

Case report

Complex Coronary Intervention in Elderly patients with Post open Heart Surgery status with Calcified Coronaries.

ABSTRACT

Elderly patients pose a big challenge for coronary revascularization due to complex lesions, multiple comorbidities. We report a case PCI in a 78-year-old female with prior open-heart surgery and coronary angiogram showing severe calcific diseased vessels using new plaque modification technique, Intravascular lithotripsy (IVL). The patient is on routine follow-up, and she is stable and asymptomatic at nine months follow-up.

INTRODUCTION

The amount of coronary artery calcification increases with age and the presence of cardiovascular risk factors and comorbidities^{1,2}. Elderly population is more prone for calcific vessels, tortuous lesions, ostial lesions, multivessel disease which makes it high risk group of PCI. Calcific lesions portends worse procedural success and increase in periprocedural rates of major adverse events and long-term rates of in stent restenosis, stent thrombosis and target and lesion revascularization.

Multiple comorbidities in old age also make them high risk candidate for coronary artery bypass surgery, heart team approach is required in such patients while planning intervention. In our case with prior open-heart surgery, repeat open heart surgery would have been difficult due to fibrosis and adhesion.

Intravascular lithotripsy is innovative technology for plaque modification using sonic waves, which helps by breaking both superficial and deep calcium deposits with minimal soft tissue impairment, while improving vessel compliance. In contrast to debulking techniques, the calcium fragments resulting from the IVL therapy remain in situ, reducing the likelihood of distal embolization.

CASE REPORT

Our patient 78-year-old female with previous history of surgical closure of ASD 28 years ago presented with complaints of angina on exertion and dyspnoea on exertion.

Patient underwent Coronary angiogram which showed significant DVD with calcification.

Angiographic findings:

RCA: Calcific, mid segment 99% stenosis (Figure 1, Figure 2)

LAD: Calcific, proximal 80-90% stenosis (Figure 3, Figure 4)

Patient was planned for PTCA to LAD and RCA with plaque modification by using Intravascular lithotripsy (IVL).

The right coronary artery was engaged using a 7F 3.5 agile guiding catheter.

The RCA lesion was crossed using a 0.014 Sion blue wire. The lesion was pre-dilated using 2.0 x 10 mm sapphire NC balloon at 12-14 atm for 20 sec. OCT of RCA lesion done using Dragonfly Optis catheter OCT- pre-PCI-Distal Diameter

= 4.02mm EEL. Proximal Diameter +4.43 EEL, MLA = 1.00 mm (Figure 5).

RCA lesion was again dilated using 3.5 x 10 mm Sapphire balloon at 12-14 atm. A 4.0 x 12 mm Shockwave C2 IVL balloon catheter was used at RCA calcified stenotic site at 4atm, % cycles of 50 Pulses given to the calcific plaque, after IVL-lesion was seen in OCT Images showing cracks of calcium with good lumen gain to deploy Stent. 4.0 x 30 mm Resolute Onyx stent was deployed across the mid distal RCA lesion at 12 atm and 4.0 x 22 mm Resolute Onyx stent was deployed across the mid RCA lesion at 12 atm, both stents were overlapped. OCT-Post PCI – Shows stent well apposed well expanded (Figure 6). Distal Diameter = 4.02 mm Proximal Diameter = 4.26 mm MLA = 9.70 mm. Angiogram post PCI to RCA (Figure 7, Figure 8).

The left Coronary artery was engaged using a 7F JL 3.5 Agile guiding catheter. The LAD lesion was crossed using a 0.014 Sion Blue wire. OCT of LAD lesion done using Dragonfly Optis Catheter (Figure 9). OCT- Pre PCI – Distal Dia =3.70 mm EEL, Proximal Dia = 3.37mm EEL, MLA= 2.03mm. 4.0 x 12 mm shockwave C2 IVL catheter was used at LAD calcified stenotic site at 4 atm, three cycles of 30 pulses given to the calcific plaque After IVL OCT Images showing cracks of calcium with good lumen gain to Deploy stent. OCT Image of LAD post PCI showing well apposed stent (Figure 10). Angiogram post PCI to LAD (Figure 11, Figure 12)

We have used same IVL catheter for treating both vessels.

