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ORIGINAL ARTICLE

Value of Intravascular Ultrasound Guidance in Patients Undergoing Unprotected Left Main Coronary Artery Stenting

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Abstract

Background: **Intravascular ultrasound (IVUS) is a new imaging technique that facilitates the process of coronary intervention. Significance of the angiographic evaluation of left main lesions is always questionable; IVUS detects the significance, guides the procedure, and some studies prove a benefit in mortality.**

Aim of the work: **We aimed to determine if intravascular ultrasonography (IVUS)-guided left main coronary intervention may enhance clinical results compared with angiographic-guided left main coronary PCI.**

Patients and methods: **In all, 60 patients who were eligible for left main coronary intervention were split into two groups for this controlled trial between 2021 and 2022 at the Maadi Military Hospital and the Cardiology Department of the Faculty of Medicine at Al-Azhar University: the IVUS-guided group (n-30) and the angiographic-guided group (n-30). The key composite end goal was the frequency of major adverse cardiac events (MACE): As the main composite end goal, records of 6 months of follow-up of (stent thrombosis, target lesion revascularizations, myocardial infarction, or death) were made.**

Results: **We found that the rate of MACE at 6 months was less in the IVUS-guided group than in the control group. Compared with the control group, the IVUS-guided group had a decreased frequency of the main composite end outcome (death, reMI, TLR, and stent thrombosis). (one case in the IVUS group (3.3%) and 10 cases in the angiography group (33.3%) (*P* value 0.003).**

Conclusion: **The present study concluded that IVUS-guided LM intervention can improve MACE events as a primary composite end point (death, reMI, TLR, and stent thrombosis) at 6 months follow-up.**

Keywords: Intravascular ultrasound, Unprotected left main coronary artery stenting, Coronary

1. Introduction

The standard revascularization method for individuals with unprotected left main coronary artery (LMCA) illness has been coronary artery bypass surgery (CABG). But studies demonstrating equivalent results to CABG have led to an increase in percutaneous coronary intervention (PCI) use in LMCA illness.[1]

There have been efforts to identify intravascular ultrasound (IVUS) parameters that correspond to the functional and clinical results due to difficulties in the assessment of the degree of left main stenosis.[2]

As a symptom of substantial LMCA stenosis, the IVUS-derived minimum lumen area (MLA) has often been utilized as a marker. To assess stent placement, lower the risk of significant adverse cardiac events (MACE), and target vessel revascularization (TVR), intravascular coronary ultrasonography[3] is used.

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IVUS guidance has been clinically beneficial in many observational trials on LMCA PCI, and currently, international regulations propose class 2 A for it.[4]

It has been suggested to use IVUS-guided left main (LM) therapies to enhance procedural outcomes in the hope that this would lead to better short- and long-term clinical outcomes.[5]

2. Study aim

The aim of this work is to test if the use of IVUS in patients undergoing unprotected LMCA stenting is associated with better outcome compared with angiography alone.

3. Patients and methods

3.1. Patient population

This is a prospective study conducted on 60 patients with significant unprotected LMCA stenosis: 30 cases in the IVUS-guided PCI group) and 30 cases in the angiographic-guided PCI group). And all patients were followed up for 6 months for acute coronary syndrome or hospital admission for cardiac causes. It was conducted in the Cardiology Department at Maadi Military Hospital and Cardiology Department, Faculty of Medicine, Al-Azhar University. The study was conducted from 2021 to 2022.

3.2. Inclusion criteria

Patients planned for elective PCI and stent implantation with significant unprotected LMCA.

3.3. Exclusion criteria

In the catheterization laboratory, patients with problems or predicted fatalities, coronary artery anomalies, patients refused to participate in the study, sever hepatic dysfunction (3 times normal reference values), any contraindications to coronary angiography, and contraindication to aspirin and clopidogrel.

3.4. Methodology

All patients were subjected to.

