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Assessment of Optimum Stent Deployment by Stent Boosts Imaging: Comparison With Intravascular Ultrasound

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Abstract

Background: In-stent thrombosis and re-stenosis are common in percutaneous coronary interventions (PCI) patients, and are significantly influenced by the coronary stent under expansion. These complications can be detected by intravascular ultrasound (IVUS) which is not used routinely in daily practice, being expensive, time-consuming, and requires trained operators and laboratory staff.

Aim: The aim of the study is to compare IVUS with stent boost (SB) imaging for the evaluation of the best stent deployment.

Patients and methods: This study comprised 30 patients who underwent elective percutaneous coronary interventions with IVUS and SB and had chronic coronary artery disease with anatomical or functional evidence of ischemic coronary artery disease.

Results: The result were: SB demonstrated favorable agreement to IVUS for MSD, which improved to ideal agreement when performed at a cutoff value of 76% for MSD/distal RLD, SB was capable of detecting ideal expansion in comparison to IVUS, having 100% sensitivity and 66.67% specificity ($P = 0.005$, $AUC = 0.808$).

Conclusion: SB demonstrated favorable agreement to IVUS for MSD, which improved to ideal agreement when performed.

Keywords: Intravascular, Optimum, Stent, Ultrasound

1. Introduction

Even in the drug-eluting stent era, coronary stents under expansion have a significant role in the development of in-stent thrombosis and re-stenosis in patients having percutaneous coronary interventions (PCI).¹

Coronary intravascular ultrasound (IVUS) used to identify stent mal-apposition and provide a more accurate evaluation of stent expansion.² According to a lot of IVUS investigations, mal-apposition and inadequate stent expansion are still powerful indicators of stent thrombosis. This method is not used routinely in daily practice due to being

expensive, time-consuming, and requiring a learning curve (requiring trained operators and laboratory staff)³ complication due to IVUS are uncommon but may include dissection, vasospasm, perforation and arrhythmia.

Stent boost subtract (SBS) is a recently developed imaging technique that enhances the fluoroscopic visibility of the stent. Motion-corrected acquisition frames provide an enhanced picture of the stent's position relative to the vessel wall by simple, quick and cost-effective tool.⁴

This study aimed to compare IVUS with stent boost (SB) imaging for the evaluation of the best stent deployment.

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2. Patients and methods

All patients submitted written informed consent before the procedure, which was conducted in accordance with ethics committee approval for this study.

2.1. Inclusion criteria

Our study was a cross-sectional study that comprised 30 patients who had chronic coronary artery disease with anatomical or functional evidence of ischemic coronary artery disease and underwent elective PCI and indicated for IVUS according to (ESC) 2018 as (assessment of intermediate lesion (40%–70%) by angiography, clarifying the anatomy where angiography is unclear, assessing extent of calcification, guiding chronic total occlusion PCI and optimizing stent deployment) for comparing IVUS and SB.

2.2. Exclusion criteria

Patient refusal, while no true absolute contraindication for IVUS exist, extreme vessel tortuosity and angulation that would preclude the ability to deliver an IVU catheter to the area of interest is relative contraindication, patients with marked renal impairment e-GFR less than 30 ml/min, intolerance to antiplatelet therapy, presence of any significant co-morbid condition that severely limit patient's life span, allergy to dye severe left ventricular (LV) dysfunction 30% and conditions that preclude the use of IVUS.

2.3. Baseline and pre-procedural assessment

After the patients were admitted, they were subjected to: Informed consent and Full history taking; as regard risk factors (HTN, DM, DLP, smoking), Ischemic symptoms, prior MI, prior coronary intervention (coronary artery bypass graft, CABG & PCI) and Drug history.

2.4. History was taken as regards

Diabetes mellitus (DM): is identified when a patient exhibits symptoms of the disease [as polyuria, polydipsia, etc. ...] confirmed by abnormal blood sugar measurements (≥ 126 mg/dl fasting or ≥ 200 2 h postprandial), or Glycated hemoglobin (HbA1C) greater than or equal to 6.5%. Hypertension; according to the 2018 ESC/ESH guidelines for the treatment of arterial hypertension.⁵ Dyslipidemia; according to the 2018 ESC/ESH Guidelines for the

definition and treatment of dyslipidemia.⁵ Smoking status; smoker (present smoker or recent quitter from less than six months), ex-smoker (quitted smoking >6 months before) or nonsmoker and Drug history (antiplatelet, lipid lowering agents, etc.).

