



HEALTHY HEART

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Honorary Editor :
Dr. Urmil Shah



Significant number of Patients have varying degree of calcium in their coronary arteries, especially more so in patients with family history, elderly, diabetic, tobacco users, Indian origin. Coronary artery calcification (CAC) hinders percutaneous coronary intervention (PCI) by impairment of device crossing, impairment of stent apposition and expansion. High-pressure noncompliant balloon dilation, specialty balloons (scoring, cutting, ultra-high pressure), and atherectomy are techniques commonly used to facilitate PCI in severe CAC; however, all suffer from significant limitations. Specialty balloons, including scoring, cutting and ultra-high pressure balloons lacks robust trial data resulting in conservative recommendations for their use in societal guidelines. Rotational and orbital atherectomy while highly effective, still may potentially leave significant calcium unmodified within the lesion. Peri-procedural complications including slow-flow, peri-procedural myocardial infarction and perforation are also known to be significantly high with atherectomy. In this article, we will discuss newer modalities called Intravascular Lithotripsy (IVL) in managing calcific coronary as well as peripheral arterial lesion.

Intracoronary Lithotripsy for the treatment of Calcified Plaque: A Novel Technology

Intravascular lithotripsy (IVL) commonly known as shockwave therapy is a novel technique based on the same principle of an established treatment strategy for renal calculi, in which multiple lithotripsy emitters mounted on a traditional catheter platform deliver localized pulsatile sonic pressure waves to circumferentially modify vascular calcium.

Typical Indications for use of Intravascular Lithotripsy

- Coronary calcification noted on fluoroscopy or noninvasive imaging (i.e. Computed tomography coronary angiogram)
- Evidence of an undilatable lesion despite high-pressure noncompliant balloon dilatation for lesion preparation
- Evidence of heavy calcification noted on intravascular imaging, either optical coherence tomography or intravascular ultrasonography.



Figure 1: IVL equipment. Pulse-generating console attached to the wand device used to connect console to lithotripsy balloon

The Coronary Intra Vascular Lithotripsy (IVL) System

The Coronary IVL System consists of a portable, rechargeable generator, (Figure 1) a connector cable with a push button to allow manually controlled delivery of electric pulses, and a 6 Fr compatible, rapid-exchange, semi-compliant balloon catheter (Figure 2) to be used on 0.014" guidewire as used in standard angioplasty.

The semi-compliant balloon available in different sizes, integrates two

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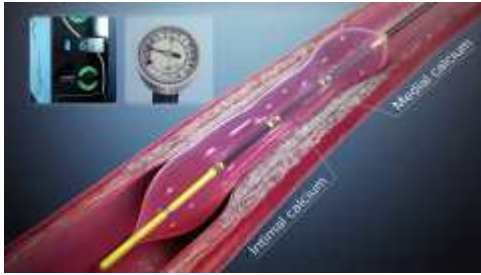
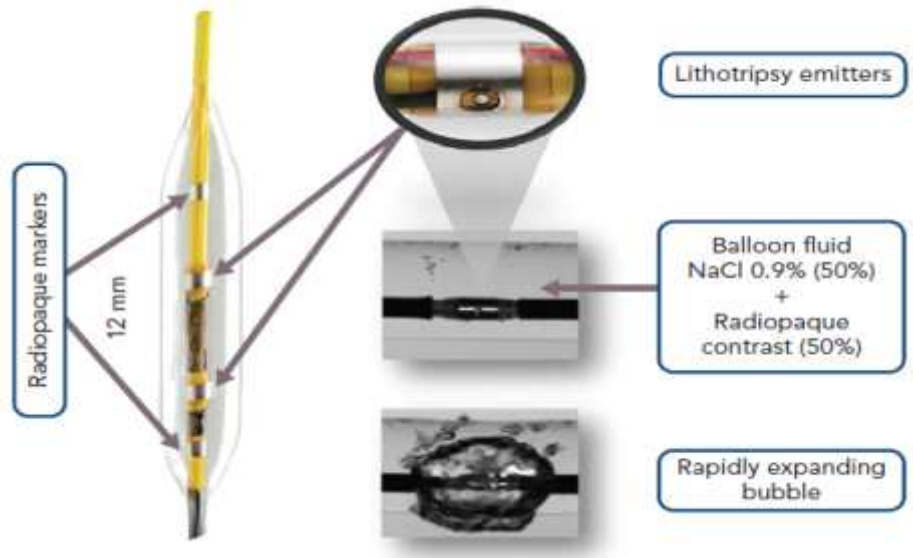


