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Review

How to identify and prepare calcified lesions safely and effectively

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Abstract: Calcified coronary lesions pose significant challenges in percutaneous coronary intervention, which can impede device placement and stent expansion, thus leading to suboptimal clinical outcomes. This paper outlines a comprehensive approach for the safe and effective preparation of calcified lesions. It emphasizes the importance of pre-procedural planning using either coronary artery calcium scoring or computed tomography coronary angiography, as well as advanced intravascular imaging techniques with intravascular ultrasound and optical coherence tomography for accurate lesion assessment. Various lesion modification strategies are reviewed, including balloon angioplasty, rotational atherectomy, orbital atherectomy, laser atherectomy, and lithotripsy. The selection criteria for each technique based on the lesion characteristics, calcium morphology, and operator experience are discussed. Additionally, clinical data is analysed to provide evidence-based recommendations for practice. The paper concludes with a discussion on future directions and innovations alongside a proposed algorithm for the management of calcified coronary lesions, which is aimed at improving patient outcomes through technological advancements and refined procedural techniques.

Keywords: calcification; coronary; intracoronary imaging; atherectomy; lithotripsy; review

1. Introduction

One of the major challenges in the field of percutaneous coronary intervention (PCI) is the treatment of severely calcified lesions. This is due to the reduced flexibility and compliance of the affected vessel, which can increase the risk of complications during the procedure. Furthermore, the presence of calcification can also affect the long-term effectiveness of stent implantation [1]. To address these challenges, proper lesion preparation is necessary to ensure optimal stent expansion, minimize structural damage, and improve the uptake of medication into the vessel wall [2].

Contemporary imaging tools have significantly advanced the ability to identify and detect coronary artery calcifications, thus providing treating interventionalists with invaluable insights for patient and lesion management [3]. These cutting-edge technologies, such as high-resolution computed tomography (CT) scans, intravascular ultrasounds (IVUS), and intravascular optical coherence tomography (OCT) allow for the precise quantification and characterization of calcified plaques within coronary arteries. By accurately assessing the extent and distribution of calcium, clinicians can better understand the severity of atherosclerosis, evaluate the risk of cardiovascular events, and tailor interventional treatment strategies accordingly [4] through the use of balloon based technologies or more advanced calcium modification tools.

Non-compliant (NC) balloons, including those with cutting or scoring capabilities, are often used to prepare calcified coronary lesions before stent implantation [2]. This is because traditional compliant and semi-compliant balloon inflations may not be enough to adequately prepare severely calcified lesions [3]. In these cases, using these more specific balloon-based therapies can help to achieve better vessel preparation and improve the success of stent implantation in patients with calcific coronary artery disease [2,3]. These therapies, which include high pressure NC balloons and cutting and scoring balloons remain the first-line therapy for preparing lesions and modifying calcium in patients undergoing PCI [5,6].

Rotational and orbital atherectomy and excimer laser systems are advanced ablative tools employed in the management of complex coronary disease. Rotational and orbital atherectomy devices utilize rotating diamond-coated burrs or elliptical orbiting crowns to selectively ablate and modify calcified atherosclerotic plaques within the arterial walls, thus improving the luminal diameter and facilitating the subsequent balloon angioplasty and stent placement. On the other hand, excimer laser atherectomy employs a high-energy ultraviolet light to precisely vaporize plaque material, including calcified and fibrotic tissues, through a process called photochemical ablation. Additionally, the recent availability of intravascular lithotripsy (IVL) has allowed for an alternate means of calcium modification in a safe and effective manner. These techniques are particularly beneficial in treating heavily calcified lesions, with recent evidence demonstrating no significant differences observed between a rotational atherectomy and IVL with regards to the minimum stent area (MSA), procedural success rate, and complications, which were not surprisingly numerically lower with IVL [7].

However, the routine use of more advanced balloon and ablative technologies in preparing calcified coronary lesions before stent implantation has been a topic of debate. These aim to increase vessel compliance and facilitate stent expansion, but do pose higher peri-procedural risks. While numerous prior algorithms have been suggested [6], there is limited randomised evidence with cardiovascular outcome data on the preferred treatment modality in this context. Therefore, this paper seeks to review the current clinical evidence on different techniques to identify and prepare severely calcified coronary lesions before undergoing PCI to ensure effective and safe calcified vessel preparation.

2. Detection and quantification of calcified lesions

Coronary artery calcium can be used as an indicator of atherosclerosis and the likelihood of future cardiac events. However, traditional methods of detecting calcium, such as coronary angiography, may not be as accurate as newer methods such as coronary computed tomography angiography (CCTA), grayscale IVUS, or intravascular OCT. Despite this, coronary angiography is still a valuable tool due to its high positive predictive value.

2.1. Coronary angiography

Angiographic calcium is a term used to describe the level of calcification found in the coronary arteries. This type of calcium buildup can be classified as none, mild, moderate, or severe based on its appearance during an angiogram. Moderate calcification is characterized by radiopacities that are only visible before contrast injection, while severe calcification is identified by radiopacities that are present in the absence of any cardiac motion and affect either side of the vessel lumen [8].

Studies showed that grayscale IVUS calcium was present in the majority (about 73%) of target lesions. This calcium was found in different amounts in different quadrants, with 26% in 1-quadrant, 21% in 2-quadrant, 15% in 3-quadrant, and 11% in 4-quadrant calcium. Surprisingly, only 26% of these lesions had moderate calcium and 12% had severe calcium when assessed through angiography.

The sensitivity of angiography was found to be the lowest in lesions with 1-quadrant calcium and the highest in lesions with 4-quadrant calcium, at 48% and 85%, respectively. Interestingly, coronary angiography was more successful in detecting superficial target lesion calcium, either alone or in combination with deep calcium, possibly because the superficial calcium was thicker and occupied a larger portion of the plaque. The accuracy of angiography in detecting severe calcium was 89%, with the highest rate of 98% seen in cases with severe calcium. However, the rate of false positives was 11%, which could not be explained by the presence of an isolated reference segment calcification. This highlights the limitations of angiography in accurately detecting calcium deposits in the coronary arteries [8].

