CASE REPORT

THE ROLE OF SHOCKWAVE INTRAVASCULAR LITHOTRIPSY IN THE TREATMENT OF HEAVILY CALCIFIED CORONARY ARTERY LESIONS: OUR FIRST EXPERIENCE

Boshev M[1,2], Jovkovski A[1,2], Manev N[1,2], Georgiev A[1,2], Pejkov H[1,2], Kedev S[1,2]

[1]*University Clinic of Cardiology, Vodnjanska Str. 17, 1000 Skopje, N. Macedonia*
[2]*Faculty of Medicine, "Ss. Cyril and Methodius" University in Skopje, N. Macedonia*

Abstract

Introduction: Coronary artery disease (CAD) is typically a chronic, progressive, inflammatory disease of the coronary arteries caused by coronary atherosclerosis. Moderate-to-severe calcification is present in up to 30% of patients undergoing coronary angiography (CA). Calcified coronary artery lesions are one of the most complex and challenging lesion subsets in interventional cardiology. Shockwave intravascular lithotripsy (IVL) is a recently introduced calcium-modifying technique for the treatment of concentric, eccentric and nodular calcifications.
Case presentation: We present a clinical case of a 73-year-old male complaining of intermittent chest pain. He was a non-smoker with a positive familiar history for CVD. He had previous myocardial infarction and stenting of the right coronary artery (RCA), previous CVI, paroxysmal atrial fibrillation, insulin-dependent type 2 diabetes, heart failure with mildly reduced ejection fraction (HFmrEF) and chronic kidney disease (CKD) stage II/IIIa. CA revealed heavily calcified CAD. A calcified lesion of the left anterior descending artery (LAD) was treated using a 3.0/12 mm Shockwave IVL balloon; and calcium cracks and fractures were confirmed by optical coherence tomography (OCT). We proceeded with an NC balloon and finally treated the lesion with a 3.5/15 mm drug-coated balloon (DCB). The calcified lesion of the RCA was treated with conventional techniques using guiding catheter extension, NC balloons and drug-eluting stent (DES).
Conclusion: Heavily calcified coronary artery lesions remain one of the biggest challenges for interventional cardiologists. Shockwave IVL is designed for treatment of all types of heavily calcified lesions using acoustic waves (shock waves). IVL is safe and effective technique that will definitely strengthen the armamentarium for modern treatment of heavily calcified lesions.

Keywords: *Calcified lesion, coronary artery disease, calcium-modifying technique, Shockwave IVL.*

Introduction

Coronary artery disease (CAD) is a typically chronic, progressive and inflammatory disease of the coronary arteries caused by coronary atherosclerosis that leads to coronary artery stenosis and clinical manifestation of either chronic coronary syndrome (CCS) or acute coronary syndrome (ACS). The main substrate of the atherosclerotic CAD is atherosclerotic coronary plaque that may contain different amount of calcium. Coronary artery calcification is associated with age and some risk factors and comorbidities such as male sex, smoking, hypertension,

