

Intravascular ultrasound guided treatment of severe coronary artery calcification with Shockwave Intravascular Lithotripsy

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SUMMARY

Coronary artery calcification is a pathological deposition of calcium in the intimal and medial layer of the arterial wall. Shockwave intravascular lithotripsy (IVL) has evolved as a new modality to treat heavily calcified coronary arteries. IVL involves using a percutaneous device to produce acoustic pressure waves resulting in the delivery of sufficient energy to break up superficial and deep calcium deposits. We present a case where highly dense coronary calcium was successfully treated with intravascular ultrasound (IVUS) guided coronary angioplasty and IVL treatment. IVUS demonstrated heavy calcification at the proximal LAD with a 360 ° calcium arc. Post procedure, IVUS demonstrated multiple fractures of coronary calcium. Stent deployment was done successfully with good stent strut apposition. There was no procedure related complication. The case demonstrates an example where IVL is an important adjunctive tool in the cardiac catheterization laboratory for lesion preparation and optimal percutaneous coronary intervention.

INTRODUCTION

Coronary artery calcification is due to deposited calcium in the intimal and medial layers of the arterial wall. Heavily calcified plaques in coronary arteries is a risk factor for major adverse cardiac events and mortality.¹ Coronary intervention in calcified coronary arteries is challenging as it may be difficult to dilate the calcified segment with semi-compliant balloons. Coronary calcium can often be treated successfully with different therapeutic calcium debulking techniques, including orbital or rotational atherectomy, excimer lasers as well as cutting and scoring balloons.² However, these techniques can be associated with serious complications, such as coronary artery dissection and perforation. There has thus been a need for alternative treatment modalities, especially those which are associated with a minimal degree of complications. Shockwave intravascular lithotripsy (IVL), a technique similar to the one used in nephrolithiasis, has evolved as a new modality to treat heavily calcified coronary arteries. IVL involves using a percutaneous device to produce acoustic pressure waves resulting in the delivery of sufficient energy to break up superficial and deep calcium deposits.³ Intracoronary artery imaging techniques such as intravascular ultrasound (IVUS) and optical coherent tomography (OCT) are often performed pre IVL treatment to

evaluate the extent of calcification and post procedure as well to demonstrate calcium fractures and evaluate procedural success.

We present a case where highly dense coronary calcium was successfully treated with IVUS guided coronary angioplasty and IVL treatment.

CASE REPORT

A 70-year-old male had presented with angina on exertion for 1 week to Subang Jaya Medical Centre, Malaysia, with ongoing chest pain. He had associated exertional shortness of breath for 1 month. He had a history of dyslipidemia and was on simvastatin 20mg once daily.

On examination, he had a blood pressure of 120/80 mm Hg and a pulse rate of 80 beats per minute. Echocardiography showed good left ventricular systolic function (Ejection Fraction of 55%). Electrocardiogram showed sinus rhythm and blood tests showed normal full blood count and renal function. Cardiac enzymes including troponin were normal. Treadmill stress testing with a Bruce protocol was performed to stage II, the patient developed angina and ST depression in the infero-lateral leads. The patient gave consent to proceed for invasive coronary angiogram.

A coronary angiogram via femoral approach showed densely calcified 70-80% stenosis of the proximal left anterior descending (LAD) and 90% stenosis at the mid-LAD coronary artery (Figure 1). The left circumflex coronary artery was non dominant and unobstructed. The right coronary artery had a proximal moderate 40-50% stenosis. Further evaluation was done with IVUS. This showed extensive circumferential calcium with a 360 degree arc at proximal LAD close to the ostium (Figure 1). The minimal lumen area (MLA) of the LAD vessel was 2.80 mm².

