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ORIGINAL ARTICLE

Evaluation of Stent Expansion during Coronary Artery Intervention by Stent Enhancement Compared with Quantitative Coronary Angiography and Intravascular Ultrasound in Diabetic Patients

Tarek Ahmed Naguib [1], Mostafa Khalifa Mousa [2], Mamdouh Hafez Abdelaziz Hafez [3*],, Baher Nabil Nashy [1]
[1]Cardiology Department, Faculty of Medicine, Zagazig University,
[2]Cardiology Department, Police Medical Complex in New Cairo,
[3]M.B.B.Ch., Faculty of Medicine, Zagazig University,
[1]Cardiology, Faculty of Medicine, Zagazig University,

[*]Corresponding author:
Mamdouh Hafez Abdelaziz Hafez

Email:
Mamdouhhafez@icloud.com

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ABSTRACT:

Background: Coronary stent under expansion has a crucial impact in the incidence of in-stent thrombosis and re-stenosis in cases subjected to percutaneous coronary interventions (PCI), even in the drug-eluting stent era. The current study aim to assess the accuracy of employing stent enhancement in order to identify stent expansion during coronary artery intervention compared with intravascular ultrasound (IVUS) and quantitative coronary angiography (QCA) in diabetic patients.

Methods: This cross-sectional study was performed on cases scheduled for elective coronary intervention at Police Medical Complex Hospital in New Cairo. All patients of the groups were subjected to complete history taking, clinical assessment, laboratory tests, and echocardiography.

Results: stent boost (or clear stent) measurements generally showed higher reliability and agreement with IVUS than QCA. stent boost measurements generally showed higher agreement with IVUS compared to QCA for both diabetic and non-diabetic cases, with the diabetic group demonstrating particularly robust agreement.

Conclusion: Stent boost (or clear stent) measurements generally showed higher agreement with IVUS compared to QCA for both diabetic and non-diabetic cases, with the diabetic group demonstrating particularly robust agreement.

Keywords: Stent, Coronary angiography, Intravascular ultrasound, Diabetes

INTRODUCTION

Coronary stent under expansion has a crucial impact in the incidence of in-stent thrombosis and re-stenosis in cases subjected to percutaneous coronary interventions (PCI), even in the drug-eluting stent era [1].

Quantitative coronary angiography (QCA) showed that having a stent under expansion elevates the risk of restenosis and stent thrombosis. However, coronary intravascular ultrasonography (IVUS) allows for a more exact measurement of stent expansion than QCA and detects stent mal-apposition [2]. Recent IVUS investigations have found that inadequate stent expansion and mal-apposition are still major predictors of stent failure. But in daily practice, this procedure is seldom employed consistently because it is costly and time-consuming, and sophisticated (requiring trained operators and skillful laboratory staff) [3].

Stent enhancement is a relatively A newly evolved imaging approach that improves stent fluoroscopic vision. Motion-corrected collection frames provide a more detailed view of the stent and its association with the vessel wall [4].

Patients who have diabetes mellitus (DM) are more susceptible than non-DM patient to have coronary artery disease (CAD). Moreover, despite advances in medications and other therapy, clinical results in CAD with diabetes are poor. When treating diabetic cases with CAD, is challengeable referring to

complex coronary lesions, more calcification, attenuated vessels, and plaques that are more vulnerable. Along with ensuring that the risk-management strategies are being properly implemented, comprehensive risk management using non-pharmacological and medical therapy is also crucial [5].

There is an increased risk of acute complications like acute coronary dissection. As atherosclerosis is diffuse, more, and longer stents are often needed. Following PCI, acute stent thrombosis is more common than in diabetics. Diabetes is one of the potential risk factors for stent restenosis. The average response to medical revascularization is weaker and less long-lasting in DM than in non-DM. Thus, surgical revascularization is the preferred approach, especially for individuals with multiple vessel disease (MVD) with inclusion of the proximal left anterior descending artery (proximal LAD), if agreeable to the participant and their family [6].

The present work aim was to assess the accuracy of employing stent enhancement in order to identify stent expansion during coronary artery intervention compared with IVUS and QCA in diabetic cases.

