

ORIGINAL ARTICLE

Four-year outcomes of unprotected left main lesion stenting in a Romanian high-volume PCI-center

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Abstract: **Background** – Coronary artery bypass surgery (CABG) has been considered the gold standard for the treatment of left main coronary artery disease, for many years. However, the development from last years in stent technology and the use of intravascular imaging to assess the results after percutaneous coronary interventions (PCIs) have rapidly increased the number of patients with unprotected left main coronary artery disease (ULMCAD) treated by PCI. The aim of the current study was to report the current practice of ULMCAD PCI in a Romanian high-volume PCI center and compare the results with those reported by other studies. **Methods and Results** – A total of 146 patients with ULMCAD treated by PCI were included, 52% presenting with acute coronary syndrome (ACS). Outcomes at 4 years were estimated using the Kaplan Meier method. Baseline SYNTAX II score for PCI was intermediate, at a median of 28.9. The early mortality rate was 8.2% with a 2% peri-procedural mortality. 4-year mortality, target lesion revascularization (TLR) and major adverse cardiac events (MACE) were 21.9%, 14% and 32.5%, respectively. The rates of in-stent thrombosis and in-stent restenosis at 4-year follow up were 2.74% and 11.1%, respectively. **Conclusions** – The early mortality rate in our study, which included an important number of patients presenting with ACS, was not significantly higher than in other studies with fewer ACS patients. The main difference with other studies was the higher in-stent thrombosis and in-stent restenosis rate. However, the rate of TLR and mortality at 4-year follow up was not significantly different than those previously reported by other studies. **Keywords:** percutaneous coronary intervention; left main coronary artery disease.

Rezumat: **Introducere** – Mulți ani, bypass-ul aorto-coronarian a fost considerat standardul de aur pentru tratamentul leziunilor de trunchi comun arteră coronară stângă. Progresele din ultimii ani în ceea ce privește tehnologia și platformele stenturilor, utilizarea imagisticii intravasculare pentru a evalua rezultatele după intervențiile coronariene percutanate (PCI) și experiența cardiologilor intervenționiști au crescut rapid numărul pacienților cu leziuni de trunchi comun neprotejat tratați prin PCI. Scopul studiului actual a fost de a vedea care este practica curentă în ceea ce privește angioplastia de trunchi comun neprotejat într-un centru de mare volum din România și compararea rezultatelor cu cele raportate de alte studii. **Metode și rezultate** – Au fost incluși în studiu 146 de pacienți cu leziune de trunchi comun neprotejat tratați prin PCI, dintre care 52% s-au prezentat cu sindrom coronarian acut. Rezultatele la 4-ani au fost estimate utilizând metoda Kaplan Meier. Valoarea scorului SYNTAX II pentru PCI a fost intermediară 28.9. Rata mortalității precoce a fost de 8,2%, cu o mortalitate peri-procedurală de 2%. Mortalitatea la 4 ani, revascularizarea leziunilor țintă și evenimentele cardiace adverse majore au fost de 21,9%, 14% și, respectiv, 32,5%. Ratele trombozei intra-stent și restenozei intra-stent au fost de 2,74%, respectiv de 11,1%. **Concluzii** – Rata mortalității precoce în studiul nostru, care a inclus un număr important de pacienți ce s-au prezentat cu sindrom coronarian acut, nu a fost semnificativ mai mare decât în alte studii cu mai puțini pacienți prezentați cu sindrom coronarian acut. Principala diferență cu alte studii a fost ratele trombozei intra-stent și a restenozei intra-stent mai mari. Cu toate acestea, rata revascularizării leziunii ținta și a mortalității la 4 ani nu a fost semnificativ diferită față de alte studii. **Cuvinte cheie:** intervenție coronariană percutană; leziune de trunchi comun.

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INTRODUCTION

Coronary artery bypass surgery (CABG) has been considered the best treatment option for left main coronary artery disease for a long time. However, the recent developments from past years in stent technology and the utilization of intravascular imaging to assess the results after percutaneous coronary interventions (PCIs) have led to a rapid increase in the number of patients with unprotected left main coronary artery disease (ULMCAD) treated by PCI¹. Many studies have excluded patients with acute coronary syndrome (ACS)^{2,3}. Therefore, there is a significant gap in knowledge regarding the treatment of patients with ULMCAD in a mixed, acute and elective patients. The aim of our study was to define the current practice of ULMCAD PCI in a Romanian high-volume PCI center and compare its outcomes with those reported by other studies, including the patients presented with ACS.

