

Procedural and Clinical Outcomes of IVUS Guided Intervention for Complex Coronary Lesions

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Abstract

Background: Intravascular Ultrasound (IVUS) allows qualitative and quantitative analysis of coronary atherosclerosis. Percutaneous coronary intervention (PCI) of complex lesions (i.e. American College of Cardiology/American Heart Association class type C) remains challenging. The use of IVUS to guide PCI of complex lesions might improve procedural and clinical outcomes.

Objectives: To compare IVUS and angiography-guided Intervention for complex lesions regarding procedural and clinical outcomes.

Patients and Methods: Our study was conducted on patients undergoing elective PCI for complex coronary lesions in Ain Shams University hospitals. The study included 100 patients who were assigned into IVUS guidance PCI or angiographic only guidance PCI for type C lesions according to the operator discretion. Major adverse cardiovascular events (MACE), a composite end-point of all-cause mortality, myocardial infarction and target lesion revascularization (TLR), were compared between the 2 groups. Mean follow-up duration was 12 months.

Results: After propensity score matching, baseline and angiographic characteristics were similar in IVUS and angiography-guided groups. Adding IVUS to the procedure lengthened the procedure time (37.40 ± 19.46 vs. 28.64 ± 10.71 min, $p = 0.006$). However, lower amount of radiographic contrast was required in the IVUS guided group during the procedure (161.40 ± 53.11 vs 194.00 ± 94.03 ml, $p = 0.035$). Patients with IVUS-guided PCI underwent more direct stenting, more post-dilatation with a final larger maximal stent diameter and greater number of implanted stents. The final diameter stenosis was significantly smaller in IVUS guided group (3.84 ± 3.25 vs. $10.39 \pm 8.09\%$, $p = 0.000$). However, IVUS guided intervention did not improve the 1-year MACE rates (6 vs. 10%, $p = 0.461$).

Conclusion: Use of intravascular ultrasound (IVUS) in complex lesions allows proper assessment of minimal lumen area, optimizing PCI procedure and confirming stent well apposition with a smaller final diameter stenosis.

Keywords: Intravascular Ultrasound (IVUS); Major Adverse Cardiovascular Events (MACE); Target Lesion Revascularization (TLR); Percutaneous Coronary Intervention (PCI)

Introduction

The intravascular ultrasound (IVUS) allows the dynamic acquisition of tomographic imaging of the vascular lumen and wall, being considered one of the best invasive imaging methods for qualitative and quantitative analysis of characteristics of coronary atherosclerosis [1].

In theory, the use of IVUS could improve the long-term results of angioplasty with stent implantation. This theory is based on three factors: exclusion of any significant residual stenosis or that artery dissection, confirmation of stent expansion and visualization of an optimal luminal gain [2].

PCI remains challenging for high-risk patient groups, especially those with complex coronary lesions, and their outcomes are often not satisfactory [3-5]. IVUS guidance of stent implantation may result in more effective stent expansion as compared to angiographic guidance alone [6]. Thus, IVUS guidance might improve short- and long-term outcomes of patients undergoing stent implantation. However, previous trials comparing IVUS guidance to angiographic guidance alone have provided conflicting results. Importantly, these studies have examined the results in unselected populations or have reported on predominantly noncomplex target lesions [7-9]. Thus, it can be argued that the impact of IVUS use on the outcome of patients with complex lesions in which the efficacy of IVUS-guided stent placement might be most effective has not been well studied.

An American College of Cardiology/American Heart Association (ACC/AHA) classification was used to differentiate between the complexities of the target lesions for PCI. Class C lesions are considered to have the highest degree of lesion complexity [10].

Patients and Methods

The study was conducted on patients undergoing elective PCI for type C coronary lesions in Ain Shams University hospitals. The study included 50 patients who underwent IVUS guided PCI for type C lesions and 50 patients who underwent only angiographic guided PCI for type C lesions for a period of 1-year starting from August 2014.