2.2. Coronary artery calcium score

The use of a coronary calcium score is a well-established method to evaluate the presence and extent of calcified plaques in the coronary arteries. This score is calculated by assigning a weighted value to the highest density of calcification in each coronary segment, multiplying it by the area, and summing it for all arteries. Studies have shown that a higher Agatston calcium score is associated with a greater plaque burden and can be used as a predictor of patient outcomes [9].

2.3. Coronary computed tomography angiography (CCTA)

CCTA is a highly effective imaging technique that allows for the evaluation of coronary plaques and stenosis severity. However, it does require the administration of contrast material, which may pose risks for certain individuals. In some cases, medications such as beta blockers and nitrates may be used to improve the image quality. In order to provide the most accurate images, it is important to select the thinnest possible slice thickness during image reconstruction, typically ranging from 0.50 to 0.75 mm. This will optimize the spatial resolution, thus allowing for the clear visualization of any potential plaque or stenosis in the coronary arteries. Additionally, it is important for the CCTA report to include a detailed description of the amount and type of plaque present, as well as the severity of luminal stenosis for each lesion. This information is crucial for a proper diagnosis and treatment planning [10–15]. Recent studies have also suggested a correlation between lesion-specific parameters, such as spotty calcium, and unstable plaques seen on imaging methods such as virtual histology (VH) and grayscale IVUS [16,17].

2.4. Intravascular ultrasound (IVUS)

IVUS is an invasive medical imaging method that allows for the visualization and analysis of plaque within blood vessels (Figure 1). There are two types of IVUS systems: solid-state and mechanical, each with its own advantages and capabilities. The IVUS image displays the plaque components in grayscale and can also use a colour conversion algorithm, known as VH, to further analyze the tissue density of the plaque [18].

Calcified lesions are characterized by the presence of a highly reflective structure on ultrasound imaging, which often resemble white spots or shadows. These lesions can be classified as either superficial or deep. When there is evidence of excessive calcium or vessel eccentricity, additional calcium modification techniques, including rotational or orbital atherectomy, cutting balloons, or lithotripsy, can be employed to enhance the lesion dilation and optimize the vessel for stent implantation. The IVUS calcium score, proposed by Zhang et al., is a useful tool to identify calcified stenoses at risk for stent underexpansion that may require adjunctive modifications before stent implantation [19]. It has the following elements: >5mm length of >270° superficial calcium, circumferential 360° calcium, presence of a calcified nodule and <3.5 mm vessel size. Calcium modification is recommended if the score is ≥2.

Calcium is an important factor in assessing the severity of atherosclerosis, and can be quantitatively measured using IVUS technology by measuring the arc and length of calcium deposits within coronary arteries. Semiquantitative grading of calcium classifies it as either absent or present in 1, 2, 3, or 4 quadrants. It is important to note that due to the limited penetration of the ultrasound beam, only the leading edge of the calcium deposit is visible, and the apparent thickness seen in grayscale IVUS images is not a true representation of its anatomical thickness. However, a volumetric calculation of calcium can be determined by integrating the arc and length measurements [20]. Furthermore, it should be noted that IVUS may not be able to detect microcalcifications, which could potentially lead to a false negative result. Therefore, it may be important for physicians to use a combination of imaging techniques to accurately assess the presence and severity of calcified plaques [20].

Post modification and before stent implantation, IVUS is also crucial to evaluate the effectiveness of treatments such as shockwave fracture or atherectomy in reducing the extent of calcification. To ensure optimal results, the MSA post stent deployment should generally be at least 5.0 mm^2 in coronary arteries, or 90% of the distal reference lumen [20]. In cases where these IVUS benchmarks are not met, the ULTIMATE trial authors recommend the use of a larger post dilatation balloon. Additionally, it is suggested that plaque burden at the proximal and distal stent edge should be less than 50%, with no edge dissections involving the media [20]. This helps to minimize the risk of stent under-expansion, which could lead to restenosis [21] and target vessel failure (TVF) [20].

There are still some uncertainties surrounding the effectiveness of IVUS compared to a visual assessment. In vitro analyses have shown high sensitivities, specificities, and predictive accuracies; however, it remains to be seen if this translates to in vivo results. Furthermore, it is important to note that this approach may not be as accurate in areas where there is shadowing, thus potentially limiting its overall reliability [13]. Further research and testing is needed to fully understand the potential benefits and limitations of this technology.

2.5. Optical coherence tomography (OCT)

The advanced technology of intravascular OCT is highly accurate in imaging coronary arteries. This is achieved by using infrared light waves to reflect off the internal microstructure within the biological tissues (Figure 1).

Through OCT, calcium can be easily identified as a signal-poor or heterogeneous region with distinct borders. Unlike other imaging methods such as IVUS, OCT has the capability to accurately measure the calcium thickness, area, and volume, thus making it a valuable tool for coronary imaging. Additionally, the superior penetration of calcium by OCT allows for the automatic quantification of these parameters, thus making it a more efficient and reliable method compared to IVUS [21] (Figure 2).

OCT technology offers a more detailed and accurate view of the coronary vasculature compared to IVUS [22]. Its high image resolution allows for a better characterization of the individual structures and the detection of various components of plaque. This makes it an essential tool to identify issues such as thrombus, calcium deposits, and stent placement problems. In particular, OCT is crucial in cases of calcified disease, where it can accurately identify the presence of calcium and its characteristics. Similar to the IVUS calcium score, an OCT based scoring system has also been devised and validated in calcified lesions to help determine which calcific morphologies can lead to stent underexpansion [23]. The identified factors may be easily recalled as the “rule of 5s”: 1 point for maximum thickness >0.5 mm, 1 point for contiguous length of calcium >5 mm, and 1 point for maximum arc >50% of the circumference of the vessel (i.e., >180° of the circumference). Hence, OCT plays a critical role in accurately diagnosing and treating calcified lesions.

