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Consensus of the National Heart Center in collaboration With the Saudi Arabian Cardiac Interventional Society on the Clinical Use of Intracoronary Imaging

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Abstract

Objectives: Studies show that intracoronary imaging (ICI)-guided PCI is associated with a significantly lower risk of stroke, Q-wave myocardial infarction, and death compared to angiography-guided PCI in the management of acute coronary syndromes, complex coronary lesions and left-main interventions. Despite these well-established clinical benefits, the utilization of ICI-guided PCI in Saudi Arabia remains suboptimal.

Methods: The National Heart Center (NHC) and the Saudi Arabian Cardiac Interventional Society (SACIS) gathered national experts to develop a consensus document on how to integrate ICI-guided PCI in routine clinical practice in Saudi Arabia. The consensus was based on the nominal group technique, whereby a committee of interventional cardiologists affiliated with the NHS and SACIS developed and discussed a number of statements on the clinical use of intracoronary imaging based on a systematic review of the literature.

Results: A total of 17 statements were discussed in light of scientific evidence and agreed upon. Initiatives to improve operator skills when it comes to image acquisition and interpretation are crucial in the incorporation of ICI-imaging guided PCI in Saudi Arabia. Local data on reference diameters and measurements and epidemiological data on Saudi patients being treated in catheterization laboratories are necessary.

Conclusions: Herein, we provide the first national consensus on the use of ICI-guided PCI in Saudi Arabia. We anticipate that this document contributes to a more optimal and integrative use of ICI-guided PCI in the Kingdom.

Keywords: Percutaneous coronary intervention, Intracoronary imaging, Intravascular ultrasound, Optical coherence tomography, Saudi Arabia

1. Introduction

Percutaneous coronary intervention (PCI) remains a cornerstone in the management of obstructive coronary artery disease (CAD). While

angiography has traditionally been the primary imaging modality guiding PCI, its limitations in offering accurate, cross-sectional visualization of the coronary lumen and vessel wall have been recognized [1]. The management of acute coronary

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syndromes and complex coronary lesions and left-main interventions using angiography-guided PCI poses a considerable challenge, largely due to the high risk of major adverse cardiac events (MACE), the potential for stent thrombosis, and the rate of in-stent restenosis (ISR) warranting repeat revascularization [2]. In an effort to mitigate these risks, adjunctive intracoronary imaging (ICI) modalities, such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT), have emerged to provide detailed insights into plaque morphology, lumen dimensions, and stent expansion, among other parameters [3,4].

Pivotal trials advocate the use of ICI-guided PCI combined with drug-eluting stents. Long-term studies showed that IVUS-guided PCI was associated with a significantly lower risk of stroke, Q-wave myocardial infarction (MI), and death compared to angiography-guided PCI [5–9]. Likewise, meta-analyses demonstrated that ICI-guided PCI was associated with a significantly lower risk of MACE than angiography-guided PCI. Regarding revascularization, the risk of target vessel revascularization (TVR) and target lesion revascularization (TLR) was also lower in the ICI-guided patients compared to the angiography-guided respectively [10–12].

Despite the well-established clinical benefits of ICI-guided PCI, its utilization remains suboptimal in several countries, including Saudi Arabia. Recent reports suggested that the lack of national consensus and tailored algorithms for using ICI-guided PCI contributed to its suboptimal use in modern PCI procedures [13]. Thus, the National Heart Center (NHC) in collaboration with Saudi Arabian Cardiac Interventional Society (SACIS) gathered national experts to develop a consensus document and workflow to integrate ICI-guided PCI in routine practice in Saudi Arabia.

2. Methods

This consensus is based on Nominal Group Technique (NGT). The NHC and the SACIS employed the NGT to develop a consensus statement on the utility of intracoronary imaging and the corresponding clinical pathway algorithm.

2.1. Committee development

We used a non-probability purposive sampling technique to recruit interventional cardiologists affiliated with the NHC and SACIS in Saudi Arabia. All experts are required to have an active license in the field of interventional cardiology by the Saudi Commission for Health Specialties. Eligible experts

List of abbreviations:

ACR	Angio co-registration
AI	Artificial Intelligence
CAD	Coronary Artery Disease
CSA	Cross-Sectional Area
CTA	Computed Tomography Angiography
EEL	External Elastic Lamina
EEM	External Elastic Membrane
EtD	Evidence to Decision
FFR	Fractional Flow Reserve
ICI	Intracoronary Imaging
iFR	Instantaneous Wave-Free Ratio
ISR	In-Stent Restenosis
IVUS	Intravascular Ultrasound
LCBI	Lipid Core Burden Index
LMCA	Left Main Coronary Lesions
LPR	Lipid-Rich Plaque
MACE	Major Adverse Cardiac Events
MI	Myocardial Infarction
MLA	Mean Luminal Area
MLD	Mean Luminal Diameter
MSA	Minimum Stent Area
NGT	Nominal Group Technique
NHC	National Heart Center
NIRS	Near-Infrared Spectroscopy
OCT	Optical Coherence Tomography
OFDI	Optical frequency domain imaging
OFR	OCT-based FFR
PCI	Percutaneous coronary intervention
QFR	Quantitative flow ratio
SACIS	Saudi Arabian Cardiac Interventional Society
TLF	Target Lesion Failure
TLR	Target Lesion Revascularization
TVF	Target Vessel Failure
TVR	Target Vessel Revascularization

vetted by the NHC directorship and subsequently participated in the consensus development. The statements were independently reviewed by an external reviewer, with an internationally-recognized contribution to the field of ICI.

2.2. Statement development

A systematic literature search was conducted on Medline via PubMed from its inception to November 2022 to collect relevant and contemporary data by the Survey development committee. Various combinations of the following keywords were used to identify potentially eligible literature: (Saudi Arabia; Consensus; Experts opinion; ICI; IVUS; OCT; PCI). The statements were primarily extracted from studies with high quality of evidence, as classified by GRADE [14]. Additional statements were retrieved from studies with lower quality of evidence whenever deemed required by the survey development committee. The strength of recommendations was assessed using the GRADE

Table 1. Quality of evidence grades.

Grade	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Evidence to Decision (EtD) frameworks. This system was developed and refined to assess the certainty of evidence of effects and strength of recommendations, as shown in Table 1 [14]. All agreed upon statements are presented in Table 2.

3. Intracoronary imaging (IVUS and OCT)-guided PCI

3.1. Intracoronary imaging and PCI outcomes

The safety of ICI-guided PCI is well-established, as evidenced in pivotal trials and various meta-

Table 2. Consensus statements on the clinical use of intracoronary imaging.

Section	Statements	Quality of Evidence
I. Intracoronary imaging and PCIs outcomes	1. ICI-guided PCI demonstrates superior safety, efficacy, and enhanced patient outcomes compared to angiography-guided PCI, especially in complex lesions. The clinical benefit of imaging guidance of PCI mainly depends on baseline planning and stent optimization.	High
	2. Each catheterization laboratory in Saudi Arabia should be equipped with high-resolution ICI system (s) that corresponds to catheterization lab needs. The lab should also be equipped with staff trained in image acquisition, interpretation, and measurement.	High
	3. ICI-guided PCI is recommended in patients with complex coronary lesions and left-main interventions due to a reduction in MACE, revascularization, and stent thrombosis. Both IVUS and OCT-guided PCI provide comparable short and long-term benefits on stent expansion, MACE, revascularization, and stent thrombosis. The choice between both techniques should be based on the operator's expertise, patient characteristics, and clinical scenarios.	High
	4. In heavily calcified and bifurcation lesions, OCT provides valuable additional information, such as calcium thickness and three-dimensional stent views, that can better guide the step-by-step PCI optimization. When compared to standard IVUS devices, OCT may be preferred for detecting lumen or stent-related features with potential clinical impact in heavily calcified coronary lesions.	Moderate
	5. In patients with renal failure undergoing PCI, IVUS is preferred over OCT. This preference is primarily driven by the significant concern of contrast-induced nephropathy in this patient population.	Moderate
	6. ICI-guided PCI is recommended for patients with: <ul style="list-style-type: none"> a- Unprotected left main coronary lesions b- Ostial lesions c- True bifurcation lesions with side branch diameter ≥ 2.5 mm. d- Chronic total occlusions with duration ≥ 3 months e- Severely calcified lesions (requiring a calcium modification) f- ACS culprit lesion and/or non-culprit ambiguities g- Long lesions (implanted stent length ≥ 28 mm) h- Multi-vessel PCI (≥ 2 major epicardial coronary vessels treated at one PCI session) or multiple stent implantation (3 or more stents per patient) i- Stent thrombosis and In-stent restenosis (ISR) lesion j- Any time an unexplained complication happens during PCI 	High
	7. Routine ICI-guided PCI may be considered in patients presenting with non-complex disease, especially those with diffuse disease, to allow lesion preparation, optimize stent expansion and apposition, and improve short and long-term outcomes.	Low
III. Principles of Imaging Acquisition	8. The availability and use of co-registration of ICI with coronary angiography (angio co-registration) should be considered to facilitate imaging-guided PCI.	Moderate

