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Original Article

Left main PCI: An observational analysis from large single-centre experience



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ABSTRACT

Background: Although trials have shown efficacy of unprotected left main percutaneous coronary intervention (uLMPCI), data from Indian subcontinent are lacking. Hence, we planned this observational analysis of single-center uLMPCI data.

Objectives: To study long-term outcome after uLMPCI and identify predictors of adverse outcome.

Methods: Case details of 62 consecutive patients of uLMPCI between 2006 and 2013 were retrieved from a computerized database wherein detailed records were maintained.

Results: Mean follow-up duration was 669.8 ± 404.2 days. Procedural success rate was 98.4%. Primary endpoint was composite of major adverse cardiovascular and cerebrovascular events (MACCE), which included cardiac death (CD), cerebrovascular accident (CVA), myocardial infarction (MI), and need for repeat intervention (RI) at three years. MACCE occurred in 13 (20.9%) patients. Cardiac death (CD), (including possible stent thrombosis), RI, and CVA occurred in 6 (9.7%), 5 (8%), and 2 (3.2%) patients, respectively. Overall three-year MACCE-free survival rate was 76.7%. Event-free survival rate was similar among patients who underwent uLMPCI alone and patients who underwent uLMPCI along with additional one-vessel PCI [(88.9% vs 81.8%), $p = 0.492$], while survival rate was lower in patients who underwent uLMPCI along with PCI of additional two or more vessels (40%, $p = 0.036$). Patients with syntax score ≤ 32 had higher event-free survival rate than those with syntax score > 32 [(87.1% vs 33.3%), $p = 0.001$]. Syntax score > 32 was the only independent predictor of adverse outcome.

Conclusion: uLMPCI is safe and effective alternative to CABG for LM alone and LM plus single-vessel disease with syntax score ≤ 32 .

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1. Introduction

In patients with coronary artery disease, approximately 6% have significant left main (LM) disease.¹ In view of the large area of myocardium under jeopardy, LM interventions have potential for major ischemic impediment and thus remain a major therapeutic challenge.

In patients with high surgical risk and low-risk anatomical features, PCI for ULMCA lesion is a class IIa indication according to recent guidelines.² Recent randomized controlled trials (RCTs),^{3–6} registries,^{7–9} and meta-analysis¹⁰ have shown feasibility and safety of DES implantation in this challenging subset of patients and results comparable with CABG in terms of MACCE occurrence. However, CABG still remains the procedure of choice for treatment in patients with high-risk anatomy.

Although several multicentric studies are available from the western world and far east, there is insignificant data of uLMPCI from the Indian subcontinent. Moreover, results often vary depending on the experience of the operator in this challenging subset of patients. Hence, we aimed to evaluate the procedural success and long-term outcome of uLMPCI with drug-eluting stents (DES) and identify predictors of adverse outcome in our large single-center study spanning over a 7-year time period.

2. Methods

2.1. Study population

A total of 62 consecutive patients, who underwent LMPCI between January 2006 and December 2013, were analyzed in this single-center registry. The decision to perform LMPCI was made at the discretion of performing physician on the basis of lesion characteristics, hemodynamic condition of the patient, and patient preference. A written informed consent was obtained prior to the procedure in all patients as per institution protocol. All data related to the procedure, patient's clinical presentation, and follow-up were retrieved from individualized computerized database software, where all such records were maintained with yearly follow-up information. Incomplete records were refreshed with telephonic contact with the patients between December 2013 and August 2014. Patients were risk stratified also according to syntax score.¹¹ Approval of the institutional ethics committee was taken for data analysis.

2.2. Medication

All patients were pre-treated with Aspirin and loaded with clopidogrel 600 mg. Unfractionated heparin was given at the time of procedure and titrated to maintain ACT >280 seconds intraprocedure. GpIIb/IIIa inhibiting agents were given at discretion of operator in view of complexity of the lesion, stent length, multiple stents, and patient's clinical status. Post-procedure, all patients were prescribed clopidogrel at least for one year and advocated aspirin for whole life. Other cardioactive medication was prescribed in accordance with

patient's clinical need and guidelines recommendation. Complete revascularization was aimed in all patients, except those who presented with ACS, in whom only culprit lesion was done at first go and significant nonculprit lesion was revascularized later in a staged procedure, usually within two weeks of index PCI.