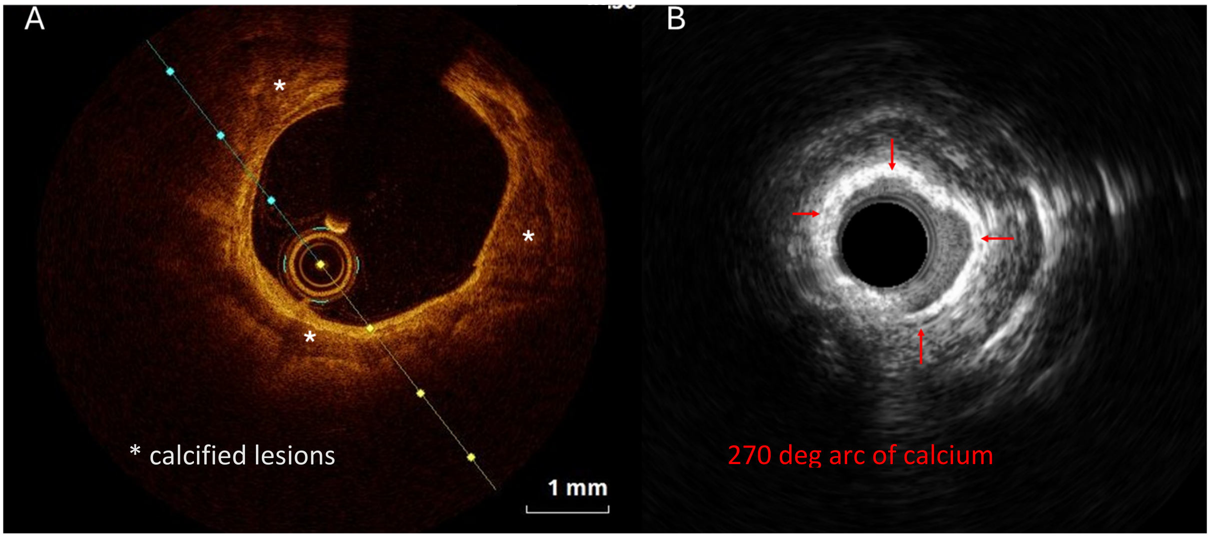

Figure 1. Comparison of calcified lesions on intravascular Optical Coherence Tomography (OCT) versus Intravascular Ultrasound (IVUS).

3. Consequences of calcified lesions

The presence of highly calcified plaques significantly increases the complexity of PCI, making the procedure technically more challenging with an increased risk of periprocedural complications [24–26]. The lower compliance of a calcified plaque than a lipid or fibrous plaque may result in difficult device delivery, equipment damage and entrapment, stent underexpansion and malapposition, or complications such as coronary perforation [27]. The severity of calcifications and the improper preparation of a calcified lesion significantly increase the risk of stent underexpansion and malposition [23,28]. Lesion recurrence due to stent thrombosis or restenosis is the critical prognostic factor that increases the risk of repeated revascularisation and cardiovascular events, both periprocedurally and in a long-term follow-up [29–31].

When predicting the course of PCI, the morphology and location of calcifications should be considered. Patterns and amounts of coronary artery calcifications strongly correlate with periprocedural complications and the rate of future cardiac events. Predicting the need for advanced calcification modification methods before stent implantation and selecting the best atherectomy strategy are supported by specific algorithms based on intracoronary imaging [23]. The assessment includes the calcium arc, length, and thickness. Calcification located in the intima can lead to significant luminal stenosis and downstream ischemia, while calcification that involves the media and peri-adventitia primarily reduced in a reduced vascular compliance [28].

Lesions with the morphology of a calcified nodule (CN) and nodular calcification (NC) require a special approach in the process of lesion preparation and optimization of the procedure (Table 1). A calcified nodule is an eruptive nodular calcification protruding into the coronary artery lumen, which causes 2–8% of acute coronary syndrome (ACS) cases [32]. Nodular calcification does not significantly increase the risk of coronary thrombosis directly; however, it can impact the device crossability by creating mechanical resistance, increasing the risk of balloon or stent hangup, and making lesion preparation more challenging. Both calcified nodules and nodular calcification increase the risk of stent strut damage, stent malposition, and asymmetrical stent expansion, which, as shown by Suwannasom et al., is an independent factor associated with device-oriented composite endpoint (DOCE) [25]. Moreover, the presence of CN and NC significantly increases the incidence of DOCE in the long-term follow-up, regardless of the immediate outcome of the procedure. Watanabe et al. observed stent malappositions more frequently in calcified nodule [33]. Furthermore, the use of a high-pressure noncompliant or semi-compliant balloon post-dilatation may increase the risk of vessel perforation on an adjacent noncalcified site [34].

Given the risks and possible future adverse outcomes associated with calcified lesions, the accurate appreciation of calcified plaque is essential. This, in turn, would allow one to predict the need for calcium modification and select appropriate devices and technologies for vessel preparation prior to PCI.

Table 1. Types of calcified lesions (Nodular vs concentric, superficial vs deep).

Calcified lesion types	Features
Nodular	1. Small rounded calcified fragments 2. Eruptive calcium protrusion into the lumen 3. Overlying fibrin-rich thrombus 4. Fibrous cap disruption
Concentric	1. Less than totally occlusive 2. Non-angulated segment (<45º) 3. Readily accessible 4. Not ostial lesion 5. No major side-branch involvement 6. Smooth contour 7. Absence of thrombus
Superficial	1. Located at the intimal lumen interface or closer to the lumen than to the adventitia 2. Acoustic shadowing appears within the shallowest 50% of the plaque 3. Media thickness
Deep	1. Located at the media or adventitia border or closer to the adventitia than to the lumen 2. Acoustic shadowing appears within the deepest 50% of the plaque 3. Media thickness

4. Balloon-based therapies

The challenges of negating coronary calcium during PCI have been addressed by various calcium-modification tools over the past two decades. There are two main principles when dealing with calcium: some tools such as atherectomy devices are designed to ablate the calcium, and balloon-based devices fracture the calcified plaques, thus leading to improved stent expansion contributing to procedural success. In this section, we will be discussing balloon-based approaches when dealing with calcified lesions (Figure 2).