diabetes and chronic kidney disease (1). It has been widely accepted that coronary artery calcification is a true marker of coronary atherosclerosis. Nevertheless, atherosclerotic lesions that contain only spotty calcifications are often unstable and more frequently lead to plaque rupture, which is clinically manifested as an ACS. On the contrary, lesions that contain higher amount of calcium are usually more stable and are related to CCS (2). Heavily calcified atherosclerotic lesions cause decreased vessel elasticity and increased artery stiffness. According to different authors, calcified atherosclerotic lesions may be present in 18-60% of patients, but moderate-to-severe calcification is present in up to 30% of patients undergoing coronary angiography and percutaneous coronary interventions (PCIs) (1-4). There are mainly two types of vascular calcifications: intimal and medial. Intimal calcifications are generally related to atherosclerosis (and its pathogenesis includes inflammation and subintimal lipid deposition) whereas medial calcifications are more associated with diabetes, chronic kidney disease and dialysis where serum hyperphosphatemia plays a main role (5-7).
Although revolutionary advances in the calcium modification technology have been recently achieved, heavily calcified coronary artery lesions may still be a challenge in interventional cardiology. They may prolong the total procedural time, increase the rate of intraprocedural complications (such as dissection, rupture), hinder stent delivery, and may be the main reason for suboptimal stent expansion and malapposition, thus increasing the risk for in-stent thrombosis and restenosis and poor clinical outcomes (8-11).
Coronary artery calcifications can appear as concentric (involving most of the circumferential arc or whole arc), eccentric or as calcific nodule.
Visualization of the coronary artery calcification. Visualization of the coronary artery calcifications can be obtained by several non-invasive and invasive imaging modalities. Non-invasive assessment of the coronary artery calcification can be performed by determining the so-called coronary artery calcium score (CACS, Agatston score), which is a specific marker of atherosclerosis. It is calculated by using non-contrast computed tomography (CT) and it is generally applied in asymptomatic patients to predict their cardiovascular risk (12). Agatston score >400 is associated with a significant CAD and carries an increased risk of major adverse cardiac events (MACE) (13). Coronary angiography (CA), as an invasive procedure, can also detect moderate to severe coronary artery calcifications, but with low sensitivity. Moderate to severe coronary calcifications appear as linear shadows or radio-opaque deposits of various intensity, clearly seen before contrast injection, which usually follows the contour of the coronary vessel wall (tram-track appearance). Heavily calcified atherosclerotic plaques that grow intraluminally can be detected by intracoronary contrast injection as areas of haziness or even as a filling defect if calcified nodule is detected. The latter appearance can often create diagnostic challenges in differentiating it from thrombi, especially in patients with an ACS (10, 14-16).
Intravascular imaging modalities like intravascular ultrasound (IVUS) and optical coherence tomography (OCT) have the highest sensitivity and specificity in detection of coronary artery calcifications *(Figure 1)*. IVUS allows detailed assessment of the circumferential (360-degree arc) and longitudinal extension of the coronary artery calcifications. Due to its high penetration power, IVUS can discriminate superficial from deep calcium. Coronary artery calcifications are visualized as hyperechoic areas with consecutive acoustic shadows. But IVUS cannot assess the real thickness of the coronary artery wall calcification. This imaging modality can serve as a PCI-guiding modality in terms of planning of the procedure and selection of sizes of the balloons and stents (10, 12, 14, 15).

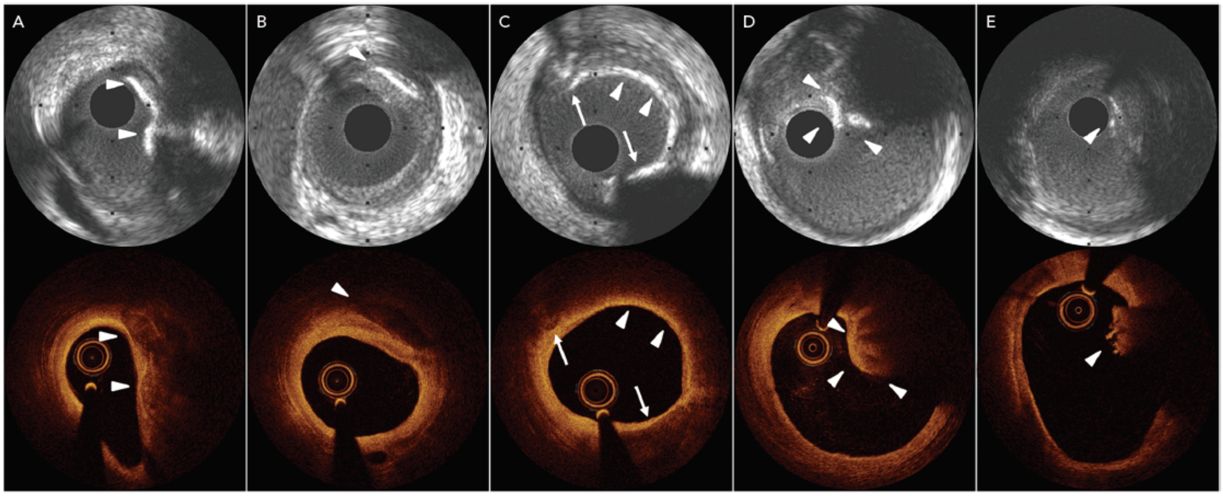


Figure 1. Images of calcified plaque by intravascular ultrasound (upper panel) and optical coherence tomography (lower panel). A. superficial calcium with arrowheads, B. deep calcium with arrowheads, C. IVUS reveals hyperechogenic tissue without shadows (arrowheads) between spotty calcium (arrows), suggesting dense fibrous plaque or a thin layer of calcium; OCT reveals fibrous tissue with no evidence of calcium (arrowheads), D. calcified nodule (arrowheads), E. OCT depicts irregular mass protruding into the lumen (could be misinterpreted as red thrombus), IVUS shows hyperechogenic mass with shadowing suggesting calcified nodule; IVUS, intravascular ultrasound; OCT, optical coherence tomography (*Adapted from Interventional Cardiology Review 2019;14(3):164–8)*

