors, 21(42%) had DM, 33 (66%) were hypertensive, 22 (44%) were smoker, 19 (38%) had dyslipidemia, 09 (18%) had previous h/o MI, 11 (22%) had family h/o CAD & 01 (02%) had previous h/o CVD. Pre-procedural LVEF was 49.92 ± 6.60 % and post procedural 54.84 ± 4.55 % which showed significant improvement of LVEF after PCI ($p=0.003$). Most of the patients presented with LM with SVD (82%). Among all patients, 39 (78%)

underwent complete revascularization in compare to 11 (22%) had incomplete revascularization. Thirty eight (76%) patients received a single-stent DES and 12 (24%) received two-stents DES. Among double stent strategy, majority underwent TAP (50%). All access was femoral & No reflow phenomena were found in any of the patients during the procedure. No perioperative mortalities were noted and no urgent coronary bypass graft surgery was required. One patient was lost to follow-up. After 1-year follow-up period, 1 (02%) patients had non-fatal myocardial infarction, 7 (14%) had episodes of unstable angina (UA) and 3 (06%) had heart failure (HF). After 2-years there was no new MI but 09 (18%) had UA & 4 (08%) patients had HF episode in total. TLR was 2 (04%) in first year and 3 (06%) in 2nd year. Total mortality was 1(02%) in first year & 3(06%) in 2nd year. The multivariable analysis showed a good prognosis in patients receiving LM PCI with a total event rate of 28% & mortality 6%. A multivariate regression analysis with risk factors for coronary artery disease as predictive variables showed that high SYNTAX score ($p = 0.013$), incomplete revascularization ($p=0.002$) & low post procedural LVEF ($p= 0.001$) was an independent predictor of MACE.

Conclusion: Percutaneous coronary intervention of left main coronary disease without use of IVUS showed good prognosis after 1-year & 2-years follow-up. It would not only save a procedure time for physicians but also prevent a financial burden on patients if they cannot afford intravascular imaging.

Key Words: Left Main (LM), Percutaneous Coronary Intervention (PCI), Single vessel disease (SVD), Intravascular Ultrasound (IVUS), Major Adverse Cardiac Events (MACE)

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Introduction:

The fundamental revascularization strategy (coronary artery bypass surgery [CABG] or percutaneous coronary intervention [PCI]) for patients with complex coronary artery disease is a continuing topic of debate. Patients undergoing revascularization of unprotected LMCA diseases are considered at high risk for adverse cardiovascular events. There are many large studies and meta-analyses that have compared outcomes between CABG & PCI; most have found similar intermediate and long term safety outcomes and low rate of strokes but an increased requirement for repeat revascularization with PCI in compare to CABG; a few studies have also suggested a long-term survival with CABG. This analysis describe the 5-year outcomes of the LMCA disease patients who were receive PCI or CABG randomly in the Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) trial.¹⁻³

LMCAD, defined as >50% lumen narrowing, found in about 5-7% of all patients after coronary angiography.⁴ CABG always confer a survival benefit and is the gold standard for patients with LM stenosis in compare to medical therapy. The first balloon angioplasty case for the Left Main disease was reported in 1979 by Gruntzig, the series of 129 patients were reported by Hartzler and O'Keefe in 1989, who received bare metal stents (BMS) for LMD that showed a 10% index hospitalization mortality and 64% after 3 years mortality.^{5,6} The ULTIMA experience reported that PCI was associated with improved outcomes for the patients with acute ST-elevation myocardial infarction (STEMI) associated with LMCAD.⁷

The evolution of drug-eluting stent (DES) showed a new hope for PCI in LMCAD. DES were reported to have good durability, efficiency and significant reduction in restenosis and need for revascularization in several observational, single- and multicenter registries.⁸ In the ACC/ AHA/SCAI 2004 Guideline describes PCI for LMD was put in class IIa for unstable angina Canadian Cardiovascular Society (CCS) class III/non-STEMI and class IIb indication for asymptomatic ischemia, CCS class I or II angina.