4.1. Non-compliant balloons

Non-compliant (NC) balloons represent a category designed with rigidity in mind. They tend to uniformly expand over their longitudinal axis and generally cannot be expanded past a predetermined maximum diameter. Unlike their compliant counterparts, these devices maintain their shape and size regardless of the inflation pressure [35]. NC balloons are the first choice in calcified lesions, where a higher degree of force is required for an effective dilation. They provide a consistent radial force during dilation and do not conform as much to the vessel wall, thus making them ideal for scenarios where a more forceful dilation is necessary. The balloon angioplasty should start with a smaller-sized balloon (balloon/artery ratio <1) and then escalate to a larger size. The balloon inflation should start with a low pressure and gradually escalate to a higher pressure (16–20 atm). The balloon expansion should be assessed in 2 orthogonal views to check for a uniform expansion. The use of intravascular imaging is highly recommended in calcified lesions, and the presence of calcium fractures has to be confirmed on intra-vascular imaging before considering the final treatment with stents or a drug coated balloon (DCB). If there are no adequate fractures, then the lesion preparation has to be upscaled to specialized balloons.

4.2. High pressure non-compliant balloons

In cases of severe CAC where conventional NC balloons have been ineffective, a double-layered OPN NC balloon (SIS Medical) may be a viable option. The OPN NC balloon features a proprietary twin-layer technology that allows for very high-pressure inflations and promotes a consistent expansion across a broad pressure range. It is highly non-compliant, with a nominal pressure of 10 atm and a rated burst pressure of 35 atm. Reports indicate a success rate of 75% for treating calcific non-dilatable lesions without significant adverse effects [30,31]. These OPN balloons offer a new approach for dilating calcific lesions and under-expanded stents when traditional NC balloons have failed. However, their effectiveness is still constrained by the severe calcification, and they perform best when the calcium arc is less than 200° and the calcium thickness is under 6 mm [32]. In addition, some operators feel uncomfortable expanding balloons to such a high pressure given the risk of coronary perforation, especially when much safer options are available in the current era, especially with shockwave and cutting balloons.

4.3. Cutting balloons

Cutting balloons (Boston Scientific) feature three to four sharp, in-folded metal microtome blades attached to a NC balloon. As the balloon inflates, the blades open to incise and score the atheroma. These balloons work by enhancing the vessel compliance through the creation of discrete incisions in the plaque, which facilitates a controlled dissection, minimizes the risk of recoil, and allows for an improved lesion expansion [33]. To avoid embedding the blades into the vessel wall, the balloon pressure should be kept below 12–14 atm. The balloon has to be fully deflated prior to withdrawing into the guiding catheter to prevent damage to the vessel.

4.4. Scoring balloons

Scoring balloons have flexible nitinol strings that are either wrapped over the NC balloons or just placed next to the balloon. They are designed to incise scoring effects on the fibrotic and calcific plaques to facilitate stent expansion [36]. As it has a low crossing profile, this system is encouraged as a more flexible alternative to cutting balloons; however, evidence on this technology remains scarce, with no available randomized controlled data demonstrating a superiority over traditional balloon compliant and NC balloons.

4.5. Intravascular lithotripsy (IVL)

The shockwave balloon, or IVL, is a relatively novel technology. The IVL device (Shockwave Medical Inc., Santa Clara, CA) is a 6-French compatible, rapid-exchange, semi-compliant balloon catheter designed for use over a standard 0.014" guidewire. It comes in balloon sizes ranging from 2.5 to 4.0 mm in diameter, with a standard length of 12 mm. Two radiopaque lithotripsy emitters positioned 6 mm apart are embedded within the semi-compliant balloon, along with two conventional markers at the proximal and distal ends. The emitters receive electrical impulses from a bedside generator, thus generating bubbles within the balloon's fluid, which consists of a 50% saline-contrast mix. This process converts electrical energy into unfocused, circumferential pulsatile mechanical energy, thus creating sonic pressure waves equivalent to 50 atmospheres. These acoustic waves traverse the vessel wall, which selectively fracture intimal and medial calcium, thereby enhancing vessel compliance and optimizing stent expansion. Shockwave therapy is administered in a maximum duration of 10 seconds or 10 pulses (with each cycle consisting of 10 pulses at a rate of 1 pulse per second), and a maximum of 120 pulses is allowed (12 cycles) [35,36].

Unlike other balloon-based technologies, such as high-pressure NC balloons and cutting/scoring balloons, IVL leverages acoustic shockwaves delivered by semi-compliant balloons at sub-nominal pressures, thus reducing the risk of barotrauma associated with high-pressure balloon usage. In addition, unlike other specialised balloons, IVL incites both superficial and deep fractures by providing better balloon and stent expansion. There are no head-to-head trials that compared IVL with other balloon-based technologies, but there is ample data in the literature which have demonstrated the safety and efficacy of this device [37,38].

While promising for treating calcified coronary arteries, IVL does have several limitations. Its effectiveness can be reduced in cases of severe, diffuse, or nodular calcifications, where shockwave penetration may be insufficient [39]. Accurate positioning is crucial, and tortuous or complex coronary anatomy can make deliverability of the device challenging. There is also a risk of complications, albeit low, such as arrhythmias, vessel rupture, or dissection, especially with over-inflation [40]. Additionally, long-term clinical outcome data are limited, and the cost of the device may be prohibitive in some healthcare settings, particularly in resource-limited environments.

