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Clinical Outcomes and Prevalence of Intravascular Ultrasound Use at a Tertiary Care Hospital in a South Asian Country

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ABSTRACT

Objectives: Intravascular ultrasound (IVUS) plays a pivotal role in the current era of coronary interventions. We aimed to determine the prevalence of IVUS use and clinical outcomes of IVUS-guided percutaneous treatment of coronary arteries lesions in a South Asian country.

Material and Methods: It is a retrospective observational study, a total of 134 consecutive patients having done IVUS, was enrolled from January 2013 to March 2020 at a single center.

Results: Out of 134 patients, 97 (72.4%) were male with a mean age of 63.1 ± 12.9 years. The prevalence of IVUS in our center was 3.0%. The most frequent comorbidity observed was dyslipidemia, *n* = 111 (82.8%). Non-ST-elevation myocardial infarction, *n* = 50 (37.3%), was the common mode of presentation. On coronary angiogram, the left main (LM) disease was found in *n* = 46 (34.3%), however, single-vessel disease, *n* = 51 (38.1%), was most commonly noted. IVUS utilization was higher in the left anterior descending, *n* = 94 (70.1%), followed by LM, *n* = 46 (34.3%). The LM mean minimal luminal area was 6.0 ± 2.6 mm^2 and minimal luminal diameter was 4.53 mm ± 0.6 (mean). The coronary artery dissection was noted in *n* = 15 (11.2%). The mean duration of follow-up in our study was 40.3 ± 30.1 months. Major adverse cardiac events (MACEs) were recorded in *n* = 13 (9.7%), which included heart failure, *n* = 4 (3%). Cardiovascular death and target vessel revascularization occurred in *n* = 3 (2.2%).

Conclusion: IVUS results in a significant decrease in MACE. Our data might support the broader use of IVUS in both developed and in our part of the world.

Keywords: Intravascular Imaging, Coronary artery disease, Coronary artery dissection

INTRODUCTION

Intravascular ultrasound (IVUS) is an invasive imaging modality used to visualize coronary cross-sectional anatomy.[1] IVUS technology has been proven to be superior to coronary angiography in terms of the assessment of vessel size, plaque composition, vessel dissection, calcium content, and lesion severity. However, despite these benefits, routine IVUS use is limited by cost and additional time that is needed to perform the procedure.[2]

Percutaneous coronary intervention (PCI) of the left main (LM) vessel and complex lesions remains challenging with a higher risk of procedural complications and poor early and late outcomes. The role of IVUS guidance has been previously explored, however, limited

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information is available on how the pre-procedural use of IVUS might impact the intervention strategy and clinical outcome, particularly when approaching complex coronary lesions. We believe that additional information provided by IVUS beyond angiography leads to more optimal results and improving the outcome after PCI, particularly in the LM intervention.[3] Given the continuous expansion of PCI for treating sicker patients and more complex coronary lesions, we believe that IVUS plays a pivotal role in the current practice era of complex PCI.[4] In this study, we described the prevalence and clinical outcomes in current practice at a tertiary care hospital in a low- to middle-income South Asian country, Pakistan.

MATERIAL AND METHODS

This is a single-center, retrospective observational study.

Objectives

The objective of the study was to determine the clinical outcomes associated with using IVUS for percutaneous treatment of coronary arteries lesions and prevalence of IVUS use in a tertiary care hospital of low- to middle-income country.

Study population

This was a single-center retrospective observational study conducted after the approval of the ethical review committee in the Department of Medicine section of Cardiology at the Aga Khan University Hospital, Pakistan. We retrospectively studied 134 consecutive patients who had IVUS done from January 2013 to March 2020. Data were collected on a pre-designed pro forma from the patient medical record using Health Information Management Service. Total data of 71 variables were collected, including, age, gender, comorbidities at presentation, mode of hospital presentation, procedural details, IVUS details, PCI details including, dissection, stent size/length/type, discharge medications, and follow-up. Final follow-up and informed consent were taken by reviewing medical records and telephonic interviews.

Exclusion criteria

The following criteria were excluded from the study:

1. Patients who were <18 years of age and
2. Those who lost follow-up and we were unable to contact them through phone calls/e-mails.

PCI procedure

All patients were pre-medicated with aspirin and clopidogrel. Therapeutic activated clotting time was achieved during PCI using unfractionated heparin. IVUS imaging was done using 20 MHz, 2.9 French Eagle Eye® Platinum RX digital IVUS catheter (Eagle Eye, Philips Volcano San Diego, CA, USA) and data recorded. PCI was performed as per standard protocol.

