



2024

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### Recommended Citation

Al-Shaibi, Khaled; Alasnag, Mirvat; AlShemmari, Owayed; AlSaleh, Ayman; AlKashkari, Wail; AlMutairi, Fawaz; Alanazi, Nouf; Alameer, Mognee; and Tash, Adel (2024) "Consensus of National Heart Center and the Saudi Arabian Cardiac Interventional Society on the Current Landscape of the Management of Intracoronary Calcification in Saudi Arabia," *Journal of the Saudi Heart Association*: Vol. 36 : Iss. 2 , Article 11.

Available at: <https://doi.org/10.37616/2212-5043.1385>

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# Consensus of National Heart Center and the Saudi Arabian Cardiac Interventional Society on the Current Landscape of the Management of Intracoronary Calcification in Saudi Arabia

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## Abstract

**Objectives:** We aimed to develop a streamlined algorithm for the management of intracoronary calcification that includes guidance on intracoronary imaging and the appropriate selection of atherectomy devices.

**Methods:** National experts representing both the National Heart Center (NHC) and the Saudi Arabian Cardiac Interventional Society (SACIS) met to develop a consensus document on the assessment and management of intracoronary calcification in Saudi Arabia. The nominal group technique was utilized; a number of statements on the assessment and management of coronary artery calcification were developed based on a systematic review of the literature. The authors discussed the developed statements until a consensus was reached.

**Results:** Twenty statements were discussed and agreed upon. Invasive and non-invasive imaging modalities in the assessment of coronary artery calcification, and management of intracoronary calcification using calcium ablation techniques, excimer laser coronary atherectomy, balloon-based techniques, and shockwave lithotripsy; were all thoroughly discussed in light of scientific evidence and the experts' clinical practice.

**Conclusions:** We present a national consensus on the assessment and the multifaceted management of intracoronary calcification in Saudi Arabia.

**Keywords:** Intracoronary calcification, Major adverse cardiovascular outcomes, Atherectomy

## 1. Introduction

Cardiovascular disease, primarily driven by atherosclerosis, continues to be a leading cause of mortality worldwide [1]. Intracoronary calcification, a common manifestation of advanced atherosclerosis, complicates revascularization of coronary artery disease due to its association with suboptimal stent expansion and subsequent stent thrombosis and

restenosis [2]. Recent advances in non-invasive and invasive imaging technologies, along with the development of innovative calcium-modifying devices, have significantly improved the management of heavily calcified coronary lesions [3]. However, these methods have distinct advantages, limitations, and their use in practice varies significantly.

Conventionally, fluoroscopy was the primary modality to detect calcification. It is now largely

Received 28 February 2024; revised 9 June 2024; accepted 11 June 2024.  
Available online 1 August 2024

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replaced by intracoronary imaging and to a certain extent coronary computed tomography angiography (CCTA) [4]. The purpose of this consensus document elaborated by the National Heart Center (NHC) in collaboration with Saudi Arabian Cardiac Interventional Society (SACIS) is to create a roadmap for better patient-centered care and inform future research efforts in this critical area of interventional cardiology.

## 2. Methods

This consensus is based on the nominal group technique (NGT) [5]. The NGT has proven its reliability for building consensus in a variety of clinical settings through the utilization of repeated discussions between experts on a specific set of statements, which are developed via a series of systematic literature search and expert feedback [6].

### 2.1. Task force development

A non-probability purposive sampling technique was employed to recruit interventional cardiologists affiliated to the NHC and SACIS in Saudi Arabia. All experts were required to have an active research profile in the field of interventional cardiology with qualifications verified by the Saudi Commission for Health Specialties. Each task force member contributed their specialized knowledge and expertise to specific sections of the article, ensuring the accuracy, validity, and relevance of the consensus statements. Four authors (KA, MA, AA, and WA) were responsible for the development and drafting of the sections related to calcium-ablation and Excimer laser techniques due to their extensive experience and scholarly contributions in this area. Likewise, three authors (FA, NA, and AT) contributed significantly to the sections on balloon-based techniques and shockwave lithotripsy. Lastly, two authors (OA and MA) contributed to the development of the sections on peri-procedure imaging assessment. All authors reviewed and approved the final version of the consensus statement.

### 2.2. Literature search and statements development

A systematic literature search was conducted on Medline via PubMed from its inception to November 2022 to collect relevant information. Various combinations of the following keywords will be used to identify potentially eligible literature: (Saudi Arabia; Consensus; Experts opinion; Coronary Artery Calcification; Intracoronary calcification; Coronary calcium score; coronary artery disease;

#### Abbreviation

CAC	Coronary Artery Calcification
CAD	Coronary Artery Disease
CB	Cutting Balloon
CCTA	Coronary Computed Tomography Angiography
CSA	Cross-Sectional Area
CTO	Chronic Total Occlusion
DCB	Drug-Coated Balloons
DES	Drug-Eluting Stent
ELCA	Excimer Laser Coronary Atherectomy
EtD	Evidence to Decision
ISR	In-Stent Restenosis
IVL	Intravascular Lithotripsy
IVUS	Intravascular Ultrasound
LHCC	Lesions with a High Calcium Content
LVEF	Left Ventricular Ejection Fraction
MACE	Major Adverse Cardiac Events
MB	Modified Balloons
NC	Non-Compliant
NCB	Non-Compliant Balloon
NGT	Nominal Group Technique
NHC	National Heart Center
OA	Orbital Atherectomy
OCT	Optical Coherence Tomography
PCI	Percutaneous coronary intervention
PTCA	Percutaneous Transluminal Coronary Angioplasty
RA	Rotational Atherectomy
RCT	Randomized Controlled Trial
SACIS	Saudi Arabian Cardiac Interventional Society
TLR	Target Lesion Revascularization

Recommendations; Treatment; Diagnosis). The statements were primarily extracted from studies with high quality of evidence, as classified by GRADE (4). Additional statements were retrieved from studies with lower quality of evidence whenever deemed required by the survey development committee.

