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In-Hospital and 1-Year Results of Intravascular Ultrasound-Guided Versus Angiography-Guided Intervention for Type C Coronary Lesions

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Abstract

Background: *Class C lesions are considered to have the highest degree of lesion complexity so we compared between Intravascular Ultrasound (IVUS)-guided and angiography-guided PCI for Type C coronary lesions regarding procedural success and occurrence of Major Adverse Cardiac Events (MACE).*

Results: *Our study was conducted on patients undergoing elective PCI for type C coronary lesions. The study included 50 patients who underwent IVUS guided PCI and 50 patients who underwent angiographic guided PCI. We evaluated IVUS guidance on clinical outcomes. MACE, all-cause mortality, ST elevation infarction, and target lesion revascularization, were end points for comparison. Follow-up duration was 12 months. Adding IVUS to the procedure was associated with more procedure time but with less amount of contrast. Patients with IVUS-guided PCI underwent more direct stenting, post-dilatation, larger maximal stent diameter, and greater number of implanted stents. The IVUS guided group had significantly better final diameter stenosis but at 1-year follow up, IVUS use failed to reduce MACE significantly in comparison to angiographic guidance.*

In conclusion: *use of IVUS is associated with lower amount of radiographic contrast used during the procedure, more procedural time, more post dilatation and less postintervention final diameter stenosis. In addition, use of IVUS in complex lesions allows optimizing PCI procedures and stent apposition. A strategy of IVUS for stent implantation in complex coronary lesions didn't reduce the 1-year MACE rates and thus, isn't recommended routinely*

Keywords: *Intravascular ultrasound, Type C coronary lesions*

Abbreviations: *IVUS: Intravascular Ultrasound; CABG: Coronary Artery Bypass Graft; PCI: Percutaneous Coronary Intervention; CHF: Congestive Heart Failure; MACE: Major Adverse Cardiac Events; ISR: In-Stent Restenosis; MLD: Minimal Lumen Diameter; MLA: Minimal Lumen Area*

Introduction

The intravascular ultrasound (IVUS) is considered one of the best invasive imaging methods for the analysis of coronary atherosclerosis both quantitatively and qualitatively [1].

The use of IVUS could improve the long-term results of coronary angioplasty. These results are derived from at main three factors; confirming that there is no coronary dissection, no significant residual stenosis, definite removal of the calcific plaques that could limit stent expansion, and presence of an optimal lumen gain [2].

Coronary intervention for type C lesions patients remains challenging, and their outcomes are often compromised [3-5]. Type C coronary lesions include: 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. Stent implantation with IVUS guidance may result in more effective stent expansion as compared to angiographic guidance alone [6]. Thus, it is reasonable that IVUS guided PCI may improve short- and long-term outcomes of patients undergoing coronary stenting. However, previous trials showed conflicting results especially the studies were mainly on predominantly simple target lesions [7-9]. Thus, the impact of IVUS use on the patient's outcome with complex lesions might be more effective than use of angiographic guidance alone.

More complex lesions are associated with lower procedural success rates with poorer late outcomes according to the American College of Cardiology/American Heart Association (ACC/AHA). Type C coronary lesions are considered to be the highest degree of lesion complexity [10]. So, the use of IVUS to guide PCI was suggested to improve outcome [11]. This study was done to compare intravascular ultrasound-guided and angiography-guided PCI for Type C coronary lesions regarding procedural success and occurrence of Major Adverse Cardiac Events (MACE) over 1-year follow up.

Methods

The study was conducted on patients undergoing elective PCI for type C coronary lesions in the Cardiology Department 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 from the period of August 2014 till August 2015. An American College of Cardiology/American Heart Association (ACC/AHA) classification was applied to differentiate between the complexities of the target lesions for PCI [10].

The following patients were included in the study: Patients referred for elective PCI of type C lesions for a period of 1 year. All referred patients were indicated for intervention on basis of whether stress imaging scintigraphy study revealing large area of ischemia in the territory of the coronary artery with type C lesion or presence of uncontrolled stable angina symptoms on medical treatment. Those presented with acute myocardial infarction, cardiogenic shock or cardiac arrest, type A or B coronary lesions and those with acute renal failure were excluded from the study.