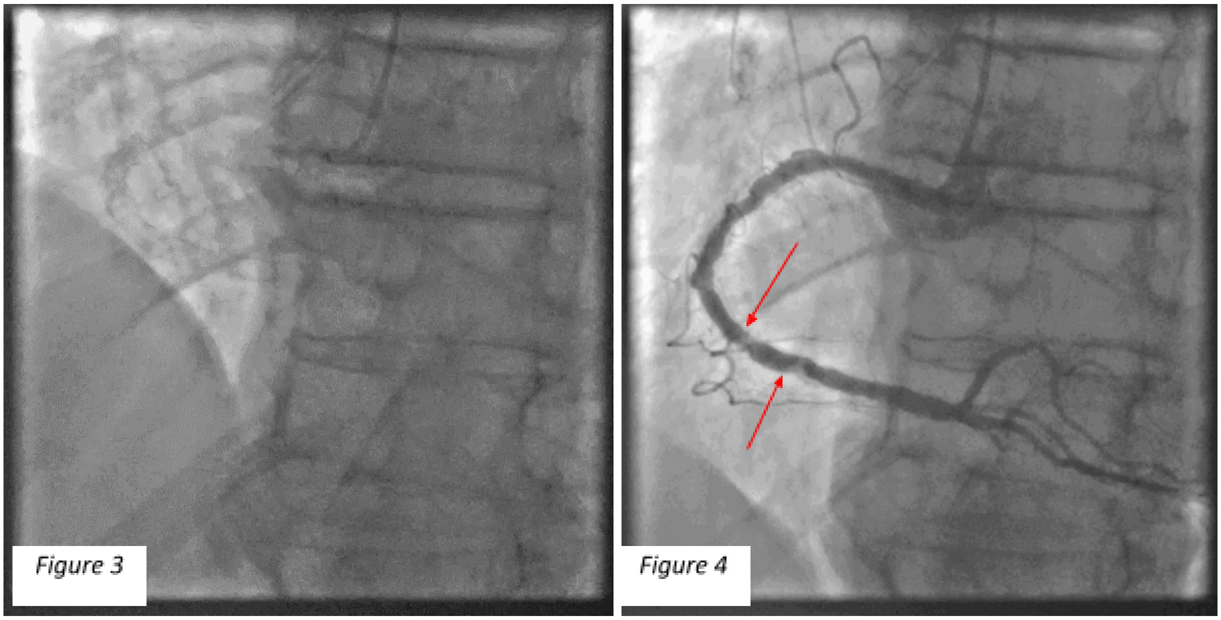
OCT has higher resolution than IVUS and it can easily and accurately detect and assess coronary artery calcifications, with sensitivity and specificity approaching 100%. Coronary artery calcification on OCT appears as heterogeneous or low-intensity signal area which is clearly delineated. OCT can precisely calculate the thickness of the calcified lesion and determine its circumferential and longitudinal distribution. In addition, it can be also used for intravascular guidance of the complex PCI procedures. However, the penetration power of OCT is lower than that of IVUS, which may result in deep calcification if assessed by OCT (10, 12, 15-17).
Intravascular imaging can be used to guide PCIs and to assess the risk for suboptimal stent expansion regarding extent of coronary artery calcification. Moreover, there are two risk scores, IVUS-derived and OCT-derived, which can predict the risk for stent underexpansion based on certain criteria. IVUS-derived calcium risk score includes 4 criteria (360-degree arc of calcium, >270-degree of calcium with length >5 mm, calcified nodule and vessel diameter <3,5 mm) and coexistence of at least 2 of them (2 points). According to Zhang et al. it can predict suboptimal stent expansion. Similarly, Fujino et al. presented an OCT-derived calcium risk score for prediction of suboptimal stent expansion based on 3 parameters (maximal calcium angle >180 degrees, maximal calcium thickness >0,5 mm and longitudinal calcium length >5 mm) (*Figure 2*). It is of great importance to underline the fact that these calcium risk scores are primarily intended for patients with CCS and coronary artery calcifications. Their application in patients with an ACS need further validation, as calcium and thrombi can coexist in this clinical setting (10, 11, 15, 18).