The recommendation strengths were assessed using the GRADE Evidence to Decision (EtD) frameworks. This system was developed and refined to assess the certainty of evidence of effects and strength of recommendations. The GRADE system classifies the quality of evidence as high, moderate, or low (Table 1).

## 3. Assessment of coronary artery calcification

### 3.1. Non-invasive modalities

Coronary artery calcification (CAC) is a critical predictor of adverse cardiovascular outcomes, significantly increasing the risk of mortality, myocardial infarction, and ischemic complications post-stenting, as evidenced by meta-analyses and pooled analyses of multiple trials [7–10]. A cumulative body of evidence indicates that non-invasive

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

assessment of CAC burden using CT to calculate the coronary artery calcium scoring (CACS) can significantly predict coronary artery stenosis and the risk for major adverse cardiac events (MACE) [11]. These findings highlight the importance of assessing calcium burden using the CACS before stenting to mitigate risks such as stent malapposition and fracture [12,13] (Statement 1).

### 3.2. Invasive imaging

#### 3.2.1. Use of intracoronary imaging in calcified lesions

Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) are pivotal in identifying and quantifying coronary calcification, with IVUS revealing calcium in 73% of lesions compared to angiography's 38%. However, previous reports showed that IVUS underestimates calcified plaque area by 39% [14,15]. OCT excels by providing detailed visualization beyond calcium shadows, crucial for precise assessment of calcium thickness and aiding in the selection of appropriate lesion modification therapy to reduce MACE [16–19] (Statement 2).

#### 3.2.2. Predictors of stent underexpansion

Stent underexpansion is a critical factor associated with stent failure and adverse events such as stent thrombosis and restenosis [20]. It occurs when a stent, once deployed, does not fully expand to the intended or optimal size. Various factors can contribute to stent underexpansion, including heavy calcification, inappropriate stent sizing, inadequate lesion preparation, and high lesion complexity. In heavily calcified lesions, the rigid calcific plaque resists stent expansion, thus increasing the risk of underexpansion [21]. IVUS and OCT provide high-resolution, cross-sectional images of the vessel, aiding in the accurate measurement of lumen dimensions, plaque morphology, and stent deployment. OCT, due to its higher resolution compared to IVUS, provides detailed images of the vessel, enabling precise measurements of calcium thickness and depth, which are vital parameters in predicting stent underexpansion [22]. OCT can also

visualize and measure calcium thickness, whereas infrared waves used in OCT are able to penetrate calcium, providing detailed and spatial representation of their morphology [23].

OCT was able to predict the stent underexpansion in the following conditions: calcium arc  $>180^\circ$ , maximum thickness  $>0.5$  mm, and length  $>5$  mm (Table 2) [24]. On the other hand, Zhang et al. demonstrated that IVUS predicted stent underexpansion in patients with de novo lesions with a maximum superficial calcium angle greater than  $270^\circ$ . Their findings showed that the key factors linked with stent underexpansion were identified as superficial calcium length longer than 5 mm, complete ( $360^\circ$ ) superficial calcium, presence of calcified nodules, and a vessel diameter less than 3.5 mm [25] (see Table 3).

#### 3.2.3. Lesion preparation according to intracoronary imaging findings

The nuances of lesion preparation are greatly influenced by key intracoronary imaging findings such as the calcific arc, calcium length, and thickness. In a study investigating the effects of rotational atherectomy (RA) and balloon angioplasty on calcified coronary lesions via OCT, researchers discovered that larger calcium arc and thinner calcium thickness significantly correlated with the formation of calcium cracks. Importantly, they noted that the presence of these calcium cracks directly influenced optimal stent expansion [26]. These findings highlight the role of intravascular imaging in predicting optimal stent expansion and the need for the use of atherectomy devices.

Table 2. OCT-based calcium score [24].

Criteria	Score
Maximum calcium angle	$\leq 180 = 0$ point $> 180 = 2$ points
Maximum calcium thickness (mm)	$\leq 0.5$ mm = 0 point $> 0.5$ mm = 1 points
Calcium length (mm)	$\leq 5$ mm = 0 point $> 5$ mm = 1 points
Total score	0–4

Table 3. Consensus statements on the management of intracoronary calcification.