The patient is on routine follow-up, and she is stable and asymptomatic at nine months follow-up.

Discussion

Coronary artery calcification (CAC) is an independent predictor for major cardiovascular events.³ Additionally, coronary calcification can hinder successful percutaneous coronary intervention as a result of inadequate stent expansion, difficulty transiting the catheter through a calcified lesion, coated drug separation from a stent, tendency for in stent restenosis and stent thrombosis.

The prevalence of CAC is age and gender dependent, occurring in over 90% of men and 67% of women older than 70 years of age.

Shockwave intravascular lithotripsy (IVL) is a novel technique evolved from the established therapy for renal and ureteral calculi that utilises a percutaneous device to produce acoustic pressure waves resulting in the delivery energy to break superficial and deep calcium deposits and aid with subsequent deployment of a vascular stent.^{4,5,6,7}

Guidance with an intravascular imaging device either with intravascular ultrasound or optical coherence tomography is crucial in defining the calcium density and choosing optimal lesion modification strategy, i.e., rotational atherectomy, orbital atherectomy or IVL.

The Disrupt Coronary Artery Disease studies I and II demonstrated the safety and feasibility of IVL in calcified lesions.

The coronary IVL system has two emitters integrated on a rapid exchange balloon-based system and is available in diameters from 2.5 mm to 4.0 mm (in 0.5-mm increments) and is 12 mm in length. The IVL balloon is selected in a 1:1 ratio to the reference coronary diameter, often guided by intravascular imaging, which is recommended for optimal lesion preparation. The coronary IVL generator is pre-programmed to deliver 10 pulses in sequence at a frequency of 1 pulse/second for a maximum of 80 pulses per catheter.

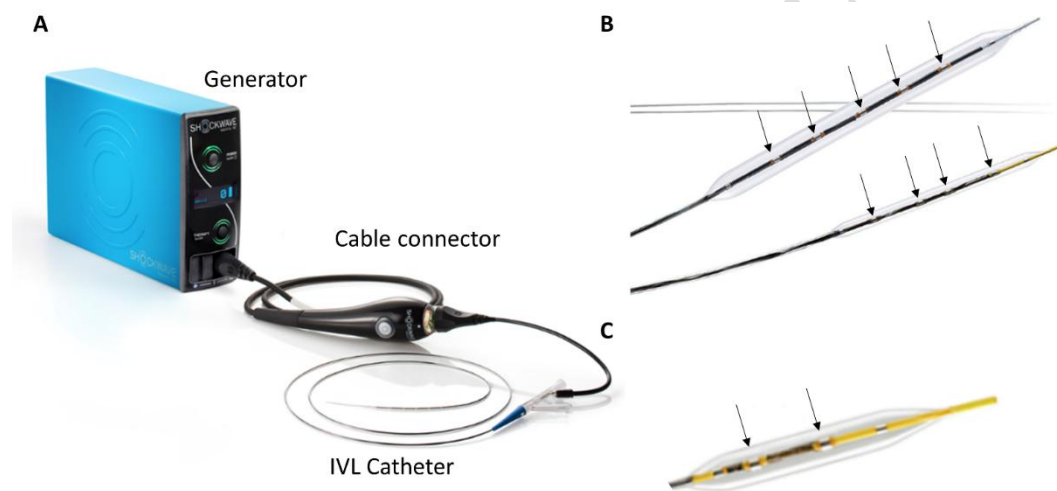


Image 1 : (A) The IVL set-up consists of a portable and battery-chargeable generator, a cable connector with a push button for IVL activation, and the IVL catheter. (B) The peripheral IVL catheters with integrated emitters (arrows). Compared to the IVL catheter at the top (referred to as M5), the newer set of catheters (S4) have a smaller crossing profile, different emitter spacing for optimized shock wave distribution along the target field, a longer shaft, and a hydrophilic coating. (C) Coronary IVL catheter (referred to as C2) with two emitters (arrows).

In the optical coherence tomography substudy of Disrupt CAD I, calcium fracture was seen along the circumference of the calcified plaques, and multiple fractures in a single cross-section were detected in >25% of lesions, leading to an average acute area gain of ~2.1 mm² with IVL alone.⁸ IVL-induced fractures were independent of calcium depth, with multiple fractures per lesion occurring more frequently as the severity of the underlying calcification increased. IVL-facilitated percutaneous coronary intervention resulted in stent apposition and expansion approaching those observed in contemporary series of drug-eluting stent implantation in less complex and non-calcified lesions.