2.3. Follow-up

All patients were followed up in cardiology outpatient department, initially at 3 months after PCI, followed by a visit after 6 months, and then yearly. No routine follow-up angiography was done. However, symptomatic patient was subjected to check angiography.

2.4. Endpoints

The primary endpoint of study was a composite of major adverse cardiovascular and cerebrovascular events (MACCE), which included CD, myocardial infarction (MI), stroke, and need for RI. Secondary endpoint was composite of all the above, and symptoms of angina in addition.

2.5. Definitions

Technical success: Technical success was defined as deployment of stent in the target lesion successfully.

Procedural success: It was defined as target lesion (vessel) revascularization with residual diameter stenosis of <10% and TIMI 3 flow without any major procedural complication or immediate post-procedure adverse event like MI, acute stent thrombosis, need for emergency target revascularization, or CD.

Complete revascularization: Complete anatomic revascularization was defined as treatment of all coronary artery segments >1.5 mm in diameter with ≥50% diameter stenosis.¹²

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.¹³

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, RI, 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 hour, 30 days, <1 year, or >1 year, respectively after

procedure. Definite, probable, and possible stent thrombosis was defined according to ARC definition.¹³

2.6. Statistical analysis

Statistical analysis was done using IBM SPSS Statistical Software (IBM SPSS Statistics version 17.0, IBM SPSS, USA). Continuous variables were expressed as mean \pm standard deviation (SD) and categorical variables were expressed as percentage. *p* values ≤ 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 on Cox regression analysis. Multiple variable Cox proportional hazard analyses were then performed, with the enter method for all pertinent covariates. Results of multiple variable Cox analyses are reported as hazard ratios with 95% confidence intervals (CI) and *p* values. Kaplan–Meier survival analysis was used to analyse 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

Baseline characteristics of study group are summarized in Table 1. A total of 62 patients were included in the study. Mean age of the patients was 59.5 ± 10.3 years. Men comprised 45 (72.6%) and females constituted 17 (27.4%) of the total. A total of 16 (25.8%) patients were diabetics. All were on oral antidiabetic drugs and none of these patients were on insulin therapy. HTN was present in 29 (46.8%) and 21 (33.9%) were current smokers. Multiple-risk factors were present in 25 (40.3%) patients.

The most common clinical presentation was stable angina in 37 (59.7%), followed by unstable angina (USA) in 16 (25.8%).

Table 1 – Patients demographics.

Baseline characteristics (n = 62)	
Age	59.5 \pm 10.3
Male	45 (72.6%)
Female	17 (27.4%)
DM	16 (25.8%)
HTN	29 (46.8%)
Current smoking	21 (33.9%)
Familial-risk actor	4 (6.5%)
Multiple-risk factor	25 (40.3%)
Hospital stay (days)	3.42 \pm 1.98
LVEF (in % age)	47.1 \pm 9.16
Syntax score	22.05 \pm 7.5
Clinical presentation (n = 62)	
Chronic stable angina	37 (59.7%)
Unstable angina	16 (25.8%)
NSTEMI	7 (11.3%)
STEMI	2 (3.2%)

Non-ST elevation myocardial infarction (NSTEMI) was diagnosed in 7 (11.3%) at admission and 2 (3.2%) presented with ST elevation myocardial infarction (STEMI). The mean syntax score was 22.05 ± 7.5 . Mean LVEF was $47.1 \pm 9.16\%$. A total of 12 (19.3%) patients had LV dysfunction, including moderate in 5 (7.1%) and severe in 7 (11.2%).

