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Long Term Outcome of Percutaneous Coronary Intervention for Left Main Coronary Artery Disease in Al-Najaf Cardiac Centre

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Abstract

Long term outcome of percutaneous coronary intervention for left main coronary artery disease in Al-Najaf cardiac center.

Objective: To investigate the safety and outcome of percutaneous coronary intervention for unprotected left main coronary artery disease in Al Najaf Cardiac center with comparison outcome between single provisional stent and double stents technique.

Method: Between January 2014 and Jan 2016, 258 patients enrolled in this study whose diagnosed with left main coronary artery disease and refused coronary artery bypass graft surgery in Al Najaf cardiac centre and other centers. Data including clinical course, angiographic characteristics, and 1- and 3-years outcomes were recorded and analyzed.

Result: The major finding of the study including cardiac death, target lesion revascularization, stroke and MACCE was demonstrated in post procedure , 12 mn and 3 yr, as nine patients died from 258 pt. (6 pt. due to cardiac cause), target lesion revascularization (1.55 -3.9%), MACCE (3.1- 8.14 %). In comparison to double stent (DS), single stent (SS) had been better outcome than DS in this of study.

Conclusion: Percutaneous treatment for unprotected left main stem diseased with DES has good 12mn and 3years term outcome so it is safe and feasible in patients with unfit for surgery or high risk and refused surgery. Provisional single stent for unprotected left main stem has been better out come when is compared with double stent technique.

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Background

Left main coronary artery disease is prognostic ally important because LMS (left main stem) is responsible for 84% of blood supply of left ventricle in left coronary dominant system [1]. So patients with severe LMS disease have very high risk because of extent of ischemic myocardium significant. LMS disease was diagnosed in 5-7% in coronary angiography [2]. Three year mortality has been reported 50% in patients with significant LMS disease who medically treated [3]. CABG had been the gold stander for treated LMS disease, many study has been reported benefit of CABG over those who's treated medically [4-7]. PCI (percutaneous coronary intervention) was reserved for those with high risk for surgery [8].

Anatomical and morphological considerations

LMS run from its origin of aorta and bifurcated into LAD and LCX with average diameter 4.5±-0.5 mm in male and 3.9±0.4 mm in female angiographically in non diseased LMS [9]. While the length of LMS is highly variable 2-40 mm [10] short left main stem has been associated with bicuspid aortic valve [11]. LMS divided into: ostium (origin from left coronary sinus), body (mid portion), and bifurcation (distal part) [12].

Anatomical variants and anomalies

There are several important anatomical anomalies in origin and course of LMS, two third of LMS cases bifurcated into LAD, LCX and one third trifurcated with ramus branch [13]. There may be no LMS (short or separated ostium) and these are the most common anomalies and usually associated with aortic valve disease in adult (less than 1%), the second common anomalies is originated of LAD or LCX from right coronary artery or non coronary sinus origin [13,14].

Classification and definitions of left main stem disease

LMS disease has been classified according to table (Table 1), while LMS disease defined as significant when 50% or greater than that of luminal stenosis as judged by coronary angiography [15]. Etiology of left main coronary artery disease.

Table 1: Showing Base line demographic data of patients.

Variable	No.(258)	Percentage
AGE (years	65+-11	-
Sex: Male Female	188 70	72.87% 27.125
DM	78	30.23%
HTN	182	70.54%
Smoking	168	65.12%
Family History of CAD	58	22.48%
COPD	31	12.02%
PAD	5	1.94%
Stroke	2	0.78%

Obstructive

Atherosclerosis

Coronary dissection (Spontaneous, Iatrogenic)

Arteritis (Syphilitic aortitis, Takayasu's arteritis)

Aortic valve pathology including prosthesis malposition

Vasospasm, Iatrogenic, Percutaneous, Direct injury during surgery

External compression (Aortic aneurysm, Tumor)

Non-obstructive

Congenital anomalies, Aneurismal dilatation, Atherosclerotic aneurysm, Kawasaki's disease

Incidence and Epidemiology

The prevalence of atherosclerotic LMS disease in more than 65 yr male (NYHA class II, III, and IV angina) was 11%, 13% and 9% respectively non atherosclerotic [16]. LMS lesion was rare (tertiary syphilis one case in 100000 [17], Takayasu was 2-3 case per million [18] and spontaneous dissection was very rare [19].

Clinical association: There is strong association between LMS and carotid artery disease (40% in comparison to 5% in single vessels disease) [20-21].

