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Comparison of Immediate and Intermediate-Term Outcomes of Intravascular Ultrasound-Guided Versus Angiography-Guided Intervention for Type C Coronary Lesions

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ABSTRACT

Background: the intravascular ultrasound (IVUS) is an invasive access technique that allows analysis of characteristics (qualitative and quantitative) of coronary atherosclerosis. Percutaneous coronary intervention (PCI) of complex lesions (i.e., American College of Cardiology/ American Heart Association class type C) remains challenging and the outcome may be compromised. The use of intravascular ultrasound (IVUS) to guide PCI was suggested to improve outcome.

The Objectives: aim of this study was to compare intravascular ultrasound-guided and angiography-guided Intervention for Type C coronary lesions regarding major adverse cardiac events (MACE).

Patients and Methods: 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. 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. Mean follow-up duration was 12 months. **Results:** baseline clinical characteristics were similar in both patient groups. 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. Regarding the target coronary vessel in our study 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. Patients with IVUS-guided PCI underwent more direct stenting, more postdilatation, larger maximal stent diameter and greater number of implanted stents. Consequently, the final diameter stenosis was significantly better in IVUS guided group. A strategy of routine IVUS for drug-eluting stent implantation in complex coronary lesions did not improve the 1-year MACE rates.

Conclusion: use of intravascular ultrasound (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 intravascular ultrasound (IVUS) in complex lesions allows proper assessment of minimal lumen area, optimizing PCI procedures and confirming stent well apposition.

Keywords: intravascular ultrasound, major adverse cardiac events.

INTRODUCTION

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

In theory, the use of IVUS could improve the long-term results of angioplasty with stent implantation. These better results derive from at least three factors: the confirmation that there is no significant residual stenosis or that artery

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dissection did not occur; definite identification and removal of the calcified plaque that limits stent expansion; visualization of an optimal luminal gain[2].

Percutaneous coronary intervention (PCI) remains challenging for high-risk patient groups, especially those with type C lesions, and their outcomes are often compromised[3–5]. It is further known that IVUS guidance of stent implantation may result in more effective stent expansion as compared to angiographic guidance alone[6]. Thus, it is plausible that IVUS guidance may 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 examined in detail.

An American College of Cardiology/American Heart Association (ACC/AHA) classification was applied to differentiate between the complexities of the target lesions for PCI and to suggest that more complex lesions are associated with lower procedural success rates and poorer late outcomes. Class C lesions are considered to have the highest degree of lesion complexity[10]. Percutaneous coronary intervention (PCI) of complex lesions (i.e., American College of Cardiology/ American Heart Association class type C) remains challenging and the outcome may be compromised. The use of intravascular ultrasound (IVUS) to guide PCI was suggested to improve outcome[11].

PATIENTS AND METHODS

The 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 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.

An American College of Cardiology/American Heart Association (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:

Patients referred for elective PCI of type C lesions for a period of 1 year.

Exclusion criteria:

1) Patient presenting with acute myocardial infarction either STEMI or NSTEMI
2) Patients presenting with cardiogenic shock or cardiac arrest.
3) Patients presenting with type A or B coronary lesions
4) Acute renal failure.
5) 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 was 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, predilatation, postdilatation, cutting balloon use, prediameter 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 Corp./SCIMED, Minneapolis, MN, USA) or Eagle Eye (Volcano Therapeutics, Inc., Rancho Cordova, CA, USA) 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.

Major adverse cardiovascular events (MACE), a composite end-point of all-cause mortality, acute myocardial infarction, and target lesion revascularization (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].

.C-Statistical analysis:

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 20. Qualitative data were presented as number and percentages while quantitative data with parametric distribution were presented as mean, standard deviations and ranges.

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***.

RESULTS

I- Baseline Clinical Characteristics

1) Demographics and clinical history

Baseline characteristics of the study population were similar between the 2 groups. 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 **(Figure 1,2)**.