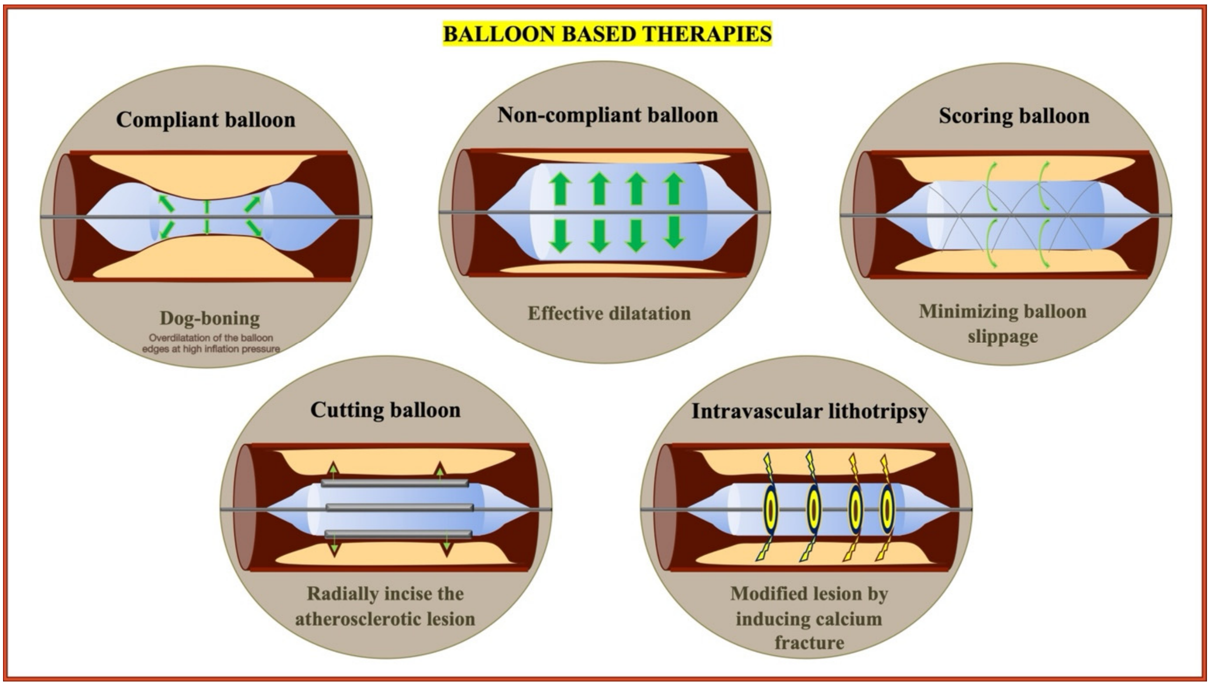

Figure 2. Balloon based therapies. Dog Boning: Overdilatation of the balloon edges at high inflation pressure.

5. Ablative technologies

Atherectomy devices represent essential tools in dealing with severely calcified lesions and nodules, as they increase the luminal size by ablating calcified plaques into fine particles debris, therefore enabling the crossing of very tight stenoses and facilitating the use of further devices such as balloons or stents for these lesions.

5.1. Rotational atherectomy (RA)

Since the first in-human rotational atherectomy (RA) performed in 1988, multiple randomized trials have been conducted in order to determine the role of this technique for calcified lesions preparation. The Rotablator System consists of an elliptical burr plated with nickel and coated with diamond microscopic crystals rotating concentrically at a high speed, usually ranging from 140,000 to 160,000 rpm [41].

The burr is advanced over a 0.009-inch wire (RotaWire Floppy or RotaWire Extra Support). While larger burr sizes were preferred in the past, which required femoral access, currently, radial access can be used safely for burr sizes up to 1.75 mm, which is compatible with 6 and 7 Fr guide catheters [41]. While aggressive debulking is associated with a higher rate of complications, without improving the procedural success rates, an adequate burr to vessel ratio is considered to be less than 0.7 [42]. In order to optimize the outcomes, a repetitive quick push-forward/pull-back movement of the burr in the proximal portion of the lesion is recommended using a continuous saline infusion (usually mixed with verapamil or nitroglycerine) [42]. Of great importance, shorter passages and an avoidance of decelerations above 5000 rpm are associated with lower rates of adverse events, including vasospasms, no-/slow-flow, artery perforations, microembolizations, or vessel dissections [43].

Despite the long experience accumulated with the RA, there are only two randomized clinical trials that have investigated the efficacy of this technique: the ROTAXUS trial [44] and the PREPARE-CALC trial [45]. In the ROTAXUS trial, 240 patients with calcific lesions in native coronary arteroes were randomized to either RA followed by stent implantation or stenting without lesion preparation by means of an atherectomy. With a procedural success rate of 92.5% and a clinical success rate of 91.9% for RA group, the 9 month follow-up showed surprising results: there was a higher late lumen loss in the RA group (0.44 ± 0.58 vs. 0.31 ± 0.52, $p = 0.04$), despite an initially higher acute lumen gain (1.56 ± 0.43 vs. 1.44 ± 0.49 mm, $p = 0.01$) [44]. However, the secondary endpoints were similar between the groups: nn-stent binary restenosis (11.4% vs. 10.6%, $p = 0.71$), target lesion revascularization (11.7% vs. 12.5%, $p = 0.84$), definite stent thrombosis (0.8% vs. 0%, $p = 1.0$), and major adverse cardiac events (24.2% vs. 28.3%, $p = 0.46$). The results of the later PREPARE-CALC trial, which included 200 patients, were more encouraging, as this study was the first RCT to compare two strategies for the preparation of severely calcified coronary lesions: a modified (scoring or cutting) balloon-based strategy and RA [45]. RA was shown to improve the procedural success (98% vs. 81%, relative risk of failure with an MB- versus RA-based strategy, 9.5; 95% CI, 2.3–39.7; $p < 0.01$); however, at the 9 months follow up, this did not translate into improved outcomes, as the target lesion revascularization (7% versus 2%; $p = 0.17$), definite or probable stent thrombosis (0% versus 0%; $p = 1.00$) and target vessel failure (8% versus 6%; $p = 0.78$) were low and not significantly different between the MB and RA groups [45]. However, in contrast with the findings from the ROTAXUS trial, RA was not associated with an excessive late lumen loss. One of the most plausible explanation for the differences is the use of OCT in the PREPARE-CALC trial; however, the trials can not be compared, as the patient inclusion criteria were different, as well as the definition of the end-points.