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 received aspirin, 81-162 mg/d, for ≥ 24 hours before the procedure and continued a maintenance dose indefinitely. 600 mg Clopidogrel was given as a loading dose prior to PCI in all patients who were not on a maintenance dose. 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, number of drug eluting stents, type of drug-eluting stents, total stent length, stent diameter, predilatation, postdilatation, cutting balloon use, prediameter stenosis, and final-diameter stenosis [11].

IVUS was performed using the standard technique, preintervention, and post intervention. One of two commercially available systems-Atlantis S (Boston Scientific Corp./SCIMED, Minneapolis, MN, USA) or Eagle Eye (Volcano Therapeutics, Inc., Rancho Cordova, CA, USA) were used. 100-200 mg of intra-coronary nitroglycerin was given then IVUS images were recorded. 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 was performed and interpreted by the treating physician and ≥ 1 experienced IVUS technician. Measurements were recorded before and after stent implantation. The IVUS details pre and post intervention data were recorded such as stent malposition, under expansion, plaque shift or edge dissection. Dealing with the problem was done by the treating physician.

Procedural outcomes including angiographic success, procedural success, dissection, abrupt closure, no-reflow were noted. Angiographic success was defined as increase in the lumen at the target site with the achievement of a minimum stenosis diameter < 20% in addition to achieving TIMI 3 (Thrombolysis In Myocardial Infarction grade 3) coronary flow. Procedural success was defined as angiographic success without in-hospital major cardiac adverse effects (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].

The physicians recorded the in-hospital outcome blindly (to the procedural information), including all-cause death, cardiac death, CABG in hospital, Post procedure myocardial infarction, acute renal failure, periprocedural bleeding (hematocrit drop >15%) and stroke. Major Adverse Cardiovascular Events (MACE), a composite end-point of all-cause mortality, acute myocardial infarction, and Target Lesion Revascularization (TLR), were compared between the both groups. Clinical follow-up was performed at 1 and 12 months via clinic visits. Cardiac death and Stent Thrombosis (ST) were secondary end points. 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 ischemia, 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 ischemia or (ii) new ischemic 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 with a non-proved non-cardiac cause. TLR was defined as need for percutaneous or surgical revascularization, for a stent stenosis or stenosis 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: Beyond 30 days unexplained death [14].

The study was approved by the Research Ethics Committee (Faculty of Medicine, Ain Shams University, FWA 00006444) and all patients signed an informed consent for participation in the study in accordance with the Declaration of Helsinki.

The Statistical Package for Social Science (IBM SPSS) version 20 was used for data organization and statistical analysis. Quantitative data were presented as mean, standard deviations and ranges while qualitative data were expressed as number and percentages.

Chi-square test and/or **Fisher exact test** was used to compare between 2 groups with qualitative data. When the expected count in any cell was less than 5, the **Fisher exact test** was used.

Independent t-test was used to compare between 2 independent groups regarding quantitative data with parametric distribution.

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	No = 50		No = 50			
	No.	%	No.	%	X^2	P-value
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
CHF NYHA III or IV	0	0.0%	0	0.0%	NA	NA
LVEF<40%	3	6.0%	1	2.0%	1.042	0.307

HTN: Hypertension, DM: Diabetes Mellitus, FH of CAD: Family History of Coronary Artery Disease, PVD: Peripheral Vascular Disease, MI: Myocardial Infarction, CABG: Coronary Artery Bypass Grafting, PCI: Percutaneous Coronary Intervention, CHF: Congestive Heart Failure, UA: Unstable Angina, NYHA: New York Heart Association Classification, LVEF: Left Ventricular Ejection Fraction.

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

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	n = 73		n = 71			
Target coronary vessel	No.	%	No.	%	X^2	P-value
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
SVG	0	0.00%	0	0.00%	NA	qNA

LM: Left Main, LAD: Left Anterior Descending, LCX: Left Circumflex, RCA: Right Coronary Artery, SVG: Saphenous Vein Graft

Table 2. Target coronary lesion in both groups.