ACC/AHA classification was applied to differentiate between the complexities of the target lesions for PCI. Type C lesions included in the study were: diffuse (more than 2 cm length), excessive tortuosity of proximal segment, extremely angulated segments more than 90° and total occlusion more than 3 months old [10].

Inclusion criteria include patients referred for elective PCI of type C lesions for a period of 1 year. Exclusion criteria include patient presenting with acute myocardial infarction either STEMI or NSTEMI, patients presenting with cardiogenic shock or cardiac arrest, patients presenting with type A or B coronary lesions, acute renal failure and malignancy.

All patients included in the study had demographics and clinical history taking including age, sex, body mass index (Kg/m²), family history of coronary artery disease, history of systemic hypertension, hypercholesterolemia, diabetes mellitus, chronic renal insufficiency, peripheral vascular disease, prior myocardial infarction, prior coronary artery bypass grafting, prior percutaneous coronary intervention, congestive heart failure (CHF), unstable angina pectoris and medications taken by the patient such as aspirin, clopidogrel, ACE inhibitor and/or ARB, Ca antagonist, beta blocker and statin.

All patients gave written consent for the PCI procedure. In addition, all patients signed an informed consent for participation, and the study was approved by the ethical committee of the Faculty of Medicine, Ain Shams University.

All patients received aspirin, 81 - 325 mg/d, for ≥ 24 hours before the procedure and continued on a maintenance dose indefinitely. Clopidogrel 600 mg was given as a loading dose prior to PCI in all patients who were not already on a maintenance dose. Use of platelet glycoprotein IIb/IIIa inhibitors was at the discretion of the operator.

Procedural details were noted including target coronary lesion location, number of lesions treated, number of stents implanted, procedural length in minutes, contrast volume in mL, glycoprotein IIb/IIIa use, number of bare-metal stents, number of drug eluting stents, type of drug-eluting stents, total stent length, stent diameter, pre-dilatation, post-dilatation, cutting balloon use, pre-diameter stenosis and final-diameter stenosis [11].

IVUS was performed using standard technique, preintervention, and post intervention. One of two commercially available systems- Atlantis S (Boston Scientific) or Eagle Eye (Volcano Therapeutics) will be used. IVUS images will be recorded after administration of 100 - 200 mg of nitroglycerin. The ultrasound catheter was advanced > 5 mm beyond the lesion/stent and pulled back to a point > 5 mm proximal to the lesion/stent. IVUS will be performed and interpreted by the treating physician and ≥ 1 experienced IVUS technician. Routine measurements were recorded pre- and post-stent implantation.

The IVUS details pre and post intervention data was recorded such as stent under expansion, malposition, edge dissection, or plaque shift. The action taken in response to the IVUS findings was at the discretion of the treating physician.

Procedural outcomes including angiographic success, procedural success, dissection, abrupt closure, no-reflow was noted. Angiographic Success was defined as enlargement of the lumen at the target site with the achievement of a minimum stenosis diameter reduction to < 20% in the presence of grade 3 TIMI flow. Procedural Success was defined as angiographic success without in-hospital major clinical complications (e.g. death, myocardial infarction [MI], emergency coronary artery bypass surgery [CABG]) during hospitalization. No-reflow was defined as an acute reduction in coronary flow (TIMI grade 0 - 1) in the absence of dissection, thrombus, spasm, or high-grade residual stenosis at the original target lesion [12].

In-hospital outcome was recorded including all-cause death, cardiac death, CABG in hospital, Post procedure myocardial infarction, acute renal failure, periprocedural bleeding (hematocrit drop > 15%) and stroke.

MACE, a composite end-point of all-cause mortality, acute myocardial infarction, and TLR, will be compared between the 2 groups. Clinical follow-up will be performed at 1 and 12 months. The follow up will be by an office visit or a telephone contact.