METHODS

Study Population

All patients with ULMCAD treated by PCI between January 2014 and December 2018 were reviewed from the electronic hospital records at the “Prof. Dr. C.C. Iliescu” Institute for Cardiovascular Diseases, Bucharest, Romania. Patients with a history of CABG and occluded grafts and patients presenting with ACS were included, also. Only patients with ULMCAD and complete data (discharge letter, angiography and angioplasty operation notes) were included. This resulted in a total of 146 patients for which demographic, clinical, angiographic, procedural, post-procedural and outcome data were extracted from the hospital electronic records. All patients were followed by in-hospital reevaluation. Data analysis was performed with the approval of the institutional ethics committees of the hospital involved.

Study Outcomes

MACEs were defined as the occurrence of death, myocardial infarction (MI) or target lesion revascularizations (TLRs). ACS was defined as either unstable angina, non-ST segment elevation MI (NSTEMI) or ST segment elevation MI (STEMI). The diagnosis of periprocedural MI was made when after PCI there was an increase in CK-MB or troponin levels that was 5 times the upper normal level. TLR was defined as repeated PCI for restenosis of the entire segment involving the implanted stent. Stent thrombosis was defined as acu-

te (0-24 hours), subacute (1-30 days), late (31-360 days), or very late (>360 days)⁴. Angiographic success was defined as residual stenosis of <30% by visual estimation in the presence of Thrombolysis in Myocardial Infarction (TIMI) flow grade 3. Complete revascularization was defined as any attempt to revascularize all diseased segments (≥ 2.5 mm in diameter).

Statistical Analysis

Frequencies are given as numbers and percentages, continuous values as median (inter-quartile range or minimum-maximum values). Early outcomes (mortality, stent thrombosis, need for intra-aortic balloon pump (IABP), access site complications) are based on known status at 30 days and presented as percentage. Late outcomes are estimated using the Kaplan Meyer method. Late outcomes of interest were mortality, TLR and MACE. Statistical analyses were done with STATA/SE 12.0 (StataCorp LP, College Station, TX).

RESULTS

A total of 146 patients undergoing unprotected left main PCI were included, age ranging from 33 to 86 years (mean of 62 years). Detailed demographic and baseline clinical characteristics and laboratory tests are presented in Table 1 and 2. The most prevalent cardiovascular risk factors were dyslipidemia (87%) and hypertension (84%). 40% of patients with ULMCAD had a history of ACS and 23% of previous non-left main PCI. The most frequent comorbidity was the chronic kidney disease, which was present in 77% of patients.

52% of patients with ULMCAD presented with ACS, 12.33% with STEMI and 8.2% with ACS complicated with cardiogenic shock (Figure 1). The association of coronary artery disease with heart failure was common (77% of patients). Most patients were on antianginal treatment (90.2%) at admission.

56% of patients had an abnormal electrocardiogram tracing at presentation. The mean left ventricular ejection fraction at diagnosis was 46%.

Angiographic characteristics

The mean Syntax Score was 21. The mean Syntax Score II for PCI and CABG were 28.9 and 31.5. The corresponding 4-year mortality estimate were 8.3% for PCI and 6.2% for CABG. The mean EuroSCORE II was 1.1%.

Table 3 shows the main angiographic findings of patients with ULMCAD. Coronary angiogram was done in more than two third of patients by femoral approach.

Table 1. Demographic and baseline clinical characteristics in patients with left main coronary artery disease treated by PCI

	Number	Percentage (%)
Gender		
Male	102	69.86
Female	44	30.14
Cardiovascular risk factors		
Hypertension	122	84.14
Dyslipidemia	126	86.9
Diabetes mellitus	42	28.97
Obesity	38	26.3
Active smoker	43	29.86
Past smoker	26	18.06
Family history of premature CAD	7	4.83
Comorbidities		
Peripheral artery diseases	25	17.24
Atrial Fibrillation / Flutter	19	13.1
Stroke/TIA	15	10.34
Gastrointestinal bleeding	5	3.45
COPD	2	1.38
CKD	11	7.708
Neoplasia	6	6.21
History of PCI/ACS		
Non-left main PCI	34	23.29
ACS	58	39.72
Unstable angina*	6	10.34
NSTEMI	16	27.59
STEMI		
*percentage of patients with a history of ACS	36	62.07
EKG stress test	18	12.41
Clinical presentation		
Asymptomatic	3	2.05
Stable angina	67	45.89
Unstable angina	30	20.55
NSTEMI	16	10.96
STEMI	18	12.33
ACS with cardiogenic shock	12	8.22
CCS Class (percentage of patients presented with stable angina)		
CCS I	2	2.99
CCS 2	27	40.3
CCS 3	31	46.27
CCS 4	7	10.45
Heart failure and NYHA class		
Without heart failure	23	23
NYHA I	5	5
NYHA II	60	60
NYHA III	11	11
NYHA IV	1	1
Antianginal therapy before admission	129	90.21
Electrocardiogram		
Sinus rhythm	131	91.61
Atrial Fibrillation / Flutter	12	8.39
Non-sustained ventricular tachycardia	1	0.7
Sustained ventricular tachycardia	2	1.4
Left bundle branch block	9	6.29
Right bundle branch block	11	7.69