The current European Guidelines for Myocardial Revascularization recommend RA only for heavily calcified or fibrotic lesions before stent implantation (Class IIa, level of evidence C) [46]. It should also be noted that the PREPARE-CALC trial did not report significant differences between RA and modified balloons regarding the acute luminal gain, which contrasts the results from other studies that compared RA with a standard balloon angioplasty [47]. However, more recently, the PREPARE-CALC trial group reported the 5 years follow-up results. While TVF was similar between the balloons and RA groups (19% vs. 21%, HR 1.14, $p = 0.69$), target lesion revascularization (TLR) was significantly less common with RA for the first time (12 vs. 3%, HR 0.28, $p < 0.05$) [48], which could result in further recommendation updates by future guidelines. It is worth mentioning that 6–15% of the patients experienced clinical and procedural complications, including myocardial infarction (MI), stroke, death, dissection, perforation, rotawire interruption, burr entrapment, or slow-flow/no-flow phenomena due to distal embolization [49].

5.2. Orbital atherectomy (OA)

OA uses a crown which rotates in an orbital motion at two possible speeds of 80,000 rpm or 120,000 rpm, which enables continuous blood flow during lesion modification, better microparticle flush, and lower heat generation [50]. While RA produces debris with an average size of 5–10 µm, OA produces debris with an average size of 2.04 µm, which are narrower than the capillary diameter;

taking into consideration that the elliptical orbit reduces the thermal injury, the slow flow phenomena is significantly less common than with RA [50] (Table 2).

The OA device uses a 0.012 inch stainless steel guide wire (ViperWire) and a Viper Slide (a combination of anticoagulation and vasodilator drugs). The system is compatible with 6 F guiding cathters, as the only availabe crown size is 1.25 mm in diameter. The front and back surfaces of the crown are coated in micro-diamonds, which offer the OA its major advantage over RA, namely the posibility of both antegrade and retrograde movement, thereby increasing sanding while preventing entrapment of the system. The maximum passage time is recommended to be 30 seconds and the total treatment time should be limited to less than 5 minutes [51].

OA was FDA approved in 2013; in the same year, the ORBIT I trial, a prospective, nonrandomized study, was conducted in two centers in India, thereby evaluating the safety and efficacy of OA in fifty patients with de novo calcified coronary lesions. The device success was 98%, and the procedural success was 94%, with the major adverse cardiac events (MACE) rate raging from 4% during hospitalization to 8% at 6 months [52]. Following these preliminary encouraging results, the ORBITA II trial enrolled 443 consecutive patients with severely calcified coronary lesions at 49 U.S. sites [53]. In this trial, the procedure was shown to be effective, as the stents were successfully delivered in 97.7% of the cases, with <50% stenosis in 98.6% of subjects; additionally, they were shown to be safe: 89.6% subjects were free from 30-day MACE, only 0.7% in-hospital Q-wave MI, 0.2% cardiac death, and 0.7% target vessel revascularization were reported. Additionally, at 3 years, 360 patients completed the follow-up, where the overall cumulative rate of 3-year MACE was 23.5% and the TLR rate was 7.8% [54]. These trials used an OA preparation followed by a drug eluting stent (DES) implantation strategy; however, in a recent study conducted by Koike et al., 81% of lesions were treated with drug-coated balloons following the OA preparation, and the procedural success rate was high (96.3%) [55]. Nevertheless, the incidence of MACE at 12 months was 8.4%, which included 2.1% cardiac deaths and 6.9% TLR. Similar results were reported in the LOAR registry, which enrolled 96 patients with severely calcified coronary lesions who underwent PCI facilitated by OA. In-hospital major adverse cardiac and cerebrovascular events (MACCE) were 5.2%, while at the 6-month follow-up, the MACCE rate was 10.4%, with a concomitant TLR rate of 1% [56].

The ECLIPSE trial, which was recently published, compared the OA preparation to conventional PCI in terms of the stent expansion and revascularization failure in patients with calcified coronary lesions [57]. Although there were some limitations to the trial, it failed to show that OA prior to DES implantation was superior to conventional PCI without atherectomy. The MSAs at the maximum calcium site was similar between the treatment groups, though with a numerical increase in this outcome, which favored OA. There was no difference in TVF at 1 year; however, at 30 days, there was an increase in the all-cause and cardiovascular mortality in the OA group, of which four were either related or possibly related to the device [58].

A recent paper published in EuroIntervention that debated whether OA should be the main debulking approach for most of the calcific lesions highlighted the advantages of this techonology: the 1.25 mm OA crown can create a lumen up to 1.75 mm given the orbital rotation of the device; a very low rate of haemodynamic compromise or bradyarrhythmia during atherectomy runs due to bidirectional ablation; lower overall rotational speeds (80,000 rpm for most cases); and a greater flow rate of the lubricating/cooling solution (up to 20 mL/min). However, a head-to-head comparison of the clinical outcomes of the two atherectomy devices has never been conducted, and the potential advantages of OA over RA remain only hypotheses, while the experience accumulated with RA is really large and the results have been validated by randomized controlled trials (RCTs) [58]. Okamoto et al. recently conducted the the DIRO trial, which randomly allocated the enrolled patients to lesion preparation with RA vs OA [59]. The study's results suggest that RA could produce a more favorable tissue modification, which may lead to a larger stent expansion than OA in heavily calcified lesions, but without any significant differences regarding the procedural outcomes or clinical events between the groups at 8 months. However, data from a meta-analysis that compared the 2 techniques suggested more frequent coronary dissections and perforations in OA and a higher rate of long-term MACE (1-year), long-term TVR, and in-hospital and 30-day MI in RA [49], though RCT are needed to confirm these differences.

6. Excimer laser coronary atherectomy (ELCA)

The ELCA systems utilize ultraviolet B light (308 nm) to achieve a penetration depth of 30–50 µm, thereby employing xenon chloride, which generates microparticle debris of less than 10 µm that does not impact the coronary microcirculation [58] (Table 2). However, the application of laser energy can lead to tissue disruption through the formation of expanding and collapsing vapor bubbles. This phenomenon momentarily dilates the adjacent arterial segment for a few microseconds before causing it to invaginate, thus posing risks of dissections or vessel perforations, as well as significant medial necrosis, intramural hemorrhage, and subluminal infiltration by leukocytes [59].

