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## Original Article

# Ulembe study: Unprotected left main PCI study at 3 years follow up

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## ABSTRACT

**Objectives:** To study left main registry for Indian population, demographic and procedural characteristic of patient outcomes after uLMPCI and identify the predictors of prognosis in 109 patients at long term follow up.

**Methods:** A total of 109 consecutive patients, who underwent uLMPCI, were analyzed in this single-center registry. All data related to the patient's clinical presentation, procedure and follow-up were collected. Syntax score and medina score were calculated for all patients. Mean follow-up duration of the study was 3 year. Procedural success rate for left main intervention was 100%. Primary endpoint was composite of major adverse cardiovascular and cerebrovascular events (MACCE), including cardiac death (CD), cerebrovascular accident (CVA), myocardial infarction (MI), and need for repeat revascularization and intervention.

**Results:** Patients with syntax score  $\leq 32$  had higher event-free secondary end point rate than those with syntax score  $> 32$ . Syntax score  $> 32$  was found to be significantly correlated to prior PCI/CABG patients, patients with multiple stenting and multiple vessel stenting. Syntax score  $> 32$  and diabetes were the independent predictor of MACCE at long term follow up of 3 years.

**Conclusion:** uLMPCI is safe and effective treatment alternative to CABG in non diabetic patients with selected LM alone, single vessel and single stent patients with low and intermediate syntax score ( $\leq 32$ ) at 3 years.

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## 1. Introduction

LM interventions have potential for major ischemic injuries and hence remain a huge therapeutic challenge for specialists. The incidence of left main (LM) disease is 6%.<sup>1</sup>

In patients with high surgical risk, PCI for ULMCA lesion is a class IIa indication according to recent guidelines.<sup>2</sup> Various randomized controlled trials (RCTs),<sup>3–6</sup> registries,<sup>7–9</sup> meta-analysis<sup>10</sup> and recent trials<sup>11,12</sup> have proved the use and safety of DES.

Multiple multicentric studies have been done in the western world but there is very minimal data of uLMPCI with follow up in the Indian population. Hence, our objective was to evaluate the demographic features, angiographic variables, predictors of procedural success and long term follow up of uLMPCI with drug-eluting stents (DES) in Indian subcontinent.

## 2. Study population

A total of 109 consecutive patients, who underwent LMPCI between 2006 and 2015, were analyzed at 3 years follow up in this single-center registry. The study was approved by the Ethical committee of the institution. A written informed consent was obtained prior to the procedure in all patients as per institution protocol. All data related to the patient's clinical presentation, procedure and follow-up were collected. Syntax score<sup>13</sup> and medina score were calculated for all patients.

All patients were pre treated with loading dose of aspirin and clopidogrel/prasugrel/ticagrelor. Unfractionated heparin was administered during the procedure and ACT  $> 250$  s was maintained intraprocedurally. GpIIb/IIIa inhibiting agents were given at discretion of the operator. Post-procedure, all patients were continued on dual antiplatelets. Other cardiac medication (beta-blockers and statins) was prescribed post procedure.

### 2.1. Follow-up

All patients were followed up in cardiology outpatient department at 1, 3, 6 months, 1-year and 3 years after PCI. Only

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symptomatic patients were evaluated, first subjected to stress testing and then if required, check angiography.

## 2.2. Endpoints

The primary endpoint of the study was a composite of major adverse cardiovascular and cerebrovascular events (MACCE) which was nonfatal Myocardial infarction (MI), Cardiac death (CD), including target lesion revascularization (TLR)/target vessel revascularization (TVR) and any new vessel revascularization or cerebrovascular accident (CVA).

## 2.3. Definitions

**Complete revascularization:** Complete anatomic revascularization was defined as treatment of all coronary artery segments > 1.5 mm in diameter with  $\geq 50\%$  diameter stenosis.<sup>14</sup>

**Target lesion revascularization (TLR):** TLR was defined as repeat intervention of target lesion up to 5 mm segment proximal and distal to stent.

**Target vessel revascularization (TVR):** TVR was defined as repeat intervention of any segment of coronary vessel proximal or distal to the target lesion, involving its branches and/or target lesion itself.

**Cardiac death (CD):** Any death due to proximate cardiac cause (e.g. MI, low-output failure, fatal arrhythmia), unwitnessed death and death of unknown cause, and all procedure-related deaths, including those related to concomitant treatment, will be classified as CD.<sup>15</sup>

**Myocardial infarction (MI):** MI was defined as increase in CPK-MB level of more than three times the upper limit of normal range associated with typical chest pain and fresh ST elevation or new onset LBBB.