Risk stratification in left main stenosis

There are different score that used to predict the outcome of LMS cases treated by PCI or CABG. SYNTAX score is anatomical dependent score (SYNTAX trial revealed low score including osteal LMS and one vesseles disease with LMS ,high score including multivesseles LMS) [22,23] clinical SYNTAX was combined anatomical and clinical variable which was more predictive in one year mortality in PCI LMS disease [24,25]. Euro SCORE was used to estimate mortality post CABG [26] (Figure 1).

Diagnostic Modalities

Intravascular ultrasound (IVUS) provide tomographic 360 sagittal scan of vessels from lumen to wall (minimal and maximal diameter, cross sectional area and plaque area, calcification and stent implantation) [27,28]. Fractional flow reserve (FFR) represented fraction of normal blood flow through stenotic area (less than 0.8 is significant for reversible ischemia [29]. Optical coherence tomography (OCT) is safe and more feasibility for assessment of stent diameter, length and position [30] frequency dominant OCT are more sensitive than IVUS in detecting edge dissection and malapposion of stent in LMS [31-33].

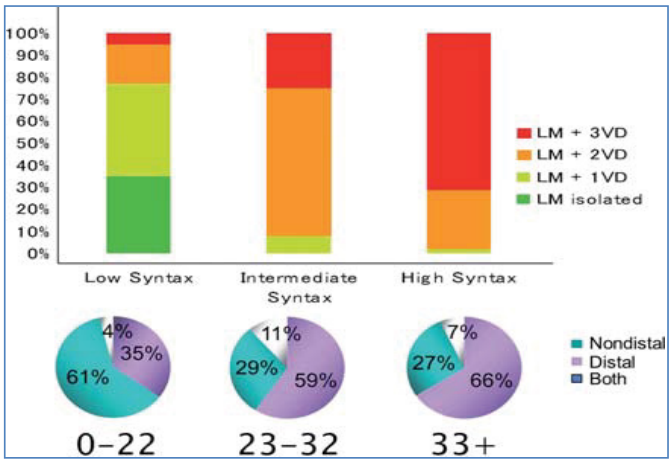

Figure 1: 1 reveal syntax score.

Pciforlmca Disease over time

The LMCA has the most elastic tissue of the coronary vessels, so plain balloon angioplasty was associated with immediate procedural unpredictability and also with unacceptable high rates of rest enosis and early mortality [34]. The adoption of bare-metal stents (BMS) rejuvenated interest in PCI for LMCA disease, with reduction of acute procedural complications (e.g., recoil, abrupt closure, or dissection) [35,36] but, the rate of in-stent rest enosis remained excessive (20% to 40%), especially when distal bifurcation was involved [37,38]. After the introduction of DES, with a remarkable reduction of rest enosis and repeat revascularization, PCI with DES has been widely performed for more complex clinical and anatomic subsets of LMCA disease and newer-generation DES further decreased the risk of stent thrombosis and rest enosis compared to the previous ones [39-42].

Revascularization guidelines change over time

In the 2005 U.S. and European guidelines, PCI for LMCA was not recommended as long as CABG was a viable option for the patient [43,44]. Since then, favorable results from comparative effectiveness studies have continued to be updated; therefore, the recommendations of PCI for LMCA from the 2009 American College of Cardiology (ACC)/American Heart Association (AHA)/Society for Cardiovascular Angiography and Interventions (SCAI) guidelines were revised to a Class IIb indication for anatomically-eligible LMCA disease that is expected to have a low risk of procedural complications [45]. In 2010, the European guideline reflected the results of the SYNTAX trial and other nonrandomized studies and, thus, upgraded PCI as a reasonable treatment mainly according to the anatomic complexity [46,47]. Although considerations of clinical and anatomic factors are slightly different, the most recent recommendations from the 2014 European Society of Cardiology/European Association for Cardio-Thoracic Surgery and 2014 ACC/AHA/American Association for Thoracic Surgery/Preventive Cardiovascular Nurses Association (PCNA) / SCAI / Society of Thoracic Surgeons guidelines similarly provide a Class II indication for PCI in patients with low to intermediate anatomic complexity (Class IIa for relatively simple anatomy and Class IIb for intermediate complexity) and provide a Class III indication for PCI in those with highly complex disease [48,49].