Section	Statements	Quality of Evidence	
I. Assessment of coronary artery calcification – non-invasive modalities	1. Coronary calcification is commonly associated with larger plaque burden, greater degree of lesion complexity, and adverse PCI clinical outcomes. Thus, pre-procedural calcium burden assessment before stenting is recommended to avoid the risk of stent loss; stent underexpansion/fracture; and reduce the rate of intraprocedural complications.	High	
II. Use of intracoronary imaging in calcified lesions	2. Intracoronary imaging with IVUS and OCT is critical for detecting coronary calcium and guiding optimal stent expansion. Both IVUS and OCT can identify calcified plaques that require modification before stent implantation. In addition, they both can be used to ensure stent expansion that meets minimum area thresholds to reduce ISR. OCT can better assess calcium thickness and detect malapposition and edge dissections. The use of high definition-IVUS (>40 MH) is recommended, when available.	High	
III. Calcium ablation techniques	3. In patients with fibrotic or heavily calcified lesions, plaque modification techniques, according to their indications, should be considered to improve procedural success	High	
IV. Rotational atherectomy	4. The use of upfront RA for lesion preparation before DES or DCB implantation is associated with greater acute diameter gain, greater luminal cross-sectional area gain, and superior strategic success in comparison with a non-RA approach in select cases with calcified coronary arteries.	High	
	5. RA is recommended as a primary strategy or as a bailout after a failed balloon pre-dilation attempt of: <ol style="list-style-type: none"> <li>Severely calcified de novo coronary stenoses (is at least 270° based on IVUS or OCT) which are unlikely</li> <li>To expand adequately with balloon angioplasty.</li> <li>Napkin ring calcification</li> <li>Calcification showing reverberation in IVUS.</li> <li>IVUS/OCT could not cross</li> <li>Microcatheter could not cross.</li> </ol>	High	
	6. RA should be considered for patients with OCT measures of plaque calcium predictive of stent under-expansion (maximum angle >180°, maximum thickness >0.5 mm, and length >5 mm).	High	
	7. RA may not be effective in calcified nodules depending on wire bias. IVL and OA might be useful.	Moderate	
	8. RA should be used with caution in patients with severe left ventricular dysfunction due to the increased risk of no-reflow. A smaller burr size, higher speed, fewer Rev drops during ablation, shorter runs and longer pauses between runs might help reduce complications.	High	
	9. In patients with calcified bifurcation lesions, RA can be considered as a safe and feasible calcium-modification technique.	High	
	10. The use of intravascular imaging enhances the safety of RA, provides useful information regarding the target lesion and the selection of the appropriate guidewire and burr size, and predicts the optimal route of passage of the RA burr. We recommend using IVUS or OCT before, during, and after RA.	High	
	V. Orbital atherectomy	11. OA is feasible and effective in patients with de novo calcified coronary lesions, with a high device and procedure success rate, which allow it to change compliance of calcified coronary lesions and facilitate optimal stent placement.	High
		12. The main indication of OA is for the management of calcified lesions non-dilatable using conventional methods to modify the plaque, increase vessel distensibility, and facilitate the proper stent expansion.	High
		13. OA is not advisable when coronary anatomy shows significant tortuosity (>90° angulations) or the vessel diameter is < 2.5 mm due to increased risk of vessel perforation.	High
VI. Excimer laser coronary atherectomy	14. The clinical use of ELCA is limited in the treatment of heavily calcified plaques but can be very useful in the following scenarios: <ul style="list-style-type: none"> <li>De-novo heavily calcified lesions that are non-dilatable through conventional methods, when the lesion cannot be crossed with a microcatheter or with the RotaWire/ViperWire guidewires.</li> <li>ISR due to stent under-expansion and peri-stent calcium &gt;90°</li> <li>Under-expanded stents.</li> </ul>	High	

(continued on next page)

Table 3. (continued)

Section	Statements	Quality of Evidence
VII. Balloon-based techniques	15. NC balloons should always be used for post-dilation as it can optimize stent expansion in all cases with calcified coronary lesions (where the calcium arc is restricted [ $<90^\circ$ ]).	High
	16. In patients with severely calcified coronary lesions, super high-pressure non-compliant balloons are safe and associated with high angiographic, strategy, and procedural success, and should be considered when conventional non-compliant balloons fail to expand properly, although their use may necessitate atheroablative techniques to facilitate crossing (ECLA RA OA).	Moderate
VIII. Shockwave lithotripsy	17. In patients with severe coronary artery calcification who require coronary revascularisation, Intravascular Lithotripsy (IVL) can significantly modify the calcified plaque allowing optimal stent delivery and high clinical & angiographic success, without significant procedural complications (i.e., vessel perforation, embolization, or no reflow).	High
	18. IVL should be considered in patients with moderate to severe calcification as defined by fluoroscopic or IC imaging criteria.	High
	19. If an IVL balloon cannot cross successfully, crossing can be facilitated by pretreatment with NC balloons or ablative technology (RA, OA, ECLA).	High
	20. IVL may be less effective in patients with vessels diameter $>4$ mm or important plaque eccentricity, as these preclude appropriate IVL balloon apposition to the vessel wall and may reduce the efficacy of the therapy	Moderate

Integrating the use of intracoronary imaging, specifically OCT, guided the selection and application of the Shockwave Coronary Rx Lithoplasty System in treating heavily calcified coronary lesions in a study involving 31 patients. The post-lithoplasty OCT observations identified calcium fractures in 43% of treated lesions, which increased in frequency among the most severely calcified plaques. This led to significant acute area gain and improved stent expansion. Furthermore, OCT facilitated the handling of deep dissections, which occurred in 13% of the cases. They were able to successfully manage these with stent implantation, thereby avoiding incidents of acute closure, slow flow/no-reflow, or perforation [27]. This experience underscores the crucial role that intracoronary imaging plays in guiding the selection of calcium modification techniques and atherectomy devices, enhancing patient outcomes in the treatment of complex calcified lesions.

#### 3.2.4. Post-stent assessment

The use of intravascular imaging techniques, such as IVUS and OCT, has become increasingly indispensable for post-stent assessment of medial dissections, adequate stent apposition, and stent expansion, as a part of the MLD MAX algorithm [28], to provide valuable insights into the final stent result [29]. Research demonstrates that the recommended absolute minimum stent area should be  $>90\%$  in both the proximal and distal halves of the stent relative to the closest reference segment for OCT [30], and greater than  $4.5 \text{ mm}^2$  with OCT [31,32], for a successful stenting outcome. In

addition to the absolute measurements, the relative stent expansion—defined as the ratio of the minimal stent area to the average reference lumen area—should ideally be greater than 80% [33–35]. Several studies reported that IVUS can detect stent malapposition and underexpansion, but may not detect minimal stent malapposition [36–38]. In assessments where both IVUS and OCT were utilized for the same lesions, it was found that acute malapposition was detected by OCT more than twice as frequently compared to IVUS. This was seen in studies such as OPUS-CLASS which showed 14% for IVUS and 39% for OCT [39], and ILUMIEN III [30], with 19.3% for IVUS versus 38.5% for OCT. Consistent findings were seen in large cross-sectional studies using IVUS and OCT, with prevalence rates for acute malapposition being 8%–15% with IVUS and 39%–62% with OCT [40,41]. Therefore, IVUS and OCT, in combination with quantitative coronary angiography, play a critical role in ensuring optimal stent implantation and patient outcomes.