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 and Figure 3).**

II-Angiographic and Procedural Characteristics (Lesion-Based)

1)Target coronary vessel and Lesion Location (Table 2,3 and Figure 4,5)

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.

2) Procedural details (Table 4,5)

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 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.

3)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%). 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)**.

III- 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.7,8,9 and Figure 6)**.

DISCUSSION

The introduction of the drug-eluting stent (DES) has contributed to a significant reduction in in-stent restenosis and repeat revascularization. However, despite the use of the DES, percutaneous coronary intervention (PCI) of complex coronary lesions still remains challenging because the prevalence of in-stent restenosis and stent thrombosis.

Intravascular ultrasound (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 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.

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

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.

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). 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.

Optimization with ICUS to reduce stent restenosis study (**OPTICUS study**) was conducted between October 1996 and February 1998. a total of 550 patients were randomized (273 to ultrasound-guided stent implantation and 277 to angiography-guided stent implantation) at 26 centers. There were no differences between the 2 study groups with respect to baseline clinical and angiographic characteristics. In the ultrasound guided group, the number of balloons used and volume of contrast medium were higher, and fluoroscopy and total procedural time were longer[15].

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 value= 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 value= 0.049).

Patients with IVUS guided PCI underwent similar percentage of predilatation (56.16% vs. 59.15%), P value= 0.846) and more postdilatation (90.41% vs. 47.89%, P value <0.001). 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 (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 predilatation (40.0% vs. 46.8%, P=0.005), more postdilatation. (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 ± 11% vs. 7 ± 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±3.3 mm2, with proximal and distal reference areas of 8.8±3.3 and 5.9±2.5 mm2, respectively; the MLD was 2.8±0.3 mm, with proximal and distal reference diameters of 3.3±0.4 and 2.7±0.4 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. 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.

In the study conducted by Wakabayashi et al., In-hospital and 30-day outcomes were similar between the 2 groups Importantly, post procedure MI, while high in both groups, was not affected by use of IVUS (12.5% vs. 13.5%, P = 0.57). Further, there were no significant differences between groups in the rates of in hospital acute renal failure, bleeding, and neurological events. Overall, the primary end-point (1-year MACE) occurred in 169 patients (13.3%). The incidence was significantly less in patients who underwent IVUS-guided PCI as compared to those in whom the procedure was guided by angiography alone (70 [11.0%] vs. 99 15.6%], P = 0.017). Among the secondary

end-points, all-cause mortality tended to be lower when IVUS guidance was employed (37 [5.9%] vs. 53 [8.4%], P = 0.077). Further, the incidence of cardiac deaths was significantly lower in the IVUS-guided cohort (12 [1.9%] vs. 28 [4.4%], P = 0.010).

In the study conducted by Yun et al., there was no significant difference in total MACE between IVUS guided PCI and angiography guided PCI groups (14.8% vs. 18.8% p=0.12). However, IVUS guidance reduced the development of stent thrombosis (1.0% vs. 2.8% p=0.05) and ISR (11.0% vs.15.8% p=0.04) compared with angiography guided PCI group[15].

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.

Jakabcin et al. conducted a study to assess the role of the intravascular ultrasound (IVUS) during implantation of Drug-eluting stents (DES) on long-term outcome in patients with complex coronary artery disease and high clinical risk profile with special attention to the development of late stent thrombosis (LST). Two hundred and ten patients were randomly assigned to receive DES either with (N = 105) or without (N = 105) the IVUS guidance. At the 18-month follow-up, there was no significant difference between both groups regarding MACE (11% vs. 12%; P = NS). Stent thrombosis has occurred in four patients (3.8%) in the group with and in 6 patients (5.7%; P = NS) in the group without the IVUS guidance. The trial has failed to demonstrate the superiority of routine IVUS guidance during DES implantation over standard high pressure postdilatation regarding the incidence of MACE at 18-month follow-up[19].