2.5. Full clinical examination

All patients would be clinically evaluated and assess risk factors: ECG: Standard 12-lead ECG for all patient after admission and after PCI and whenever indicated for detection of any ischemic change and arrhythmias, routine laboratory tests: kidney and liver function tests, random blood sugar, hepatitis markers, lipid profile, International Normalized Ratio (INR), and complete blood picture was done for all patients. Echocardiography: to detect left ventricular dysfunction.

2.6. Procedural considerations

(Angiography and PCI) the diagnosis angiograms have been acquired employing a Digital Imaging and Communications in Medicine (DICOM)-compatible digital system for arterial cannulation: *Trans*-femoral or *trans*-radial approaches with insertion of a 6 or 7 F sheathes accompanied by angiography catheters then guiding catheters of the same size, patients were given a weight-adjusted dosage of unfractionated heparin (70–100 IU/kg) then PCI guide wire 0.014 mm was passed and positioned distally in the diseased vessel across the culprit lesion. The IVUS catheter had been advanced in the coronary over a standard 0.014'guide wire under fluoroscopy guidance around 10 mm distal to an anatomical landmark (i.e., side branch) after intracoronary infusion of nitroglycerine (100–200 μ g) to reduce vasospasm, and then the IVUS catheter had been retracted slowly, IVUS assessed the distal reference lumen area (RLA), distal RLD, minimal lumen area (MLA), and plaque type and burden, hence allowed the true decision for stent deployment.

2.7. Evaluation after stent deployment

SB imaging was done immediately after stent deployment, using the deflated balloon of the inflated stent in the most appropriate projection for the imaged coronary artery segment and that showed the most obvious stent deformation and indentation, introduction of the IVUS catheter was done after withdrawing the balloon of inflated stent to obtain IVUS measures post stenting as regard minimal stent diameter and area, maximum stent

diameter and diameters at proximal and distal stent edges as well as to detect any complications, post stenting balloon Optimization of inadequately expanded stents using balloon postdilatation was done whenever necessary according to IVUS criteria for under expansion.

2.8. Modalities of coronary lesion and stent assessment

Our methods included the following assessments: IVUS assessment and SB enhancement assessment were performed pre and poststenting using the Volcano s5i IVUS system and the IVUS probe Eagle Eye Platinum ST IVUS catheter. Prestenting IVUS: IVUS study was done before stent deployment to assess lesion plaque type and burden with measurement of MLA, minimal luminal diameter (MLD) and distal RLA for detecting the optimal diameters of the needed stent.

The stent diameter has been chosen based on the distal reference lumen diameter ratio (ratio of 0.8 to the media diameter or 1 : 1 to the lumen diameter). An IVUS measurement was used to choose the stent's proximally and distally located landing areas.

According to the IVUS results and the type of plaque, predilatation has been left up to the doctor's opinion.

2.9. Definitions

Stenosis: Narrowing of the lumen by at least 50% by CSA (in comparison with a predefined reference lumen). Successive stenosis with 5 mm separation or more in a single coronary segment is said to be distinct lesions whereas those with less than 5 mm separation is considered a single long lesion Plaque burden: $(EEM\ CSA - Lumen\ CSA) / EEM\ CCA$. Lumen CSA: The area surrounded by the luminal border. Distal RLA: The site distal to a stenosis but within the same segment (usually within 10 mm of the stenosis with no intervening branches). It should have less than 40% plaque burden. MLA: The slice with the smallest lumen area. MLD: The slice with the smallest lumen diameter.

2.10. Atheroma morphology and types

The plaque can be composed of fibrous tissue, lipids, calcium, necrotic tissue or mixture of any of these components which are described as Soft (echo lucent) plaques: low echogenicity that result from high lipid content and Fibrous plaques: Intermediate echogenicity between soft and calcific plaques. Calcific plaques: highly echogenic bright echoes

that hinder ultrasound penetration 'acoustic shadowing'. Mixed Plaques: fibro calcific or fibro fatty with more than one acoustical subtype. The stent diameter had been chosen based on the distal reference lumen diameter ratio (a ratio of 0.8 to the media diameter or 1 : 1 to the lumen diameter). The landing areas for the stent proximally and distally were selected according to IVUS measurement as the locations where the plaque burden was less than 40%.