An excimer laser has been used for coronary interventions for more than 20 years in different clinical and angiographic settings, such as in-stent restenosis and chronic total occlusion, for myocardial salvage in patients with ST-elevation myocardial infarction (STEMI) and for acute and chronic coronary syndromes [60]. However, the results from multiple early studies failed to support the wide appplication of this technology. Despite these, more recent studies have reported encouraging results, especially for a ELCA-DCB combination. Shibui et al. [60] analyzed 118 patients treated with a paclitaxel coated balloon, 27 of which had a lesion preparation using ELCA, while the rest had a lesion preparation using different conventional or scoring balloons. The two groups were not different in terms of the cumulative incidence as estimated by the Kaplan-Meier method (log-rank test, $p = 0.60$), and a causal relationship between ELCA and MACCE was not identified (OR, 2.22, $p = 0.22$). In another study, which enrolled sixty-two patients with STEMI within 24 h after the onset of symptoms, no ELCA-related adverse events occurred [61]. Additionally, the use of ELCA in these STEMI patients permitted the use of DCB in 60 patients, which completed a 2 year angiographic follow-up at which moment binary restenosis was observed in only five patients (8.1%), in whom target lesion revascularization was performed. In the LEONARDO study, 80 patients with 100 lesions were recruited from four centers, and ELCA was conducted on 96 lesions [62]. Procedural success was achieved in 88 lesions (91.7%), and there were no reports of perforation, major side branch occlusion, spasm, no-reflow phenomenon, dissection, or acute vessel closure.

Disappointingly, in the recently published ROLLER-COASTR-EPIC22 RCT that compared RA, IVL, and ELCA for the treatment of patients with calcified coronary lesions, ELCA did not meet the non-inferiority for stent expansion [7]. In contrast, IVL was found to be non inferior to RA. As such, larger studies and RCTs are needed in order to definitively conclude on the efficacy and safety of this strategy.

Table 2. RA vs OA vs ELCA.

Device	Lesion type	Device feature
OA	1. Long severely calcified lesion 2. Diffuse severely calcified lesion	1. Continuous blood flow while lesion modification 2. Good microparticle flush 3. Lower heat generation 4. Less slow flow phenomena 5. Possibility of both forward and backward movement, thus increasing sanding while preventing entrapment
RA	1. Calcified in-stent restenosis 2. Under-expanded stent 3. Uncrossable lesion by balloon	1. Max burr to artery ratio 2. Max burr to artery ratio 0.4 to 0.6 3. Rotational speed 140k to 150k rpm 4. Gradual burr advancement with pecking motion 5. Short ablation runs of 15 to 20 seconds
ELCA	1. Thrombotic calcified lesion 2. Under-expanded stent 3. Uncrossable lesion by balloon	1. Penetration depth of 30–50 µm using xenon chloride 2. Resulting <10 µm microparticles debris, which do not affect the coronary microcirculation

Note: ELCA: Excimer laser coronary angioplasty; OA: Orbital atherectomy; RA: Rotational atherectomy.

7. Research gaps and future directions

Highly calcified lesions are still seen as the Achille's heel in coronary interventions, as they are associated with poorer immediate and late outcomes. Despite continuous improvements in the lesion preparation devices, there are still multiple limitations in improving the procedural and clinical results due to still insufficient data.

A calcified lesion leading to acute occlusion and a subsequent STEMI is an interventional nightmare, with limited data on the optimal approach for these cases. Although the use of RA is off-label for STEMI cases, it can sometimes be the only viable option to achieve procedural success in severely calcified culprit lesions. Hemetsberger et al. [63] conducted a retrospective observational study that involved 104 STEMI patients who underwent RA during primary PCI across 12 European centers. 86.5% of the cases achieved procedural success, with in-hospital stent thrombosis occurring in 0.96%, perforation in 1.9%, and burr entrapment in 2.9%. Notably, the in-hospital mortality was significantly higher in patients who experienced shock (50%) compared to those who were not shocked (1.5%; $p < 0.01$). As several other studies and case reports have also shown good results with the use of RA in severely calcified lesions in STEMI patients [62–64], further larger studies are needed to establish the role of atherectomy in this setting, as they are traditionally avoided given the concern for slow or no reflow and are considered a contraindication in lesions with a visible thrombus by its manufacturer (Rotablator, Boston Scientific).

As calcified lesions often require atherectomy procedures, which are associated with an increased risk for periprocedural MI in comparison to conventional lesion preparation, there is an urgent need for further research in order to identify the predictors of periprocedural MI, which could better guide the procedural decisions and enhance the patient outcome. A retrospective study identified female gender, older age, the presence of no/slow flow, and prior coronary artery bypass graft surgery (CABG) and non-dilatable lesions as major risks [65]. however, further studies are needed for a better patient selection.

An important number of trials are currently ongoing, thereby investigating the role of different debulking devices and comparing these devices, sinces direct comparisons between these devices are still lacking. The high-pressure OPN balloon is being compared with IVL in the ISAR-CALC 2 (Comparison of Strategies to Prepare Severely Calcified Coronary Lesions; NCT05072730) trial. The rotational atherectomy combined with Cutting balloon to optimize stent expansion in calcified lesions (ROTACUT; NCT04865588) trial will compare RA plus the Wolverine cutting balloon vs RA plus plain conventional balloon angioplasty in 60 patients with advanced calcific de novo disease. The shockwave Lithoplasty Compared to Cutting Balloon Treatment in Calcified Coronary Disease Trial (Short-Cut trial; NCT06089135) aims to randomize 410 patients with calcified lesions to receive either IVL or the cutting balloon treatment, divided into two groups based on whether they were prepared with or without RA. The Shockwave Balloon or Atherectomy With Rotablation in Calcified Coronary Artery Lesions (SONAR trial; NCT05208749) is a multicenter randomized controlled trial that involves 170 patients, and compares IVL and RA while evaluating the incidence of postprocedural MI. With the fast development of artificial intelligence (AI), there are now studies aimed to identify the role of CCTA in AI based decision making for calcific lesions [66].

