Cracking the Coronary Calcium with IntraVascular Lithotripsy

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ABSTRACT

Intervention in calcified coronaries remains a particular challenge as it is tough to crack the calcium with semi-compliant balloon dilatation. Coronary calcium is cracked with the non-compliant balloon, cutting balloon, scoring balloon, and rota ablation. Intravascular lithotripsy (IVL) has emerged now as a new modality to crack the coronary calcium and bring successful outcomes in coronary angioplasty. We present a case series of two cases where we cracked multi-vessel high dense coronary calcium with IVL and stented the coronary segments with drug-eluting stents to bring good angiographic results and Thrombolysis in Myocardial Infarction (TIMI) III flow.

Key words: Calcium, Intravascular lithotripsy, Balloon

Coronary artery calcification (CAC) hinders successful percutaneous coronary intervention (PCI) due to difficulty in the crossing of coronary hard wires such as guidewires and balloons, inadequate stent expansion, and coated drug separation from the stent. It is also an independent predictor for major cardiovascular events (MACE) [1-4]. Shock wave intravascular lithotripsy (IVL) is a novel technique evolved from the established therapy for renal and ureteral calculi that utilizes a percutaneous device to produce acoustic pressure waves resulting in the delivery of energy to break superficial and deep calcium deposits and aid with the subsequent deployment of a vascular stent [5-7]. The use of IVL is presently limited to calcific plaque modification within coronary and peripheral arterial vasculature; however, growing evidence suggests that the device may also be beneficial for facilitating major aortic arch, distal abdominal aorta, and iliofemoral interventions for facilitating large bore access and therapies such as transcatheter aortic valve replacement (TAVR), endovascular aneurysm repair (EVAR), and thoracic endovascular aortic repair (TEVAR) [8,9]. The use of IVL in chronic total occlusion, unprotected left main lesion is under investigation.

CASE SERIES

Case 1

A 62-year-old male, recently detected diabetic presented with rest angina for the last 24 h with ongoing chest pain. The patient had a walk through angina with exertional shortness of breath for the last 6 months without any history of palpitation, presyncope, or syncope in the past and categorized as the New York Heart Association (NYHA) Class II patient. He was on a single antiplatelet therapy with high dose statin and multiple anti-anginal without substantial benefit.

On examination, he had a blood pressure of 110/70 mm Hg in the right arm supine position and a pulse rate of 92 beats per minute with the left ventricular fourth heart sound (LVS_4) and bilateral clear lung fields. Echocardiography revealed regional wall motion abnormality in the left anterior descending (LAD) coronary artery with moderate left ventricular systolic dysfunction (EF-38%). Invasive coronary angiogram revealed densely calcified 90% occlusion of the mid-LAD coronary artery and 80% occlusion of the mid-left circumflex coronary artery (Fig. 1).

We planned the patient for intravascular lithotripsy for densely calcified coronary segments and subsequent coronary stenting. Through the right transfemoral approach, the left main coronary artery (LMCA) was engaged with XtraBackup (XB) a 6F 3.5 mm and the lesion in LAD was crossed with 0.014" Balanced Middle Weight (BMW) coronary guidewire. Most of the calcified lesions during IVL are crossed initially with BMW wire as hydrophilic and more slippery wires are notorious to cause coronary perforation. The lesion was predilated with a 2.5 mm × 10 mm non-compliant balloon at 18 atm pressure for the initial break of coronary calcium and it is mandatory that a 2.5 mm balloon should be able to cross the calcific lesion so that to allow the IVL balloon to cross the lesion subsequently. Then, the IVL balloon

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was made completely air free with negative suction with a 20 cc syringe and connected to the hub of the IVL pulse generator, and a 2.5 × 12 mm IVL balloon (Shock wave C2 IVL) was placed across the lesion, dilated up to 4 atm pressure, and four sessions of 10 pulses each were delivered to the lesion covering proximal to the distal segment. Each session was followed by post-dilatation of the cracked segment with the same IVL balloon at 6 atm pressure.