ST-T changes	80	56.34
Type of ST-T changes		
Negative T waves	26	32.5
ST depression	18	22.5
ST elevation	36	45
ST elevation in aVR	13	9.15
Localization of ischemia		
Anterior wall	28	35
Inferior wall	3	3.75
Lateral wall	9	11.25
Antero-lateral wall	25	31.25
Infero-lateral wall	8	10
Anterior and inferior wall	7	8.75
Echocardiography		
Left ventricular systolic dysfunction		
Yes	70	48.61
Severity of left ventricular systolic dysfunction		
Mild	29	41.43
Moderate	25	35.71
Severe	16	22.86
Left ventricular diastolic dysfunction	120	88.89
Segmental wall motion abnormalities	96	67.13
Left ventricular aneurysm	9	6.29
Left ventricular thrombus	2	1.4
Left ventricular hypertrophy	45	30.1
Dilated cardiomyopathy	7	4.86
Mitral regurgitation	129	90.21
Severity of mitral regurgitation		
Mild	96	74.42
Moderate	22	17.05
Severe	11	8.53
Aortic regurgitation	42	29.37
Severity of aortic regurgitation		
Mild	35	83.33
Moderate	7	16.67
Severe	0	0
Severe aortic stenosis	3	2.1
Tricuspid regurgitation	90	62.5
Pulmonary hypertension	19	14.39

(CAD – coronary artery disease; COPD – chronic obstructive pulmonary disease; CKD – chronic kidney disease; ACS – acute coronary syndrome; NSTEMI – nonST segment elevation myocardial infarction; STEMI – ST segment elevation myocardial infarction; PCI – percutaneous coronary intervention)

76.7% of lesions involved the distal segment of left main (Figure 2). The left main lesions were associated with triple vessel disease in 9.59% of patients and a chronic total occlusion was present in 21% of patients. Approximately, one third of patients had complex left main lesions, calcified, ulcerated and diffuse lesions. According to Medina classification, the most prevalent lesions involved the ostium of left anterior descending artery (LAD) (27.4%) and the distal left main bifurcation (Medina 1/1/1 lesion) (25.2%).

Procedural characteristics

In 59 cases (40.4%) the PCI procedure was performed during the same session as the diagnostic coronary an-

Table 2. Demographic and laboratory characteristics in patients with left main coronary artery disease treated by PCI

	min	max	median	p25	p75	mean	sd
Age	33	86	63	55	71	62.43	11.83
LVEF before PCI (%)	10	67	50	35	57.5	46.23	13.2
Hb before PCI (g/dl)	8.6	17.2	13.55	12.3	14.7	13.45	1.74
CK-MB before PCI (mg/dl)	7	1265	22	17	50	81.77	178.58
Troponin before PCI (ng/ml)	0	50	0.3	0.03	2.93	6.11	14.34
CrCl before PCI (mL/min)	9.8	132.4	80.5	64.2	96.9	78.08	25.44

(min – minimum; max – maximum; sd – standard deviation; Hb – hemoglobin; LVEF – left ventricular ejection fraction; PCI – percutaneous coronary intervention; ACS – acute coronary syndrome; CrCl – creatinine clearance)