METHODS:

Patients:

This cross-sectional study performed on cases scheduled for elective coronary intervention at Police Medical Complex Hospital in New Cairo. The study included 50 patients who had chronic CAD with functional or anatomical evidence of ischemic CAD and underwent elective PCI and indicated for IVUS and stent boost. The present study was conducted after receiving approval from Institutional Review Board (IRB#11233) and written informed consent from all participants. The research was conducted under the World Medical Association's Code of Ethics (Helsinki Declaration) for human research.

Cases with the following characteristics were excluded; Patient refusal. 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. Known allergy to iodine contrast media. Severe LV dysfunction <30%. Conditions that preclude the use of IVUS.

Methods:

Preoperative data:

All patients of the groups were subjected to complete history taking full history taking; as regard risk factors (HTN, DM, DLP, smoking), Ischemic symptoms, prior MI, prior coronary intervention (CABG & PCI), laboratory assessment (kidney and liver function tests, random blood sugar, hepatitis markers, lipid profile, INR and complete blood picture were done for all patients) and Drug history in addition to performing echocardiography for all cases.

Procedural Considerations:

Arterial access for the procedure was achieved via trans-femoral or trans-radial approaches using 6F or 7F sheaths, followed by appropriate angiography and guiding catheters. Patients received a weight-adjusted dose of unfractionated heparin (70–100 IU/kg) to maintain adequate anticoagulation. A 0.014 mm PCI guidewire was advanced across the culprit lesion, and intracoronary nitroglycerine (100–200 mcg) was administered to prevent vasospasm. Intravascular ultrasound (IVUS) was performed over the guidewire under fluoroscopic guidance, positioned approximately 10 mm distal to an anatomical landmark, and slowly withdrawn to provide a detailed assessment of the vessel for optimal procedural planning.

Pre-stenting IVUS was conducted to assess plaque type, burden, minimal lumen area (MLA), minimal luminal diameter (MLD), and distal reference lumen area (RLA), aiding in the selection of the optimal stent size and diameter. Lesions causing ≥50% stenosis by cross-sectional area (CSA) were classified as significant, and plaque burden was calculated using (EEM CSA - Lumen CSA) / EEM CSA. Proximal and distal reference points were defined as the largest lumens 10 mm before and after the stenosis, respectively, without intervening branches. These measurements ensured precise stent selection and placement, improving procedural success and minimizing complications.

Post-stenting assessment involved IVUS and Stent Boost (SB) imaging to evaluate stent dimensions, apposition, and expansion and to detect complications such as dissection, hematoma, or perforation. Measurements included stent CSA, minimum stent diameter (MSD), maximum stent diameter, and the stent symmetry index. Under-expansion was flagged if the minimal stent area (MSA) was <90% of the distal reference lumen area, prompting high-pressure balloon post-dilatation. SB imaging, using radiopaque markers from the delivery balloon, provided a 2D stent assessment for clear visualization of deformation and indentation, ensuring adequate stent deployment.

Post-procedure, offline manual digital reconstruction of stent edges was performed independently and blinded to SB and IVUS values. Measurements included maximum and minimum stent diameters, mean stent diameter (automatically calculated), and the stent symmetry index using the formula (Max SD - MSD) / Max SD, along with proximal and distal edge diameters. SB measurements were categorized into well-expanded stents (MSD ≥70% of the distal reference lumen diameter) and under-expanded stents, allowing for precise post-procedural analysis, comparison, and statistical evaluation to optimize patient outcomes.

Statistical Analysis:

Data analysis were carried out with SPSS version 28. The Shapiro-Wilk test and direct data visualization approaches were used to determine the normality of quantitative data. Normality dictated that quantitative data presented as means±SD, or medians and ranges. Categorical data were presented as numbers and percentages. The agreement of QCA and stent boost measurement with IVUS measurement was evaluated using intraclass correlation (ICC). ICC is a measure of agreement. The reference values of ICC are as follows: <0.50 indicates poor agreement; 0.50-0.75 indicates moderate agreement, 0.75-0.90 indicates very good agreement; and>0.90 indicates excellent agreement. The 95% confidence intervals were calculated for ICC. All statistical tests were two-sided. P < 0.05 were considered significant