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	n = 73		n = 71			
	No.	%	No.	%	X^2	P-value
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
ISR	10	13.70%	6	8.45%	0.632	0.427

ISR: In-Stent Restenosis

Table 3. Lesion Location in both groups.

Variable		IVUS Guided	Angiography Guided	Independent t-test	
		No = 50	No = 50	t/X²*	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

Table 4. Number of lesions and stents, procedural length and contrast amount in the studied groups.

Variable		IVUS Guided	Angiography Guided	Independent t-test	
		No = 73	No = 71	t/X2*	P-value
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		
Predilatation	No. (%)	41 (56.16%)	42 (59.15%)	0.038	0.846
Postdilatation	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
Prediameter 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 5. Procedural details in the studied groups.

Variable		Total no. 50
IVUS System	Boston Scientific	36 (72.0%)
	Volcano	14 (28.0%)
MLA, Pre intervention (mm^2)	Mean ± SD	3.36 ± 1.63
	Range	0 – 8.35
MLA, Post intervention (mm^2)	Mean ± SD	7.72 ± 2.92
	Range	3.7 – 17.3
Stent well apposition	No. (%)	84 (100.0%)

IVUS: Intravascular Ultrasound, MLA: Minimal Lumen Area

Table 6. IVUS analysis in IVUS Guided group.

Variable	IVUS Guided		Angiography Guided		Chi-square test	
	No = 50		No = 50			
	No.	%	No.	%	X^2	P-value
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

MACE: Major Adverse Cardiac Events, CABG: Coronary Artery Bypass Grafting, MI: Myocardial Infarction

Table 7. IVUS analysis in IVUS Guided group.

Variable		IVUS Guided		Angiography Guided		Chi-square test	
		No = 50		No = 50			
		No.	%	No.	%	X^2	P-value
MACE	30-Day	1	2.0%	2	4.0%	0.344	0.557
	12-Month	3	6.0%	5	10.0%	0.544	0.461
All-cause death	30-Day	1	2.0%	1	2.0%	0.000	1.000
	12-Month	2	4.0%	2	4.0%	0.000	1.000
Cardiac death	30-Day	0	0.0%	0	0.0%	NA	NA
	12-Month	1	2.0%	1	2.0%	0.000	1.000
MI	30-Day	0	0.0%	1	2.0%	1.010	0.315
	12-Month	0	0.0%	1	2.0%	1.010	0.315
TLR	30-Day	0	0.0%	0	0.0%	NA	NA
	12-Month	1	2.0%	2	4.0%	0.344	0.557
Stent thrombosis	30-Day	0	0.0%	0	0.0%	NA	NA
	12-Month	0	0.0%	0	0.0%	NA	NA

MACE: Major Adverse Cardiac Events, MI: Myocardial Infarction, TLR: Target Lesion Revascularization

Table 8. 30-Day and 12-Month outcomes in the studied groups.

Results

Baseline clinical characteristics

Demographics and clinical history

The Clinical characteristics of the study population were similar between the 2 groups regarding coronary risk factors, history of heart disease and clinical presentation with no statistically significant difference between the two studied groups (Table 1).

Angiographic and procedural characteristics (Lesion-Based) Target coronary vessel and Lesion Location (Table 2 and Table 3): 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 (Table 4 and Table 5): 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 min, P value = 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 value = 0.035).

Regarding stent implantation, all the implanted stents (Sirolimus-eluting stent, Everolimus-eluting stent, Biolimus-

eluting stent, Zotarolimus-eluting stent and Paclitaxel-eluting stent) are drug eluting stents FDA and/or CE approved. 41 Everolimus-eluting stents were implanted in the IVUS guided group and only 18 Everolimus-eluting stents were implanted in the angiography guided group (48.81% vs. 24.00%, P value = 0.002). 8 Biolimus-eluting stents were implanted in the IVUS guided group while 20 Biolimus-eluting stents were implanted in the angiography guided group (9.52% vs. 26.67%, P value = 0.009). The implantation of Sirolimus-eluting stent, Zotarolimus-eluting stent and Paclitaxel-eluting stent was similar in both groups with no significant difference.