8. Proposed management algorithm

Any treatment algorithm for the assessment and management of calcified coronary disease involves a multi-step approach to enhance the diagnostic accuracy and optimize the therapeutic strategies. Initially, non-invasive imaging modalities such as coronary artery calcium scoring and CCTA are recommended to assess the extent and severity of calcification. For significant findings, further evaluation with invasive coronary angiography may be necessary. Then, the evaluation of the burden of calcified disease should be undertaken using intracoronary imaging. PCI with either balloon-based therapies, ablative therapies, or excimer laser can then be used to manage heavily calcified lesions prior to the stent implantation or DCB application. Figure 3 is an example of one such proposed treatment algorithm.

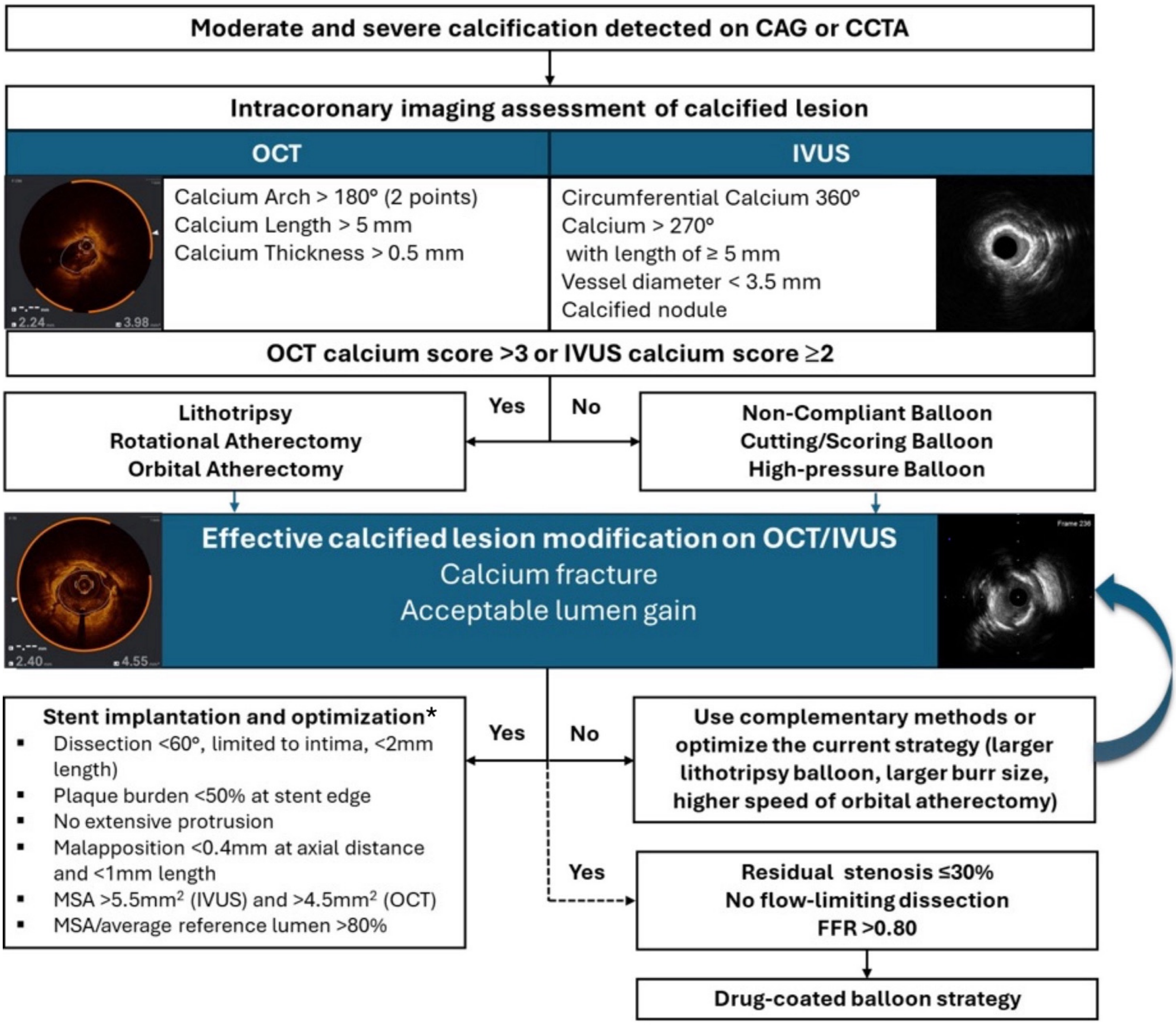

Figure 3. Algorithm for management of calcified coronary lesions. CAG: Conventional coronary angiography; CCTA: Coronary computed tomography angiography; IVUS: intravascular ultrasound; OCT: Optical coherence tomography; FFR: Fractional flow reserve; MSA: Minimum stent area. *Adapted from Räber et al. [67].

9. Conclusions

Calcified coronary lesions pose significant challenges in PCI due to their impact on the mechanical properties of the arterial walls. Consequently, the presence of calcified lesions is associated with worse clinical outcomes, thus necessitating careful assessments and advanced therapeutic strategies to effectively manage these complex cases. Safely and effectively preparing calcified lesions necessitates a comprehensive and strategic approach that integrates advanced diagnostic techniques and tailored therapeutic interventions. By integrating these strategies, the management of calcified coronary lesions can be significantly improved, thus enhancing patient safety, the procedural efficacy, and the long-term cardiovascular outcomes.

Author contributions

Bharat Khialani: conceptualisation and design, drafting of original manuscript, critical revision of manuscript for important intelluctual content, validation, supervision. Sara Malakouti: conceptualisation, drafting of original manuscript, critical revision of manuscript for important intelluctual content, curation of figures/tables, referencing. Sandeep Basavarajah: conceptualisation, drafting of original manuscript. Leontin Lazar: resources, drafting of original manuscript. Sylwia Iwanczyk: resources, drafting of original manuscript, curation of figures/tables. Bernardo Cortese: conceptualisation and design, project administration, critical revision of manuscript for important intellectual content, validation, supervision.

Use of AI tools declaration

The authors declare they have not used artificial intelligence (AI) tools in the creation of this article.

Conflict of interest

Bernardo Cortese is an editorial board member for AIMS Medical Science and was not involved in the editorial review or the decision to publish this article. All authors declare that there are no competing interests.

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