2.11. Poststenting IVUS

Was used for assessment of stent measures, apposition, and under expansion as well as detection of any complications of stent deployment: Stent Measurements Stent CSA: The area surrounded by the stent border, Minimum stent diameter: The narrowest diameter along the stent's center of mass, Maximum stent diameter: The widest diameter along the stent's center of mass and Stent symmetry index: $(Max\ SD - MSD) / Max\ SD$.

2.12. Detection of under expansion

IVUS guided detection of inadequate stent expansion was determined based on the following criteria MSA greater than or equal to 90% of the area of the distal reference lumen. Patients with a suggested stent under expansion by IVUS criteria underwent postdilatation using high pressure and Detection of complications: dissection flap, hematoma, and perforation.

2.13. Stent boost

The SB was produced by performing 20 cine frames n 3 s and using the delivery balloon's radiopaque dots as an anchor to align the stent through all frames.

SB enhancement allowed two-dimensional assessment of diameters except if taken in two perpendicular planes with area calculation. Offline manual digital reconstruction of the enhanced stent edges was acquired independently of and blinded to the SB and IVUS measurements to produce the following stent diameter measurements: Maximum, Minimum Stent Diameters, Mean Stent Diameter: automatically calculated, Stent symmetry index: $(Max\ SD - MSD) / Max\ SD$ and Diameters of the stent's proximal and distal edges.

After obtaining SB measures, they were filed for comparison and then were divided into two groups according to being well or under expanded where

the well expanded stents had MSD greater than or equal to 70% of the distal RLD.

3. Results

Figs. 1–4 and Tables 1–4.

4. Discussion

Even in the drug-eluting stent era, coronary stents under expansion have a significant role in the development of in-stent thrombosis and re-stenosis in patients having PCI Fujii and colleagues.¹

According to a lot of IVUS investigations, malapposition and inadequate stent expansion are still powerful indicators of stent thrombosis. This method is not used routinely in daily practice due to being expensive, time-consuming, and requiring a learning curve (requiring trained operators and laboratory staff) Orford and colleagues.³

SBS is a recently developed imaging technique that enhances the fluoroscopic visibility of the stent. Motion-corrected acquisition frames provide an enhanced picture of the stent's position relative to the vessel wall De Scheerder and colleagues.⁶

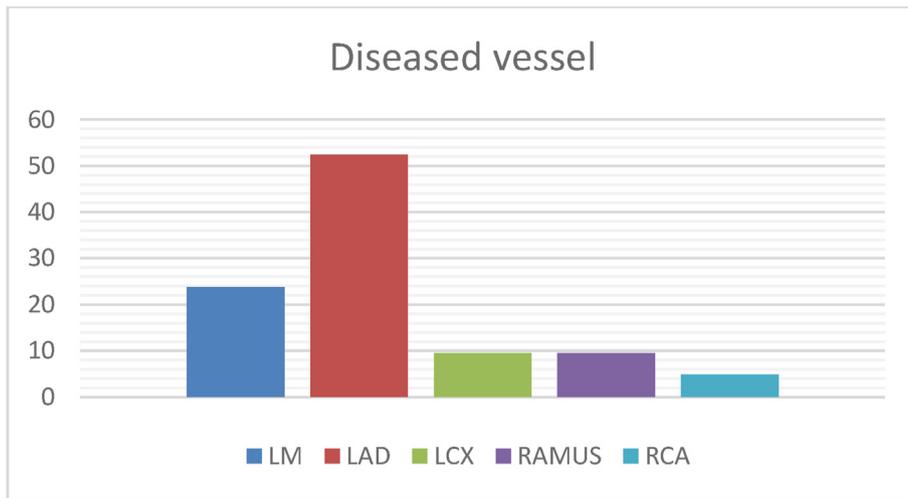
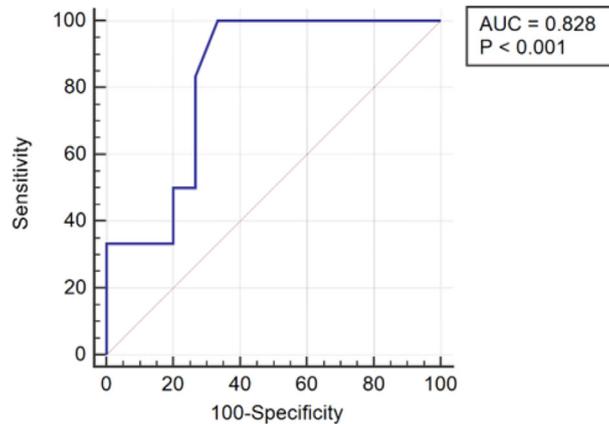