As regard stent diameter, there was no statistically significant difference between the IVUS group and the angiography guided group (3.11 ± 0.51 vs 2.99 ± 0.33, P value = 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 value = 0.049).

As regard predilatation, there was no statistically significant difference between the IVUS group and the angiography guided group (56.16% vs. 59.15%), P value = 0.846). However, patients with IVUS-guided PCI underwent more postdilatation (90.41% vs. 47.89%, P value <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, prediameter 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). 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 Corp./SCIMED, Minneapolis, Minnesota) in 36 patients (72%) and Eagle Eye (Volcano Therapeutics, Rancho Cordova, California) in 14 patients (28%). Minimum Lumen Area (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%) (Table 6).

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. Both primary and secondary end points were similar between the two studied groups with no statistically significant difference (Table 7 and Table 8).

Discussion

In-stent restenosis and repeat revascularization were significantly reduced since introduction and use of drug-eluting stents. However, complex coronary lesions still have high prevalence of in-stent restenosis and stent thrombosis.

IVUS allows accurate assessment of the lumen, vessel wall, and atherosclerotic plaque. So, its use has become essential in clinical practice.

Our study was conducted on patients undergoing elective PCI for type C coronary lesions in cardiology department in Ain Shams University hospitals. The study included 50 patients who underwent IVUS guidance PCI for Type C lesions and 50 patients who underwent only angiographic guidance PCI for Type C lesions. The IVUS or angiographic guidance was according to operator discretion.

Adding IVUS to the procedure lengthened the procedure time. On the other hand, lower amount of radiographic contrast was required in the IVUS guided group during the procedure and this is due to the ability of IVUS to accurately measure lumen, plaque, and vessel dimensions.

Optimization with IVUS to reduce stent restenosis study (OPTICUS study) enrolled a total of 550 patients who were randomized into two groups (ultrasound-guided and angiography-guided stent implantation) at 26 centers. The number of balloons used, contrast volume (in contrast to our study), longer fluoroscopy and procedural time were higher in the IVUS guided group [15].

In our study, Patients with IVUS guided PCI underwent similar percentage of predilatation and more postdilatation. On Quantitative Coronary Angiography (QCA) analysis, prediameter stenosis pre-intervention was similar in both groups but the final diameter stenosis post-intervention was less in the IVUS guided group. The angiographic success was the same in the IVUS guided group as in the angiography guided group.

In the study conducted by Wakabayashi, et al. Patients with IVUS guided PCI underwent significantly less predilatation, more postdilatation (as in our study), with greater use of cutting balloons. Larger diameter stents were implanted resulting in significantly smaller final diameter stenosis (P < 0.001). Further, IVUS guidance has led to a greater angiographic success (P < 0.001) [11].

Greater number of stents in our study were implanted in the IVUS group than in the angiography guided group. In the IVUS group, the stent diameter was similar to the angiography guided group while the total stent length was shorter in the IVUS group than the angiography guided group. This was in contrast to the study done by Yun and his colleagues who showed that IVUS guided PCI group showed longer stent length and larger maximal stent diameter. While, as in our study, the number of stents implanted was greater in the IVUS guided group [16].

Oemrawsingh, et al. conducted the Tulip Study (Thrombocyte activity evaluation and effects of Ultrasound guidance in Long Intracoronary Stent Placement study), it showed that with IVUS guidance, there was a significant increase in stent length and number of stents. In addition, larger Minimal Lumen Diameters (MLDs) were significantly present in the IVUS group versus 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%).

It is believed that a larger minimal lumen diameter after PCI is a major contributing factor for restenosis prevention after DES implantation [17,18]. In TULIP Study, 65 patients (89%) have achieved criteria for optimal stent placement with mean MLA of 6.0 ± 3.3mm2 post-procedure.

Regarding the clinical outcomes of patients in our study, the In-hospital, 1-month and 12-month clinical outcomes were similar between both groups. Rates of in-hospital acute renal failure,

bleeding, neurological events and the adverse cardiac events were statistically non-significant between both groups. Both primary and secondary end points were similar between the two studied groups with no statistically significant difference.