The **AVIO trial**, Randomized, multicenter, international, open label, investigator-driven 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). During hospitalization, no patient died, had repeated revascularization, or a Q-wave MI. No difference was observed in the occurrence of non-Q wave MI (6.3% in IVUS vs. 7.0% in angio-guided group). At 24-months clinical follow-up, no differences were still observed in cumulative MACE (16.9%vs. 23.2 %), cardiac death (0%vs. 1.4%), MI (7.0%vs. 8.5%), target lesion revascularization (9.2% vs. 11.9%) or target vessel revascularization (9.8% vs. 15.5%), respectively in the IVUS vs. angio-guided groups. In total, only one definite subacute stent thrombosis occurred in the IVUS group. A benefit of IVUS optimized DES implantation was observed in complex lesions in the post-procedure minimal lumen diameter but no statistically significant difference was found in MACE up to 24 months[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. A randomized trial with a larger study population demonstrating the clinical usefulness of IVUS in complex coronary lesions intervention is required.

REFERENCES:

1- ***Guimarães JI, Abizaid A, Costantine C et al.*** **(2003**): Guidelines for the indications of intracoronary ultrasonography in clinical practice. *Arq Bras Cardiol*.,81(2):1-10.

2- ***Figueiredo Neto JA De, Nogueira IAL, Figueiro MF, Buehler AM and Berwanger O*** **(2013):** Angioplasty guided by intravascular ultrasound: meta-analysis of randomized clinical trials. *Arq Bras Cardiol.*, 101(2):106-116.

3- ***Madan P, Elayda MA, Lee VV and Wilson JM*** **(2008):** Predicting major adverse cardiac events after percutaneous coronary intervention: the Texas Heart Institute risk score. *Am Heart J*., 155(6):1068-

1074.

4- Romagnoli E, Burzotta F, Trani C *et al.* (2009): EuroSCORE as predictor of in-hospital mortality after percutaneous coronary intervention. *Heart*, 95(1):43-48.

5- *Ito H, Nussbaum M, Hermiller JB et al.* (2011): An integer based risk score for predicting 30-day major adverse cardiac or cerebrovascular events after percutaneous coronary intervention with drug-eluting stents: results from a large prospective multicentre registry, the STENT Group. EuroIntervention, 6(8):942-948.

6- *Fitzgerald PJ, Oshima A, Hayase M et al.* (2000): Final results of the Can Routine Ultrasound Influence Stent Expansion (CRUISE) study. *Circulation*, 102(5):523-530.

7- *Gil RJ, Pawłowski T, Dudek D et al.* (2007): Comparison of angiographically guided direct stenting technique with direct stenting and optimal balloon angioplasty guided with intravascular ultrasound. The multicenter, randomized trial results. *Am Heart J*., 154(4):669-675.

8- *Russo RJ, Silva PD, Teirstein PS et al.* (2009): A randomized controlled trial of angiography versus intravascular ultrasound-directed bare-metal coronary stent placement (the AVID Trial). *Circ Cardiovasc Interv*., 2(2):113-123.

9- *Oemrawsingh PV, Mintz GS, Schalij MJ, Zwinderman AH, Jukema JW, van der Wall EE.* (2003): Intravascular ultrasound guidance improves angiographic and clinical outcome of stentimplantation for long coronary artery stenoses: final results of a randomized comparison with angiographic guidance (TULIP Study). *Circulation*, 107(1):62-67.

10- *Krone RJ, Shaw RE, Klein LW et al*. (2003): Evaluation of the American College of Cardiology/American Heart Association and the Society for Coronary Angiography and Interventions lesion classification system in the current "stent era" of coronary interventions (from the ACC-National Cardiovascular. *Am J Cardiol*., 92(4):389-394.

11- *Wakabayashi K, Lindsay J, Romaguera R et al.* (2012): Utility of Intravascular Ultrasound Guidance in Patients Undergoing Percutaneous Coronary Intervention for Type C Lesions. *J Am Coll Cardiol*., 59(13): E111.