Fig. 1. Distribution of studied sample according to patient's diseased vessel.



Stent boost	IVUS		Cut off	Sensitivity	Specificity	AUC	P value
	Adequate	Inadequate					
Adequate	9	9	76	100	66.67	0.828	<0.001
Inadequate	0	12					
Adequate	9	15	70	100	33.33		
Inadequate	0	6					

Fig. 2. ROCcurve analysis between IVUS and stent boost.

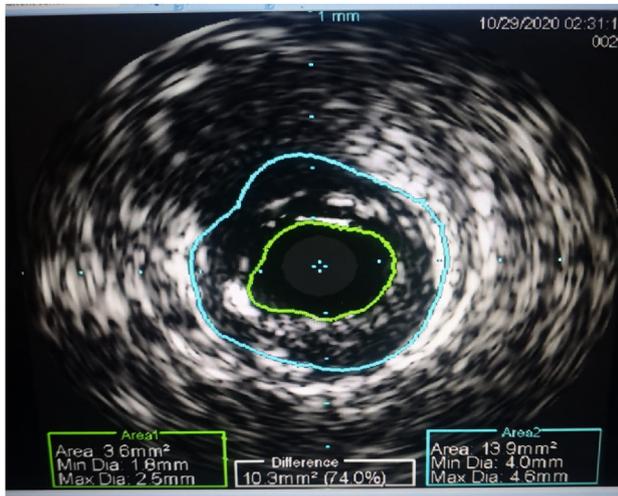


Fig. 3. IVU Smeasures.

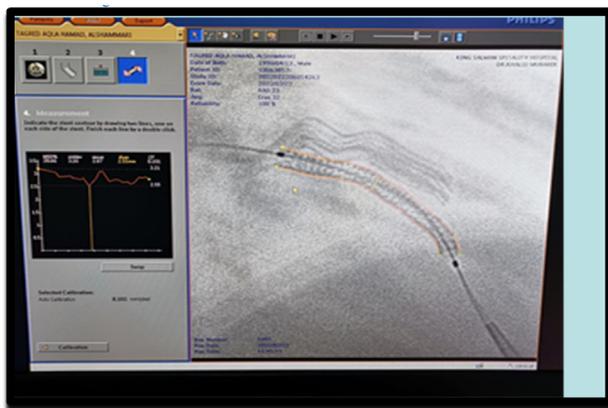


Fig. 4. SB measures.

The purpose of this study has been to assess the utility of employing SB for detecting stents under expansion by comparing stent diameters derived by SB to gold-standard IVUS measurements.

Thirty patients who had chronic coronary artery disease with anatomical or functional evidence of ischemia underwent elective PCI and favorable for using IVUS and stent boost.

4.1. Baseline demographic data

All of the participants in our study their age ranged from 48 to 65 years with mean value

Table 1. Distribution of studied patients according to demographic data.

	NUMBER (PERCENT)
Age (Years)	
Range	48–65
Mean ± S.D	57.19 ± 5.501
Sex	
Male	n = 21 (71.43%)
Female	n = 9 (28.57%)

Table 2. Distribution of studied sample according to IVUS findings.