In Disrupt CAD II, the IVL catheter was successfully delivered to all target lesions. The post-IVL angiographic acute luminal gain was 0.83 ± 0.47 mm, and residual stenosis was $32.7 \pm 10.4\%$, which further decreased to $7.8 \pm 7.1\%$ after drug-eluting stent implantation. The primary safety endpoint occurred in 5.8% of patients, consisting of 7 non-Q-wave myocardial infarctions. There were no incidences of procedural abrupt closure, slow flow/no reflow, or perforation.

Disrupt CAD III (NCT03595176; n = 384 patients), which recently completed enrolment, and Disrupt CAD IV (NCT04151628; n = 64 patients) are designed for US Food and Drug Administration (FDA) approval and pre-marketing approval in Japan, respectively.

Clinical experience with IVL has shown that IVL may induce calcium fracture where rotational atherectomy has failed to adequately modify the calcium.⁹ IVL has also been used in in-stent restenosis due to calcified neoatherosclerosis¹⁰ or

under expanded stents implanted in severely calcified lesions,¹¹⁻¹³ where the metallic scaffold impedes interaction of devices such as rotational atherectomy, cutting or scoring balloons with the calcified plaque.

Acoustic shockwaves of IVL can induce localized myocardial depolarization, likely by activation of mechano-sensitive cardiomyocyte membrane ion channels, resulting in atrial or ventricular ectopic beats ("shocktopics"), either as isolated capture beats or asynchronous cardiac pacing (≥ 2 beats).¹⁴ Although there is a theoretical risk of inducing tachyarrhythmias if the capture occurs during the vulnerable phase of repolarization, no ventricular tachyarrhythmias induced by IVL have so far been reported.

Conclusion

Higher age is associated with comorbidities like renal derangements, COPD and systemic disorders making coronary intervention more complex. Aging population has high risk of bleeding, so antiplatelet and anticoagulation need to be given more cautiously. Each case needs to be individualised before planning revascularization.

IVL is an intuitive and attractive modality for the treatment of severely calcified lesion that combines the calcium-disrupting capability of lithotripsy with the familiarity of balloon catheters. Clinical studies to date support the effectiveness of IVL in inducing circumferential fracture in calcific plaques, leading to significant luminal gain and facilitating optimal stent expansion.

INFORMED CONSENT:

Informed consent was taken from patient for publication.

FIGURES:

