Shockwave Intravascular Lithotripsy in large vessels with eccentric calcium using intravascular imaging: A case series

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ABSTRACT

Rationale: Up to 20% of percutaneous intervention (PCI) procedures are challenged by severe calcification, lesion calcification increases procedural complexity and time. S-IVL is supposed to be less effective in vessel size greater than or equal to 3.5 mm and lesions with eccentric calcium. S-IVL devices apply localized pulsatile sonic pressure waves that pass through the soft tissue and modify and fracture the underlying calcium. In literature, S-IVL is found to be useful when the calcium is circumferential and superficial as well as deep. It's efficacy in large vessel diameter and eccentric calcium is questionable.

Findings: Here with present two cases. The first one is a 75-year-old male patient in whom PCI to LAD was done as a first stage procedure. RCA PCI was deferred as it was a calcified vessel proximally, and there was dog boning with a NC balloon distally. There was a concentric ring of deep calcium as imaged on IVUS. Calcium was treated with a IVL balloon and energy pulses delivered over short separate balloon inflations. The procedure was completed with a good angiographic result. The second patient is a 65-year-old male in whom the angiogram showed LM to LCX lesion. IVUS showed that there was eccentric and superficial calcium. Lesion was then treated with a 3.5mm IVL balloon with energy pulses delivered over short separate balloon inflations. The procedure was completed with a good final angiographic result.

Conclusion: In our cases, we found S-IVL to be useful for large diameters, deep calcium, and eccentric lesions as characterized by IVUS imaging.
Keywords
Diagnostic Imaging, Lithotripsy, Percutaneous Coronary Intervention, Vascular Calcification.

Abbreviations
S-IVL: Shockwave Intravascular Lithotripsy; IVUS: Intravascular Ultrasound imaging; PCI: Percutaneous Intervention; LM: Left main; EBU: Extra back-up; ACS: Acute coronary syndrome; LAD: Left anterior descending artery; RCA: Right coronary artery; CAD: Coronary artery disease; LV: Left ventricular; DVD: Double vessel disease; VT: Ventricular tachycardia; AICD: Automatic implantable cardioverter and defibrillator; MLA: Minimal lumen area; NC: Non compliant; DES: Drug eluting stent; CABG: Coronary artery bypass grafting; LCX: Left circumflex artery; LIMA: Left internal memory artery; POT: Proximal Optimization Technique.

Introduction
Several techniques to treat calcified lesions in native coronary arteries are available, including high pressure and super high pressure, NC balloons, cutting/scoring balloons, and excimer lasers [1]. These devices rely on tissue compression and/or tissue debulking have higher rates of procedural complications like dissections, perforations, and distal embolization. Moreover, their success rate is reduced when deep, thick, and eccentric calcifications are present [1,2]. In this context, S-IVL might represent a promising technology. In our case series, S-IVL was effective in larger diameter vessels and lesions with eccentric calcium.

Case presentations
Case 1
A 75-year-old male patient with hypertension, dyslipidemia, obesity, diabetes was admitted with angina on exertion for one year with LV dysfunction (EF 35%) with recurrent polymorphic VT. Angiography showed DVD. The patient's PCI to LAD was done as a first stage procedure, RCA PCI was deferred as it was a calcified vessel, and there was dog boning with 2.5 x 15mm balloon (Mozec NC; Meril) inflated at 22 atm in proximal and distal RCA, respectively. As the patient continued to have recurrent VT episodes, an AICD was inserted, and RCA was taken for PCI as a second stage procedure. The procedure was performed using the right femoral artery approach using 7-F 3.5 JR guide catheter (Medtronic). There was a concentric ring of deep calcium as imaged on IVUS. After wiring the RCA, the lesion was predilated with a 2.75 x 15mm balloon (Mozec NC; Meril) at 18 atm, both distally and proximally. The RCA stenosis was then treated over the RCA wire with a 3.5mm IVL balloon (Shockwave Medical Inc., Santa Clara, USA) with 40 energy pulses delivered over short separate balloon inflations to prevent myocardial ischemia. The ring of calcium was seen to be fractured at all levels, and full expansion of the lesion with the balloon was seen. The procedure was completed by implanting two DES (Tetralimus-eluting, Sajanand Medical technologies, Surat, India) - a 3.5 x 28mm distally and a 4 x 32mm proximally at 16 atm. Post dilatation with a 4 x 28mm balloon (Mozec NC; Meril) was done at 22 atm with a good angiographic result. At a follow-up of 3 months, the patient is stable and free of angina. (Figure 1).