3.2. Procedural and angiographic characteristics

Procedural and angiographic characteristics are shown in Table 2. Urgent PCI was done in 2 (3.2%) and 60 (96.7%) underwent elective PCI. DES was implanted in all patients among which 14 (22.5%) were 1st generation and 48 (77.5%) were 2nd generation DES. Lesion location was in distal LM in 30 (48.4%), in proximal LM (ostial/LM shaft) in 22 (35.5%), and 10 (16.1%) patients had ostial LAD/LCx lesions converting into LM bifurcation stenting intraprocedure. Among total 40 bifurcation lesions, single-stent procedure was done in 25 (62.5%) and two-stent procedure was done in 15 (37.5%) patients. Multiple stents (≥ 2 stents) were used in 39 (62.9%) patients. PCI to LM alone was done in 26 (41.9%) and multivessel PCI was done in 36 (58.1%). One additional vessel along with LMPCI was stented in 23 (37.1%) and 2 or more additional vessels were stented in 13 (21%). Mean stent diameter and length were 3.54 ± 0.4 mm

Table 2 – Angiographic and procedural characteristics among patients (n = 62).

Site of lesion	
Ostial/Shaft	22 (35%)
Distal bifurcation	40 (64.5%)
(a) Preexisting LM bifurcation lesion	30/40 (48.4%)
(b) Ostial LAD/LCx converting in LM bifurcation	10/40 (16.1%)
Number of stents	
Single stent	23 (37.1%)
Multiple stent (≥ 2)	39 (62.9%)
(a) Bifurcation site alone	15/39 (38.4%)
(b) Additional site	24/39 (61.5%)
Number of vessels intervened	
Single vessel (LM alone)	26 (41.9%)
Multivessel	36 (58.1%)
(a) LM + 1 additional vessel	23
(b) LM + 2 or more vessels	13
Guiding catheter size (n = 62)	
6F	22 (35.5%)
7F	40 (64.5%)
Access site (n = 62)	
Radial artery	30 (48.4%)
Femoral artery	32 (51.6%)
Syntax score (n = 62)	
<22	28 (45.2%)
22–32	23 (37.1%)
>32	11 (17.7%)
Other procedural details	
Mean stent diameter (mm)	3.54 \pm 0.4
Mean stent length (mm)	15.5 \pm 7.8
IVUS	35 (56.5%)
Kissing balloon	13 (21%)
Rotablation	2 (3.2%)
Cutting balloon	4 (6.4%)

and 15.5 ± 7.8 mm, respectively. Radial artery approach was done in 30 (48.4%) patients and femoral artery approach in 32 (51.6%). Twenty two (73.3%) radial PCI were done with 6 F guiding catheter and 8 (26.6%) were done with 7F guiding catheter. All femoral procedures were done with 7F catheter. Imaging with IVUS was used in 35 (56.5%) patients. Rotablation was used in 2 (3.2%) patients. Complete revascularization was done in 53 (85.5%) patients while it could not be achieved in 9 (14.5%) patients.

3.3. Procedural and in-hospital outcome

Average hospital stay was 3.42 ± 1.98 days. Technical success and procedural success were 100% and (61/62) 98.4%, respectively. There were total of 3 (4.8%) in-hospital deaths. One patient died immediately post-procedure while awaiting CABG/advised for an uncontrollable leak due to LM perforation post-stenting. One patient died in hospital due to persistent hypotension and acute renal failure and another died due to major gastrointestinal bleed. One patient developed delayed pericardial effusion, which was managed with intrapericardial glue, but later the same patient developed ischemic CVA on fourth day of procedure but could be discharged successfully. There was no post-procedural MI. Flow limiting dissections occurred in 5 (8%) patients, all of which were managed with a stent. Minor bleed in the form of arm hematoma and gum bleed occurred in 3 (4.8%) patients.

3.4. Follow-up clinical outcome

Mean follow-up duration was 669.8 ± 404.2 days. Follow-up was terminated at the first occurrence of a MACCE (CD, MI, CVA, RI), and asymptomatic patients were followed up to 3 years.

Event details are summarised in Table 3.

3.5. 30-day outcome

At the end of 30-day follow-up, the incidence of CD was 3 (4.8%) only (all in-hospital). There was no fresh CVA. One patient developed ISR during index hospitalization itself and underwent CABG. Total event rate at 30 days was 5 (8%).