RESULTS

The average age of the participants was 57 years, with a standard deviation of 8 years. The cohort included 50 individuals, predominantly males (66%), with females accounting for 34%. Hypertension was present in 64%, while 80% had diabetes mellitus and 62% had dyslipidemia. Smoking history was reported in 44%, and 38% had prior PCI, while only 6% had undergone CABG. (Table 1)

The study included various stent types, with Xience (48%) being the most common, followed by ONYX (16%) and others. The mean maximal stent diameter was 3.4±0.59 mm, and the mean minimal stent diameter (MSD) was 2.68±0.56 mm, with a median stent symmetry index of 0.23. Proximal and distal edge MSDs measured 3.21±0.66 mm and 2.89±0.57 mm, respectively. Stent Boost imaging showed slightly lower values, with a mean maximal stent diameter of 3.34±0.56 mm and mean MSD of 2.58±0.54 mm, indicating minor variations in measurements across imaging modalities. (Table 2)

Mixed plaques were the most common type, observed in 34% of cases. The median reference luminal area was 8.9 mm² (range: 3.3–100 mm²), while the mean minimal luminal area (MLA) was 3.7±1.1 mm². The median minimal stent area (MSA) was 5 mm² (range: 2.9–11.8 mm²). The mean minimal stent diameter (MSD) was 2.62±0.53 mm, and the mean maximal stent diameter was 3.43±0.63 mm, with a median stent symmetry index of 0.2 (range: 0.04–3.66). Proximally, the mean stent diameter measured 3.32±0.71 mm, while distally, it was 2.83±0.51 mm. (Table 3)

Stent Boost (SB) showed higher ICC values compared to QCA for stent measurements in both overall and non-diabetic patients. For MSD, ICC was 0.451 for QCA and 0.75 for SB overall, and 0.673 for QCA and 0.764 for SB in non-diabetics. Maximal stent diameter had ICCs of 0.584 (QCA) and 0.815 (SB) overall, and 0.645 (QCA) and 0.776 (SB) in non-diabetics. Proximal edge ICCs were 0.646 (QCA) and 0.733 (SB) overall, and 0.647 (QCA) and 0.745 (SB) in non-diabetics. Distal edge ICCs were 0.415 (QCA) and 0.605 (SB) overall, and 0.535 (QCA) and 0.558 (SB) in non-diabetics. The symmetry index showed poor agreement in both groups, with ICCs of 0.215 (QCA) and 0.618 (SB) overall, and 0.02 (QCA) and 0.033 (SB) in non-diabetics. SB consistently demonstrated better reliability than QCA. (Tables 4,5)

The maximum stent diameter showed an ICC of 0.57 (p <0.001) for QCA, and 0.823 (p <0.001) for stent boost. The stent diameter at the proximal edge had an ICC of 0.648 (p <0.001) for QCA, and 0.736 (p <0.001) for stent boost. The stent diameter at the distal edge had an ICC of 0.389 (p =0.006) for QCA, and 0.603 (p <0.001) for stent boost. The symmetry index for diabetic patients had an ICC of 0.181 (p =0.132) for QCA, and 0.643 (p <0.001) for stent boost. (Table 6)

Table (1): Demographics, general characteristics, echo findings and affected vessels of the studied patients:

Demographics		
Age (years)	**Mean ±SD**	**57 ±8**
Sex		
Males	n (%)	33 (66)

Females	n (%)	17 (34)
Hypertension	n (%)	32 (64)
Diabetes mellitus	n (%)	40 (80)
Dyslipidemia	n (%)	31 (62)
Smoking	n (%)	22 (44)
Prior PCI	n (%)	19 (38)
Prior CABG	n (%)	3 (6)
Echo & affected vessels		
Ejection Fraction	Mean ±SD	56 ±7
Resting wall motion abnormalities	n (%)	18 (36)
LAD	n (%)	27 (54)
LCX	n (%)	9 (18)
LM	n (%)	6 (12)
RCA	n (%)	12 (24)
RAMUS	n (%)	2 (4)

SD: Standard Deviation; n: Number; %: Percentage; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Graft, LAD: Left Anterior Descending artery; LCX: Left Circumflex artery; LM: Left Main artery; RCA: Right Coronary Artery; RAMUS: Ramus Intermedius.