Secondary end-points included cardiac death and stent thrombosis (ST). Acute myocardial infarction (MI) was defined as Detection of a rise and/or fall of cardiac biomarker values [preferably cardiac troponin (cTn)] with at least one value above the 99th percentile upper reference limit (URL) and with at least one of the following: i) Symptoms of ischaemia, ii) New or presumed new significant ST-segment-T wave (ST-T) changes or new left bundle branch block (LBBB), iii) Development of pathological Q waves in the ECG, iv) Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality, v) Identification of an intracoronary thrombus by angiography or autopsy. Percutaneous coronary intervention (PCI) related MI was defined by elevation of cTn values (> 5 x 99th percentile URL) in patients with normal baseline values (≤ 99th percentile URL) or a rise of cTn values >20% if the baseline values are elevated and are stable or falling. In addition, either (i) symptoms suggestive of myocardial ischaemia or (ii) new ischaemic ECG changes or (iii) angiographic findings consistent with a procedural complication or (iv) imaging demonstration of new loss of viable myocardium or new regional wall motion abnormality [13]. Cardiac death was defined as all deaths where a non-cardiac cause could not be demonstrated. TLR was defined as need for revascularization, either percutaneous or surgical, for a stenosis within the stent or in the 5-mm segments proximal or distal to the stent [14].

Stent thrombosis was classified according to Academic Research Consortium (ARC) into i) Definite Stent Thrombosis: Angiographic or pathologic confirmation of partial or total thrombotic occlusion within the peri-stent region and at least ONE of the following, additional criteria: Acute ischemic symptoms, Ischemic ECG changes or Elevated cardiac biomarkers. ii) Probable Stent Thrombosis: Any unexplained death within 30 days of stent implantation, any myocardial infarction, which is related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause. iii) Possible Stent Thrombosis: Any unexplained death beyond 30 days [14].

Statistical analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 20.

The comparison between two groups with qualitative data was done by using Chi-square test and/or Fisher exact test. Fisher exact test was used instead of Chi-square test when the expected count in any cell was found less than 5.

Comparison between two independent groups regarding quantitative data with parametric distribution was done by using Independent t-test and Kaplan Meier survival analysis.

Results

Baseline characteristics

Baseline characteristics of the study population including the Clinical characteristics were similar between the 2 groups with no statistically significant difference between them (Table 1). The average age in the IVUS guided group is 56.74 years and in the angiography guided is 56.36 years. Regarding the gender, 12 (24%) patients were female in the IVUS guided group and 38 (76%) were male while in the angiography guided group 13 (26%) patients were female and 37 (74%) were male.

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	No = 50		No = 50		X ²	p
	No.	%	No.	%		
HTN	35	70.0%	35	70.0%	0.000	1.000
Hypercholesterolemia	10	20.0%	4	8.0%	2.990	0.084
DM	21	42.0%	24	48.0%	0.364	0.546
CKD	1	2.0%	4	8.0%	1.895	0.169
Current Smoker	2	4.0%	6	12.0%	2.174	0.140
FH of CAD	1	2.0%	1	2.0%	0.000	1.000
PVD	1	2.0%	1	2.0%	0.000	1.000
Prior MI	8	16.0%	13	26.0%	1.507	0.220
Prior CABG	4	8.0%	2	4.0%	0.709	0.400
Prior PCI	20	40.0%	14	28.0%	1.604	0.205
History of CHF	1	2.0%	0	0.0%	1.010	0.315
UA	12	24.0%	6	12.0%	2.439	0.118
LV EF < 40%	3	6.0%	1	2.0%	1.042	0.307

Table 1: Patients Demographics and clinical history in the studied groups.

Angiographic and procedural characteristics (Lesion-Based)

Target coronary vessel and Lesion Location

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	n = 73		n = 71		X ²	P-value
Target coronary vessel	No.	%	No.	%		
LM	11	15.07%	11	15.49%	0.005	0.9436
LAD	37	50.68%	37	52.11%	0.029	0.8639
LCX	14	19.18%	13	18.31%	0.018	0.8938
RCA	11	15.07%	10	14.08%	0.028	0.8672
Ostial	16	21.92%	10	14.08%	1.493	0.222
Proximal	18	24.66%	20	28.17%	0.228	0.633
Mid	30	41.10%	33	46.48%	0.424	0.515
Distal	9	12.33%	8	11.27%	0.039	0.844

Table 2: Target coronary vessel and lesion location in both groups.