12- *Mintz GS, Nissen SE, Anderson WD et al.* (2001): American College of Cardiology clinical expert consensus document on standards for acquisition, measurement and reporting of intravascular ultrasound studies (IVUS). *J Am Coll Cardiol*., 37(5):1478-1492.

13- *Di Mario C, Görge G, Peters R et al.* (1998): Clinical application and image interpretation in intracoronary ultrasound. Study Group on Intracoronary Imaging of the Working Group of Coronary Circulation and of the Subgroup on Intravascular Ultrasound of the Working Group of Echocardiography of the Eu. *Eur Heart J*.,19:207-229.

14- *Hausmann D, Erbel R, Alibelli-Chemarin MJ et al.* (1995): The Safety of Intracoronary Ultrasound: A Multicenter Survey of 2207 Examinations. *Circulation*, 91(3):623-630.

15- *Mudra H, di Mario C, de Jaegere P et al.* (2001): Randomized comparison of coronary stent implantation under ultrasound or angiographic guidance to reduce stent restenosis (OPTICUS Study). *Circulation*,104(12):1343-1349.

16- *Yun HE, Chae JK, Lee SW et al.* (2010): The impact of IVUS guided PCI for complex lesion on long-term clinical outcomes in a real-world practice. EuroIntervention, 21:22-25.

17- *Kastrati A, Dibra A, Mehilli J et al.* (2006): Predictive factors of restenosis after coronary implantation of sirolimus- or paclitaxel-eluting stents. *Circulation*, 113(19):2293-2300.

18- *Hong SJ, Kim MH, Ahn TH et al.* (2006): Multiple predictors of coronary restenosis after drug-eluting stent implantation in patients with diabetes. *Heart*, 92(8):1119-1124.

19- *Jakabcin J, Spacek R, Bystron M et al*. (2010): Long-term health outcome and mortality evaluation after invasive coronary treatment using drug eluting stents with or without the IVUS guidance. Randomized control trial. HOME DES IVUS. *Catheter Cardiovasc Interv.*, 75(4):578-583.

20- *Chieffo A, Latib A, Caussin C et al.* (2013): A prospective, randomized trial of intravascular-ultrasound guided compared to angiography guided stent implantation in complex coronary lesions: the AVIO trial. *Am Heart J.*, 165(1):65-72.

TABLES AND FIGURES

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

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
LV EF<40%	3	6.0%	1	2.0%	1.042	0.307

Table (2): Target coronary lesion in both 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

Table (3): Lesion Location 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

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 = 50	No = 50	t/X^2*	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 (5): Procedural details in the studied groups

Variable		IVUS Guided	Angiography Guided	Independent t-test	
		No = 73	No = 71	t/X^2*	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 (6): IVUS analysis in IVUS Guided group

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%)

Table (7): In-hospital outcome in the studied groups

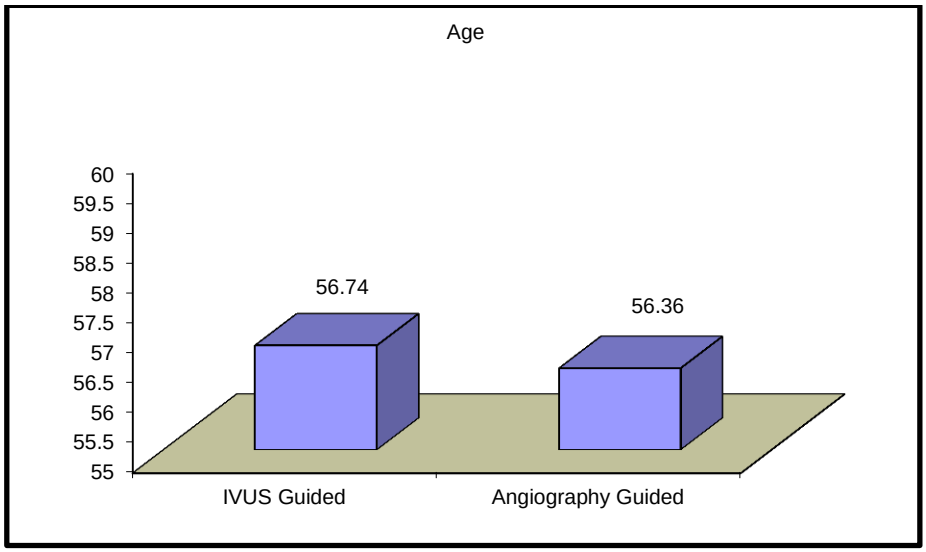
Variable	**IVUS Guided**		**Angiography Guided**		**Chi-square test**	
	No = 50		**No = 50**			
	No.	**%**	**No.**	**%**	**X^2**	**P-value**
MACE	0	0.0%	2	4.0%	2.041	0.153
All-cause death	0	0.0%	1	2.0%	1.010	0.315
Cardiac death	0	0.0%	0	0.0%	NA	NA
CABG in hospital	0	0.0%	0	0.0%	NA	NA
Post procedural 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