	SB	IVUS
Maximal SD (MaxSD)		
Range	2.61–4.77	2.60–5.00
Mean ± SD	3.52 ± 0.524	3.61 ± 0.644
P	0.379	
Minimal SD (MSD)		
Range	1.47–3.53	1.8–3.9
Mean ± SD	2.50 ± 0.504	2.65 ± 0.528
P	0.343	
Mean SD		
Range	2.42–4.15	2.03–4.27
Mean ± SD	3.11 ± 0.523	2.99 ± 0.187
P	0.100	
Stent symmetry index (SI)		
Range	0.12–0.53	0.05–0.48
Mean ± SD	0.28 ± 0.09	0.26 ± 0.143
P	0.495	
Stent diameter at the proximal edge		
Range	1.47–4.77	2.10–5.00
Mean ± SD	3.08 ± 0.730	3.48 ± 0.804
P	0.076	
Stent diameter at distal edge		
Range	1.60–3.57	2.00–3.90
Mean ± SD	2.68 ± 0.584	2.82 ± 0.510
P	0.400	

Table 3. Distribution of studied sample according to plaque type.

	Number (PERCENT)
Plaque type	
Fibro fatty	n = 16 (53.3%)
Calcific	n 1 (3.3%)
Soft	n = 5 (16.6%)
Mixed	n = 8 (26.8%)
Reference luminal area (mm ²)	
Range	6.0–20.30
Mean ± S.D.	9.15 ± 3.713
Minimal luminal area (mm ²)	
Range	1.9–4.9
Mean ± S.D.	3.32 ± 0.774
Minimal stent area (mm ²)	
Range	3.9–11.8
Mean ± S.D.	6.53 ± 2.253

57.19 ± 5.5 years. Hypertension was the most prevalent risk factor (81%), followed by dyslipidemia 76.2% and diabetes 66.7% while smoking was present in 52.4% of patients. As regard prior interventions, more than half of cases (57.1%) had prior PCI and nonhad prior CABG. The range EF

Table 4. Distribution of studied sample according to diseased vessels.

Diseased vessel	Number (Percent)
LM	n = 7 (23.8%)
LAD	n = 16 (52.4%)
LCX	n = 3 (9.5%)
RAMUS	n = 2 (4.8%)
RCA	n = 2 (9.5%)

was 45–65 with mean \pm SD of (57.29 \pm 5.169%). There were 47.6% of patients who had abnormal resting wall motion.

Hypertension was the most prevalent risk factor in our patient with incidence 81%, this concurred with the previously conducted studies by Yang *and colleagues*, while in the study done by Cura and colleagues⁷ dyslipidemia was the most prevalent risk factor in 84.2% of the patients.

Mishell and colleagues⁸ studied 30 patients with mean age of 68.8 \pm 9.5 years with hypertension (67%) and dyslipidemia (61.4%) as main risk factors.

Yang and colleagues⁹ studied 52 patients with mean age' 64.62 \pm 11.78 years and mean EF 59 \pm 8% and main risk factors were hypertension (65%), dyslipidemia (59%) and smoking (41%).

Angiographic Data: in our study, LAD was the main target vessel in 52.4% of cases followed by LM in 23.8% then left circumflex artery (LCX) and RCA in 9.5% for each and finally Ramus in (4.8%).

Our results were concordant with those in other similar following studies. Although being the main indication of IVUS use, the number of LM lesions assessed by IVUS in our study and the following studies were lower than that for other vessels especially LAD lesions. The explanation is that LAD affection has large rate of occurrence and also we used of IVUS for other indications such as LAD-CTO lesions, distal LM lesions extending into LAD and assessment of LAD ambiguous hazy lesions as well as assessment of LAD instant stenosis.

In Sanidas and colleagues¹⁰ total of 42 lesions were treated: RCA (31%), LAD (28.6%), LCX (21.4%), diagonal coronary artery (7.1%), obtuse marginal (OM) (7.1%), ramus (2.4%), and LM (2.4%).

In Tanaka and colleagues¹¹ study, LAD was the culprit vessel in 65% of lesions.

In Mishell and colleagues⁸ study, patients underwent elective PCI. LAD was the culprit vessel in 48% of lesions.

In Zhang and colleagues¹² study, elective PCI for de novo ostial lesions of LAD (41%), RCA (22%), CX (19%), left main (14%) and Ramus intermedium (3%).