(continued on next page)

Table 2. (continued)

Section	Statements	Quality of Evidence
IV. Plaque composition	9. ICI-guidance prior to stent implantation is recommended to assess plaque composition and distribution (calcification, lipid-rich plaque), allow plaque modification, and facilitate the choice of stent size (diameter and length).	High
	10. The low sensitivity of coronary angiography to identify high calcium content in native vessels and cases of ISR increases the risk of stent under-expansion and malapposition. Thus, pre-stenting imaging is recommended for plaque assessment in all calcified lesions or in undilatable coronary stenosis. ICI images of calcium distribution (circumferential and longitudinal) and thickness guide the selection of the calcium modification technique, allowing for better lesion preparation and stent expansion.	High
V. Assessment of angiographically indeterminate coronary artery stenosis	11. IVUS is recommended over OCT for the evaluation of angiographically indeterminate ostial left main. Either modality can be used for distal or shaft disease of the left main artery.	Low
	12. In indeterminate LMCA disease, a mean luminal diameter (MLD) < 2.8 mm and mean luminal area (MLA) < 5.9 mm ² correlate with significant lesions. Lesions with MLA >7.5 mm ² are not hemodynamically significant. Lesions with MLA of 6–7.5 mm ² require further physiological assessment. These cutoffs should be used cautiously and with other clinical factors to guide practice. Further studies are needed to validate these cutoffs and establish more robust criteria for identifying hemodynamically significant lesions using ICI.	Moderate
	13. There are ethnic differences in coronary atherosclerosis morphology. The optimal MLA cutoff to determine significant lesions is still unknown in the Arab ethnicity, which requires future research.	Moderate
	14. In non-LMCA disease, MLA <4 mm ² may be significant but requires additional physiological assessment. Lesions with MLA of >4 mm ² and MLD > 2 mm are not hemodynamically significant. These cutoffs should be used cautiously and with other clinical factors to guide practice. Further studies are needed to validate these cutoffs and establish more robust criteria for identifying hemodynamically significant lesions using ICI.	Moderate
VI. Stent failure	15. An ICI analysis of stent restenosis and stent thrombosis is strongly recommended to understand failure mechanisms, including stent malapposition, stent underexpansion and extent of neointimal hyperplasia.	Moderate

analyses. These studies have demonstrated a superior safety profile compared to traditional angiography-guided stent implantation. These techniques significantly reduce the risk of stent thrombosis due to more precise stent placement and sizing, addressing initial concerns about acute complications [5–12,15–17]. The comprehensive three-dimensional imaging provided by OCT and IVUS offers detailed insights into vessel wall and plaque characteristics, leading to better-informed procedural decisions and reduced short-term and long-term complications.

This has established ICI as a safe alternative and a superior approach to optimizing coronary interventions. Pivotal clinical trials, long-term studies, and meta-analyses demonstrated that ICI-guided PCI was associated with a significantly lower risk of stroke, Q-wave myocardial infarction (MI), and death compared to angiography-guided PCI [5–12]. In a real-time, updated network meta-analysis by Stone et al., it was found that the IVUS and OCT-

guided PCI reduced the target lesion failure (TLF) by 29% compared to angiography-guided PCI. There were significant reductions in cardiac death (45%), target vessel myocardial infarction (18%), target lesion revascularization (28%), and stent thrombosis (48%) compared to angiography-guided PCI as well [18]. A more recent meta-analysis showed that OCT-guided PCI was associated with a significant reduction of stent thrombosis compared with angiography-guided PCI (51%) [19]. Interestingly, the ILUMIEN IV study, alongside IVUS trials, highlighted the limitations of angiography-guided PCI regarding suboptimal minimum stent area (MSA), stent under-expansion, and high rates of major dissections, malapposition, and focal plaque protrusion compared to ICI-guided PCI. The trial found no difference between OCT- and angiography-guided PCI with regard to the target-vessel failure within 2 years [20].

The evidence also shows comparable outcomes between IVUS and OCT-guided PCI. In patients

with simple lesions, the OPINION and ILUMIEN III trials showed comparable outcomes of IVUS- and OCT-guided PCI in terms of stent thrombosis, MACE, and cardiac death [21,22]. Subsequent trials in patients with complex lesions, such as the OPTIMIZE PCI, OCTOBER, and OCTIVUS trials, showed similar findings regarding stent thrombosis, MACE, and cardiac death [15,22–24]. Appendices 1 and 2 present examples of IVUS-guided and OCT-guided PCI, respectively.

As such, the expert agreed that ICI-guided PCI demonstrates superior safety, efficacy, and enhanced patient outcomes compared to the angiography-guided PCI, especially in complex lesions and depends on baseline planning and stent optimization (*Statement 1*). Each catheterization laboratory in Saudi Arabia should be equipped with high-resolution ICI system(s) and staff trained in image acquisition, interpretation, and measurement; the number of systems depends on catheterization laboratory size and volume (*Statement 2*). ICI-guided PCI is recommended for patients with complex coronary lesions and left-main interventions due to its demonstrated benefits in reducing MACE, revascularization, and stent thrombosis rates. Both IVUS and OCT-guided PCI provide comparable short and long-term benefits on stent expansion, MACE, revascularization, and stent thrombosis. The choice between both techniques should be based on the operator's expertise, patient characteristics, and clinical scenarios (*Statement 3*).

When compared with IVUS, OCT demonstrated a more accurate estimation of calcium thickness and plaque morphology [25]. Previous studies demonstrated superior precision of OCT in evaluating post-PCI residual dissection, plaque prolapse, incomplete stent apposition, and stent coverage over time compared to standard IVUS. (30–40 Mhz) [26,27]. OCT is also preferred for thrombus detection, ACS mechanism definition (eruptive nodules, erosion, rupture, dissection), and recrossing assessment of bifurcation, while IVUS is preferred in ostial lesions [28]. However, with the newer generations of IVUS devices, the precision of IVUS has significantly improved and become more comparable to OCT [29]. Hence, when compared to standard IVUS devices, OCT is preferred for detecting lumen or stent-related issues (such as dissection, thrombi, and incomplete stent apposition) with potential clinical impact in heavily calcified coronary lesions (*Statement 4*).

On the other hand, IVUS has a high reliability in assessing plaque burden [30]. Additionally, one of the primary benefits of IVUS in patients with renal failure is the reduction in the use of contrast media. OCT

relies on contrast agents, which can exacerbate kidney damage, particularly in patients with pre-existing renal impairment. IVUS significantly reduces the risk of contrast-induced nephropathy by providing detailed images of the coronary arteries without the need for contrast media [31] (*statement 5*).

3.2. Patient selection

Several studies provided compelling evidence that some patient/lesion cohorts can benefit the most from ICI-guided PCI. These include those with unprotected left main coronary lesions (LMCA) [5,32–34], ostial lesions [15,17], bifurcation lesions with side branch diameters of 2.5 mm or more [5,35–37], multi-vessel PCI (those requiring treatment at one PCI session of 2 or more major epicardial coronary vessels) [5,35], multiple stent implantation (3 or more stents per patient) [5,35], those with calcified lesions necessitating calcium modification [5,35,38,39], those with stent thrombosis and ISR [5,35,40–43], those with long lesions (implanted stent length ≥ 28 mm), particularly when multiple stents are placed [44,45], those chronic total occlusion with a duration ≥ 3 months [46], those with unknown stent apposition/position in the LMCA [27,47,48], and those with possible stent fracture after overexpansion [48,49]. Accordingly, experts suggest these patient/lesion subsets as primary candidates for ICI-guided PCI to improve cardiovascular outcomes (*Statement 6*).

Multiple studies have shown that ICI-guided PCI optimizes stent expansion and apposition and improves short- and long-term outcomes compared to angiography-guided PCI [22,50,51]. Specifically, in patients where the minimum lumen area achieved in the stented segment was >5.0 mm² or $>90\%$ of the lumen area at the distal reference segments, the residual plaque burden at the stent edges (5-mm proximal or distal to the stent) was less than 50%, without major edge dissection, ICI-guided PCI led to a substantial reduction of 3-year target vessel failure (TVF) and stent thrombosis [16]. These findings suggest that ICI-guided PCI should be considered in patients presenting with a de novo culprit lesion ($\geq 50\%$ diameter stenosis), especially those with diffuse disease on the same vessel, to allow lesion preparation, optimize stent expansion and apposition, and improve short and long-term outcomes (*Statement 7*).