Isolated LMCA disease involving the ostium or shaft only, can be treated well with either PCI or CABG. However, distal LM bifurcation lesions or complex multivessel disease may give better outcome with CABG.⁹

Currently, in the US & ESC guidelines, PCI has a class IIa recommendation ("is reasonable") for isolated LMCAD involving the ostium or shaft and without coexisting multivessel disease and those have risk for

surgical correction. PCI has a class IIb recommendation ("may be reasonable") for LMCAD involving the distal bifurcation or with less complex multivessel disease with low or intermediate SYNTAX score (≤ 33) and also those have an increased surgical risk. The current US & ESC guidelines recommend against PCI in patients who are good candidates for CABG including complex type multivessel disease with high SYNTAX score (≥ 33).^{3,4}

Regardless of method of revascularization, current guidelines highlights the "heart team" approach for managing complex coronary artery disease including LMCAD. The heart team discuss the risks, benefits & outcome among medical treatment alone, PCI or CABG, considering patient's informed preference. MACE are higher in patients with incomplete revascularization in compare to complete revascularization regardless of the revascularization strategy.¹⁰

Intravenous ultrasound (IVUS) is an important tool for deciding the approach of revascularization as well as post procedural prognosis. According to ESC guideline⁴ use of IVUS is placed under Class IIb indication in all LM PCI but its availability is not possible in every PCI center because of its cost effectiveness. Our center had no IVUS facility during study period so our study focused the outcome of LM PCI by experience operator without IVUS facility.

Methods & Materials:

This prospective observational study was performed in National Institute of Cardiovascular Diseases & Hospital (NICVD), Dhaka, Bangladesh and first 50 cases were enrolled in the study. Patients diagnosed as LMCAD at NICVD between March 2014 and June 2019 whose coronary angiography showed a greater than 50% lumen narrowing, and/or who refused for CABG, were enrolled into this study. Patients those had previous history of PCI or CABG, valvular heart disease and other significant comorbidities, were excluded from the study.

Clinical outcomes were followed-up at 1st year and 2nd year. Outcome variables were Unstable angina, Myocardial infarction, Target lesion revascularization (TLR), Heart failure, Stroke and Death.

The angiographic data were analyzed with SYNTAX (Synergy between PCI with TAXUSTM and Cardiac Surgery) score and classified as low (0-22), intermediate (23-32), and high (≥ 33).^{11,12} Procedural-related mortality was defined as any cases of mortality during the procedure of index LM PCI in the catheterization laboratory.

All patients were followed-up clinically. If the patients had no clinical presentation of further myocardial ischemia or staged PCI for non-LM lesions, coronary angiography was not performed. LM target vessel revascularization was defined as any revascularization procedure that is done for restenosis at the region of the previously treated lesion along with clinical evidence of myocardial ischaemia whether it involved the LM alone or the LM crossing to LAD or to LCX.

Data collection and statistical analyses:

The numerical data obtained from the study was analyzed and significance of differences were estimated by using statistical methods. The Statistical Package for Social Sciences version 20 software (SPSS Inc., Chicago, Illinois, USA) was used for data analysis. Categorical variables were expressed as percentage and frequency and continuous variables as mean and standard deviation. Continuous variables were compared through the Student's t-test and for the categorical variables the chi-square test and Fisher's Exact test were done as appropriate. Multivariate logistic regression analysis was done to identify independent effect on in hospital outcome after LM PCI. A p-value of <0.05 was considered statistically significant.

Results:

In total, 50 patients (mean age 58.4 ± 4.1 years, 44 male, 06 female) were enrolled, of whom 32 (64%) had stable angina, 17 (34%) had unstable angina/NSTEMI, and 1 (02%) had STEMI. The demographic data of all patients with risk factors and the angiographic and procedural characteristics are listed in Table I & Table II. Among the risk factors, hypertension (66%) is more prevalent followed by dyslipidemia (52%), smoking (44%), diabetes (42%), previous h/o MI (34%), family h/o coronary artery disease (11%) and h/o stroke (02%).

Table-I
Demographic data & risk factors of study patients

Variables	Total Patients N=50 (%)
Age (years) Mean ± SD	58.4±4.1
Sex	
Male	44 (88%)
Female	06 (12%)
Risk Factors	
Hypertension	33 (66%)
Diabetes	21 (42%)
Dyslipidemia	26 (52%)
Previous H/O MI	17 (34%)
Smoking	22 (44%)
H/O CVD	01 (02%)
Family H/O CAD	11 (22%)

Upon coronary angiogram of selected patients, 01 (02%) had LM ostial disease only with no LM distal involvement, 39 (78%) had LM disease with single vessel disease, 09 (18%) had LM with double vessel disease, and 01 (02%) had LM with triple vessel disease (TVD). Among them only 12% involved LM ostium or mid zone, majority (88%) lesion involved in LM distal region. After proper assessment of all patients, 39 (78%) patients underwent complete revascularization and 11 (22%) incomplete revascularization with planned stage PCI in later date. After 1 year of index LM PCI, 94% patients underwent complete revascularization and 3 (06%) patients had residual CTO (2 in RCA and 1 in LCX) which could not negotiated due to lack of rotational atherectomy in our center.(Table II)

Among the study patients pre procedural mean left ventricular EF (LVEF) was 49.92±6.60 % and post procedural LVEF 54.84±4.55% which was statistically significant (p value 0.003) [Table III].