Techniques for percutaneous coronary intervention of left main stem lesions

Single-stent strategy Provisional T-stenting is the most frequent

used strategy. It consists of the deployment of a single stent from LMS to the LAD or LCx, whichever has the highest diameter. The stent is post dilatated in its proximal part from the LMS using proximal optimization technique (POT) [50]. The side branch (most frequently the LCx) can be left untouched, but there are arguments for performing the final kissing balloons post dilatation (KBPD). Provisional T-stenting allows the placement of a second stent into the side branch if it is severely narrowed. In a recent study, the simple crossover LMS-to-LAD stenting without opening of a strut on the LCx ostium was associated with acceptable long-term clinical outcomes [51]. Two-stent strategy the angle between LMS branches dictates the choice of the two- stent strategy. When this angle approaches 90 the T-stenting technique is used and when the angle is <60 strategies which generate a new carina are used, like: mini-crush, T-stenting and protrusion TAP or V-stenting techniques. Other two-stent techniques are culotte's technique and simultaneous kissing stents technique [52]. The choice of the two-stent strategy used depends on the morphology of the lesion and operator preference. The choice of which two-stent strategy to use in distal LMS stenosis has not been shown to affect 2-year survival rate and MACE rate [52]. Whenever the two-stent strategy is used, final KBPD is mandatory [53].

Patients and Methods

In prospective study of 258 patients with unprotected left main coronary artery disease underwent coronary intervention with drug stent implantation, which was performed at AL-Najaf Cardiac Centre between Jan. 2014 to Jan.2016.

Inclusion criteria

- Patients with LMCAS with one, two or three vessels disease, (stable angina, unstable angina, non Q wave MI, and Q wave MI).
- Silent ischemia diagnoses by Non invasive test (TMT, DSE...).
- Patients who refuse CABG opinion.

Exclusion criteria

- Significant comorbidities (advance renal failure, malignancy, bleeding tendency,)
- Non complain medication
- Patients with history of CABG.

All data related to hospital admissions, procedures, and outcomes were collected in our center with the hospital recording files. Information regarding to the clinical status at the latest available clinical follow-up was collected by clinical visits, telephone interviews, or from referring physicians.

Stent Implantations Procedure

- All patients were pretreated with aspirin tab (300 mg), plavix tab (600 mg), then intravenous heparin during procedure (100-150 IUper Kg).
- Arterial access was done via transfemoral (majority of cases) or transradial approach (using 6 Fr, 7Fr, 8Fr sheath with 6 or 7 Fr guiding catheter).
- Predilation was performed by repeated ballooning inflation with more than 15 atm to obtain satisfactory lumen in order to facilitated stent implantation.
- Rotational atherectomy a Rotablator™ was used in two patients with heavily calcified plaques to facilitate balloon expansion and stent deployment guided by IVUS. Stent deployment was performed with high pressure more than 15 atm.
- After removal of the sheath, all patients were monitoring for 24 hr duration.

Definitions

Angiographic success was defined as a reduction in percent of diameter stenosis to 0%. Procedural success required, in addition to angiographic success, the absence of any major adverse cardiac events during the period of hospitalization. Major cardiac events included recurrent angina requiring repeat catheterization, Q- or non-Q-wave myocardial infarction (MI), the need for urgent bypass surgery, and death. Myocardial infarction was defined clinically as the occurrence of symptoms or typical electrocardiographic changes following the stent procedure. Cardiac enzymes were not measured routinely unless there was clinical suspicion of an ischemic event. A MACCE was defined as death of any cause, myocardial infarction, stroke, target lesion revascularization (TLR), or acute stent thrombosis. Death was considered either cardiac or non cardiac. Deaths that could not be classified were considered cardiac. Myocardial infarction was defined as elevation of cardiac enzyme 3 times above the upper limit of normal with a positive MB fraction. A TLR was defined as any revascularization in the treated segment within LM, or if distal LM was stented, in related proximal segments of left anterior descending and circumflex arteries.

Follow-up

Follow-up status, MACCE including death (cardiac or non cardiac), reported MI ,symptomatic, stroke and need for repeat revascularization, were obtained for all patients at approximately 12 months and 3 years after the PCI LMS procedure. Long-term survival data were obtained in all patients from clinic visits or telephone interview with the patient's referring physician.

Statistical Analysis

SPSS Software version 23.0 was used for performing statistical analysis. Continuous data are presented as mean ± standard deviation and qualitative data are presented as number and percentage. Comparison of study groups was carried out using chi-square test for categorical data, and using Student's t-test and ANOVA for continuous data. P value of < 0.05 was considered statistically significant.

Aim of study

To investigate the safety and 1st and 3rd year outcome of percutaneous coronary intervention for left main coronary artery disease in Al Najaf Cardiac Centre with comparison outcome between single provisional stent and double stent technique.

Results

This research included a total of 258 participants. The demographic, clinical characteristic of the study groups are in table (Table 1), these revealed that patients were mostly male (72.8%) with risk factor mostly hypertension (70%), with either stable or unstable condition.