Gray scale IVUS analysis

IVUS images were interpreted by interventional cardiologist and radiographer during the procedure and IVUS details were recorded on DVD-ROM for offline interpretation, which was done both after the procedure and during our study by an expert team including an interventional cardiologist, interventional cardiology fellows, and a radiographer. All IVUS data were analyzed using standard validated software. External elastic membrane (EEM) and minimal luminal area (MLA) were measured proximal to the lesion, at the lesion, and distal to the lesion. Plaque and media cross-sectional area (CSA) was calculated as EEM minus lumen CSA. A cross-sectional analysis was carried out at the MLA.

Follow-up

Follow-up of clinical events was performed by reviewing hospital medical charts, clinic visits, hospital admission, and telephonic interview with the patient or immediate family member in case if the patient was deceased or unapproachable. The clinical events recorded were cardiovascular death, all-cause mortality, non-fatal myocardial infarction (MI), arrhythmias, target vessel revascularization (TVR), admission with heart failure, and stroke. MI was defined as having typical cardiac symptoms, elevated cardiac enzymes, and/or ischemic ECG changes. Life-threatening arrhythmias were defined as ventricular tachycardia or ventricular fibrillation recorded by ECG or device interrogation. TVR was defined as PCI or application of bypass grafts for restenosis of the previously done IVUS-guided PCI.

Statistical analysis

All the data analyses were conducted using STATA software (version 14.2; StataCorp). Mean and standard deviation were computed for quantitative variables and frequencies/percentages were reported for qualitative variables. Chi-square test or Fisher's exact test was used to compare qualitative data whereas quantitative data were compared using independent *t*-test or Mann–Whitney U-test, as appropriate, considering two-sided $P < 0.05$ statistically significant.

RESULTS

A total of 134 patients who underwent IVUS imaging between January 2013 and March 2020 and fulfilled the inclusion

criteria were included in our study. Baseline characteristics are shown in Table 1. The majority of the patients included in our study were male (72.3%) and the mean age at presentation was 63.1 ± 12.9 years. The prevalence of utilization of IVUS at our center was 3% and the majority of IVUS was done in 2020 [Figure 1]. The most common comorbidity noted was dyslipidemia (*n* = 111 [82.8%]) followed by hypertension (*n* = 104 [77.6%]). Notably, non-ST-elevation MI (*n* = 50 [37.3%]) was observed to be the main reason for presentation. The most common medication prescribed at discharge was statins (*n* = 128 [99.2%]) followed by dual antiplatelet (*n* = 125 [97.9%]).

The procedural characteristics are shown in Table 2. The most common route of access adopted for the procedure in our study population was femoral access (*n* = 69 [51.5%]). Although the LM disease was found (*n* = 46 [34.3%]), single-vessel disease was most commonly noted (*n* = 51 [38.1%]). Drug-eluting stents (*n* = 92 [68.6%]) were deployed in the majority of patients.

The IVUS details are shown in Table 3. The IVUS was done mostly in the left anterior descending artery (*n* = 94 [70.1%]) followed by the LM (*n* = 46 [34.3%]). The LM mean MLA was 6.0 ± 2.6 mm^2 and the mean MLD was 4.53 ± 0.6 mm. Coronary artery dissection was noted in 11.2% of patients (*n* = 15).

In our study, we were able to collect follow-ups of all patients [Table 4]. The mean duration of follow-up in our study was 40.3 ± 30.1 months. MACE occurred in *n* = 13 (9.7%) patients, which was largely driven by heart failure (*n* = 4 [3%]). Cardiovascular death and TVR occurred in *n* = 3 (2.2%) patients.

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The IVUS details are shown in Table 3. The IVUS was done mostly in the left anterior descending, *n* = 94 (70.1%) followed by LM, *n* = 46 (34.3%). The LM mean MLA was 6.0 ± 2.6 mm^2 and the mean luminal diameter was 4.53 mm ± 0.6 [Figure1]. In our study, we found coronary artery dissection in 11% (*n* = 15) of total cases, which were either iatrogenic (before the use of IVUS in index procedure) or primary spontaneous dissection. Calcification and stent underexpansion were noted in 57.5% (*n* = 77) [Figure 2] and 34.3% (*n* = 46) [Figure 3], respectively. Dual antiplatelets aspirin (75–150 mg) and clopidogrel (75 mg) were prescribed to most of the patients who underwent revascularization at the time of discharge for 1 year and then switched to single antiplatelet.