Full medical history including demographic data, full clinical examination, local cardiac examination, and a 12-lead resting surface ECG. Full labs including CBC, Troponin I, urea, serum creatinine, coagulation profile, RBS. lipid profile, and Hba1c) and transthoracic echocardiography.

Coronary angiography: Coronary angiography was performed through the femoral approach or radial approach according to the current PCI guidelines. Two impartial, skilled interventional cardiologists who are blinded to the patient features read the coronary angiograms.

After coronary angiography, patients with no exclusion criteria and eligible to LM PCI were split into two groups; in **the first group (30 patients)**, the IVUS-guided group, the stenting method was chosen in accordance with both the angiographic and IVUS findings and **the second group (30 patients),** is the angiography-guided group. Only angiographic findings were used to choose the stenting technique.

3.5. IVUS image interpretation

3.5.1. Grayscale imaging

Grayscale IVUS makes use of tiny crystals to provide very detailed cross-sectional pictures of the vessel lumen and the wall. Both cross-sectional pictures and longitudinal mode images are available in IVUS display modes. The vessel looks to be made of three layers. The narrow white band close to the lumen is the intima. Media makes up the core layer, while adventitia makes up the outer layer[6] (Fig. 1).

3.6. Basic IVUS measurements

The optimal stent size was determined using IVUS to measure the reference vessel size as the LM stem is often bigger than it looks angiographically.

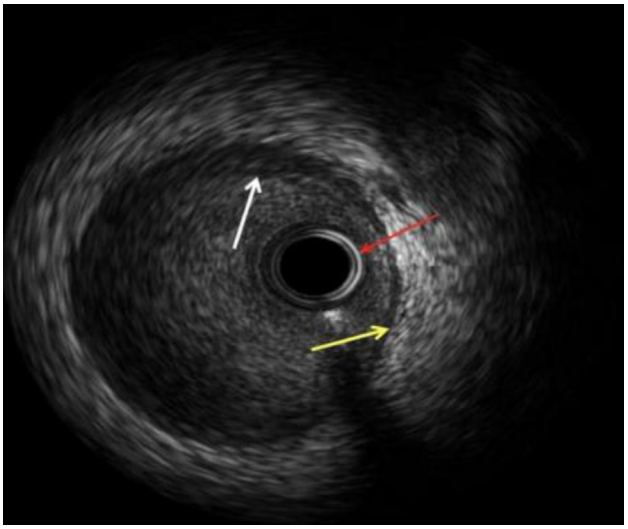

Fig. 1. Three layers are detected by IVUS in a normal IVUS appearance: Intima is shown by the white arrow, while the yellow arrow emphasizes the exterior elastic membrane that serves as the contact between the media and the adventitia. The IVUS catheter may be seen via the red arrow.[7]

Based on the distal reference's lumen diameter, the stent's diameter was estimated (media diameter to lumen diameter ratio of 0.8 or 1:1). The length of the stents was determined by IVUS by identifying the landing zone with no or less than 50% plaque load. Minimal lumen diameter (MLD), MLA, and plaque burden are the most frequently utilized IVUS metrics. A lumen size 90% larger than the typical reference lumen area before the intervention was considered a successful stent expansion.[8]

3.7. Follow-up

Clinical follow-up was conducted on all patients in the two groups on monthly basis for 6 months following hospital release careful inquiry about symptoms and events or hospital admission due to any cause were done, full clinical examination and 12-lead ECG, echocardiography and routine lab investigations were done to detect any MACE events.

3.8. Statistical analysis

SPSS (Statistical Package for the Social Sciences) version 26 was used for data analysis. Means, standard deviations, medians, and ranges were used to characterize numerical variables. When necessary, categorical factors were compared using the chi-square test and the Fisher's exact test, and they were described using their absolute frequencies. To validate presumptions for use in parametric tests, Kolmogorov-Smirnov (distribution-type) and Levene (the uniformity of variations) tests were utilized. Quantitative continuous data from two groups were compared utilizing the Mann− Whitney test (for data that are not distributed normally) and independent sample *t*-test (for data that are distributed normally). $P < 0.05$ was used as the statistical significance threshold. If $p \leq 0.001$, a very substantial variation was detected.