3.6. Long-term clinical outcomes

1-Year outcome: At 1 year, there were a total of 5 (8%) CDs, with two new deaths occurring between 30 days and 1 year,

including a sudden CD after 45 days in one and similar death after 6 months of procedure in another patient. A total of three more patients developed angiographic restenosis and needed RI during this period. Of the total of four patients with need for RI, 2 (3.2%) underwent CABG and another 2 (3.2%) patients underwent repeat PTCA. One (1.6%) patient developed a fatal CVA after 8 months of procedure. Total event rate at 1 year was 11 (17.7%).

3-Year outcome: At the end of 3 years, the incidence of total CD was 6 (9.7%), which includes 1 death due to possible stent thrombosis at 485 days after procedure. Another patient needed RI after 2 years due to new lesion in another vessel with repeat PCI. RI was needed in a total of 5 (8%) patients. Four (6.4%) presented with in-stent restenosis (ISR) and one had disease in new vessel. Two of these (3.2%) underwent CABG and 3 (4.8%) were revascularized with repeat PTCA.

Table 3 shows the details of combined MACCE. A cumulative MACCE rate was 13/62 (20.9%) at the end of 3 years. At end of follow-up period, the incidence of CD (including three possible stent thrombosis), need for RI, and CVA were 6 (9.7%), 5 (8%), and 2 (3.2%), respectively (Fig. 1).

3.7. Predictors of adverse outcome (MACCE)

Predictors of MACCE using univariate and multivariate analyses have been shown in Table 4. Higher syntax score >32 [HR = 11.5 (95% CI 3.7-35.7), $p = 0.001$], multivessel stenting [HR = 2.3 (95% CI 1.1-4.65), $p = 0.027$], and use of multiple stent [HR = 1.9 (95% CI 1.1-3.2), $p = 0.016$] were significant factors predicting MACCE on univariate analysis while on multivariate analysis higher syntax score (>32) [HR = 9.3 (95% CI 2.8-30.2), $p = 0.001$] was found to be the only independent predictor of adverse outcome. Although there was a trend toward poorer outcome in diabetic patients on univariate analysis [HR = 2.6 (95% CI 0.9-7.8), $p = 0.084$], it was not statistically significant.

3.8. Secondary outcome

It is composite of CD, MI, CVA, and recurrent angina after procedure. A total of 11 (17.7%) patients presented with recurrent post-PTCA angina. All patients with recurrent angina were subjected to repeat angiography and other

Events	In-hospital	30 days	1 year	3 years
CD	3 (4.8%)	3 (4.8%)	5 (8%)	6 (9.7%)
CVA	1 (1.6%)	1 (1.6%)	2 (3.2%)	2 (3.2%)
Repeat Intervention	1 (1.6%)	1 (1.6%)	4 (6.4%)	5 (8%)
Total MACCE	5 (8%)	5 (8%)	11 (17.7%)	13 (20.9%)

CD, cardiac death; CVA, cerebrovascular accident; MACCE, major adverse cerebrovascular and cardiovascular events.

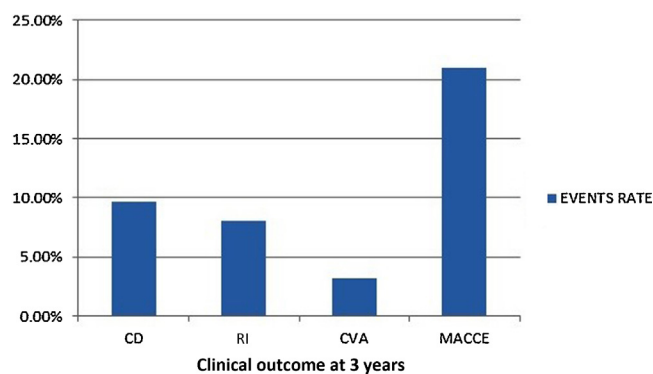


Fig. 1 – 3-Year clinical outcome in RI need for repeat intervention, CVA, cerebrovascular accident; MACCE, major adverse cerebrovascular and cardiovascular events.

Table 4 – Univariate and multivariate predictors of adverse outcome.