OCT-based calcium score		
Maximal calcium angle (°)	≤180°	0 points
	>180°	2 points
Maximal calcium thickness (mm)	≤0.5 mm	0 points
	>0.5 mm	1 point
Calcium length (mm)	≤5 mm	0 points
	>5 mm	1 point
IVUS-based calcium score		
360° arc of calcium	Absence	0 points
	Presence	1 point
>270° arc of calcium with length > 5 mm	Absence	0 points
	Presence	1 point
Calcified nodule	Absence	0 points
	Presence	1 point
Vessel diameter (mm)	≥3.5 mm	0 points
	<3.5 mm	1 point

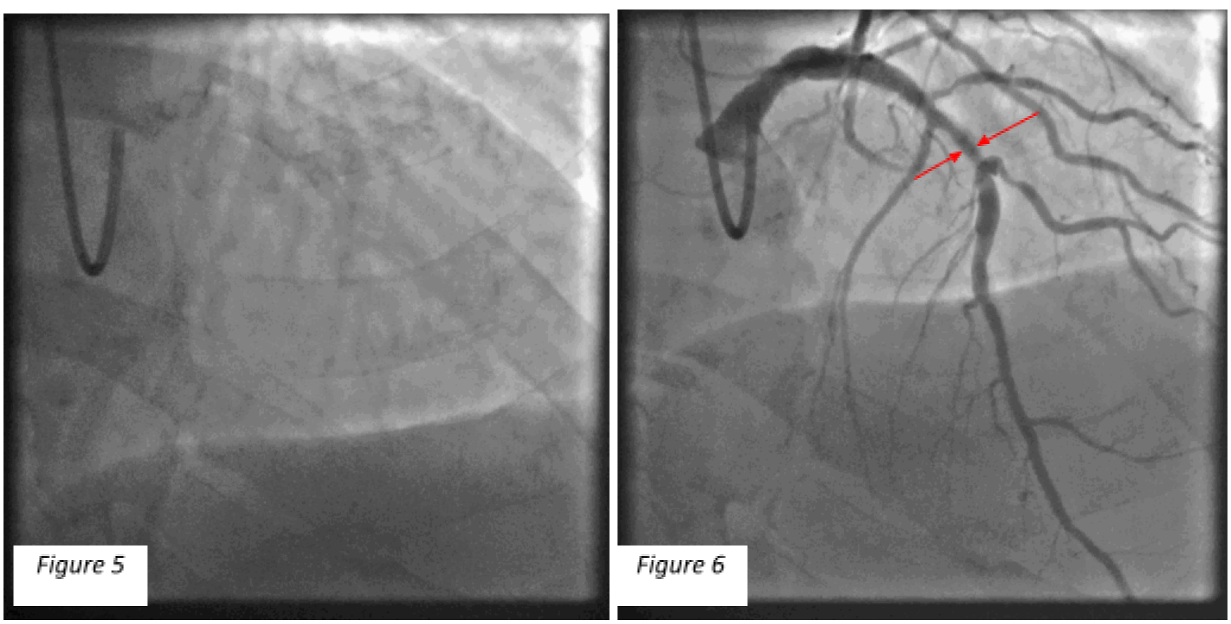
Figure 2. Intravascular imaging-based calcium scores. Each score is calculated by adding the points assigned to each parameter. Lesion with an OCT-based score of 4 and/or an IVUS-based score ≥ 2 is more likely to result in stent underexpansion, highlighting the need for adequate lesion preparation. IVUS, intravascular ultrasound; OCT, optical coherence tomography (*Adapted from Percutaneous Revascularization of Thrombotic and Calcified Coronary Lesions. J. Clin. Med.* ***2025****, 14, 692*).

Case presentation

We present a clinical case of a 73-year-old male complaining of intermittent chest pain that had started several months ago. The patient had typical effort angina that was worsening over time. He was a non-smoker with positive familiar history for CVD and BMI 27,4 kg/m2. He had a previous myocardial infarction and stenting of the right coronary artery (RCA) in 2011, a previous ischemic CVI in 2013, episodes of paroxysmal atrial fibrillation, insulin-dependent type 2 diabetes, heart failure with mildly reduced ejection fraction (HFmrEF, LVEF 45%) and chronic kidney disease (CKD) stage II/IIIa. His ascending aorta was dilated and measured 48 mm by echocardiography. The patient was treated with optimal medical therapy including bisoprolol, valsartan, empagliflozin, furosemide, spironolactone, rivaroxaban, atorvastatin, and proton-pump inhibitor. Diabetes was therapeutically managed with insulin, metformin and empagliflozin. Recent laboratory findings revealed HbA1c of 8,4% and lipid profile as follows: total cholesterol 2,1 mmol/l, LDL-c 0,94 mmol/l, HDL-c 0,73 mmol/l, and triglycerides 1,27 mmol/l. The ECG on admission was unremarkable, showing sinus rhythm with leftward axis deviation and left anterior hemiblock. The patient has already underwent coronary angiography 3 months ago, which revealed diffusely and heavily calcified CAD. He was now scheduled for repeated elective coronary angiography with the aim of treating the heavily calcified right and left coronary arteries with Shockwave intravascular lithotripsy (IVL) – a novel calcium-modifying technique for treatment of all types of heavily calcified coronary lesions (*Figures 3-6*).