3.3. Co-registration of ICI and angiography

Identifying corresponding segments between intracoronary imaging and angiography during PCI

is crucial for an imaging guidance procedure. On-line angio co-registration (ACR) can significantly help in pinpointing the target segment [52], assist in selecting the correct stent length and landing zones, and avoid geographical misses [53]. Therefore, experts recommend the use of ACR for precise stent guidance (Statement 8).

3.4. Plaque composition

ICI-guided prior to stent implantation is recommended to assess plaque composition and distribution (calcification, lipid-rich plaque) and facilitate choice of stent size (diameter and length) (Statement 9).

3.4.1. Calcium

The impact of coronary calcification on adverse events following PCI has been demonstrated in multiple studies and large multiethnic registers [54,55]. Compared to standard angiography, ICI is more accurate in detecting calcium within the coronary arteries [56–58]. IVUS detected calcification in a staggering 73% of cases, while angiography detected calcification in only 40% of instances [59]. This finding underscores ICI's high sensitivity and specificity in identifying intralumenal calcium, drawing parallels with pathological studies [60,61]. ICI can accurately characterize calcium distribution, length, thickness, angle, depth, and morphology (eccentric, concentric, eruptive) [58]. Recently, an IVUS-based calcium scoring was validated to predict stent expansion, which includes superficial calcium angle $>270^\circ$ longer than 5 mm, 360° of superficial calcium, calcified nodule, and vessel diameter <3.5 mm [38]. There is also an elevated risk of the stent under expansion in lesions with calcium pools on OCT exhibiting characteristics such as a maximum angle greater than 180° , a maximum thickness exceeding 0.5 mm, and a length surpassing 5 mm [62]. Based on these findings, the experts recommend pre-stenting imaging for plaque assessment in calcified lesions for lesion preparation and selecting calcium modification techniques (Statement 10).

3.4.2. Lipid-rich plaque

It has been well established that the presence of residual plaque, particularly lipid-rich plaque (LRP), at the edges of the stent, as a result of an inappropriate landing zone, is associated with an increased risk of restenosis and other adverse events. An integrated analysis of the TAXUS trials showed that factors such as external elastic membrane, lumen areas, and plaque burden play a role in predicting 9-month angiographic edge restenosis post-stent

implantation. However, only edge plaque burden stood as an independent predictor of stent edge restenosis [63].

3.5. Pre- and Post-PCI workflow

3.5.1. Pre-PCI imaging strategy

A proposed ICI-guided peri-PCI workflow is shown in Fig. 1. The assessment of lesion morphology is crucial to guide treatment decisions. In lesions with a calcific circumferential extension of more than 180° had a higher calcific burden, resulting in a diminished stent area and increased stent eccentricity [64].

The next step is to specify a predefined reference segment to identify optimal landing zones and stent length. The largest lumens proximal and distal to the lesion on the lumen profile should be used to create a region of interest; defining lesions distinctly requires a separation of at least 5 mm between them. This distance ensures the greatest visibility of the arterial medial (external elastic lamina [EEL]) and prevents potential overestimation of disease burden if multiple lesions are considered single lesions [65]. If lesions are closer than 5 mm, treating the disease as a single lesion is advised. An ideal landing zone is defined as a 360° EEL visualization; the largest adjacent lumen should be selected in the case of EEL visualization $<180^\circ$ [66]. It should be noted that IVUS holds better ability in defining external elastic membrane (EEM) (when calcium burden is not high) and plaque burden, particularly in lipid-rich plaque; it was previously reported that OCT exhibited high discordant rates in detecting thin-cap fibroatheroma (TCFA) [67].

Following the selection of reference segments in ICI imaging, conducting both quantitative and qualitative evaluations is crucial to determine the stent diameter. For IVUS, the measurements are the lumen cross-sectional area (CSA) at the reference and at the lesion, defined as the area encircled by the luminal border, and the minimum and maximum lumen diameters. The lumen area stenosis is calculated as the difference between the reference lumen CSA and the minimum lumen CSA [68]. In addition, EEM and plaque measurements are performed. EEM, the interface between the media and adventitia, helps determine the vessel size and the remodeling response of the vessel to plaque accumulation [69]. Plaque measurements assist in characterizing the composition and distribution of atherosclerotic lesions within the coronary artery, offering insight into their potential vulnerability and risk for future adverse events [70].

On the other hand, for OCT assessment, an EEL-guided device sizing strategy is preferable to a lumen-guided strategy as it leads to the selection of a larger device size (≈ 0.5 mm) and consequently a larger lumen area without an increase in post-procedural complications. If EEL visualization is insufficient, the mean lumen diameter, recorded from the automated lumen profile feature, is utilized for device sizing.

3.5.2. Post-PCI imaging strategy

Several factors have been reported to be associated with poststent adverse events, including stent underexpansion, dissections, geographic miss, plaque or tissue prolapse, and incomplete stent apposition [71,72]. Stent underexpansion is defined as an area where the stent is inadequately expanded relative to the normal adjacent reference segment [70]. Stent expansion remains the strongest

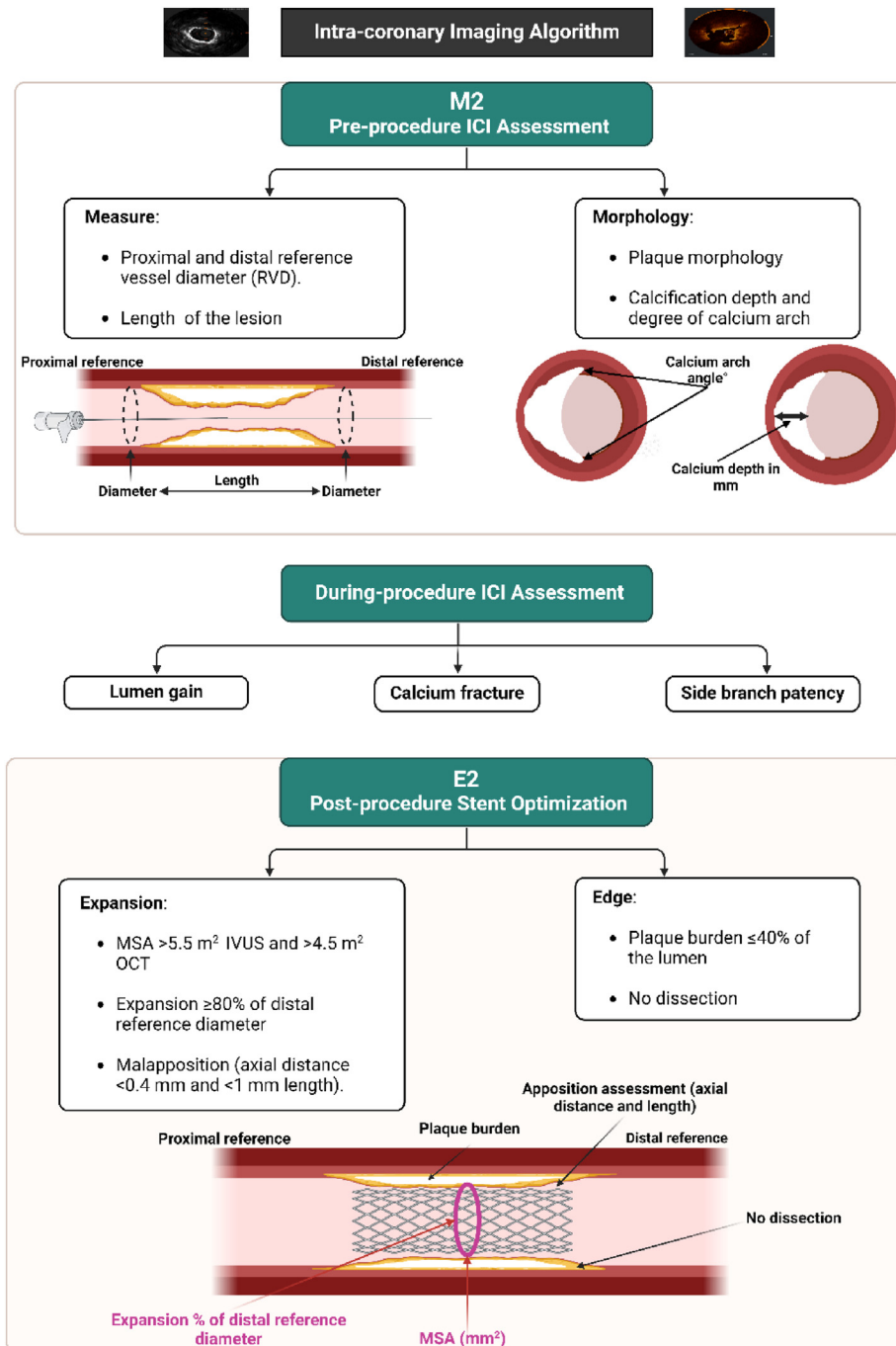


Fig. 1. Intracoronary imaging-guided peri-PCI workflow.

predictor of adverse events, while the current literature shows conflicting results regarding the predictive utility of other measures [73]. Despite a lack of consensus regarding the definition of adequate expansion, the MUSIC study suggested that stent expansion greater than 80%–90% of the reference cross-sectional area reduces restenosis [74]. There is significant evidence that stent underexpansion [75], significant tissue (plaque/thrombus) protrusion (more than the median that narrowed the lumen to $<4 \text{ mm}^2$), significant stent edge dissection, significant residual stenosis ($>50\%$), and minimum lumen area of $<5 \text{ mm}^2$, were associated with increased risk of early stent thrombosis [76,77].