Figure 2 revealed that patients were mostly male (72.8%) while female were 27.2%.

Angiographic data results

Table 3 shows angiographic data that revealed most cases were

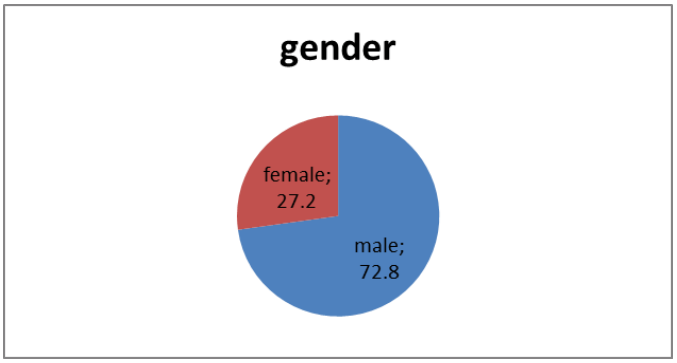

Figure 2: Gender distribution of the study subjects

Table 2: Base line clinical data of patients.

Variable	No.(258)	Percentage
Clinical		
Stable Angina	132	51.16%
Unstable Angina	122	47.29%
MI	4	1.55%
RENAL impairment	6	2.33%
CABG	0	0.0%

Table 3: Showing angiographic data.

Variable	No.(258)	Percentage (%)
Radial Approach	14	5.43%
Location		
Osteal and Body	39	15.12%
Distal	219	84.88%
Bifurcation	210	81.40%
Trifurcation	9	3.49%
Isolated LMS	16	6.20%
LMS WITH 1 vessels disease	52	20.16%
LMS WITH 2 vessels disease	66	25.58%
LMS WITH 3 vessels disease	124	48.06%
Procedure Data		
Lesion Treated		
Predilalation	178	68.99%
Direct Stenting	78	30.23%
Rotablator Technique	2	0.78%
Provisional stenting with or without final ballon kissing	74	28.68%
Double stenting technique with final ballon kissing	184	71.32%
Type of Stent		
DES	258	100.00%
BMS	0	0.00%
No. of Stent		
One Stent	42	16.28%
Two	125	48.45%
Three	78	30.23%
Four	13	5.04%
Nominal Stent Diameter (mm)	3.5±0.5	
Total Stent Length (mm)	22.6±18.4	

done by femoral approach (94.6%), with distal LMS diseased (84.8%), technique usually used was provisional stenting (22.4%), and T stenting with final kissing (71.3%).

Provisional SS (28.6%) were used less than double stent technique (71.3%), while table (Table 4) showing procedure data that revealed no emergent or urgent complication that leaded to death or urgent CABG.

Clinical follow up

Table 5 revealed immediate follow up no cardiac death and no repeated revascularization so MACCE (0.0%) while 12mn follow up revealed MACCE (3.1%), 3 yr. follow up revealed repeated revascularization (5.58%) with MACCE (8.59%).

Comparison between Techniques

Table 6 revealed Comparison between provisional single stenting(SS) and double stenting (DS) technique that was as more cardiac death in DS stenting technique (p value 0.076), more cardiac hospital admission, more target lesion revascularization (0.065 p value), so MACCE in DS stenting more significant (p value 0.0054) in comprised to provisional SS stenting technique.

Discussion

The outcome of percutaneous treatment of left main stem diseased has been improved dramatically due to introduced DES, balloon dilatation, and glycoprotein IIb/IIIa [54]. The major finding of the study (prospective study) demonstrated the following point.

Table 4: Procedure data.

Variables	No.(258)	Percentage (%)
Procedural success	258	
Periprocedural complications		-
Post procedure cardiogenic shock	0	-
Vascular perforation	0	-
LMCA dissection	0	-
Abrupt closure	0	-
Tamponade	0	-
Aortic dissection	0	-
Emergent CABG	0	-
Death	0	-
Other complication	0	-

Table 5: Clinical follow up immediate, 12 mn, and 3 yr.

Variables	No.(258)	Percentage (%)
Hospital Events		
Cardiac Death	0	0.00%
Non Cardiac Death	0	0.00%
Repeated Revascularization		
Target Lesion	0	0.00%
New Vessels	0	0.00%
CVA	0	0.00%
MACCE	0	0.00%
One Year Follow Up		
Cardiac Death	2	0.77%
Non Cardiac Death	1	0.39%
Repeated Revascularization	5	1.98%
Target Lesion	4	1.55%
New Vessels	1	0.39%
CVA	0	0.00%
MACCE	8	3.10%
3 Year Follow Up		
Cardiac Death	4	1.55%
Non Cardiac Death	2	0.78%
Repeated Revascularization	14	5.58%
Target Lesion	11	3.93%
New Vessels	3	1.55%
CVA	1	0.39%
MACCE	21	8.19%

Table 6: Revealed comprised between DS stenting and provisional stenting technique.