Table (2): Stent type, QCA, stent, and stent boost measurements of the studied patients:		
Stent type		
Biofreedom	**n (%)**	1 (2.0)
Firehawk	**n (%)**	6 (12.0)
ONYX	**n (%)**	8 (16.0)
Promus	**n (%)**	6 (12.0)
Ultimaster	**n (%)**	5 (10.0)
Xience	**n (%)**	24 (48.0)
QCA		
Maximal stent diameter	Mean ±SD	3.4 ±0.59
Minimal stent diameter	Mean ±SD	2.68 ±0.56
Stent Symmetry index	Median (range)	0.23 (0.004 – 0.57)
Stent diameter at prox. edge	Mean ±SD	3.21 ±0.66
Stent diameter at distal edge	Mean ±SD	2.89 ±0.57
Stent boost		
Maximal stent diameter	Mean ±SD	3.34 ±0.56
Minimal stent diameter	Mean ±SD	2.58 ±0.54
Stent Symmetry index	Median (range)	0.22 (0.05 – 0.56)
St diam at prox. edge	Mean ±SD	3.08 ±0.68
St diam at distal edge	Mean ±SD	2.79 ±0.59

Table (3): IVUS measurements in the studied patients:		
IVUS		
Plaque type		
Calcific	n (%)	8 (16)
Fibrofatty	n (%)	15 (30)

Table (4): Agreement of QCA and stent boost (clear stent) measurements with IVUS				
	QCA		**Stent boost (or clear stent)**	
	ICC (95% CI)	**P-value**	**ICC (95% CI)**	**P-value**
Minimal stent diameter	0.451 (0.195 - 0.649)	**0.001***	0.75 (0.597 - 0.85)	**<0.001***
Maximal stent diameter	0.584 (0.366 - 0.741)	**<0.001***	0.815 (0.694 - 0.891)	**<0.001***
Stent diameter at proximal edge	0.646 (0.453 - 0.782)	**<0.001***	0.733 (0.503 - 0.854)	**<0.001***
Stent diameter at distal edge	0.415 (0.156 - 0.62)	**0.001***	0.605 (0.394 - 0.755)	**<0.001***
Symmetry index	0.215 (-0.062 – 0.462)	0.064	0.618 (0.413 – 0.764)	**<0.001***
***Significant P-value; ICC: Intraclass Correlation Coefficient; CI: Confidence Interval**				
Mixed	n (%)		17 (34)	
Soft	n (%)		10 (20)	
Reference luminal area (mm)²	Median (range)		8.9 (3.3 - 100)	
Minimal luminal area (mm)²	Mean ±SD		3.7 ±1.1	
Min stent area (mm)²	Median (range)		5 (2.9 - 11.8)	
Max stent diameter (mm)	Mean ±SD		3.43 ±0.63	
Min stent diameter (mm)	Mean ±SD		2.62 ±0.53	
St symmetry index	Median (range)		0.2 (0.04 - 3.66)	
Stent diameter at prox. edge	Mean ±SD		3.32 ±0.71	
Stent diameter at distal edge	Mean ±SD		2.83 ±0.51	

Table (5): Agreement of QCA and stent boost measurements with IVUS in non-diabetics:				
	Non-diabetics			
	QCA		**Stent Boost**	
	ICC (95% CI)	**P**	**ICC (95% CI)**	**P**
Min st diameter	0.673 (0.11 - 0.908)	**0.014***	0.764 (0.287 - 0.936)	**0.004***
Max st diameter	0.645 (0.106 - 0.897)	**0.015***	0.776 (0.329 - 0.939)	**0.003***
SD at prox edge	0.647 (0.114 - 0.897)	**0.015***	0.745 (0.273 - 0.93)	**0.005***
SD at dist edge	0.535 (-0.151 - 0.863)	0.055	0.558 (-0.114 - 0.871)	**0.046***
Symm index	0.02 (-0.442 – 0.572)	0.473	0.033 (-0.596 – 0.626)	0.463
***Significant P-value; ICC: Intraclass Correlation Coefficient; CI: Confidence Interval**				