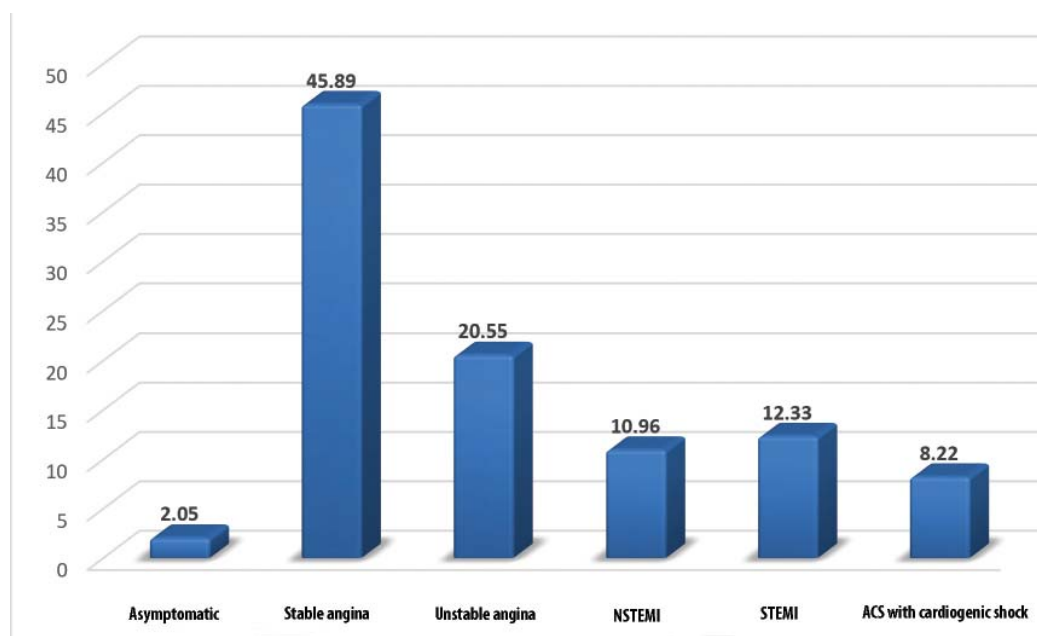


Figure 1. Clinical presentation of patients with unprotected left main coronary artery disease (percentage) (NSTEMI – nonST segment elevation myocardial infarction; STEMI – ST segment elevation myocardial infarction; ACS – acute coronary syndrome).

giogram. In the remaining cases the time between the two procedures ranged from 1 to 1068 days, with a median of 11 days. Six patients (4.1%) were on mechanical support system with intra-aortic balloon pump (IABP) prior to the PCI procedure. Femoral access was the preferred approach, in 89.7% of cases (Table 4).

A variety of stents and combinations were used. 42.47% of patients were treated using a self-apposing stent and the rest with a balloon-expandable stent. Rotational atherectomy was used in a minority of cases (2%).

59% of patients were treated using a single stent technique. The first three most used two stents technique were: T stenting and small protrusion (TAP) (35.1%), mini-crush (31.6%) and Culotte (22.8%). Pro-

ximal optimization technique (POT) was done in only 64.4% of patients and kissing balloon post-dilatation (KBPD) in 45.9% of cases.

Procedural success with TIMI 3 flow was achieved in 94.5% cases, with complete revascularization in 74.7% patients. Only 9% of patients had a more than 50% residual side branch stenosis. Instantaneous wave-free ratio (iFR) was performed before the PCI in 6 cases (4.1%) and after in 4 cases (2.7%). In 2 cases (1.37%) intravascular ultrasound (IVUS) was used before the procedure, while in 26 (17.8%) it was used after the procedure.

The mean left main diameter after PCI was smaller than the mean reference left main diameter before PCI. The same result was seen about left circumflex artery (LCX). The mean LAD diameter after PCI was

Table 3. Angiographic findings of patients with unprotected left main coronary artery disease treated by PCI

	Number	Percentage (%)
Arterial access site		
Radial	34	23.29
Femoral	112	76.71
Left main lesion localization		
Ostium	10	6.85
Mid segment	1	0.68
Distal segment	112	76.71
Ostium and distal segment	4	2.74
Whole length	19	13.01
Bifurcation	115	78.77
Trifurcation	31	21.23
Association with other lesions		
None	49	33.56
One vessel	44	30.14
Two vessels	39	26.71
Three vessels	14	9.59
Chronic total obstruction	48	32.88
LAD ostium diseased	31	21.23
LCX ostium diseased	95	65.07
LAD non-ostial lesion	60	41.1
LCX non-ostial lesion	64	43.84
RCA lesion	40	27.4
Left Main lesion characteristics		
Diffuse lesion	76	52.05
Eccentric lesion	107	73.29
Calcified lesion	43	29.45
Ulcerated lesion	36	25.7
Involvement of carina	9	6.16
Medina classification (in patients with distal left main lesions)		
1/1/1	34	25.2
1/0/0	23	17.1
1/1/0	16	11.8
1/0/1	6	6.7
0/1/0	37	27.4
0/1/1	10	7.4
0/0/1	6	4.4
Medina 1/1/1	34	25.75
Bifurcation angle (between LAD and LCX)		
≥90	12	10
70-89	48	40
45-69	21	17.5
<45	39	32.5

(LAD – left anterior descending artery; LCX – left circumflex artery; RCA – right coronary artery)

bigger than the mean reference LAD diameter before PCI (Figure 3).