Following intravascular lithotripsy, distal slow flow in the coronary artery was noted which was managed with intracoronary 200 µgm of nitro-glycerine, and 2 mg of intracoronary nicorandil. Distal slow flow or no flow phenomenon in the coronaries may be encountered following IVL as fragments of calcium embolize to the distal coronary microcirculation. Post-resolution of distal slow flow the calcified coronary segment was stented with a 2.75 × 21 mm Drug-Eluting Stent (DES) at 14 atm pressure which revealed distal TIMI III flow with good angiographic apposition and result (Fig. 1).

Then, the lesion in the mid LCX (Fig. 1) was crossed with the same 0.014" BMW wire and predilated with 2.5 × 10 mm non-compliant balloon at 18 atm pressure and the same IVL balloon was parked across the calcified segment and four sessions of 10 pulses each was delivered to the lesion which nicely cracked the calcium which was evident in coronary angiography and the lesion was stented with a 2.75 × 18 mm DES at 14 atm pressure with good angiographic results (Fig. 1).

Delivery of 10 pulses of the shock wave was well-evident in the electrocardiogram (ECG) (Fig. 2). The patient was hemodynamically stable post-procedure and was discharged the next day from the hospital with stable vitals. He was put on dual anti-platelets in the form of aspirin and ticagrelor with high dose statin for one year. On follow-up, the patient had good ST-T resolution with improvement in the left ventricular ejection fraction. The patient on follow-up after 1 month was doing well with no rest or effort angina or exertional shortness of breath.

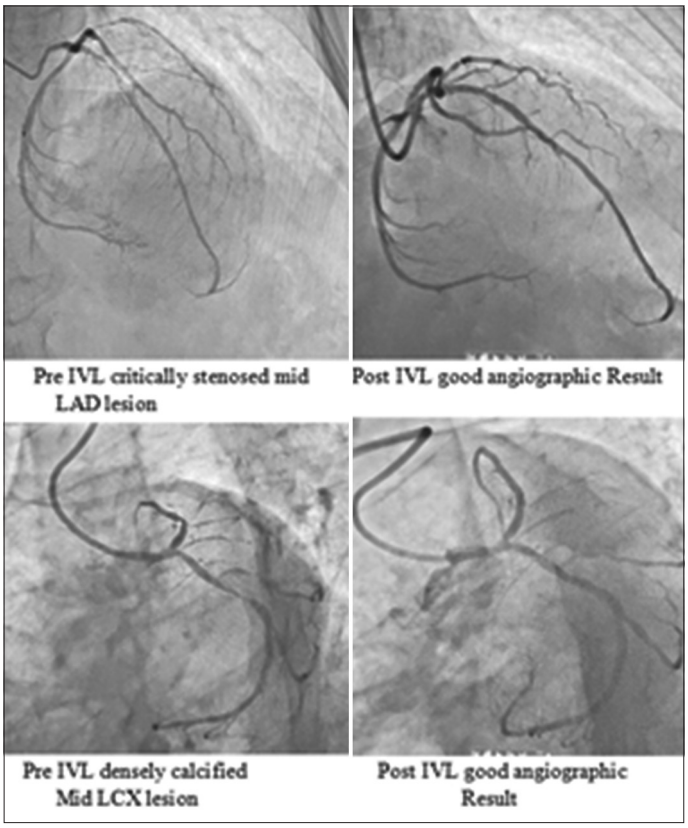

Figure 1: Pre-IVL densely calcified lesion in LAD and LCX and post-IVL good angiographic results

Case 2

A 72-year-old male hypertensive since 30 years presented with rest angina for the last 2 days with ongoing angina. ECG revealed acute anterior wall ST elevated myocardial infarction (STEMI). He had exertional angina Canadian Cardiovascular Society (CCS) Class II with exertional shortness of breath for the last year. The patient was on a single antiplatelet, high-dose statin, beta-blockers, and multiple anti-anginal without much improvement in angina class.

At presentation, he had a blood pressure of 150/90 mm Hg in the right arm supine position with a heart rate of 88 beats per minute with the presence of the left ventricular fourth heart sound (LVS_4) and clear lung fields. Paradoxically, radial pulse was feeble with bounding brachial pulse, that is, Osler;s sign was positive.