In Laimoud and colleagues¹³ study, LAD was the main target vessel in 78.8% of cases followed by RCA in 12.1% and CX in 9.1%.

IVUS PreStenting: IVUS was done prior to PCI which allowed accurate assessment of the distal RLA, RLD, MLA and plaque type and burden hence the decision regarding the need for pre dilatation or stent size and length.

In our study, the mean distal RLA was (13.14 \pm 20.763), the mean distal RLD was (13.14 \pm 20.763) and the mean MLA was (3.32 \pm 0.774).

Plaque characteristics of the lesions were mostly fibro fatty (52.4%), mixed (28.6%), soft (14.3%) and calcific (4.8%).

In accordance with our study, Laimoud and colleagues¹³ study most of lesions were fibrotic (68.7 \pm 11.97%) with little calcifications (4.7 \pm 4.38%).

Stents Criteria: In our study, all the deployed stents were DES of different types. Stent diameters ranged from 2.5 to 4.5 mm with Mean \pm S.D (3.50 \pm 0.518).

In Mishell and colleagues,⁸ study, the majority of the stents were of drug eluting stent types.

In Laimoud and colleagues¹³ study, most of the deployed stents were drug eluted types (87.9%).

IVUS PostStenting: IVUS was obtained after stenting and SB acquisition. It allowed for circumferential stent evaluation, whereas SB only allowed for two-dimensional assessment and could only measure diameters.

Our findings revealed MSA with mean value of 6.53 \pm 2.253, max SD with mean \pm SD of 3.61 \pm 0.644, MSD with mean \pm SD of 2.65 \pm 0.528, SI with mean \pm SD of 0.26 \pm 0.143, SD at proximal edge with mean \pm SD of 3.48 \pm 0.804 and SD at distal edge with mean \pm SD of (2.82 \pm 0.51).

IVUS revealed patients with adequate expansion according to the following criteria MSA greater than or equal to 90% of distal RLA (41, 95, 106). According to these IVUS criteria there were (30) patients who developed the criteria of optimal expansion and (75) patients who showed under expansion.

In Tanaka and colleagues¹¹ IVUS revealed inadequate stent expansion in 21 out of 72 patients according to the IVUS definition criteria for adequate stent expansion: A stent's minimum area is greater than or equal to 5.0 mm². Adequate stent deployment has been specified as MSA greater than or equal to 4.5 mm² when the reference vessel was 2.8 mm.

In Laimoud and colleagues¹³ study, IVUS assessment showed the mean stent CSA was 8.17 \pm 2.48 mm², 3.45 \pm 0.62 mm was the mean Max SD, 2.77 \pm 0.53 mm was the mean MSD, the diameter of the mean stent was 3.18 \pm 0.47 mm, and the symmetry index of the stent was 0.24 \pm 0.09.

Stent boost: in our study, SB revealed max SD with mean \pm SD of (3.52 \pm 0.524 vs 3.51 \pm 0.625), MSD with mean \pm SD of (2.50 \pm 0.504 vs 2.38 \pm 0.583), Symmetry index with mean \pm SD of (0.28 \pm 0.096 vs 0.33 \pm 0.091), SD at proximal edge with mean \pm SD of (3.08 \pm 0.730 vs 3.09 \pm 0.878) and SD at distal edge with the mean \pm SD of (2.68 \pm 0.584 vs 2.64 \pm 0.611). In accordance with our study, Laimoud. 14. study Most of lesions were fibrotic (68.7 \pm 11.97%) with little calcifications (4.7 \pm 4.38%).

We measured the MSD by SB in the appropriate projection view for the coronary segment that showed the clearest stent borders. We used the following SB criteria to detect adequate stent expansion: The minimal stent diameter greater than or equal to 70% of the reference diameter Orford and colleagues.³

MSD was significantly higher by IVUS versus quantitative coronary angiography (QCA) ($P.001$) and SB versus QCA ($P.001$) in the Laimoud¹³ study, where Max SD was significantly higher by IVUS versus QCA ($P.009$) and SB versus QCA ($P.001$). The stent symmetry index was significantly higher with IVUS than with QCA ($P.001$) and with SB than with QCA ($P.001$). QCA had a positive correlation with IVUS measures of Max SD ($P < 0.0001$ and r 0.69) and Min SD ($P < 0.0001$ and r 0.63). QCA had positive links to SB measures of Max SD ($P < 0.0001$ and r 0.61) and MSD ($P.003$ and r 0.49).