Figures 3 & 4. Heavily calcified right coronary artery on coronary angiography seen prior to contrast injection (Fig. 3) (tram-track appearance) and during contrast injection (Fig. 4). Red arrows show calcified coronary lesions that lead to a significant coronary artery stenosis.



Figures 5 & 6. Heavily calcified left coronary artery on coronary angiography seen prior to contrast injection (Fig. 5) and during contrast injection (Fig. 6). Red arrows show calcified coronary lesion that leads to a significant coronary artery stenosis

Repeated coronary angiography confirmed diffusely and heavily calcified coronary arteries causing significant coronary artery stenosis at mid segment of the LAD and mid-to-distal segment of the RCA. After initial anticoagulation with 100 IU/kg unfractionated heparin (UFH), we initiated the interventional procedure with canulation of the left anterior descending artery

(LAD) using EBU 3.5 catheter and placement of standard coronary BMW wire. Then we proceeded with positioning of the IVL balloon, its expansion to 4 atm, and further application of 40 pulses from the Shockwave system. *Figure 7* shows the IVL balloon catheter with its emitters during pulse application. After that we performed an OCT pullback of the LAD which clearly showed cracks and fractures of the heavily calcified coronary artery lesion (*Figure 8*). We continued with further lesion preparation using NC balloon, achieving solid lumen gain. The final step was treating the lesion with paclitaxel drug-coated balloon (DCB) 3,5/15 mm on 7 atm, achieving solid angiographic result with no significant residual stenosis, no dissection and TIMI 3 flow (*Figure 9*). RCA was treated using Amplatz right guiding catheter (AR 2), standard BMW coronary wire and a guiding catheter extension to increase support and enhance preparation of the calcified coronary artery lesion. Lesion preparation was performed using standard NC balloons with different sizes. The procedure was completed with implantation of one 3,5/24 mm DES into the mid-to-distal segment of the RCA achieving optimal angiographic result (*Figure 10*).

During the procedure, the patient remained asymptomatic, with stable vital signs and excellent tolerability of the novel therapeutic tool. We completed the interventional procedure successfully with no periprocedural complications. The loading dose of Clopidogrel 600 mg was given to the patient right upon completing the procedure.

This clinical case reflects our very first experience of using Shockwave IVL in the treatment of heavily calcified CAD at the University Clinic of Cardiology in Skopje, N. Macedonia. We believe that this tool may become one of the preferred treatment modalities for heavily calcified CAD concerning the ease of use, the safety profile and the effectiveness of the treatment.

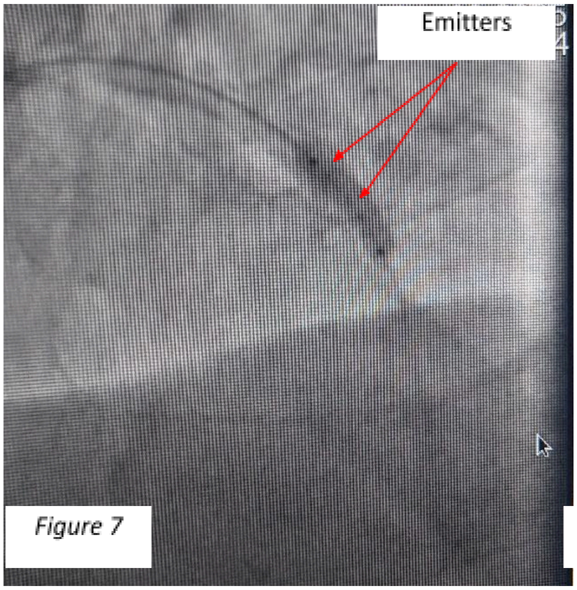
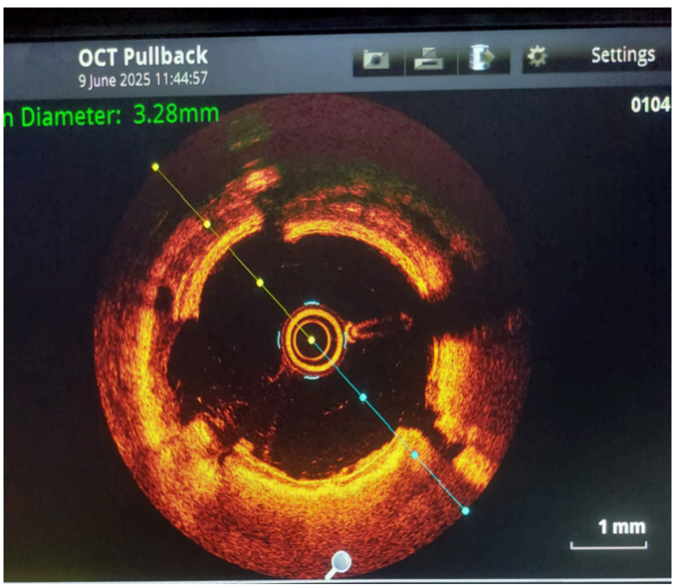