## 4. Management of intracoronary calcification

### 4.1. Calcium-ablation techniques

Technologies developed for the treatment of lesions with a high calcium content (LHCC) typically fall into two main categories: ablation and balloon-based techniques. Ablation techniques, such as rotational atherectomy (RA), orbital atherectomy (OA), and excimer laser, are designed to ablate or

remove calcium, thereby facilitating stent expansion [42]. On the other hand, balloon-based techniques do not eliminate calcium but rather aim to enhance the elasticity of the plaque and support stent expansion by fracturing the calcified component in one or multiple areas with LHCC. The feasibility, effectiveness, and safety of these strategies have been demonstrated in several studies [43–48]. However, to ensure optimal outcomes, it is imperative that these techniques are applied according to their specific indications (Statement 3). Recently, an expert consensus was developed to establish a systematic algorithm for calcium modifications devices [49]. Below, we provided expert recommendations for the use of each technique according to the Saudi context.

#### 4.1.1. Rotational atherectomy (RA)

Several studies have demonstrated the advantageous role of upfront RA for lesion preparation prior to the implantation of drug-eluting stents (DES) or drug-coated balloons (DCB). The ROTAXUS trial indicated that the application of RA before stenting led to a more significant acute lumen gain ( $1.56 \pm 0.43$  mm vs.  $1.44 \pm 0.49$  mm) compared to stenting without RA, suggesting improved initial luminal cross-sectional area gain [46] (Statement 4). Nevertheless, the strategy success in the RA group in the ROTAXUS trial was higher than in the standard therapy group (92.5% vs. 83.3%,  $p = 0.03$ ) [46]. A further RCT conducted by Abdel-Wahab et al. demonstrated superior strategic success in the RA group (98% versus 81%), underscoring the higher procedural success of this approach [50]. Moreover, the multicenter ROTATE registry, investigating in-hospital and midterm outcomes of RA followed by metallic stent implantation, emphasized the safety and effectiveness of RA, showing an acceptable rate of MACE in both in-hospital and follow-up periods [51]. These findings underscore the potential benefits of RA in achieving superior luminal gain and strategic success compared to non-RA strategies in patients with calcified coronary lesions.

Published data have reported inconsistent results regarding routine use of RA before DES deployment in calcified lesions. De Waha et al.'s study found no significant reduction in angiographic late lumen loss at 9 months post-PES placement with RA. After 2 years, MACE occurred in 29.4% of RA patients versus 34.3% in the standard therapy group ( $P = 0.47$ ) [52]. Abdel-Wahab et al. compared RA and modified balloons (MB) before DES placement. Despite RA showing higher initial success (98% vs. 81%,  $P = 0.0001$ ), in-stent late lumen loss at 9 months was similar for both groups

( $P = 0.21$ ) [50]. Hence, the routine use of RA before DES deployment remains controversial due to these findings (Statement 5).

#### 4.2. Indications and patient selection

RA is typically recommended as a primary strategy or as a subsequent option after unsuccessful balloon pre-dilation in specific cases. This includes instances of severely calcified de novo coronary stenoses, which are not expected to expand sufficiently with balloon angioplasty, especially when calcification is at least  $270^\circ$  based on IVUS or OCT examination. Other suitable situations for RA include napkin ring calcification, instances where calcification shows reverberation in IVUS or cases where either IVUS/OCT or a microcatheter struggle to cross the lesion [53,54]. Additionally, RA should be considered in patients whose OCT measurements of plaque calcium suggest a high likelihood of stent under-expansion (Statement 6). Such measurements can include a maximum angle exceeding  $180^\circ$ , a maximum thickness over 0.5 mm, uncrossable lesions, undilatable lesions, and a length above 5 mm [24].

Conversely, RA should be avoided in degenerated saphenous vein graft lesions or thrombus (Statement 7). Whiteside et al. showed that patients with severe left ventricular dysfunction (LVD) who were treated with RA were at increased risk of no-reflow and prolonged procedural hypotension, compared to those with preserved left ventricular ejection fraction (LVEF) ( $P = 0.019$  and  $P = 0.041$ ), respectively [55]. RA should be used with caution in patients with severe LVD due to the increased risk of no-reflow. A smaller burr size, higher speed, fewer Rev drops during ablation, shorter runs and longer pauses between runs might help reduce complications (Statement 8).

In patients with very long lesions ( $>25$  mm) and lesion angulation  $>45^\circ$ , angiographic success and procedural complications of RA were comparable to short lesions (93% vs 91%,  $p = 0.24$  and 9.8% vs 9.4%,  $p = 0.84$  respectively). Additionally, over a follow-up period of 28 months, MACE rates were similar between the two groups (28% vs 29.1%,  $p = 0.95$ ) [56]. These findings support the use of RA in this group of patients; however, there is a need for high-quality evidence to confirm these findings.

More contemporary evidence indicated variable cardiovascular outcomes when using RA for severe in-stent restenosis (ISR). Ferri et al.'s study involving 16 patients reported an 87.5% RA success rate and a mean postprocedural lumen diameter increase of  $2.3 \pm 0.8$  mm but noted complications in two cases

[57]. Another study with 200 ISR patients reported TLR rates of 40.7%, 35.0%, and 27.3% for balloon angioplasty, DES implantation, and DCB angioplasty post-RA, respectively, with complications in three cases [58]. The data affirm RA's viability for severe ISR; however, stent ablation with RA should be used with extreme caution by highly experienced operators, ideally with on-site surgical backup. Excimer laser coronary atherectomy (ELCA) can effectively reduce plaque and enhance lumen diameter in cases of ISR with DES, and is thus recommended for such scenarios [59,60].