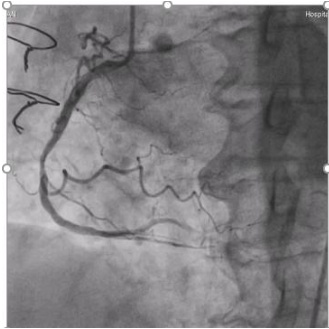


Figure 1 RCA: Calcific

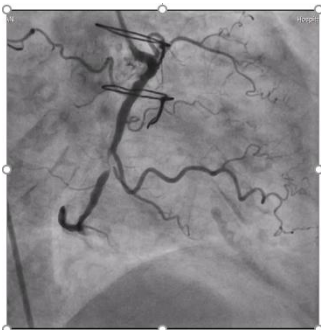


Figure 2, mid segment 99% stenosis



Figure 3 LAD: Calcific



Figure 4 proximal 80-90% stenosis

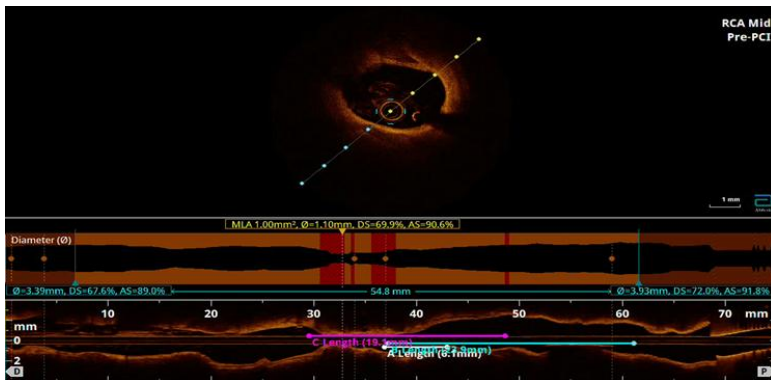


Figure 5 OCT of RCA lesion done using Dragonfly Optis catheter OCT

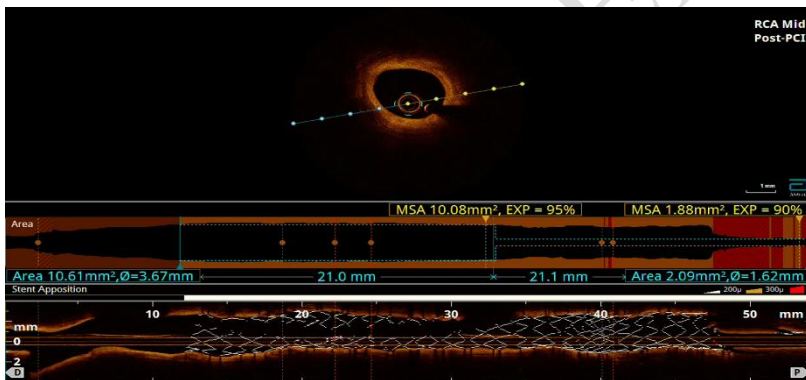


Figure 6 OCT-Post PCI - Shows stent well apposed well expanded



Figure 7 Angiogram post PCI



Figure 8 Angiogram post RCA

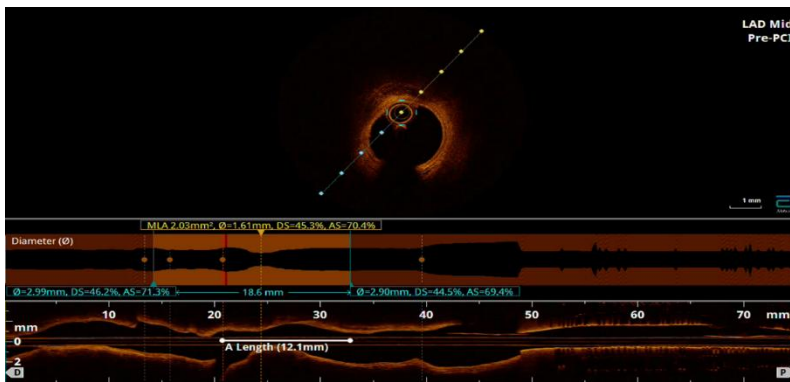


Figure 9 calcific plaque

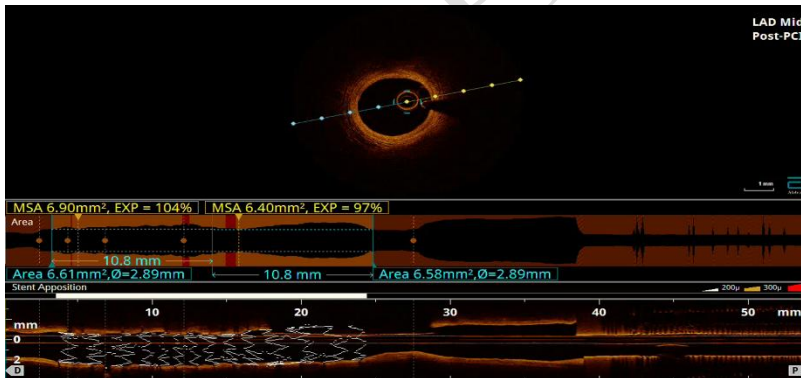


Figure 10 OCT Image of LAD post PCI showing well apposed stent



Figure 11 Angiogram post PCI

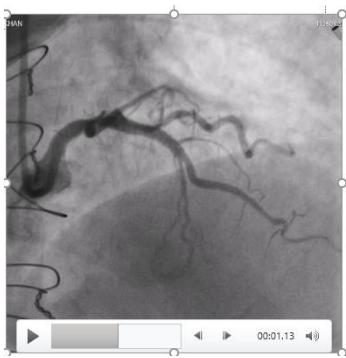


Figure 12 Angiogram post LAD

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UNDER PEER REVIEW