4. Results

Table 1.

Table 1. Comparison of the researched groups' demographic information.

Parameter	Groups		Test	
	IVUS-guided group	Angiographic-guided group		
	$N = 30$ (%)	$N = 30$ (%)	χ^2/t	*P*
Sex:				
Female	19 (63.3%)	19 (63.3%)	0	>0.999
Male	11 (36.7%)	11 (36.7%)		
Age (year)	64.47 ± 7.0	63.27 ± 8.61	0.592	0.556

χ^2 Chi square *t*-test independent sample *t*-test.

Table 2. Clinical data comparison between the study groups.

Parameter	Groups		Test	
	IVUS-guided group		Angiographic-guided group	
	$N = 30$ (%)	$N = 30$ (%)	χ^2	*P*
Diabetes	23 (76.7%)	19 (63.3%)	1.27	0.26
Hypertension	20 (66.7%)	23 (76.7%)	0.739	0.39
Hyperlipidemia	27 (90%)	23 (76.7%)	1.92	0.166
Smoking	17 (56.7%)	13 (43.3%)	1.067	0.302
Family history	15 (50%)	13 (43.3%)	0.268	0.605
Dialysis	1 (3.3%)	3 (6.7%)	Fisher	>0.999

χ^2 Chi square test.

Table 3. Comparison of the angiographic data between the groups under study.

Parameter	Groups		Test	
	IVUS-guided group		Angiographic-guided group	
	$N = 30$ (%)	$N = 30$ (%)	χ^2	*P*
Pre-dilatation	30 (100%)	24 (80%)	Fisher	0.024[a]
Post-dilatation	30 (100%)	22 (73.3%)	19.048	0.005[a]
	Mean ± SD	Mean ± SD	T	*P*
NC balloon diameter	4.55 ± 0.36	4.18 ± 0.36	3.689	0.001[b]

t independent sample *t*-test.
[a] $P < 0.05$ is statistically substantial t.
[b] $P \leq 0.001$ is statistically greatly substantial.

Age and Sex differences between the examined groups are statistically insignificant (Table 2).

Comparing the study groups in terms of concomitant diabetes, hypertension, dyslipidemia, smoking, family history, or requirement for dialysis is statistically insignificant (Table 3).

On studying angiographic data of the studied patients, all patients within the IVUS-guided group underwent pre-dilatation versus 80% of angiographic-guided group with statistically significant

Table 4. Comparison of the major composite end goal (death, reMI, TLR, and stent thrombosis) at 6 months between the study groups.

Parameter	Groups		Test	
	IVUS-guided group	Angiographic-guided group		
	$N = 30$ (%)	$N = 30$ (%)	χ^2	*P*
Absent	29 (96.7%)	20 (66.7%)	9.017	0.003
Present	1 (3.3%)	10 (33.3%)		

Table 5. Comparison of stent sizes between the groups under study.

Parameter	Groups		Test	
	IVUS-guided group		Angiographic-guided group	
	Mean ± SD	Mean ± SD	t	*P*
Size (mm^3)	4.48 ± 0.37	3.98 ± 0.26	6.04	0.001**