In Sanidas and colleagues¹⁰ study (171), QCA tended to underestimate the measures of MSD when compared with SB or IVUS (2.2 ± 0.5 vs 2.6 ± 0.4 vs 2.5 ± 0.5) but gives comparable measures of edge diameters (2.8 ± 0.5 vs 2.8 ± 0.4 vs 2.7 ± 0.5).

Tanaka and colleagues study in stent boost, MSD was 2.6 ± 0.5 mm. MSA was calculated by minimum stent diameters of two orthogonal directions and was $5.8\pm 2.1\text{mm}^2$. Seven patients were classified as having inadequate stent expansion by the pre-defined criteria.

Our results agreed with Sanidas and colleagues¹⁰ because: proximal and distal edges are fitted to reference luminal segments which almost have no plaque burden, condensation of plaque burden and its probable protrusion through stent struts may affect amount of residual lumen filled with dye, technical issues related to edge deviations.

Correlation of SB and IVUS: Our findings showed no statistically significant differences in max SD, MSD, SI, or stent diameters at the proximal or distal stent edges between IVUS and SB. There were no detectable complications from Ivus-post PCI.

Bland–Altman analysis revealed good agreement between IVUS and SB regarding MSD, and when we compared Bland-Altman analysis demonstrated optimal agreement in MSD between SB and IVUS (which could be attributed to the physical properties of the Xience stent in terms of metal type or strut thickness).

ROC curve analysis for comparison between SB and IVUS regarding optimal expansion detection according to the predefined criteria [(MSA/distal RLA greater than or equal to 90% by IVUS) vs (MSD/distal RLD greater than or equal to 70% as a cutoff point by SB)] revealed that SB was capable of detecting optimal

expansion with 100% sensitivity and 33.33% specificity (P -value = 0.005, AUC = 0.808). According to our results, the best SB cutoff value criteria of MSD/distal RLD was 76% with 100% sensitivity and 66.67% specificity ($P = 0.005$, AUC = 0.808).

In comparison to our study, Tanaka and colleagues¹¹ study, predicted poor IVUS results with 100% specificity, 33% sensitivity, and 81% agreement. They claimed that even while the SB image's sensitivity for determining a sufficient stent deployment was poor, its specificity was good enough for it as the first line of surveillance right following stent insertion in centers where IVUS is not frequently employed.

Our findings were similar to those of the Cura⁷ study, which analyzed 54 stents using IVUS and SB. MSD was significantly higher by IVUS versus QCA, SB and IVUS stent diameters had a high connection, and IVUS and SB had the best agreement.

According to Sanidas¹⁰ study (171), the correlation between ESI-based measures and IVUS was stronger ($r = 0.721$, $P < 0.0001$) than it was for QCA with IVUS ($r = 0.563$, $P < 0.0001$). When comparing ESI and IVUS, Bland-Altman analysis revealed a tendency for better agreement than when comparing QCA and IVUS (mean differences = 0.038 versus 0.121; $P = 0.19$, respectively).

When compared with QCA, Yang⁹ found that SB showed better associations for stent diameters measured using IVUS. In comparison to QCA and SB ($r = 0.973$, $P < 0.0001$) and QCA and IVUS ($r = 0.964$, $P < 0.0001$), MLD was most strongly associated with IVUS and SB ($r = 0.979$, $P < 0.0001$).

4.2. Conclusion

From the present study, we conclude that: SB demonstrated favorable agreement to IVUS concerning MSD, which became an ideal agreement, SB was capable of detecting optimal expansion in comparison with IVUS with 100% sensitivity and 66.67% specificity ($P = 0.005$, AUC = 0.808), MSD/distal RLD of 76% as a cutoff value criteria and SB can be termed IVUS of the poor, being readily available, easily interpretable, inexpensive, and can reliably detect stent under expansion.

Conflicts of interest

Authors declare that there is no conflict of interest, no financial issues to be declared.

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