Variable	Univariate		Multivariate	
	HR (95% CI)	p value	HR (95% CI)	p value
Syntax score	11.5 (3.7–35.8)	0.001	9.3 (2.8–30.2)	0.001
Multiple stent	1.9 (1.1–3.2)	0.016	1.2 (0.4–4.0)	0.728
Multiple vessels	2.25 (1.1–4.6)	0.027	1.36 (0.3–6.3)	0.698

routine investigation. Only 5 (8%) patients were found to have in-lesion/in-segment restenosis or a significant new vessel disease. The other 6 (9.7%) patients were found to have no ISR or new disease on repeat angiography. One patient was found to be severely anemic while the rest 5 (8%) patients had treatment optimized and were asymptomatic on optimal medical therapy on further follow-up.

3.9. Event-free survival

Mean event-free survival was 2.46 years (2.2–2.7). Actuarial survival rate free of MACCE was 82.3%, 80%, and 76.7% at 1 year, 2 years, and 3 years, respectively (Fig. 2).

3.10. Predictors of MACCE

- (1) **Syntax score ≤ 32 vs syntax score > 32 (Fig. 3):** Patients with syntax score ≤ 32 had higher mean event-free survival [2.8 years (95% CI 2.6–3.0)] compared to patients with syntax score > 32 [1.1 years (95% CI 0.4–1.9), $p < 0.0001$]. Patients with lower score (≤ 32) had event-free survival rate of 87.1% at 3 years as compared to 3-year event-free survival rate of 33.3% in patients with syntax score ≥ 32 ($p < 0.0001$) (Fig. 3).
- (2) **Diabetics vs non-diabetic patients (Fig. 4):** Non-diabetic patients had a mean event-free survival comparable with diabetic patients [2.6 years (95% CI 2.34–2.9) vs 2.0 years (95% CI 1.4–2.6), $p = 0.073$]. In non-diabetic patients, 3-year event-free survival rate was 81% while in diabetic patients the respective survival rate was 62.5%, which was not statistically different (p value = 0.073).

- (3) **LM alone PCI vs LM plus additional vessels PCI:** Fig. 5 shows Kaplan–Meier curve of event-free survival in accordance with the different number of vessels intervened along with uLMPCI. Patients with PCI of LM alone had mean event-free survival of 2.7 years (95% CI 2.3–3.0), which is comparable to mean event-free survival in patients who underwent PCI of LM and additional one vessel PCI [2.5 years (95% CI 2.1–2.9), $p = 0.492$] while patients with LMPCI with additional 2 or more vessel PCI had lower mean event-free survival [1.9 years (95% CI 1.2–2.6), $p = 0.036$]. Patients with LMPCI alone had a 3-year event-free survival rate comparable to those who underwent PCI of additional one vessel (88.9% vs 88.1%, $p = 0.569$), which is superior to 3-year event-free survival rate of 40% ($p = 0.036$) in patients who underwent LMPCI along with additional 2 or more vessels PCI.

4. Discussion

The present study is a single-center experience of ULMCA PCI with drug-eluting stent (DES) from the Indian subcontinent. There was high technical success and procedural success rate with three in-hospital deaths. The main finding of this study is that uLMPCI is safe and effective treatment alternative to CABG in low- to moderate-risk anatomy patients (syntax score < 32). Patients' selection was done at the discretion of the primary operator having discussed the pros and cons in individual cases with the patients and in-house cardiac surgeon and according to patient preference for PCI relative to surgery.