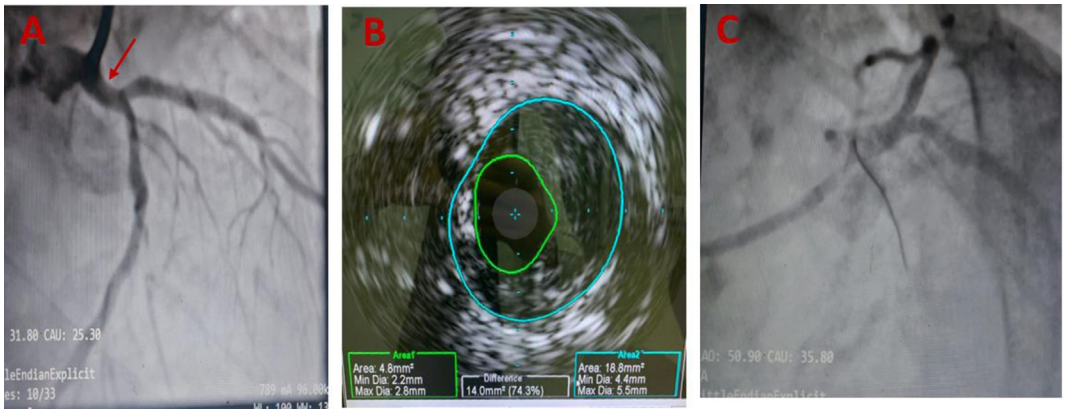

Fig. 2. A case of IVUS role to determine the significance of borderline LM lesion: (A) Caudal view showing nonsignificant LM lesion distally, (B) IVUS measured MLA about 4.8 mm^2, and (C) the final result.

difference. All patients within the IVUS-guided group underwent pre-dilatation versus 73.3% of angiographic-guided group with statistically significant difference. On comparing the diameter of NC balloons in patients who need post-dilatation between both groups, the IVUS-guided group had the higher largest diameter (Table 4).

Between the analyzed groups, there is a statistically substantial variation in the major composite end point at 6 months (3.3% and 33.3% within the IVUS-guided and angiographic-guided groups, respectively) (Table 5).

Regarding stent size, there is a considerable variation between the analyzed groups (markedly greater in the IVUS-guided group).

Selected cases from the study that explain these results: from the IVUS group many cases explain how IVUS change the operator decision that can improve outcome.

Case (30).

The patient has angiographically borderline LM lesion that can be easily missed and left untreated but IVUS declared the significance by measuring MLA of 4.8 mm^2 (Fig. 2).

5. Discussion

In contrast to coronary angiography, IVUS offers useful anatomic details as regards the coronary artery lumen, wall, and plaques.[9]

The IVUS specified the following criteria for the ideal stent deployment: (1) 90% of the MLA at the distal reference segments or >5.0 mm^2 is present in the stented segment; (2) plaque load is 50% or less 5 mm proximally or distally from the stent edge; and (3) media longer than 3 mm do not require edge dissection at all.[10]

In our study, we studied the short-term clinical outcome represented in the incidence of MACE events as regards primary composite end point (death, reMI, TLR, and stent thrombosis) at 6 months follow-up and value about the strategy of treatment, proper stent sizing in patients who received IVUS guidance during PCI comparing them to another group treated with conventional coronary intervention with no-IVUS use.

De la Torre et al. in 2015 conducted a patient-level pooling analysis using data from four registers of patients with LM illness managed with DES in Spain, including two from single facilities (Bellvitge and Valdecilla) and two from statewide registers (RENACIMIENTO [Registro Nacional Sobre el Tratamiento del TroncoComu n] and ESTROFA-Left Main).[11]

In all, 505 individuals (30.2%) received DES implantation under IVUS supervision out of a total of 1670 patients (the IVUS group). They were chosen using the matching approach who would not have revascularization while using the IVUS (no-IVUS group). At 3 years, the IVUS group had a 3-year survival rate of 88.7%, compared with the no-IVUS group's (83.6%, for the general population. For the subgroups with distal LM lesions, the survival rates were 90% and 80.7%, respectively ($P = 0.03$). In the IVUS group, the frequency of both certain and likely thrombosis was much reduced. This study matches our results regarding all primary end points in mortality, myocardial infarction, benefits and reduction of TLR in the IVUS group.[11]

The Tan et al. study, 2012 on 123 elder patients (age >70) with ULMCA, 61 were randomly allocated to the IVUS-guided group and 62 to the control group, who had normal angiography as the intervention.[12]

In the IVUS-guided group, there were fewer cases of 2-year MACE than in the control group (13.1% vs.29.3%, $P = 0.031$). Target lesion revascularization was less common (9.1% vs. 24%) in the IVUS-guided group than in the control group, and these findings were consistent with our study. However, there

were no changes in the rates of fatality and myocardial infarction between the two groups, and these findings do not line up with those of our research in regard to deaths and MI.[12]