Figure 2: Intravascular Lithotripsy Balloon

radiopaque lithotripsy emitters 6 mm apart and these emitters receive electrical pulses from the generator vaporizing the fluid (a standard mixture of 50% Normal Saline 0.9% and 50% radiopaque contrast) within the balloon and creating a rapidly expanding and collapsing bubble. This bubble can transmit unfocused circumferential pulsatile mechanical energy into the vessel wall in the form of sonic pressure waves equivalent to approximately 50 atmospheres (Figure 3). After advancing the IVL catheter to the target lesion guided by radiopaque markers on the catheter, the balloon is inflated at 4 atm pressure to contact with vessel wall, facilitating optimal energy delivery. The lithotripsy cycle once activated and pulses one per second for ten seconds are generated. After every cycle, the balloon is inflated up to 6 atm pressure, which compresses the fractured calcium with maximum 8 repeatable cycle with the same catheter.

The Coronary IVL System, with controlled pulses delivered under low pressure, might potentially improve plaque modification with a lower risk of vessel closure, perforation or embolization and is very useful in undilatable lesion due to heavy calcification.

Figure 3: Intravascular Lithotripsy Therapy



Advantages and disadvantages of Intravascular Lithotripsy compared with other methods of calcium modification

Advantages

- Provides a more controlled means of calcium modification
- Has the ability to modify calcification without further vessel injury with minimal trauma on soft tissue
- Less complications like no-reflow/slow flow and perforation compared to atherectomy device.
- Technically less demanding when compared with atherectomy and hence has a short learning curve to become familiar with the technology.
- Tackle both superficial and deep calcium
- More useful for concentric calcium

Disadvantages

- Bulky balloon makes crossing of lesion troublesome.

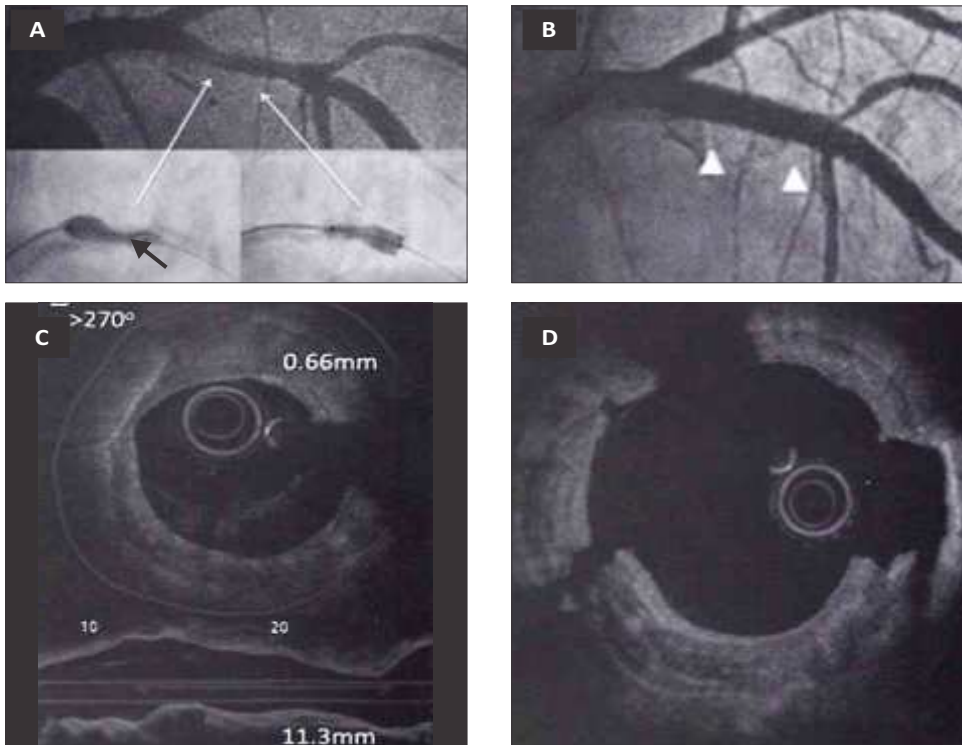
Potential Uses

At present, Shockwave Coronary IVL System is used mainly for lesion preparation in native coronary arteries (Figure 4) with severe calcific and

undilatable lesion which otherwise carries the risk of stent under expansion and subsequent re-stenosis or thrombosis. OCT criteria like calcification greater than 180 degree in circumference and calcium length greater than 5 mm are very useful to identify such lesion. IVL is especially more useful and safe compare to other methods of calcium modification in calcific left main disease, where atherectomy is associated with high complication rate. Rotational atherectomy may be unsuccessful when entire burden of calcification is present in deep circumference, where IVL can be very helpful.