Table-II
Clinical & angiographic characteristics of study patients

Variables	Total Patients N=50 (%)
Diagnosis on Admission	
SCAD	32 (64%)
UA/NSTEMI	17 (34%)
STEMI	01 (02%)
LM disease subtypes	
LM only	01 (02%)
LM plus SVD	39 (78%)
LM plus DVD	09 (18%)
LM plus TVD	01 (02%)
Location of LM disease	
Ostium & Mid Zone	06 (12%)
Distal LM	44 (88%)
Pattern of Revascularization	
Incomplete Revascularization	11 (22%)
Complete Revascularization	39 (78%)

Table-III
Echocardiographic variable of study patients

Variables	LVEF Mean, SD	P Value
LVEF		
Pre procedural	49.92 ± 6.60%	0.003 ^s
Post Procedural	54.84 ± 4.55%	

The mean SYNTAX score was 24.8 ± 2.6 , including 25 (50%) patients with low, 18 (36%) with intermediate, and 07 (14%) with high scores (Fig 1).

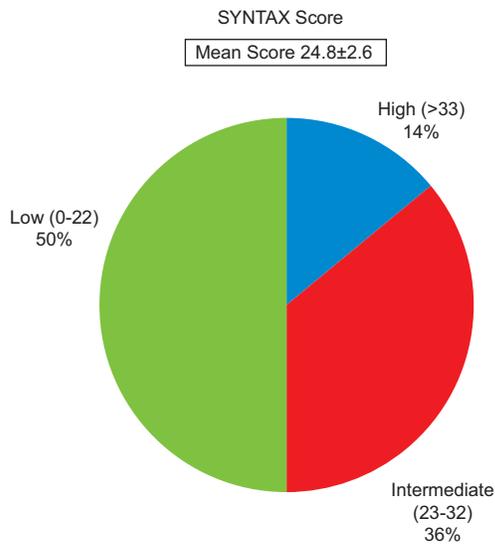


Fig.-1: SYNTAX Score of study populations

Thirty eight (76%) patients received a single stent strategy, including 01 (02%) cases of LM only, 34 (68%) of LM crossing over LAD, and 03 (06%) of LM crossing over LCX. Twelve (24%) patients received two-stents, including 06 (50%) with TAP, 03 (25%) with culotte stenting, and 03 (25%) with a DK Crush (Fig 2 a & b)

All patients were treated with drug eluting stent (DES). There were no cases of procedure related mortality, and no emergency CABG were required. Default route was

femoral for every patient. The mean diameter of the stent from LM crossing over LAD was 3.29 ± 0.39 mm and mean length 26.1 ± 5.7 mm, for LM crossing over LCX mean stent diameter was 2.96 ± 0.38 mm and mean length 22.3 ± 5.8 mm (Table IV).

Table-IV
Mean Diameter & Length of Stents among study patients

Variables	Diameter Mean, SD mm	Length Mean, SD mm
Stent Characteristics		
LM crossing over LAD	3.29 ± 0.39	26.1 ± 5.7
LM crossing over LCX	2.96 ± 0.38	22.3 ± 5.8

During index hospitalization after LM PCI, four (08%) patients underwent cardiogenic shock which required continuous inotropic support in coronary care unit. Among these 04 patients, three (06%) developed Killip class III acute heart failure which improved with diuretics. The average admission duration after index LM PCI was 3.7 ± 1.2 days. No death was recorded on index hospitalization.

Within 1 year of follow-up, one patient (02%) was lost to follow-up. 11 (22%) patients were hospitalized due to repeated cardiovascular events, including 01 (02%) case of recurrent myocardial infarction (MI), 07 (14%) of unstable angina, 03 (06%) of congestive heart failure (Table V).