For SCAAR (The Swedish Registry for Coronary Angiography and Angioplasty). 621 patients (25.2%) out of 2468 unprotected LMCA PCI patients between 2005 and 2014 utilized IVUS guidance. The IVUS group had more complicated lesions but was younger (median age, 70 vs 75 years) and had less adverse effects. The stent sizes were greater when IVUS was used (median, 4 mm versus 3.5 mm). The major composite end goal of all-cause mortality, restenosis, or definitive stent thrombosis was substantially related with considerably reduced incidence when possible confounders were taken into account, and these findings were consistent with those of our research.[1]

The Adapt-DES study showed that IVUS guidance is particularly useful in complex PCIs including the LM disease subgroup and the MACE event rate is less in the LM-IVUS-guided group 5.6% vs 10.2% (P value = 0.15).[4]

The ultimate trial which was published in December 2018 was discussing the question 'Is IVUS beneficial even in the outcome of simple lesions?' It is a multicenter, prospective, randomized research that compares the efficacy and safety of implanting second-generation DES with IVUS guidance vs angiography guidance in all-comer patients with coronary artery illness, regardless of the kind of lesions present.[10]

Our analysis agrees with the findings of the ULTMATE trial, which showed that target vessel failure was significantly reduced when PCI operations were guided by IVUS. However, our study does not agree with the results of the ULTMATE trial when comparing cardiac mortality between the two groups. On prespecified subgroup evaluation, individuals with ACS or multivessel disorders may be more likely to gain from IVUS guidance, even if the research shows advantages for all patients from IVUS guidance.[10]

IVUS MLA <6 mm^2 is the best anatomical parameter of LM stenosis significance that correlates functionally with FFR <0.80. We propose in our study that A safe and suitable threshold for delaying LMCA revascularization is an MLA of more than 6 mm^2.

The best IVUS parameter that correlated best with hemodynamically significance of LM lesions as correlated with FFR measures was MLA <5.9 (sensitivity, 93%, specificity, 95%). These are the figures used in EXCEL trial, The LITRO trial, a prospective multicenter study with 354 patients, provided clinical validation for the 6 mm^2 cutoff value.[13]

In the case of LM disease, functional assessment can be substituted with anatomical imaging by IVUS, as there are different studies that have demonstrated a strong correlation between lumen area and functional significance of LM stenosis. The capacity to gather crucial morphologic data, such as a description of the degree and breadth of the illness, using IVUS over FFR for LMCA assessment is a significant benefit.[14]

Jacek Legutko et al. (2012) revealed that an MLA of less than 5,9 mm^2 correlate with FFR<0.75 in LM coronary disease. In another prospective clinical trial applied on 354 patients, Dela Torre Hernandez et al., in 2011 revealed that an MLA of less than 6 mm^2 suggests substantial LMCA stenosis.[11]

In comparison with Asian population, Kang et al., 2011[14] and Park et al. in 2014[15] concluded that there is a small variation for the LMCA MLA cutoff of roughly 6 mm^2 as an IVUS- based MLA <4.5 mm^2 in Park et al.'s research and an IVUS- based MLA <4.8 mm (2) in Kang et al.'s study are effective criteria for predicting FFR <0.80 in isolated LM illness. To create a unique, case-based choice, additional considerations must be taken into account. IVUS seems to be helpful in evaluating lesions that are seen in the LMCA.[12]

According to the meta-analysis, delaying revascularization in individuals with unclear LMCA disease is safe in regard to overall fatality and future myocardial infarctions. In 2015, Mallidi et al. conducted 525 patient prospective cohort studies and came to the conclusion that there is no statistically substantial distinction between the groups' rates of the primary end point, which includes rates of total mortality and subsequent myocardial infarctions, when revascularization is delayed for patients with unclear LMCA stenosis depending on FFR and that these patients' long-term clinical results are favorable and comparable to those of the revascularized group (41%).[16]

5.1. Conclusion

The present study concluded that IVUS-guided LM intervention can improve MACE events as a primary composite end point (death, reMI, TLR, and stent thrombosis) at 6 months follow-up.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article.