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DISCUSSION

The results of the present study help us to acknowledge the prevalence and outcomes of IVUS guided PCI in our

Table 1: Baseline characteristics of patients.

Mean age (years)	63.1±12.9
Male (%)	97 (72.4%)
Hypertension	104 (77.6%)
Diabetes	73 (54.5%)
Dyslipidemia	111 (82.8%)
Current smoker	13 (9.7%)
Former smoker	40 (29.8%)
CKD	13 (9.7%)
Prior PCI	58 (43.2%)
Prior CABG	8 (6%)
Mean ejection fraction at presentation (%)	44.9±11.9
Mean hospital stay (days)	4.11±4.2 days
Diagnosis at presentation	
Stable angina	39 (29.1%)
Unstable angina	13 (9.7%)
NSTEMI	50 (37.3%)
STEMI	32 (23.9%)
Discharge medications	
Aspirin	125 (97.9%)
Clopidogrel	113 (87.6%)
Ticagrelor	12 (9.3%)
Statins	128 (99.2%)
Beta-blockers	115 (89.1%)
ACEi/ARBs	62 (48%)
Anticoagulants	16 (12.4%)

CKD: Chronic kidney disease, PCI: Percutaneous coronary intervention, CABG: Coronary artery bypass grafting, NSTEMI: Non-ST-elevation myocardial infarction, STEMI: ST-elevation myocardial infarction, ACEi/ARBs: Angiotensin-converting enzyme inhibitors/angiotensin receptors blockers

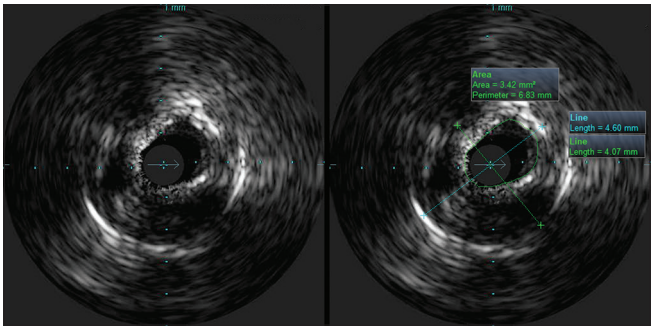

Figure 1: A 56-year-old lady came to emergency with chest pain and recurrent polymorphic ventricular tachycardia. Intravascular imaging of the left anterior descending artery done showing mean luminal area and mean luminal diameter.

Table 2: Procedural details.

Vascular access site for procedure	
Femoral	69 (51.5%)
Radial	65 (48.5%)
Angiographic details	
LM disease	46 (34.3%)
Single-vessel disease	51 (38.1%)
Two-vessel disease	21 (17.2%)
Three-vessel disease	23 (17%)
PCI details	
DES	92 (68.6%)
BMS	7 (5.2%)
POBA	18 (13.4%)
Left main stent diameter (mean)	3.52±0.4 mm
Left main stent length (mean)	25.9±8.1 mm
Other vessel's stent diameter	3.12±0.5mm
Other vessel's stent length	23.6±9.2mm
CABG	8 (6%)

LM: Left main. PCI: Percutaneous coronary intervention, DES: Drug-eluting stent, BMS: Bare-metal stent, CABG: Coronary artery bypass grafting

Table 3: IVUS details.

IVUS details (*n*=134)	
Pre-stent deployment IVUS done in	99 (73.9%)
Post-stent deployment IVUS done in	102 (76.1%)
Both pre- and post-stent deployment	67 (50%)
In-stent restenosis	36 (26.9%)
Calcifications	77 (57.5%)
Coronary dissection	15 (11.2%)
Stent underexpansion	46 (34.3%)
IVUS of LM	46 (34.3%)
IVUS of LAD	94 (70.1%)
IVUS of LCX	8 (6%)
IVUS of RCA	12 (9%)
IVUS of ramus intermedius	1 (0.8%)
IVUS of diagonal	1 (0.8%)
IVUS of graft	2 (1.5%)
LM MLA (mean)	6.0±2.6 mm
LM minimal luminal diameter (mean)	4.53±0.6 mm
Other vessels MLA (mean)	4.24±2.6
Other vessels diameter (mean)	3.98±0.6 mm