	Provisional Stenting (74) SS	DS stenting(184)	P value	RR	95%CI
Cardiac hospital admission	1	15	0.0403	6.03	1.3-44.8
Cardiac death	0	6	0.0768	5.2	0.300-92.3
Target lesion revascularization	1	14	0.0652	5.6	0.75-42.01
Stroke	0	1	0.5	1.2	0.05-26.3
MACCE	2	36	0.0054	7.2	1.7-29.008

Procedure safety and pre procedure complication

- Follow up clinically and angiographic ally for PCI main stem patients?
- Which technique was preferable for PCI main stem diseased? Is it provisional technique or other technique?

Regarding procedure safety

An increase the early risk of death in patient underwent PCI for main stem with BMS had been reported due to high risk of in stent rest enosis, so evolution of DES had been decreased these complication (decrease ISR and target lesion revascularization) [55,56]. The risk of sub-acute thrombosis after stent placement has been estimated at about 1% with the current technique of stent implantation utilizing high pressure and/or intravascular ultrasound guidance, together with the use of combined aspirin and clopidogrel therapy. Both the high concentration of elastic fibers in the aorto-ostial and proximal segment of LMCA and subsequent marked elastic recoil have been proposed as possible causes of the high rest enosis rates seen after conventional balloon angioplasty. In this situation, stent implantation should result in significant reduction in rest enosis [56,57]. Procedure success was high (100%) with low hospital death, and low pre procedure complication.

Follow up (Immediate, 12 mn, 3 yr)

The major finding of the study including cardiac death, target lesion revascularization, stroke and MACCE was demonstrated in hospital, 12 mn and 3 yr, as 9patients died from 258 pt (6 pt. due to cardiac cause), target lesion revascularization (1.55-3.9%), MACCE (3.1-8.14%). There are two single centre studies that showed procedure success with low procedure complication and good long term outcome. Chieffo A, et al. (2010) in a long term follow-up registry, and Morice MC, et al. (2010) in the subset of patients with ULM disease included in the Syntax trial, reported a very low risk profile of patients with similar baseline clinical and angiographic characteristics [58,59]. Clinical outcomes of these studies were similar to our results. At 1 year follow-up, all-cause of death was 2.8% and 4.2%; respectively. Pavei A, et al. (2009) and Vaquerizo B, et al. (2009) reported two PCI registries with similar inclusion criteria to our study [60,61]. Nevertheless, even though the similarity of the inclusion criteria. Accordingly, clinical outcomes were different from our results. In these studies, all cause death rates were 10.1% and 9.3% at 2 year follow-up; respectively.

Regarding single stent and double stent

In comparison to DS, SS had been better outcome than DS in the result of study (cardiac admition, cardiac death, TLR and MACCE). There are many causes that is worsening outcome of DS *vs.* SS technique (firstly, complexity and difficulties in deploying of two stent *vs.* one stent that increase procedure time, contrast volume, radiation exposure and myocardial injuries due to long procedure time, secondly incomplete coverage of ostium of side branch with subsequent suboptimal drug release, multiple metal layer concentration, and stent fracture can cause worse outcome of DS due to focal rest enosis at the Ostia [62,63]. Karrowni W, et al. (2014) had been assessed the outcome of SS versus DS for unprotected distal left main stem [64]. Clinical outcome of this study was similar to our study as (decrease risk of TLR in SS (10.1%) *vs.* DS (24.7%), decrease risk of MACCE in SS (20.1%) versus DS (31.8%)) [64]. BBC ONE study revealed significant difference between provisional SS *vs.* complex DS in TLR and cardiac death (11.3% *vs.* 3.2%) [65]. CACTUS trial revealed no significant difference between provisional stent *vs.* complex stent with crush technique (provisional 15 % *vs.* crush 15.8%) [66].

Study Limitation

- The study was done in single centre (Al Najaf cardiac centre).
- Not all patients did for him complete angiographic analysis by IVUS or OCT.
- No specific type of DES.
- Need long period for follow up.

Conclusion

Percutaneous treatment of unprotected left main stem diseased with DES has good short and long term outcome so it is safe and feasible in patients with unfit for surgery or high risk and refuse surgery. Provisional single stent for unprotected left main stem has been better out come when is comprised with double stent technique (TAP, T stent, mini crush technique) regarding cardiac death, TLR and MACCE.

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