After stent implantation, ICI can identify abnormalities that can be related to the stent or vascular wall [78]. There are no consistent guidelines for PCI optimization in clinical practice for determining relative stent expansion. An MSA higher than the distal reference lumen area, or $>80\%$ of the average reference area, is an additional goal for stent improvement [51]. Notably, OCT excels over IVUS in detecting malapposition and stent edge dissections [22]. Moreover, OCT's unique ability to detect thrombus, often a signal of mechanical or anticoagulation issues, emphasizes its superiority [72,79]. In the case of tissue prolapse, OCT has been shown to provide clearer and more frequent visualization than IVUS [22]. Therefore, post-PCI OCT evaluation is crucial for assessing reference segments and detecting stent malapposition; a MSA of $\geq 80\%$ of the mean reference lumen area and/or $>4.5 \text{ mm}^2$ is desirable for stent expansion, with reference segments outside the stent used for re-measuring vessel size, preferably via EEL guidance or lumen guidance if the EEL is not visible (See Fig. 1).

3.6. Assessment of angiographically indeterminate coronary artery stenosis

While angiography is the standard method for assessing coronary artery disease, it may have limitations in accurately determining the significance of LMCA lesions. ICI is a valuable tool for evaluating and providing treatment guidance for angiographically indeterminate LMCA disease [80,81]. A long-term follow-up study showed that IVUS is a safe method to accurately assess the degree of disease in the LMCA that appears indeterminate by angiography [82]. Moreover, the role of ICI in assessing coronary stenoses of angiographically intermediate severity (50–70%) continues to evolve [80]. Based on this evidence, the panel experts recommended IVUS-guided PCI in assessing LMCA and non-LMCA lesions when the angiographic degree of stenosis is ambiguous (Statement 11).

Several investigations have illustrated that in the context of indeterminate LMCA. Reduced mean luminal diameter (MLD) and mean luminal area (MLA) values are associated with more pronounced stenosis, which in turn is linked to a higher risk of adverse cardiac events [82–85]. Based on these findings, the panel experts agreed that, in indeterminate LMCA, an MLD $<2.8 \text{ mm}$ and MLA $<5.9 \text{ mm}^2$ correlate with significant stenosis. Lesions with MLA $>7.5 \text{ mm}^2$ are not hemodynamically significant; however, $6\text{--}7.5 \text{ mm}^2$ lesions require further physiological assessment (Statement 12). Studies have suggested that an OCT-based MLA of $>5.4 \text{ mm}^2$ correlates with not hemodynamically significant lesions [86]; however, further research is needed.

Several studies showed a significant difference between different ethnicities in terms of coronary atherosclerosis morphology, particularly in patients with LMCA disease [83,87,88], while, in Asians, the MLA cutoff appears lower at around $4.5\text{--}4.8 \text{ mm}^2$ [87]. On the other hand, the optimal MLA cutoff to determine significant lesions is still unknown in the Arab ethnicity, and this requires future research (Statements 13).

For patients with non-LMCA disease, the majority of studies used $<4 \text{ mm}^2$ MLA cutoff point [89–93]. The panel agreed that MLA $<4 \text{ mm}^2$ might be significant but may require additional physiological assessment in non-LM disease (Statement 14). With regard to OCT, previous studies showed that OCT-derived MLA cutoffs of $1.39\text{--}1.64 \text{ mm}^2$ had high diagnostic accuracy for predicting non-LM disease [94,95].

3.7. Stent failure

ISR and stent thrombosis remain significant problems in PCIs. The RIBS III study demonstrated the value of IVUS in treating ISR, showing larger acute gain and minimum lumen diameter at a 9-month follow-up. Still, it did not reduce the incidence of TLR at two years [41]. The iOPEN-ISR study also indicated that IVUS guidance reduced the incidence of major adverse cardiac events at 1-year follow-up compared to angiography alone guidance [40]. ICI has proven useful in identifying common causes of ISR and stent thromboses, such as stent underexpansion, under-sizing, non-overlapping stents, stent fracture, edge dissection, and increased plaque at the stent edge [75,96–98]. Recent studies reveal that identifiable leading mechanisms were found in the majority ($>90\%$) of stent thrombosis cases [99,100]. Therefore, a customized treatment strategy based on OCT findings appears reasonable, pending confirmatory prospective data [100].

Thus, the experts strongly recommend using ICI in evaluating and treating patients with ISR and stent thrombosis (*Statement 15*). Emerging evidence suggest that, in patients with a high risk of future events, including those with prior acute coronary syndrome or diabetes), OCT may be beneficial to detect vulnerable plaques [101,102]. However, the current evidence is not conclusive yet.

4. Emerging directions

Emerging evidence reported that coronary computed tomography angiography (CTA) could allow for noninvasive assessment of change in coronary plaque at lower costs [103,104]. The ability of ICI to provide high-resolution, direct visualization of the plaque characterization allows a level of detail that is essential for confirming the accuracy of plaque characterization obtained from coronary CTA. By correlating the findings from noninvasive CTA with ICI, clinicians can validate the reliability of CTA in detecting and monitoring changes in plaque [105]. This correlation is particularly valuable in complex cases where the plaque characteristics determined by CTA may need further clarification or in scenarios where the risk stratification based on CTA findings requires additional validation.

In addition to advances in coronary CTA, there are emerging diagnostic tools that provide both anatomic and functional insights into coronary lesions. For example, quantitative flow ratio (QFR) is a novel method that uses angiographic images to calculate the Fractional Flow Reserve (FFR) without the need for a pressure wire. QFR has been shown to correlate well with FFR and may be useful in identifying hemodynamically significant coronary stenosis [106]. FFR can also be calculated using a technique called OCT-based FFR (OFR), which has been shown to correlate well with wire-based FFR without the need for pressure wire or induced hyperaemia. It was found that OFR had good diagnostic accuracy in the assessment of flow-limiting coronary [107]. Another tool, optical frequency domain imaging (OFDI), combines the high resolution of OCT with the ability to measure blood flow velocity, providing both anatomic and functional information. Previous reports showed that OFDI-based PCI was non-inferior to IVUS-based PCI in terms of in-segment minimum lumen area at 8 months, arterial healing, and other composite endpoints [108]. While these tools are promising, further studies are needed to establish their clinical utility and define their role in guiding decision-making.

The evolution of Artificial Intelligence (AI) in the realm of ICI and its integration with physiological parameters like FFR, Instantaneous Wave-Free Ratio

(iFR), and others represents a significant advancement in interventional cardiology. AI algorithms have been increasingly employed to enhance the analysis of ICI data, such as from IVUS and OCT. These algorithms can rapidly interpret complex imaging data, identifying plaque characteristics, vessel dimensions, and optimal stent placement with greater accuracy and efficiency than traditional methods [109]. The integration of AI with physiological assessments like FFR and iFR, which measure the pressure gradient across a coronary lesion to assess its significance, has further augmented the diagnostic and therapeutic capabilities of ICI [110]. AI can process the combined imaging and physiological data to provide a more comprehensive assessment. This fusion of AI with ICI and physiological measurements not only increases the precision of PCI procedures but also significantly reduces the time required for analysis, leading to quicker and more efficient patient care [111]. Moreover, AI's ability to learn and adapt from vast datasets continuously improves its diagnostic accuracy, potentially leading to better patient outcomes and more personalized treatment strategies in the future. This evolution signifies a transformative shift towards more data-driven, precise, and patient-specific interventions in cardiology.

Virtual stenting, resulting from advancements in medical imaging and computational techniques, has emerged as a transformative tool in coronary interventions. Virtual stenting enables patient-specific modelling of coronary arteries by harnessing high-resolution imaging modalities like IVUS and OCT in conjunction with computational fluid dynamics. This facilitates predictive analysis, allowing clinicians to anticipate complications and optimize stent positioning before actual procedures. Such a proactive approach paves the way for personalized care, potentially reducing procedural complications and promoting cost-effectiveness by minimizing repeat interventions and streamlining the stenting process for patients with coronary artery disease [112].