In view of ongoing angina, the patient was subjected to an invasive coronary angiogram. Radial access could not be obtained because of bilateral long-segment radial arteriosclerosis which was evident in fluoroscopy; although radial puncture was easy, the wire was not being able to negotiate distally due to diffuse calcification of radial artery. The right transfemoral coronary angiogram revealed dense and heavily calcified 95% occlusion of the osteoproximal LAD and the right coronary artery (Fig. 3). In view of dense calcium, we planned the patient for IVL to crack the coronary calcium.

Through the right transfemoral approach, LMCA was engaged with an Extra Back-Up (EBU 6F 3.5) and the lesion in LAD was crossed with 0.014 " BMW guidewire. A 2 × 10 mm semi-compliant balloon was not able to cross the lesion as it was critically stenosed. The lesion was initially crossed with a 1.5mm × 8 mm semi-compliant balloon and dilated at 14 atm pressure which did not yield the lesion. Then, we dilated the lesion with a 2.5mm × 10mm non-compliant (NC) balloon at 16 atm pressure which also did not yield the calcified lesion. Then, we decided to dilate the lesion with a 2.5 × 10 mm high-pressure inflation OPN NC balloon. The characteristic feature of this high-pressure OPN NC balloon is that we can dilate with very high pressure up to

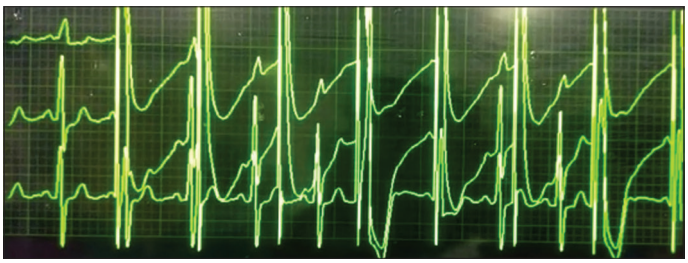

Figure 2: Delivery of IVL pulses evident in the ECG

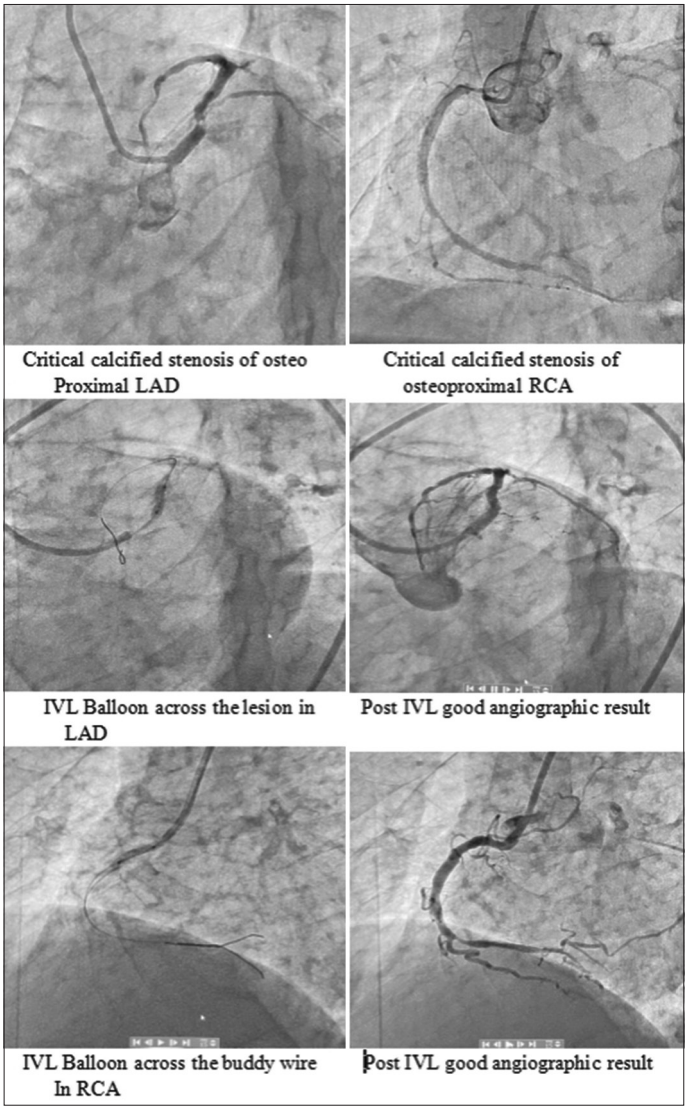

Figure 3: Pre-IVL densely calcified lesion in osteoproximal LAD and osteoproximal RCA, IVL Balloon across the calcific lesions, post-IVL good angiographic results

35 atm pressure which will provide a high radial force across the junk of coronary calcium to break it.

We dilated the OPN NC balloon up to 35 atm pressure which cracked the calcium and the lesion yielded to a little extent with small antegrade flow. Post-OPN NC balloon dilatation, we parked the IVL balloon 3 × 12 mm across the lesion (Fig. 3) and delivered four sessions of 10 pulses which cracked the coronary calcium. There was no slow flow or no flow noted after the shock wave delivery. We deployed a 3 × 16 mm DES at 14 atm pressure across the lesion with good angiographic results (Fig. 3) and TIMI III flow. Then, the right coronary artery was engaged with Judkins Right (JR) 6F 3.5 and we crossed the lesion with a BMW guidewire.

Guide catheter was stabilized with buddy wire technique. We dilated the right coronary ostial lesion with a 2×10 mm semi-compliant balloon and then parked a 3.0 × 12 mm IVL balloon (Shock wave C2 IVL) across the right coronary ostium (Fig. 3) and delivered 4 sessions of 10 pulses each to crack the coronary calcium. Post-IVL, no slow flow or no flow was noted and we deployed a 3 × 18 mm DES across the diseased segment with good angiographic results (Fig. 3).