Table (6): Agreement of QCA and stent boost measurements with IVUS in diabetics:				
	Diabetics			
	QCA		**Stent Boost**	
	ICC (95% CI)	**P**	**ICC (95% CI)**	**P**
Min st diameter	0.396 (0.091 - 0.632)	**0.006***	0.747 (0.569 - 0.858)	**<0.001***
Max st diameter	0.57 (0.315 - 0.748)	**<0.001***	0.823 (0.69 - 0.902)	**<0.001***
SD at prox edge	0.648 (0.427 - 0.797)	**<0.001***	0.736 (0.458 - 0.867)	**<0.001***
SD at dist edge	0.389 (0.092 - 0.623)	**0.006***	0.603 (0.361 - 0.768)	**<0.001***
Symm index	0.181 (-0.138 – 0.465)	0.132	0.643 (0.418 – 0.794)	**<0.001***
***Significant P-value; ICC: Intraclass Correlation Coefficient; CI: Confidence Interval**				

DISCUSSION

Coronary stent under expansion has a crucial impact in the incidence of in-stent thrombosis and re-stenosis in cases subjected to PCI, even in the drug-eluting stent era [9].

The aim of this work was to assess the impact of employing stent enhancement techniques e.g. stent boost (or clear stent) to detect stent under expansion by comparing their derived stent diameters with the gold-standard values by IVUS.

This study was performed on cases scheduled for elective coronary intervention at Police Medical Complex Hospital in New Cairo. The mean age of the cases was 57 years. The cohort comprised 50 individuals, predominantly males (66%), with females making up 34%. Hypertension was prevalent in 64% of the participants, while 80% had diabetes mellitus. Dyslipidemia was observed in 62% of the cases, and 44% of the participants were smokers. A history of PCI was reported in 38% of the subjects, whereas only 6% had prior CABG.

Hypertension was the most prevalent risk factor in our patient with incidence 81%, this concured with the previously conducted reports by Jacob et al and Yang et al, while in the study done by Cura et al. [2] dyslipidemia was the most incedent risk factor in 84.2% of the patients.

Zhang et al. [4] studied 55 cases with mean age of 65.4 ± 13.9 years and with hypertension (71%), dyslipidaemia (82%) and smoking (62%) as main risk factors.

Laimoud et al. [10] studied 30 patient with a mean age of 51.83 ± 9.36 years and mean EF was 59.03± 5.93%.

The main risk factors in their study were smoking (63.3%), hypertension (63.3%) and dyslipidaemia (60%).

Also, Omran et al., [11] studied 21 individuals, predominantly males (100%), with no females. Hypertension was prevalent in 81% of the participants, while 66.7% had diabetes mellitus. Dyslipidemia was observed in 76.2% of the cases, and 52.4% of the participants were smokers. A history of PCI was reported in 57.1% of the subjects, whereas no one had prior CABG.

In our study, LAD was affected in 54% of the patients, LCX in 18%, LM in 12%, RCA in 24%, and the ramus artery in 4%.

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 in stent restenosis.

In Sanidas et al. [12] 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 Zhang et al. [4] study, elective PCI for de novo ostial lesions of LAD (41%), RCA (22%), CX (19%), left main (14%) and Ramus intermedius (3%).

In Laimoud et al. [10] study, LAD was the main target vessel in 78.8% of cases followed by RCA in 12.1% and CX in 9.1%.

In our study, all the deployed stents were DES of different types, The distribution of stent types among the participants was as follows: Biofreedom stents were used in 2% of cases, Firehawk in 12%, ONYX in 16%, Promus in 12%, Ultimaster in 10%, and Xience in 48%.. Stent diameters ranged from 2.5-4.5 mm with Mean±S.D (3.50±0.518).

In Omran et al., [11] study the distribution of stent types and their diameters among the participants was as follows: Biofreedom stents were used in 4.8% of cases, Firehawk in 14.3%, ONYX in 9.5%, Promus in 4.8%, Ultimaster in 14.3%, and Xience in 52.4%.

In Sanidas et al. [12], study, the majority of the deployed stents were 88.1% everolimus-eluting stents. The overall stent diameters were 3.0 ± 0.4 mm. In Zhang et al. [4] study, (72%) of deployed stents were drug eluting stents. In Laimoud et al., [10] study, Most of the deployed stents were drug eluted types (87.9%).