Table (8): 30-Day outcome in the studied groups

Variable	**IVUS Guided**		**Angiography Guided**		**Chi-square test**	
	No = 50		**No = 50**			
	No.	**%**	**No.**	**%**	**X^2**	**P-value**
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 (9): 12-month outcome in the studied groups

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



Figure(1): Mean age (years) in the studied groups

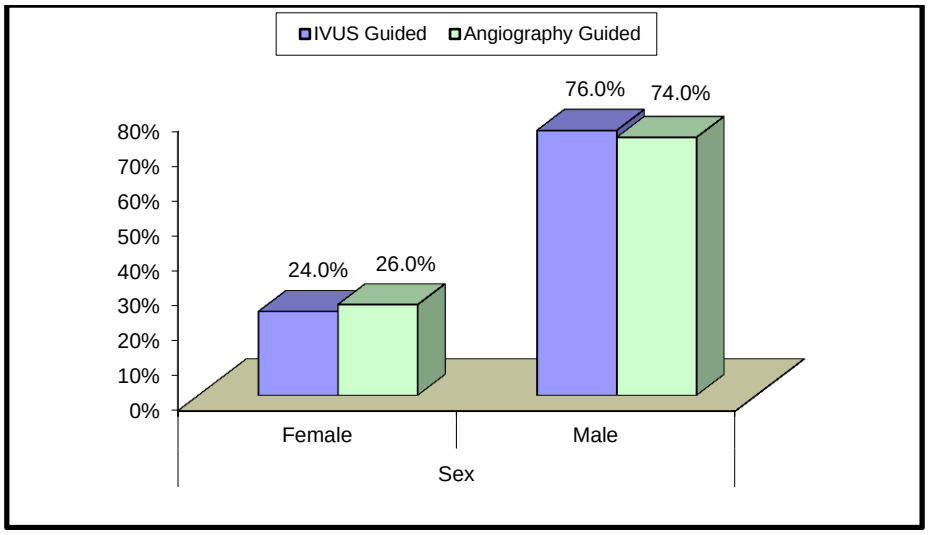


Figure (2): Gender distribution in the studied groups

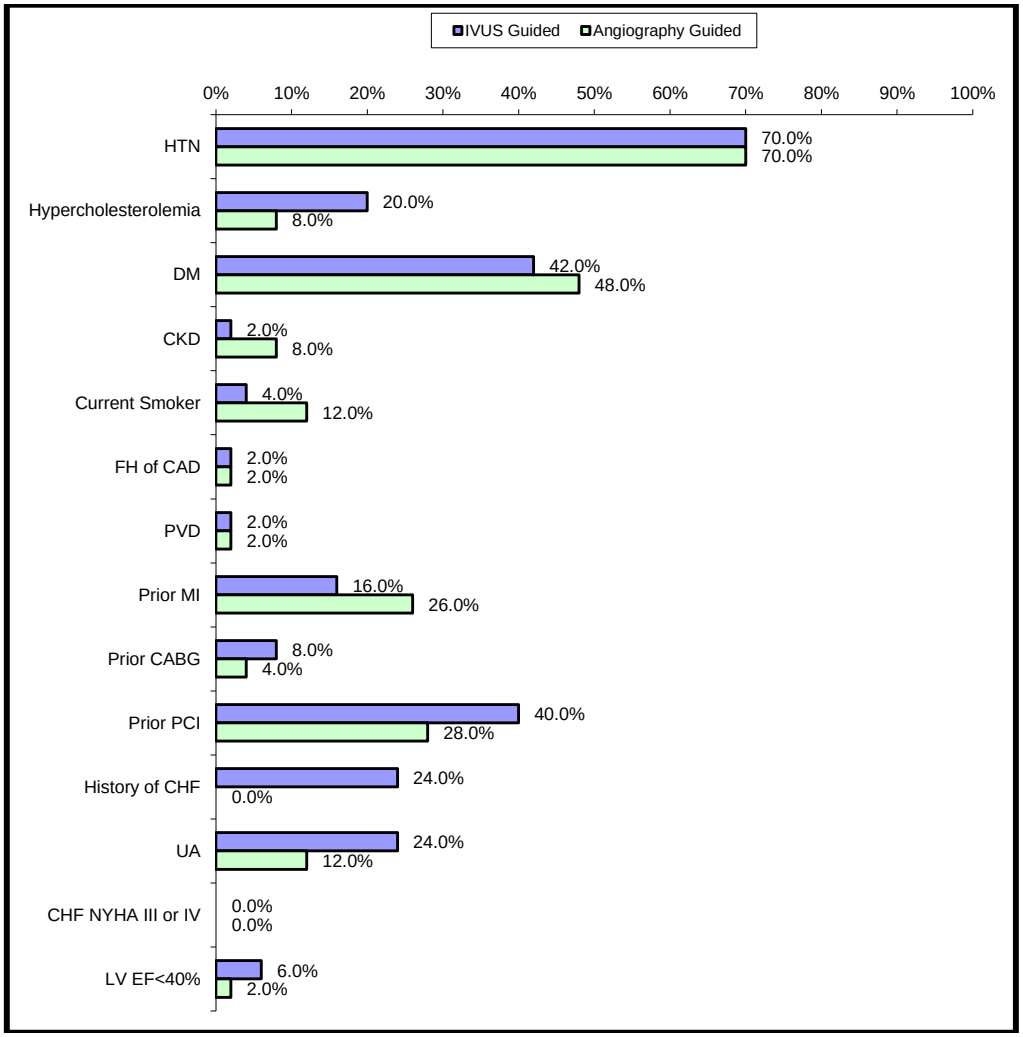


Figure (3): Patients demographics and clinical history in the studied groups

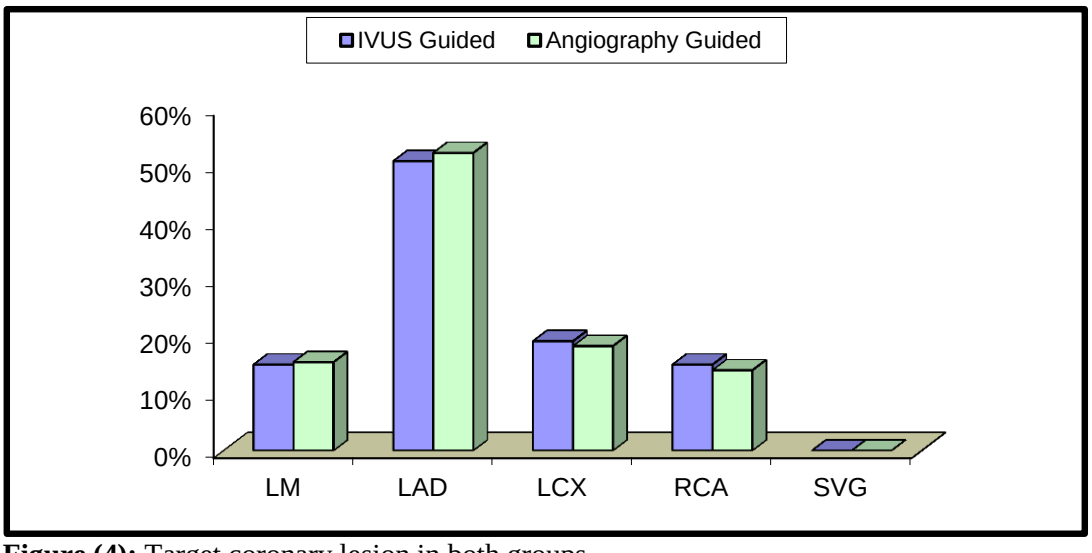