5. Conclusion and future recommendations

ICI has unequivocally been shown to improve procedural success with a better minimal stent area following PCI. More importantly, the totality of the evidence has noted a reduction in major adverse cardiac events and target vessel failure, particularly in more complex and high-risk lesions. The current guidelines recommend the use of imaging prior to, during, and after stent deployment to achieve optimization. The experts recognize that initiatives to improve operator skills in the field of image acquisition and interpretation are necessary. It is

incumbent upon national societies and authorities to provide training opportunities for those currently in practice. Finally, there is a recognizable paucity of data from the local population on reference diameters and measurements. As such, this document encourages the generation of regional data to capture the demographics of the local population receiving therapies in the catheterization laboratory.

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Author contribution

Conception and design of Study: MA, MA, AA, HA, FA, HA, WA, AT, WHA. Literature review:

Appendix

Appendix 1

MA, MA, AA, HA, FA, HA, WA, AT, WHA. Acquisition of data: MA, MA, WHA. Drafting of manuscript: MA, MA, AA, HA, FA, HA, WA, AT, WHA. Revising and editing the manuscript critically for important intellectual contents: MA, MA, AA, HA, FA, HA, WA, AT, WHA. Supervision of the research: MA, WA, AT, WHA. Research coordination and management: MA, WA, AT, WHA.

Conflict of interest

None to declare.

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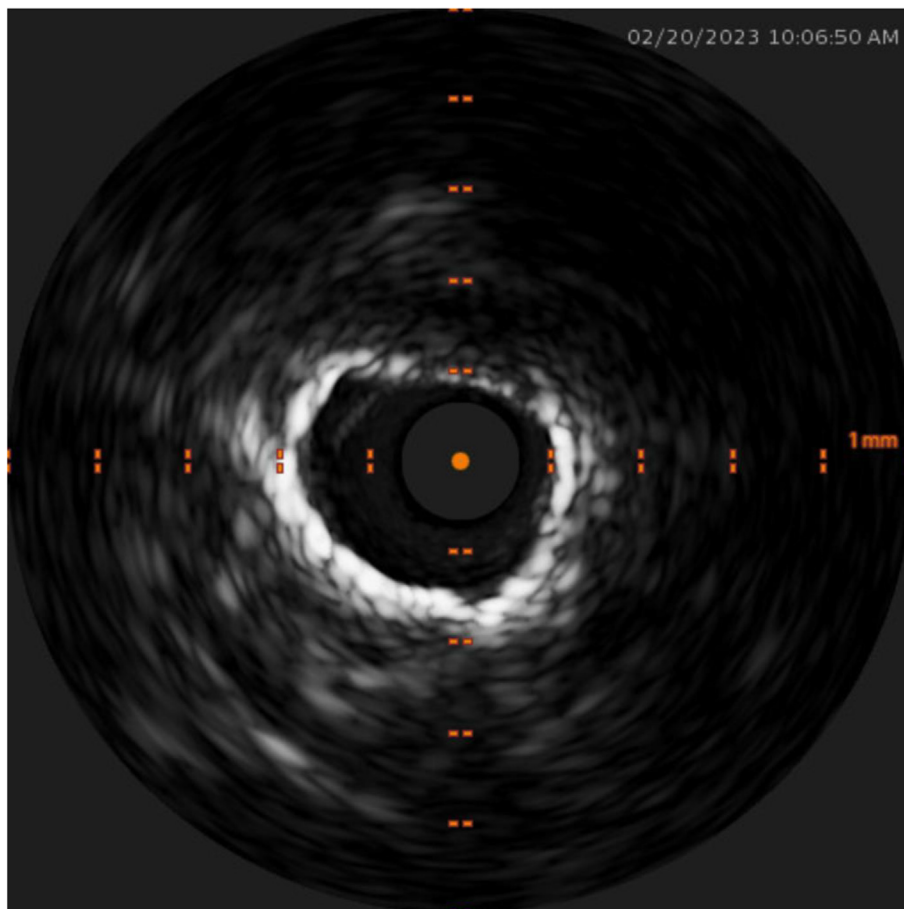


Figure 1. IVUS image demonstrates 360° of circumferential superficial calcium.

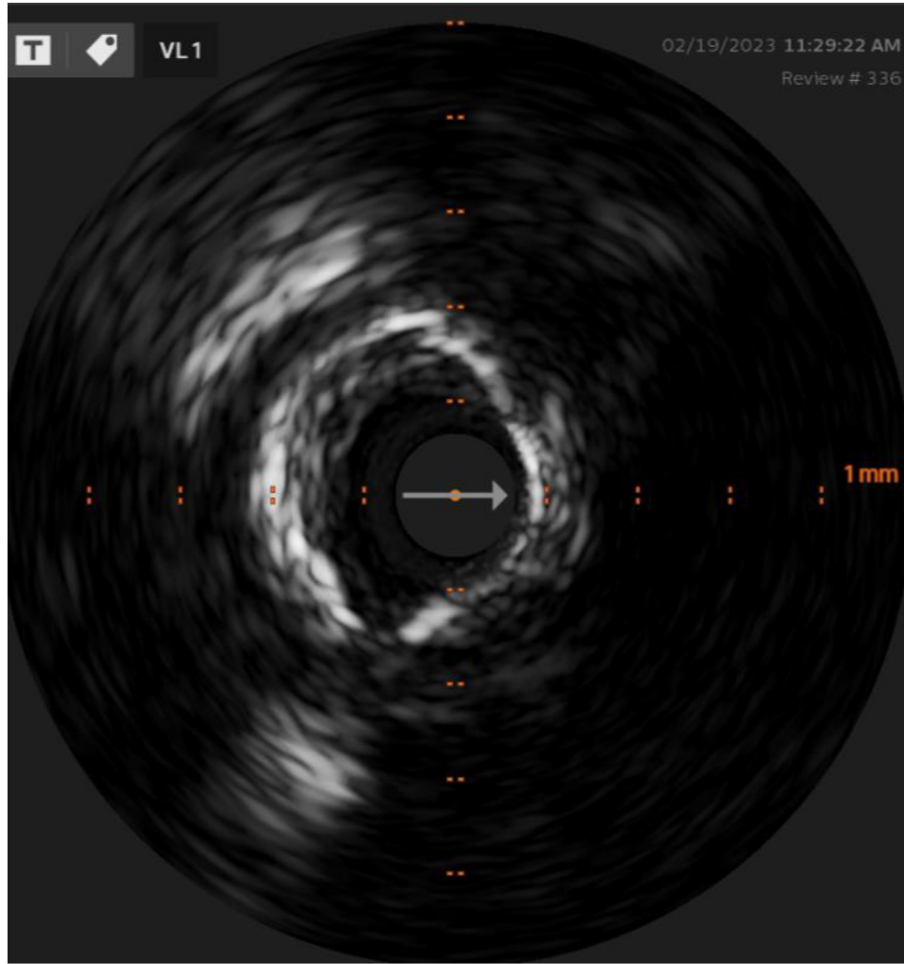


Figure 2. IVUS image demonstrates circumferential calcium which is cracked at the 6 O'Clock position following intra-coronary lithotripsy.