The number of lesions treated was 73 lesions in the IVUS guided group and 71 lesions in the angiography guided group. Regarding the target coronary vessel, the number of lesions in left main coronary artery, left anterior descending coronary artery, left circumflex coronary artery and right coronary artery was similar in both groups with no significant difference.

Procedural details

Variable		IVUS Guided	Angiography Guided t/X ² *	Independent t-test	
				P-value	
Number of lesions treated	Total	73	71	NA	NA
	Mean ± SD	1.46 ± 0.79	1.42 ± 0.70	0.268	0.789
	Range	1 - 5	1 - 4		
Number of implanted stents	Total	84	75	NA	NA
	Mean ± SD	1.68 ± 0.87	1.50 ± 0.76	1.102	0.273
	Range	1 - 5	1 - 4		
Procedural length (min)	Mean ± SD	37.40 ± 19.46	28.64 ± 10.71	2.788	0.006
	Range	20 - 100	20 - 60		
Contrast amount (mL)	Mean ± SD	161.40 ± 53.11	194.00 ± 94.03	-2.135	0.035
	Range	100 - 600	100 - 600		
Glycoprotein IIb/IIIa use		1 (2.0%)	1 (2.0%)	0.000	1.000
Stent diameter (mm)	Mean ± SD	3.11 ± 0.51	2.99 ± 0.33	1.386	0.169
	Range	2.5 - 4	2.25 - 3.75		
Total stent length (mm)	Mean ± SD	25.05 ± 7.82	27.86 ± 6.20	-1.990	0.049
	Range	12 - 39	10 - 38		
Pre-dilatation	No. (%)	41 (56.16%)	42 (59.15%)	0.038	0.846
Post-dilatation	No. (%)	66 (90.41%)	34 (47.89%)	28.701	< 0.001
Angiographic success	Mean ± SD	73 (100.0%)	68 (95.77%)	1.419	0.234
Pre-diameter stenosis (%)	Mean ± SD	78.93 ± 9.86	80.05 ± 12.35	-0.499	0.619
	Range	50 - 100	58 - 100		
Final-diameter stenosis (%)	Mean ± SD	3.84 ± 3.25	10.39 ± 8.09	-5.310	0.000
	Range	0 - 14.5	2 - 54		
Rotational atherectomy		0 (0.0%)	0 (0.0%)	NA	NA*
Cutting balloon		1 (1.37%)	0 (0.0%)	0.002	0.988
Dissection		2 (2.74%)	2 (2.82%)	0.001	0.981
Abrupt closure		0 (0.0%)	0 (0.0%)	NA	NA*
No reflow		1 (1.37%)	1 (1.41%)	0.479	0.489

Table 3: Procedural details in the studied groups.

The number of lesions treated was 73 lesions in the IVUS guided group and 71 lesions in the angiography guided group with an average 1.46 ± 0.79 per patient in the IVUS guided group and 1.42 ± 0.70 per patient in the angiography guided group. Regarding stent implantation, 84 stents were implanted in the IVUS group and 75 stents were implanted in the angiography guided group with an average 1.68 ± 0.87 per patient in the IVUS guided group and 1.50 ± 0.76 per patient in the angiography guided group.

Adding IVUS to the procedure lengthened the procedure time (37.40 ± 19.46 vs. 28.64 ± 10.71 minutes, $p = 0.006$). On the other hand, lower amount of radiographic contrast was required in the IVUS guided group during the procedure (161.40 ± 53.11 vs 194.00 ± 94.03 , $p = 0.035$).

Regarding stent Implantation, all the implanted stents were drug eluting stents CE approved. There was no statistically significant difference between the IVUS group and the angiography guided group in the used stent diameter (3.11 ± 0.51 vs 2.99 ± 0.33 , $p = 0.169$). However, the total stent length was shorter in the IVUS group than in the angiography guided group (25.05 ± 7.82 vs 27.86 ± 6.20 , $p = 0.049$).