4.1. In-hospital result and procedural complication

The procedural success rate was 98.4% in this study including patients who presented with acute coronary syndrome, which is comparable to other reports.⁷ Higher complete revascularization (85.5%) was achieved in our patients as compared to other studies.^{3,4,14} Average hospital stay (3.42 ± 1.98 days) was also short in our study in comparison to PCI arm of other studies,⁴ which may be attributed to higher rate of transradial procedure. At our center at least 50% of these LMPCI were done

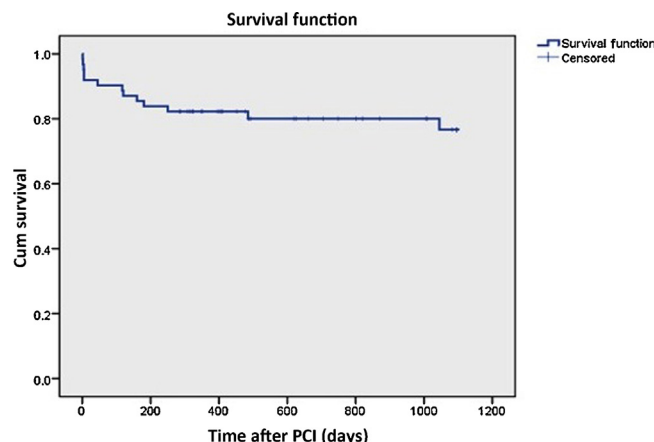


Fig. 2 – Kaplan–Meier estimates of Event-free survival in whole study population

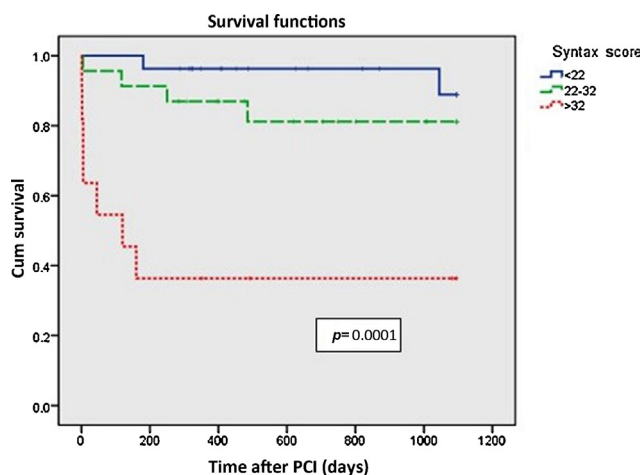


Fig. 3 – Kaplan–Meier estimates of Event-free survival in patient subgroups divided according to syntax score

transradially. Among the three in-hospital deaths, only one was attributable to procedural complication. All of these three patients had high-risk anatomy with syntax score of ≥ 32 and two were elderly (age ≥ 75 years), although one of them died of major GI bleed unrelated to these characteristics. No post-procedural myocardial infarction was documented. Post-procedure, there were three minor bleeds in the form of arm hematoma and a minor gum bleed, which were managed conservatively without any need for blood transfusion. Again radial site of access might contribute to lower rate of major bleeding complication.

4.2. 30-day outcome

Our series has overall MACCE rate of 5 (8%) at 30 days, which is slightly higher than PCI arm of LEMANS Study³ (4.8%) and as reported in PCI arm (4%) of study by Boudriot et al.⁵ This may be due to the fact that these RCTs had excluded highest risk patients and ours was a all-comers design. DELFT registry⁷ has higher (11.4%) event rate at 30 days as patients with emergent PCI had higher adverse events in that study. Although our study also included ACS patients but no emergent PCI was done and none of our patient were in cardiogenic shock. Only 2

(3.2%) patients were of acute ST elevation MI in ACS group and all were in Killip class I

4.3. 1-Year and 3-year clinical outcome

The one-year incidence of MACCE in our patients was 17.7%, which is comparable to PCI arm of SYNTAX trial⁴ and the study by Buodriot et al.⁵ and lower than DELFT⁷ registry and other studies.¹⁵ The 3-year rate of overall MACCE was 20.9% in our study, which was lower than other reported MACCE rates in some studies.^{4,7-9} The higher event rates in these multicentric studies could be driven by multiple operators with varying levels of expertise giving varied acute outcomes while ours was a single-center experience with largely a single-primary operator with procedural technique very much reproducible and a level of expertise, which may also be rather good if not best, which is bound to play a role in outcome of these cases, and which form a challenging subset within all PCIs. Further, higher event rate in these studies might also be explained by higher lesion complexity as compared to our population because our mean syntax score (22.05 ± 7.5) was lesser. Mean