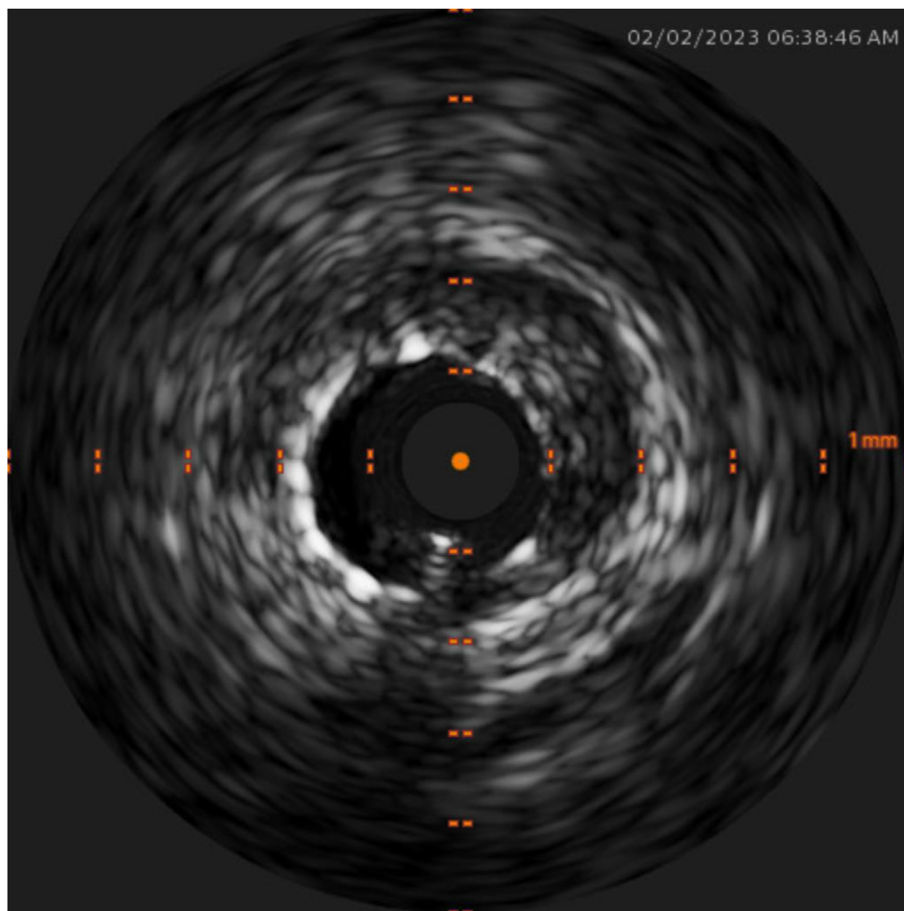


Figure 3. Undersized stent in a larger vessel.

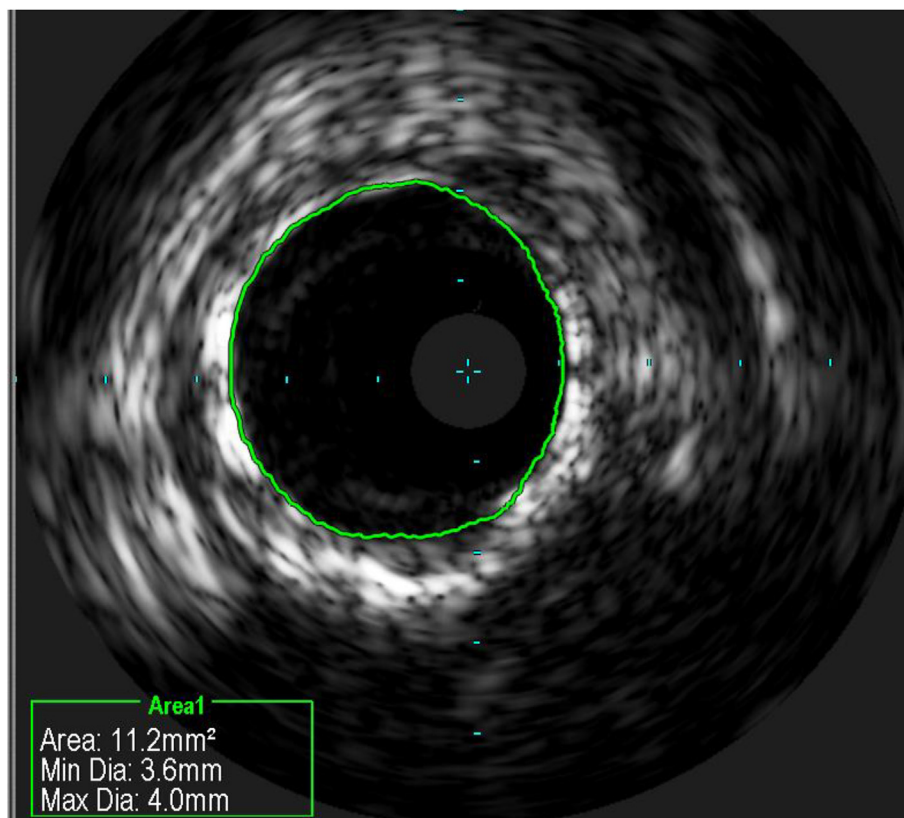


Figure 4. An example of a well-apposed stent.

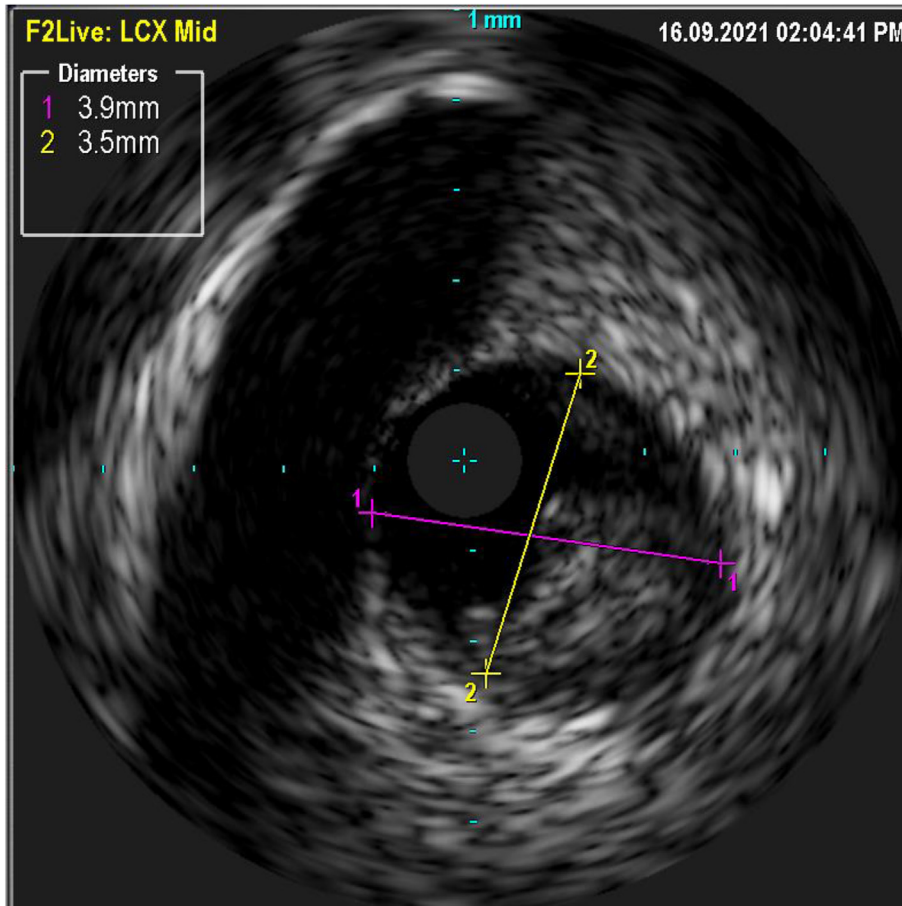


Figure 5. An example of a soft eccentric ulcerated plaque (in the left circumflex artery).

Appendix 2

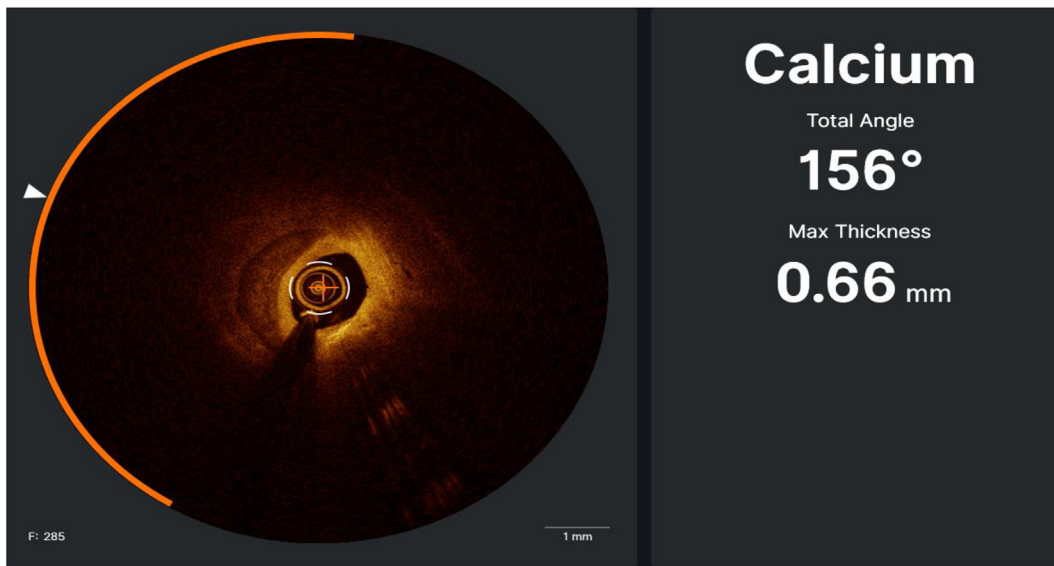


Figure 1. Calcified lesion from 7 to 12 o'clock characterized by well delineated border low back scattering and low attenuation. The artificial intelligence detect the arc and the maximum thickness of the calcium as shown in the right. Side of the picture.