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Conflicts of interest

The authors declared that there were no conflicts of interest.

References

1. Andell P, Karlsson S, Mohammad MA, et al. Intravascular ultrasound guidance is associated with better ocome in patients undergoing unprotected left main coronary artery stenting compared with angiography guidance alone. *Cire Cardiovasc Interv*. 2017;10:5.
2. Leesar MA, Mintz GS. Intravascular ultrasound assessment of an ambiguous left main coronary artery stenosis. *Cathet Cardiovasc Interv*. 2007;70:721–730.
3. Steinvil A, Zhang Y-J, Lee SY, et al. Intravascular ultrasound-guided drug-eluting stent implantation: an updated meta-analysis of randomized control trials and observational studies. *Int J Cardiol*. 2016;216:133–139.
4. Witzenbichler B, Machara A, Weisz G, et al. Relationship between intravascular ultrasound guidance and clinical outcomes after drug-eluting stents. *Circulation*. 2014;129:463–470.
5. Maehara A, Mintz GS, Witzenbichler B, et al. Relationship between intravascular ultrasound guidance and clinical outcomes after drug-eluting stents: two-year follow-up of the ADAPT-DES study. *Circ: Cardiovasc Interv*. 2018;11:e006243.
6. Honda S, Kataoka Y, Kanaya T, et al. Characterization of coronary atherosclerosis by intravascular imaging modalities. *Cardiovasc Diagn Ther*. 2016;6:368–381.
7. Layland M, Jamie M, Vivek B. The invasive assessment of coronary atherosclerosis and stents using optical coherence tomography: a clinical update. *Heart Asia*. 2013;5:154–161.
8. Mintz GS, Nissen SE, Anderson WD, et al. American college of Cardiology clinical expert consensus document on standards for acquisition, measurement and reporting of intravascular ultrasound studies (IVUS). A report of the American college of Cardiology task force on clinical expert consensus documents. *J Am Coll Cardiol*. 2001;37:1478–1492.
9. Choi S-Y, Maehara A, Cristea E, et al. Usefulness of stent cross sectional area a predictor of angiographic restenosis after primary percutaneous coronary intervention in acute myocardial infarction (from the HORIZONS-AMI Trial IVUS Substudy). *Am J Cardiol*. 2012;109:455–460.
10. Zhang J, Gao X, Kan J, et al. Intravascula ultrasound versus angiography-guided stent implantation. *J Am Coll Cardiol*. 2018;72:3126–3137.
11. De la Torre Hernandez JM, Garcia Camarero T. Intravascular ultrasound for the diagnosis and treatment of left main coronary artery disease. *Interv Cardiol Clin*. 2015;4:361–381.
12. Tan Q, Wang Q, Liu D, et al. Ultrasound-guided unprotected left main coronary artery stenting in elderly. *Saudi Med J*. 2015; 36:549–553.
13. Kassimis G, de Maria GL, Patel N, et al. Assessing the left main stem in the cardiac catheterization laboratory. What is "significant"? Function, imaging or both? *Cardiovasc Revascularization Med*. 2018;19(1 Pt A):51–56.
14. Kang S-J, Mintz GS, Park D-W, et al. Mechanisms of in-stent restenosis after drug-eluting stent implantation. *Circ Cardiovasc Interv*. 2011;4:9–14.
15. Park S-J, Kim Park D-W, Yun S-C, et al. Randomized trial of stents versus bypass surgery for left main coronary artery disease. *N Engl J Med*. 2014;364:1718–1727.
16. Mallidi J, Atreya AR, Cook J, et al. Long-term outcomes following fractional flow reserve-guided treatment of angiographically ambiguous left main coronary artery disease: a meta-analysis of prospective cohort studies. *Cathet Cardiovasc Interv*. 2015;86:12–18.