#### 4.2.1. Special lesions

The experts agreed that RA can be considered in patients with calcified bifurcation lesions or severely calcified side branches over 2.5 mm diameter as a viable calcium-modification technique (Statement 9). A retrospective study by Ito et al. involving 40 patients with bifurcation coronary disease found RA of the side branch ostium to be safe and feasible with no acute closures or coronary perforations, despite MACE occurring in a small proportion (2.5–5%) during the 21.3 months follow-up period [61]. Meanwhile, Chen et al.'s study on 292 patients found RA to be effective for heavily calcified, balloon-uncrossable, or undilatable side branches, with a MACE rate of 27.1% over a 25.1-month period. However, due to a higher rate of side branch perforations and acute contrast-induced nephropathy, RA's application in these scenarios necessitates experienced operators [62]. In the case of significant tortuosity (>90° angulations), there is an increased risk of burr-related wire damage, leading to perforation and burr entrapment [63].

#### 4.2.2. Patient preparation, guidewire, and burr size

The feasibility and safety of radial artery access for RA has been established in recent trials. A study of 8622 patients showed similar 30-day mortality between radial (2.2%) and femoral (2.3%) access, but lower major bleeding complications with radial access [64]. Further, Watt & Oldroyd found comparable procedural success (93.3% radial vs. 94.7% femoral), endorsing radial access due to potentially reduced bleeding risk [65]. Kotowycz et al. reported identical success rates between radial and femoral approaches despite smaller catheters used in the radial group [66]. Based on these findings, the experts recommended that radial artery access should be considered routinely. Angulated and tortuous subclavian arteries and acute aorto-subclavian angles should be considered when using the radial artery. In the case of angulated and tortuous subclavian arteries and acute aortic-subclavian angles, a

burr of more than 1.5 mm will need a 7F guide; in these cases, the radial artery should be able to accommodate a 7F guide or, alternatively, femoral access can be used.

Although the choice of guide catheters depends on the vessel anatomy and the expected need for backup support, single curve catheters should be considered routinely as they are associated with less resistance to burr advancement to the catheter tip. The experts recommended using a microcatheter in cases where the balloon will not cross the lesion to permit wire exchange to bring RotaWires to the target. RA operators should use the conventional 0.014-inch guidewire to cross the lesion and then exchange the conventional guidewire to the RotaWire using a microcatheter. The operator can use the microcatheter's nose cone at the mouth of the lesion if the microcatheter does not cross.

In terms of the burr size, the STRATAS and CARAT studies have shown that using smaller burrs (with a burr: artery ratio of <0.7) can achieve procedural and angiographic success comparable to larger burrs [67,68]. Additionally, smaller burrs are associated with fewer angiographic complications, less creatine kinase-myocardial band released during the procedure, and the use of smaller sheaths and guide catheters, which subsequently reduce the risk of bleeding and vascular complications. The European expert consensus recommended a burr/artery ratio of 0.6, and the North America and Japanese expert consensus recommended a burr/artery ratio of 0.4–0.6 [53,54,69]. In this consensus, the experts advocated for a burr-to-artery ratio of 0.5–0.6. They also recommended the use of a single burr in all cases, except for special situations like when the first burr cannot cross the lesion, operators aim to use the big burr, or start with the small burr for safety and then size up to the big burr.

Burr motion and speed variations in RA significantly influence complications to risk, particularly myocardial infarction and slow-flow/no-reflow. Rotation speed can vary from 140,000 to 220,000 rpm among practitioners [70]. In preclinical studies, lower-speed RA (140,000 rpm) was associated with reduced slow flow due to less platelet aggregation [71], but a single-centre randomized controlled trial (RCT) showed no significant slow flow difference between low and high speed (OR = 1.00; 95% CI: 0.40 to 2.50) [72]. In terms of burr motion, several guidelines and consensus agreed that the pecking motion is the standard burr manipulation in RA [53,54,69]. Therefore, the experts recommended these fundamental elements of optimal RA technique include (1) a rotational speed of 140,000 to



180,000 rpm, (2) gradual burr advancement with a slow, pecking motion, and (3) short ablation runs lasting no more than 20 s, pausing between runs.

**4.2.2.1. Safety considerations.** RA is considered safe with low rates of serious complications and acceptable MACE rates, as shown by the ROTAXUS trial [46]; preventive measures such as regular flushing, antithrombotic therapy, and using short pecking motions during the procedure are recommended to mitigate risks like slow-flow/no-reflow. Patient characteristics and institutional experience are crucial in minimizing peri-procedural complications, with factors such as age, vascular disease, and emergent PCI increasing the risk [73,74] (Statement 10).

#### 4.2.3. Orbital atherectomy (OA)

The ORBIT II study evaluated the efficacy of OA in patients with de novo calcified coronary. Their findings demonstrated a procedural success of 88.9%, comparable to the 85% in the COAST trial. Furthermore, 89.6% of patients in the ORBIT II trial remained free from MACE at 30 days post-procedure, which was not significantly different from the 85% in the COAST [47,75,76]. These findings encouraged the experts to highlight that the OA system demonstrates high feasibility and effectiveness for de novo calcified coronary lesions (Statement 11), facilitating optimal stent placement and improving both immediate and 30-day clinical outcomes, including residual stenosis, lesion revascularisation rate, and major adverse cardiac events. Evidence increasingly suggests that OA may offer enhanced plaque/vessel modifications compared to RA.