Figure 7

Figure 8



Figures 7 & 8. Shockwave IVL balloon catheter showing its emitters that are responsible for generation of the acoustic waves (Fig. 7). Cracks and fractures of the heavily calcified coronary artery lesion caused by Shockwave IVL and detected by OCT pullback (Fig. 8); IVL, intravascular lithotripsy; OCT, optical coherence tomography.

Figure 9

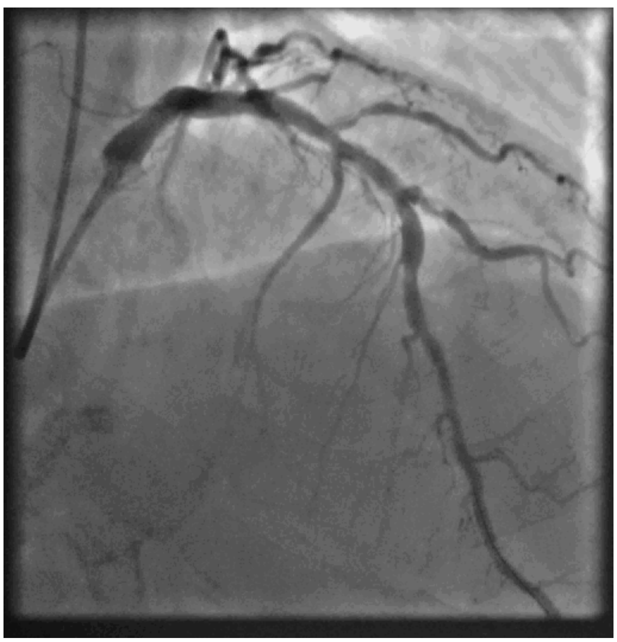
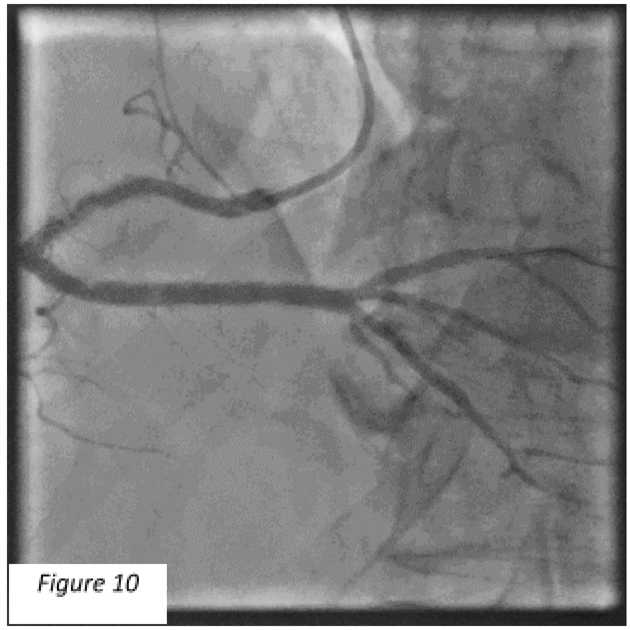


Figure 10



Figures 9 & 10. Final result of the left anterior descending artery after Shockwave IVL, NC balloon and final treatment with DCB (Fig. 9). Final result of the right coronary artery after implantation of one 3,5/24 mm DES (mid to distal segment). (Fig. 10); DES, drug-eluting stent; IVL, intravascular lithotripsy; NC, non-compliant; DCB, drug-coated balloon.