Early outcomes

Peri- and post-procedural complications are summarized in Table 5. The most common peri-procedural complications were: bradyarrhythmia (6.85%), peri-procedural myocardial infarction (2.74%) and ventricular tachycardia or fibrillation (2.74%). Vascular

puncture site complications were present in 4.1% of cases, in the context of a high proportion of patients treated by a femoral approach.

There was an 8.2% early mortality (30 days mortality) (n=12), with a 2% peri-procedural mortality (n=3) (Table 6). Most deaths occurred in patients presenting with ACS (n=11) and mostly in patients complicated with cardiogenic shock (n=8). As such, early mortality in non-ACS patients was 1.4% with no peri-procedural deaths and early mortality in ACS patients was 14.47% with 3.95% peri-procedural mortality.

Three patients underwent an emergency angiographic reevaluation during the same hospitalization. In two cases an acute in stent thrombosis was found, while in the third case an acute LCX thrombosis was found, with permeable left main stent. All three patients had presented initially with MI and died during the same hospitalization.

Post-procedural IABP was used in 8 cases (n=5.5%), only in ACS patients, with 4 of them having IABP support prior to the PCI procedure. We found that in patients with cardiogenic shock at presentation pre-procedural IABP was not associated with decreased early mortality (60% vs 71%, p=0.6), but use of IABP for post-procedural support was associated with a decrease in early mortality (20% vs 100%, p=0.01).

Late outcomes

59% of patients had no angina after ULMCAD PCI on long-term follow up. In 29.8% of patients the coronary angiogram was repeated, routinely only in 11.2% of patients. The in-stent restenosis rate was 11.1% and the in-stent thrombosis rate was 2.74%. Only 0.68% of patient had a late in-stent thrombosis (Table 6).

The mortality, TLR and MACE rates at 1 years were 16.5%, 10.9%, 27.2% and at 4 years 21.9%, 14% and 32.5% overall (Figure 4). In non-ACS patients, the mortality, TLR and MACE rates at 4 years were 9.6%, 15% and 24.1% compared to 33.3%, 12.8% and 40.1% in ACS-patients.

DISCUSSIONS

Our study included an unselected population with ULMCAD PCI without considering the clinical presentation. Patients presenting with ACS and ULMCAD were not excluded. The aim of this study was to show the result of real-life practice of ULMCAD PCI in a Romanian high-volume PCI-center with experience in treating elective and urgent patients with complex LM lesions. The study included 146 patients with ULMCAD PCI of which 52% presented with ACS.

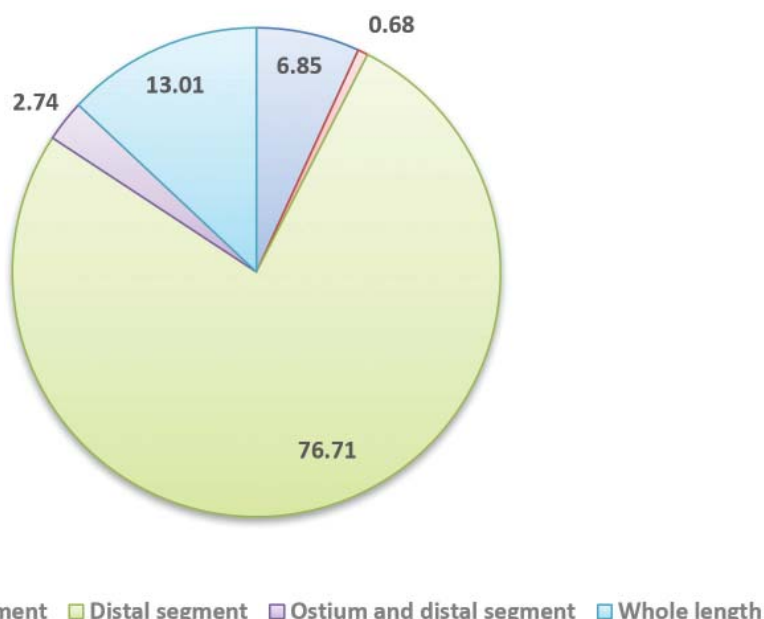


Figure 2. Localization of left main lesion (percentage).