LM: Left main, LAD: Left anterior descending, LCX: Left circumflex, RCA: Right coronary artery, MLA: Minimal luminal area

population. This is the first study from Pakistan on IVUS with such an extended period of follow-up. Our analysis demonstrated that the use of this ancillary modality improves clinical outcomes of PCI in terms of MACE. Similar improvement in MACE has been noted in the previous studies from upper and upper-middle-income countries.[5-12]

The utilization rate of IVUS in our hospital is 3.0% which in comparison to upper and upper-middle-income countries

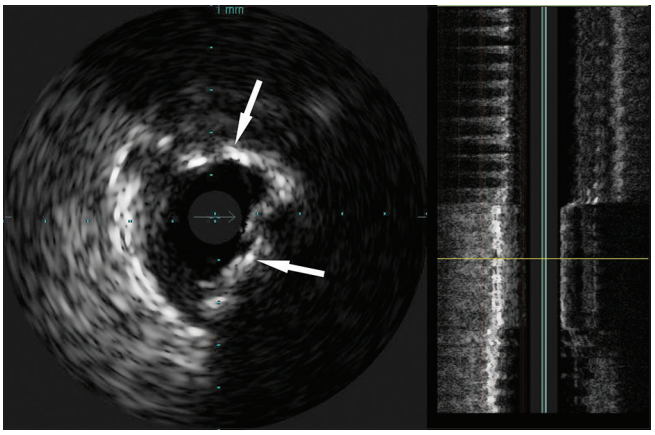

Figure 2: A 66-year-old gentleman came with complaint of unstable angina. Intravascular imaging of the left anterior descending artery done showing significant calcification (arrow).

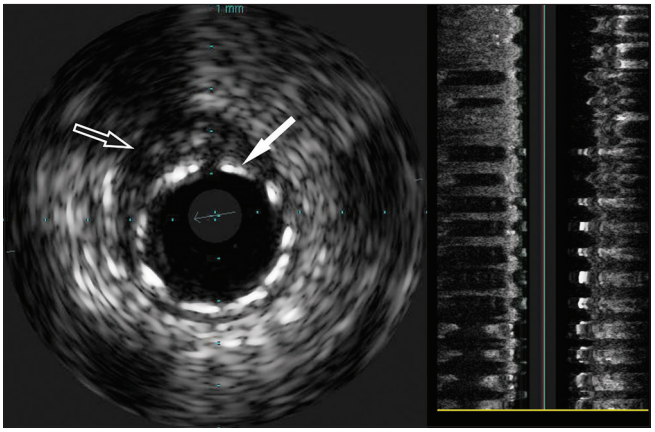

Figure 3: A 68-year-old gentleman came with complaint of stable angina. The patient had previous stenting in LAD 6 months back. Intravascular imaging of the left anterior descending artery done showing significant underexpansion of stent (Stent: Solid arrow, vessel wall: Hollow arrow).

is significantly low [Figure 4]. The use of IVUS varies in different parts of the world. Data from the USA demonstrated IVUS use in 5.6–20% of cases,[13-15] Japanese multicenter PCI registry data show IVUS use in 84% of cases,[16] in Italy, IVUS was used in 5.2% of cases in bifurcations lesions,[17] and a large center Korean registry showed IVUS use in 27.9% of cases of complex PCI.[18] The previously published data from Japan demonstrated frequent use of IVUS in the last decade and that's might be the reason for reduced mortality, stent thrombosis, and in-stent restenosis (ISR) as compared to many European countries.[15] The major reason behind low utilization of IVUS was increased cost of the procedure, additional time needed for the procedure, and lack of confidence in intravascular imaging (IVI). However, we observed an upgoing trend of utilization of IVUS in the last several years at our center. But still, the use of IVUS

technology needs a significant increase to improve both short- and long-term outcomes by decreasing incidences of iatrogenic coronary dissection, stent thrombosis, and ISR. In our study, iatrogenic coronary dissection with IVUS use was zero. Iatrogenic coronary dissection rates of 4.26% were reported by Khalid *et al.* in the IVUS arm while[7] the SIPS trial reported 3% rate of iatrogenic coronary dissection due to IVUS, with exclusion of chronic total occlusion (CTO) lesions and emergent procedures.[19] A possible explanation for this difference could be relatively smaller sample size in our study.

In our study, post-PCI IVUS evaluating stent expansion revealed suboptimal expansion in n = 46 (34%) of cases thus requiring further post-dilation. It was also observed in our study that IVUS was more frequently used post PCI for the assessment of adequate stent expansion and ruling out edge dissections in suspected cases. The higher incidence of stent underexpansion can also be explained by selection bias, with IVUS being primarily done in cases where non-optimal post-PCI results such as under expansion were suspected.