Discussion

Calcified coronary artery lesions are one of the most complex and challenging subsets of lesions in interventional cardiology. Every single heavily calcified coronary artery lesion has to be appropriately prepared, which usually means applying a proper debulking and/or calcium-modifying technique.

Generally speaking, the preparation of the heavily calcified lesions can be performed by plaque (calcium) debulking (ablative) techniques and plaque (calcium) modifying (balloon-based) techniques. The former involves atherectomy devices like rotational atherectomy (rotablation), orbital atherectomy and laser atherectomy (excimer laser coronary atherectomy, ELCA) and they can debulk/decrease the thickness of the calcium, however, unfortunately, they do not increase vessel compliance/elasticity. The latter includes semi-compliant (SC) balloons, non-compliant (NC) balloons, specialized high-pressure balloons (OPN), cutting and scoring balloons, and intravascular lithotripsy (IVL)(15). These techniques do not change the thickness of the calcium, but rather lead to crack and/or fracture of the calcium, thus increasing the vessel compliance/elasticity. All balloon-based techniques rely on mechanical high-pressure treatment except shockwave IVL, which relies on acoustic waves and utilizes an external source of energy. However, it is worth mentioning that IVL-based techniques beside shockwave IVL include the recently introduced LithiX Hertz Contact IVL (HC-IVL) that does not require an external source of energy. It utilizes a balloon catheter with several metallic hemispheres that deliver focus stress on the calcified plaque with no impact on the surrounding soft tissue (mechanical IVL) (19). Any of these techniques can be used for the treatment of calcified coronary lesions as a single technique or in combination, depending on the lesion characteristics.
Shockwave IVL is one of the most recently introduced techniques for treatment of this lesion subset. The whole system includes a generator, a connector cable, and a semicompliant balloon (*Figure 11*).

Figure 11

Figure 12

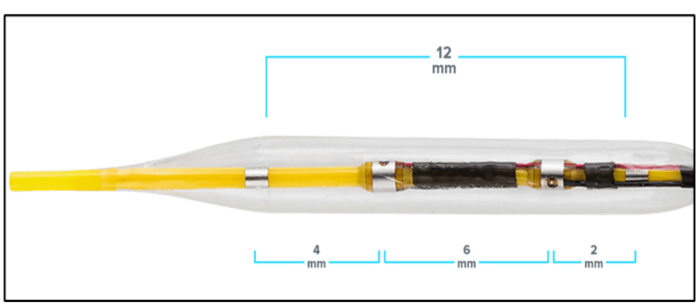


Figure 11. Shockwave IVL system consisting of a generator, a connector cable and a semicompliant balloon; IVL, intravascular lithotripsy. *Figure 12*. Balloon for Shockwave IVL containing 2 emitters; IVL, intravascular lithotripsy

(*Adapted from* *https://shockwavemedical.com/en-eu/products/shockwave-c2-plus/*)

The balloon contains two emitters that generate acoustic pressure waves (shockwaves). The first (distal) emitter is positioned 4 mm from the distal balloon marker and the second (proximal) emitter is positioned 6 mm proximally to the distal one (*Figure 12*). As a general rule, it is recommended to select a 1:1 balloon size and position the IVL balloon so that the emitters face the most heavily calcified region of the plaque in order to have most efficient interaction with calcium. Then, it is inflated at 4 atm and the button for energy generation and transmission is pressed. It is now not recommended to inflate the balloon to 6 or more atmospheres because of the highe risk of balloon rupture (15). Energy delivery can start with 10 shockwave pulses per location. When the shockwave pulse interacts with the calcium, it transfers energy that is usually equal to 50 atm pressure, which is achieved with a conventional balloon technique. The first generation original IVL balloon catheters were designed to deliver the total of 80 pulses (C2), while the new ones called $C2^{+}$ can deliver up to 120 pulses per balloon catheter. Shockwaves interact with the superficial and the deep calcium of the atherosclerotic lesion; while soft vascular tissues remain untouched, which makes this modality safe (20).

If properly used, this technique is completely safe, and the risk of complications is typically below 0,5%. The main indications for Shockwave IVL usage are all types of calcified atherosclerotic lesions, including concentric, eccentric, and nodular. There are currently 4 commercially available balloons with sizes 2.50, 3.0, 3.50, and 4.0 mm over 12 mm length (20).