We planned for intravascular lithotripsy for densely calcified coronary segments and subsequent coronary stenting. The left main coronary artery was engaged with a 6 french sized guiding catheter (EBU) with diameter 3.5 mm and the lesion in LAD was crossed with 0.014" hydrophilic guidewire. The lesion was predilated with 2.5 mm x 10 mm and 3.0 mm x 10 mm non-compliant (NC) balloons up to 16 atm pressure. Then, the IVL balloon was prepared with negative suction

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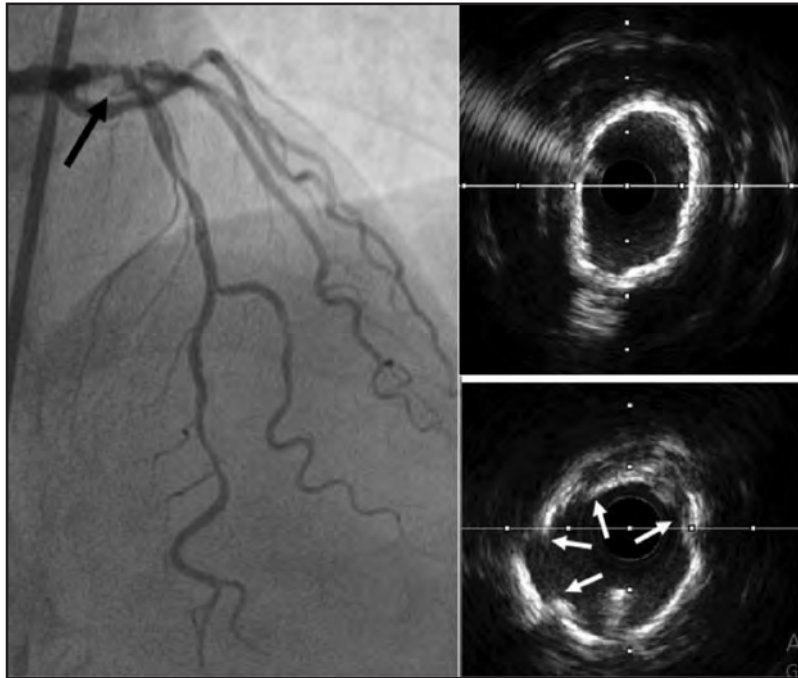


Fig. 1: Pre procedure angiogram (left) showing severely calcified stenosis at the LAD (arrow) and tight stenosis at the mid LAD. IVUS Image shows surrounding a 360 calcium arc (above). Post IVL and calcium fractures (arrows) in the vessel (below).

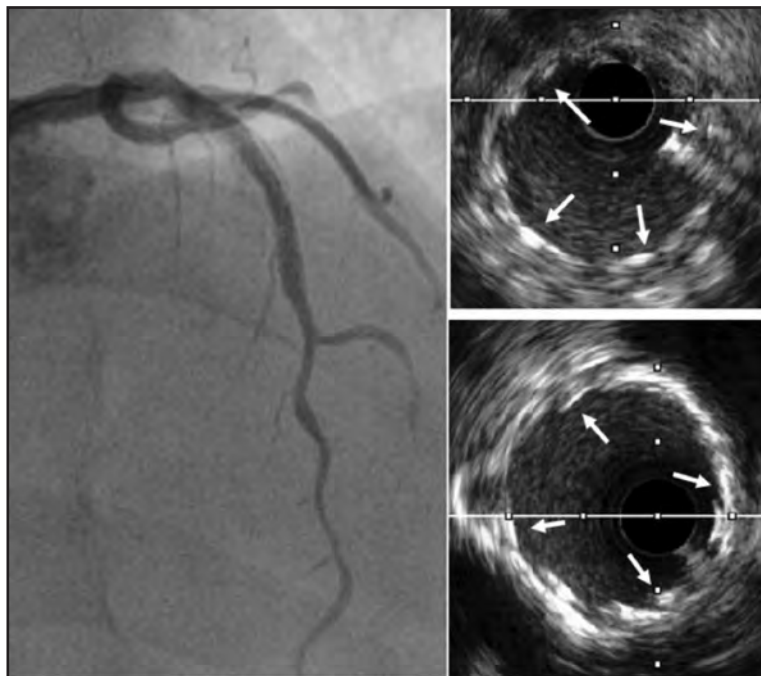


Fig. 2: Postprocedure angiogram after IVL and stenting of the lesion (left). IVUS images of the distal LAD (above) and proximal LAD (below) showing good stent struts apposition (arrows).

with a 20 cc syringe and connected to the IVL pulse generator. A 2.5 × 12 mm IVL balloon (Shockwave C2 IVL, Shockwave Medical) was placed across the proximal LAD calcified lesion, dilated up to 8 atm pressure. Five balloon inflations with 10 shockwave pulses each were delivered to the lesion at the proximal LAD. Following IVL treatment, blood flow in the coronary artery remained good. Repeat IVUS images showed multiple fractures of calcified plaque at the proximal LAD (Figure 1).