Table 4. Procedural characteristics of patients with unprotected left main coronary artery disease treated by PCI

	Number	Percentage (%)
IABP before PCI	6	4.11
IABP after PCI	8	5.48
Arterial access site		
Radial	15	10.27
Femoral	131	89.73
Guiding catheter		
6 French	78	53.42
7 French	66	45.21
8 French	2	1.37
Rotational atherectomy	3	2.05
Self-apposing stents	62	42.47
Balloon expandable stents	84	47.53
PCI technique		
1 stent	86	58.9
2 stents	57	39.05
3 stents	3	2.05
Two stents technique		
Provisional T stenting	1	1.7
T stenting and small protrusion	20	35.1
Mini-crush	18	31.6
Double Kissing - Crush	3	5.3
Culotte	13	22.8
V-Stenting	2	3.5
First stented vessel		
LAD	92	68.15
LCX	41	30.37

Main vessel predilatation	111	78.72
Side branch predilatation	48	36.1
Predilatation at nominal diameter	45	36
Dissection after predilatation	28	23.4
POT	87	64.44
POT after stent implantation	68	50.37
POT after KBPD	38	28.15
KBPD	62	45.92
TKBPD	5	3.7
Stent underexpansion >30%	14	9.59
iFR before PCI	6	4.11
iFR after PCI	4	2.74
IVUS before PCI	2	1.37
IVUS after PCI	26	17.8
Stented undiseased ostial left main	18	13.33
Side branch residual stenosis	50	37.04
Severity of side branch residual stenosis		
None	83	62.4
<50%	38	28.6
>50%	12	9
Procedural success	138	94.52
Complete revascularization	109	74.65
TIMI Flow		
0	0	0
1	4	2.74
2	4	2.74
3	138	94.52

(PCI – percutaneous coronary intervention; IABP – intra-aortic balloon pump; LAD – left anterior descending artery; LCX – left circumflex artery; POT – proximal optimization technique; KBPD – kissing balloon post dilatation; TKBPD – triple kissing balloon post dilatation; iFR – instantaneous wave-free ratio; IVUS – intravascular ultrasound)

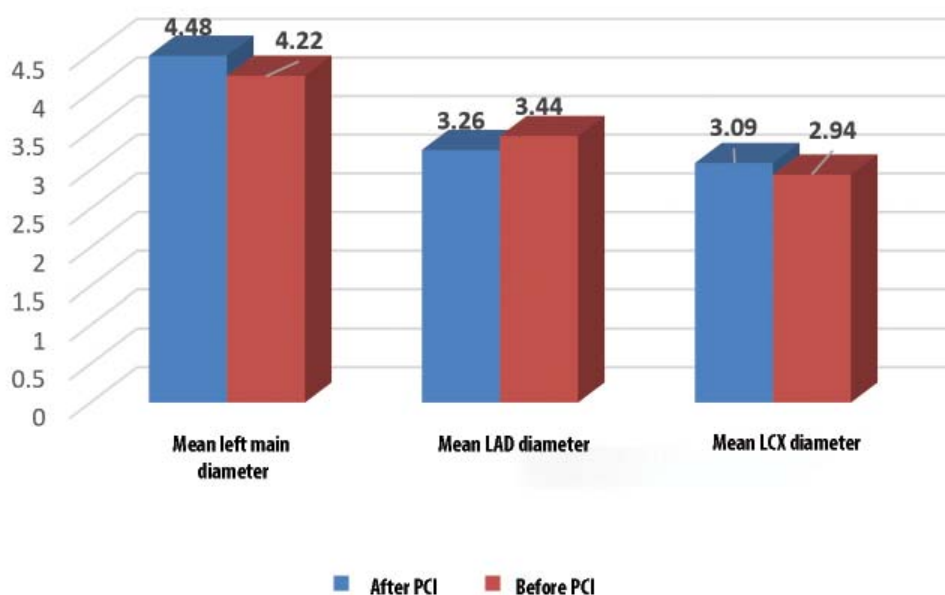


Figure 3. Mean left main, LAD and LCX diameters before and after PCI – mm (LAD – left anterior descending artery; LCX – left circumflex artery; PCI – percutaneous coronary intervention).

Although, mean Syntax score, that depends on the anatomical complexity of left main lesions, was 21, the study population included high risk patients considering that 8.2% of cases presented with ACS complicated with cardiogenic shock. Many patients (39.7%) had a history of ACS, also. The study population wasn't an elderly population considering the mean age was 62 years. The most prevalent comorbidity was chronic kidney disease (77%) followed by peripheral artery disease (17%).