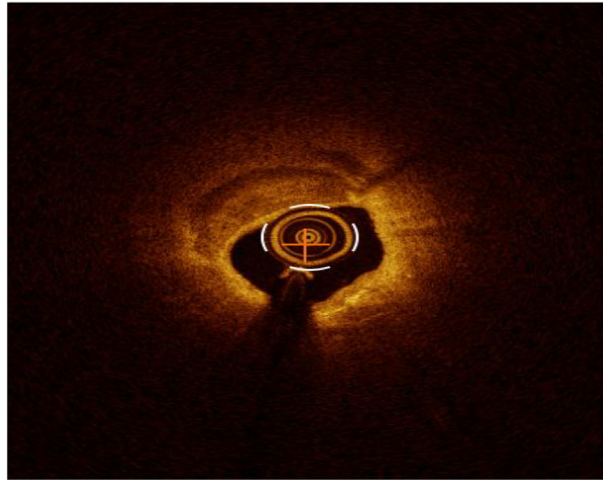


Figure 2. Fibrofatty plaque with calcification from 1 to 9 o'clock and calcification from 9 to 1 o'clock. Cholesterol crystals (white arrow) which is the area with high backscattering and low attenuation.

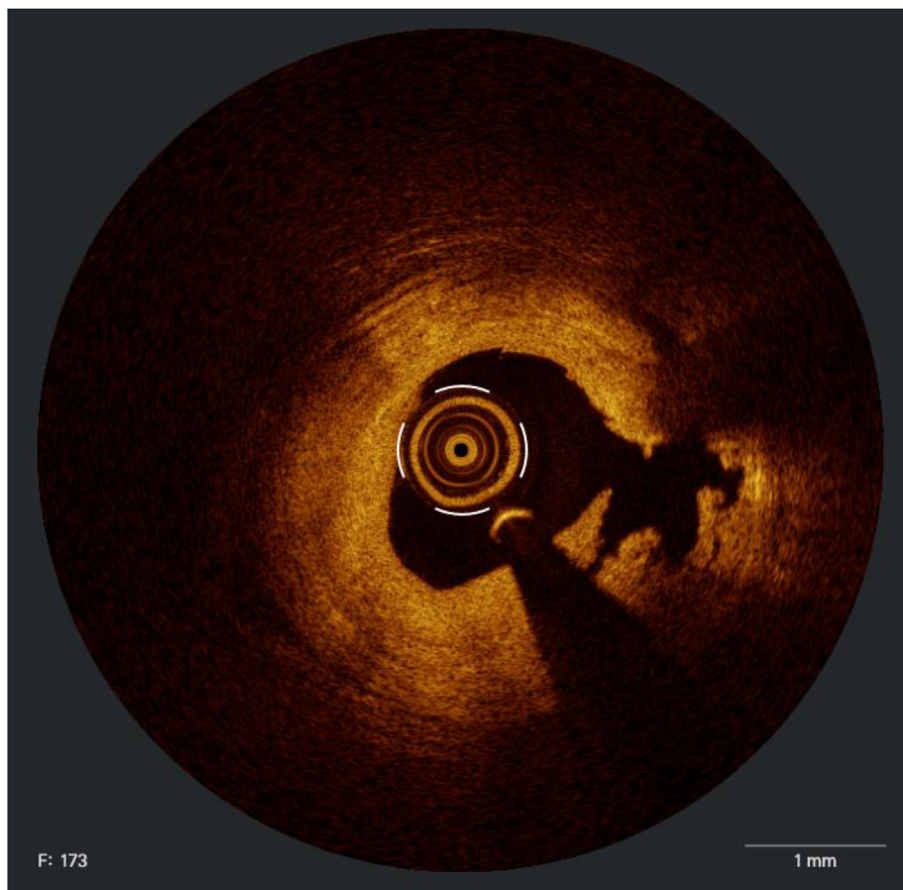


Figure 3. Fibrotic lesion after ballooning, dissection created at 3 o'clock.

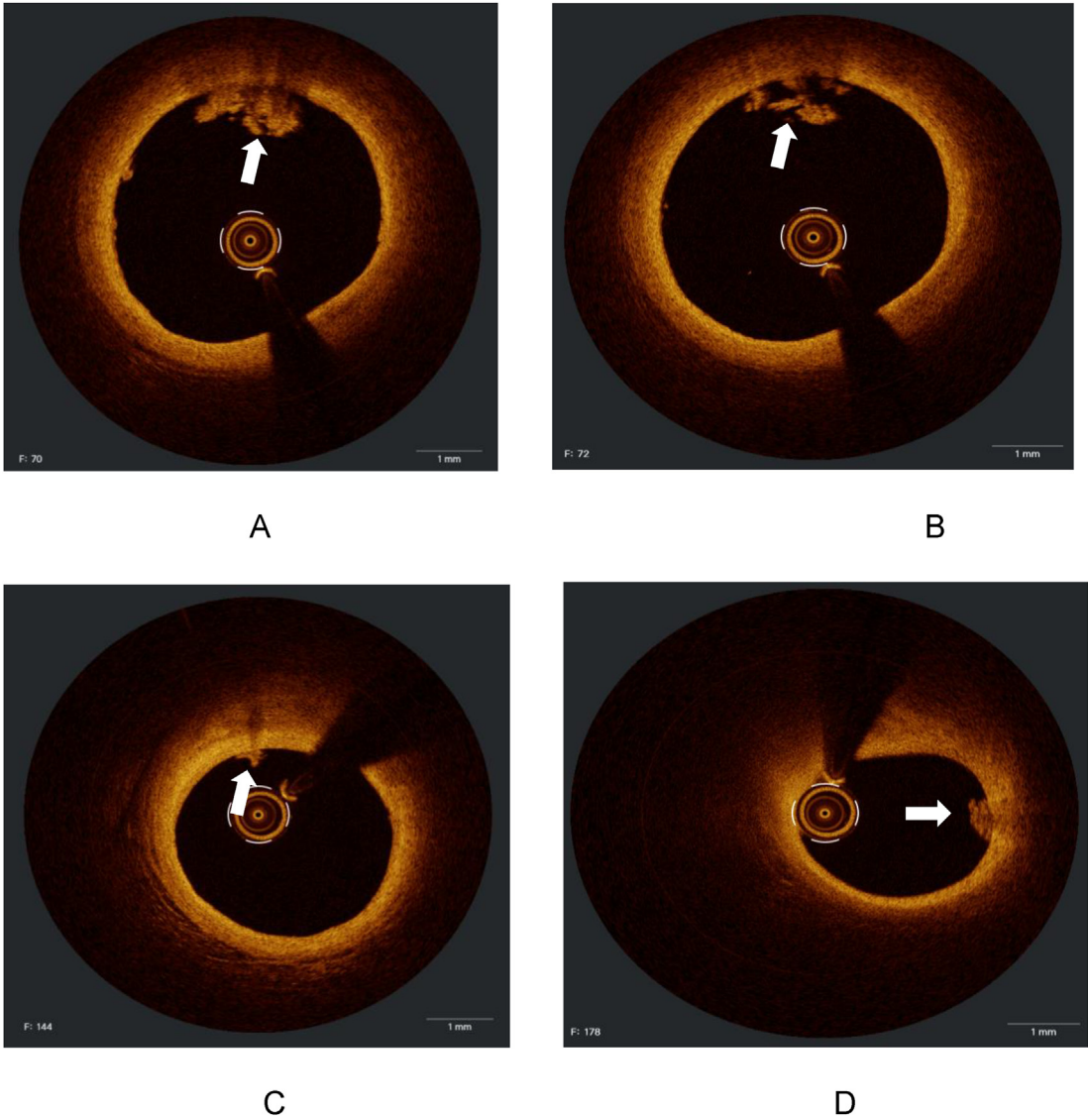


Figure 4. (A, B, C and D). Cross-sections from the same vessel (LAD) of a patient with atrial fibrillation after stopping anticoagulant for three days showed a white thrombus (white arrows), with the absence of vessel disruption, representing an embolic event.