The crux of our second case was that we cracked the coronary calcium with the combined use of high-pressure OPN NC balloon and IVL which yielded good angiographic results. High-pressure OPN NC balloon dilatation also cracks the calcium and makes the job of IVL easier as demonstrated in our case. The only drawback with high-pressure inflation is that there remains a risk of coronary perforation, so OPN balloon dilatation should be performed slowly and steadily and should be done in a staged manner up to 20 atm first and hold it for 10–15 s and then up to 35 atm pressure and hold for 10–15 s. "Go slow and take your time" is the dictum in dilatation of the OPN NC balloon.

DISCUSSION

Coronary calcification occurs in the intimal and medial layers of the arterial wall. Vascular smooth muscle dysfunction leads to release of microvesicles which dysregulates mineralization inhibitors leading to extracellular calcium deposition. Calcified coronary lesions cause significant hindrance to percutaneous interventions; such lesions have been conventionally treated with high-pressure non-compliant balloon expansion and atherectomy in the form of rotational atherectomy or orbital atherectomy.

In recent years, to treat those lesions more effectively shock-wave IVL evolved that utilizes a percutaneous device to produce acoustic pressure waves which deliver energy to break both superficial and deep calcium and aid in subsequent deployment of the coronary stent. The disrupt Coronary Artery Disease studies I and II (CAD I and II) demonstrated the safety and feasibility of IVL in calcified coronary lesions [10]. The feasibility and safety of IVL in the peripheral vasculature were demonstrated in Disrupt Peripheral Arterial Disease (PAD) studies and the Disrupt below the Knee (BTK) study [11-13].

Contraindications to IVL are the inability to cross the lesion with a 0.014-in guidewire and the presence of in-stent restenosis (ISR) [14]. IVL utilizes one single-time disposable monorail catheter with an internally mounted ultrasound core.

An IVL balloon comes in a constant length of 12 mm with various diameters ranging between 2.5 and 4.0 mm. The system has a portable regenerator to provide energy to two sets of radiopaque and traditional emitters, which are within the central and lateral boundaries of the balloon; these emitters produce intermittent sonic pressure waves which deliver mechanical energy to the target lesion. This acoustic energy creates micro-cracks within the calcified plaque and consecutive impulses increase in vessel compliance allowing complete balloon opening at substantially reduced atmospheric pressure compared to the conventional balloon.