Case 2
A 65-year-old male, diabetic, hypertension, and dyslipidemic, was admitted with angina on exertion and breathlessness (grade 3). The patient was post CABG with LIMA to LAD patent and EF of 40%. The patient's angiogram was done, which showed LM to LCX lesion in CAG. The procedure was performed using the right femoral artery approach with a 6-F EBU 3.5 guide catheter (Medtronic) using IVUS, which showed vessel size >4mm in LM, and there was eccentric and superficial calcium. The LM stenosis and the LCX lesion was then treated over the LCX wire with a 3.5mm IVL balloon (Shockwave Medical Inc., Santa Clara, USA) with 40 energy pulses delivered over short separate balloon inflations to prevent myocardial ischemia. Then, a 3.5 x 32mm DES (Tetralimus-eluting, Sajanand Medical technologies, Surat, India) was implanted at 16 atm, and POT with 4.5 x 10mm balloon (AccuForce; Terumo) in the LM was done with a good final angiographic result. At a follow-up of 3 months, the patient is stable and free of angina. (Figure 2).

Discussion
Moderate to severe calcification is present in one-third of patients presenting with stable disease or ACS [3]. A promising new addition to the armamentarium for treating severely calcified lesions in coronary vasculature is the adaption of lithotripsy technology for vascular calcification. Clinical experience with IVL has shown that IVL may induce calcium fracture where rotational atherectomy has failed to modify the calcium adequately [4]. In literature, vessels with a diameter of more than 3.5mm or important plaque eccentricity preclude appropriate IVL apposition of the balloon [5]. However, in these 2 patients, we found it effective in large vessels and eccentric calcium. The other devices generally have limited efficacy when it comes to treating eccentric circular (>180 degrees) and deep calcifications [6].

Conclusion
Here we present our initial experience with the shock wave IVL system. We assume it an innovative technology where the calcified lesions, which were not amenable with other methods, were treated, and there appear to be lesser complications like perforations and no-reflow. In literature, S-IVL is found to be useful when the calcium is circumferential and superficial as well as deep. It’s efficacy in large vessel diameter and eccentric calcium is questionable. In our case, we found it to be useful for large diameters, deep calcium, and eccentric lesions as characterized by IVUS imaging.
Figure 1: Case 1

1a- Calcified lesion in RCA
1b- Dog boning in proximal RCA with 2.5\*15mm NC balloon proximally
1c- Dog boning in distal RCA with 2.5\*15mm NC balloon distally

2a- Distal RCA vessel size 3.2mm
2b- MLA at tightest point 3.3mm²
2c- Proximal RCA showing concentric deep calcium. Vessel size 3.5mm

3a- IVL balloon 3.5\*15mm at 4 atm distally
3b- IVL balloon 3.5\*15mm at 4 atm proximally

Post IVL
4a- Fractured calcium
4b- MLA 4.4mm² and vessel size 4.3mm
4c- Fractured calcium MLA 6.6mm² and vessel size 4mm

5a- Post dilatation with 4.5mm balloon distally
5b- Post dilatation with 4.5mm balloon proximally
5c- Final angiographic result
Figure 2: Case 2

1a - Coronary angiogram left main to LCX stenosis
1b - Coronary angiogram left main of LCX stenosis

2a - Vessel size of 4.4mm
2b - MLA of 3.3mm² at tightest portion, eccentric superficial calcium
2c - Eccentric superficial calcium

3a - IVL with 3.5*15mm balloon proximally
3b - IVL with 3.5*15mm balloon distally

4a - Fractured calcium with vessel size 4.5mm
4b - Fractured calcium with MLA at tightest point 7.7mm²
4c - Fractured calcium

5a - Expanded stent from LM to LCX
5b - POT in LM with 4.5mm balloon
5c - Final angiographic result
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Supplementary Material

Link to the PowerPoint presentation