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## Original Article

# Angioplasty of unprotected left main coronary stenosis: Real world experience of a single-operator group from eastern India



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## ABSTRACT

**Background:** Coronary artery bypass graft surgery is the standard treatment of unprotected left main coronary stenosis (ULMCA). However, in the real world scenario, many of these patients are unfit for CABG or prefer angioplasty as an alternative when offered the choice. **Methods:** A total of 86 clinically stable patients with ULMCA stenosis who were unfit or unwilling for CABG underwent PCI with DES at two tertiary care centers in Kolkata. Patients were followed up prospectively for a median of 34.6 months for major adverse cardiovascular events. Angiographic follow-up was done after 1 year of index procedure or earlier, if indicated. **Results:** Fifty-five patients (64%) had distal left main stenosis. Two-stent technique was used in 19 patients (22%) and single-stent technique in 36 patients (42%) with distal left main lesion. Thirteen patients (15.1%) had left ventricular ejection fraction (LVEF) of  $\leq 45\%$ . There was no in-hospital death, MI, or stent thrombosis. During follow-up, major adverse cardiac event (MACE) occurred in 9 patients (10.5%). Our study revealed significantly greater MACE in patients with distal left main lesion with LVEF  $\leq 45\%$  (50% vs 6.38%,  $p = 0.0002$ ), high SYNTAX score (36.36% vs 6.82%,  $p = 0.008$ ), and diabetes (17.95% vs 0.00%,  $p = 0.07$ ). Overall, also patients with Diabetes, LVEF  $\leq 45\%$ , and SYNTAX score  $> 32$  had significantly higher MACE. Use of IC Stent, IVUS, or procedural strategy in distal lesion did not affect MACE. **Conclusion:** In selective patients with low-intermediate SYNTAX score and without diabetes and LV dysfunction, ULMCA PCI with DES is feasible.

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## 1. Introduction

Significant, unprotected left main coronary stenosis (ULMCA) is a life threatening condition. It is found in 3–10% of the patients undergoing coronary angiogram.<sup>1,2</sup> Treated medically, this condition has unacceptably high 1-year mortality of 21%<sup>3</sup> and 3-year mortality of 30–40%.<sup>4–7</sup> Coronary artery bypass graft surgery has shown improved long-term survival in several trials,<sup>4–7</sup> and currently, the standard of care for ULMCA stenosis.<sup>8</sup> PCI has long been tried as an alternative option in treatment of coronary artery disease. PCI with bare metal stents (BMS) were found to have low-procedural complications but they had unacceptably higher rate of repeat revascularization rate.<sup>9–12</sup> Since the advent of drug eluting stents (DES) in 2002, with the promise of vastly reduced rate of restenosis, there has been a resurgence of interest of ULMCA stenting. Several registries from different parts of the world have shown comparable short-term outcomes in terms of death or MI that rivals those of CABG.<sup>13–19</sup> Guidelines support PCI in patients with ULMCA stenosis who are not suitable for CABG.<sup>8</sup> Here we present our experience in ULMCA PCI from two tertiary care hospitals in Kolkata using DES.

## 2. Methods

**Study objective.** Primary study objective was to assess major adverse cardiac events (MACE), including all cause mortality, MI, and TVR. Secondary objective was stent thrombosis (ST).

**Patient population.** From October 2008 to February 2014, patients with de novo ULMCA stenosis, treated with new DES implantation at two centers (AMRI Hospital, Salt Lake and Fortis Hospitals, Anandapur, Kolkata) by a single group of interventional cardiologists, were included in our registry. Patients presenting with STEMI were excluded. Patients with NSTEMI-ACS or unstable angina were medically stabilised before PCI. SYNTAX score was calculated for all patients. As ULMCA disease is still a Class I indication for surgery in the current guidelines, patients were enrolled after proper counseling by interventional cardiologists, cardiac surgeons, and internists (Heart Team since 2012) in situations like (a) advanced age, (b) critical co-morbidities, (c) patient unwilling for CABG, (d) Estimated short life expectancy (known malignancy) and (e) post-CABG with occlusion of left internal mammary artery/RSVG graft to LAD & LCx making the situation as unprotected LMCA disease.

**Medications and PCI.** Each patient was preloaded with clopidogrel (600 mg) and used 75 mg in combination with aspirin 150 mg daily for 12 months. Aspirin 75 mg was continued indefinitely thereafter. All the procedures were performed via transfemoral route. Intraprocedural unfractionated heparin (with a goal activated clotting time of  $\geq 300$  s) was administered during the procedure.

Coronary angioplasty and stent implantation, including bifurcation strategy in the case of distal disease, were performed according to the operator's preference, with the aim of complete coverage of the diseased segment. The use of prophylactic intra-aortic balloon pump (IABP), periprocedural glycoprotein IIb/IIIa inhibitors, atherectomy devices, IVUS

guidance (Boston Scientific), and Enhanced Stent Visualisation (ESV) system (Siemens IC Stent) was at operator discretion. Stents used in our patients include Cypher (Cordis) Sirolimus eluting stent, Taxus Liberte (Boston Scientific) Paclitaxel eluting stent, Promus Element/Promus Element Plus/Synergy (Boston Scientific) or Xience V/Xience Prime (Abbot Vascular) Everolimus eluting stent, and Endeavour Sprint/Endeavour Resolute/Integrity Resolute (Medtronic) Zotarolimus eluting stent.

All patients gave informed written consent for the procedure and subsequent data collection during follow-up. The study was approved by ethical committees of the respective institutes.

**Follow-up.** All patients were followed up during hospital stay, after discharge at 1 month, 6 months, 1 year and then yearly by clinic visit or telephonic contact. Coronary angiogram was planned in all patients after 1 year of index procedure or earlier if indicated. Follow up was recorded till February 2015.

**Definitions.** Death was classified as either cardiac or non-cardiac according to the Academic Research Consortium (ARC) definitions.<sup>20</sup>

*Periprocedural non-Q wave MI* was defined as elevation of the serum creatinine kinase isoenzyme MB (CK-MB) to 3-times the upper limit of normal, in the absence of new pathological Q-waves. *Q-wave MI* was defined as the development of new pathological Q-waves in 2 or more contiguous leads, with or without CK-MB elevation above normal. *Spontaneous MI* was defined as the occurrence after hospital discharge of any value of troponin and/or CK-MB greater than the upper limit of normal if associated with clinical and/or electrocardiographic changes.

*TVR* was defined as any repeat PCI or surgical bypass of any segment of the target vessel, defined as the entire major coronary vessel proximal and distal to the target lesion, including upstream and downstream branches and the target lesion itself.

*TLR* was defined as any repeat PCI of the target lesion, or bypass surgery of the target vessel performed for restenosis. The *target lesion (restenosis)* was defined as the treated segment from 5 mm proximal to 5 mm distal to the stent.

Definite, probable, and possible ST were determined according to the ARC definitions.<sup>20</sup>

**Statistical analysis.** Data are presented in percentages and mean  $\pm$  S.D. Categorical variables are presented as percentages and compared with chi-square testing. Statistical significance was established at  $\alpha = 0.05$  level. Kaplan–Meier survival curves were obtained along with 95% confidence limits for survival curves in overall population and analysed with log rank test method. Cox's proportional hazard model was used to determine hazard ratios (using Efron approximation). Analysis was performed using Statistical software R (R Foundation for Statistical Computing, version 2.6.2).

## 3. Results

A total of 86 patients with de novo ULMCA stenosis treated with DES were included in the study. Baseline patient characteristics and angiographic characteristics are shown in [Tables 1 and 2](#).

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