Six patients underwent repeat angiogram at one year. The LM TLR rate was 04% (02 patients) at 1 year of

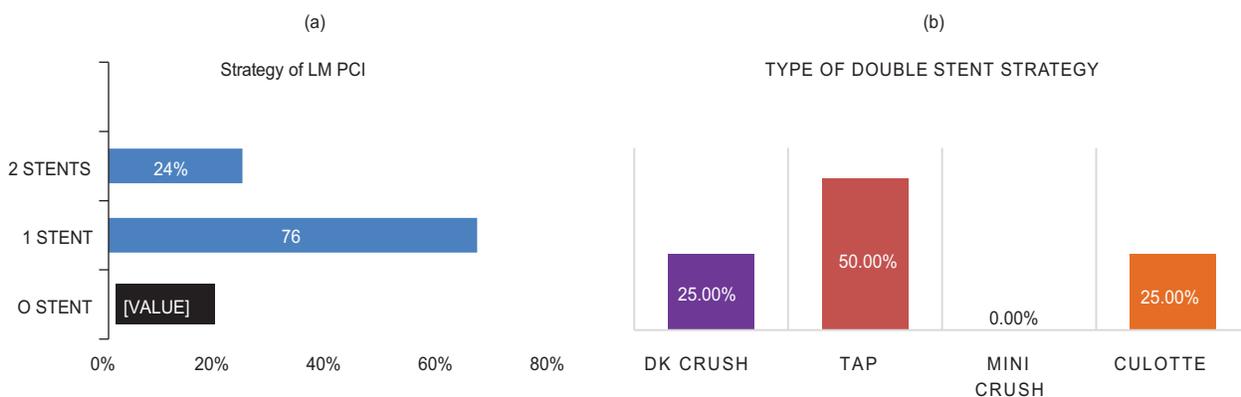


Fig.-2: PCI variable of study population
(a) Number of stent used during index LM PCI, (b) Strategy of double stent technique

which one patient treated with single DES and another by balloon angioplasty alone. One (02%) patient was found large LM aneurysm on repeat angiogram who died after sending for emergency surgical repair.

Within 2 years of follow-up, total 15 (30%) patients were hospitalized for cardiovascular events, amongst them 03 new cases detected on 2nd year, 02 (04%) patients with unstable angina and one (02%) with heart failure. Another 02 (04%) new death was recorded on 2nd year both due to congestive heart failure with incomplete revascularization. Total TLR rate was 06% with another one patient was treated with single DES on 2nd year. MACE were defined as cardiac mortality, acute MI, heart failure, unstable angina, stroke, and any revascularization, were 22% at 1 year and 28% at 2 years. Total death was 2% at 1 year and 6% at 2 year (Table 5).

Table-V
Outcome of study patients after One year and Two year

Variables	After 1 Year (Total)	After 2 Year (Total)
Lost To Follow up	1 (02%)	1 (02%)
Re-hospitalization (MACE)	11 (22%)	14 (28%)
MI	01 (02%)	01 (02%)
Unstable Angina	07 (14%)	09 (20%)
Heart Failure	03 (06%)	04 (08%)
LM TLR	02 (04%)	03 (06%)
Death	01 (02%)	03 (06%)

In multivariate analysis, high SYNTAX Score [odds ratio (OR) 1.654, 95% confidence interval (CI) 1.112~13.604, $p < 0.05$], low post procedural LVEF [odds ratio (OR) 6.553, 95% confidence interval (CI) 1.984~21.643, $p < 0.05$] & incomplete re-vascularized [odds ratio (OR) 3.854, 95% confidence interval (CI) 1.321~11.193, $p < 0.05$] patients have a relatively higher mortality rate after LM PCI along with increase re-hospitalization due to MI, Unstable Angina, Heart failure or TLR (Table VI).

Table-VI
Multivariate regression analysis among the study patients

Variables of interest	Multivariate analysis		
	OR	95% CI of OR	p value
Age (>50 year)	0.684	0.246-2.856	0.778 ^{ns}
Male Sex	0.378	0.286-3.775	0.478 ^{ns}
Smoking	1.470	0.151-2.118	0.998 ^{ns}
Diabetes mellitus	1.690	0.546-3.876	0.473 ^{ns}
Hypertension	0.900	0.267-3.035	0.866 ^{ns}
Dyslipidemia	0.670	0.259-3.017	0.805 ^{ns}
Family history of CAD	0.993	0.980-1.006	0.295 ^{ns}
Low post procedural EF	6.553	1.984-21.643	0.002 ^s
High SYNTAX score	1.654	1.122-13.604	0.013 ^s
Incomplete Revascularization	3.854	1.321-11.193	0.002 ^s