Shockwave Lithotripsy Clinical Data

The Disrupt Coronary Artery Disease (Disrupt-CAD) study which was presented at TCT Conference in 2016 is a prospective multi-centre, single-arm study enrolling 60 patients with severely calcified lesions treated with shockwave coronary IVL. The main inclusion criteria was severely calcified lesions in a native coronary artery with ≥ 50 percent



A. Mid LAD lesion - IVL Balloon showing dog bone effect (arrow) due to heavy calcification
 B. Excellent final angiographic result
 C. Evidence of circumferential, deep and long calcification on OCT
 D. Evidence of calcium fractures post IVL on OCT

diameter stenosis and >32 mm length. The primary performance endpoint was clinical success defined as a residual diameter stenosis of <50 percent following stenting without in-hospital major adverse cardiovascular events (MACE: composite of cardiac death, myocardial infarction or target vessel revascularization). The primary safety endpoint was freedom from MACE through 30 days follow-up.

This study demonstrated compelling safety and performance results. Shockwave IVL treatment was highly effective in facilitating the delivery of stents and reducing re-stenosis. Stent deployment was successful in all patients with reduction in residual stenosis to less than 50 percent despite all patients having more than 90 percent of heavily calcified lesions. There were

no major intra-procedural complications including perforation, embolization, slow-flow or no reflow and a low MACE rate out at 6 months (8.5 percent). Consistent, reproducible luminal gain was also achieved. The clinical success rate was achieved in 57 (95 percent) patients; limited only by 3 (5 percent) asymptomatic non-Q-wave MI. IVL catheter delivery and treatment at the target lesion was successful in 59 (98.3 percent) patients. The primary safety endpoint of 30-day MACE rates were achieved. There were no cardiac deaths, Q-wave MIs or target vessel revascularizations during this time.

Future Prospects for Intervascular Lithotripsy

The shockwave intravascular lithotripsy is an innovative approach for treating severely calcified lesions during angioplasty. Initial clinical experience

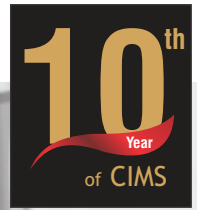
using IVL for lesion preparation in real-world patients with severely calcified lesions has been promising, resulting in excellent final angiographic and OCT results. It has also demonstrated that IVL was effective in cracking the thick (more than 180 degree) calcium burden. **Recently Shockwave Therapy (IVL) has been approved in India by DCGI for calcific native coronary artery disease. Recently we had performed three angioplasty at CIMS Hospital in highly calcific lesions with very good result and without any complications.** It is also useful in calcific peripheral artery blockage using large diameter balloon.

Take Home Message

- Intravascular Lithotripsy (IVL) has shown to be a safe and feasible alternative method for coronary calcium modification.
- The Coronary IVL System is a promising new treatment modality to tackle moderate to severe calcified coronary lesions, with a high rate of success and low risk of complications.
- Indications for the use of IVL include coronary calcification noted on angiographic fluoroscopy, the presence of an undilatable lesion, stent underexpansion, and a heavy calcium burden noted on intra-vascular imaging.
- There are several specific clinical scenarios in which IVL can be advantageous, particularly in left main stem intervention, when other methods such as atherectomy, have been associated with more complications.
- **Larger studies and long-term clinical data are needed to confirm the safety and efficacy of this technique with special attention to the effects on cardiac conduction and vessel healing response. Randomized controlled clinical trials are required to evaluate its superiority against currently available calcium-modifying devices like rotational atherectomy.**



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CASE -1					
CASE -2					
CASE -3					
CASE -4					

Shockwave IVL (Intra-Vascular Lithotripsy) is a new technology which uses acoustic Sonic Waves to break down heavily calcified block in coronary arteries.



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Programme Overview:

It is important to have a sound knowledge and correct interpretation of 12-lead ECG to help in diagnosis and management of medical patients. This necessitates that not only specialists, but also other healthcare professionals like General Practitioners, Interns, Post-graduate Students, Nurses and Paramedical Staff should have basic understanding of ECG for timely diagnosis. The Basic ECG course has been designed to provide understanding on basic concepts of 12-lead ECG which will be very useful in treating Ischemic and Rhythm Disorders of heart.

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