Shockwave IVL has received CE marking for official use in Europe in 2017, following the results from the Disrupt CAD I study (21). The Disrupt CAD I study was the first prospective, multicenter, single-arm, pre-market study in a series of studies that successfully demonstrated the safety and the efficient performance of the Shockwave IVL in treating heavily calcified coronary lesions in 60 patients followed for 6 months. The results of this study showed that the rate of vessel perforation, abrupt vessel closure, slow flow and no reflow was 0,0% for each event separately. The rate of 30-day MACEs was 5%, whereas the rate of 6-month MACE was 8,3% (20, 22). The next study, Disrupt CAD II, was a prospective, multicenter, single-arm, post-approval study encompassing 120 patients with heavily calcified coronary lesions between May 2018 and March 2019. It achieved similar results like Disrupt CAD I, in terms of vascular complications and MACEs. The effectiveness of Shockwave IVL was confirmed by optical coherence tomography (OCT) (20, 23). Disrupt CAD III was a prospective, single-arm, pivotal study demonstrating the safety, effectiveness and ease of use of Shockwave IVL, designed for regulatory approval of coronary IVL. The results from 384 patients in this study treated with Shockwave IVL showed that 92,2% of them were free from MACEs at 30 days after the procedure, whereas the rate of vessel perforation (0,3%), abrupt closure (0,3%) and slow flow/no reflow (0,0%) remained low. This study also demonstrated the ease of use of the device, simultaneously achieving Shockwave IVL crossing and therapy delivery in 98% of lesions (20, 24). The results from this study led to obtaining the approval from the US FDA for the use of Shockwave IVL in treating severely calcified CAD in 2021 (25). The latest from this series of studies is the Disrupt CAD IV, a prospective, multicenter study specifically designed for Japanese regulatory approval of the Shockwave coronary IVL. It was conducted on 64 patients with severely calcified CAD, achieving a high degree of procedural success (93,8%), with low rates of MACEs at 30-day (6,3%) and 1-year follow up (9,4%) and no vascular complications, including vessel perforation (0%), abrupt vessel closure (0%), slow flow/no reflow (0%) and major dissections (0%) (26). As a conclusion, the Disrupt CAD IV study demonstrated a high procedural success rate with low MACEs of Shockwave IVL in heavily calcified lesions in a Japanese population.

The direct comparison of Shockwave IVL to conventional lesion preparation in heavily calcified CAD, regarding procedural and target vessel failure (TVF) was studied in the BALI trial (200 patients) and the results were announced at the most recent EuroPCR Congress 2025 in Paris. This study showed that in patients with severely calcified CAD, IVL significantly reduced the incidence (35,4% vs 51,5%) of primary endpoint (procedural failure or TVF) compared to conventional lesion preparation (RR 0.69; 95% CI 0.48–0.97; p=0.02) (27).

But maybe one of the most interesting trials conducted in this field was the ICARE trial, comparing Shockwave IVL to rotational atherectomy (RA) in 169 patients with heavily calcified CAD. This was a prospective, randomized, multicenter trial that investigated the efficacy of IVL in comparison to RA assessed by minimal stent area measurements (MSA) with optical frequency domain imaging (OFDI), and the safety of IVL in comparison to RA in terms of MACEs at 30 days. The results confirmed that IVL was non-inferior to RA in achieving optimal stent expansion. Moreover, RA was associated with a significantly higher rate of periprocedural myocardial infarction compared to IVL (5,8% in RA vs 0,0% in IVL, p=0.06) (28, 29).

We are now awaiting results of the last and most important clinical trial – the ISAR WAVE trial. This trial tests whether IVL is superior to other calcium debulking or modifying techniques (atherectomy devices, super high-pressure balloons) in de novo heavily calcified coronary artery lesions. It is a multicenter, randomized clinical trial which plans to include 666 patients (30).

Conclusion

Heavily calcified coronary artery lesions remain one of the biggest challenges for interventional cardiologists. There are currently many useful tools and techniques designed for appropriate lesion preparation. Shockwave IVL is one of the most recently introduced technique for handling all types of heavily calcified lesions using acoustic waves (shock waves) that are capable of plaque modification without risk of soft vascular tissue injury. They crack the superficial and deep calcium, allowing improvement of the vessel compliance and elasticity, which in return enhances further treatment of the lesion with high-pressure balloons (NC and OPN) and final treatment with DCB or DES. This step is critical since it leads to optimal lesion preparation and eventually optimal stent expansion and apposition, which significantly reduces the rate of subsequent adverse events like in-stent thrombosis and restenosis. Many clinical trials and meta-analyses confirmed its safety and efficacy in the fight against calcium. Shockwave IVL will definitely strengthen the armamentarium for modern treatment of heavily calcified lesions.

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