Table-VII
Comparison with Other studies

Study name	Year	MACE (%)	TLR (%)	Mortality (%)
Lee et al ²²	2007	32%	24.8%	9.1%
Cheng et al ²³	2007	25.6%	10.3%	11.8%
Wang et al ²⁴	2010	28.4%		8.1%
Pedrazzini et al ²⁵	2011	17.9%		7.2%
EXCEL Trial ²⁰	2016	23.1	12.9%	8.2%
NOBEL Trial ²¹	2016	28.9	16.2%	11.6%
Stone et al ¹⁵	2019	22%	16.9%	5.0%
This Study	2019	28%	6.0%	6.0%

Discussion:

The LM coronary artery differs from the other coronary arteries by its relatively greater elastic tissue content which can explain high restenosis rate & elastic recoil tendencies following balloon angioplasty. Ostial and mid vessel lesions (~30%) can essentially be treated like other vessels and can follow single-stent strategy. Distal left main lesions (~70%) are our main concern & can be treated as true bifurcation lesions. Restenosis rate are approximately 5% for LMCAD but higher in patient with distal LMCAD (~10%). TLR rate < 10%. Distal LMCAD shows lower success rate but higher rate of restenosis¹³. In our study majority patients also found LM distal disease (88%) followed by LM ostial or mid segment disease (12%).

To determine the strategy of revascularization (single vs double stent), IVUS shows most reliable information for both main vessel and side branch disease. IVUS is also useful for PCI optimization for distal LMCA bifurcation lesion. After stent implantation, IVUS secures proper expansion & apposition at the level of the polygon of confluence, ostial LAD & LCX and the distal LMCA.¹⁴ But IVUS facility required some instrumental & technical support which lacks in many PCI center. In this study we demonstrate the outcome of LM PCI without availability of IVUS facility.

In total, 50 patients were enrolled, of whom 88% were male & 12% female with mean age 58.4 ± 4.1 years. Among the risk factors, hypertension (66%) is more prevalent followed by dyslipidemia (52%), smoking (44%), diabetes (42%), previous h/o MI (34%), family h/o coronary artery disease (11%) and h/o stroke (02%). Stone GW et al¹⁵, showed the mean (\pm SD) age of the patients with LM disease was 66.0 ± 9.6 years, 76.9% of were male, and predominant 29.1% had diabetes. Hussain C et al¹⁶, reported mean age of LM patients were 54.98 years with male (70.63%) predominance. Hypertension was present in 50.8% and diabetes in 26.9% patients.

The mean SYNTAX score was 24.8 ± 2.6 , including 50% patients with low, 36% with intermediate, and 14% with high scores. Cheng et al¹⁷ showed the mean SYNTAX score of LM intervention was 34.8 ± 12.6 , including 17.1% patients with low, 27.1% with intermediate, and 55.7% with high scores. Stone GW et al¹⁵, the mean SYNTAX score was 20.3 ± 3.4 assess in local sites and 26.6 ± 7.5 analyzed in angiographic core laboratory and nearly 80.5% patients has distal Left main bifurcation disease.

After proper assessment of all patients, 78% patients underwent complete revascularization and 22% incomplete revascularization with planned stage PCI in

later date. After 1 year of index LM PCI, 94% patients underwent complete revascularization and 06% patients had residual CTO (2 in RCA and 1 in LCX) which could not negotiated due to lack of rotational atherectomy in our center.

Among the study patients pre procedural mean left ventricular EF (LVEF) was 49.9 ± 6.6 % and post procedural LVEF 54.8 ± 4.5 % which was statistically significant (p value <0.005). The multi-centre Left Main Coronary Artery Stenting (LE MANS) trial¹⁸ showed at 10 years, there was a higher ejection fraction with PCI compared with CABG ($54.9\% \pm 7.3$ versus $49.8\% \pm 9.3$; $p=0.07$).

Thirty eight (76%) patients received a single stent strategy, including 01 (02%) cases of LM only, 34 (68%) of LM crossing over LAD, and 03 (06%) of LM crossing over LCX. Twelve (24%) patients received two-stents, including 06 (50%) with TAP, 03 (06%) with culotte stenting and 3 (06%) with a DK Crush (Fig 2 a & b).