Observational studies demonstrate OA's substantial lumen volume increase of  $9.68 \pm 17.22$  mm<sup>3</sup> and larger ablation area of  $0.55 \pm 0.41$  mm<sup>2</sup> [77]. Importantly, post-atherectomy dissections were significantly deeper with OA (1.14 vs. 0.82 mm,  $P = 0.048$ ), indicating longer and deeper cuts. Moreover, OA provided superior stent apposition, as seen in a reduced percent of stent strut malapposition compared to RA (4.36 vs. 8.02%,  $P = 0.038$ ) [78]. Finally, while the ORBIT II and COAST trials highlight the potential advantages of the OA system for de novo calcified coronary lesions, it is essential to note that direct head-to-head comparisons of ablation technologies are lacking. Moreover, the selection of the ablation technique may be heavily influenced by the operator's experience and the availability of the respective devices. Thus,

recommendations should incorporate these factors when discussing the choice of technology.

**4.2.3.1. Indications.** The experts agreed that the main indication of OA is for the management of calcified lesions non-dilatable using conventional methods to modify the plaque, increase vessel distensibility, and facilitate the proper stent expansion (Statement 12). A retrospective study showed that, among these patients, a greater proportion of noncalcified plaque modification was observed in the OA group (16.9% vs. 10.0%,  $p = 0.01$ ). There was also a trend towards more post-atherectomy calcium modification after OA compared to RA, especially in areas with a post-atherectomy lumen cross-sectional area (CSA)  $> 4$  mm<sup>2</sup> (53.0% vs. 35.0%,  $p = 0.001$ ). Calcium fracture behind the stent was frequent (82%) with comparable prevalence and length between OA and RA [79].

According to the experts, OA is not advisable when coronary anatomy shows significant tortuosity ( $>90^\circ$  angulations) or when vessel diameters  $<2.5$  mm due to increased risk of vessel perforation. As the OA has a non-ablating, rigid forward metallic nose, which may not penetrate through tighter lesion, it is advisable for more proximal and larger vessels (Statement 13).

**4.2.3.2. Safety considerations.** Contrary to RA, OA maintains a constant blood flow through the artery during ablation. Perdoncin et al., compared OA vs. RA in patients from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2). Their findings showed that the rates of perforation ( $p = 0.021$ ) and bleeding events within 72 h ( $p = 0.014$ ) were higher in the RA compared to OA [80]. These characteristics of OA could potentially minimize the risk of slow-flow/no-reflow phenomenon, lower the incidence of thermal damage during the procedure, and eliminate the routine need for temporary pacing during OA.

#### 4.3. Excimer laser coronary atherectomy

##### 4.3.1. Effectiveness and clinical benefits

ELCA is a plaque-modifying technique that has shown promise in the treatment of ISR, achieving high procedural success rates in trials such as the ELLEMENT registry and LEONARDO trial [81,82]. Studies indicate that ELCA can effectively reduce plaque and enhance lumen diameter, particularly in cases of ISR with DES, and is thus recommended for such scenarios [59,60]. However, while ELCA alone or in combination with RA has been successful in

chronic total occlusions (CTOs), further research is necessary to confirm its long-term clinical benefits over traditional PCI [81,83].

#### 4.3.2. Indications

Recent advancements in ELCA technology have enabled its safe application in heavily calcified lesions and CTOs, with a high success rate and low complication rate also observed in cases of ISR, stent underexpansion, and acute myocardial infarction, making it a recommended option for complex coronary interventions [84–90]. ECLA's main role is in treating uncrossable lesions where a RotoWire or viper wire cannot be delivered and the lesion is otherwise uncrossable with balloon or microcatheters. It is also useful for treating ISR when the initial stents were inadequately deployed due to underlying calcium (Statement 14).

#### 4.3.3. Safety considerations

Early studies documented ELCA was associated with complication rates of 4–7% [91,92], restenosis rates of 46% [92], perforations of 1–2% [85,93], and in-hospital mortality of 0.5–1.5% [85,93]. In an ISR study, major complications were reported at 1% and long-term MACE at 30% [94]. However, recent studies like the LEONARDO trial, showed that ELCA was not associated with major complications [82]. Therefore, the experts stated these complications could be managed with the use of a technique with continuous infusion of a saline solution, and the use of smaller caliber catheters.

### 4.4. Balloon-based techniques

#### 4.4.1. Clinical benefits and indications

In clinical practice, the OPN Non-compliant (NC) balloon by SIS Medical is favored for dilating mildly to moderately calcified stenoses and shows over 90% success in previously undilatable lesions with a low risk of coronary rupture [95,96] (Statement 15). The ISAR-CALC and PREPARE-CALC trials suggest that super high-pressure NC balloons can be as effective as scoring balloons in stent expansion for severely calcified lesions and serve as a viable secondary option when RA or OA are insufficient [50,97]. Conversely, the cutting balloon (CB) Global Randomized Trial and other studies suggest that CBs may not offer significant advantages over percutaneous transluminal coronary angioplasty (PTCA) for mild-to-moderate calcified lesions [98–100]; yet, the PREPARE-CALC-COMBO study indicates their utility following RA in more challenging, severely calcified lesions for better acute outcomes [101]. CBs

are advised mainly for predominantly fibrotic disease, ostial lesions, and in-stent restenosis (Statement 16).

#### 4.4.2. Safety considerations

High-pressure OPN NC balloons, recommended for their low risk of complications, are suitable for certain interventions, though they are less favorable for eccentric lesions and calcified nodules due to increased risk of adverse effects, while cutting and scoring balloons share similar limitations and moderate dissection risk, especially in circumferential calcium and long lesions [102].

### 4.5. Shockwave lithotripsy

#### 4.5.1. Effectiveness and clinical benefits

Research evidence supports the assertion that in patients necessitating coronary revascularization due to severe CAC, intravascular lithotripsy (IVL) is significantly beneficial (Statement 17). Disrupt CAD II demonstrated successful IVL catheter delivery in all cases, substantial calcific plaque fracture in most lesions, and only a 5.8% rate of MACE [103]. Complementarily, the Disrupt CAD IV study on a Japanese population established high procedural success (93.8%) with high freedom from the 30-day MACE rate (93.8%) [104]. Moreover, a systematic review and meta-analysis, encompassing eight observational studies and 980 patients, exhibited clinical success in 95.4% of cases and angiographic success in 97% of cases, as well as a noteworthy increase in postprocedural lumen area and significant reductions in calcium angle and maximum calcium thickness [105]. Across these studies, there were no significant procedural complications reported, such as vessel perforation, embolization, or no-reflow. Therefore, these findings validate the considerable effectiveness and safety of IVL in managing severe CAC.