In the current study according to Agreement of QCA and stent boost measurements with IVUS: The interclass correlation coefficient (ICC) was employed to evaluate the agreement between IVUS measurements and both QCA and stent boost.

For MSD, the ICC was 0.451 (95% CI: 0.195 - 0.649) with p= 0.001 for QCA, and 0.75 (95% CI: 0.597 - 0.85) with p<0.001 for stent boost. The maximal stent diameter had an ICC of 0.584 (95% CI: 0.366 - 0.741) with a p<0.001 for QCA, and 0.815 (95% CI: 0.694 - 0.891) with a p<0.001 for stent boost. The stent diameter at the proximal edge showed an ICC of 0.646 (95% CI: 0.453 - 0.782) with a p<0.001 for QCA, and 0.733 (95% CI: 0.503 - 0.854) with a p<0.001 for stent boost. The stent

diameter at the distal edge had an ICC of 0.415 (95% CI: 0.156 - 0.62) with a p= 0.001 for QCA, and 0.605 (95% CI: 0.394 - 0.755) with a p<0.001 for stent boost.

Finally, the symmetry index had an ICC of 0.215 (95% CI: -0.062 – 0.462) with a p= 0.064 for QCA, and 0.618 (95% CI: 0.413 – 0.764) with a p=0.001 for stent boost. These results indicate that stent boost measurements generally showed higher reliability and agreement with IVUS than QCA.

Our results agree with Omran et al., [11] study, that showed insignificant differences between IVUS & SB regarding max SD, MSD, SI and stent diameters at proximal or distal stent edges.

Also there was agreement between IVUS & SB concerning MSD but less agreement between QCA and IVUS, when they compared Bland–Altman analysis in patients with Xience xpedition stent type, it demonstrated optimal agreement in MSD between SB and IVUS (might be resulting from the physical properties of Xience stent as regard metal type or strut thickness) and suboptimal agreement between QCA and IVUS.

Tanaka et al., [13] showed that SB predicted insufficient IVUS findings with a100% specificity, 33% sensitivity, and 81% agreement. Tanaka et al., [13] stated that although the sensitivity of SB imaging for appropriate stent placement was low, its specificity was good enough for it to be the first line of monitoring in locations where IVUS is not commonly employed.

The findings of the present study are comparable to Cura et al., [2] study which analyzed 54 stents using IVUS, Stent Boost and QCA and there was positive association between SBS and IVUS stent diameters and optimum compatibility between IVUS and SB although there was only little agreement between IVUS and QCA.

Sanidas et al., [12] study the ESI-based measures positively correlated with IVUS (P< 0.0001) compared to QCA with IVUS (P< 0.0001). Analysis by Bland-Altman revealed a tendency toward greater concordance between ESI and IVUS than between QCA and IVUS (0.038 vs. 0.121; P =0.19, respectively).

Zhang et al., [4] studied SBS imaging and IVUS following stenting of 58 ostial lesions in 55 individuals. All patients underwent SBS and IVUS to identify stent placement. A substantial positive association was established between MSA by SBS and MSA by IVUS.

In Laimoud et al., [10] study, there were insignificant differences between IVUS & SB concerning max SD (p= 0.53) or MSA (p= 0.07) and a substantial positive relationship were observed between both techniques and maximum SD (p< 0.0001) and MSD (p< 0.0001). In addition, there was insignificant difference in stent symmetry index between IVUS and SB in the absence of a significant connection.

In the current study according to Agreement of QCA and stent boost measurements with IVUS measurements in non-diabetics and diabetics: results indicate that stent boost measurements generally showed higher agreement with IVUS compared to QCA for both DM and non-DM cases, with the diabetic group demonstrating particularly robust agreement.

To the best of our knowledge this was the first study to discuss agreement of QCA and stent boost measurements with IVUS measurements in non-diabetics and diabetics.

Conclusion

Stent boost (or clear stent) measurements generally showed higher agreement with IVUS compared to QCA for both DM and non-DM cases, with the diabetic group demonstrating particularly robust agreement.

Conflict of interest: None.

Financial Disclosures: None.

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Citation

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