**Major adverse cardiovascular and cerebrovascular events (MACCE):** MACCE was defined as occurrence of nonfatal MI, CD, including TLR/TVR and any new vessel revascularization or cerebrovascular accident (CVA) during follow-up period.

**Stent thrombosis (ST):** Stent thrombosis was labeled as acute, subacute, late, and very late when event occurred within 24 h, 30 days, <1-year, or >1-year, respectively after procedure. Definite, probable, and possible stent thrombosis was defined according to ARC definition.<sup>15</sup>

## 2.4. Statistical analysis

Statistical analysis was done using univariate and multivariate analysis. Chi square testing was used to assess the equality of survival distribution at different levels.  $p$  values  $\leq 0.05$  were considered significant. Demographic, clinical, angiographic, and procedural variables were tested to determine significant ( $p < 0.05$ ) univariate correlates of immediate and long-term poor outcomes. Results of multiple variable analyses are reported as hazard ratios with 95% confidence intervals (CI) and  $p$  values. Kaplan–Meier survival analysis was used to analyze actuarial survival rates, and a log-rank test was used to compare different survival curves. Kaplan–Meier estimates were used to determine event-free survival (survival with freedom from CD, MI, ST, RI, and CVA). Mean survival time was reported.

## 3. Results

### 3.1. Basic demographic profile

A total of 109 patients were included and followed up till 3 years in the study. Mean age of the patients was 58.06 years with 80.7% males and 19.3% females. The major risk factor associated was

Hypertension in 58.7% followed by Diabetes mellitus 43.1% and smokers 15.6%. Multiple modifiable risk factors were seen in 32.35% patients.

The most common clinical presentation was unstable angina in 43%, followed by TMT positive in 33.02%. Non ST Elevation MI and ST Elevation MI were seen in 7.3% and 28.4% patients.

78 (71.5%) had normal LV function with LV dysfunction seen in 31 (28.4%) patients, mild 9 (8.2%), moderate 7 (6.4%) and severe 15 (13.7%).

Baseline characteristics of study group are summarized in Table 1.

### 3.2. Procedural and angiographic characteristics

The decision for unprotected left main intervention for all patients included in the study instead of coronary artery bypass surgery was based upon Syntax score, Heart team unanimous decision and patient refusal for surgery.

All patients underwent drug eluting stent (DES) implantation, first generation DES in 62.5% (68), second generation in 34.8%(38) and bare metal stent in 2.7%(3).

Ostial LM lesion was seen in 25.6%, mid in 8.2%, and distal LM in 66.05% patients.

Bifurcation lesions were done in 58.4% patients with a majority with culotte technique. Medina scoring was done for all bifurcation lesion patients.

LM stenting alone was done in 37.6% with additional vessel stenting done in 62.3%. LM with one additional vessel stenting was done in 49 whereas LM with two additional vessel stenting in 19 patients. Single stent was used in 32 (29.3%) patients with multiple stents (>2 stents) were used in 77 (70.6%) patients.

All procedures were done with 7F/8F catheter, transfemoral route. Rotablation was used in 3.6% patients and IVUS in 9.1% to image the LM pre and post procedure.

Angiographic and procedural characteristics of all patients is summarized in Table 2.

### 3.3. Procedural and in-hospital outcome

There was no intraprocedural and post-procedural MACCE. Flow limiting dissection was noted in 23 (21%) patients, which were managed with by stent implantation. Minor groin hematoma were seen in 7(6.4%). Average hospital stay was  $3.51 \pm 1.2$  days.

### 3.4. Follow-up clinical outcome

Follow-up was terminated at the first occurrence of a MACCE (CD, MI, CVA). Asymptomatic patients were followed up to 3 years on outpatient basis(OPD). None of the patients had any CD/CVA/ Repeat revascularization in hospital at 30 days and at the end of

**Table 1**  
Patients demographics.

<b>Baseline characteristic (n = 109)</b>	
Age	58.06
Male	88 (80.7%)
Female	21 (19.2%)
DM	47 (43.1%)
HTN	64 (58.7%)
Current smoking	17 (15.5%)
Prior MI/CABG	17 (15.5%)
<b>Clinical presentation (n = 109)</b>	
Unstable angina	47 (43.1%)
NSTEMI	8 (7.3%)
STEMI	31 (28.4%)
TMT+	36 (33.02%)

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