#### 4.5.2. Indications and patient selection

In the previously mentioned trials, the participant selection criteria were explicitly designed to include patients who met the pre-dilatation requirements for deep calcification and were able to undergo successful balloon crossability [103,104]. These stringent requirements entailed the presence of circumferential calcification, as evidenced by fluoroscopic radio-opacities absent of cardiac motion enveloping both arterial wall sides, and at least one intravascular imaging cross-section demonstrating calcium covering  $\geq 270^\circ$ . Further stipulations included diameter stenosis  $\geq 70\%$ , a native coronary artery lesion length of  $\leq 40$  mm, and intense

calcification characterized by a calcium arc greater than 180°, calcium length exceeding 5 mm, and calcium thickness surpassing 0.05 mm. Based on the promising results of these studies, the experts recommended using IVL for patients with high calcium burden (as outlined in the criteria above), which is not amenable to routine balloon pre-dilatation. For those patients not meeting these criteria, IVL was considered as an alternative intervention after the unsuccessful application of a super-high-pressure balloon or cutting/scoring balloon (Statement 18).

Additionally, IVL should be considered if the balloon crosses successfully, but the optimal balloon expansion could not be obtained (Statement 19). There is evidence that IVL may be considered for eccentric lesions, defined as a stenotic lesion that had one of its luminal edges in the outer one-quarter of the apparently normal vessel lumen whereas a concentric lesion has the same criteria but involves both luminal edges. A pooled analysis from the Disrupt CAD I and CAD II studies showed that the clinical success of IVL in patients with eccentric lesions was 93.6% compared to 93.2% in those with concentric lesions ( $p = 1.00$ ). Furthermore, the final acute gain and percentage of remaining stenosis showed comparable outcomes between the two groups. There was final residual stenosis of  $8.6 \pm 9.8\%$  in eccentric stenosis and  $10.0 \pm 9.0\%$  in concentric stenosis ( $p = 0.56$ ), corroborating the substantial impact of IVL in treating calcified coronary lesions [106]. However, in patients with severe lumen reduction, upfront IVL is not the preferred option (due to the slightly higher lesion entry profile and lesion crossing profiles) unless pre-dilatation with standard balloons achieves reasonable passage for the IVL. Moreover, IVL is less preferred in patients with vessels diameter  $>4$  mm or important plaque eccentricity, as these preclude appropriate IVL balloon apposition to the vessel wall and may reduce the efficacy of the therapy (Statement 20).

#### 4.5.3. Technical aspects

In the clinical setting, most practitioners are generally advised to carry out non-compliant balloon (NCB) dilation, but only when there's over 30% incomplete expansion of IVL catheters [107]. NCB should be used for optimal preparation after IVL. The required number of pulses to guarantee adequate lesion preparation is still a topic of uncertainty. It should be noted that one catheter is capable of administering a maximum of 120 pulses. For lesions with eccentric calcium, additional pulses might be necessary as the distance from the emitter to the calcium root is greater, and the wave

reflection observed with concentric calcium is absent. If a full set of 120 pulses has been deployed, the application of a non-compliant balloon can assist in evaluating the efficacy of the procedure and deciding if there is a need for an additional IVL catheter to guarantee complete balloon expansion.

#### 4.5.4. Safety considerations

Research has consistently demonstrated the safety and efficacy of IVL in treating patients with intracoronary calcification. According to the Disrupt CAD II study, freedom from MACE at 30 days was observed in 93.8% of cases [103]. Concurrently, the Disrupt CAD IV study reported in a multicenter study involving 120 patients that the primary endpoint (in-hospital MACE) occurred in only 5.8% of patients, consisting primarily of non-Q-wave myocardial infarctions [104]. Furthermore, both studies highlighted minimal procedural complications such as perforations, abrupt closures, or slow/no-reflow events [103,104]. Moreover, Kereiakes et al., 2022, confirmed these findings, noting that clinical trials have consistently illustrated low rates of MACE and severe angiographic complications associated with IVL [108]. In summary, these studies underscore the safety of IVL in treating patients with intracoronary calcification, further evidenced by the associated minimal complications and procedural risks.

The experts also highlighted that IVL may not be considered in pacemaker carriers due to the high risk of ectopic beats and asynchronous cardiac pacing until further evidence becomes available. A retrospective study showed that the incidence of coronary IVL-provoked ventricular capture was 77.8%. The beat morphology was predominantly consistent in each patient, and it seemed to be influenced by the location of the target lesion, which was in line with the concept of mechano-electric coupling through the activation of stretch-activated cardiomyocyte channels in the local region. Importantly, no adverse clinical events were found to have resulted from coronary IVL-induced capture [109]. The experts suggested that the IVL system should be avoided in patients with critical stenosis or severe vessel tortuosity due to the risk of balloon rupture and increased risk of vessel dissection [110,111]. Additionally, there is a need for careful consideration of IVL in tortuous lesions due to difficult delivery and possible balloon entrapment after use.