Only half of patients had an abnormal EKG tracing. Although, even if we are referring to patients with

ULMCAD, only 9% of cases had ST segment elevation in aVR lead. 48% of patients had an abnormal LVEF, but the mean LVEF of study population was 46%.

Although, a lot of studies recommended the use of radial approach, especially in STEMI patients, both coronary angiogram and PCI were done using femoral approach (76% for coronary angiogram and 89% for PCI)^{5,6}.

Only 4.1% of patients received an IABP (the only available hemodynamic support system in our institution at that time), although 8.2% of patients were in cardiogenic shock at presentation. The use of IABP

Table 5. Peri- and post-procedural complications of patients with unprotected left main coronary artery disease treated by PCI

	Number	Percentage (%)
Hematoma	6	4.11
Pseudoaneurysm	2	1.37
Arteriovenous fistula	0	0
Stroke/TIA	1	0.68
Peri-procedural myocardial infarction	4	2.74
Post-procedural atrial fibrillation	2	1.37
Ventricular Fibrillation/ Ventricular Tachycardia	4	2.74
Bradycardia/ AV Block/ Asystole	10	6.85
Coronary dissection	1	0.68
Contrast induced nephropathy	14	15.05
Intra-procedural mortality	3	2.05
In hospital mortality*	12	8.22
*equivalent with the 30 days mortality		

(TIA – transient ischemic attack; PCI – percutaneous coronary intervention; AV block – atrio-ventricular block)

after the procedure was associated with a decrease in early mortality, but this result must be interpreted with caution due to the low number of patients.

One third of patients had complex left main lesions (calcified, ulcerated, diffuse lesions), 25% had a Medina 1/1/1 lesion, 21% had a chronic total occlusion and only 11 patients had an ostial or mid segment left main lesion. Given the complexity of left main lesions, only 58.9% of patients were treated with a one-stent strategy. The most common two-stent strategies were TAP (35.1%), mini-crush (31.6%) and culotte (22.8%). The use of two-stent strategy for ULMCAD PCI was significantly higher than in other studies⁷.

The use of POT and KBPD was low when compared to other studies^{7,8}. This can be explained by the high number of STEMI patients were the “keep it simple” principle is highly recommended. Another reason is the high number of patients treated with a self-apposing stent (42%). Although there is no clear recommendation, with self-apposing stents there is no need to perform routinely POT and KBPD, considering that the stents have the property to continue their expansion and appose to the vessel wall.

The use of intracoronary imaging was low (17.8%) considering that around 40% of patients were treated with a two-stent strategy. This can also be explained by the high number of patients with ACS, also.

The procedural success rate was 94.5% and complete revascularization was achieved in 74.6% of patients.

Although, our study has included the patients presented with ACS, the early mortality was similar to the EXCEL (*Evaluation of XIENCE Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization*) trial (8.2% in our study vs 8.1% in EXCEL trial)^{9,10}. The early mortality in our study is slightly higher when we compare with a recent american registry (8.2% vs 5%)¹¹.

The 4-year mortality rate and TLR were significantly higher than those in the NOBLE (*Nordic-Baltic-British left main revascularization*) trial at 5 year follow up (mortality and TLR rate in our study were 21.9% and 14%, respectively versus 12% and 16% in NOBLE trial)¹². When we excluded the patient presented with ACS, the long-term mortality and TLR rates were comparable in the two studies (mortality and TLR rate in our study were 9.6% and 15%, respectively versus 12% and 16% in NOBLE trial)¹². In EXCEL trial the 3-year TLR and mortality rates were 9.5% and 8.2%, respectively^{9,10}.

The rates of in-stent thrombosis and in-stent restenosis were 0.7% and 7.4%, respectively, in a recent

Table 6. Clinical follow up, early and late outcomes of patients with unprotected left main coronary artery disease treated by PCI