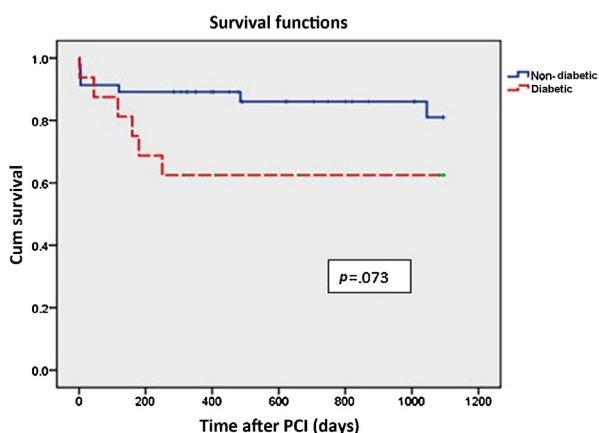


Fig. 4 – Kaplan–Meier estimates of Event-free survival in Diabetics vs non-diabetics

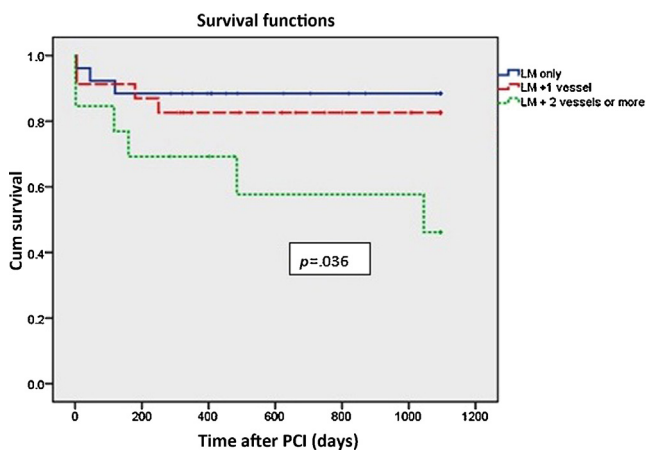


Fig. 5 – Kaplan–Meier estimates of Event-free survival in patients with different groups according to number of vessels involved

syntax scores in SYNTAX trial⁴ and Boudriot et al. study⁵ were 29.6 ± 13.5 and 23.5 , respectively.

Our study showed a three-year actuarial event-free survival rate of 76.7%, which is comparable to PCI arm of DELTA registry,⁷ study by Lee et al.,¹⁶ and the MAIN COMPARE study,⁹ but higher than DELFT⁷ registry (73.5%). A lower rate of RI may contribute to higher event-free survival rate in our study as compared to other reports. Again a fact that may be contributing to the better results might be a good case selection with lower mean syntax score. As such the syntax score stood as an independent predictor of adverse event on multivariate analysis in our study results. Moreover, all other data are from European or far eastern population and our study involves only the Indian population. There may be a racial and ethnic difference in tendency toward restenotic and thrombotic complications.

4.4. Comparison with CABG

Although evidence from recent RCTs has shown that uLMPPCI may provide at least equivalent results to CABG in less complex anatomy, practice guidelines still consider CABG as class I indication. In these studies, MACCE rate was higher in PCI arm as compared to CABG mainly due to a higher need for RI. In our study, RI rate was significantly lower than reported previously. Although overall three-year mean event-free survival was lower than that reported for CABG, it is similar (86%) to CABG¹⁷ in a patient with syntax score ≤ 32 . Therefore although our sample size is small, it shows a similar efficacy to CABG in low to intermediate complex anatomy and the results do reflect what best could be achieved in left main intervention.

5. Limitation

We do feel that our study has few limitations. First, it is a single-center experience with largely a single-primary operator, and second, there could be a selection bias in patient population. Third, it is an observational analysis with total number of patients being small, and lastly, the study group was heterogeneous with all types of LM patients being included.

5.1. Conclusion

We conclude that uLMPPCI is safe and effective treatment alternative to CABG in selected LM alone and LM plus single-vessel disease patients with syntax score ≤ 32 .

Conflicts of interest

The authors have none to declare.

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