There was no statistically significant difference between the IVUS group and the angiography guided group regarding pre-dilatation, (56.16% vs. 59.15%), $p = 0.846$). However, patients with IVUS-guided PCI underwent more post-dilatation (90.41% vs. 47.89% , $p < 0.001$).

Rotational atherectomy was not used in any patient, cutting balloon was used in only one patient in the IVUS guided group and Glycoprotein IIb/IIIa was used in one patient in each of the two studied groups.

On quantitative coronary angiography analysis, pre-diameter stenosis pre-intervention was similar in both groups but the final diameter stenosis post-intervention was less in the IVUS guided group ($p = 0.000$). There was no statistically significant difference between the IVUS group and the angiography guided group regarding the angiographic success (100.0% vs. 95.77% , $p = 0.234$). There were no significant differences between the two groups in the rates of dissection, abrupt closure and no reflow.

IVUS Analysis

IVUS analysis was done in the IVUS guided group using Atlantis S or I-Lab (Boston Scientific) in 36 patients (72%) and Eagle Eye (Volcano Therapeutics) in 14 patients (28%). MLA, pre-intervention was 3.36 ± 1.63 mm² and increased to 7.72 ± 2.92 mm² post-intervention with stent well apposition confirmed in all patients (100%) (Figure 1).

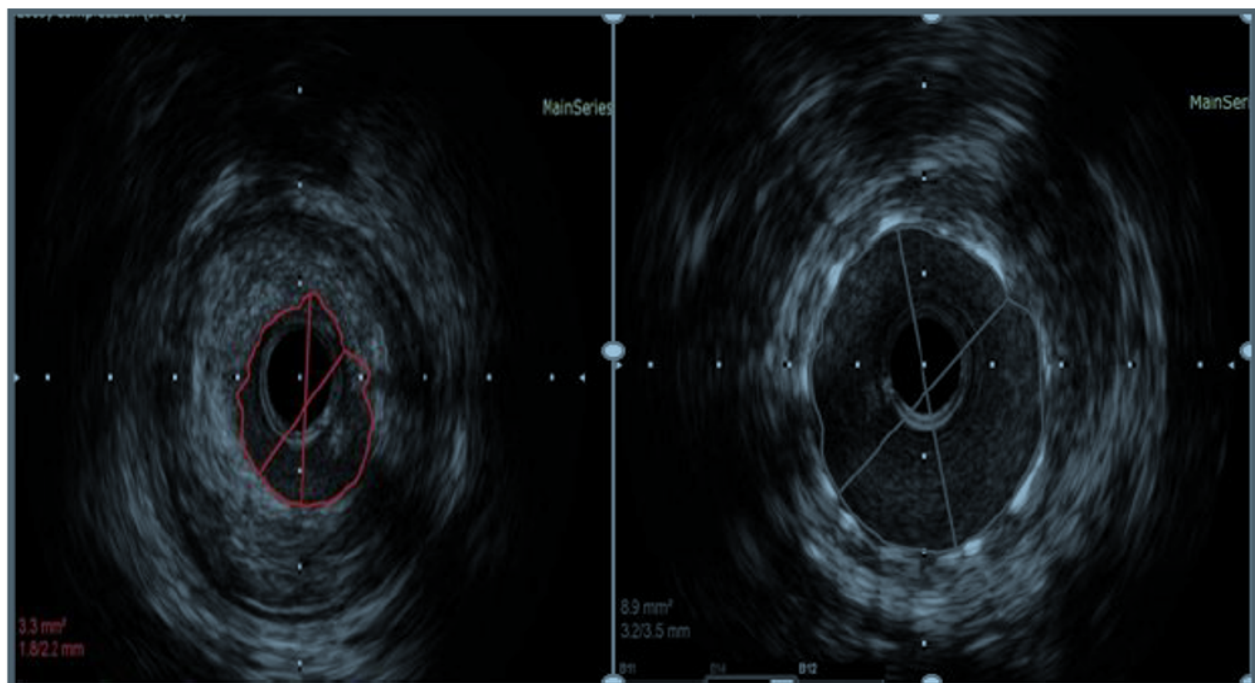


Figure 1: IVUS analysis images per and post intervention.