	Number	Percentage (%)
Angina relief		
None	2	2.74
Partial	28	38.36
Yes	43	58.9
Dyspnea relief	32	57.14
Myocardial infarction	1	0.74
Bleeding	2	1.49
Coronary angiogram reevaluation	40	29.85
Routine coronary angiogram reevaluation	15	11.19
Increase of LVEF with >5%	11	16.92
Mitral regurgitation reduction	1	1.54
In-stent intimal hyperplasia	11	27.5
In-stent restenosis	15	11.19
Target lesion revascularization	11	11.19
Target vessel revascularization	9	6.72
Non-target vessel revascularization	6	4.48
PCI for in-stent restenosis	11	8.21
Type of PCI for in-stent restenosis		
Noncompliant balloon dilatation	2	
Drug eluting balloon dilatation	8	
Different DES implantation	1	
DAPT modification for restenosis	2	13.33
In-stent thrombosis	4	2.74
Acute in-stent thrombosis	3	2.05
Subacute in-stent thrombosis	0	0
Late in-stent thrombosis	1	0.68
Very late in-stent thrombosis	0	0
Intra-procedural mortality		2.05
In hospital mortality		8.22
Mortality at 1 year follow up	16.5	(11.4;23.6)
Mortality rate at 4 year follow up	21.9	(15.8;29.9)
TLR at 1 year follow up	10.9	(6.2;18.6)
TLR at 4 year follow up	14	(8.3;23.1)
MACE at 1 year follow up	27.2	(20.3;35.8)
MACE at 4 year follow up	32.5	(24.6;42.1)

(LVEF – left ventricular ejection fraction; PCI – percutaneous coronary intervention; DES – drug eluting stent; DAPT – dual antiplatelet therapy; TLR – target lesion revascularization; MACE – major adverse cardiac events)

American registry and 2.74% and 11.1% in our study¹¹. In the EXCEL trial the in-stent thrombosis was 1.3%^{9,10}.

The 4-year mortality after PCI estimated by the SYNTAX score II was 8.3% that is similar with the 4-year mortality of 9.64% from our study.

STUDY LIMITATIONS

Although it might have offered more data on restenosis, routine angiographic reevaluation is no longer recommended and was not performed. The small num-

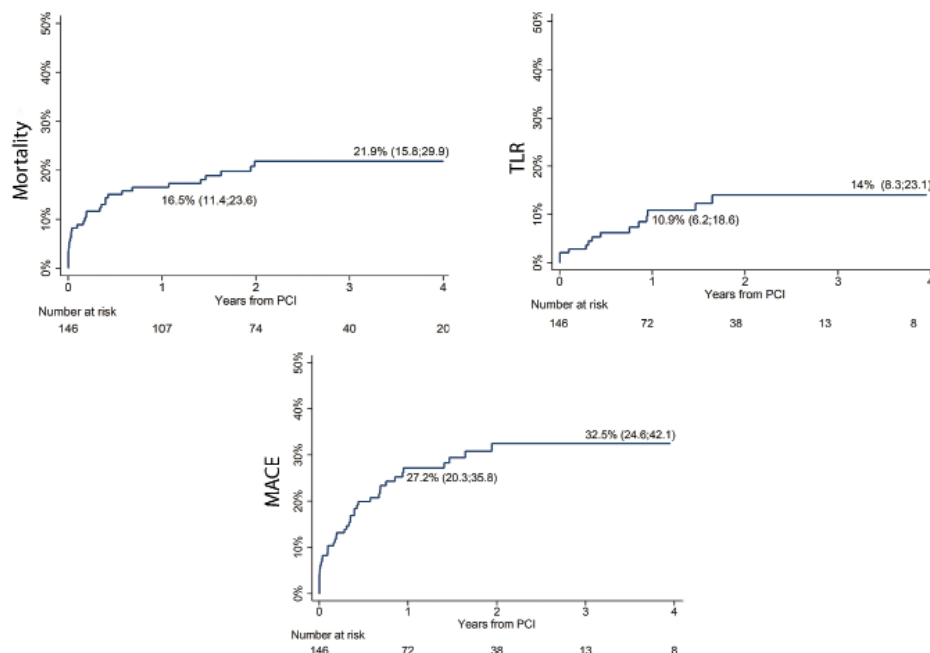


Figure 4. Mortality, TLR and MACE rates at 4-year of patients with unprotected left main coronary artery disease treated by PCI - Curves represent Kaplan-Meier failure function (TLR – target lesion revascularization; MACE – major adverse cardiac events; PCI – percutaneous coronary intervention).

ber of early events prevented multivariable analyses, so the results are subject to confounding. The use of various types of stents introduces a degree of heterogeneity.

CONCLUSIONS

Although, our study included patients presented with ACS, the early mortality rate was not significantly higher than in other studies, that included less ACS patients. The main difference with other studies was the higher in-stent thrombosis and in-stent restenosis rate. However, the rates of TLR and death weren't significantly different of other studies.

Conflict of interest: none declared.

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