Our follow-up period in comparison to other studies was longer.[8,19] In the present data, total events rates on follow-up were 13% which is comparable to what Schroeder *et al.*,[18] observed, 14%, and were 12% in SIP trial.[19] In our study, target vessel/lesion failure was only 2.24% (n = 3), which is incredibly very low in comparison to Intracoronary Stenting and Antithrombotic Regimen trial,[20] 14.6%, SIPS trial TLR was 17%, Jeremias *et al.* have also used IVUS guidance for stent placement and found 33.3% restenosis rate at 6 months.[21] However, we need a multicenter randomized trials and further large sample size studies in this regard. The findings of our study will help to increase the confidence in utilization of IVUS and would improve clinical outcomes.

Two predominant IVI modalities are IVUS and optical coherence tomography (OCT). The basic principle of IVUS imaging is the oscillatory movement of a piezoelectric transducer (crystal), resulting in generation of sound waves when electrically excited.[1] The sound waves generated by transducers propagate through and reflect off different tissues, varying according to acoustic properties of the tissues. OCT generates images by measuring the echo time delay and intensity of light that are reflected/backscattered from the tissues. OCT has high resolution and low penetration while IVUS has lower resolution but high penetrance as compared in Table 5.[22-26] Due to scattering of light from erythrocytes, OCT requires temporary clearance of the vessel lumen using contrast injection to improve image quality.[24]

Our study has several limitations; it's a retrospective, single-center study, coronary angiography and revascularization were clinically driven, so were performed only in those patients who were symptomatic after the index procedure. IVUS use during PCI was dependent on the operator's decision either for pre-PCI assessment of lesion or post-PCI, for evaluation of stent expansion or suspicion of dissection. Detailed IVUS parameters such as plaque burden, plaque contents quantification, calcium quantification, or post-PCI measurements were not recorded.

Table 4: Follow-up details.

Follow-up (n=134)	
MACE (%)	14 (10.4%)
Cardiovascular death (%)	3 (2.2%)
Non-fatal MI (%)	3 (2.2%)
Stroke (%)	1 (0.8%)
Heart failure (%)	4 (3%)
Life-threatening arrhythmias (%)	3 (2.2%)
TVR (%)	3 (2.2%)

MACE: Major adverse cardiac event, MI: Myocardial infarction, TVR: Target vessel revascularization.

Table 5: Comparison of IVUS and OCT.[1,22-26]

	IVUS	**OCT**
Source of image	Ultrasound waves	Light waves (near infrared)
Wavelength	20–60 μm	1.3 μm
Axial resolution	20–170 μm	10–20 μm
Lateral resolution	50–260 μm	20–40 μm
Tissue penetration	4–8 mm	2–3.5 mm
Pullback type	Mechanical/manual	Mechanical
Pullback length	150 mm	Up to 150 mm
Pullback speed	0.5–1.0 mm/s	Up to 40mm/sec
Need for blood clearance	No	Yes

IVUS: Intravascular ultrasound, OCT: Optical coherence tomography. Wavelength, resolution, and penetrance vary by vendor and device used.

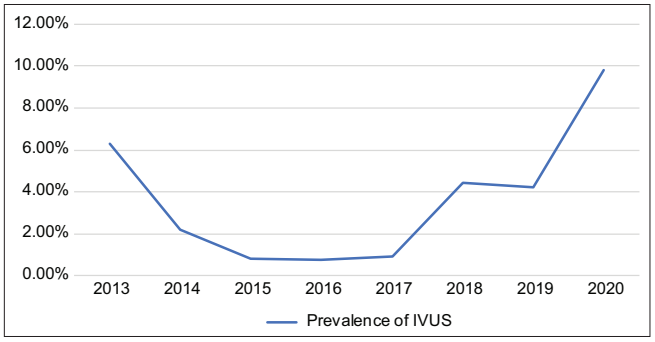

Figure 4: Prevalence of IVUS use over years 2013–2020. IVUS: Intravascular ultrasound.

CONCLUSION

IVUS technology is an adjunctive tool to coronary angiography in lesions requiring detailed assessment, stent

deployment, evaluating stent expansion, and dissection which results in a significant decrease in MACE, both in hospital and on follow-up and hence cost effective. Our data might support the broader use of IVUS in both developed and in our part of the world.

Declaration of patient consent

Institutional Review Board (IRB) permission obtained for the study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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