Reference vessel diameter is the determining factor for appropriate balloon sizing during IVL; 1:1 reference vessel to balloon ratio is used for appropriate balloon sizing. Although typically a 6 French (Fr) system is used for IVL insertion, a 5 Fr catheter can also be an option in small-caliber radial artery.

The device is inflated to 4 atmospheric pressures (ATM) and ten rounds of pulsatile sound waves are delivered via transmitters within each emission cycle which become well evident in ECG and the balloon is subsequently deflated, allowing formed bubbles to disburse safely, then, the procedure is repeated for a minimum of two interventions per 12 mm target field.

Aksoy *et al*. [15] studied 78 patients with calcified coronaries where the lesion was treated with the Shockwave C2 balloon. In all the cases, the primary endpoint of adequate stent expansion with < 20% in-stent residual stenosis was achieved; four type b dissections were observed without further sequelae, no patient suffered from an in-hospital major adverse cardiovascular event. Seven shockwave balloons ruptured during treatment without any sequelae. They concluded that IVL provides a valid strategy for lesion preparation in severely calcified coronary lesions with high success rates, low procedural complications, and low major adverse cardiovascular event rates.

Hill *et al*. [16] studied 431 patients with calcified coronaries in Disrupt CAD III study which was a prospective, single-arm multicenter study with primary safety endpoint of freedom from major adverse cardiovascular events (cardiac death, myocardial infarction, or target vessel revascularization) at 30 days with procedural success. The primary safety endpoint of the 30-day freedom from major adverse cardiovascular events was 92.2%, procedural success was 92.4%, mean calcified segment length was 47.9 ± 18.8 mm, calcium angle was 292.5 ± 76.5°, and calcium thickness was 0.96 ± 0.25 mm at the site of maximum calcification. Optical coherence tomography (OCT) demonstrated multiplane and longitudinal calcium fractures after IVL in 67.4% of lesions. The minimum stent area was 6.5 ± 2.1 mm^2 and was similar regardless of demonstrable fractures on OCT. They concluded that coronary IVL safely and effectively facilitate stent implantation in severely calcified lesions.

Watkins *et al*. [17] used IVL to treat a severely under expanded coronary stent in which they achieved good angiographic lesion post-PCI and they concluded the future use of IVL is likely to be in de novo lesions to prepare the vessel better for stent deployment and ultimately avoid under expansion. Blachutzik *et al*. [18], in DISRUPT I and II study, studied the role of IVL in 180 patients with calcified coronaries from December 2015 to March 2019 across 19 sites in ten countries, there was no difference in procedural success or MACE between concentric and eccentric calcification, there was no perforation, abrupt closure, slow flow, or no-reflow events observed in either group and they confirmed consistent improvement in procedural and clinical outcomes in both eccentric and concentric calcified lesions.

Intravascular ultrasound (IVUS) and OCT can be performed following the procedure to localize calcium fractures and evaluate procedural success. Coronary artery perforation is a rare phenomenon secondary to high energy acoustic wave emission. The beauty of this device is that it does not require further training and can be performed by a majority of interventional cardiologists; low balloon opening pressure reduces the risk of vascular injury with a reduction in distal embolization. IVL creates significant fractures in densely calcified coronary lesions, optimizes stent expansion by allowing more effective vessel lumen dilatation with a small incidence of complications. IVL is an important adjunctive tool in the cardiac catheterization laboratory for lesion preparation and optimal percutaneous coronary interventions.

CONCLUSION

Coronary calcium hinders stent expansion which is a predisposing factor for acute stent thrombosis and subsequent In-stent restenosis. Adequate cracking of coronary calcium by IVL prepares an ideal bed for successful coronary stent deployment with good apposition, achieving TIMI III flow and prevent immediate stent thrombosis and further In-stent restenosis. The beauty of IVL is that it has the quickest learning curve; an index case for the primary operator is often sufficient to achieve successful outcomes. In near future, IVL will replace the age-old rota ablation for calcified coronary plaque modification.

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