Clinical Outcomes

In-hospital, 30-day and 12-month outcomes were similar between the 2 groups. There were no significant differences between the two groups in the rates of in hospital acute renal failure, bleeding, neurological events and the adverse cardiac events (Table 4-6 and Figure 2).

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	No = 50		No = 50		X ²	P-value
	No.	%	No.	%		
MACE	0	0.0%	2	4.0%	2.041	0.153
All-cause death	0	0.0%	1	2.0%	1.010	0.315
Cardiac death	0	0.0%	0	0.0%	NA	NA
CABG in hospital	0	0.0%	0	0.0%	NA	NA
Post procedural MI	0	0.0%	1	2.0%	1.010	0.315
Acute renal failure	0	0.0%	2	4.0%	2.041	0.153
Pre-procedural bleeding	0	0.0%	0	0.0%	NA	NA
Transfusion	0	0.0%	0	0.0%	NA	NA
Stroke	0	0.0%	0	0.0%	NA	NA

Table 4: In-hospital outcome in the studied groups.

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	No = 50		No = 50		X ²	P-value
	No.	%	No.	%		
MACE	1	2.0%	2	4.0%	0.344	0.557
All-cause death	1	2.0%	1	2.0%	0.000	1.000
Cardiac death	0	0.0%	0	0.0%	NA	NA
MI	0	0.0%	1	2.0%	1.010	0.315
TLR	0	0.0%	0	0.0%	NA	NA
Stent thrombosis	0	0.0%	0	0.0%	NA	NA

Table 5: 30-Day outcome in the studied groups.

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	No = 50		No = 50		X ²	P-value
	No.	%	No.	%		
MACE	3	6.0%	5	10.0%	0.544	0.461
All-cause death	2	4.0%	2	4.0%	0.000	1.000
Cardiac death	1	2.0%	1	2.0%	0.000	1.000
MI	0	0.0%	1	2.0%	1.010	0.315
TLR	1	2.0%	2	4.0%	0.344	0.557
Stent thrombosis	0	0.0%	0	0.0%	NA	NA

Table 6: 12-month outcome in the studied groups.