## 5. Conclusion

In conclusion, the management of intracoronary calcification represents a multifaceted challenge in

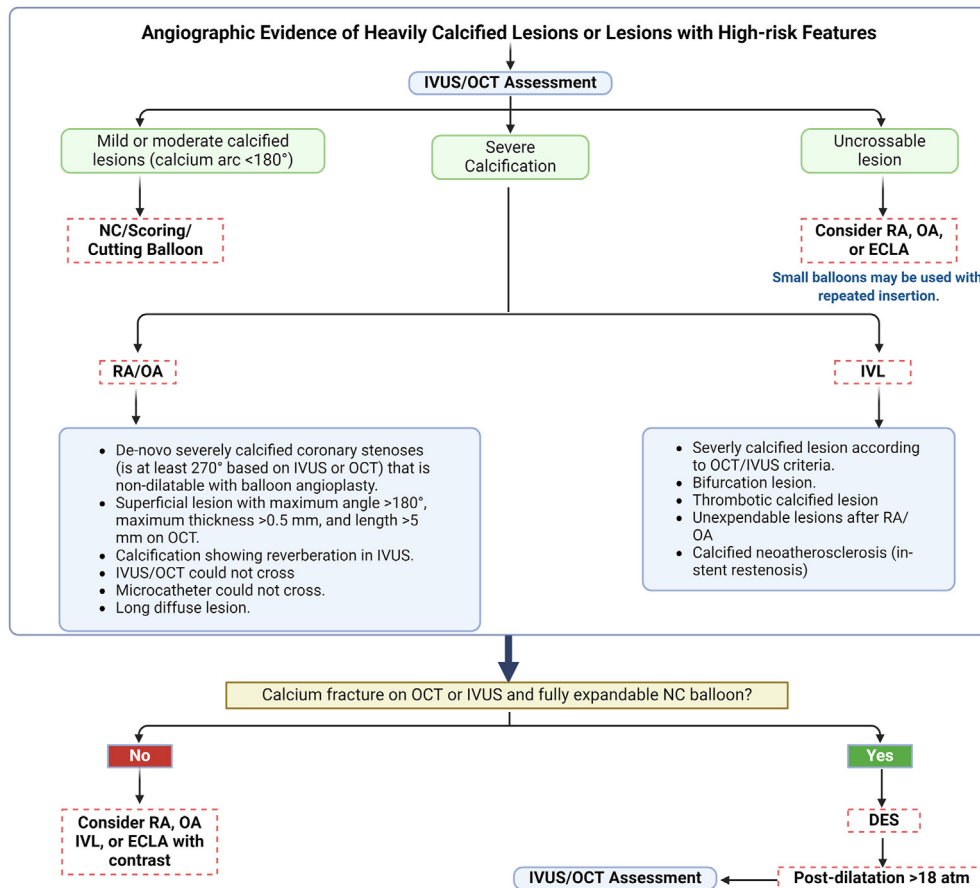


Fig. 1. A Proposed Algorithm for the Management of Lesions with Angiographic Evidence of Severe Calcification or High-risk Features\*. IVUS/OCT, Intravascular Ultrasound/Optical Coherence Tomography; RA, Rotational Atherectomy; OA, Orbital Atherectomy; ECLA, Extracorporeal Life Support; IVL, Intravascular Lithotripsy; NC Balloon, Non-Compliant Balloon; DES, Drug-Eluting Stent. \*High-risk features include End-stage renal disease, Elderly, Smoking, Hypertension, and Diabetes mellitus.

interventional cardiology, particularly in Saudi Arabia. The spectrum of available diagnostic modalities, from non-invasive techniques such as coronary CT angiography and fluoroscopy, to invasive approaches including IVUS, OCT, and coronary angiography, provides a comprehensive toolkit for the identification, quantification, and localization of coronary calcifications. Through the judicious application of these modalities, we can better predict stent underexpansion, thereby improving patient outcomes. The interventional strategies currently available, encompassing RA, OA, IVL, ELCA, and balloon-based techniques, offer a robust suite of treatment options (Fig. 1). Yet, their efficacy is dependent on thorough lesion preparation according to intracoronary imaging findings and vigilant post-stent assessments.

However, it should be acknowledged that the lack of Saudi Arabian data on calcified lesions and their treatment presents a challenge in this consensus, as it may not fully reflect the local disease landscape,

clinical practice, and management strategies. While Western data and guidelines provide valuable insights, they may not directly apply to the Saudi Arabian context due to potential differences in disease patterns, patient characteristics, and healthcare systems. Therefore, there is a need for further research and data collection in the context of Saudi Arabia. Identifying potential barriers to data collection and proposing strategies to overcome them is crucial in encouraging more research in this area. This can contribute to developing guidelines tailored to the Saudi Arabian population, enhancing their relevance and utility for local clinicians and researchers.

There also remain notable limitations and knowledge gaps, with challenges persisting in addressing uncrossable lesions—mainly in small vessel—, calcium nodule management, and the high operational costs of certain techniques. We also recognize the constraints imposed by the availability and accessibility of advanced imaging and intervention tools, and the

necessity of further research to understand their optimal deployment in diverse patient cohorts.

## Funding

The authors retained the editorial process, including the discussion, at all times. There was no financial reward associated with writing the paper. The medical writing and editorial activities of the present document were provided by Dr. Ahmed Elgebaly from Advocacy for Pharmaceutical Consultancy Co. and funded by Boston Scientific Co. The views and opinions expressed are those of the authors. All authors meet the International Committee of Medical Journal Editors (ICMJE) authorship criteria and approve the final version of the manuscript.

## Author contribution

Conception and design of Study: KS, MA, OA, AA, WA, FA, NA, MA, AT. Literature review: KS, MA, OA, AA, WA, FA, NA, MA, AT. Acquisition of data: KS, MA, OA, WA, AT. Drafting of manuscript: KS, MA, OA, WA, AT. Revising and editing the manuscript critically for important intellectual contents: KS, MA, OA, AA, WA, FA, NA, MA, AT. Supervision of the research: KS, MA, WA, AT. Research coordination and management: KS, MA, WA, AT.

## Conflict of interest

None to declare.

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