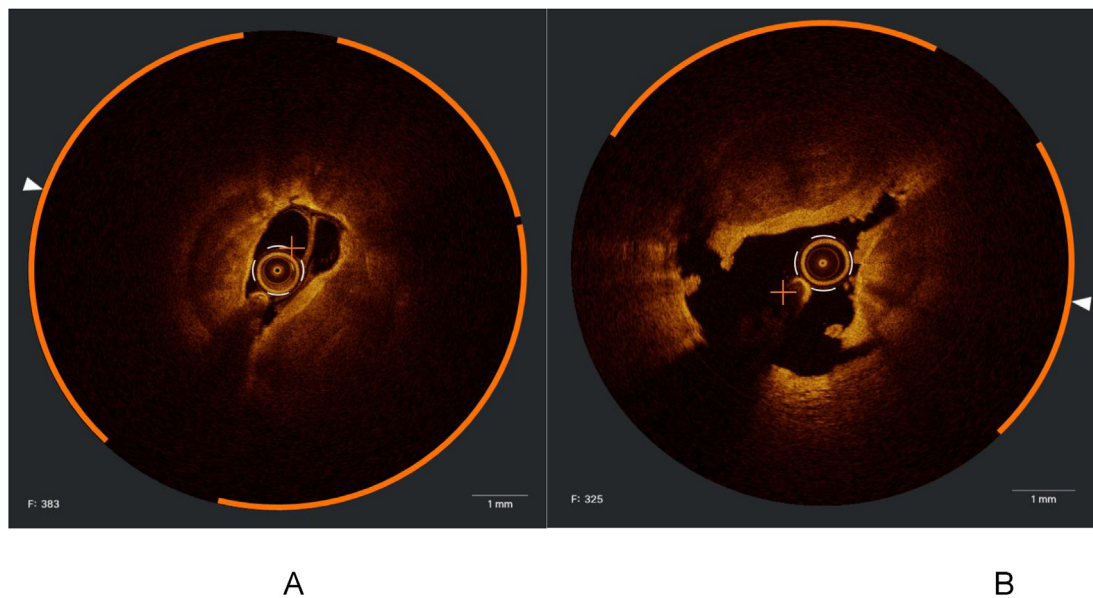


Figure 5. A- Calcified lesion with about 360 calcium arch. B- Post IVL, dissections and calcium cracks at 5, 10 and 2 o'clock.

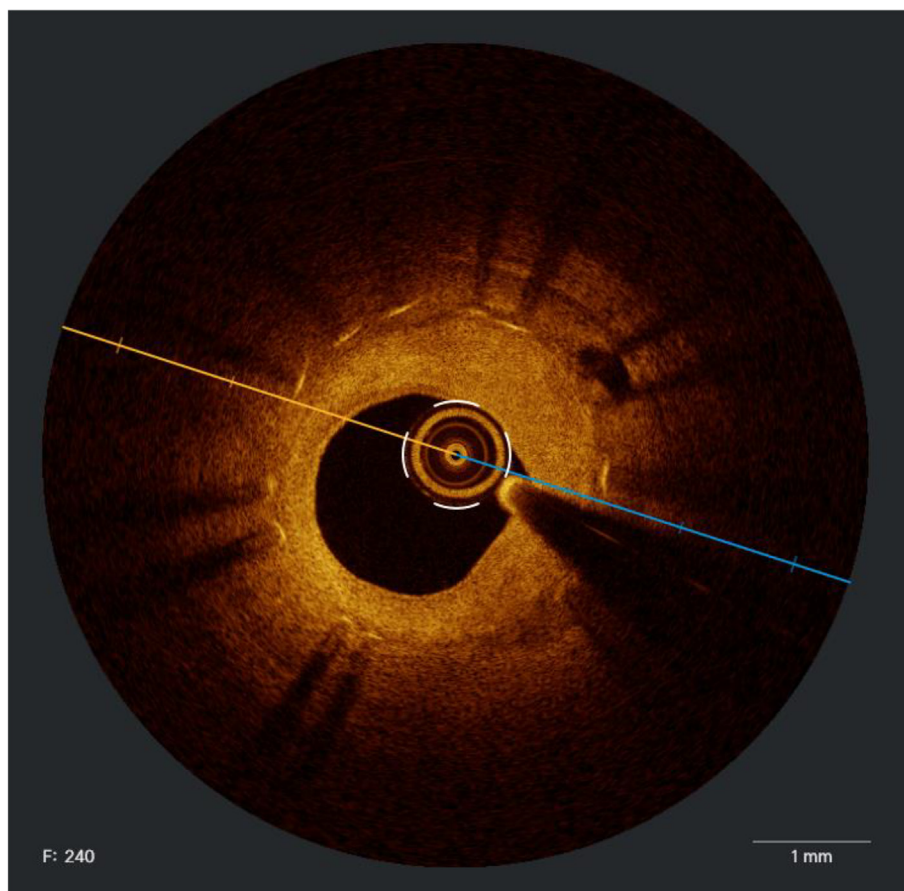


Figure 6. Neointimal hyperplasia.

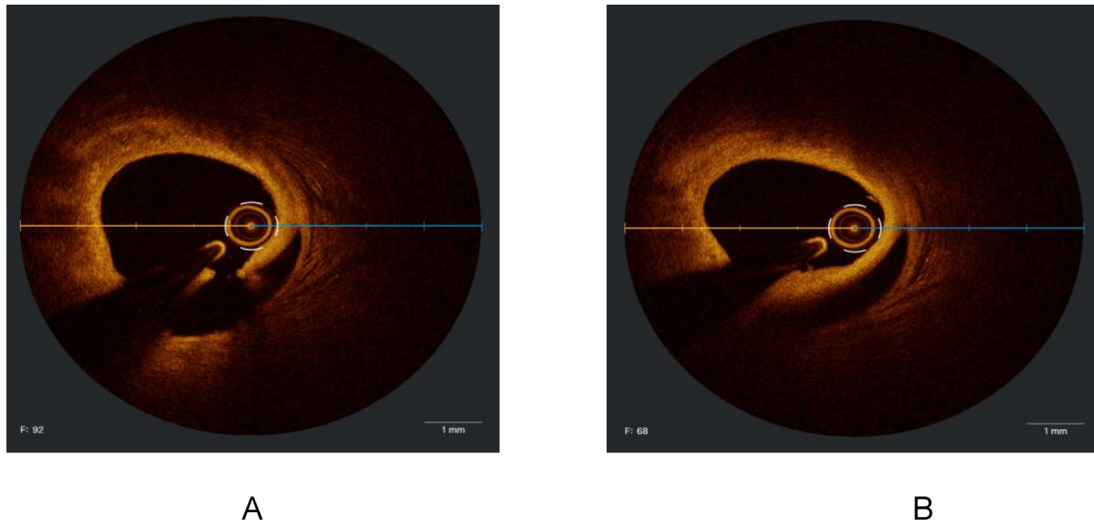


Figure 7. A- Iatrogenic dissection. B- Intramural hematoma.

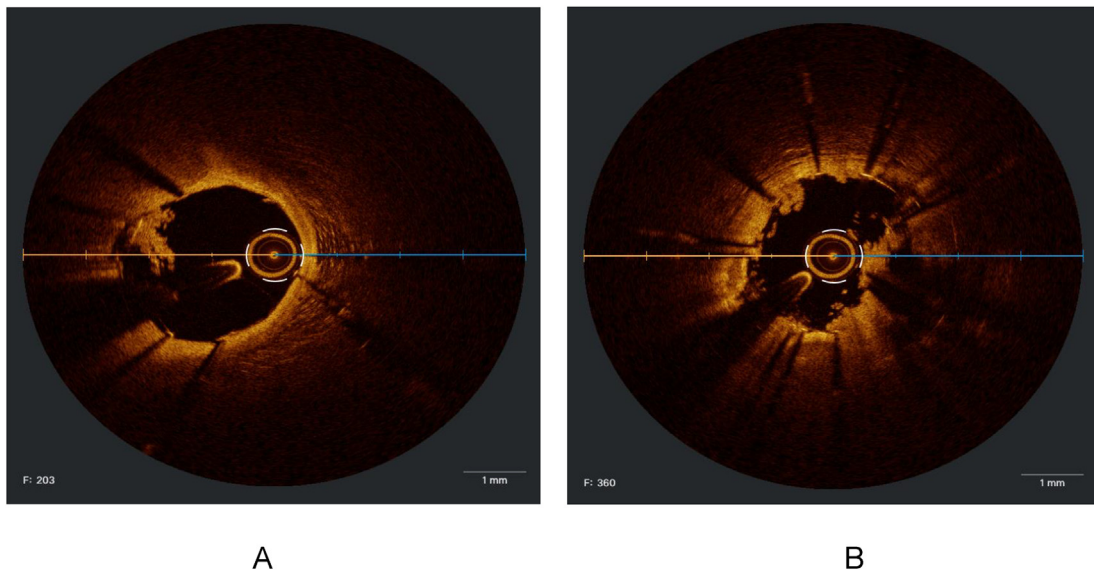


Figure 8. A and B. Hyperacute stent thrombosis occurred during the same index procedure.

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