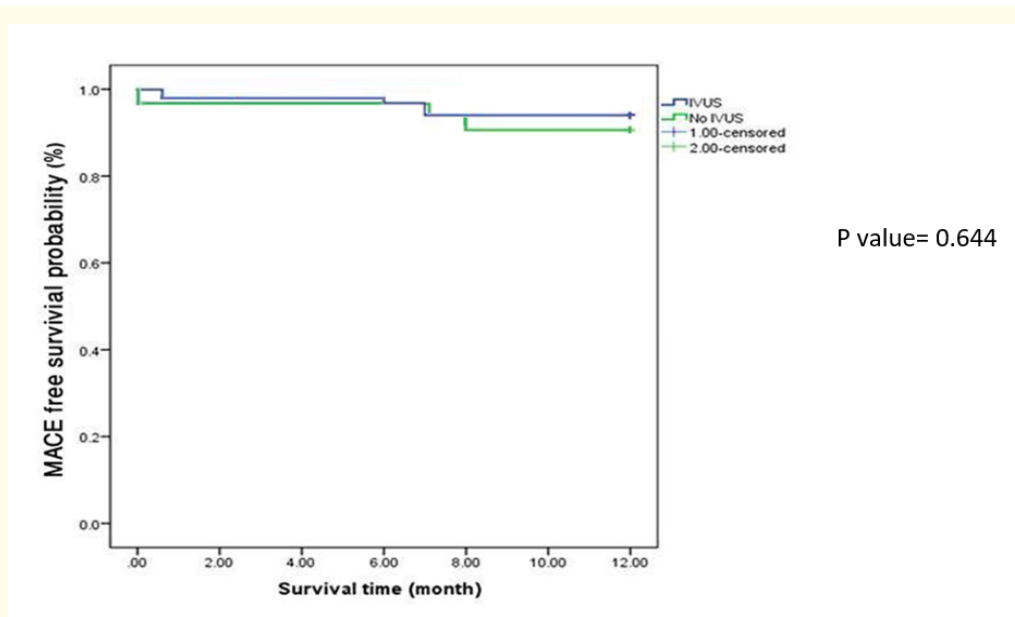


Figure 2: Kaplan-Meier curve illustrating freedom from MACE in IVUS and no IVUS groups over 12 months.

Discussion

PCI of complex coronary lesions still remains challenging because the prevalence of in-stent restenosis and stent thrombosis. IVUS is an imaging modality often used as a supplement to coronary angiography and allows accurate assessment of the lumen, vessel wall, and atherosclerotic plaque. IVUS has become indispensable in everyday clinical practice.

Our study which was conducted on patients undergoing elective PCI for type C coronary lesions compared IVUS guidance PCI for type C lesions and 50 patients versus angiographic guidance PCI for type C lesions. The IVUS or angiographic guidance was according to operator discretion.

Baseline characteristics of the study population were similar between the 2 groups. Regarding the age and gender:

Adding IVUS to the procedure lengthened the procedure time (37.40 ± 19.46 vs. 28.64 ± 10.71 minutes, $p = 0.006$), but lower amount of radiographic contrast was required in the IVUS guided group during the procedure (161.40 ± 53.11 vs 194.00 ± 94.03 , $p = 0.035$). The use of lower amount of radiographic contrast in the IVUS guided group is due to its ability to accurately measure lumen, plaque, and vessel dimensions, thus IVUS might serve as an alternative tool to angiography in many steps during PCI.

Regarding the target coronary vessel in our study, the number of lesions in left main coronary artery, left anterior descending coronary artery, left circumflex coronary artery and right coronary artery was similar in both groups with no significant difference. In addition, the number of ostial, proximal, mid and distal lesions was similar between the two studied groups.

All the implanted stents in our study are drug eluting stents CE approved. Greater number of stents were implanted in the IVUS group than in the angiography guided group (84 vs 75 with an average 1.68 ± 0.87 per patient in the IVUS guided group and 1.50 ± 0.76 per patient in the angiography guided group). In the IVUS group, the stent diameter was similar to the angiography guided group (3.11 ± 0.51 vs 2.99 ± 0.33 , $p = 0.169$) while the total stent length was shorter in the IVUS group than the angiography guided group (25.05 ± 7.82 vs 27.86 ± 6.20 , $p = 0.049$).

Patients with IVUS guided PCI underwent similar percentage of pre-dilatation (56.16% vs. 59.15%), $p = 0.846$) and more post-dilatation (90.41% vs. 47.89%, P value < 0.001). On quantitative coronary angiography (QCA) analysis, pre-diameter stenosis pre-intervention was similar in both groups but the final diameter stenosis post-intervention was less in the IVUS guided group (P value = 0.000). The angiographic success was the same in the IVUS guided group as in the angiography guided group (100.0% vs. 95.77%, $p = 0.234$).

In the study conducted by Wakabayashi, *et al.* Patients with IVUS guided PCI underwent less pre-dilatation (40.0% vs. 46.8%, $P = 0.005$), more post-dilatation. (21.9% vs. 13.4%, $P < 0.001$), and had greater use of cutting balloons (8.2% vs. 5.3%, $p = 0.013$). Larger stents were implanted (3.05 ± 0.37 vs. 2.90 ± 0.36 , $p < 0.001$). Consequently, the final diameter stenosis was significantly smaller in such patients ($3 \pm 11\%$ vs. $7 \pm 19\%$, $P < 0.001$). Further, when IVUS guidance was employed, higher angiographic success was found (97.9% vs. 94.8%, $p < 0.001$) [11].