Figure (4): Target coronary lesion in both groups.

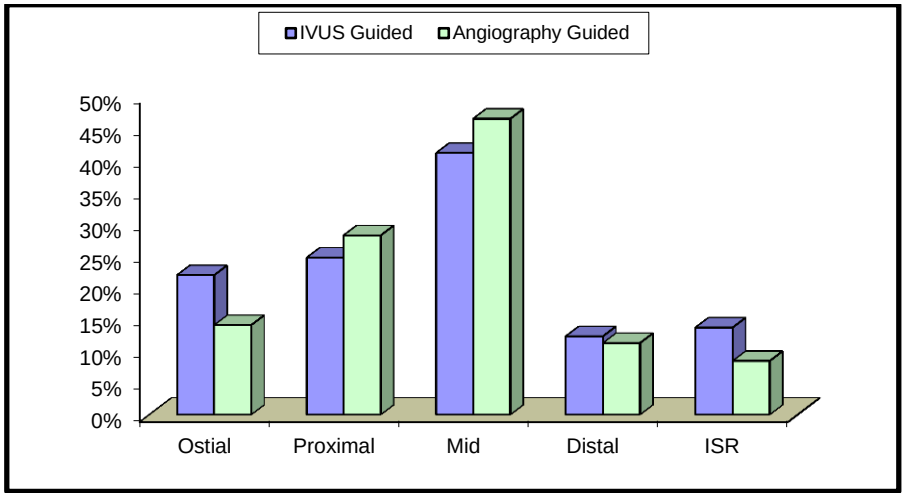
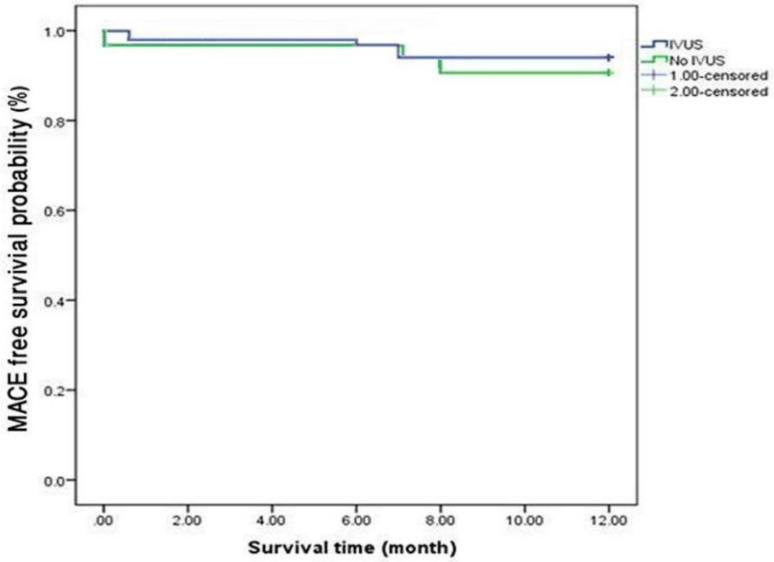


Figure (5): Lesion Location in both groups.



P value= 0.644

Figure (6): Kaplan-Meier curve illustrating freedom from MACE in IVUS and no IVUS groups over 12 months