A 2.75 × 19 mm Drug-Eluting Stent (DES) was deployed at the mid LAD and a second 3.0 × 14 mm DES was deployed at the proximal LAD close to the LAD ostium, with both stents overlapping. The stents were post dilated with a 3.0 × 10 NC balloon. Repeat IVUS was performed following LAD stenting. IVUS showed an improvement in MLA from pre angioplasty of 2.80 mm² to post angioplasty MLA of 5.60 mm². The stent struts were well opposed to the LAD vessel wall (Figure 2). The patient was hemodynamically stable post-procedure and was

discharged the following day. He was put on dual antiplatelet treatment with aspirin and clopidogrel for 1 year. The patient was seen for follow-up in clinic after 1 month was stable with no further angina.

DISCUSSION

Shockwave IVL has evolved over recent years as a device which can successfully treat both superficial and deep calcium and aid in effective deployment of the coronary stent. IVL utilizes 2 shockwave ultrasound emitters positioned inside an expandable balloon. The IVL balloon comes in a constant length of 12 mm with various diameters ranging between 2.5 to 4.0 mm. The treatment is delivered by placing the balloon catheter within the coronary artery at the site of stenosis, and inflating it up to 4 atm pressure.⁴ On activation, the battery-powered generator delivers a series of electrical pulses into the lithotripsy emitters which convert it into mechanical energy (sonic pressure waves). The combined solution of saline and contrast within the balloon allows transmission of sonic pressure waves into the vessel calcium deposits. These acoustic waves create micro-fractures within calcium deposits in the vessel wall. Since severe calcification is an important predictor of restenosis after PCI, treatment with IVL can potentially increase the vessel diameter and ensure better stent placement.

Trial Evidence for IVL

The Disrupt Coronary Artery Disease (Disrupt CAD) I and II trials demonstrated initial safety and feasibility of IVL in calcified coronary lesions. The first multicentre prospective study, Disrupt CAD I, enrolled 60 patients with severely calcified vessels.⁵ There was successful stent implantation following IVL in all patients. The second prospective trial, Disrupt CAD II, studied 120 cases with extensive coronary artery calcification.⁶ There was similarly successful delivery and use of the IVL catheter was achieved in all patients. Furthermore, there was no complication of slow coronary flow or coronary artery perforation.

The largest study so far was the Disrupt CAD III study, which was a prospective, single-arm multicenter study including 431 patients with calcified coronary arteries.⁷ The primary safety endpoint of the 30-day freedom from major adverse cardiovascular events was 92.2%, procedural success was 92.4%. OCT demonstrated multiplane and longitudinal calcium fractures after IVL in 67.4% of lesions. This study showed that coronary IVL had high procedural success in angioplasty of severely calcified lesions with low complication rate.

Another multicentre registry studied 78 patients with calcified coronaries where the lesion was treated with the Shockwave C2 balloon.⁸ The study demonstrated a significant reduction in mean diameter stenosis of up to $26.7 \pm 4.3\%$ after IVL therapy. In all the cases, the primary endpoint of adequate stent expansion with $< 20\%$ in-stent residual

stenosis was achieved. There was no major adverse cardiovascular event, thus demonstrating good success rate with low procedural risk.

Complications of IVL

The procedural complications of IVL may include slow coronary blood flow, lack of reflow, distal embolization, coronary artery perforation, and arterial dissection. Coronary artery perforation is a rare phenomenon secondary to high energy acoustic wave emission. There were four cases of coronary artery dissection in Disrupt CAD I trial⁵ whilst only two patients experienced Type B and C dissection in Disrupt CAD II study.⁶

CONCLUSIONS

Coronary calcium hinders adequate stent expansion which is a predisposing factor for complications of acute stent thrombosis and subsequent in-stent restenosis. The Shockwave IVL is a safe and effective treatment approach to disrupt the coronary calcification through localized, circumferential sonic pressure waves. Adequate fracture of coronary calcium by IVL allows successful coronary stent deployment with good stent strut apposition, thus reducing the risk of acute stent thrombosis and further in-stent restenosis. IVL is an important adjunctive tool in the cardiac catheterization laboratory for lesion preparation and optimal percutaneous coronary intervention.

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