All patients were treated with drug eluting stent (DES). There were no cases of procedure related mortality, and no emergency CABG were required. Default route was femoral for every patient. The mean diameter of the stent from LM crossing over LAD was 3.29 ± 0.39 mm and mean length 26.1 ± 5.7 mm, for LM crossing over LCX mean stent diameter was 2.96 ± 0.38 mm and mean length 22.3 ± 5.8 mm (Table 4).

During index hospitalization after LM PCI, 8% patients underwent cardiogenic shock which required continuous inotropic support in coronary care unit. Among these, 6% developed Killip class III acute heart failure which improved with diuretics. The average admission duration after index LM PCI was 3.7 ± 1.2 days. No death was recorded on index hospitalization.

Within 1 year of follow-up, 2% was lost to follow-up. 22% patients were hospitalized due to repeated cardiovascular events, including 2% case of recurrent myocardial infarction (MI), 14% of unstable angina, 6% of congestive heart failure.

12% patients underwent repeat angiogram at one year. The LM TLR rate was 4% at 1 year of which one patient treated with single DES and another by balloon angioplasty alone. 2% patient was found large LM aneurysm on repeat angiogram who died after sending for emergency surgical repair.

Within 2 years of follow-up, total 28% patients were hospitalized for cardiovascular events, amongst them 6% new cases detected on 2nd year, 4% patients with

unstable angina and 2% with heart failure. Another 4% new death was recorded on 2nd year both due to congestive heart failure with incomplete revascularization. Total TLR rate was 6% with another one patient was treated with single DES on 2nd year. The major adverse cardiac events (MACE) rate, which were defined as cardiac mortality, acute MI, heart failure, unstable angina, stroke, and any revascularization, were 22% at 1 year and 28% at 2 years. Total death was 2% at 1 year and 6% at 2 year.

Stone GW et al¹⁵, The secondary composite outcome of death, stroke, myocardial infarction, or ischemia-driven revascularization at 5 years occurred in 31.3% of the patients in the PCI group

10-year follow-up data of the SYNTAX trial¹⁹ showed 10-year mortality in LM PCI 29.4% in the overall cohort.

The multi-center Left Main Coronary Artery Stenting (LE MANS) trial¹⁸ showed at 10 years, there was lower mortality (21.6%) and lower MACCE (51.1%) in LM PCI group in compare to CABG group. Re-occurrence of MI (8.7%) stroke (4.3%) and repeat revascularization rates (26.1%) are lower in LM PCI group.

In the EXCEL trial²⁰, the primary endpoint (all cause death, MI & stroke) occurred in 15.4% of the patients in the PCI group. The secondary endpoint (all-cause death, MI, ischemia-driver revascularization or stroke) at 30 days occurred in 4.9% patients in the PCI group & at 3 years in 23.1% patients in the PCI group. In summary, 30-day MACE was lower in PCI group, but 3-year follow-up shows similar result between PCI & CABG.

In the NOBLE trial²¹, the 30-day outcomes were similar to those of the EXCEL trial, but at 5 years, estimates of MACCE were 29% for PCI among them 12% for all-cause mortality, 7% for non-procedural MI, 16% for any revascularization, and 5% for stroke.

In multivariate analysis, high SYNTAX Score [odds ratio (OR) 1.654, 95% confidence interval (CI) 1.112~13.604, $p < 0.05$], low post procedural LVEF [odds ratio (OR) 6.553, 95% confidence interval (CI) 1.984~21.643, $p < 0.05$] & incomplete re-vascularized [odds ratio (OR) 3.854, 95% confidence interval (CI) 1.321~11.193, $p < 0.05$] patients have a relatively higher mortality rate after LM PCI along with increase re-hospitalization due to MI, Unstable Angina, Heart Failure or TLR .

Conclusion:

This study demonstrated that high SYNTAX Score, low post procedural LVEF & incomplete re-vascularized patients have a relatively higher mortality rate during LM

PCI along with increase re-hospitalization due to MI, UA, HF or TLR. Our clinical outcomes demonstrate that PCI for patients with LM coronary artery disease is also an effective strategy in a high-volume hospital with experienced operator even without IVUS facility. Careful attention should be given to case selection, comprehensive clinical judgment and excellent PCI technique. It prevents a financial burden on patients if they cannot afford intravascular imaging & refuse CABG, also reduce procedure time & radiation exposure.

Limitation

- Small sample size
- Prolonged follow-up may require (5 years)
- Multi center data may require

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