In the study conducted by Wakabayashi, et al. [11], In-hospital and 30-day outcomes were similar between the 2 groups. Incidence of myocardial infarction post PCI was high in both groups, but not affected by IVUS use (12.5% vs. 13.5%, P = 0.57). Rates of in hospital acute renal failure, bleeding, and neurological events were non-significant between the 2 groups. 1-year MACE was significantly less in patients who underwent IVUS-guided PCI with significantly lower incidence of cardiac deaths.

Yun, et al. showed that there was no significant difference in total MACE between IVUS guided and angiography guided PCI groups (14.8% vs. 18.8% p = 0.12). However, IVUS guidance reduced the incidence of stent thrombosis (1.0% vs. 2.8% p = 0.05) and in-stent restenosis (ISR) (11.0% vs.15.8% p = 0.04) compared with angiography guidance [16].

In OPTICUS study, the in-hospital clinical outcome was non-significant between both groups except for significantly higher incidence of repeat PCI in the angiography guided PCI group versus no patients underwent repeat PCI in the ultrasound-guided stenting group (P = 0.030). Clinical follow-up after 6 and 12 months showed non-significant incidence of major adverse cardiac events between both groups [15].

In a study conducted by Jakabcin, et al. 210 patients were randomly assigned to receive DES either with (N = 105) or without (N = 105) IVUS guidance. After 18-month follow-up, there was no significant difference between both groups regarding MACE (11% vs. 12%; P = NS). Stent thrombosis has occurred less in the IVUS guidance group (4 "3.8%" vs. 6 "5.7%" patients) but with no statistical significance. They concluded that routine IVUS guidance during PCI with DES implantation is not superior over standard high-pressure post-dilatation regarding the incidence of MACE at 18-month follow-up [19].

The AVIO trial has evaluated IVUS guided vs angiographically guided PCI with DES implantation in 284 patients with complex lesions. The in-hospital outcomes were non-significant between both groups. At 24-months clinical follow-up, no differences were still observed in cumulative MACE (16.9% vs. 23.2 %) [20].

Regarding our study, a strategy of routine IVUS for drug-eluting stent implantation in complex coronary lesions did not improve the 1-year MACE rates. These results were in contrast to the results of the meta-analysis done by Dong-Ho Shin, et al. [21] who concluded from a total of 2,345 patients from 3 randomized trials (included patients with complex coronary lesions) that compared with angiographic guidance, IVUS-guided new-generation DES implantation was associated with favorable outcomes in terms of major adverse cardiac events, the composite of cardiac death, myocardial infarction, or stent thrombosis. The conflicting data with our results may be attributed to the large number of patients in the meta-analysis compared to our number of patients.

Limitations

The study population sample was small and in addition, it was a single center study. So, a multi-center randomized trial with a larger study population demonstrating the clinical usefulness of IVUS in complex coronary lesions intervention is required.

Conclusions

Use of IVUS is associated with lower amount of radiographic contrast used during the procedure, more procedural time, more post dilatation and less postintervention final diameter stenosis. In addition, use of IVUS in complex lesions allows optimizing PCI procedures and stent apposition. A strategy of IVUS for stent implantation in complex coronary lesions didn't reduce the 1-year MACE rates and thus, isn't recommended routinely.

Disclosures

All authors had no conflict of interest to disclose.

Declarations

Ethics approval and consent to participate

The study was approved by the Research Ethics Committee (Faculty of Medicine, Ain Shams University, FWA 00006444) and all patients signed an informed consent for participation in the study in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

The data sets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interest

The authors have no conflicts of interest.

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Authors' Contributions

H G: participated in the study design and coordination, performed the primary PCI procedures, followed up patients and drafted the manuscript.

A A: participated in performance and analysis of CMR studies, followed up patients, performed data collection and statistical analysis.

K D: participated in performance and analysis of CMR studies.

A S: participated in performance and analysis of CMR studies, followed up patients, performed data collection and statistical analysis.

- All authors read and approved the final manuscript.

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