Yun, *et al.* conducted a study enrolling total 966 patients who underwent PCI for type C lesion from June 2003 to December 2010. Mean follow-up duration is 33.1 months. 342 patients were treated with IVUS guided PCI and 624 patients treated with angiography guided PCI. The clinical end point was major adverse cardiovascular event (MACE) composite of cardiac death, myocardial infarction (MI), target lesion revascularization (TLR) and definite or possible stent thrombosis. Baseline clinical characteristics were similar in both patient groups. IVUS guided PCI group had higher frequency of ostial and proximal lesion. IVUS guided PCI group showed longer stent length, larger maximal stent diameter and greater number of implanted stents [16].

Oemrawsingh, *et al.* conducted Thrombocyte activity evaluation and effects of Ultrasound guidance in Long Intracoronary Stent Placement study (TULIP Study), The TULIP Study showed that There was a significant increase in stent length and number of stents associated with IVUS guidance. On quantitative coronary angiography (QCA) analysis, the preintervention lesion parameters were equivalent. Final and follow-up MLDs in the IVUS group were significantly larger than in the angiography group [9].

In our study, online IVUS analysis was done in the IVUS guide group. MLA, pre-intervention was 3.36 ± 1.63 mm² and increased to 7.72 ± 2.92 mm² post-intervention with stent well apposition confirmed in all patients (100%).

A larger postprocedural minimal lumen diameter is believed to be a major contributing factor for the prevention of restenosis after DES implantation [17,18].

In TULIP study, online IVUS measurements at the end of the procedure showed an MLA of $6.0 \pm 3.3 \text{ mm}^2$, with proximal and distal reference areas of 8.8 ± 3.3 and $5.9 \pm 2.5 \text{ mm}^2$, respectively; the MLD was $2.8 \pm 0.3 \text{ mm}$, with proximal and distal reference diameters of 3.3 ± 0.4 and $2.7 \pm 0.4 \text{ mm}$, respectively. All criteria for optimal stent placement were achieved in 65 patients (89%). In the other 8 patients (10%), final in-stent MLA remained smaller than the distal reference lumen despite a balloon-to vessel ratio up to 1.3 and/or high-pressure inflations.

We evaluated the impact of IVUS guidance on clinical outcomes of patients undergoing PCI for complex lesions defined as ACC/AHA type C. Major adverse cardiovascular events (MACE), a composite end-point of all-cause mortality, Q-wave myocardial infarction and target lesion revascularization, were compared between the 2 groups. In-hospital, 30-day and 12-month outcomes were similar between the 2 groups, with no statistically significant difference.

In OPTICUS study, Clinical follow-up was complete for 535 (98%) patients after 6 months and for 524 (95%) after 12 months. In-hospital clinical outcome did not show significant differences in either study group except for repeat percutaneous interventions which occurred in no patient assigned to ultrasound-guided stenting and in 6 (2.2%) patients assigned to angiography-guided stenting ($p = 0.030$). The incidence of major adverse clinical events was not different in both groups.

In the AVIO trial which is randomized, multicenter study evaluating IVUS vs angiographically guided DES implantation in 284 patients with complex lesions (defined as bifurcations, long lesions, chronic total occlusions or small vessels), the benefit of IVUS optimized DES implantation was observed in complex lesions in the post-procedure minimal lumen diameter only but no statistically significant difference was found in MACE up to 24 months [19].

Limitations

This was a single-center non-randomized study with a relatively small sample size, thus it was not sufficiently powered to make a statistically significant conclusion with respect to the hard end points. Due to the different study procedures for DES implantations (angiography guided or IVUS guided), blinding the patients and treating physicians to the treatment was not feasible.

Conclusion

The use of intravascular ultrasound (IVUS) in complex lesions allows proper assessment of minimal lumen area, optimizing PCI procedure and confirming stent well apposition with a smaller final diameter stenosis. A randomized well powered study is needed to make a statistically significant conclusion with respect to MACE.

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